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Pediatric medical device development by surgeons via capstone engineering design programs☆,☆☆,★

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ABSTRACT

Background: There is a need for pediatric medical devices that accommodate the unique physiology and anatomy of pediatric patients that is increasingly receiving more attention. However, there is limited literature on the programs within children's hospitals and academia that can support pediatric device development. We describe our experience with pediatric device design utilizing collaborations between a children's hospital and two engineering schools.
Methods: Utilizing the academic year as a timeline, unmet pediatric device needs were identified by surgical faculty and matched with an engineering mentor and a team of students within the Capstone Engineering Design programs at two universities. The final prototypes were showcased at the end of the academic year and if appropriate, provisional patent applications were filed.
Results: All twelve teams successfully developed device prototypes, and five teams obtained provisional patents. The prototypes that obtained provisional patents included a non-operative ureteral stent removal system, an evacuation device for small kidney stone fragments, a mechanical leech, an anchoring system of the chorio-amniotic membranes during fetal surgery, and a fetal oxygenation monitor during fetoscopic procedures.
Conclusions: Capstone Engineering Design programs in partnership with surgical faculty at children's hospitals can play an effective role in the prototype development of novel pediatric medical devices.
Levels of evidence: N/A – No clinical subjects or human testing was performed.

Pediatric and adult surgeons often encounter limitations that prohibit more accurate diagnoses and efficient treatments that could be addressed with new or improved medical devices. Current standard of care practices in pediatric medicine often involve the utilization of adult-designed technologies for pediatric applications. According to the Food and Drug Administration (FDA), there is a need for pediatric medical devices specifically designed to accommodate the unique physiology and anatomy of pediatric patients [1]. The lower pediatric disease incidence, the poor incentives for medical device industry financial return, the high cost of pediatric clinical studies relative to the market size, and the difficulty in enrolling pediatric clinical trial participants [2] have caused a significant lag in pediatric device development compared to adult devices [1]. These limitations have resulted in pediatric surgeons using adult devices for off-label pediatric indications [3–5], with potential legal and ethical ramifications.

In 2007, the passage of the Pediatric Medical Device Safety and Improvement Act (PMDSIA) led to important advances for the pediatric medical device field. This act mandated the tracking of pediatric devices, the facilitation of pediatric device design, as well as the elimination of previous profit restrictions on humanitarian device exemption (HDE)

Abbreviations: FDA, Food and Drug Administration; PMDSIA, Pediatric Medical Device Safety and Improvement Act; HDE, Humanitarian Device Exemption; IP, Intellectual Property; SBIR, Small Business Innovation Research.

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devices [6], and thereby improving the device approval pathway for pediatric diseases associated with low incidence rates that meet HDE requirements (no greater than 4000 uses annually) [7]. The other commonly used FDA approval pathway is through premarket approval, which often requires the manufacturer to conduct clinical trials to demonstrate efficacy and safety [8]. Of note, the FDA recently released guidance on pediatric extrapolation that allows the use of adult clinical data for pediatric device approvals that may improve the developmental pathway for pediatric devices [9].

A major component of PMDSIA was the development of the FDA Pediatric Device Consortia Grant program, which created pediatric device consortia at several children's hospitals and universities across the United States. The goals of the pediatric device consortia are to encourage innovation, mentoring, and collaborations amongst pediatric surgeons, engineers, and industry for pediatric device design [6]. To date, over 775 pediatric device projects have been supported through the consortia since 2009, including 148 currently active projects and 13 collaborations/multi-consortia projects, with 5 devices in clinical use to date [6].

However, besides a description on the Biodesign process and culture that enables pediatric medical technology innovation [10], there is limited literature on the programs within children's hospitals and academia that can support pediatric device development. Pediatric surgeons are ideally placed at the frontline of patient care where they can identify needs for medical technology improvement. Conversely, engineers have the technical expertise to create innovative devices, but may not fully appreciate the clinical needs of pediatric surgeons and their patients. With the goal of creating partnerships between surgeons and engineers toward effective pediatric medical device development, we describe our experience at a major tertiary care children's hospital with two university Capstone Engineering Design programs in developing pediatric devices through a potentially reproducible pathway.

1. Methods

A call for unmet pediatric device needs was distributed to pediatric surgical faculty members at a major tertiary care children's hospital with the intent of partnering faculty members with engineering student teams in the Capstone Engineering Design programs at two local engineering schools. These design programs are available in essentially every major city in the U.S., as all Accreditation Board for Engineering and Technology programs at universities are required to incorporate engineering design into their curriculum [11].

Through the Capstone Engineering Design programs, pediatric surgical faculty worked in interdisciplinary teams with students in biomedical, mechanical, and/or electrical engineering to develop novel solutions to real-world pediatric clinical challenges. Over the course of an academic year, the teams followed a course-specified engineering design process that included clinical immersion, development of design criteria, thorough market and field analysis, prototype development, user feedback, preliminary prototype testing, and participation in annual engineering showcase events (Fig. 1).

1.1. Identification and selection of unmet pediatric device needs

Prior to the start of the academic year [September], pediatric surgical faculty members were invited to identify unmet clinical needs that could potentially be addressed with a pediatric medical device solution. The surgical faculty described their unmet device needs and clinical goals on a one-page Capstone proposal form, but were encouraged to avoid describing solutions at this time, as this would be the focus of the engineering teams' work during the academic year. Proposals were reviewed by a team of senior engineering faculty with device design experience as well as by experienced surgical faculty to assess which projects could be addressed by an engineering team with the local available resources and expertise.

1.2. Team formation and clinical immersion

During the fall semester, the selected projects were presented to the engineering students in the program, and via a matching process specific to the engineering school, teams were formed consisting of four to five engineering undergraduate students, a senior engineering faculty mentor, and the pediatric surgical faculty member. The senior engineering faculty mentor served as a technical advisor to the team as well as monitored their progress toward completion of the prototype development milestones. Once the teams were formed, the engineering team underwent clinical immersion to expose and familiarize themselves with the clinical problem and identify areas of improvement. This included visits to the operating room, clinics, and hospital rooms. The background research was directed at the historical and modern treatment practices and their technical challenges with the goal of identifying novel engineering solutions. Teams also performed a preliminary market analysis. Building a base of clinical and technical knowledge allowed for ideas and solutions brainstorming amongst the team as they progressed toward prototype development.

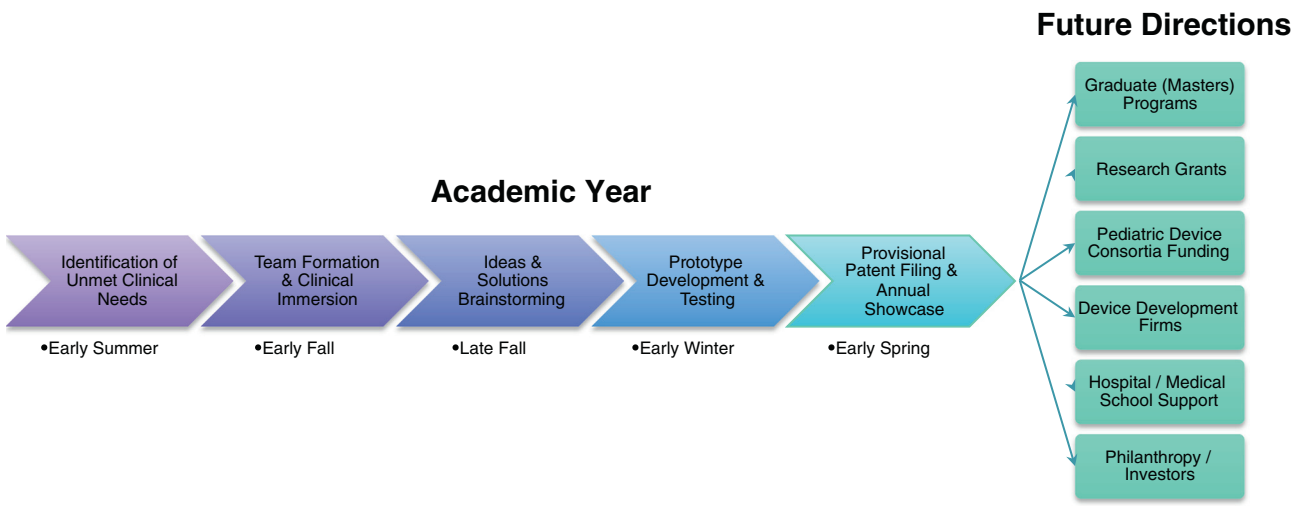

Fig. 1. Academic year timeline for capstone engineering design projects.