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Research Article

Challenges in Fetoscope Commercialization: A Market Analysis in Fetal Intervention

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ABSTRACT

Physicians historically receive little education on innovations and startup companies; however, many physi-cians have ideas to solve problems they frequently encounter. The National Science Foundation (NSF) helps innovators de-risk possible solutions they envision by providing basic business education and requiring 100 customer interviews to ensure innovators are providing a solution potential customers will consume. Two physi-cian innovators conducted 100 stakeholder interviews across the field of fetal surgery, a growing field aimed at saving life or avoiding disability due to congenital disease. End-users and economic buyers converged on sever-al value propositions, namely improved visualization of the surgical field, operating room instrument setup time, and a cost. Regulatory stakeholders pointed out that regulatory burden is largely placed on centers to file ethics approvals for off-label use of currently-available scopes, which are only approved for one indication. Fetal benefit is a hazy area for certain device approval pathways, since the fetus is not a legal person. The fetal surgery market is a small and volatile one: vulnerable to regulatory and supply-related changes, but eager for new instruments as secular trends have advanced minimally-invasive approaches in the past 20 years.

KEYWORDS

Endoscopy, Fetoscopy, Pediatric surgery.

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Abbreviations

NSF: National Science Foundation, I-Corps: I-Corps, SAM: serviceable addressable market, LLP: Lean LaunchPad, BMC: Business Model Canvas, FDA: Food and Drug Administration, SMFM: Society for Maternal-Fetal Medicine, IFMSS: International Fetal Medicine and Surgery Society, FMF: Fetal Medicine Foundation, ISUOG: International Society for Ultrasound in Obstetrics and Gynecology.

Introduction

Medical education historically included little cross-training in business practices related to innovation, but this is quickly changing [1,2]. The era of rapid prototyping and small startups is well underway, and physicians are entering the fray with a growing role in development of new technologies [3,4].

Multiple programs exist to integrate medical training and practice with basic business education vital to innovation. One example, designed by the National Science Foundation is the Innovation Corps (I-Corps). The I-Corps program was established in 2011 and helps researchers commercialize their scientific discoveries by bridging the gap between academic research and market application [5]. The National I-Corp program is an eight-week course focused on customer discovery and entrepreneurial training, participants

engage with potential stakeholders to validate market needs. I-Corps' customer discovery model is based on Lean LaunchPad (LLP), the gold-standard entrepreneurship method designed to help innovators transform their ideas into successful businesses, initially developed by Steve Bank [6]. The key components of LLP include customer discovery, Alexander Osterwalder's Business Model Canvas (BMC) [7], evidence-based decisions, rapid prototyping and iteration, and a flipped classroom approach. Teams start with a hypothesis they develop about their business, including who their target customers are and what problems they face. Next, the hypotheses are tested through customer discovery, by conducting extensive customer interviews (often requiring over 100 interviews) to validate or refute these assumptions.

A particularly challenging market in medical device design is the fetal intervention market. Fetal intervention is a relatively new field (three decades old), and emerged from a partnership between obstetricians doing minimally-invasive obstetric procedures during pregnancy, and pediatric surgeons who saw benefit of treating neonatal conditions during pregnancy [8]. It is a small market with only a few treatable conditions, and predominantly one company manufacturing fetoscopes (Karl Storz, Tuttlingen, Germany). Nevertheless, the number of families receiving fetal therapy, the odds of a good outcome after fetal therapy, and the number of fetal conditions amenable to fetal therapy have been rising and are expected to continue to increase [9]. This paper documents the development of a market analysis conducted by two physician innovators completing the I-Corps embodiment of the LLP program.

Materials and Methods

Two physician innovators were tasked with conducting at least 100 stakeholder interviews across the field of fetal intervention. Interviews were used to assess the value that stakeholders placed on various solutions to problems with current fetoscopes. Each of the nine key elements of the business model were carefully evaluated, including 1) customer segments, 2) value propositions, 3) channels, 4) customer relationships, 5) revenue stream, 6) key resources, 7) key activities, 8) key partners and 9) cost structure.

Interviews were conducted either in person, via video call, or via telephone. Notes were carefully captured for each interview and matched to hypotheses in the business model canvas. Notes were later used to confirm or refute hypotheses in order to base creation of the business model on customers' words. Important topics includ-ed pain points of current fetoscopes, stakeholders' interests while accomplishing or assisting fetal therapy, and behaviors such as preferred modes of purchasing. Stakeholders were also asked to outline purchasing processes in their institution and country. The interviewee's role, company, and relevant background information was rec-orded. Themes were highlighted, as were direct quotes capturing impactful statements. Descriptive results as well as iterations of the business model canvas are provided.

Results

101 stakeholder interviews were completed, and roles are diagrammed in Figure 1. 70 (43.5%) were end-users, 31 (19.3%) were influencers, and 15 (9.3%) were decision-makers, with some overlap between roles as some fetal interventionists were end-users and decision-makers, while others influenced hospital purchases. Eight (5%) of interviewees were economic buyers and four were saboteurs to innovation in fetal therapy. These were largely fetal interventionists who believed they needed no new tools. 53 interviewees (44.2%) were physicians, 20 (16.7% of total) of whom functioned as the director of their center. 15 interviewees were nurses (12.5%) functioning as coordinators or in the operating room. Other roles interviewed included fetal center managers, regulatory repre-sentatives, researchers, sales, and marketing.

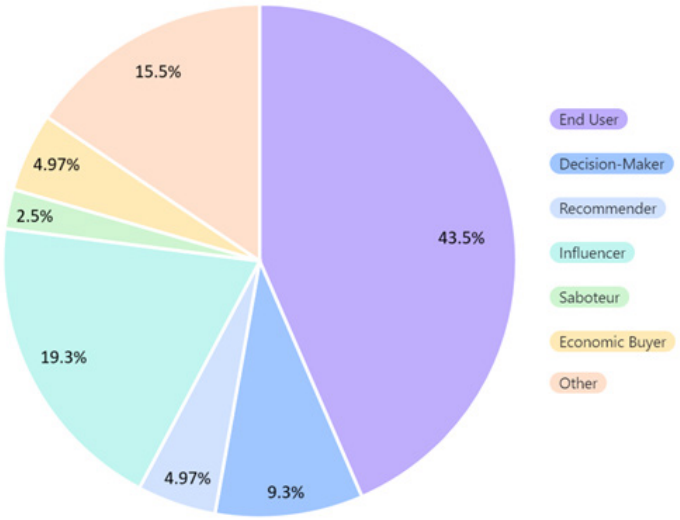

Figure 1: Contacts by Customer Type.

Customer Segments

Fetal intervention is offered in a spectrum of care centers with a spectrum of regulatory burdens. Some centers orbit around a single person who chooses and (in some countries) even purchases their own equipment with little oversight or regulatory input. In some countries, the end-user (surgeon) is also the economic buyer who writes the check for the instrument, flies it into their country, and uses it without technical support from the manufac-turer due to voided warranties. Other fetal centers are medium in size and are subject to more regulation within healthcare systems, but they are not so large as to be key opinion leaders within this space. Finally, there are large centers which are creating research, new techniques, and practice patterns that centers of all sizes look to. These large centers often face larger regulatory burdens than the others, but this differs by country with greater regula-tion present in some areas of the European Union (EU).

Aside from this characterization, our beachhead market is fetal surgeons who already hope for small, smarter tools. These will be early adopters and are often working within large centers which

function as key opinion lead-ers. Another beachhead market is trainees, who carry on practice and purchase patterns they establish during training.

Value Propositions

Across the spectrum, surgeons continued to voice interest in the value of ease of operating, good optics, and not having to face the regulatory burden themselves.

End-users and economic buyers converged on several value propositions, namely improved visualization of the surgical field, operating room instrument setup time saving via out-of-the-box device, cost savings by decreased operating room time and a price point of less than 5000 USD, below the capital expenditure threshold. Below the capex threshold, it is simpler for medium and larger fetal centers to acquire devices. Interestingly, this threshold also permits centers in low-resource areas to maintain inventory–when devices are more expensive, they are of-ten the target of theft.

Channels

The channel our potential customers preferred to be reached by was a direct sales force. We also found negative sentiment for distribution of a fetoscope via web/online sales, and medical device distributors.

Customer Relationships

We found that our customer relationships were ideally supported by device representatives and technical sup-port, and maintained via face to face interaction. Additional tools to maintain relationships included user-friendly web interfaces, social media accounts, and in-services.

Revenue Streams

We found our serviceable addressable market (SAM) to be 59 fetal centers in North America, 4 in Central/South America, 15 in Europe and 6 in Asia. The total addressable market includes all fetuses who need surgery (includ-ing untreated fetuses in global south) and potential fetal surgeries we're currently not doing due to lack of ade-quate instruments. There is also a need for miniaturized surgical devices in other specialties, including for ar-throscopy and pediatric surgery however focused our attention on fetal surgical procedures–however, these markets have separate entry costs and interviewees were cautious about market over-estimation. Positive senti-ment was observed for revenue streams in the form of direct sale with value-based pricing in a mature model, with an initial business model relying additionally on grants.

Key Resources

Manufacturing entities such as those specializing in producing medical devices based on provided designs were validated as key resources.

Key Activities

Key activities that are essential to the value proposition with positive sentiment were animal studies, clinical trials, a non humanitarian device exemption Food and Drug Administration (FDA) approval pathway, and academic conferences including the Society for Maternal-Fetal Medicine (SMFM), International Fetal

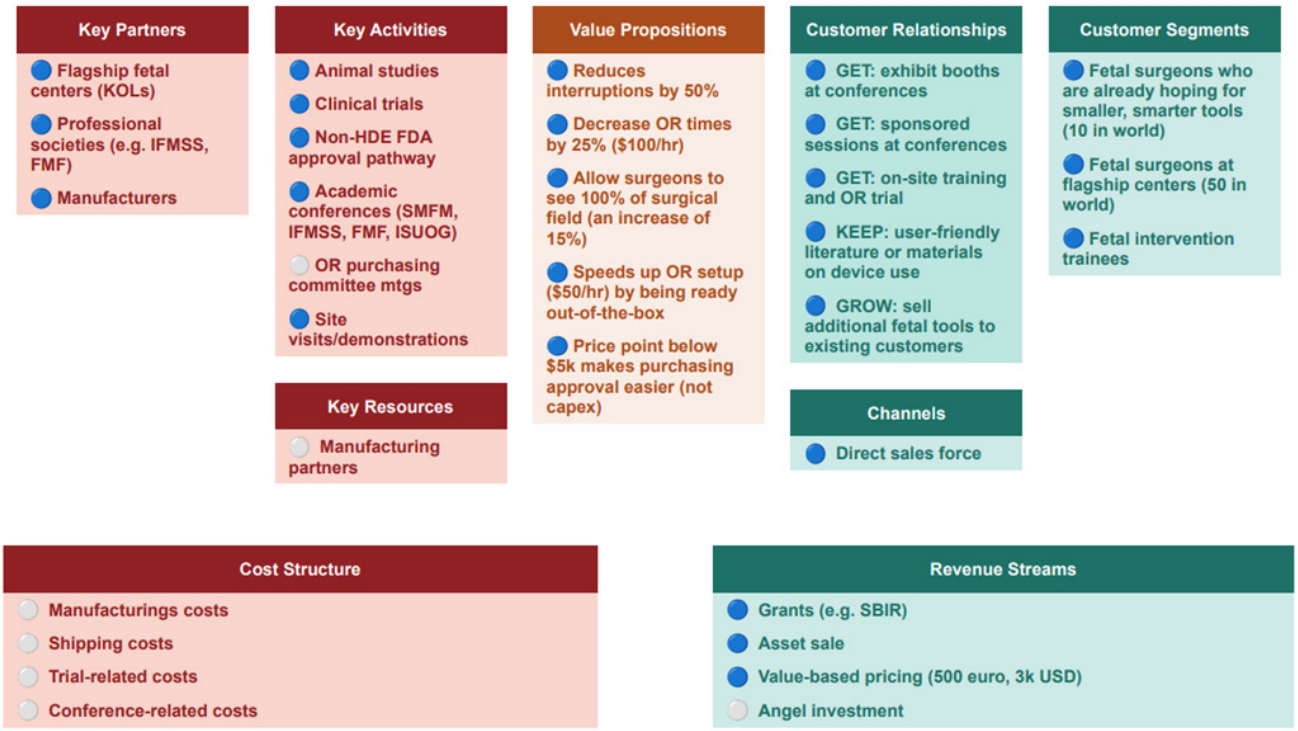

Figure 2: Final Business Model Canvas after 101 stakeholder interviews.

Medicine and Surgery Society (IFMSS), Fetal Medicine Foundation (FMF) and International Society for Ultrasound in Obstetrics and Gynecology (ISUOG). Neutral sentiment was found in regards to operating room purchasing committees.

Key Partners

We found key partners to be flagship fetal centers, home of key opinion leaders who, being experts in the field, provide trusted opinions and influence.

Cost Structure

Finally, the cost structure of manufacturing, shipping, clinical trials and academic conferences were found to be major cost drivers. Figure 2 documents a final business model canvas

Discussion

Lean LaunchPad and the National Science Foundation's I-Corps program permitted an analysis of the fetal inter-vention space. This market is a highly specialized and complex segment of the medical field, characterized by unique challenges that make it both small and volatile. The market is inherently constrained by the rarity of fetal conditions that require surgical intervention, limiting the size of the patient population and, consequently, the demand for associated products and services. This creates significant hurdles for companies seeking to enter or expand within this space, as economies of scale are difficult to achieve.

Additionally, the market is highly vulnerable to external factors, particularly from regulatory bodies and policy-makers at the national, local, and hospital level. Regulatory requirements for fetal surgery devices are stringent, as they must meet the highest safety and efficacy standards due to the dual risk to both mother and fetus. Delays or changes in regulatory approval processes can disrupt product development timelines and market entry strategies. On the supply side, the reliance on highly specialized materials, components, or manufacturing processes intro-duces vulnerability to supply chain disruptions, whether from geopolitical tensions, material shortages, or logisti-cal challenges.

Despite these obstacles, the market is eager for innovation. Over the past 20 years, there has been a gradual but steady shift toward minimally-invasive surgical approaches, driven by advancements in imaging, instrumentation, and surgical techniques. However, secular trends in innovation within the field have been relatively slow com-pared to other areas of surgery, leaving room for significant breakthroughs in precision, safety, and efficacy. Fetal surgeons and healthcare systems are actively seeking new instruments and technologies that can improve patient outcomes, reduce procedural risks, and address currently unmet clinical needs.

In this context, companies operating in the fetal surgery market must navigate a delicate balance: overcoming regulatory and supply-related hurdles while delivering innovative solutions that address the unique demands of the field. Those that succeed are likely to do so by fostering close collaboration with clinicians, investing in innova-tion, and maintaining agility to adapt to regulatory and market dynamics. This combination of challenges and opportunities underscores the complexity of the fetal surgery market and its potential for transformative innova-tion.

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