Pediatric Electrophysiology Device Needs: A Survey from the Pediatric and Congenital Electrophysiology Society Taskforce on Pediatric-Specific Devices

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BACKGROUND: There are few US Food and Drug Administration (FDA)–approved devices specifically aimed at the pediatric patient with arrhythmia. This has led to a high off-label utilization of devices in this vulnerable population. The Pediatric and Congenital Electrophysiology Society (PACES), the international organization representing pediatric and congenital heart disease arrhythmia specialists, developed a task force to comprehensively address device development issues relevant to pediatric patients with congenital arrhythmia.

METHODS AND RESULTS: As a first step, the taskforce developed a 26-question survey for the pediatric arrhythmia community to assess providers’ understanding of the FDA approval process, specifically in regard to pediatric labeling. There were 92/211 respondents (44%) with a >90% completion rate. The vast majority of respondents believed there was a paucity of devices available for children (96%). More than 60% of respondents stated that they did not understand the FDA regulatory process and were not aware of whether the devices they used were labeled for pediatric use.

CONCLUSIONS: Pediatric electrophysiologists are keenly aware of the deficit of available pediatric devices for their patients. The majority do not understand the FDA approval process and could benefit from additional educational resources regarding this. A collaborative forum including PACES, FDA, patients and their families, and Industry would be an important next step in clarifying opportunities and priorities to serve this vulnerable population.

Key Words: device therapy ■ FDA ■ pediatric

There have been great strides in the past 10 years in technologies available to electrophysiologists to aid in the care of patients with arrhythmias. Leadless pacemaker systems, subcutaneous implantable cardioverter defibrillator systems, wearable ambulatory monitoring devices, and improved ablation technology all have enhanced patient care. However, these technologies often are not suitable for use in small children and patients with congenital heart disease, who are among the most vulnerable of patients with arrhythmia.

Moderate to severe congenital heart disease (CHD) occurs in 6 of 1000 live births in the United States, and is often complicated by tachyarrhythmias and bradyarrhythmias. Patients with CHD may require implantable pacemakers, defibrillators, or catheter ablation therapy; however, device placement can be complicated by cardiac and vascular anatomic considerations including intracardiac shunting. When utilizing device therapy in children, the pediatric electrophysiologist must take into consideration the device functionality, size, and longevity. With improvements in surgical and interventional
techniques to correct CHD lesions, the pediatric electrophysiologist is increasingly challenged with a need for interventions in children as small as 3 kg.³

At present, because of a paucity of devices approved for use in children, there is a high rate of off-label device utilization in this population.⁴ While devices typically undergo thorough preclinical testing, human clinical trials, post-approval studies and post-marketing surveillance in adults, pediatric electrophysiologists often need to improvise novel ways of using these technologies that have not been rigorously tested for safety and effectiveness in children and in patients with CHD.

The Pediatric and Congenital Electrophysiology Society (PACES), the international organization representing pediatric and congenital heart disease arrhythmia specialists, with support from the Heart Rhythm Society developed a task force to comprehensively address device development issues relevant to pediatric patients and patients with congenital arrhythmia.⁵ The mission of this group is to improve the outcomes of pediatric patients and patients with congenital heart disease with electrophysiologic disease by improving the range of available diagnostic and therapeutic devices. This will be accomplished by developing a relationship between care providers, researchers, medical device industry stakeholders, US Food and Drug Administration (FDA), and our patients in order to facilitate device development and appropriate evaluation in the pediatric electrophysiology population.

As an initial step of information collection, the taskforce developed an online questionnaire to assess current needs specific to the pediatric and CHD arrhythmia patient and to investigate providers’ understanding of the FDA approval process, specifically with respect to pediatric labeling. The results of that survey comprise this report.

METHODS

The survey was developed and reported conforming to the Checklist for Reporting Results of Internet E-Surveys.⁶ The PACES taskforce developed a 26-question survey to assess caregivers’ opinions of the current availability of pediatric-specific devices; the most important areas of need; and an understanding of the FDA pediatric labeling process (see Data S1 for the questionnaire). The questionnaire was circulated to 212 members of PACES using Qualtrics (Provo, Utah) for online administration. The Stanford University Institutional Review Board reviewed this study and determined that it was not human subjects research. Data are available on request from the authors.

All study participants had the option of completing the survey anonymously. Questionnaires that were <90% completed were rejected from analysis. Normally distributed continuous variables are presented as mean±SD. We were unable to analyze characteristics predictive of understanding the FDA process because our sample was quite homogeneous, with the vast majority of respondents being attending physicians in academic practice.

RESULTS

From the group of 212 PACES members, a total of 102 responses were received (48%), of which 92 were ≥90% completed and used for analysis. The demographics of respondents are shown in Table 1. Briefly, the majority of respondents were attending pediatric electrophysiologists (87%), and the majority were from the United States (86%) with broad geographic distribution. Additionally, most respondents have been in practice for >10 years and practice in an academic medical center.

PACES members were asked whether they believed there is a deficiency in devices (pacing/implantable cardioverter defibrillator device, lead, EP catheter or ambulatory monitoring) available to serve the needs of pediatric patients and whether they believed there is a deficiency in devices labeled for pediatrics to serve the need of their patients. The vast majority of respondents agreed or strongly agreed with those statements (96% and 94%, respectively) (Figure 1).

Respondents were also asked if they understood the process by which a device received FDA approval for pediatric use and whether they would like to learn more
about this process. The majority (63%) did not understand this process, and 83% were interested in learning more about how this process operated (Figure 2).

Furthermore, PACES members were not aware of the FDA approval status (regarding pediatric labeling) for the majority of devices they use and did not refer to the labeling on devices to assess this. However, most did state they would be more likely to use a device if labeled by the FDA for pediatric use and would specifically use a device labeled for pediatrics over one that was not if the devices were otherwise equivalent (Figure 3).

Members were asked to give a priority score (1–10, 1 denoting highest priority) to 7 possible pediatric or CHD innovations that they feel would be important for their patients (Table 2). A smaller removable leadless pacemaker was thought to be most important, with a ranking of 2.3 ± 1.9. All of the 7 suggested innovations scored >3.5 in importance. When asked for additional suggested innovations, members identified that magnetic resonance imaging–compatible epicardial leads and fetal pacemakers as specific needs (Table 3).

The respondents were asked for the biggest unmet needs in pediatric electrophysiology practice. Physicians requested pediatric-specific cardiovascular implantable electronic devices that were smaller, had better battery life, and had pediatric-specific algorithms. Specifically, a leadless pacemaker designed for pediatric care was consistently seen as needed.

**DISCUSSION**

This survey reveals attitudes and beliefs of pediatric electrophysiologists in regard to electrophysiologic device

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**Table 1. Demographics of Respondents**

| Demographic | Number (Percentage) |
|-------------|---------------------|
| N           | 92                  |
| Description |                     |
| Attending EP| 80 (87%)            |
| APP         | 5 (5%)              |
| Trainee     | 4 (4%)              |
| Other       | 3 (3%)              |
| Area of practice |                 |
| Northeast US| 17 (18%)            |
| South US    | 19 (21%)            |
| Midwest     | 22 (24%)            |
| West US     | 21 (23%)            |
| Other       | 13 (14%)            |
| Years in practice |              |
| <5 y        | 13 (14%)            |
| 5–10 y      | 20 (22%)            |
| >10 y       | 59 (64%)            |
| Type of practice |             |
| Academic    | 83 (90%)            |
| Private     | 7 (8%)              |
| Other       | 2 (2%)              |

APP indicates advanced practice provider; and EP, electrophysiologist.

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**Figure 1.** Deficiency of devices in pediatrics.
development and highlights important knowledge gaps regarding the FDA process for device approval and labeling. These knowledge gaps will be important to address if we are to advance pediatric-specific device development.

First, and probably most strikingly, the overwhelming majority (96%) of the responding pediatric electrophysiology community believes that there is a deficiency in electrophysiologic devices suitable for or labeled for pediatric use. While this viewpoint is not surprising, it is important to note how universal this opinion was, and the fact that the majority of practicing arrhythmia specialists do not believe that there is adequate technology available to suit the needs of this vulnerable population.

This opinion is well supported by historical data. In the past 10 years only 5 devices have been approved for use in the pediatric electrophysiology patient. Thus, the pediatric electrophysiology community is obligated to use available device technology in an off-label manner. Sutherell and colleagues found an off-label use of an approved device in 63% of pediatric cardiology patients undergoing transcatheter interventions. This trend is seen across all pediatric subspecialties.

The majority of pediatric electrophysiology physicians do not understand the process by which a device receives FDA approval for pediatric use and most are unaware of the FDA approval status on devices they use. This is likely related to lack of specific studies in children and lack of designated FDA labeling for pediatric use for the majority of devices used by the pediatric electrophysiology community. While most responding physicians expressed a preference for using devices with pediatric labeling, that option is generally not available for most interventional electrophysiology products currently. At the same time, this demonstrates a potential competitive advantage for companies that are able to obtain pediatric indications from the FDA for their products.

There were several recurring suggestions from survey respondents as to important technologies that needed improvement for use in children, and the majority revolved around the theme of smaller, longer lasting and more reliable devices. Leadless pacemaker technology has recently become available in the United States. This technology eliminates several complications that are associated with transvenous pacemaker generators.
and leads, including lead and pocket infection, pocket erosion, lead dislodgement and fracture, and venous thrombosis and occlusion. Such a device would reasonably be preferred in a child who might require several decades of pacing and is at risk of developing total venous occlusion over their lifespan. Unfortunately, currently marketed leadless pacemakers, requiring a 27-Fr (outer diameter) introducer, are too large to be used in small children. In addition, the issues of extractability and need for multiple leadless devices over a lifetime have not yet been fully addressed.

Finally, the need for magnetic resonance imaging conditional epicardial pacing and defibrillation systems was also described. Most small children and many patients with CHD are unable to use existing magnetic resonance imaging conditional pacemakers, because their size or anatomy precludes a transvenous approach to pacing, and these patients therefore often require epicardial pacemaker systems. Thus, these patients may not be able to undergo magnetic resonance imaging, which can be a critical diagnostic and care management tool over a lifetime. Several pediatric and adult CHD programs have performed magnetic resonance imagings in patients with epicardial systems without overt adverse events reported. However, this clinical off-label use information has not been submitted to the FDA for review.7 This issue illustrates the potential of real-world evidence for support of regulatory purposes whether it be through collection of structured clinical data in the electronic health record, or through prospective registries. These data would facilitate FDA review of safety and effectiveness.

The deficit of smaller devices is not limited to pacemakers and implantable cardioverter defibrillators alone. Electrophysiologists also believed that the need for smaller radiofrequency ablation and cryoablation catheters and related equipment is just as important. Pediatric electrophysiologists are performing invasive life-saving electrophysiology studies and ablations on very small children, sometimes in neonates as small as 2 kg.8–11 At the present time, there is a single 5-Fr ablation catheter available to aid in these studies in the US market. Pediatric electrophysiologists have pioneered the use of 3-dimensional mapping systems

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**Table 2. Possible Pediatric/CHD Innovation in Order of Importance**

| Innovation                                    | Order of importance (median, rank and IQR) |
|-----------------------------------------------|--------------------------------------------|
| Smaller removal leadless devices              | 2 (2)                                      |
| Smaller SCICD systems (with lower energy)    | 3 (4)                                      |
| Smaller traditional ICD and pacemaker systems | 2 (3)                                      |
| Smaller RF ablation catheters                 | 3 (3)                                      |
| Pediatric specific ICD algorithms             | 2 (3)                                      |
| Steroid-eluting epicardial pacing lead        | 3 (2)                                      |
| Smaller wearable defibrillators               | 3 (3)                                      |

Ranking of importance of access to each item (1–10 with 1 highest importance, 10 lowest). CHD indicates congenital heart disease; ICD, implantable cardioverter defibrillator; IQR, interquartile range; RF, radiofrequency; and SCICD, subcutaneous implantable cardioverter defibrillator.
as a replacement for fluoroscopy during these studies, an important safety development.12,13 Unfortunately, there are no small catheters with 3-dimensional mapping capabilities. This exposes small children to much higher levels of ionizing radiation for procedures that can be performed in older children and adults with significantly reduced radiation exposure. Additionally, it is known that neonates and infants have higher vulnerability to the adverse impact of ionizing radiation, increasing the risk of malignancies over a lifetime.14 The development of smaller 3-dimensional mapping catheters and patches would further aid in the care of pediatric patients, potentially reducing the risk of these procedures.

Most devices utilized in pediatric electrophysiology are class III devices (products that usually sustain or support life, are implanted, or present a potential unreasonable risk of illness or injury). The usual pathway for class III devices to obtain FDA approval is the Pre-Market Application. This requires 1 or more large clinical studies or randomized trials to demonstrate a reasonable assurance of both safety and effectiveness. For rare conditions, which include many forms of CHD, the Humanitarian Device Exemption pathway may be used as an alternative means to secure FDA approval. The Humanitarian Device Exemption pathway usually necessitates a clinical trial and is typically less onerous, with historical controls at times sufficient. An Humanitarian Device Exemption is exempt from the effectiveness requirements of a Pre Market Application and must meet the evidentiary standard of a reasonable assurance of safety and “probable benefit.” Over the past decade, only ≈10% of Pre Market Application and Humanitarian Device Exemption approvals by FDA have been for devices designed and indicated for children younger than 18 years.15 Often the number of patients needed for a Pre Market Application trial may be challenging to obtain in the heterogeneous and limited patient populations served by the pediatric electrophysiologist. The FDA has recognized the constraints and difficulties with traditional means of generating evidence for FDA approval in small populations and has developed options that support device development in small populations such as pediatric and CHD patients.

Two of these developments are the Center for Devices and Radiological Health Early Feasibility Study Program and the use of real-world evidence for regulatory applications. The Early Feasibility Study Program takes into consideration the relative rarity of many pediatric diseases. It requires a small number of patients (usually <15) to undergo initial clinical testing of a novel device and allows for device iteration during the study. This program encourages industry to consider pediatric device technology and may allow pediatric patients to “gain earlier access to a device that may improve their own health or advance the standard of care for other” patients.15

In 2016, the 21st Century Cures Act was signed into law, placing additional focus on the use of real-world evidence to support regulatory decision making. This evidence may include data from electronic health records, registries, and patient-generated data. Real-world evidence may also utilize observational studies, retrospective trials, and case histories. The FDA published a guidance document in 2017 that clarified how real-world data are evaluated.16 The PACES community has a long history of conducting multicenter research and registry studies, which could potentially be used to support safety and effectiveness data for many of the devices that are used in pediatric cardiology without FDA labeling.

### CONCLUSIONS AND FUTURE DIRECTIONS

There is a paucity of specific pediatric technology available to serve the vulnerable pediatric and congenital heart disease patient, reflected in the results of this survey. The pediatric electrophysiology community

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**Table 3. How Should PACES Facilitate Device Development and Availability of Pediatric-Specific Devices?**

| Area                        | Comments                                                                 |
|-----------------------------|--------------------------------------------------------------------------|
| Education/Dialogue          | Development of summit with industry representatives interested in pediatrics to discuss pediatric needs |
|                             | Open conversation with device companies and help development of pediatric-specific devices |
|                             | Break out session at HRS or pre-HRS meeting, set up standing committee of interested researchers from PACES |
| Centralized research resource | PACES should be the FDA’s #1 resource when approving/labeling devices for pediatrics |
|                             | Facilitate studies, establishing a centralized database (CIED registry) |
|                             | Create a centralized research group to study priority subjects |
|                             | PACES could provide “post approval study” organization for devices that are already approved for adults to provide the FDA with safety and efficacy numbers in pediatrics when we use them in an off-label manner |
|                             | Recognition by the FDA so that PACES representative is a regular consultant to the FDA |

AAP indicates American Academy of Pediatrics; CIED, cardiovascular implantable electronic device; FDA, US Food and Drug Administration; HRS, Heart Rhythm Society; and PACES, Pediatric and Congenital Electrophysiology Society.
has a clear idea of what developments are necessary at this time for their patients, specifically smaller removable cardiovascular implantable electronic devices and smaller ablation equipment. FDA has recognized the particular challenges of device development in the pediatric arena and has instituted several regulatory programs to help address these issues.

The pediatric electrophysiology and device development community may benefit from a more comprehensive understanding of these regulatory options. Collaborative forums, bringing together PACES, patients/families, FDA, and industry partners (Physician-FDA-Industry Collaboratives), focused on clarifying opportunities to develop prioritized necessary devices, would be a first step toward improving outcomes for this underserved community of children. In addition, the development of a consortium of centers willing to participate in pediatric electrophysiology-specific data gathering, either through prospective registry participation or retrospective gathering of data, could aid in providing real-world evidence for devices already in use in children (Table S1).

ARTICLE INFORMATION
Received May 22, 2022; accepted October 4, 2022.

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Sources of Funding
None.

Disclosures
Dr. Bar-Cohen has issued and pending patents related to fetal and epicardial micropacemaker devices and implantation methods and equipment. Dr. Berul has patents related to percutaneous pericardial device implantation tools and methods. Dr. Shah is a consultant for Medtronic,Inc, with no financial compensation. Drs. Dubin, Friedman, Saarel, and Cannon have nothing to disclose.

Supplemental Material
Data S1

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Data S1. Questionnaire

1. What term best describes you?
   a. Attending EP physician
   b. EP fellow
   c. Advanced Practice Provider
   d. Other ______

2. Where do you practice?
   a. Northeast US
   b. South US
   c. Midwest US
   d. Western US
   e. Europe
   f. Asia
   g. Africa
   h. New Zealand/Australia

3. How long have you been in practice?
   a. < 5 years
   b. 5-10 years
   c. > 10 years

4. How would you describe your primary site of employment?
   a. Academic medical center
   b. Private practice
   c. Other ______

Indicate your response to the following statements:

5. There is a deficiency in devices (pacing/ICD device, lead, EP catheter, ambulatory monitoring etc.) available to serve the electrophysiologic needs of pediatric patients.
   a. Strongly agree
   b. Agree
   c. Neither agree nor disagree
   d. Disagree
   e. Strongly disagree

6. There is a deficiency in devices (pacing/ICD device, lead, EP catheter, ambulatory monitoring etc.) labelled to serve the electrophysiologic needs of pediatric patients.
   a. Strongly agree
   b. Agree
   c. Neither agree nor disagree
   d. Disagree
   e. Strongly disagree

7. Do you understand the process by which a device receives FDA approval for a pediatric indication?
8. Are you interested in learning how a device receives FDA approval for a pediatric indication?
   a. Yes
   b. No

9. I am aware of the FDA approval status, specific to pediatrics, for the majority of EP devices I use on a frequent basis
   a. Strongly agree
   b. Agree
   c. Neither agree nor disagree
   d. Disagree
   e. Strongly disagree

10. I read the FDA labeling of any EP device I am using to assess whether approved for pediatric use
    a. Strongly agree
    b. Agree
    c. Neither agree nor disagree
    d. Disagree
    e. Strongly disagree

11. If an electrophysiology device (pacing/ICD device, lead, EP catheter, ambulatory monitoring etc.) were approved for a specific pediatric indication (ie labeled for pediatrics by the FDA) I would more likely to use it because of that pediatric label
    a. Strongly agree
    b. Agree
    c. Neither agree nor disagree
    d. Disagree
    e. Strongly disagree

12. If I had access to 3 equivalent devices, and one was labeled for pediatric use, I would choose the pediatric device
    a. Strongly agree
    b. Agree
    c. Neither agree nor disagree
    d. Disagree
    e. Strongly disagree

13. I have influence in device purchasing decisions for our hospital/healthcare system
    a. Strongly agree
    b. Agree
    c. Neither agree nor disagree
    d. Disagree
    e. Strongly disagree

14. My hospital/healthcare system takes pediatric labeling into consideration when deciding on device contracts
    a. Strongly agree
b. Agree
   c. Neither agree nor disagree
   d. Disagree
   e. Strongly disagree
   f. Don’t know

15. On a score of 1-10 (1 is highest, 10 is lowest) how important would it be to have access to each of the following items:
   a. Steroid-eluting epicardial screw in lead ____
   b. Pediatric specific ICD algorithms for rhythm determination____
   c. Wearable defibrillator for younger/smaller patients ______
   d. Smaller Fr ablation catheters____
   e. Smaller SubQ ICD generators with decreased energy capacity for smaller patients____
   f. Smaller traditional ICD/pacemaker generators (for pericardial or epicardial systems) ____
   g. Smaller removable leadless devices____

16. Other device innovations you consider important (and priority):_______

17. What do you believe are the biggest unmet needs in pediatric EP device development at the present time?

18. How should PACES help facilitate device development and availability of EP devices for pediatric patients?
Table S1. Other possible pediatric/CHD innovations

| Topic                     | Number of times suggested | Suggestions                                                                 |
|---------------------------|---------------------------|------------------------------------------------------------------------------|
| Pacing/ICD issues         | Multiple                  | MRI compatible epicardial leads-7                                            |
|                           |                           | Leadless pacer (dual chamber pacing rechargeable, removable) – 6             |
|                           |                           | Improved pacing/ICD algorithms for small children (increased upper rate behavior)-5 |
|                           |                           | Fetal pacemaker-4                                                           |
|                           |                           | Smaller dual chamber pacer for infants – 3                                   |
|                           |                           | Smaller temporary TV pacing wire-3                                           |
|                           |                           | Improved strength of epicardial leads-2                                     |
|                           | Single                    | Greater battery longevity-2                                                 |
|                           |                           | Additional sheaths for 3830 lead                                            |
|                           |                           | Lead extraction tools for pediatrics                                         |
|                           |                           | Longer TV helical electrodes                                                |
|                           |                           | Minimally invasive epicardial pacing systems                                |
|                           |                           | Robust 6 Fr ICD leads                                                        |
|                           |                           | Shorter sheaths and leads for His Bundle pacing                            |
|                           |                           | Smaller TV pacing lead                                                       |
| Ambulatory monitoring     | Multiple                  | Other wearables for pediatrics (Watch, Band Patch)-2                        |
|                           |                           | Default incorporation of all remote CIED monitoring data into pediatric registry/database |
|                           | Single                    | Improved single patch monitor                                               |
|                           |                           | Smaller ILR (chip-like)                                                      |
|                           |                           | Smartphone ECG hardware and software                                        |
| Ablation tools            | Single                    | Better esophageal leads                                                      |
|                           |                           | Fluoro-less procedure tools tailored to pediatrics                           |
|                           |                           | MRI compatible catheters                                                     |
|                           |                           | Pediatric irrigated contact force catheters                                  |
|                           |                           | Smaller 3d mapping patches                                                  |
|                           |                           | Smaller multipolar mapping catheters                                         |

Innovations listed by number of respondents who suggested them. Those with no number were suggested by single respondents. CHD = Congenital Heart Disease, ICD = Implantable Cardioverter Defibrillator, MRI = Magnetic Resonance Imager, TV = transvenous, CIED = Cardiac Implantable Electronic Devices, ILR = implantable loop recorder.