Reflections from the Chair
Section on Advances in Therapeutics and Technology (SOATT)

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It has gone too far, it really has. I received a call the other day from a former resident. He had a dilemma. A product representative from a company whose products were used in his practice showed up to detail him on several new products. He made up an excuse about having an urgent meeting to go to and left the representative in the office with his assistant.

“Dr. Goldstein”, he began, “I know that I am not supposed to talk to these guys, but it was just so awkward. Don't they know that they can't visit us in a professional office where we see patients?” I was surprised. I mean I have always known that there was a sometimes-narrow line between what was an acceptable interchange between pediatricians in practice and product representatives, but this seemed extreme. Yes, on the instruction of ACGME, we have eliminated all financial dependencies of our various residencies and fellowships on industry based support, we have banished product representatives to the first floor of the hospitals, and we have restricted them to “vendor space” on the exhibit floor at our national meetings. Industry is considered a necessary but inconvenient association.

We’ve come a long way. I can remember when I was a medical student. The grand rounds were sponsored by “some drug company” or medical device manufacturer. I remember the doughnuts; they were heaven after a busy call night. I remember the pens; I had lost my last one just minutes before. The coffee was fresh. I cannot remember what drug or medical device was being touted; it just wasn't something that stayed with me as I struggled to remain awake during the lecture. Is it possible that this information somehow entered my subconscious and influenced my prescribing practices for the next 30 years? Well, anything is possible. Should I acknowledge the lifelong impact these gifts of coffee and doughnuts had on my formable training? I wonder if there is some remediation that might help me in the remainder of my years in practice. I suspect that I would not be alone. CME and recertification credit for part II or part IV of MOC would be offered. Perhaps industry would provide an unrestricted educational grant so that I and many of my more senior colleagues could finally exile our demons?

But, I digress. We have a new problem. There is just no good way that industry and pediatricians in practice can meet and discuss advances; and more importantly, how to apply advances in therapeutics

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and technology to leverage improvements in care. How is it then that a pediatrician can find out about a new medical device that can improve care in his office and decrease the cost of follow up? How does a new gene therapy or monoclonal antibody find its way to the patient who is at risk?

The answer is that there is no good way for this to happen. There is no communication. Our new graduates from residency and fellowship have no idea how to interact with a product sales representative. And if they should decide to talk to the representative, what will they talk about? We haven't taught them anything about what is appropriate. Certainly, there is no place for junkets to exotic islands in the South Pacific. But what if the product representative offers them a business card

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that contains a thumb drive, or perhaps a pen with an insignia? Does this constitute financial interest? Practically speaking, it does not. But, no one knows. My former resident is afraid that he will placed on a list. He is afraid that his patients or his employer will discover “through transparency” that he has been a bad doctor because he went to one too many sponsored educational opportunities about a new pharmaceutical product. Where does that leave us?

Moreover, how do we accommodate the pediatricians that have elected to work with industry or for industry? There is a conflict of interest that prevents them from presenting research or other academic activities even at our American Academy of Pediatric meetings. They are effectively isolated. As a section chair, I must be mindful of who I choose to present at an NCE plenary. Perceptions of conflict even at a low high level are not acceptable for our meetings. What if innovation occurs at a company that has even a minor medical focus? It is still out of bounds.

Then there is the ultimate conflict. As the American Academy of Pediatrics, we are engaged in the support of development of new therapeutics and technologies with specific FDA approved indications. We bemoan the fact that industry often bypasses or ignores our children in the development of new and beneficial therapies. Despite various programs that promise incentives for pediatric development, it is just not enough. What we need is an active program of engagement complete with representation at all levels of pediatric training. We need to sit down with industry, detail our concerns, and move forward with a comprehensive plan to improve access for our children to meaningful therapies. But we cannot even convince our newly minted pediatricians that there is anything to be gained by this interaction; it has been trained out of them.

Sincerely,
Mitchell Reid Goldstein, MD, FAAP

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

Please submit your idea or article to:
Chester J. Koh, MD, FACS, FAAP at cxkoh@texaschildrens.org
I wish everyone a “Happy Holidays!” as we approach the end of the year.

2017 was a busy year for pediatric devices, pharmaceuticals, and digital health, as evidenced by the articles in the newsletters, and the outlook for 2018 looks bright.

A special thanks to our colleagues at the FDA, including Dr. Vasum Peiris and Eric Chen, who are encouraging innovation and improving the regulatory pathways to allow a more efficient and streamlined processes that will allow both innovative and safe technologies that can be used for improving the care for children.

Please mark your calendars for the 2018 AAP NCE meeting in Orlando, Florida in the fall (November 2 – 6, 2018) with the Section's Educational program on Pediatric Innovation. Please note that the meeting is taking place at a later date than in the past.

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 seed funding.

Further details can be found in the previous editions of the newsletter at: [https://www.aap.org/en-us/about-the-aap/Committees-Councils-Sections/soatt/Pages/newsletters.aspx](https://www.aap.org/en-us/about-the-aap/Committees-Councils-Sections/soatt/Pages/newsletters.aspx)

**Atlantic Pediatric Device Consortium**
(Georgia Institute of Technology / Emory University / Children’s Healthcare of Atlanta / Virginia Commonwealth University Institute for Engineering and Medicine)
[www.atlanticpediatricdeviceconsortium.org](http://www.atlanticpediatricdeviceconsortium.org)

**Boston Pediatric Device Consortium**
(Boston Children’s Hospital / Harvard Medical School)
[www.childrenshospital.org](http://www.childrenshospital.org)

**National Capital Consortium for Pediatric Device Innovation**
(Children’s National Health System / University of Maryland)
[innovate4kids.org](http://innovate4kids.org)

*Continued on Page 5*
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)  
www.FDA.gov/PDC

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Section on Advances in Therapeutics and Technology Listserv® Today!  
If you are interested in joining the Listserv,  
email tcoletta@aap.org
What can we learn about pediatric clinical research from social listening?

Grant Smith, MPA, Digital Communications and Social Listening;
Leigh Anne Naas, BA, Community Manager @LillyTrials, and Mary A Short, MSN, Pediatric Capabilities Function;
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Introduction
Pharmaceutical companies have had an active voice in social media (specifically, on Twitter and in blogs) focused on general education and awareness of clinical research. However, the vast majority of content to date has been focused on research in adults, partly because of uncertainty about the appropriateness of discussing pediatric research online. As public concerns and government guidance regarding pediatric research has increased, there may now be the potential for the pediatric research community to join and influence the online conversation about clinical trials in the pediatric population. In order to understand the current landscape for this topic, a year-long social listening project was undertaken.

Materials and Methods
A Crimson Hexagon boolean-based topic monitor was used to review social media posts from August 1, 2015 to August 31, 2016. A random sample of posts were manually reviewed in order to verify sentiment and emotion categorization and improve overall reporting accuracy. Data was sourced from all publically available data sources within the following content categories: News, Forums, Blogs, Twitter, Facebook, Google Plus, Reviews and Comments.

Analysis was conducted using netnography, the digital application of traditional ethnographic research, characterized as an immersive study that seeks to understand a subculture through up-close, personal observation. The included findings were derived from analysis of a random subset of 15,000 social media posts.

Within this study, posts were identified as either emotional or neutral using a key word targeting algorithm that associates a given set of words with one of six basic emotions: joy, sadness, disgust, anger, surprise and fear. Once categorized, posts were manually reviewed in order to verify the applied categorization. For long-form posts that shared multiple emotions, the prevailing emotion within the post was applied as the overall emotion. For posts categorized as neutral, a manual review was performed to verify the accuracy of categorization. Posts deemed to be emotional shared personal feelings or sentiments beyond a simple stating of enrollment opportunities, news headlines or trial outcomes.

This method is limited by its predication on human interpretation of written text. While some posts contain overtly emotional tones, others are more subtle, relying heavily on the reviewer’s ability to use contextual clues to identify the author’s original intent. As a result, the interpretation could misconstrue the original author’s intent, or fail to account for subtleties such as sarcasm.

Results

Post Volume
Over the 13 months of the study, there were 148,834 posts within the pediatric clinical trial conversation.

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This was a 28% increase in overall post volume relative to the 13 months prior to the study.

**Participants in Social Media**

Several third-party organizations entered the digital and social space to help facilitate the process of connecting patients with applicable trials. Most cover both adult and pediatric trials. Pharmaceutical sponsors also started to enter the pediatric trial online recruiting space though most have not created pediatric-specific channels.

**Source Breakdown**

Within the pediatric clinical trials conversation, news stories comprised the largest portion of the conversation, accounting for more than 57% of total content. Forums accounted for the next largest share, with 16% of the overall content, followed by Twitter (13%) and Blogs (11%). Throughout July and August of 2016, Twitter content volume grew by more than 15%, giving the conversation its largest major social media volume to date.

**Figure 1: Distribution of content across social media channels**

![Distribution of content across social media channels](image)

**Sentiment Analysis**

A random sample of 15,000 posts were manually reviewed in order to verify sentiment and emotion categorization and improve overall reporting accuracy. The conversation sentiment has remained relatively steady compared to the previous year. In total, 18% of the conversation spoke about pediatric trials with a negative tone, compared to just 4% of content that was clearly positive. Overall, 79% of the conversation was neutral. This content was primarily the result of data reporting or enrollment advertising.

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Emotive Content
Emotive analysis revealed that fear is a primary emotion within the conversation. Of the 37% of people that spoke about clinical trials in an emotional way, 47% percent spoke about the trial from a fearful perspective. This means that 17.4% of the overall clinical trials conversation was framed from the position of a patient or prospective patient being afraid of either their diagnosis or their specific trial. Of posts that expressed fear, over 50% were because of potential side effects from their specific trial.

Social Media Topics
Within the conversation, the primary focus traditionally was data sharing. This content consisted of scientific journals of patient communities discussing the outcomes of recent research. During the study, the trial data content was steadily represented throughout the conversation. The true growth in the topics for online discussion has come in the areas of advocacy and enrollment advertising.
When analyzing the pediatric clinical trials conversation, it became apparent that there is a vibrant digital community focused on rare disease clinical trials. Overall, nearly 10% of the clinical trials conversation referenced a rare disease. Of note, both the overall conversation and the rare disease subset discuss oncology-related trials at a higher volume than other disease states. In total, users within the pediatric clinical trials space discuss oncology topics 234x more often than the average Twitter user.

**Discussion**

Social media excels in two major areas that other patient engagement and recruitment methods do not.

First is *humanization*. As social media creates awareness, it concurrently forges a human connection and builds trust. Prior to social media, this process could not really begin until patients made contact with a research site. But now social media allows us to humanize clinical research earlier, ultimately growing the number of potential clinical trial patients. Given the general public’s mistrust and trepidation towards clinical trials, this benefit has powerful potential.

The other major area social media excels at is *amplification*. Social media accelerates the speed and heightens the visibility of word-of-mouth. Because of this quality, social media offers a relatively easy and effective mechanism to amplify information about clinical trials. As a result, social media strengthens the ability of any social media user to become a clinical trial advocate. These advocates provide powerful “social proof” for other social media users that clinical trials are a viable healthcare option.

Much has been made about the development of patient portals and the role of health IT in the adult clinical trial experience. What researchers are now beginning to understand is that IT may play...
What can we learn about pediatric clinical research ... Continued from Page 9

an equally important role in the pediatric clinical trial space; however, the mere presence of these technologies does not ensure patient engagement. Researchers must understand the specific needs of their patient and caregivers, and establish a digital rapport with these communities.\(^1\) The results from this study begin to inform us of the needs of pediatric patients and their caregivers.

Digital and social media provide a significant opportunity within the clinical trials education and recruitment spaces. Several third-party organizations have launched in to the digital and social space to help facilitate the process of connecting patients with applicable trials. Most cover both adult and pediatric trials.

Although digital and social media provide a significant opportunity within the clinical trials education and recruitment spaces, they face significant perception challenges, especially when it comes to pediatric trials. Findings of this research indicate that fear is a primary emotion within the online conversation.

Scandals and new stories during the conduct of the study with concern over pediatric trials may have resulted in the conversation's negative sentiment spiking at more than 50%. Reports in that time frame include the BBC confirming that the British Home Office approved experimental drug trials on school-age children in the 1960's.\(^2\) The story likely stoked the public concern over “experimenting” on children, especially via studies that happen without the consent of a guardian. The story generated a significant conversation on Twitter that had the potential to reach more than 44.5 million people. In addition, a study was published by Harvard Med and found that 19% of pediatric clinical trials were stopped early, and 30% of completed trials went unpublished. This story was picked up by major outlets, such as Forbes, and was shared by advocates within the clinical trials community.\(^3\) When a preexisting fear of the potential implications of joining a trial are met with the realization that nearly one-fifth of trials are never completed, and nearly one-third ever materialize into new scientific knowledge, parents are left without the appropriate motivation to consider enrolling their children in trials.\(^4\)

The pediatric research community has the opportunity to answer questions and alleviate fears with accurate, reliable, trustworthy content. While there seems to be a recent increase in social media content related to pediatric clinical trials, overall there is still a small volume of content coming from Twitter, Facebook, Blogs and YouTube. Resources and expertise devoted to developing and disseminating clinical trial content through these channels have the opportunity to contribute valuable content about pediatric clinical research via these channels on a periodic basis.

The AAP Guidelines for the Ethical Conduct of Studies to Evaluate Drugs in Pediatric Populations\(^5\) mentions the role of advocacy groups, pediatric patients, and parents in aspects of protocol design and the potential need for advertising to successfully enroll pediatric trials. Social media may have a roll in both design and recruitment of pediatric research. As pharmaceutical sponsors and others foray into social media engagement to meet those needs, guidance from the AAP on engagement with young people and parents via social media to support pediatric research may be warranted.

**Conclusion**

After exploring the pediatric clinical trial social space it appears that companies are beginning to

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actively explore engaging in this digital conversation. While the space is still sparsely populated, some organizations have begun to actively engage. Research and trial matching organizations have begun to expand into pediatric social media recruiting.

Social listening has the potential to inform the pediatric research community of the perceptions and needs of pediatric patients, parents, and caregivers looking for pediatric clinical trials. In the 13 months of social listening there have been more than 148,000 social posts related to pediatric clinical trials; a conversation that has a potential reach of more than 101 million on Twitter alone during the same period. Findings of this research indicate that fear is a primary emotion within the online conversation. The pediatric research community, including the AAP Section on Advances in Therapeutics and Technology, has the opportunity to address the findings of this study to answer questions, alleviate fears with accurate, reliable, trustworthy content, and to proactively shape digital conversation related to pediatric research.

References:
Scheuermann Disease and Vitamin D Levels in Children and Adolescents

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ABSTRACT

Study Design: Case Series

Introduction: Scheuermann kyphosis and disc disease is not an uncommon diagnosis. Despite being well characterized clinically and radiographically, the etiology for this disorder remains poorly understood. A recent study in piglets demonstrated a much higher prevalence of kyphotic deformities when animals and their mothers were fed diets low in vitamin D, calcium and phosphate. The present study is an investigation of vitamin D levels in humans with Scheuermann disease, which to our knowledge has not yet been examined.

Methods: Retrospective case series of twenty patients over a six-month period with the diagnosis Scheuermann disease identified by searching ICD-9 codes for one practitioner and the evaluations were performed by the senior author and a fellow to confirm the diagnosis of Scheuermann disease. Serum 25-hydroxyvitamin D levels were measured with a high performance liquid chromatography early in the course of routine clinical evaluation and defined as adequate if 32-100 ng/mL, insufficient 20-32 ng/mL and deficient if less than 32 ng/mL. A one-way ANOVA data analysis was performed for continuous data, a chi-square test of independence for categorical data and a Pearson correlation coefficient calculated for the vitamin D levels and deformity.

Results: Of the twenty patients with Scheuermann disease, sixteen (80%) were found to have low vitamin D levels, and 25% met criteria for deficiency (< 20 ng/mL). Chi-squared test of independence showed no significant differences between sexes for categories of vitamin D levels. One-way ANOVA tests of vitamin D levels versus sex, age and season were not statistically significant (Table 2). Magnitude of the kyphosis and vitamin D levels had a small correlation (Corr Coeff. = 0.34) which was not significant.

Discussion: A recent animal study demonstrated the very strong effect of vitamin D deficiency and low calcium and phosphate in the diet, causing a large increase in expression of a kyphotic piglet phenotype similar to Scheuermann disease in humans. Although a substantial majority of our Scheuermann disease patients had levels of 25-hydroxyvitamin D below the range considered adequate, there were no statistically significant relationships for deformity, sex, age or season of the year. This may perhaps be due to sample size, or other uncontrolled variables such as the amount of calcium or phosphate in the diet and genetic predisposition to the disease.

Conclusions: It is almost certain that vitamin D levels alone are not determinate of human Scheuermann disease; however, the life stage of the vitamin deficiency, other dietary deficiencies and genetic susceptibility

Continued on Page 13
likely interact and lead to the phenotypic expression. Further study will require an appropriate control group.

Key Points:

1. Vitamin D levels are decreased in the majority of clinic patients with Scheuermann Disease.
2. Vitamin D levels did not correlate with the degree of kyphotic deformity, nor did they significantly vary with season, sex or age.
3. A prospective study with a patient peer control group matched for season, sex, ethnicity and age is proposed.

INTRODUCTION

Scheuermann kyphosis and disc disease is not an uncommon diagnosis and was first described by Scheuermann in Danish in 1920 and in German in 1921.\(^1\) It is seen in 0.4 to 2% of children and adolescents and 1 to 8% of adolescents.\(^2\)\(^-\)\(^4\) It has been defined as a T4-T12 kyphosis of more than 45° and more than 5° vertebral wedging at three or more consecutive levels (the so-called Sorenson's Criteria).\(^5\)

Due to the hypothetical relationship of osteoporosis as an etiology of the endplate, disc and bony changes seen in Scheuermann disease, we became interested in whether or not vitamin D deficiency was present in any of these patients, who otherwise appeared to be perfectly healthy.

Summary of Background Data

In a recent study cohort looking at the incidence of the disease, 1060 children were followed from the mean ages of 10.8 to 13.8 years for assessment of posture, 79.9% (N=847) participated until the final radiographic exam and for children whose thoracic kyphosis using pantography was more than 35 degrees at entry and 45 degrees or more at the final examination underwent a lateral standing radiograph and the 3-year incidence of Scheuermann's disease was 0.4%\(^6\) A school-screening program of 10,057 children between the ages of 11 and 17 years old, identified 175 adolescents with Scheuermann disease for an incidence of 1.7%\(^3\)

It is one of several causes of severe kyphosis in the human population and in Sorenson's 1964 study, 50% of the adolescents had back pain during their growth spurt.\(^5\) An unpublished study by Ponte et al. presented a non-operative study showing that their patients' curves beyond 45° progressed and during the growth spurt, and this continued even after the age of 30 years. Kyphotic deformities can be directly related to a decrease in pulmonary function, but this is often seen in patients with osteoporosis, where worsening of pulmonary function occurs with increasing kyphosis, but the changes of pulmonary function have been shown to be not so dramatic in adolescent Scheuermann kyphosis by the group in Iowa.\(^2\)\(^,\)\(^7\)

There appears to be an autosomal dominant inheritance pattern, perhaps related to abnormal collagen IX.\(^4\)\(^,\)\(^8\) In the study by Williams et al, Schmorl's Nodes were frequently seen in patients with Scheuermann's disc disease and kyphosis and the deformity has been linked to allelic differences

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in the genes for this protein. Treatment using the Milwaukee brace has been used to successfully relieve pain. This brace has been documented to correct curves less than 74° in skeletally immature patients by Moe's group in Minneapolis, and these indications for brace treatment are still generally accepted. The etiology of Scheuermann kyphosis, and the now eponymous disease, remains unknown, or at best, ill defined. The terms osteochondrosis an epiphysitis used to describe the changes seen are poorly defined and theories of the pathologic changes and the disease have included avascular necrosis of the apophysis, abnormal enchondral ossifications, and juvenile osteoporosis have all been implicated.

**Methods**

ICD-9 codes for kyphosis, juvenile osteochondrosis of the spine and low back pain were used to identify patients with the diagnosis of Scheuermann Kyphosis. All patients with radiographic evidence of Scheuermann Kyphosis or Disc Disease were evaluated by the authoring surgeon personally, and the diagnosis was confirmed. During the course of follow-up, the clinic nurses noted that more than half of the vitamin D levels sent out in this population were returning below the laboratory accepted laboratory lower limit of 32 ng/mL. Although the range for adults and children is not well established and is controversial, it was apparent that some patients had extremely low values.

Twenty patients over a six-month period with the diagnosis Scheuermann disease evaluated by one practitioner were identified by searching ICD-9 codes for juvenile spinal osteochondrosis, acquired kyphosis, idiopathic kyphoscoliosis and lumbago. The clinical and radiographic evaluations were performed by the senior author and a fellow to identify patients with a confirmed diagnosis of Scheuermann disease. Radiographic diagnosis was based on Sorenson's criteria or the presence of Schmorl's nodes and endplate changes and regional kyphosis measured according to the technique of Stagnara from T4-T12. Serum 25-hydroxyvitamin D levels were measured with a high performance liquid chromatography early in the course of routine clinical evaluation.

The data was de-identified and analyzed for sex, age, season of assay, deformity and vitamin D level. Vitamin D levels were categorized as adequate (32-100 ng/mL), insufficient (20-32 ng/mL) and deficient (<32 ng/mL). A one-way ANOVA data analysis was performed for continuous data, a chi-square test of independence for categorical data and a Pearson correlation coefficient calculated for and the vitamin D level.

**Results**

Of the twenty patients with Scheuermann disease, sixteen (80%) were found to have low vitamin D levels and 25% met criteria for deficiency (< 20 ng/mL) (Table 1). A chi-square test of independence showed no significant differences between males and females for categories of vitamin D levels.

A one-way ANOVA tests of vitamin D levels versus sex, age and season showed that males trended towards being slightly older, with a higher prevalence of insufficiency and deficiency compared to females, but these were not statistically significant (Table 2). Vitamin D levels in the spring (N=8) had the lowest mean value, but this was not statistically significant. Kyphosis and vitamin D levels had a small correlation (Corr Coeff. = 0.34) which was also not significant.

Using the T-Test single tail statistics, the Standard Error of the patients sampled, and a hypothetical

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normal mean of 30 ng/ml (a low estimate of the normal), a power analysis predicts that with a sample of 20 patients, a 10% difference could be detected at a power of 0.80 with an alpha of 0.05. If 50 patients were enrolled in a study, a 17% difference could be detected at a power of 0.8 with an alpha value of 0.01.

Discussion

The substantial majority of our Scheuermann disease patients had levels of 25-hydroxyvitamin D below the range considered adequate and 25% were categorized as deficient. In our study, there were no statistically significant relationships for deformity, sex, age or season of the year, perhaps due to sample size, or other variables such as calcium or phosphate in the diet. This disease affects more than thoracic spine kyphosis alone, depending on the levels involved. For this reason, the use of a “kyphosis score”, as proposed one of the authors, can account for this problem. A recent animal study demonstrated the very strong effect of vitamin D deficiency and low calcium and phosphate in the diet, causing a large increase in expression of a kyphotic piglet phenotype, similar to Scheuermann disease in humans. It is almost certain that vitamin D levels alone are not determinate of human Scheuermann disease; however, the life stage of the vitamin D deficiency, other dietary deficiencies and genetic susceptibilities to disease likely interact and lead to the phenotypic expression of Scheuermann disc disease.

Vitamin D deficiency itself has not been associated with Scheuermann disease or kyphosis in humans, although it was recommended that patients with Scheuermann disease be treated with exogenous vitamin D in the 1960’s. Until recently, there was little to support this specific intervention, however, vitamin D deficiency was recently identified as a specific cause of kyphosis in piglets. There was a recent serendipitous discovery of vitamin D deficiency as a cause of kyphosis after piglets were accidentally fed a formula deficient in this vitamin. The animals developed rickets-like changes and kyphotic deformities, stimulating a formal study of acquired kyphosis deformity in relationship to maternal and nursery vitamin D deficiency in the same animal model.

There has long been a hypothetical link between osteoporosis, Scheuermann's disc disease and Scheueremann's kyphosis. In one study, BMD changes were not seen to correlate with deformity in adolescent scoliosis patients, but a decreased trabecular Z-score for BMD in the period of prepuberty was significantly correlated with an increased alkaline phosphatase, more severe disc space changes and an increased antero-posterior vertebral diameter in patients with Scheuerermann's disease. Abnormal collagen-proteoglycan ratios have been described in the vertebral body endplate but none of the histologic and biochemical analyses performed can determine if these changes are primary or secondary to abnormal loading. Weakened bone and vertebral endplates conceptually are going to be prone to disc protrusion, Schmorl's node formation and growth abnormalities, as proposed by Bradford in a study of 12 patients, but this was later contradicted in other studies. The “chicken or the egg” problem was raised by Ogden, who believed that the deformity may precede the radiographic changes in the endplates and bones, which he ascribed to the abnormal mechanical environment caused by an increased kyphosis. However, this was repudiated by the study of Foitas et al, where the weight, height and body mass index showed no correlation with deformity. The magnitude of kyphosis was significantly higher in the 175 patients with Scheuermann Disease than in the remaining screened 9,882 children. The authors concluded that Scheuermann disease is a multifactorial disease and that weight and height do not affect the size and type of kyphosis. The authors surmised that the

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disease is secondary to other disturbances, potentially hormonal; these unknown factors may play a more crucial role in the pathogenesis of the disease.

Conclusions
Our recent observations of low vitamin D levels in most of our Scheuermann Disease patients demonstrates a need for a more detailed prospective evaluation, with an appropriate control group. The major weakness of this study is the absence of a control group and other human studies show a high prevalence of vitamin D deficiency in the general in orthopedic population. A prospective study of Scheuermann disease will require an appropriate control group, matched for age, sex, month of assay, race and body mass index. Geographic region is internally controlled by our service area, but multicenter studies will also require control for latitude and geography. A larger sample size will be needed to permit subgroup analysis and additional factors, such as known genetic alleles for collagen IX and the Vitamin D receptor, are associated with disc disease and should be included.

Table 1: Demographic Characteristics: Age (yrs) and Sex.

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<th>Total (N=20)</th>
<th>Male (N=12)</th>
<th>Female (N=8)</th>
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<td>Mean Age in Years (SD)</td>
<td>15 (2.2)</td>
<td>15 (2.4)</td>
<td>14 (1.7)</td>
</tr>
<tr>
<td>Median Age</td>
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<td>16</td>
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<td>Youngest</td>
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</tr>
</tbody>
</table>

Ages of children are listed with statistical calculations for the overall population, for all males, and for all females in the group. Note: except standard deviation, calculations for ages are rounded to the nearest whole-number year.

References
Table 2: Vitamin D Levels (ng/mL) and Prevalence of Vitamin D Inadequacy by Sex and Season.

<table>
<thead>
<tr>
<th></th>
<th>Total (N=20)</th>
<th>Male (N=12)</th>
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<th>Winter (N=9)</th>
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<td>Mean (SD) in ng/ml</td>
<td>25.3 (7.5)</td>
<td>23.1 (6.8)</td>
<td>28.5 (7.7)</td>
<td>30.3 (11)</td>
<td>24.2 (8.1)</td>
<td>24.5 (5.3)</td>
</tr>
<tr>
<td>Median in ng/ml</td>
<td>24</td>
<td>22</td>
<td>26</td>
<td>24</td>
<td>21</td>
<td>24</td>
</tr>
<tr>
<td>Range in ng/ml</td>
<td>14 - 43</td>
<td>14 - 33</td>
<td>19 - 43</td>
<td>24 - 43</td>
<td>14 - 35</td>
<td>17 - 33</td>
</tr>
<tr>
<td>Groups by Range</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>32 - 100 ng/mL (Sufficient)</td>
<td>4 (25%)</td>
<td>2 (17%)</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>&lt;32 ng/mL (Insufficient)</td>
<td>16 (80%)</td>
<td>10 (83%)</td>
<td>6</td>
<td>2</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>&lt; 20 ng/mL (Deficient)</td>
<td>5 (25%)</td>
<td>4 (33%)</td>
<td>1</td>
<td>0</td>
<td>3</td>
<td>2</td>
</tr>
</tbody>
</table>

Vitamin D levels are listed with statistical calculations for each subgroup, divided according to both sex and season during which the lab value was collected. Note: percentages are calculated as percentages of the number (N) for each column. Values reflecting vitamin D deficiency are percentages for all patients, not only for those with insufficiency.

Pediatric Medical Device Spotlight

(Editor’s note: This section spotlights the development and commercialization of new pediatric medical devices and hopefully serves as a resource and inspiration)

JustRight Surgical®- A company that designs and develops surgical instrumentation that enables minimally invasive surgery in children, from neonate to teenager.

Patti Hoag, Director of Marketing and Co-Founder, JustRight Surgical
Email: PHoag@JustRightSurgical.com

JustRight Surgical® is the first company to design and develop the instrumentation necessary to make minimally invasive surgery (MIS) in children possible. MIS first gained popularity in the adult population in the 1990s, driven by patient demand and the invention of video technology. While laparoscopic and thoracoscopic procedures became the standard of care in adults, pediatric surgeons were hesitant to adopt these techniques in children. Most of the resistance was technological; the laparoscopic revolution offered only large cameras and instruments, and bulky endo-mechanical trocars and staplers. Surgical stapling has been used for ligation since the late 1970s and vessel sealing was introduced in the late 1990s. Although commonly used in adult general surgery these essential surgical tools had never been appropriately sized for the pediatric population, forcing pediatric surgeons to either rely on standard open surgical techniques or improvise with adult sized devices on babies and children. As anatomical considerations in pediatrics include smaller chests and abdomens, using these inappropriately sized adult instruments has made access and exposure particularly problematic. In addition, using bulky, overpowered laparoscopic energy devices can cause safety issues. Complications in pediatric surgery are a reality. A retrospective review of 330,000 pediatric patients indicated the 30-day incidence of adverse events to be 10.3%. In contrast, the incidence of adverse events in adult surgery is 1.9% to 3.6%. JustRight Surgical was created to address this market need, to help reduce adverse events in pediatric surgery and to bring the benefits of MIS - reduced pain, reduced risk for incisional hernia, reduced scarring and decreased hospital stay - to infants and children.

The JustRight™ Vessel Sealing System includes the only 3mm sealer in the world, which is four times smaller than adult sized instruments. Its multifunction capability makes it ideal for the challenging clinical environment in pediatric surgery. The JustRight™ Generator has an advanced vessel sealing algorithm and optimized circuitry designed to keep temperatures low and seal times fast. Delivering 25 watts of power, the JustRight Generator effectively melts and reforms proteins as necessary for sealing vessels while keeping the instrument jaws “cool” (less than 47°C). In the confined cavity of a pediatric patient this prevents adjacent tissue damage and unintended burns.

The 3mm JustRight™ Sealer is the only sealing technology to receive the FDA stamp of approval for use in pediatrics. Pediatric surgeons can now confidently and comfortably use energy and maneuver instruments making minimally invasive surgery an option for patients from neonate to teenager.

Continued on Page 19
JustRight Surgical devices increase access and maneuverability and do not crowd the tight cavities of children. Pediatric surgery is a unique clinical specialty based on patient size, much like bariatric surgery is a unique clinical application based on patient size. Both specialties require distinct, right-sized instruments that fit the patient. The JustRight™ 5mm Stapler is the only true 5mm stapling instrument in the world and is 9 times smaller than any existing stapling instrument. Incision size, especially in pediatrics, is important to consider. Clinical studies report the total tension across multiple small incisions is less than the total tension for an incision of the same total length. Therefore, it is recommended surgeons use the smallest effective trocar systems and instruments to minimize pain and scarring. The JustRight 5mm Stapler allows surgeons to downsize their port selection and provides flexibility in stapler placement, ultimately minimizing risk of post-op infection, port site herniation, and hospital stay.

JustRight Surgical was created to address this market need and reduce adverse events in pediatric surgery. These products are now available in over 120 children's hospitals across the country. You can confidentially and comfortably recommend minimally invasive surgery as a safe and reliable option for your patients. Contact Support@JustRightSurgical to find a children's hospital near you that offers JustRight Surgical products for a minimally invasive solution.
References:
Current Status of Neonatology/Pediatrics and Regulatory Clinical Trials Research Metaphor

Ronald L. Ariagno, MD, FAAP
Emeritus Professor of Pediatrics, Stanford University
Division of Neonatal and Developmental Medicine
Chair of Task Force for Neonatal Perinatal Therapeutic Development,
AAP Section on Neonatal Perinatal Medicine and Liaison to SOATT.
Email RLA@stanford.edu

An orchestra, which fails to tune or play from the same score and arrangement, will produce cacophony not symphony.

The “orchestra” represents “talented neonatology/pediatric physician investigators”
“Tuning” represents a “consensus” for collaboration
The “score” represents consensus and rigorous implementation/acceptance of “standardized clinical practice(s)”
The “arrangement” represents the “study design”
“Cacophony” represents “confusing or inconsistent or non-significant results”.
“Symphony” represents “achieving significant results when there is consensus to network and to use the same consistent and standardized clinical practices and to follow a rigorous study design”.

What about “improvisation” in which each musician is invited to be creative with the score and arrangement? That result may be remarkable and unique but it will be difficult to replicate or to generalize. In other words, that group may be able to repeat their success but others will not.

Pediatricians and neonatologists are challenged to address the critical medical needs for infants and children to discover new interventions to improve outcome and to modify or resolve the condition/disease. These populations in need may also represent infants and children with orphan conditions (incidence <200,000) so that the goal of facilitating the availability of the population and the capacity of the individual sites/clinical investigators and networks to organize investigations will be critical for the potential success of a clinical trial.

Hopefully, the metaphor above will help clinicians and physician investigators address how to optimize our success in regulatory clinical research for the approval of needed therapies. First, we will need to have an inclusive consensus to collaborate; second, it is critical to establish standardized clinical practices; and finally, continue to design ethical and robust study plans with input from our nurse and regulatory colleagues, parents, children and the families we serve.
US FDA Awards I-ACT for Children a Grant for Pediatric Medicines & Devices Network

Ed Connor, MD, MBE, FAAP
Chairman and President, I-ACT for Children
Email: ed.connor@iactc.org

The US Food and Drug Administration has awarded the Institute for Advanced Clinical Trials for Children (I-ACT for Children) a grant to improve clinical trials of new drugs and devices for children. The award establishes an alliance among I-ACT for Children and PEDSnet, the James M. Anderson Center for Health Systems Excellence, Critical Path Institute and the National Capital Consortium for Pediatric Device Innovation, to work together with leading children's institutions and health systems to address key gaps and challenges in pediatric clinical trials. The award provides $1 M in fiscal year 2017 funds with the potential for $1 M each year for an additional 4 years contingent on annual appropriations and the availability of funding to support the development of the scientific infrastructure needed to plan and execute pediatric clinical trials through collaboration with stakeholders from academia, industry, parent/patient advocacy groups, and regulatory agencies.

“This is a first-in-kind opportunity to improve the use of medicines in children. I-ACT for Children will bring together stakeholders from academia, industry, patient/parent advocacy groups and government agencies to facilitate pediatric clinical trials. The development of biomarkers, outcome assessments, data standards, and training in regulatory ready studies will improve the efficiency of pediatric clinical trials with the potential to provide safe and effective therapies for children,” said Janet Woodcock, M.D., Director of the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration.

The I-ACT for Children network will emphasize innovative trials design, improved operational efficiency and trial feasibility, shared best practices, early stakeholder and community engagement, and integrative approaches to pediatric studies. I-ACT for Children, an independent 501(c)3 non-profit, with expertise in pediatric medical product development and public-private collaboration serves as the strategic lead for the award. The Institute will continue the public-private collaboration that began in 2016 through the Pediatric Trials Consortium which launched the effort to build a sustainable clinical trials infrastructure focused on children's need for innovative medical products. The work of this consortium is described in its Advisory Report which was cited in the request for proposal as a foundational tenet for applicants.

“Through this cooperative agreement we and our alliance partners will work to establish a sustainable infrastructure for pediatric clinical trials that is collaborative, child-centered and promotes regulatory science and innovative methodologies to improve research on the safety and effectiveness of new medicines and devices for children,” said Edward Connor, MD, MBE, FAAP Chairman and President of I-ACT for Children, Emeritus Professor of Pediatrics, Microbiology, Immunology, and Tropical Medicine, George Washington School of Medicine and Children's National Health System and principal investigator for the grant. “We are honored by FDA's confidence in our approach for a new paradigm in pediatric clinical trials.”

Continued on Page 23
I-ACT for Children works to optimize and accelerate biomedical innovation and catalyze improvements in the quality and timely completion of global pediatric studies to address the gap in evidence for therapeutics in children. Strategic partners in this grant include:

PEDSnet and the Anderson Center for Health Systems Excellence that serve as the network's Data and Learning Core. PEDSnet institutions share common data elements for >5.3 million children, and the Data and Learning Core includes learning health networks in >450 centers at 225 medical institutions, representing families and children from diverse socio-demographic and clinical backgrounds. The Critical Path Institute will serve as the Regulatory Science Core and the National Capital Consortium for Pediatric Device Innovation, an FDA-funded initiative, will act as the Device Core.

“This award brings together leaders in pediatric trials innovation from across the public and private sectors in an exciting new clinical trials network and creates an environment of continuous learning that leverages real world data to inform trial design and feasibility,” said Dr. Christopher Forrest, MD, PhD, FAAP Professor of Pediatrics, Health Care Management, and Biomedical and Health Care Informatics, Perelman School of Medicine, University of Pennsylvania and Children's Hospital of Philadelphia, principal investigator, PEDSnet, and co-investigator for the grant.

About the Institute for Advanced Clinical Trials for Children (I-ACT for Children):
The Institute for Advanced Clinical Trials for Children is a new independent, nonprofit organization that works with public and private stakeholders to improve the planning and completion of pediatric clinical trials. It facilitates advanced research and education directed at improving the timeliness, quality and medical impact of clinical trials of innovative therapeutics on child health. The Institute was established by Critical Path Institute with advice and guidance from its Pediatric Trials Consortium that includes more than 30 diverse organizations, including patients/parents, government agencies, professional organizations, academia, the biopharmaceutical industry and international experts. I-ACT for Children is headquartered in Rockville, MD. For more information, visit https://www.iactc.org.

About PEDSnet:
PEDSnet is a large, national community of hospitals and healthcare organizations, researchers, clinicians, patients and families dedicated to improving the health and lives of children by identifying the most important research questions that can reduce children's suffering and support their healthy development. They have formed a multi-specialty network that conducts observational research and clinical trials across multiple children's hospital health systems governed by parents and senior leaders. Through their work, PEDSnet has produced reusable and expandable governance, logistical, informatics, regulatory, scientific, and training resources. Furthermore, across its 8 founding institutions, PEDSnet created a longitudinal data resource that dates back to 2009, cuts across all pediatric diseases and includes all pediatric specialties. For more information, visit https://pedsnet.org/.

About the Anderson Center for Health Systems Excellence:
To elevate Cincinnati Children's focus on quality improvement, and spread the impact of their improvements in children's health, the James M. Anderson Center for Health Systems Excellence was created in 2010 and is led by co-directors Peter Margolis, M.D., PhD, and Steve Muething, M.D.
The Anderson Center challenges conventional thinking in children's health care by identifying best practices, connecting research in one area with its practical application in another and collaborating and partnering with outside organizations to bring new knowledge to healthcare. For more information, visit https://www.cincinnatichildrens.org/.

About Critical Path Institute (C-Path):
Critical Path Institute is an independent, nonprofit organization established in 2005 with public and private philanthropic support from the Arizona community, Science Foundation Arizona, and the US Food and Drug Administration (FDA). C-Path's mission is to catalyze the development of new approaches that advance medical innovation and regulatory science, accelerating the path to a healthier world. An international leader in forming collaborations, C-Path has established 12 global, public-private partnerships that currently include over 1,450 scientists from government and regulatory agencies, academia, patient advocacy organizations, and dozens of major pharmaceutical companies. C-Path is headquartered in Tucson, Arizona. For more information, visit https://c-path.org.

About the National Capital Consortium for Pediatric Device Innovation (NCC-PDI):
The National Capital Consortium for Pediatric Device Innovation (NCC-PDI) is an FDA funded consortium, led by the Sheikh Zayed Institute for Pediatric Surgical Innovation at Children's National Health System and the A. James Clark School of Engineering at the University of Maryland. It was formed in September 2013 through the FDA's Pediatric Device Consortia Grant Program to provide infrastructure support and expert consultation on pediatric medical device development throughout the development lifecycle -- concept formation, prototyping, preclinical, clinical, manufacturing, marketing, and commercialization - to help in bringing devices to children faster. Since inception, NCC-PDI has supported 67 pediatric devices, and the companies and research labs owning these devices have collectively raised over $55 million in follow-on early-stage funding.

Funding for this work was made possible, in part, by the Food and Drug Administration through grant (1 U18 FD 006297).

Views expressed in written materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does any mention of trade names, commercial practices, or organization imply endorsement by the United States Government.
The 2017 iCAN Research & Advocacy Summit took place in Orlando, Florida from July 10-14, once again with the goal of bringing together youth, families and professionals to learn from one another and provide youth with opportunities to improve pediatric health, medicine, research, and innovation by sharing children's voices in an impactful way. This successful event saw a forty percent increase in attendance from last year, bringing together 250 youth advisors and their families, team leaders, and scientific partners. 19 of iCAN's 20 chapters were represented, with members from 8 countries on 3 continents. The 2017 Summit was dedicated to the memory of Félix Junquera Tejeda, a beloved youth advisor of the KIDS Barcelona chapter who lost his courageous battle with Osteosarcoma just weeks before the event. iCAN's first-ever scholarship will be created in his name, and will cover costs for an outstanding youth advisor to attend the Summit each year.

iCAN youth advisors and leadership were joined by special guest speakers from the US FDA, Health Canada, Pfizer, Premier Research, PhRMA, Eli Lilly, InVentiv Health, the American Academy of Pediatrics Section on Advances in Therapeutics and Technology, BIO, the Florida Department of Health, Boehringer Ingelheim, Live Like Bella, Dairy Council of Florida, various children's hospitals from around the world, and more. Attendees engaged with scientific leaders to learn about topics in medicine, research, innovation, pharmacogenomics, STEM careers, drug discovery and development, healthy lifestyles, patient advocacy, how to assess basic vital signs, and had multiple opportunities to learn about and provide feedback on pediatric informed consent and assent documents. Summit attendees also visited the Give Kids the World Village, received a tour of the facility to learn about its purpose and history, and participated in a hands-on community service activity to benefit the many visitors of the Village each year. iCAN was honored to welcome Florida State Senator Marco Rubio, who discussed the importance of patient engagement in research and healthcare, as well as the need for increased research of childhood cancers.

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iCAN introduced three new chapters to the growing network this year: KIDS Bari (Italy), KIDS Tokyo (Japan), and the first-ever iCAN Special Interest Chapter, KIDS Childhood Cancer. This new chapter model will connect youth and families from across the globe in specific therapeutic areas to allow us to target the specific needs of each disease, while allowing additional room for collaboration with preexisting organizations with similar goals to reduce duplicate efforts and fortify a stronger and more effective approach to change.

Recognition from important figures and the rapid growth of this event and network observed from year to year demonstrate the growing support of iCAN’s initiatives in a dynamic and constantly changing field, where patient and public engagement is quickly becoming a standard.

The next iCAN Research & Advocacy Summit will take place in July, 2018 in Edinburgh, Scotland. Follow iCAN Research on social media for announcements and updates @iCANResearch, or visit www.icanresearch.org!
2017 Award for Pediatric Innovation

Each year, the AAP SOATT recognizes and honors an outstanding pediatrician actively engaged in bringing innovation to improve the health and well-being of infants, children, adolescents and young adults. This award is supported by funding from Pfizer, Inc. This award honors the qualities and characteristics of an AAP member who has made significant innovations in the career of pediatrics. This award:

1. Recognizes an individual who has greatly contributed to the field of pediatrics in the focus areas of therapeutics, technology and advances in medicine through hard work and innovation.

2. Highlights the innovative work being done to advance pediatric therapeutics and technology.

It gives me great pleasure to introduce our award recipient for 2017:

Dr. Charles A. Thompson

Charlie earned his M.D. at the University of Connecticut School of Medicine and completed his pediatric residency at Connecticut Children's Medical Center in Hartford. He is a Clinical Instructor of Pediatrics at the University of Connecticut School of Medicine. Currently, Charlie is the Global Lead for the Pfizer Pediatric Center of Excellence. Throughout his 20 plus year career at Pfizer, Charlie has taken on diverse roles in clinical development, clinical safety/risk management, and field medical affairs. He is completing his second term as a governor-appointed member of the Connecticut Pharmaceutical and Therapeutics committee and has served on the State of Connecticut Immunization Task Force following an appointment by the Speaker of the House. Charlie is also the founder and Immediate Past Chair of the Executive Committee for our section -- the American Academy of Pediatrics Section on Advances in Therapeutics and Technology (or as we know it SOATT), an “ex officio” member of the Board of Directors for the Beardsley Connecticut Chapter of the American Academy of Pediatrics, a Steering Committee Member for the Global Alliance for Pediatric Therapeutics, a pre-competitive public/private partnership to advance the development of medicines for children, and what I feel is his crowning accomplishment the Founder and Chair of iCAN (International Children's Advisory Network).

iCAN is a global consortium of youth advisory groups working together to provide a voice for children and families in medicine, research, and innovation through synergy, communication, and collaboration. iCAN’s chapters work both locally in partnerships with their local children’s hospitals and communities, and collaborate network-wide to have a global impact -- something that had not been done before at this scale.

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Through its chapters, youth-led councils, committees and focus groups, iCAN addresses needs of pediatric clinical research and healthcare, influences state and federal regulations, and advocates for pediatric patients across the globe. In just three short years, iCAN has established an impressive number of active chapters, spanning 8 countries on 3 continents with many more chapters currently in development. iCAN's rapid expansion is a testament to the universally recognized value of this innovative bottom-up approach to the research study design process.

At present, the iCAN network has provided experiential input to over 20 pediatric healthcare initiatives, attended multiple scientific conferences & society meetings, produced over 8 publications and presentations, influenced legislation focused on pediatric clinical trials in the United States and Europe, and inspired an entire generation of medical innovators.

The ideation, facilitation and advancement of this widely impactful and innovative organization is all thanks to the Chair and Founder, Dr. Charles A. Thompson. Dr. Thompson's role within iCAN stretches well beyond the establishment of the organization itself, as he is heavily involved in the daily operations, planning the annual Research & Advocacy Summit, making critical connections with key industry players, and governing the Board of Directors.

In his community, Charlie is an active youth leader in sports and scouting. He is a former board member of the Connecticut Make-A-Wish Foundation. Charlie lives in Florida, USA, with his wife, Heather, and four children.

Christina Bucci-Rechtweg, MD, FAAP (Program Chairperson), Mitchell Goldstein, MD, FAAP (Section Chairperson), Charlie Thompson, MD, FAAP (Immediate Past Chairperson).
A Message from the Membership Committee

Chris Rizzo, MD, FAAP
SOATT Membership Committee Chair
crizzo624@gmail.com

It is an exciting time to be involved in generating new information on pediatric technology, devices and medications.

Those of you reading this newsletter are likely SOATT members. We rely on your help to recruit others to the Section. Members of the Section do not need to be eligible for AAP membership. See below for membership categories and eligibility.

Our Section continues to grow and now has 822 members!

Who Can Join?
1. AAP Members

Membership in the section is open to AAP 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. There is no fee for AAP members.

2. SOATT Affiliate Members

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 (see “How to Join” below) and have a signed letter of support from an AAP fellow in good standing. There is a $40 annual fee for section 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://membership.aap.org/Application/AddSectionChapterCouncil
Affiliates: https://membership.aap.org/Application/SectionAffiliate

If you have any questions about membership, please contact Chris Rizzo MD, FAAP at crizzo624@gmail.com or the section staff at jburke@aap.org.
Welcome New Members  
(March 2017 to October 2017)

<table>
<thead>
<tr>
<th>Abdelrahim Abdel</th>
<th>Ariani Harijono, MD, Paed</th>
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<tbody>
<tr>
<td>Abhishek Mehta, MD, MPH</td>
<td>Arpanjeet Kaur</td>
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<td>Abhishek Santos Pandya, MD</td>
<td>Ashley M. Kosier, MD</td>
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<tr>
<td>Adam Yan, MD</td>
<td>Aurea Rivero, MD</td>
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<tr>
<td>Adria Luk</td>
<td>Azza A. Abo-deeb, MD, FAAP</td>
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<tr>
<td>Ahmed Almadani, MD</td>
<td>Barbara Johnston Skelton, MD, FAAP</td>
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<td>Akshay Sharma, MBBS, FAAP</td>
<td>Bernadette Sylla</td>
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<td>Alan Rustin Greene, MD, FAAP</td>
<td>Bimal Pankaj Chaudhari, MD, MPH, FAAP</td>
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<td>Alejandro Gutierrez, MD</td>
<td>Biren Desai</td>
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<td>Alex Blanchette</td>
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<td>Alexandra Geanacopoulos</td>
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<td>Alexandra Lucas</td>
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<td>Ali Mansour Ebrahimi, MD, FAAP</td>
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<td>Alla Kushnir, MD, FAAP</td>
<td>Bridget Danielle Stuart, MD</td>
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<td>Alyssa Bianca Velasco</td>
<td>Cara Puzzio</td>
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<td>Amanda Bowers, MD</td>
<td>Carlos Omar Zuniga Reyes, MD</td>
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<td>Amethyst Alayari</td>
<td>Cheryl Cheah</td>
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<td>Amy Watson, MD</td>
<td>Cheryl Ann Clay, MD</td>
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<td>Amy Christine Clevenger, MD, PhD, FAAP</td>
<td>Chris Sebastian</td>
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<tr>
<td>Ana Claudia Teddei Sweeney, MD</td>
<td>Christian Edward Williams, MD, FAAP</td>
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<td>Andrew Hopwood</td>
<td>Christina Kim</td>
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<td>Andrew Shore, MPH</td>
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<td>Andrew Patrick Cagle, MD, FAAP</td>
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<td>Clay Edward Smith, MD</td>
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<td>Angela Rekhi</td>
<td>Coburn Huckins Allen, MD, FAAP</td>
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<td>Anish Trehun, MD, FAAP</td>
<td>Consuelo Carrillo, PhD</td>
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<tr>
<td>Ankit Singla, MD</td>
<td>Corrine O Sin Quee, MD, FAAP</td>
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<td>Ann Louise Anderson-Berry, MD, FAAP</td>
<td>Cristina Stan</td>
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<td>Ann Mary Kalapurakal</td>
<td>Curtis Wade Turner, MD, FAAP</td>
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<tr>
<td>Anne Chen</td>
<td>Daniel Horton, MD, MSCE, FAAP</td>
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<tr>
<td>Anuradha Pavuluri, MD, FAAP</td>
<td>Daniel Ibanez, MD, FAAP</td>
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*Continued on Page 31*
Welcome New Members  Continued from Page 30

Daniel Kissau  
Daniel Patrick Lamb, MD, FAAP  
Danielle Fernandes, MD  
David Sheridan, MD, FAAP  
David J. Birnkrant, MD, FAAP  
David K. Lobo, MD, MPH, FAAP  
David Raphael Spielberg, MD, FAAP  
Deandrea Ellis  
Debra L. Freedenberg, MD, FAAP  
Debra-Lynn Day-Salvatore, MD, PhD, FAAP  
Deena Miller  
Deepa Unnikrishnan Menon, MD, FAAP  
Derek A. Ching, MD, FAAP  
Devika Bhushan, MD, FAAP  
Diane E. Dubinsky, MD, FAAP  
Divya Shakti, MD, FAAP  
Eduardo A. Marrero Velis, MD, FAAP  
Eduardo J. Velasco-Sanchez, MD  
Edward Paul Southern, MD, FAAP  
Eevar Rossavik  
Ekene Evelyn Ajufo, MD  
Elisa Coccimiglio  
Elizabeth Mack, MD, FAAP  
Elizabeth Yen, MD, FAAP  
Emmanuel Diaz, MD, FAAP  
Eragapati Prazwal Kumar, MD  
Eric James Gratias, MD, FAAP  
Eric Neal Horowitz, MD, FAAP  
Eric Parks Sasine  
Eric Stanley Peeples, MD, FAAP  
Erika Barragán, MD  
Erin Nicole Hickman, MD, FAAP  
Eslam Mohamed Abdelfattah Edris, MBBCh, DCH, MRCPCH  
Faisal Alsani, MD, FAAP  
Faizeen Zafar, MD  
Farooq Shahzad, MBBS, FAAP  
Fidaul Alam  
Flaura Koplin Winston, MD, PhD, FAAP  
Fnu Sangeeta  
Francis Dick-Wai Chan, MD, FAAP  
Frantz Emmanuel Brea, MD  
Fredric T. Serota, MD, JD, FAAP  
Fredy David Valero, MD  
Gary Ira Kleiner, MD, PhD, FAAP  
Geoffrey Hart-Cooper, MD  
George S. Hsu, MD, FAAP  
George Wesley Branstiter, MD  
Gianna Guzzardo  
Graham Aufricht  
Graham Cameron Thompson, MD, FAAP  
Gregory M. Sokol, MD, FAAP  
Hima Raju, MD  
Holly Lindsay, MS, MD, FAAP  
Holly Nicole Mykolaitis  
Ibrahim Abdallah Sammour, MD, FAAP  
Ines Elena Garcia, MD, FAAP  
Irene O. Gamra  
Jacqueline Lee  
Jai C. Autar, MD, FAAP  
James Harris, MD  
James Arthur Phalen, MD, FAAP  
James M. Oleske, MD, MPH, FAAP  
James R. Hanley, MD, FAAP  
Jean Shahdadpuri, MD, MBA, FAAP  
Jeffrey Ferrell  
Jennifer Vodzak, MD, FAAP  
Jenny Rose Fox, MD, FAAP

Continued on Page 32
Welcome New Members  Continued from Page 31

Jeremy Schnall, MD, FAAP
Jesil Pazhayampallil, MD, FAAP
Jessica Krugman
Jessica Arin Groot
Jessica Mari Rosario-Falero
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Section Produces Patient Education Brochure on Clinical Trials

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.


SOATT Milestones

The Section has created a document that catalogs important highpoints for the Section since its creation in 2010. See a copy of the document here.
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