Dialogues in Pediatric Urology

An official publication of the Societies for Pediatric Urology

Richard M. Ehrlich, M.D., Founding Editor / William J. Miller, Founding Publisher

December, 2024

INSIDE THIS ISSUE:

Fellow's Edition: "Innovation" in Pediatric Urology

Innovation: Embracing Creative Solutions to Drive Us Forward

FROM THE GUEST EDITORS

Valeska Halstead, MD, MPH & Brendan Frainey, MD

Innovation has always been at the heart of pediatric urology. Even a brief review of our history shows how many have worked to find creative and novel solutions to both common and complex problems, opening doors for those who come after them. Whether it be the invention of a new medical device or development of a unique process improvement, innovation can take on many forms and is ubiquitous throughout patient care and healthcare delivery. While innovation has been consistent as long as medicine has been practiced, we are in an era bursting with new technologies like artificial intelligence and quantum computing. With the exponential increase in medical data/knowledge, innovation is a core aspect of the practice of medicine and healthcare delivery in 2024.

While the term "innovation" can sometimes feel nebulous, we believe that innovation remains at the heart of pediatric urology. Brendan vividly remembers one of his first exposures to medicine was observing a robotic pyeloplasty on a 9 month old and being in awe of both the pediatric urologist and the technology being utilized to care for this patient. Valeska has always been impressed with the novel solutions patients develop for their urologic needs (tools, altered clothing, functional assistive devices) and colleagues' innovative solutions to clinical efficiency. Instead of simply accepting the status quo they ask 'why not'. Pediatric urologists have always been at the forefront of innovation, searching for new and creative ways to care for our pediatric patients more effectively and efficiently. With overall limited numbers in the workforce, others have dedicated efforts to finding innovative solutions to improve access to care. Even with all of the progress made through these effective solutions, we are all also dedicated to protecting our patients from harm and must study new technologies, devices, and processes rigorously prior to implementation.

....to demonstrate how many of our colleagues are innovators in every sense of the word....

We are honored to be part of this edition of DPU. The hope of this Fellow's guest edition of Dialogues in Pediatric Urology is to demonstrate how many of our colleagues are innovators in every sense of the word: utilizing new processes to increase efficiency, adapting and implementing new technologies, creating and bringing to market new devices, developing new teaching methods, and so much more. We also hope this edition inspires current and future generations of pediatric urologists to continue to push the envelope, be creative, and have the courage not only to ask the important questions, but also to put in the work to make your idea the new reality. We invite you to join us in embracing the wave of innovation.

Societies for Pediatric Urology
500 Cummings Center, Suite 4400, Beverly, Massachusetts 01915 USA
Tel: (978) 927-8330 / Fax: (978) 524-8890 / **www.spuonline.org**

What does innovation mean to you?

We know innovation takes many forms. We asked our contributing authors to tell us what innovation means to them.

"To shape the future of healthcare by strategic implementation and optimization of technology for the purposes of improving processes and providing the best possible care for all children."

- Julia Finklestein, MD, MPH, FAAP

"Innovation is finding improved ways to accomplish sought after goals, resulting in better healthcare value (lower cost and/or increased efficiency)."

- Kyle Rove, MD

"Innovation describes the entire process to identify new ways to solve problems" - *Hailey Silverii, MD*

"Learning how to rearrange all the puzzle pieces to create a better vision of the future"

- Mark Cain, MD

"Merging creativity, expertise, and practicality for improved outcomes."

- Jennifer Ahn, MD

"Innovation means using creativity and technology to continually be better every day and to progress our field forward."

- Molly Fuchs, MD

"Innovation is problem-solving. The key is solving the right problem."

- Sarah Hecht, MD

Advancing Pediatric Urology through Innovation and Quality Improvement

Julia Finkelstein, MD, MPH, FAAP

I seek to drive innovation in healthcare with data-driven improvement projects that aim to provide children with the best possible care. A key area of my focus has been on the application of quality improvement and innovation via use of telecommunication technology in pediatric urology. My investigation of this emerging model of health care delivery began in 2017, when we successfully implemented a post-operative telemedicine program for pediatric urology patients.[1] In a subsequent study, we compared telemedicine with conventional in-person visits and found that, for pediatric urological post-operative care, virtual visits are associated with shorter wait times, decreased absence from work and school, and clinical outcomes like those of in-person visits.[2] In fact, travel and waiting for care accounted for 98.4% of the in-person pediatric urological postoperative visit. This work preceded the COVID-19 pandemic, and we could not have predicted how far-sighted it would be in its relevance.

In 2020, the pandemic created an urgent need to limit in-person care and forced clinicians to employ virtual visits as standard practice. At Boston Children's Hospital, we were fortunate to have already laid the foundation for the swift expansion of telemedicine services. Indeed, the COVID-19 pandemic served as a stimulus for the implementation of an array of urologic telemedicine services across the world. While we had demonstrated the feasibility, safety, and benefits of telemedicine, widespread acceptance and adoption of digital healthcare delivery became a reality. Several studies have since shown that families have high satisfaction with telemedicine across various pediatric urological diagnoses and visit types.

Nevertheless, due to the technical challenges of virtual non-tactile genitourinary exams, we sought to assess the appropriateness of this rapidly evolving model of health care delivery. We found that this technology had substantial efficacy for the management of a wide variety of pediatric urology patients.[3] However, our data suggested that virtual visits might be best suited for established patients, longitudinal care, and review of radiologic imaging. These findings incited formal local guidelines for selective use of telemedicine in new pediatric urology patients. Yet, we recognize that there are limitations to such data. Non-random selection of virtual visit patients may be a potential source of bias, though careful patient selection is also critical to the efficacy of telemedicine. In addition, there is variation in how clinicians perform a virtual genitourinary exam during each telemedicine encounter.

I urge us all to embrace digital health care tools and emerging technologies, strategically applying and safely integrating these tools into our armamentarium.

The sensitive nature of pediatric urological presentations and examinations does make our field unique. It is important for clinicians to ensure the same confidentiality and privacy during virtual visits as patients are afforded during in-person care. This requires confirmation of the patient's environment and use of effective virtual communication (i.e., "webside" manner) to foster relationships with patients and their families. Virtual visits may require greater flexibility from clinicians than with traditional face-to-face patient interactions, and clinician comfort with technology can be helpful.

The tenets of improvement processes rely on understanding quality data to formulate and develop improvement strategies. It is essential that other investigators corroborate our findings and that we establish metrics that allow for ongoing assessment of telemedicine use in pediatric urology. These data, along with implementation lessons learned, can inform the development of best practice recommendations that ensure optimal application and high-quality efficacious care delivery via this innovative technology. In addition, since telemedicine has become embedded in modern health care delivery, we must develop standardized digital healthcare training for the next generation of clinicians. Clinicians must be empowered to use telemedicine as an instrument to positively connect with children and their families. Our ability to successfully adapt and leverage digital care innovations is crucial to its impact, value, and longevity.

In conclusion, telemedicine provides an opportunity to advance pediatric urology practice and can be used effectively to manage most patients. Telemedicine challenges include a non-tactile virtual genitourinary exam, lack of recognized practice guidelines, and gaps in formal clinician telemedicine training. Continued evaluation and focus on improving digital healthcare practice is necessary. We must strive to plan, do, study, act; not just react. I urge us all to embrace digital health care tools and emerging technologies, strategically applying and safely integrating these tools into our armamentarium. With deliberate data driven efforts to facilitate access and optimize use of digital care innovations, we can transform pediatric urological care and better the lives of generations of children.

References

1. Finkelstein JB, Cahill D, Kurtz MP, Campbell J, Schumann C, Varda BK, et al. The use of telemedicine for the postoperative urologic care of children: results of a pilot program. J Urol. *2019; 202(1): 159-163.*

2. Finkelstein JB, Cahill D, Young K, Humphrey K, Cambell J, Schumann C, et al. Telemedicine for Pediatric Urologic Postoperative Care is Safe, Convenient and Economical. J Urol. *2020; 204(1): 144-148.*

3. Schults A, Tham RL, Nelson CP, Finkelstein, JB. Factors contributing to telemedicine efficacy in pediatric urology. J Pediatr Urol. *2024; 20(4):694.e1-694.e7.*

Maximizing Clinical Efficiency in the Era of the EMR

Kyle O. Rove, MD and Sarah L. Hecht, MD

Introduction

The electronic medical record (EMR) continues to be cited as a source of professional dissatisfaction among physicians, primarily driven by increased documentation requirements.[1–3] One recent study highlighted that for each hour of patient-facing time, two additional hours are spent documenting in the EMR, with even more spent after hours to finish up additional tasks.[4] For those pediatric urologists reading this hoping for an EMR panacea, we regret to inform you that the EMR is here to stay. Fortunately, pediatric urologists around the world are working with EMR vendors to design and implement workflows that are more efficient, avoiding manual data entry and repetition of common tasks. Entire courses are dedicated to clinical informatics and clinical efficiency, so we will attempt to describe high-level, quick wins here to provide a starting point.

Documentation

Most documentation in pediatric urology occurs in the form of clinic progress notes for new and return patient visits. Since the introduction of EMRs, "note bloat"—the phenomenon of ever-increasing note lengths—has become a major problem.[5–8] For reference, adult and pediatric urologists using the Epic EMR currently compose clinic progress notes using a median of 4,100 characters (interquartile range of 3,200–5,400).[9] (That's as long as this report on clinical efficiency!) There are some well-worn strategies to avoid note bloat that are worth the additional up-front effort to generate complete, accurate, efficient notes.

Stop copying and pasting into your notes

Since Centers for Medicare and Medicaid Services revised its regulatory requirements for E/M documentation in 2021, copy and paste is the number one culprit for note bloat.[10] Some claim this makes it easier to review information when patients return, but in fact it makes both creating and reading notes more time consuming. Our recommendation is to follow guidance from EMR vendors to leave most information in their dedicated sections of the chart. Information like medications, allergies, past medical history, social history, birth history, labs and radiology results can ALL be left in their respective areas of the chart, with the note referencing urology-relevant details only. For example, if your typical hydronephrosis patient had a renal bladder ultrasound that was normal, it is much more efficient to simply write "renal bladder ultrasound was reviewed and found to be normal" than to copy/paste the whole report. Including a static, point-in-time medication list in your note that is reviewed six months later might miss that the patient was placed on antibiotic prophylaxis by the pediatrician in the interim. List only pertinent information and results, and indicate that you reviewed the remaining sections.

Adopt the APSO format

While traditional notes follow the SOAP (subjective, objective, assessment, and plan) format, many institutions now prefer APSO (with assessment and plan up front) as it allows for faster review by other providers by decreasing scrolling to look for the highlights.[11,12]

Clinic note templates

Templates should aim to apply to a multitude of clinical scenarios. One way to accomplish this is with a modular template structure, which blends common shared text with a selection of modifiable options, One technique is to use list-making tools to allow a generic note template to be customized. For example, templates addressing hypospadias or bowel and bladder dysfunction will have some shared text. Coupling this with list-making tools to select options from drop downs can turn writing a 5-7 min note into writing a 1-2 minute note and doesn't require creating a prohibitive number of dedicated note templates from scratch. Note templates may be shared within a practice, which further improves efficiency with the added benefit of standardizing care.

What about complex patients? Try adopting a short-form note like that shown in **Figure 1** that includes relevant urologic summary.

(continued on next page)

Figure 1

Assessment & Plan
Spina bifida, lumbar (closed prenatally)
Urodynamics, normal capacity, low pressure, + DO, 2022
Renal bladder ultrasound, normal, 2023
CIC urethrally Q4 6 Fr (no overnight)
Oxybutynin 2 mL TID
1 febrile UTI - e coli, 2024

Thank you for asking me to see this 2 yo male patient, whom I saw in the Urology Clinic. He was accompanied by {person:10366}. He was previously seen 1 year ago.

***

Figure 1. *Example note with pediatric urology-specific problem list that is efficient and acceptable for billing practices (time or by evaluation and management). Patient summary list can be updated each visit, while the *** at the bottom can represent 2-4 sentences summarizing interval history, relevant exam, and plan.*

Clinical Efficiency in the Era of the EMR (*continued from previous page)*

Document plans that stay at least one visit ahead

Rather than "renal bladder ultrasound in 3 months," lay out next steps if imaging at the next visit is worse vs better. This will save your future self time and effort in thinking about follow up patients.

Improving Common Workflows

There are countless EMR workflows around patient portal messages, clinic orders, and communication with other providers that can be optimized and automated with the help of the EMR. Computers are good at this stuff! **Table 1** has a long list of quick wins pediatric urologists should consider, many of which are actively recommended by EMR vendors as they are known to improve efficiency. If you find yourself doing the same task over and over, ask your help desk or local EMR experts if it can be automated.

Clinical Informatics

How did we become informaticists? Our interest started with having a passion for efficiency and an appreciation for how the EMR could make clinical work more efficient. We attended EMR-sponsored courses, and our institutions created clinical informatics programs (some with financial support to buy out part of our time). Over time,

(continued on next page)

Table 1. Quick wins for improving your efficiency within the EMR.

Quick win	Note
Avoid copying/pasting radiology or lab results verbatim into the note (instead, summarize the relevant findings)	This is a best practice recommended by EMR vendors. While copying/pasting into notes may provide you one single place to review information, it is inefficient in the long run.
Delegate patient portal messages to nursing (for initial screening)	This is a best practice recommended by EMR vendors. This improves the signal to noise ratio of portal messages providers must address and improves response times.
Create a library of EMR clinic note templates	Pediatric urologists see a limited number of patient phenotypes, many of which are very common (e.g., bowel and bladder dysfunction, hydronephrosis, undescended testicle, penis-related concerns). Templates can help standardize care, but also speed up documentation.
Create a short note template with running list of relevant patient problems for complex patients	Complex patients take more time, but curating a relevant list of ongoing urology problems can make chart review at follow up visits faster. This format keeps documentation short and salient, while addressing ongoing clinical issues.
Automate letters to primary care	Most EMRs support the generation of letters. In some, this can be automated to include portions of your note, allowing you to focus on the documentation and not re-stating the same thing to PCP, thereby keeping them in the loop.
Turn long patient portal messages into an in-person or telehealth visit	Your time is valuable. Some families or patients may have a lot of additional questions after a visit. Avoid getting sucked into long back and forth exchanges via the patient portal.
Favorite common radiology, medication, lab and surgery orders	Don't reinvent the wheel. Most orders do not require customization of dose, route, frequency, quantity or even refills. Favorite this for common medications like antibiotic prophylaxis and common radiology orders (ultrasound, voiding cystourethrogram). If you find yourself repeating any tasks in the EMR, there is usually a better way! This can be even more impactful to create favorites that are shared/common across all the providers in your group.

Clinical Efficiency in the Era of the EMR (*continued from previous page*)

we have participated in numerous local improvement projects, expanding our knowledge of the EMR. **Table 2** provides a list of the current Epic Pediatric Urology Specialty Steering Board members who help design pediatric urology content for that EMR's foundation system. Foundation content can be adopted locally. If you use another EMR, check with your vendor to see if they have developed pediatric urology-specific content.

Conclusion

Modern EMRs offer staggering power but need to be appropriately configured to be useful to providers. Hospitals' investment into clinical informatics have led to improved understanding of how to leverage the EMR to improve standardization and efficiency, leading to more efficient clinical care and happier providers.

Acronyms and Abbreviations

APSO – assessment, plan, subjective, and objective
EMR - electronic medical record
SOAP – subjective, objective, assessment, and plan

Table 2. Current (as of September 2024) Epic Pediatric Urology Steering Board members. Those with dedicated clinical informatics time at their institution are noted. Board members are elected annually through a nomination process.

Pediatric urologist and email	Board role	Institution	Clinical informatics training	Support
Melise Keays melise.keays@childrens.harvard.edu	Chair	Boston Children's Hospital	Epic physician builder	0.2 FTE (Director of Surgical Informatics)
Michael Daugherty michael.daugherty@cchmc.org	Member	Cincinnati Children's Hospital Medical Center	Clinical informatics board eligible, Epic physician builder	Uses academic time
Anne Dudley adudley@connecticutchildrens.org	Member	Connecticut Children's		
Fadel Elkhairi fadel.elkhairi@ohiohealth.com	Member	Ohio State University		
Wynne Hayley hayley.wynne@mft.nhs.uk	Member	Manchester University (NHS)		
Sarah L. Hecht hecht@ohsu.edu	Member	Oregon Health & Science University	Epic physician builder	Uses academic time
Christopher Long longc3@chop.edu	Member	The Children's Hospital of Philadelphia	Epic physician builder	Uses academic time
Kyle O. Rove kyle.rove@childrenscolorado.org	Member	Children's Hospital Colorado	Clinical informatics board certified, Epic physician builder	0.3 FTE (Director of Surgical Informatics)
John S. Wiener john.wiener@duke.edu	Member	Duke University School of Medicine		
Anthony Balcom aburologyh2o@gmail.com	Outgoing member	In transition		

References

1. Rotenstein LS, Torre M, Ramos MA, Rosales RC, Guille C, Sen S, et al. Prevalence of Burnout Among Physicians. JAMA 2018;320:1131. https://doi.org/10.1001/jama.2018.12777.
2. Landi H. Survey: Physicians Cite EHRs as Biggest Contributor to Burnout. Healthcare Innovation 2018. https://www.hcinnovationgroup.com/clinical-it/news/13030577/survey-physicians-cite-ehrs-as-biggest-contributor-to-burnout (accessed August 24, 2022).
3. Downing NL, Bates DW, Longhurst CA. Physician Burnout in the Electronic Health Record Era: Are We Ignoring the Real Cause? Ann Intern Med 2018;169:50–1. https://doi.org/10.7326/m18-0139.
4. Sinsky C, Colligan L, Li L, Prgomet M, Reynolds S, Goeders L, et al. Allocation of Physician Time in Ambulatory Practice: A Time and Motion Study in 4 Specialties. Ann Intern Med 2016;165:753. https://doi.org/10.7326/m16-0961.
5. Rule A, Bedrick S, Chiang MF, Hribar MR. Length and Redundancy of Outpatient Progress Notes Across a Decade at an Academic Medical Center. JAMA Netw Open 2021;4:e2115334. https://doi.org/10.1001/jamanetworkopen.2021.15334.
6. Maguire P. Note bloat: problems with cut and paste. Today's Hospitalist 2020. https://www.todayshospitalist.com/note-bloat-electronic-health-records/ (accessed August 24, 2022).
7. Kuhn T, Basch P, Barr M, Yackel T, Physicians for the MIC of the AC of. Clinical Documentation in the 21st Century: Executive Summary of a Policy Position Paper From the American College of Physicians. Ann Intern Med 2015;162:301–3. https://doi.org/10.7326/m14-2128.
8. Kahn D, Stewart E, Duncan M, Lee E, Simon W, Lee C, et al. A Prescription for Note Bloat: An Effective Progress Note Template. J Hosp Med 2018;13:378–82. https://doi.org/10.12788/jhm.2898.
9. Systems E. Signal n.d. https://signal.epic.com/ (accessed September 20, 2024).
10. Villanueva R, Busis NA, Cohen BH, Ciccarelli L. The Transformation of Documenting and Coding: Evaluation and Management Codes for Outpatient Neurology Services. Continuum Lifelong Learn Neurology 2021;27:1790–808. https://doi.org/10.1212/con.0000000000001090.
11. Lin C-T, McKenzie M, Pell J, Caplan L. Health Care Provider Satisfaction With a New Electronic Progress Note Format: SOAP vs APSO Format. JAMA Intern Med 2013;173:160. https://doi.org/10.1001/2013.jamainternmed.474.
12. Belden JL, Koopman RJ, Patil SJ, Lowrance NJ, Petroski GF, Smith JB. Dynamic Electronic Health Record Note Prototype: Seeing More by Showing Less. J Am Board Fam Med 2017;30:691–700. https://doi.org/10.3122/jabfm.2017.06.170028.

Innovation in medicine extends beyond the classic model of patient care, but also into education and the actual process of self-improvement. We asked two surgeons and colleagues at different levels of their career to provide insight into how surgical coaching may provide innovative solutions to common problems.

Thoughts on Surgical Coaching

Mark Cain, MD, FAAP and Hailey Silverii, MD

What is surgical coaching?

MC: Surgical coaching is very different from the classic coaching role that I had been exposed to during athletics and early training, which is focused on hierarchical teaching/mentoring with less emphasis on bidirectional communication and goal setting. I think that coaching requires the coach to step away from the active teaching/instruction mode, into a more observational and conversational role.

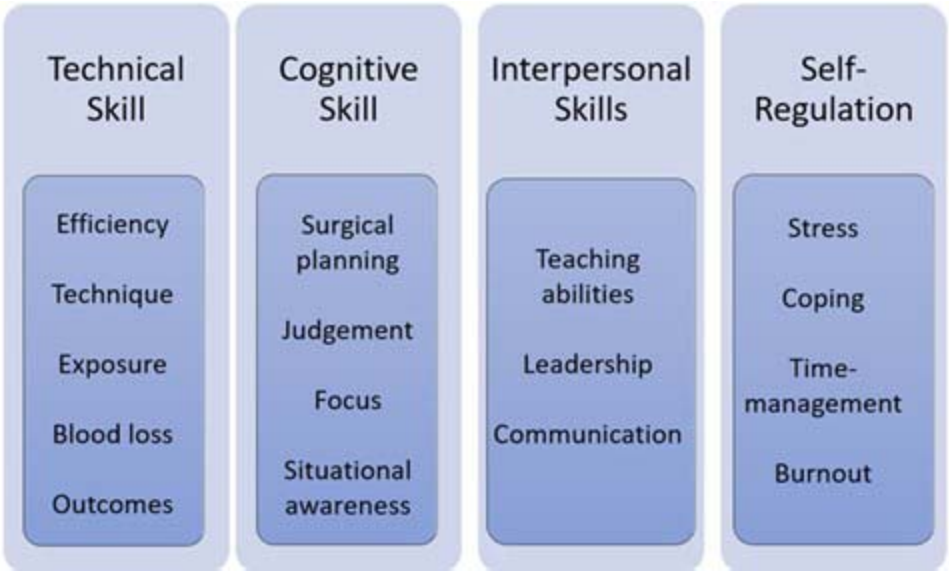
HS: I like to think of surgical coaching as an incredible resource available to surgeons to set and achieve goals. These goals can include anything from improved technical skills to improved teaching skills in the operating room. A surgeon-coach relationship is non-hierarchical and longitudinal which is the foundation upon which the coaching framework (goal setting, guided inquiry, constructive feedback, and action planning) is built [1,2].

How did you first become interested in surgical coaching and surgical mentorship? What is the difference?

MC: Most of my career has been defined more as a surgical mentor, being actively involved in the decision making and technical steps of procedures. The opportunity to transition to coaching happened as I transitioned out of leadership positions, and required a different skill set. I took a course on how to be a surgeon coach. This required a much less active role during the procedure, and letting the coachee decide the areas that he/she wanted to improve or have input from an observer. I had to learn to take my gloves off and participate outside the surgical field, and to be more patient with time out of the OR.

HS: While I was a fellow at Seattle Children's Hospital, our division leadership took steps to initiate a coaching program for faculty which was initially informal. With an interest in surgical education research, my aim in this project was to develop and evaluate a pediatric-urology specific model that could be adapted by other institutions to make an impact within our field.

Figure 1. Four Pillars of Surgical Assessment



What makes a good coach? Good trainee/learner?

MC: Success for both requires dedication and commitment to developing a standard process, and a commitment to lifelong learning.

HS: I have learned that the best coaches are those that are committed and willing to observe, listen, and be open minded. It truly was a privilege to observe coaching between surgeons at Seattle Children's and see the improvements in BOTH coaches (with practice) and coachees (with coaching).

Did you create a formal coaching curriculum? Is there training required to become a surgical coach?

MC: I think this requires time and commitment from the entire surgical team – trainees, junior faculty, and the coach. The time requirements and commitments are different and must be acknowledged. I think this is critical for both coach and coachee.

HS: When our division leaders (Dr. Merguerian and Dr. Cain) enacted the vision and support for coaching, the surgeons who were pre-designated as coaches were trained and certified by the Academy for Surgical Coaching. Other than completing this training, our program was otherwise without a specific framework, which is where I came in. I strongly feel that a framework is necessary within a coaching program to ensure commitment to the principles (as taught by the Academy for Surgical Coaching) and to the relationship between coach and coachee.

What have been the challenges you've encountered in developing and enacting this model? Does institutional buy-in matter?

MC: The biggest challenge is the current healthcare models that are production based, as they do not accommodate the reduction in productivity of two surgeons in the coaching model. This requires institutional/department commitment and buy in, both the reduction in RVU productivity, and the impact of reduced facility fees that the second surgeon might otherwise generate for the hospital.

HS: In addition to the monetary challenges noted by Dr. Cain, an additional challenge encountered is time commitment from both coach and coachee. Most participants felt that blocking out time for coaching in advance was beneficial. An additional challenge faced was lack of understanding of coaching by OR staff. We educated the staff that our endeavor was a positive one to benefit all surgeons rather than a negative one, clarifying that it was not a punitive action to make up for a deficiency.

What has been fulfilling about this?

MC: I have learned as much as I have taught.

HS: In addition to observing the numerous benefits within our coaching research study, this experience has changed the way that I approach my own goal-setting. I now compartmentalize my goals into the different pillar of surgical assessment: technical, cognitive, interpersonal, and self-regulation (Figure 1) which helps encourage "whole surgeon" improvement.

(continued on next page)

Surgical Coaching (*continued from previous page)*

What do you see as the future of surgical coaching in the context of surgical education for our future trainees?

MC: I see this as a great example of lifelong learning for both young and older surgeons. It is an opportunity to combine newer ideas and technologic advances with wisdom that can only be obtained over many years of practice. I think this is one of the potential bridges that we can use to fill in the gap of surgical exposure to rare complex problems that we frequently see in pediatric urology.

HS: Fellowship is a perfect opportunity to employ coaching as a resource for trainees. We employed a coaching model for my second year of fellowship in which my faculty served as coach rather than traditional teacher. Being able to reap the benefits of a surgical coach in training was beneficial and helped me identify specific areas of focus during my last few months of training.

What advice to you have for fellows and young faculty who want to get specific training in this?

MC: Take a coaching course and lean in – then find willing senior surgeons that will dedicate their time to the entire process with you.

HS: I highly recommend interested surgeons to seek out training with the Academy for Surgical Coaching. The more coaches in pediatric urology, the more we can come together as a field to increase the availability and utilization of this resource.

Sources:

1 Greenberg CC, Ghousseini HN, Quamme SRP, Beasley HL, Wiegmann DA. Surgical coaching for individual performance improvement. Ann Surg 261:32–4, 2015.

2 Greenberg CC, Ghousseini HN, Pavuluri Quamme SR, Beasley HL, Frasier LL, Brys NA, et al. A Statewide Surgical Coaching Program Provides Opportunity for Continuous Professional Development. Ann Surg 267:868–73, 2015.

We asked two contributors to provide viewpoints regarding open vs robotic surgery for pediatric reconstructive procedures, as a form of a point/counterpoint debate. They graciously agreed and provided compelling arguments for both. We believe both approaches can still offer new, innovative solutions.

Point/Counterpoint: Position Supporting OPEN Surgery

Jennifer Ahn, MD

Open surgery has been performed for millennia, and modern open surgery has advanced significantly over the past century with innovations in anesthesia, hemostasis, and antisepsis. Bladder reconstruction surgery, such as augmentation cystoplasty and catheterizable channel creation was first popularized in the early 1980s and is an important tool in the management of bladder dysfunction. Our field's understanding of these surgeries and subsequent outcomes is rooted in the open surgery experience. While there may be a role for robotic bladder reconstruction, open surgery remains the gold standard and it is critical that we continue to perfect, innovate, and teach open surgery.

Robotic surgery has increased magnification, ergonomic improvements, and precise instrument movements. These may provide benefit to the patient, surgeon, and system. Some adult studies suggest that lower transfusion rates, shorter hospital stay, and reduced opioid requirement are associated with some robotic surgeries, but systematic reviews generally suggest no significant difference overall between robotic and open surgery[1]. The evidence behind the advantages of pediatric robotic bladder reconstruction is even less convincing. A retrospective cohort study comparing open vs robot-assisted augmentation cystoplasty found that length of stay, intraoperative morphine equivalents, estimated blood loss, and post-operative outcomes were comparable[2]. The median operative time for robotic surgery was 135% or 6 hours longer, which would translate into an estimated $16,482 of additional operating room cost[3]. This also means more time under anesthesia for the patient, the opportunity cost of other patients waiting for surgery, not to mention surgeon fatigue. While operating at the robotic console may be less physically taxing than open surgery, longer operative time certainly increases surgeon mental fatigue. Another retrospective cohort study compared open vs robotic bladder neck reconstruction, and found similar post-operative length of stay and complications[4]. Mean operative time was 3.5 hours shorter for the open surgery group. To date, literature suggests that open surgery has a clear advantage of decreased operative time with similar outcomes, which can benefit the patient, surgeon, and system.

Robotic surgery is not always possible. Patients with multiple prior abdominal surgeries may not have adequate intraperitoneal working space for robotic instruments. A patient's physiology may not be able to tolerate pneumoperitoneum or steep Trendelenburg positioning. The historical conversion rate from robotic to open surgery is up to 8% and the reverse is not true; thus, all surgeons must be well-trained in open surgery. The pediatric urology fellowship case logs suggest a minimum of 350 index cases, and only 20 are recommended to be minimally invasive surgeries. Open surgery is clearly viewed as the mainstay of pediatric urology by the ACGME and Review Committee. However, the widespread adoption of robotic-assisted surgery for ureteropelvic junction obstruction, ureteral obstruction, and vesicoureteral reflux impacts our trainees' exposure to open surgery[5]. Trainees must learn open surgery principles to ensure they are well-prepared for their careers. Open surgery principles can all be adopted to robotic surgery or any future tools. But if trainees primarily learn to perform robotic surgery, these skills will not all successfully translate to open surgery. If we train our fellows to primarily operate robotically, they will be underprepared to repair their first augment perforation while on call.

Advocating for open surgery does not mean we are stuck in the past. Innovations can and do strengthen the open surgery experience. Enhanced recovery (ERAS) protocols are becoming widespread, focusing on early patient recovery. While one of the many ERAS elements is to utilize minimally invasive surgery when able, the remainder of the elements apply to open surgery. ERAS has shown promise

(continued on next page)

OPEN Surgery (*continued from previous page)*

in the pediatric population, particularly with bladder reconstruction, and it challenges us to optimize the open surgery experience. Innovation and technology for open surgery continues to grow, such as new models of loupes and headlights which focus on minimizing neck and eye strain. We have used SPY-PHI (Stryker) to assess tissue perfusion during catheterizable channel creation and augmentation cystoplasty; the QP function quantitates relative perfusion and is not currently available for the robotic platform (Fig 1). While the robotic surgery platform has been a significant innovation in surgery, open surgery is still the playground for much discovery.

Both open and robotic bladder reconstruction can serve our patients if selected appropriately, but it is critical that we continue to perform, teach, and advance open surgery techniques. This benefits our patients, many of whom are unable to undergo robotic surgery, our trainees who will continue to care for our patients and move the field forward, and the system, as open surgery seems to be higher value due to decreased costs and comparable quality. Until a different approach proves to be superior, open bladder reconstruction is here to stay, for the benefit of our patients, trainees, surgeons, and systems.

1. Dhanani NH, Olavarria OA, Bernardi K, Lyons NB, Holihan JL, Loor M, Haynes AB, Liang MK. The evidence bhind robot-assisted abdominopelvic surgery. Ann Intern Med. 174:1110-1117, 2021.

2. Cohen AJ, Brodie K, Murthy P, Wilcox DT, Gundeti MS. Comprative outcomes and perioperative complications of robotic vs open cystoplasty and complex reconstructions. Urology. 97:172-176, 2016.

3. Smith TS, Evans J, Moriel K, Tihista M, Bacak C, Dunn J, Rajani R, Childs B. Cost of operatime room time is $46.04 dollars per minute. J Ortho Business. 2 (4):10-13, 2022.

4. Grimsby GM, Jacobs MA, Menon V, Schlomer BJ, Gargollo PC. Perioperative and short-term outcomes of robotic vs open bladder neck procedures for neurogenic incontinence. J Urol. 195: 1088-1092, 2016.

5. Varda BK, Johnson EK, Clark C, Chung BI, Nelson CP, Chang SL. National Trends of Perioperative Outcomes and Costs for Open, Laparoscopic an Robotic Pediatric Pyeloplasty. J Urol

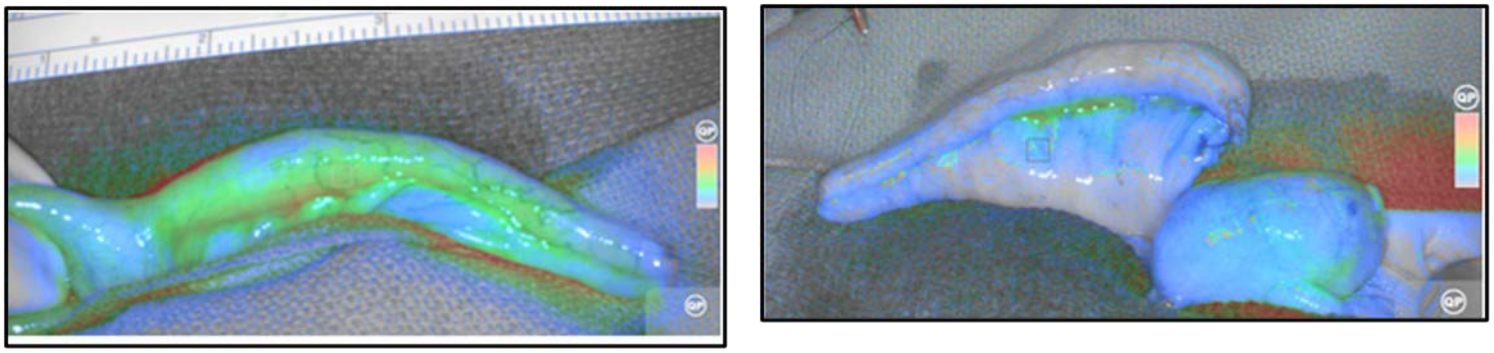


Figure 1. SPY-PHI QP assessment of appendix before and after harvesting for appendico-vesicostomy. Relative perfusion after harvesting was 86%.

Point/Counterpoint: Position Supporting ROBOTIC Surgery

Is the future of complex bladder reconstruction in the hands of a robot?

Molly Fuchs, MD

Robotic surgery has revolutionized the field of urology and - while pediatric urologists were late in adopting the technology, robotics now has a well-established role in most pediatric practices. Common operations such as pyeloplasty, nephrectomy and ureteral reimplantation are now routinely performed robotically and for many procedures, the robotic approach has become the standard of care and this can be utilized even in infants.[1,2] However, there has been resistance to adopt this minimally invasive approach to more complex bladder reconstruction procedures including bladder neck operations, bladder augmentation and appendicovesicostomy. Critics of robotic-assisted reconstructive procedures often cite lengthy operative times, increased cost, and no improvement in functional outcomes. While there is limited literature available evaluating the utility of robotics for these procedures, what has been published is promising.

Multiple centers have reported successful robotic-assisted appendicovesicostomy (Mitrofanoff) catheterizable channels. The largest series is 88 patients with a 6.8% complication rate with stomal continence rates of 92%.[3] Robotic-assisted bladder neck procedures have been reported less often in the literature. When performed open, these procedures can be very challenging because of limited working space within the pediatric pelvis. Thus, it may seem surprising that so few reports exist of robotic bladder neck procedures as the well-known robotic platform advantages of improved dexterity and visualization, when working in small spaces can alleviate these challenges. One series compared 19 robotic and 26 open bladder neck procedures. All procedures were successfully performed, and the robotic technique had the added benefit of reducing blood loss. Length of stay and complications were comparable as were continence outcomes.[4] Bladder augmentation is always complex and requires meticulous attention to the augmentation patch mesenteric pedicle and bowel anastomosis to avoid complications both open and minimally invasive. This is likely why few have adopted robotic assisted bladder augmentation to date. Only a handful of series are published of robotic bladder augmentation, the largest being a dual institution report of 15 robotic-assisted bladder augmentation compared to 17 open augmentations. Results were similar with respect to length of stay but the robotic approach had an advantage in blood loss. The robotic cohort, however, did have a higher incidence of bowel obstruction post-operatively.[5]

(continued on next page)

ROBOTIC Surgery (*continued from previous page)*

Robotic bladder reconstructive techniques universally report longer operative times compared to their open counterparts, and this is true in appendicovesicostomy, bladder neck procedures and bladder augmentation.[3-5] This seems to have been the main barrier to the technology being adopted in the mainstream and creates an easy target for critics of robotic reconstruction. However, this approach is still relatively novel, and bladder reconstruction cases are rare compared to other minimally invasive procedures such as pyeloplasty, which means most surgeons are still early in the learning curve, and it will take a longer time to achieve proficiency. Additionally, children undergoing these reconstructive procedures commonly are medically complex with challenging anatomy and have had multiple prior procedures, including ventriculoperitoneal shunt. So, in light of all of these challenges, why would anyone attempt minimally invasive robotic reconstruction?

We believe this drive to pursue robotic reconstruction stems from the drive to continue to innovate and advance our current state. While the learning curve is steep and the cases are challenging, with increased experience, operative times will decrease and as more large series are published, we remain optimistic that outcomes will be improved compared to open procedures. This has been true for radical cystectomy, where the robotic technique required a significantly longer time to show clear benefits and to become more widely utilized when compared to robotic prostatectomy. Adopting the robotic technology to such challenging procedures is expected to take time to catch up to open techniques and this two-decade pursuit by many surgeons seem to finally be coming to fruition. Several institutions routinely perform complex robotic reconstruction and even in those who have already had a history of open surgery.[6] We must continue to not only perform these procedures robotically but publish outcomes so that we can show the true benefits and to critically determine which procedures are better to perform robotically. So, to answer why anyone would attempt robotic reconstruction, we pursue this to innovate and strive for the best outcomes and experience for our most complex patients.

References

1. *Varda BK, Wang Y, Chung BI, Lee RS, Kurtz MP, Nelson CP, Chang SL. Has the robot caught p? National trends in utilization, perioperative outcomes and cost for open, laparoscopy and robotic pediatric pyeloplasty in the united states from 2003 – 2015. J Ped Urol, 15: 336.e1-336.e8, 2018.*
2. *Scoville SD, Bergus K, Diefenbach KA, Dajusat DG, Fuchs ME, Michalsky MP, Aldrink JH. Robotic-assisted surgery in pediatric patients less than 15kg: a single center review. J Laparoendosc Adv Surg Tech A, 34(5):434-437, 2024.*
3. *Gundeti MS, Petravick ME, Pariser JJ, Pearce SM, Anderson BB, Grimsby GM, Akhavan A, Dangle PP, Shukla AR, Lendvay TS, Canon GM, Gargollo PC. A multi-institutional study of perioperative and functional outcomes for pediatric robotic-assisted laparoscopic Mitrofanoff appendisocvesicostomy. J Ped Urol, 12: 386.e1 – 388.e5, 2016.*
4. *Grimbsy GM, Jacobs MA, Menon V, Schlomer BJ, Gargollo PC. Perioperative and short-term outcomes of robotic vs open bladder neck procedures for neurogenic incontinence. J Urol, 195(4): 1088-92, 2016.*
5. *Cohen AJ, Brodie K, Murthy P, Wilcox DT, Gundeti MS. Comparitive outcomes and perioperative complications of robotic vs open cystoplasty and complex reconstructions. Urology, 97:172 – 178, 2016.*
6. *Gargollo PC, Granberg C, Gong E, Tu Duong, Whittam B, Dajusta D on behalf of the Pediatric Urology Midwestern Alliance (PUMA). Complex robotic lower urinary tract surgery in patients with history of open surgery. J Urol, 201(1): 163-168, 2019.*

Accelerating Innovation in Pediatric Urology: Lessons in Pediatric Device Development Learned from the SWPDC

R. Brandon Hunter, MD, Raymond Yong, MD, and Chester J. Koh, MD, MBA

Medical device and digital health innovation has rapidly been accelerating across medicine, and the field of pediatric urology is no exception. The path from initial concept to a viable commercial and clinically available medical device is often long and challenging, and especially in pediatrics. We have long been passionate about medical device development to help accelerate promising pediatric urologic technologies to address unmet needs. This led us to establish the Southwest-Midwest National Pediatric Device Innovation Consortium (SWPDC.org) in 2018 which is supported for another 5 years (2023 – 2028) with a $7.4 million FDA P50 grant. In addition to Dr. Koh's original consortium in California (Consortium for Technology and Innovation in Pediatrics (CTIP)), both SWPDC and CTIP are FDA-supported pediatric device consortia that are dedicated to improving children's health by supporting pediatric device innovators to create novel pediatric medical devices with local, regional, and national institutional and innovation partners. SWPDC serves as a "free no-strings-attached" virtual accelerator that supports innovators throughout the pediatric device life cycle.

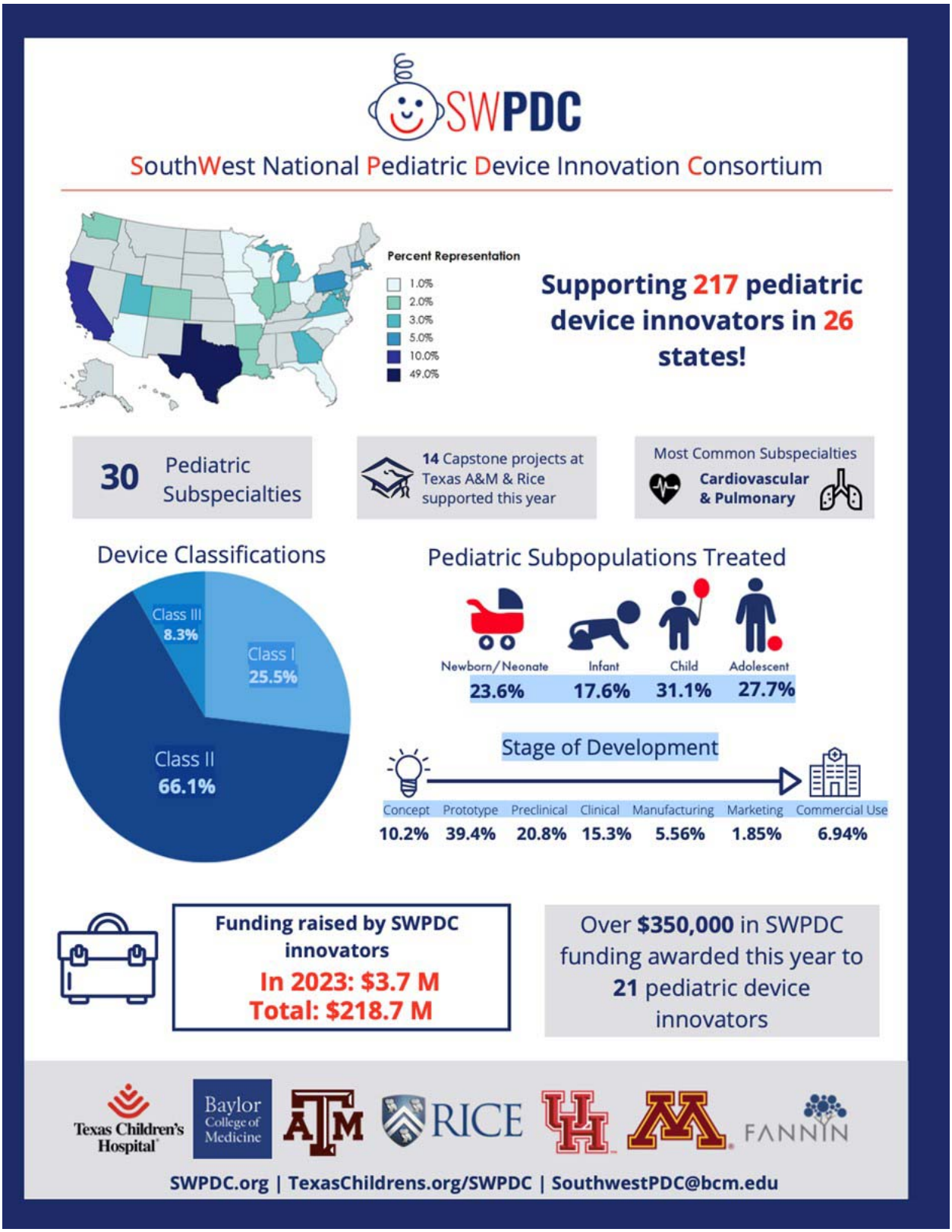
Our mission at SWPDC is simple – to enhance the development, production, and distribution of pediatric medical devices to improve care for children. This is achieved by utilizing a multidisciplinary network of stakeholders to aid in product development, advising, and direct funding. The capstone engineering design programs at Rice University and Texas A&M University, has been an effective mechanism for pediatric clinicians and surgeons to rapidly turn their innovative ideas from initial concept into functional prototypes in an academic setting.[1] To date, we have supported over 50 clinician - engineer projects, enabling clinicians to take the critical first steps in bringing their novel pediatric devices to life. In addition, we have provided innovators with product development and technology de-risking services as well as seed funding for their pediatric devices. For the 5-year cycle that ended in July 2023, SWPDC supported over 200 innovators across 24 states who then collectively raised over $218.7 million in follow-on funding which represents a 30x return on investment for SWPDC during that time. In 2023 alone, SWPDC awarded over $350,000 in seed funding to 21 pediatric device innovators (Figure 1).

SWPDC supports pediatric urology device innovators specifically through a collaboration with the American Academy of Pediatrics Section on Urology (AAP-SOU) to provide pediatric urology-specific device seed grants to promising technologies each year. Some devices

(continued on next page)

SWPDC (*continued from previous page*)

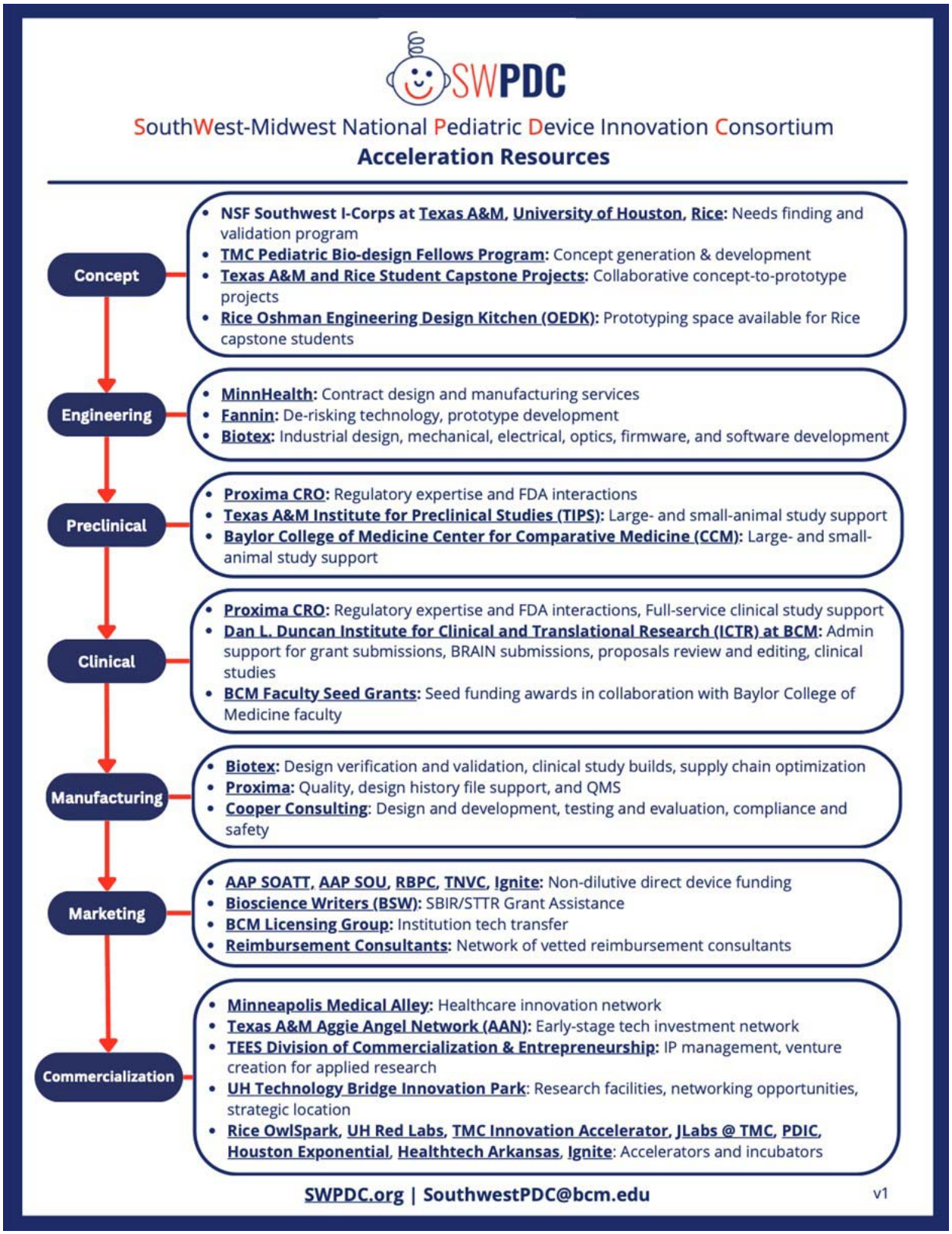
Figure 1: *SWPDC 5-year summary as of July 2023*



(continued on next page)

SWPDC (*continued from previous page*)

Figure 2: *SWPDC Acceleration Resources*



(continued on next page)

SWPDC (*continued from previous page*)

over the past few years were: GogoBand, developed by Dr. Israel Franco, as an AI-powered device to monitor and alert impending episodes of nocturnal enuresis by monitoring and predicting impending urination events to allow for proactive intervention. Dr. Christopher Cooper's Cystomanometer device enables spina bifida and spinal cord injury patients with neurogenic bladders to easily monitor intra bladder pressures and volumes at home with more consistent, real time surveillance. Dr. Andrew Kirsch's company, Global Continence, addresses nocturnal enuresis with a novel transcutaneous nerve stimulation device to rapidly halt urine flow and strengthen the urethral sphincter. And Dr. Greg Dean's DriQ Health device has an innovative moisture sensor to monitor and address urinary incontinence in wheelchair-dependent children via a disposable sensor and smartphone app. These examples are some of innovative pediatric technologies in the SWPDC portfolio for which we have been privileged to support that each have the potential to significantly improve the lives of children with urologic conditions.

One barrier that pediatric innovators face is the limited market size in pediatrics, which can deter traditional investors.[2] A critical strategy to overcome this is for pediatric device startups to stay within the walls of academia longer than adult-focused companies to avoid an early "Valley of Death" experience. Partnering with clinical champions as well as identifying appropriate regulatory pathways and reimbursement strategies upfront are also critical (Figure 2). Startups can utilize federal grant funding such as Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grants from the NIH, which offer up to $2.5 million in non-dilutive funding for device development and commercialization.[3] In addition, since the current landscape for conducting pediatric device clinical trials is challenging,[4] we are participating as stakeholders in a Foundation for the National Institutes of Health (FNIH.org/PMD) and FDA public-private partnership to establish a national system of pediatric hospitals, industry, entrepreneurs, investors, academia, and government partners to streamline the development and clinical testing of pediatric devices in the U.S.

Despite the longstanding hurdles, the future of pediatric urology device innovation is bright. Promising new technologies are emerging from dedicated pediatric urologists who have identified unmet needs in the operating rooms and in the clinics for pediatric urologic conditions ranging from urinary incontinence to kidney stones to hypospadias and robotic surgery and are collaborating with engineers and entrepreneurs to build the "next great" pediatric urologic device. With continued support from federal grants, philanthropy and the pediatric community, we are confident that our collaborative work can help accelerate the pace of innovation and improve our pediatric patients' quality of life. We encourage everyone in the pediatric urology community to consider how you can contribute your own skills and expertise to this important mission in what is often considered "clinically friendly" research that is often done in collaboration with our local engineering colleagues. Together, we can make a meaningful difference.

References

1. *Sack BS, Elizondo RA, Huang GO, et al. Pediatric medical device development by surgeons via capstone engineering design programs.* Journal of Pediatric Surgery. *2018;53(3):493-498. doi:10.1016/j.jpedsurg.2017.01.067*
2. *Dimitri P, Pignataro V, Lupo M, et al. Medical Device Development for Children and Young People—Reviewing the Challenges and Opportunities.* Pharmaceutics. *2021;13(12):2178. doi:10.3390/pharmaceutics13122178*
3. *Sun RC, Kamat I, Byju AG, et al. Advancing pediatric medical device development via non-dilutive NIH SBIR/STTR grant funding.* Journal of Pediatric Surgery. *2021;56(11):2118-2123. doi:10.1016/j.jpedsurg.2021.01.025*
4. *Hunter RB, Willson RC, Haridas B, Luk C, Toman K, Heffernan MJ, Fischer G, Wettergreen M, and Koh CJ. Navigating the challenges of initiating pediatric device trials – a case study. Journal of Clinical and Translational Science 8: e97, 1–8. doi: 10.1017/cts.2024.539*

Innovation in Pediatric Urology - Tips & Lessons Learned

Sarah Hect, MD

Innovation – a meaningless buzzword?

You'll find the word *innovation* in the mission statement or core values of nearly every health organization. Despite this, healthcare has been relatively immune to disruptive innovation (who else is still using pagers and fax machines?). So what is innovation, really? At its core**, innovation is problem-solving**. Novelty is implied, because if existing solutions were adequate the need for innovation would be moot. Just as the crux of research is asking the right research question, the **crux of innovation is identifying the right problem to solve.** And just as research follows the scientific method, innovation has a process, albeit more heterogeneous and iterative. Which such a broad definition, innovation is truly everywhere one looks for it within medicine, from clinical operations to medical education to quality improvement and more. This article will focus narrowly on medical device development, as it tends to be mysterious and unfamiliar to many physicians.

Table 1: Familiar versus foreign. Innovation is not so different from the more familiar process of research.

Research	Innovation
Answering a question	Solving a problem
The scientific method	The innovation process
Literature review	Needs assessment
Pilot study	Proof of concept

How to Identify a Problem

Nobody is better positioned than front-line clinicians to spark transformative innovation. We have the best sense of unmet needs and clinically relevant problems. Surgeons are natural innovators – we continuously iterate our surgical technique and generously share our knowledge. Unfortunately, surgeons are also highly adaptable, which can counteract the impetus for improvement and make problems seem non-urgent. For instance, most of our surgical instruments were developed for non-urologic procedures, yet we make do. Some tips on identifying meaningful problems:

Be annoyed. Be mindful of frustrations in your day. Is the instrument to big? Too shallow? What would make it better? Don't accept good enough, don't be complacent.

Are there multiple treatment options? If a problem has *multiple* solutions, there is likely no great solution.

What do you dread? Are there *no* good options? Which patients do you dread seeing because you feel you don't have a great solution to offer them? This is a problem with solving.

Is it complicated? Simplification of complex, cumbersome processes or devices is appealing to many stakeholders and represents a common target for successful innovation.

Wouldn't it be great if…? What would make this better? Easier? Define the ideal state.

The Innovation Process

There is no failproof recipe for medical device innovation – problems are highly heterogeneous and require a tailored approach. Still, there are principles, processes, and patterns worth knowing, especially for the early phases. Let's call this the back-of-the-napkin phase.

The beginning: Surgeons will generally begin with either an idea or with a problem. When starting with a *problem*, the ideation phase should follow a first principles approach to allow for maximal creativity. Much is written about design thinking. Fundamentally, it is helpful in this phase to challenge assumptions and counteract "no" with "why not?". Fresh perspective from less knowledgeable, less experienced team members is often invaluable. When starting with an *idea,* innovators can become attached to their idea and develop tunnel vision which stifles creativity. It is important to circle back to the problem to ensure an idea has widespread applicability. Innovators must also be ready to let go of their initial idea to make space for better solutions.

Protect your idea: It is advisable to contact a patent attorney to perform a prior art search, and ensure the idea is protectable. Filing a provisional patent or a patent cooperation treaty early provides some degree of protection. Avoid disclosing your idea in public settings and consider non-disclosure agreements in private conversation. Be cautious, but not so cautious as to preclude collaboration.

Opportunity Assessment: This includes a needs assessment, market analysis, understanding the competing technologies, and threats. This will help hone a value proposition. What value does your innovation bring? How is it different and better than the competition?

(continued on next page)

Figure 1: Early prototyping. Proof of concept can start anywhere. The earliest prototypes for the CathPort started with a dog toy and a trip to the hardware store.

Table 2: Highlights of current medical device innovation efforts within pediatric urology

Problem	Innovation
Nocturnal Enuresis	GOGOBand®. An electronic band that analyzes patient biometric data such as heart rate variability, then incorporates artificial intelligence to trigger an alarm capable of waking the patient prior to wetting. Physician Innovator: Dr. Israel Franco.
	Soluu®. Bedwetting device that integrates a moisture sensor with a TENS unit to stimulate external sphincter contraction and detrusor relaxation, and simultaneously alerts the parent to wake the child. Physician Innovator: Dr. Andrew Kirsch
Urinary Incontinence: Sitting in wet diapers causes skin breakdown and decreased QOL	DriQ: Remote urinary incontinence management system which alerts caregivers to wetness using a wireless sensor system, artificial intelligence, and cloud-based interconnectivity. Physician Innovator: Dr. Gregory Dean
Neurogenic Bladder: Catheterization options are cumbersome and complication-prone	CathPort: A catheterizable, low-profile vesicostomy button for use as alternative to a vesicostomy or suprapubic catheter, or as a preparatory step prior to Mitrofanoff creation. Physician Innovator: Dr. Sarah Hecht
Urodynamics are performed infrequently and in an unnatural environment	Home bladder pressure monitoring system via a cystomanometer and cystoelastometer, which transmits data to smartphone app. Physician Innovator: Dr. Christopher Cooper
Cystoscopic Stent Removal Requires Sedation in Children	Novel transurethral magnet device to remove indwelling ureteral stents with a distally attached magnetic bead. Physician Innovator: Dr. Chester Koh
Vesicoamniotic Shunt Migration	Novel barbell-shaped expandable mesh shunt, which is inserted into the bladder via a trocar-tipped delivery device. Physician Innovator: Dr. Michael Kurtz
	Vortex Shunt: Novel adjustable barbell-shaped shunt with one-way valve to allow bladder cycling. Physician Innovator: Dr. Kunj Sheth
Urethroplasty Complications: Fistulae, Dehiscence	Surgi-Zipper: A tensile-matched, elastic biomaterial adhesive patch to support surgical closures. Physician Innovator: Dr. Renea Sturm

(continued on next page)

Tips and Lessons Learned (*continued from previous page)*

Early feasibility and proof of concept: This phase includes customer discovery and input, early prototyping, and a basic understanding of the regulatory and reimbursement landscape.

Figure 1: Early prototyping. Proof of concept can start anywhere. The earliest prototypes for the CathPort started with a dog toy and a trip to the hardware store.

Other jobs to be done: Only after you are convinced your invention has a worthy value proposition, proof of concept, and a viable path to market should you begin to seek funding and formal project planning. Moving from the back-of-the-napkin phase to development and implementation is beyond the scope of this article. Still, it is important to know what boxes will need to be checked. Expect to be able to address the following:

- Prototyping and design: This process moves through a series of steps including design inputs, outputs, and controls, verification and validation. What is your quality system? Do you have a design history file?
- Regulatory strategy: What is the device class? What is needed to obtain FDA clearance/approval or CE mark, or is there an exemption pathway?
- Reimbursement strategy: Who is the customer? How is the device paid for? Is a new reimbursement code required?
- What is the intellectual property strategy?
- What is the business model? Exit strategy?
- Where will you seek funding? Consult an attorney prior to incorporating and seeking funding from investors, as there are tax implications to corporation type and location.

I have an idea! Now what?

This is where most surgeon innovators will start. As mentioned, we as surgeons are ideally positioned to spark innovation. A clear value proposition is key, which includes defining the problem and a thorough needs assessment. This bears repeating, as a solution without a true problem is no solution at all.

Table 3: A limited sampling of resources for the burgeoning pediatric urologist innovator

What	Where
AUA Innovation Nexus	https://auanexus.org/
FDA Pediatric Device Consortia (5)	https://www.ctipmedtech.org/ https://swpdc.org/ https://pedsinnovation.org/ https://pediatricdeviceconsortium.org/ https://innovate4kids.org/
Global Center for Medical Innovation	https://gcmiatl.org/
Sheikh Zayed Institute for Pediatric Surgical Innovation (Children's National Hospital)	https://research.childrensnational.org/szi
PEDSMRKT (Children's Mercy Hospital)	https://pedsmrkt.com/
Technology & Innovation Development Office (Boston Children's Hospital)	https://tido.childrenshospital.org/for-innovators/
International Society for Pediatric Innovation	https://www.ispi4kids.org/

(continued on next page)

Tips and Lessons Learned (*continued from previous page)*

The chasm between having a great idea and commercialization of a new medical device is sadly where many good ideas have vanished. There is admittedly a bit of a chicken-or-the-egg problem; it is easy to raise interest (and funding) when the idea is far enough along to de-risk investment, but how does one move the idea along in the first place? **Help is available if you look for it.** Here are some tips to get started:

Key principle #1: Immerse yourself.

When I found myself with little more than an idea, I didn't even know what questions to ask. I found the best approach was to immerse myself in the MedTech world. The learning curve is steep, however with consistent exposure, one begins to understand the language. I asked another surgeon who successfully developed a device to tell me his story. I sought and attended university lecture series related to innovation. I found MedTech device competition and watched online videos of prior years' pitches, and attended "hack-a-thons" to practice developing ideas and pitches. I applied for device competitions – even the act of filling out the application enlightened me to the questions I needed to have answers to. I failed and I failed, until I succeeded. I attended a larger MedTech conference, where eventually I raised my hand and asked a question. I followed up, and suddenly I had mentors who connected me to more mentors and medical device incubators. I was surprised by how welcoming the community was. We as surgeons have instant credibility in the startup world, and mentors have a nose for grittiness, enthusiasm, and competence.

Key principle #2: Collaborate – early!

Medical device innovation is a team sport – nobody does it alone. If you are at an academic center, you will want to examine your contract and disclose your idea to the tech transfer office. Tech transfer offices serve as channel between academia and industry and will help with initial project vetting, intellectual property protection, project planning, commercialization strategy, and typically have entrepreneurs in residence on staff to serve as advisors.

There are increasing resources available to physician innovators to move past the idea stage. Two of the most high-yield for pediatric urologists include FDA Pediatric Device Consortia and a new innovation collaborative developed within the American Urological Association (AUA). The AUA Innovation Nexus is a new urology-specific incubator which coordinates a conference with the AUA annual meeting. Due to perceived limited market size and increased barriers around testing and regulatory approval, the MedTech sector has historically shied from pediatric device development. To counteract this, the FDA funds five pediatric device consortia around the country. These consortia act as no-strings-attached incubators, accelerators, advisors, and provide direct and indirect support to their company members. Each holds an annual "shark tank" style grant competition (an excellent place to immerse yourself!). The National Science Foundation funds I-Corps, which serves as an innovation bootcamp for aspiring entrepreneurs. There are many other reputable consortia including pediatric-specific innovation institutes, state-run and funded bioscience networks, private incubators, and incubators housed within pediatric hospitals. These typically come with strings attached, but offer a wealth of resources and support.

Key principle #3: Reframe failure as success

Most medical device ventures fail. The learning curve is steep, and every failure will strengthen your next endeavor.

Conclusion

Device innovation is an intellectually stimulating pursuit with the potential for truly transformative impact. The process can be daunting as there is no protocol to follow, and initially you won't know what you don't know. Don't be discouraged! In a world of work, innovation can spark childlike feelings of exploration, curiosity, and play. Welcome to the playground.