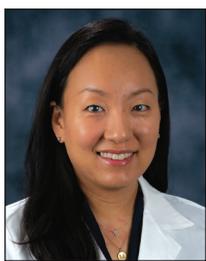




FOCUS ISSUE – Celebrate Diversity with the AUA

A Different Type of Inclusion and Diversity in Urological Research: Pediatric Device Development



Soo Jeong Kim, MD



Chester J. Koh, MD

Texas Children's Hospital and Baylor
College of Medicine

Research is indisputably important in advancing the field of urology. There are numerous examples, from the work of Huggins and Hodges, which rendered hormonal therapy the standard treatment for patients with advanced prostate cancer, to the adoption of robotic assistance in minimally invasive urological surgery.¹ As Wessells noted during the 2009 National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Urology 2.0: Advancing Urology Research Workshop, physician-scientists are driven by raw talent and ambition to expand the understanding and treatment of urological conditions, and are motivated to generate breakthrough scientific advances and new treatment paradigms. In order to be successful, physician-scientists require numerous resources, including mentors, significant protected time and funding. Federal grant funding, however, is still incredibly difficult to obtain: according to the National Institutes of Health (NIH) Research Portfolio Online Reporting Tools (RePORT), there are currently 130 funded investigators who are members of a urology department, who comprise approximately 0.1% of the 13,044 practicing urologists in the United States identified in the 2019 AUA Census.²

So what about the other 99.9%

of urologists, especially those with a more clinically oriented career instead of one that is research-prioritized? Inclusion and diversity, which have appropriately become prominent themes in today's world, perhaps can also be applied to address the shortage of urological investigators, and particularly those who are dedicated to the pediatric population, which continues to be relatively underserved. Urologists who have not chosen the physician-scientist career track can still make substantial contributions to urological research

by applying their clinical expertise and experience toward these underserved research areas.

Pediatric device development is one such research area. Despite the well worn adage, "Children are not small adults," there is a persistent shortage of medical devices designed specifically for children that can accommodate the unique anatomy and physiology of pediatric patients. Multiple factors contribute to this public health problem, including lower pediatric disease incidence, less attractive medical device industry financial returns, the high cost and perceived increased risk of pediatric clinical studies relative to the market size, difficulty in enrolling pediatric clinical trial participants and limited funding sources available

specifically for the pediatric population.³ As a result, adult devices are routinely used in children in an off-label manner.⁴ In order to address this shortage, Congress passed the Pediatric Medical Device Safety and Improvement Act in 2007, which included the creation of the U.S. Food and Drug Administration (FDA) Pediatric Device Consortia grant program. This program has allowed pediatric academic institutions to support pediatric device innovators to develop novel pediatric medical devices throughout the pediatric device life cycle with local, regional, and national institutional and innovation partners.^{5,6} Figure 1 illustrates the 5 current FDA P50 grant-supported pediatric device consortia.

As an early developmental step,

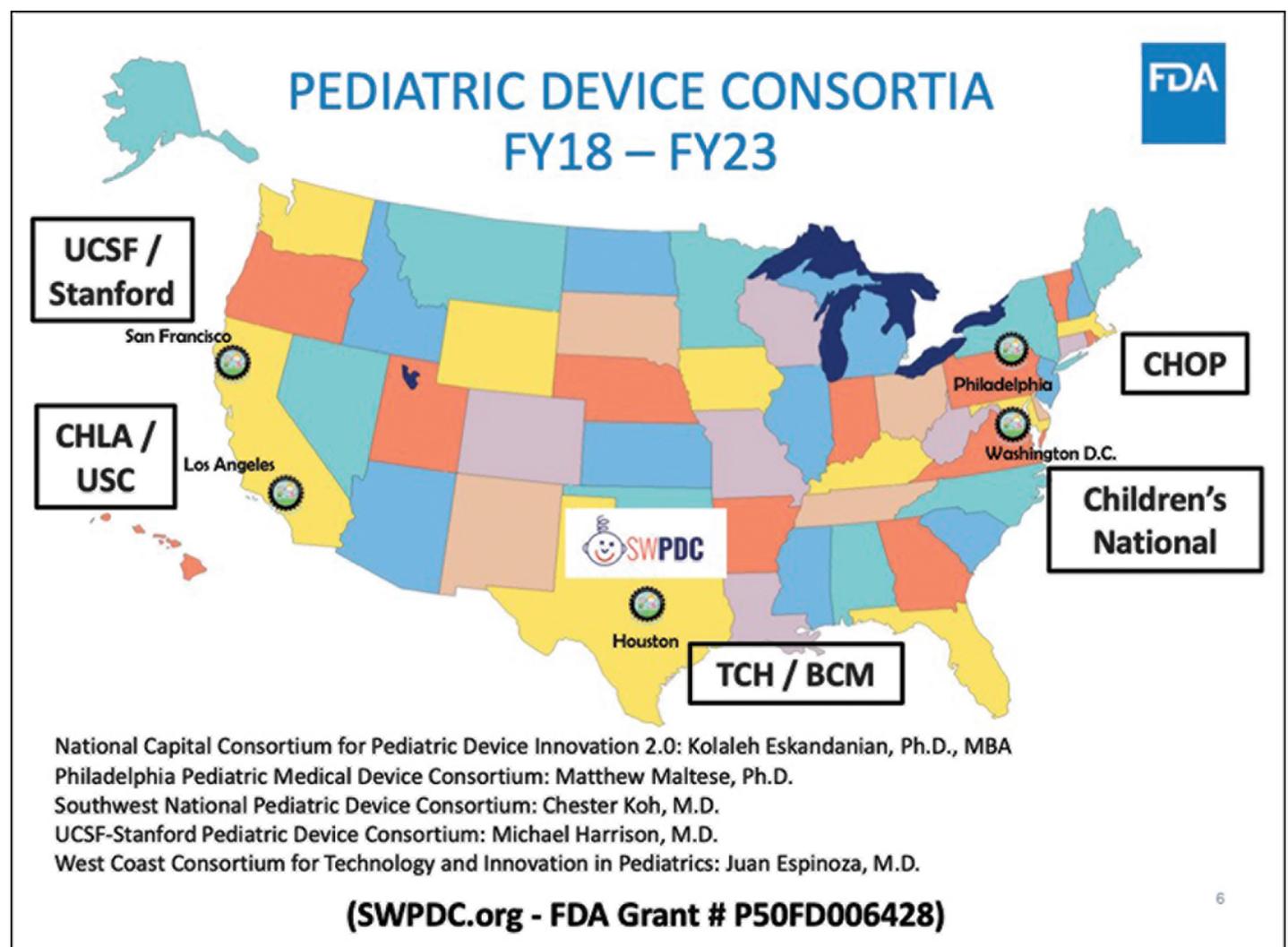


Figure 1. Five FDA P50 grant-supported pediatric device consortia and their primary associated children's hospitals. CHLA/USC, Children's Hospital Los Angeles/ University of Southern California. CHOP, Children's Hospital of Philadelphia. UCSF, University of California San Francisco.

the collaboration of biomedical engineers with pediatric clinicians and surgeons is encouraged by the consortia via capstone engineering design programs and medical product development-focused master's programs that are available at all accredited engineering schools in the U.S.⁷ Texas Children's Hospital (TCH) and Baylor College of Medicine (BCM) serve as the central hub for the Southwest National Pediatric Device Innovation Consortium (SWPDC), which also includes Rice University, University of Houston, Texas A&M University and Fannin Innovation Studio as the other consortium partners (fig. 2). Other partners include Children's Health (Dallas), Phoenix Children's, Children's Hospital of San Antonio (CHOSA [San Antonio/Austin]), Arkansas Children's and BioTex. SWPDC is supported by a \$6.75 million, 5-year FDA P50 grant (P50FD006428) that was awarded in 2018. The support for the capstone engineering design programs in partnership with the local engineering universities allows the development of prototypes during an academic year (September to April) and enables clinically busy urologists to create novel pediatric device prototypes with their engineering team partners.⁷

Once a prototype is created, the commercialization steps of device development can be facilitated by the Small Business Innovation Research (SBIR, R43/R44) and Small Business Technology Transfer (STTR, R41/42) programs, which are available through the NIH or the National Science Foundation (NSF).⁴ While engineering faculty are well aware of NSF SBIR and STTR funding opportunities, clinical faculty may not be aware of the SBIR and STTR grant programs in the NIH due to the traditional emphasis

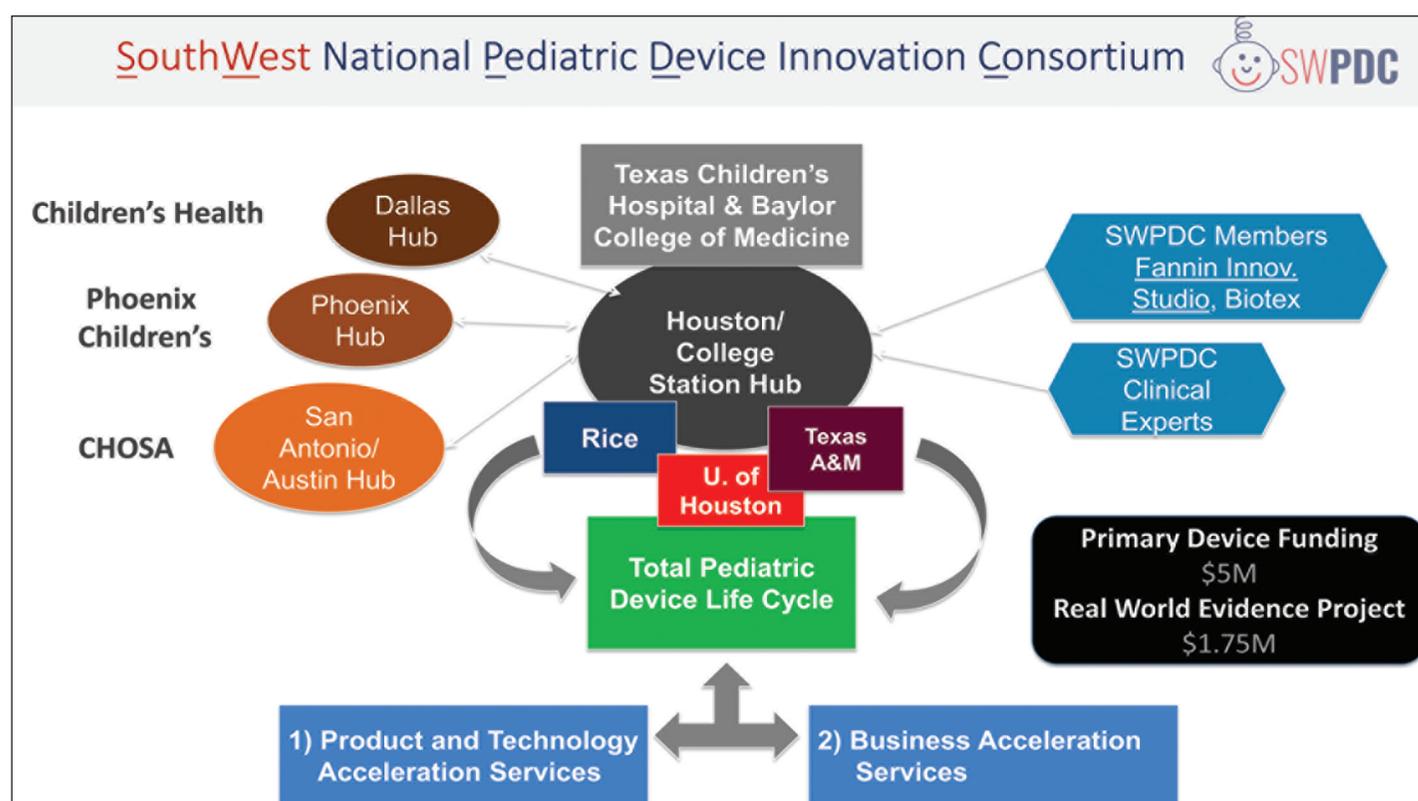


Figure 2. Institutional partners of SWPDC.

on R01 basic science funding. Pediatric faculty have been able to secure NIH SBIR or STTR funding for various pediatric/fetal devices, including 1) ureteral stent electromagnetic removal device for pediatric patients, 2) uterine wall membrane anchor device for the prevention of preterm premature rupture of the membranes in fetoscopic surgery, 3) pediatric urinary sphincter device for neurogenic bladder, 4) pediatric polymeric heart valves and 5) vaginal stent for neovagina creation in female pediatric patients.⁴ In comparison to NIH basic science research funding, the SBIR/STTR grants are often more attainable for pediatric clinicians and surgeons in partnership with qualified small business concerns, with the impact score paylines of many NIH institutes above 25. As a result, this nondilutive funding source should be considered by

those who are interested in pediatric device innovation.

In conclusion, pediatric device development represents a viable pathway for clinically oriented urologists to participate in a different type of inclusion and diversity where they can make a substantial contribution to urological research that addresses an underserved population (children and their pediatric device needs) while maintaining a busy clinical practice. NIH SBIR/STTR grants, as well as the existing infrastructure of pediatric device consortia with partnerships with local engineering universities, provide pediatric clinicians and physician-scientists with less well-known avenues for the development of innovative technology for pediatric urological patients. These important activities not only will support academic promotion and tenure pathways for faculty members, but more importantly will positively

impact pediatric patients who are in need of these innovations. ♦

1. Dellis A, Skolarikos A and Papatsoris AG: Why should I do research? Is it a waste of time? *Arab J Urol* 2014; **12**: 68.
2. American Urological Association: The State of the Urology Workforce Census Book. 2019. Available at <https://www.AUAnet.org/common/pdf/research/census/State-Urology-Workforce-Practice-US.pdf>. Accessed January 15, 2021.
3. Joseph PD, Craig JC and Caldwell PH: Clinical trials in children. *Br J Clin Pharmacol* 2015; **79**: 357.
4. Sun RC, Kamat I, Byju AG et al: Advancing pediatric medical device development via non-dilutive NIH SBIR/STTR grant funding. *J Pediatr Surg* 2021; doi: 10.1016/j.jpedsurg.2021.01.025.
5. Ulrich LC, Joseph FD, Lewis DY et al: FDA's pediatric device consortia: national program fosters pediatric medical device development. *Pediatrics* 2013; **131**: 981.
6. Grant M, Stanasel I and Koh CJ: Pediatric medical device consortia: a novel pathway for pediatric device development for pediatric urologists and other pediatric specialists. *Urol Pract* 2015; **2**: 206.
7. Sack BS, Elizondo RA, Huang GO et al: Pediatric medical device development by surgeons via capstone engineering design programs. *J Pediatr Surg* 2018; **53**: 493.