



“An Advance in Technology that Has Not Really Brought Improvement to the Practice of Medicine”

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As I thought about writing this column, I was distracted by my beeper going off several times in a row. “So many pages, and all at once?” I thought. What was going on? I stopped thinking about what I should have put to paper several weeks ago and started going through my pages. One was for a routine Tuesday morning conference; it had been sent the afternoon before I received it. Another was for sign-out that morning three hours previous. I had not thought about missing this because the NP had come to me directly to sign out after I did not answer the page. The third page was for an urgent ECMO consult. It was sent an hour previously. Now, I was worried. Was this patient crashing? Well, they could not find me, so they found someone who called someone else who was not on call who had to come in early to cover my “absence.” The outcome was good, and there was no delay but “what if?” Meanwhile, I was just two floors down in the hospital sitting at the computer. However, it does not have to be a patient going on ECMO; it could be a child with an allergic reaction or anaphylaxis, a parent worried about her child’s suicidal ideation or a colleague with a family emergency.

To provide context, let me provide a little background. My beeper is not really a beeper anymore. Several years ago, the hospital incentivized faculty members to give up our ultrareliable digital pagers and use a software package that replicated the functionality on a software app on a cell phone. The pages are encrypted, HIPAA compliant, receivable over wireless and cellular networks, and unpredictable. I have tried all of the diagnostic testing, replaced my cell phone, replaced my cellular network provider, complained on multiple occasions, and even set up my phone so that my “pager app” is always in the foreground. Reception in the hospital was always the go-to solution to the problem. Several months ago, my cellular provider put a “tower” in the basement of the hospital. I can now ride up and down in the freight elevators all day long without losing cell phone reception or dropping a call. But receive a stat page in a timely manner on this system? I think not.

Information systems were sympathetic. I explained my situation. As it turns out, our software app was not designed for “critical care applications.” They came up with a special in-house beeper that could be passed around to those on call and who were in house. It has a less than 20-second latency and really works well, but it will not work outside of the hospital. “Okay, I thought,” we can always go to our cell phones.

Well, not all of the cell providers have towers in the basement of the hospital. My colleagues complain of not being able to receive cell phone calls in the hallways, the basement of the hospital, or the procedure room tucked behind the nurse’s station. No, cell phones are not the panacea.

So, we are back to the pager. What is the problem with going back to a physical pager? As it turns out, pagers are expensive. In the mid-1990’s, there were more than 12 times as many pagers in circulation as today. Pagers are more durable than cell phones and are generally fixed in function. Most physicians will go years without replacing their pager. I have yet to meet someone who holds on to their cell phone for more than a couple of years. As it was explained to me, maintaining

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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:
Chester J. Koh, MD, FACS, FAAP at cxkoh@texaschildrens.org**

and fixing old pagers was a major cost for the hospital, notwithstanding the service contracts which could be more than a basic cellular plan. Physicians who give up their pager in place of the “pager app” are even given an incentive payment on a monthly basis. Although individual physicians may request a long-range physical pager, the goal is to phase them out entirely in the next few years especially as bandwidth becomes even more scarce as it is used for applications such as 5G.

Moreover, a few days later, our contract matrix for the division was released. Over ten years ago, this was a very useful document. Everyone had a separate freestanding pager that corresponded to a pager number, a cell phone with its own cell phone number, and a real plain old telephone home phone number. This year, over half of the members of my division did not have a home phone listed. From three physical devices, most were now down to just one, their cell phone.

The implications are clear. If their cell phone is incapacitated for any reason, there is no way to reach most of the physicians in my division when they are at home. And yes, perhaps cell phones are more durable, waterproof, and crush resistant, but it just takes one good electrical storm to knock out a cell tower, one tired physician who leaves their cell phone in the car, or one super mischievous toddler to flush a cell phone down the toilet. Then what? I am told by more “enlightened” physicians that social media can work in the event of an emergency. To prove their point, they show me how easy it is to message someone on Facebook, using their cell phone.

In the interest of moving forward, we have moved way backward. I would argue that by “condensing” our technology, we have gone back a hundred years in communication reliability. As we embrace newer forms of communication and more compliant ways of sending messages, we have abandoned the failsafe backup systems that we all had access to less than 20 years ago. To move forward, we must advocate for the necessary redundancy in communication technologies to keep our patients safe.



From the Editor’s Desk

“Pediatric Innovation Springs Forward”

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Welcome to the Spring 2019 edition of the AAP SOATT newsletter! We hope that you’re enjoying the Spring weather.

We thank Dr. Ron Day from the University of Utah for the suggestion that the current FDA-supported pediatric device consortia provides their descriptions and their approach to pediatric device innovation. In this edition, three of the consortia descriptions are included, and we hope to add the others to future editions soon.

Ron Ariagno, MD, FAAP, and Andrew Hopper, MD provide tips on creating research abstracts for meetings such as the SOATT sections, and Amy Ohmer, the director of the International Children’s Advisory Network (ICAN) provides a preview of the upcoming annual Summit in June in Kansas City which brings children together from all over the world to increase their voice and participation in clinical research.

The Pediatric Device Spotlight section describes the development and commercialization of new pediatric medical devices and hopefully serves as a resource and inspiration. This edition highlights QuickLoop Abscess Treatment Device from EM Device Lab, Inc.

Please mark your calendars for the 2019 AAP NCE meeting in New Orleans, LA in the fall (October 25 - 29, 2019) with the Section’s Educational program on Pediatric Innovation.

We hope that you enjoy reading this edition of the newsletter, and please share it with a colleague, patient, or friend. We

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welcome all suggestions for articles, and especially those related to innovations in therapeutics and technology. 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, pediatric specialists, engineers, and entrepreneurs 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>

FDA Pediatric Device Consortia Grants Program

(Office of Orphan Products Development)

www.FDA.gov/PDC

National Capital Consortium for Pediatric Device Innovation

(Children's National Health System / University of Maryland)

innovate4kids.org

Pennsylvania Pediatric Medical Device Consortium

(Children's Hospital of Philadelphia / University of Pennsylvania / Drexel University / University of Pittsburgh)

ppdc.research.chop.edu

Southwest National Pediatric Device Consortium

(Texas Children's Hospital and Baylor College of Medicine / Texas A&M / Rice / Univ. of Houston / Fannin Innovation Studio)

SWPDC.org

West Coast Consortium for Technology and Innovation in Pediatrics

(Children's Hospital Los Angeles / University of Southern California)

www.westcoastctip.org

University of California San Francisco-Stanford Pediatric Device Consortium

(University of California San Francisco / Stanford University)

pediatricdeviceconsortium.org

(Editor's note: As requested by a newsletter subscriber, this section spotlights three of the current FDA-funded pediatric device consortia that support the development and commercialization of innovative pediatric medical devices. The other consortia will be described in future editions.)

Introduction to the UCSF-Stanford Pediatric Device Consortium

Principal Investigator: Michael Harrison, MD michael.harrison@ucsf.edu

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Website: <https://www.pediatricdeviceconsortium.org/>

The UCSF-Stanford Pediatric Device Consortium (PDC) leverages the established device innovation talent of two world-class universities and an unsurpassed entrepreneurial network in the heart of Silicon Valley to equip pediatric innovators at all stages of development to translate their innovations into high-value, commercially viable products. Combining the experience and resources of the nine-year-old UCSF Pediatric Device Consortium and the long-established and world-renowned Stanford Biodesign program, the new "UCSF-Stanford PDC" features an emphasis on concept-stage market assessment and value analysis; in-house product development, regulatory, patenting, and entrepreneur-in-residence (EIR) services; a hands-on Commercialization Advisory Board to create situation-specific go-to-market strategies; and a deep and committed network of medtech advisors and product development resources in the world's innovation capital.

Our direct funding program, the UCSF-Stanford PDC Accelerator, is announced annually in January with applications due in February. Finalists pitch to a panel of industry judges for the chance to share in \$250,000 of awards. The Accelerator is open to any U.S. based company or innovator with a pediatric device technology at any stage of development that is committed to achieving marketing clearance/approval for a pediatric population and is not currently funded by another FDA-supported consortia. In addition to up to \$50,000 in funding, the award involves comprehensive mentoring and coaching services tailored to the individual project's risks and needs. More information is available at <https://www.pediatricdeviceconsortium.org/funding>.

In addition to our annual Accelerator, the PDC offers assistance on a rolling basis through our weekly Innovators Forum, a lively meeting where device developers share their ideas and challenges and receive feedback from a wide range of veteran pediatric innovators. Presenters located outside of the Bay Area may present via video conference. Projects that demonstrate a strong value premise and market opportunity are eligible to receive in-depth assistance in areas such as prototyping, technology validation, patenting, regulatory and reimbursement strategy, market analysis, manufacturing planning, supply chain entrance, and [Biodesign](#) coaching.

Since its founding in 2009, the UCSF PDC has advanced 10 internally developed pediatric devices from the concept stage to first-in-human trials, guided three devices to market availability, and leveraged over \$30M in external funding to support continued development of its technologies. Stanford's Biodesign program has established an internationally recognized model for device innovation and development, having launched 46 successful startup companies whose technologies have now reached over a million patients. Now under a unified banner, the UCSF-Stanford PDC is combining our respective strengths and infrastructures to create a powerhouse program accelerating high-impact, value-based pediatric device solutions to commercialization and patient impact.

Introduction to the Pennsylvania Pediatric Medical Device Consortium (PPDC)

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Program Managers:

Joshua Dienstman DienstmanJ@email.chop.edu

Patrick Cantini cantinip@upmc.edu

Website: ppdc.research.chop.edu

The Pennsylvania Pediatric Medical Device Consortium (formerly the Philadelphia Pediatric Medical Device Consortium), connects Children's Hospital of Philadelphia (CHOP) with the McGowan Institute for Regenerative Medicine and sciVelo, both based at the University of Pittsburgh. This new partnership comes on the heels of a five- year, \$5 million grant renewal from the Consortium's sponsor, the U.S. Food and Drug Administration. The mission of the PPDC is to support the development and commercialization of promising medical devices that address unmet clinical needs in children.

The PPDC leadership includes Robert Levy, MD (Principal Investigator, Chair of the Clinical and Scientific Advisory Committee, and Professor of Pediatrics, CHOP & the University of Pennsylvania), Matthew Maltese, PhD (Executive Director and CSO, X-Biomedical, Inc.), Shahram Hejazi, PhD (Chair of the Oversight Committee and Partner, BioAdvance), and William Wagner, PhD (Co-Chair of the Clinical and Scientific Advisory Committee and Director and Professor, the McGowan Institute, University of Pittsburgh). The PPDC organizational structure includes a Clinical and Scientific Advisory Committee composed of pediatric specialists and engineers from the participating institutions with expertise relevant to virtually all pediatric medical devices. This committee reviews and provides assistance for every pediatric medical device submitted to the PPDC. The Oversight Committee of the PPDC is the other major organizational component. This group is composed of business executives and investors. The Oversight Committee is responsible for final approval of all direct device funding and provides product development guidance, as needed, for all pediatric medical devices reviewed by the PPDC. The PPDC Project Managers who coordinate all operations are Josh Dienstman, Children's Hospital of Philadelphia, and Patrick Cantini, the University of Pittsburgh.

Since its founding in 2013, the PPDC has provided both guidance and seed funding for a range of pediatric products, including an airway clearance system, a powered arm brace, a speech-generating communication system, a vision acuity test for preverbal children, and a portable phototherapy device for newborns with neonatal jaundice. It has assisted more than 90 innovative projects, and over the past five years the PPDC has awarded 16 seed grants of up to \$50,000 each to companies in Pennsylvania and beyond.

In addition to the annual round of seed grants, the PPDC accepts applications at all times for in-kind services and expert advice.

Be Informed! Get Involved!
Join the Section on Advances in Therapeutics and Technology
Listserv® Today!
If you are interested in joining the Listserv, email tcoletta@aap.org

Introduction to the Southwest National Pediatric Device Consortium (SWPDC)

Principal Investigator: Chester Koh, MD cxkoh@texaschildrens.org
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Website: SWPDC.org

The Southwest National Pediatric Device Consortium (SWPDC) is a multi-institutional consortium anchored by Texas Children's Hospital (TCH) and Baylor College of Medicine (BCM), and includes clinical, scientific, business, financial, regulatory, reimbursement, engineering, intellectual property, and academic partners in the Houston / Southwest U.S. region. The principal investigators for the consortium include Chester Koh, MD (Contact PI) and Henri Justino, MD at TCH / BCM; Balakrishna Haridas, PhD at Texas A&M University; Maria Oden, PhD at Rice University; Richard Willson, PhD at the University of Houston, and Michael Heffernan, PhD at Fannin Innovation Studio. SWPDC also has a large Steering Committee and Advisory Committee.

SWPDC supports innovation, mentoring, and collaborations amongst pediatric clinicians and surgeons, engineers, industry, and other partners for pediatric device development. Since pediatric device projects often cannot progress through the standard market-based approach that adult device projects follow, SWPDC has continued to emphasize the need for an extended life cycle of pediatric device projects in the children's hospital / academic setting before exposure to the external market. Pediatric device innovators have access to comprehensive assistance from SWPDC members and others to help them progress toward commercialization and clinical implementation.

SWPDC developed from the local maturation of the "Third Coast" of medical device development (vs. the East Coast and West Coast hubs), with a medical industry that includes the world's largest medical complex, the Texas Medical Center (TMC), the largest children's hospital in the U.S (TCH) with over 1,000 beds, Texas Medical Center Innovation Institute (TMCx), and JLABS@TMC. We also have active hubs in Phoenix (Phoenix Children's) and San Antonio (Children's Hospital of San Antonio and Incube Labs). As a result, SWPDC provides assistance to pediatric device developers locally, regionally, as well as nationally.

Up to \$200,000 per year in non-dilutive seed funding / direct device funding is awarded to pediatric device innovators annually from SWPDC. The funds are distributed in association with three established pitch competitions: Impact Pediatric Health at SXSW which is jointly sponsored by 7 leading children's hospitals (impactpediatric.health); Rice Business Plan competition, which is the world's largest and richest student startup competition (rbpc.rice.edu); and the Texas A&M New Ventures Competition (texasnvc.org).

Please visit SWPDC.org for more information, and please let us know how we can assist!

We Need You!
How to Join . . .
It's easy! There are NO DUES to join the SOATT
if you are an AAP member.
Send an e-mail to Jackie Burke at jburke@aap.org
to request to be added to the Section.

Essentials for Research Meeting Abstracts

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Introduction:

The impetus for this article followed from discussions in the Sections on Advances in Therapeutics and Technology (SOATT) and on Neonatal Perinatal Medicine (SONPM) Executive Committees, which expressed interest in establishing guidance for abstract submissions to improve the quality and to establish criteria for acceptance. Furthermore, the reviewers from both Sections requested input and guidance on how to evaluate abstract submissions. RLA proposed to lead a subcommittee to discuss on behalf of both sections. In order to expedite this process, this article is intended to form the basis for further discussion with abstract committee chairs in order to develop guidance for future abstract authors and for the reviewers to improve consistency in their reviews. To achieve this improvement there will need to be a consensus on the criteria for acceptance (and ranking) or rejection of submissions.

RLA as a postdoctoral neonatology fellow (1973-75) in the Cardiovascular Research Institute (CVRI) at the University of California San Francisco (UCSF), had the benefit of “Essentials of Writing Biomedical Research Papers”, that was started by Julius H Comroe, Jr. MD the founder and first director of the CVRI. My notes are long gone but many of the lessons are memorable; E.g., the most important part of a research report is the “Methods”. If you find a “fatal flaw” in the method section there is no need to ponder the rest of paper. Readers who have the expertise should send letter to author(s) and the editor of the journal indicating that there are issues with the Methods that need to be evaluated. The most frequently read part of a scientific report is the “Title”, which should either stimulate the reader to proceed or not. If the paper is passing muster so far, the “Conclusion” would be the next most read to see if it had stated the significance of the findings, which may be considered by the reader to be of interest and importance.

We were delighted to find the continuation of the course (1978) written by Ms. Mimi Zeiger, M.A. in a textbook, “Essentials of Writing Biomedical Research Papers” 2nd Edition McGraw-Hill, 2000. We highly recommend this text to all colleagues, trainees and future abstract authors and reviewers. What will follow will be a combination of our thoughts about expectations and guidance for future abstracts and a summary of the valuable input presented by Ms. Zeiger, Lecturer in Scientific Writing CVRI, UCSF.

Categories or Types of Abstracts:

The abstract may be considered in categories or types such as: hypothesis testing research, descriptive results, methods (presenting novel or modified) and abstracts for meetings. Abstracts for meetings include hypothesis testing, descriptive, methods, and case reports. Although many journals have discontinued accepting case reports, these abstracts may be valid to submit if they provide new information beyond what has previously been published; e.g., presentation not previously described or novel diagnostics or management and treatments, which augment our understanding scientifically and/or clinically.

In general, abstracts for meetings are intended to show the preliminary results of research and to attract the audience to a poster and/or platform presentation and to engage in productive discussion of findings and potential significance with the authors(s). **Abstracts for research meetings should follow the same guidelines as for a paper.** Some exceptions are that more details for the methods to understand the research results and a table or graph may be used to give significant data so the reader will have enough information to evaluate the validity of the results. It is more common for the meeting abstract to indicate the importance of the work. However, excessive details and abbreviations (e.g., more than three) should be avoided to make the abstract more readable and clearer. The table and graph should be designed carefully. The title for table and legend for the graph can be omitted but there should include the essential information needed to understand the results presented. The results should be provided in a sentence before the table and graph so the reader can determine if it is clearly substantiated in the table or graph.

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Brief review of essentials for writing different types of abstracts:

There are at least four different types of abstracts viz., **hypothesis testing**, descriptive, methods, and **case reports** to address when they might be included in the “call for abstracts”.

For all abstracts the title should identify the main topic and the message. The hallmark of a good title is when it accurately, completely, and specifically identifies the main topic or message of the abstract, is unambiguous, and begins with an important term.

I Hypothesis testing Research

In this abstract the title should have both the independent and dependent variables.

E.g., The Effect of A and B in C (Effect of Racemic Epinephrine on Airway Function in Infants with Asthma).

If one dependent variable.

E.g., The Effect of Darbepoetin on term neonates with Asphyxia. An example of a message is: Novel surfactant improves lung function in preterm infants.

An outline for content of an abstract: Begin with relevant Background, State the question (hypothesis), The Experiments that were done and the important details of the materials and methods used, Results (give data only for the most important result which address the question and present % change rather than exact data when possible; state the result in a sentence before table or graph), State answer to the question, Provide implications, speculation or recommendation.

II. Descriptive Research

The title should indicate the message or the message and the implication.

E.g., Improved Educational Performance in primary school for extremely low birthweight (ELBW) Preterm infants who had received Caffeine for one month.

The abstract has three main parts: the message, the results that support the message and the implication of the message. Because there is no hypothesis in descriptive abstracts the message is stated at the beginning.

The organization: *Background, Message, Results and implications.*

The results should provide data obtained by the investigators. A review of the literature and opinions about the subject are not a substitute for real data obtained in the research.

III. Methods Research

The title of methods research should indicate whether the abstract describes a method, an apparatus, or a material, should state its purpose, and should name the animal or population used. Include if the method is new, modified or improved.

E.g., Novel pneumotachometer for measuring minute ventilation in non-intubated preterm neonates with chronic pulmonary insufficiency of prematurity (CPIP).

Methods research abstracts describe new or improved methods, apparatus, device or materials (chemicals: drugs, culture media, buffers, gases; molecules, cell lines, and tissues). The abstract should include: name or category term of the method, apparatus, device or material; purpose; the animal or population; key features and how it works; advantages; how tested and how well it functions.

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Examples of content for abstract are: A. Name, Purpose, How it works, Advantages, How it was tested, How well it works and Advantages, B. Name, purpose, population, Key features, Advantage, How it was tested and How well it works

IV. Case Report Abstract

As in the descriptive research abstract the title in the case report should indicate the message and implication.

E.g., Diagnosis of congenital Syphilis in a neonate presenting as Direct Hyperbilirubinemia; Necrotizing Enterocolitis after intravenous contrast in a term Newborn Infant.

The organization may follow the plan above in Descriptive Research; however, to be qualified for acceptance the case report should provide more than a description of what is already in the published literature or text books.

Some general writing tips to improve readability

To achieve continuity throughout the abstract: repeat key terms, use consistent order for details, keep the same point of view (*e.g., use the same person or personal pronoun throughout a sentence or paragraph*) in the question and the answer, and use either parallel form (*e.g., Pulse rate decreased by 40 beats/min., systolic blood pressure declined by 50 mmHg, and cardiac output fell by 18% vs. revised, Pulse rate decreased by 40 beats/min, systolic blood pressure by 50 mmHg and cardiac output by 18%*) or consistent point of view for comparisons and other parallel ideas.

Verb tense in the abstract should be the same as those in the paper: present tense for the question and the answer; past tense for the experiment done and the results found.

Write short sentences and avoid noun clusters (*e.g., chronic sheep experiments vs. revised, chronic experiments in sheep; or peripheral chemoreceptor stimulation vs revised, stimulation of peripheral chemoreceptors*). Use simple words for the sake of foreign readers and for readers who work in other fields, avoid jargon.

Guidance for prospective abstract authors and reviewers to determine quality and significance for ranking and accepting abstracts for presentation at meetings.

The brief presentation above on specific types of abstracts hopefully will provide a basis for further discussion and debate among abstract committee chairs and reviewers on how to judge submitted abstracts based on what is known about the essentials for writing abstracts. In the *Essential of Writing Biomedical Research Papers* there are more details and exercises on how to write and improve an abstract and manuscript. Ideally, it would be best if this manual was read by the reviewers (and by future authors) so that they would be better informed in order to achieve the basis for more consistency between reviewers reviewing and evaluating abstracts for presentation.

At the outset reviewers must recuse themselves if there is obvious conflict of interest or potentially a publicly perceived one. It would be reasonable to also provide an opt-out if the reviewer does not feel they have the competence or expertise for a particular research area.

The purpose of this article is to provide some background to start discussion for the SOATT and SONPM Abstract Chairs to develop and recommend a useful guideline for authors submitting and reviewers of abstracts who must decide on acceptance and ranking for presentation. The results from the discussion of abstract chairs can be presented to their respective Executive Committees for further debate, a motion and approval. The guideline would provide a numerical scoring system for reviewers that should quantify the quality of the science, the importance of the scientific question, and the quality of the abstract.

In the course of this discussion it may be valuable to ask whether a course on writing biomedical papers and abstracts is provided by training programs such as the Organization of Training Program Directors (ONTPD) or is this a gap, which needs to be addressed. Furthermore, would templates for writing various types of abstracts be useful for trainees or even established researchers in order to facilitate the presentation of preliminary results?

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The initial goal will be to have consensus for guidelines that could improve the success of abstract authors and to provide the basis for consistency among the reviewers working to assess the quality, significance and ranking of abstracts selected for presentation.

2019 NCE Preview



2019 SOATT Programs for AAP National Conference New Orleans

Section/Council Program

Monday, October 28, 2019

2:00 PM - 3:30 PM

Section on Advances in Therapeutics and Technology “H” Program

Partners in Progress: Bringing Medical Advances to Children

This program will bestow the annual SOATT Award for Pediatric Innovation. The awardee will deliver a Keynote address to Section members related to pediatric innovation. The program will conclude with a review of the section’s poster showcase.

Focused Topic

Date and Time TBD

The Role of Health Technology Innovation in Revolutionizing Pediatric Care

The focus of the session is to share ground-breaking health technologies from the past 5 years that hold the most promise to bring the greatest good for child health globally.

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

Pediatric Medical Device Spotlight

Quickloop™ Abscess Treatment Device

EM Device Lab, Inc, a physician founded company, introduces the Quickloop™ Abscess Treatment Device. **The device is intended to improve and simplify a minimally invasive “loop” abscess drainage technique in children and adults.**

Michael Gorn, MD, Chief Medical Officer and Co-Founder, EM Device Lab, Inc.

Website: www.emdevicelab.com Email: mgorn@emdevicelab.com

Background

Abscess incision and drainage (I&D) is a common procedure. Most of the estimated 4.5 million annual I&D's in the US are performed in outpatient/acute care settings. Abscess drainage is the second most painful emergency procedure after nasogastric tube placement, and in children it is often performed under sedation. Since the beginning of recorded medicine, the I&D technique has remained virtually unchanged – cut, wash, pack and repack. Unfortunately, the traditional technique is plagued by 10-20% failure rate, need for painful repacking, uncomfortable home care and frequent follow-up visits. In 2014, a NEJM review by Singer and Talan concluded that **“Because of the relatively high failure rates (of I&D) even with optimal treatment, patient education and follow-up are recommended.”**

In the age of value-based healthcare, abscess care is ready for an innovation. In 2005, a small trial by Ginnis et al, introduced the Jacobi ring - a “loop” drainage technique for Bartholin cyst abscesses. The technique involves the placement of a drain (tubing, surgical drain or vessel loop) between two incisions in the abscess cavity. The drain is tied together to form a loop and is removed after 5-10 days when the infection resolves. Ginnis demonstrated equal success in the treatment group as compared to a Ward catheter, and greater comfort and patient satisfaction in subjects treated with the loop. Since then, over a dozen mostly pediatric publications demonstrated that the use of the loop procedure for cutaneous abscesses was associated with increased efficacy, decreased pain, decreased need for follow-up or home care, and an overall decrease in cost of care and hospital length of stay.

In 2018, two meta-analyses by Gottlieb and Long mirrored each other's conclusion that **“Existing literature suggests that loop drainage is associated with a lower failure rate than (Standard) I&D. However, the data is limited by small sample sizes and predominantly retrospective study designs. Given the potential for less pain, decreased scarring, and lower associated healthcare costs, this technique may be considered for the treatment of skin and soft tissue abscesses in the ED setting, but further studies are needed.”** Despite mainly retrospective data, many pediatric emergency medicine and surgery physicians have recognized the benefits of the loop technique and advocate its' adoption as the gold standard. In 2017, Starr-Seal reported that when the loop technique was introduced into their facility, the first-year adoption rate was 30%, and by year 3 it was 56%. At the end of 3 years, they reported a significant drop in repacking and return visits – from 24% to 9.3%. In 2017, surgeons Gaszynski et al and Apprahemian et al independently concluded that the “loop” drainage technique should be adopted as the gold standard in abscess care in children and adults.

Quickloop – an all-in-one loop abscess drainage device

Michael Gorn, MD, FAAP and Matthew Wilkinson, MD, MPH, FAAP are pediatric emergency physicians at Dell Children's Medical Center in Austin TX. While conducting a prospective pediatric loop trial, they saw an opportunity to improve both patient and provider experience with a unique medical device. With the support from their colleagues, they founded EM Device Lab, Inc. and created the Quickloop.

There is currently no medical device that helps to streamline the loop procedure. Therefore, practitioners must gather, at a minimum, a blade, a drain (various kinds), irrigation syringe with a shield or catheter. In addition, it can be technically challenging and cumbersome to make the required incisions, tunnel the drain, and tie an appropriately sized knot in place. The knots have been known to unravel prematurely or cause skin necrosis if too tight. In a 2015, EM Device Lab conducted a survey of over 300 emergency medicine providers, which demonstrated that a significant minority were

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using the loop technique consistently (about 12%). Major reasons given were that: the equipment needed is not readily available, the technique is unfamiliar, it is more difficult for the provider, and more painful for the patient.

EM Device's Quickloop is intended to simplify the loop procedure in children and adults, and to improve provider confidence and patient experience. The design combines all the elements of the loop procedure into a single unit and removes the equipment and technical barriers. Quickloop consists of a puncture element, a cutting blade, a hollow silicone tube, and a clip with a Luer lock in a connected series. (Figure 1) The device is easily inserted in familiar single step suturing fashion, followed by simple and fast securement of the clip to form a closed loop. The Luer lock is continuous with the fenestrated tubing that allows for irrigation of the abscess cavity from the inside out, both during the procedure and later at home by the patient or caregiver. (Figure 2)

Aside from ease of use, Quickloop's irrigation feature is an important addition to the loop technique. Currently, patients are asked to apply warm soaks or use a shower head to clear the debris from the wound daily. We anticipate the ability to easily perform inside-out irrigation at the time of the device placement and subsequently during home care will improve procedural efficacy and healing time even further.

The benefit of using the Quickloop in the pediatric population may be amplified by decreasing the need for procedural sedation and eliminating anxiety associated with follow-up visits for packing changes. Even a marginal reduction in the use of procedural sedation may result in a significant overall decrease in the cost of abscess care. A decrease in costs may be amplified if Quickloop use allows for more procedures to be removed from emergency departments and in to primary care or urgent care settings.

Quickloop is in final development and was designed with the input of over 450 emergency medicine physicians. We anticipate US market launch in Q4 of 2019. If you are interested in learning more please contact Michael Gorn at mgorn@emdevicelab.com or visit www.emdevicelab.com.

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Figure 1



Figure 2

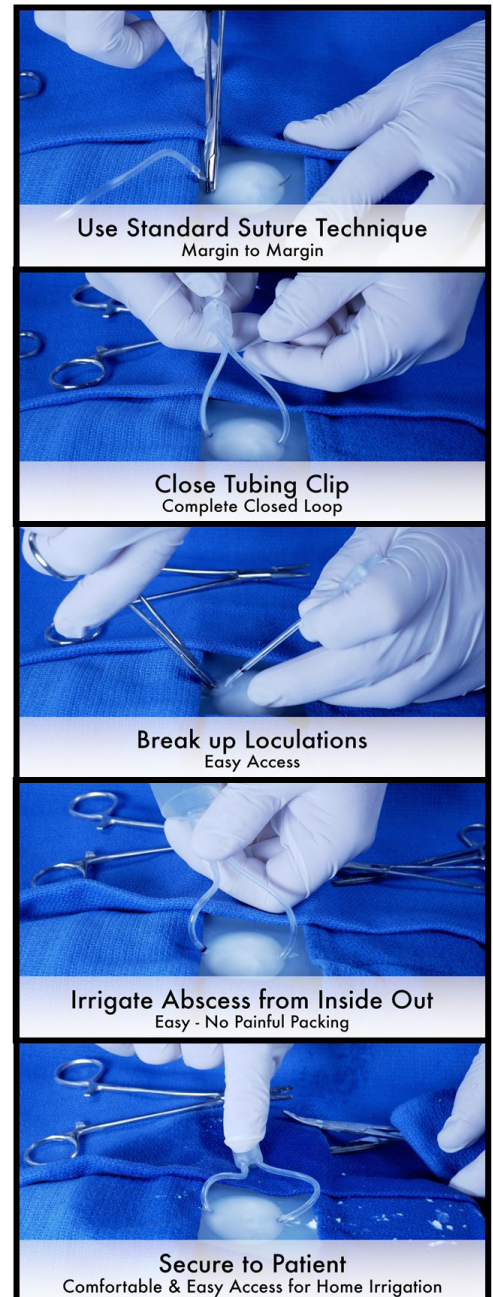


Figure 3



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iCAN Update - International Children's Advisory Network

Preview: 2019 iCAN Summit

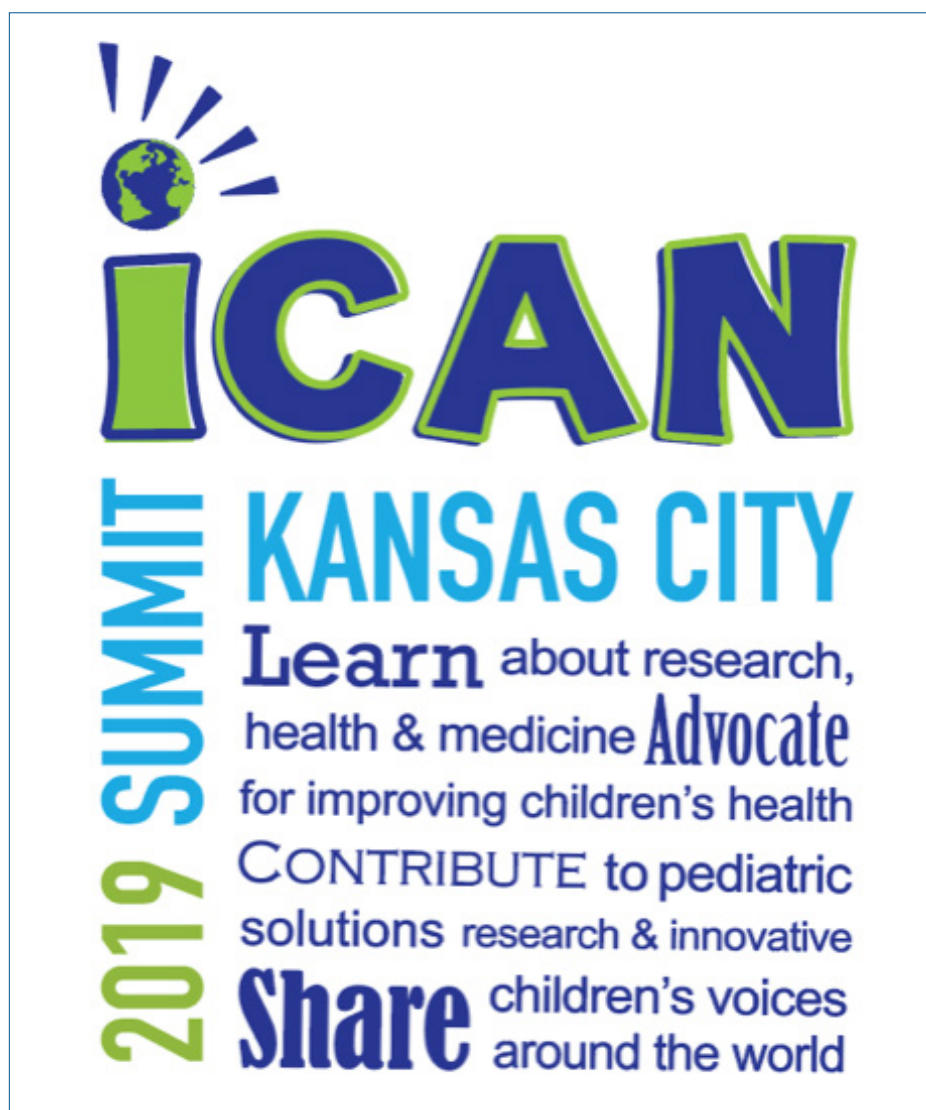
Amy Ohmer

Director, iCAN

Email: amyohmer@icanresearch.org

2019 marks a very special 5th year anniversary for the International Children's Advisory Network (iCAN). Heading into the year with a brand-new website at www.icanresearch.org, the team at iCAN is excited to share the voice of the pediatric patient within all facets of healthcare, science, research, technology, and advocacy.

Launched by Dr. Charlie Thompson in 2015, iCAN has become a leader in pediatric patient-centered care. For those that might be new to iCAN, one of the best ways to discover how iCAN youth advisors are changing the world of medicine, is through attendance at the annual iCAN Research & Advocacy Summit. This year, the Summit will be held in Kansas City, Missouri from June 24th- June 28th, in partnership with iCAN's Kids Impacting Disease Through Science (KIDS) Kansas City Chapter and Mercy Children's Hospital. The



strong line-up includes topics such as Including Children in Research and Science, Spina Bifida, Vaping, the role of IRBs, and a special case study review of the roles of the Patient, Parent, and Provider. In addition, there are a multitude of special sessions designed to engage both professionals as well as youth members. Evening events include a kick-off celebration, a night touring classic Kansas City BBQ venues, learning about robotics, and the always-fun closing ceremony and dance party.

iCAN, led by Leanne West, PhD, President and Christine Woods, Vice-President, will also engage attendees with opportunities to be further involved with special youth-oriented projects designed to positively impact global healthcare. As many of the previous attendees have shared, the iCAN Research & Advocacy Summit is a great way to learn from the greatest experts – pediatric patients and their families. Registration is open through June 1st and details are available on the iCAN website for reduced rates at the official Summit hotel, the Kansas City Westin Crown Center.

For additional questions or to offer support as a Sponsoring Partner, please contact, Amy Ohmer at amyohmer@icanresearch.org.

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 875 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

(October 2018 to March 2019)

Hamza Fawwaz Hussein Abbasi, MD, FAAP
Mavara M Agrawal, MD, FAAP
Madhia Ahmad
Loay Abdulfattah Al Kamel, MD
Byron Alex, MD, MPH, FAAP
Syed Arshad Ali, MD, FAAP
Yasser Dawoud Ali, MSC
Omar M. Alsiyud Sr., MD
Alison Mae Armstrong
Elisa Arthur
Diaa Abdel-Halim Ayoub Sr., MD
Asmaa Farag Azab, MD
Marcus Anthony Baca, MD, FAAP
Hemina Bailey, MD, FAAP
Jose Domingo Baule, MD
Shaundra L. Harris Blakemore, MD, FAAP
Amanda Catherine Brett, MD
Allison Marie Callejas, MD
Margaret G. Carolan, MD, FAAP
Victoria Carvajal
Maria Presentacion Casado, MD
Eric Chen, MS
Hanrong Cheng, MD, PhD
Rebecca Cobb, DO, FAAP
Nada Darwish
Arjun Chandra Dey, MD
Anita Doshi, MD
Carol Yoshie Endo, MD, FAAP
Arlene C Espiritu, MD, FAAP
Arjumand Farhana, MD, FAAP
Alysa S. Frenkel, MD, FAAP
Ria Garg
Lovya George, MD, FAAP
Majd Ghanim, MD, FAAP
Natasha Gill, MD, FAAP
Michael Gorn, MD, FAAP
Jacqueline Marie Gowan
Austin Dean Hager
Haille Hardison
Lacy Jean Heberlig
Alyssa Heiser
Emiliano Sol Higuera, MD, FAAP

Romana Iqbal Hosain, MD, FAAP
Kenenth Hui
Maridee Kaye Hunter, FNP-C
Louise Ing, MD
Marie Jean-Baptiste, DO
Carolyne Jean-Philippe, MD, FAAP
Jennifer Anne Jenks
Katelyn Michelle Johnson
Wedad M. Khedr, MD, FAAP
Susannah Kisvarday, MD, FAAP
Taylor Kolb
Nikhil Vasudev Kottapalli
Janelle R Kringel, MD, FAAP
Sarah Turner Kuestner, MD, FAAP
Sujata Kumar, MD, FAAP
Sanjay Nagindas Lakhani, MD, FAAP
Juliana Olufunke Lawson MD
Juan Alonso Leon-Abarca
Li Li, MD, FAAP
Weerapong Lilitwat, MD, FAAP
Chun-Yen Lin, MD
Clayton W. Long
Susan Nicole Manganaro, MD, FAAP
Jessie Mangs, PA-C
Mydili Rani Maniam-Mohan, MD, FAAP
Joseph Patrick Marshalek
Richard James Martin, DO, MPH, FAAP
Hugo R Martinez, MD, FAAP
Asha Mathew, MD, FAAP
Mitra Shamsian Mays
Constance Melchionna
Michael Alejandro Munoz, MD
Devin Murphy
Kathryn Murray, MD, FAAP
Sumbul Naqvi, PA-C
Moneesha Narula-Isaac, MD, FAAP
Hong-Van Nguyen
Bryan Noblett
Ryan Nolan M.Eng, CCRP
Samone Nore, MD, FAAP
Donald M. Null Jr., MD, FAAP
Vladislav Obsekov

Daniel Oder
Karolina Ogrodnik, DO
Ideobi Albert Onyebuchi, MD
Rajavee Ashok Panchal, MD
Megha Patel
Inmaculada Puig, MD
Mildred D Quinones, MD
Aysha Rafaquat, MD, FAAP
J. Routt Reigart, MD, FAAP
Jessica L Roberts, MD, FAAP
Betsy Rodriguez
Kelly Roschen
Sukanya Roy
Amanda Salih, MD, MPH, FAAP
Danielle Sanders
Amandeep Sehra
Thomas Joseph Sferra, MD, FAAP
Manisha Sharma, MD
Cassandra Simonich, PhD
Rizwan Siwani, MBBS, FAAP
Chantal Soobhanath
Temilola Sopeju, MBBS, FAAP
Leslie Ann Soto, MD, FAAP
Timothy Spear, PhD
Philip J. Spevak, MD, FAAP
Robert D. Steiner, MD, FAAP
Shervette Stevens, MD
Animesh (Aashoo) Tandon, MD, MS, FAAP
Rupa Thacker, MD, FAAP
Arti Thiagarajan, MD, FAAP
Alexandra Thompson
James Ting
Cynthia Stephenson Torrence, DO, FAAP
Tory Rochelle Twito, DO, FAAP
Alvaro Gabriel Valdivia
Meghan Wiggins
Holly Wobma, PhD
Ijeoma Akachi Miracle Wogu
Gwendolyn V. Youngblood, MD, FAAP
David Anthony A. Zainey, MD, FAAP

Announcements from the AAP

SOATT 2019 Section Election Results and 2020 Call for Open Positions

The following members have been elected by SOATT members to the Executive Committee:

Chairperson Elect:
Christopher Rizzo, MD, FAAP

Executive Committee Member:
Jacqueline Williams-Phillips, MD, MBA, FAAP, FCCM

Thank you to each person who voted in the election. The new terms will commence November 1, 2019.

2020:

- The Section is looking for candidates to fill one open executive committee member position. (3-year term renewable once, positions begins November 1, 2020.)

If you are a member of the AAP and the SOATT and are interested in a position, please submit your 250-word bio-sketch to tcoletta@aap.org no later than December 31, 2019.

Leadership responsibilities include:

- Reviews all relevant material before meetings. Makes contributions and voices objective opinions on issues.
- Attends all meetings and conference calls (1 face to face meeting in October each year = travel paid by AAP) (conference calls, 1 hour each quarterly).
- Take the lead in section activities appropriate to expertise and to serve on a subcommittee as necessary.
- Carries out individual assignments made by the chairperson and/or staff.
- Represents the section in meetings of other sections, committees, or organizations as directed by the Academy.
- Serves as spokesperson on behalf of the Academy to the media, outside organizations, and others as requested by the Academy.
- Discloses potential conflicts of interest.

If you have questions about the positions, please contact the Section's Nominations Chairperson, Paul Wang, MD, FAAP at pwang@simonsfoundation.org

Thank you!

Thank you to Paul Wang, MD, FAAP for chairing this election.

Announcements from the AAP

Section Produces Patient Education Brochure on Clinical Trials

Should My Child Join a Clinical Trial? Patient education brochure was updated and published in March 2019. The brochure covers:

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

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

The brochure can be viewed and downloaded (pdf) by *Patient Education Online* subscribers at <https://patiented.solutions.aap.org/handout.aspx?gbosid=177590>. Nonsubscribers can view the content at www.HealthyChildren.org (AAP parenting Web site).

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](#).

Have You Visited SOATT's New Web Page?

<https://collaborate.aap.org/SOATT>

Only basic information about SOATT is on AAP.ORG

<https://www.aap.org/SOATT>

All of the members only documents are on the collaboration page. Check it out!

SOATT Leadership Team

Mitchell Goldstein, MD, FAAP
Chairperson, Executive Committee

Ron Ariagno, MD, FAAP
Co-chair, Research Subcommittee

Francis Dick-Wai Chan, MD, FAAP
Liaison to Council on Clinical Information Technology

Susan Cummins, MD, MPH, FAAP
Member, Executive Committee
Co-chair, Research Subcommittee

Karen Kaplan, MD, FAAP
Member, Executive Committee

Chester J. Koh, MD, FACS, FAAP
Newsletter Editor

Robert Leggiadro, MD, FAAP
Member, Executive Committee

Christina Bucci-Rechtweg, MD, FAAP
Chairperson, Educational Program

Eric Ng, MD, FAAP
Website Editor

Mark Puder, MD, FAAP
Member, Executive Committee

Chris Rizzo, MD, FAAP
Chair, Membership and Communication Subcommittee, Chairperson - Elect

Charlie Thompson, MD, FAAP
Immediate Past Chairperson

Robert Walker, MD, FAAP
Member, Executive Committee

Paul Wang, MD, FAAP
Nominations Chairperson

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