REINVENTING MANAGEMENT OF FETAL HEAD IMPACTION

by

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DISSERTATION

Presented to the Faculty of the Medical School
The University of Texas Southwestern Medical Center
In Partial Fulfillment of the Requirements
For the Degree of

DOCTOR OF MEDICINE WITH DISTINCTION IN RESEARCH

The University of Texas Southwestern Medical Center
Dallas, TX

ABSTRACT
REINVENTING MANAGEMENT OF FETAL HEAD IMPACTION

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Background:

Fetal head impaction is a life threatening event that occurs when the baby's head does not fit through the birth canal and becomes wedged deep in the pelvis during labor. Since the baby's head cannot advance, a cesarean section must be performed, often with significant complications caused by the difficulty of dislodging the fetal head from the mother's pelvis, and elevation of the fetal head in the uterus towards the cesarean incision. Physicians use complicated and violent maneuvers such as pulling on baby's legs and pushing on the baby's head with the tips of their fingers to release the impaction. The use of these maneuvers results in poor maternal and fetal outcomes including risk of intracranial hemorrhage, lower APGAR scores, maternal hemorrhage, thromboembolism, and infection, as well as added psychological and financial burden for families.

Fetal head impaction presents to some degree in 25% of all C-sections, translating to approximately 320,000 cases annually in the U.S. Although prevalent, little has yet been done to fully quantify its health burden or propose alternative ways to resolve impaction.

Objective:

To determine whether a novel obstetrics device for facilitating C-section in cases of fetal head impaction would be both financially viable and technically feasible.

Methods:

In order to estimate the rate of complications and healthcare costs associated with fetal head impaction in the U.S., we first used published literature to identify the diagnosis codes related to fetal head impaction. Utilizing these, we queried a national database of diagnosis codes for associated complications and then matched these complications to their corresponding hospital charges and costs.

With the feedback of practicing obstetricians, we built a prototype device to facilitate delivery in cases of fetal head impaction with emergency cesarean section. We tested the device with a formal fetal head impaction simulator to measure pressure exerted and rate of disimpaction to facilitate a cesarean delivery. We then compared this to the gold standard, manual disimpaction.

Results:

We have found that C-section deliveries with associated with failure to progress, a proxy for fetal head impaction, result in $1,444 in added direct hospital costs in cases resulting in complication versus those resulting in no complication. We have further found that our prototype device generates 94% less pressure than the current standard of care while

facilitating rapid disimpactions that are difficult to achieve manually on a fetal impaction simulator. Finally, we estimate an addressable market given projected device development costs, and outline a strategy by which this novel device could be brought to patient care.

Conclusion:

Preliminary prototype testing suggests that the Safe-C Pump could improve upon the standard of care by facilitating rapid, low-pressure disimpactions. Clinical testing of efficacy will be necessary to determine whether the device will be able to achieve improved patient outcomes and healthcare cost savings.

Given our findings, we believe that significant healthcare cost savings can be achieved by improving on the current standard of care for C-section deliveries in fetal head impaction. While our estimates capture direct hospital costs for associated complications, we have not yet estimated the additional associated costs of morbidity and decreased quality of life.

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PRIOR PUBLICATIONS & PRESENTATIONS

PUBLICATIONS:

None

PRESENTATIONS AND POSTERS:

Atluru, A., Carstens, E., Ganji, S., Harris, A., & Walk, D. (2014). *Pneumom: Novel Device for Fetal Head Disimpaction in Cesarean Section.* Poster presented at: NCIIA Alliance Open Conference; San Jose, CA.

Walk, D., & Carstens, E. (2014). *The Safe-C Pump: Mitigating Impacted Fetal Head.* Oral Presentation presented at: UT Southwestern Global Health Conference; Dallas, TX.

Atluru, A., Carstens, E., Ganji, S., Harris, A., & Walk, D. (2016). *Safe-C: Reinventing Management of Impacted Fetal Head in Cesarean Section.* Poster presented at: Society of American Gastrointestinal and Endoscopic Surgeons Annual Meeting; Boston, MA.

CHAPTER 1: FETAL HEAD IMPACTION

Background

C-section delivery is the most common surgical procedure in U.S. hospitals, accounting for 33% of the 4 million births recorded in 2012 (U.S.). C-section rates, up from 21% in 1996, are projected to remain steady, if not rise, and are driven by many factors including labor induction, use of epidurals, and patient health risk factors. [6] Rising rates of C-sections performed at full dilation and/or during the second stage of labor further increase risk of impaction. Fetal head impaction is thought to present in 25% of all emergency C- sections in the U.S. annually.

Disease State Fundamentals: Impacted Fetal Head

Cesarean section delivery (C-section) is now performed in about a third of births in the United States. [1] One of the serious complications of this procedure is called impacted fetal head. This life threatening event occurs when the baby's head does not fit through the birth canal, and the mother's contractions force the baby's head deep into the pelvis, where it becomes stuck during a prolonged second stage (pushing phase) of labor. The baby's head cannot advance and it is difficult to pull or push the head back into the uterus for a cesarean delivery. Physicians use complicated and violent maneuvers such as pulling on baby's legs and pushing on the baby's head with the tips of their fingers to release the impaction. Impacted fetal head is associated with adverse maternal and fetal outcomes including increased risk of intracranial hemorrhage, lower Apgar scores, maternal hemorrhage, thromboembolism, and infection, as well as added psychological and financial burden for some families. Globally, it is estimated by the World Health Organization that up to 8% of annual maternal deaths are attributable to prolonged second stage of labor. [2]

Though the exact cause of impaction is not fully understood, there are many potential contributing factors. [3] It may arise from weak or uncoordinated contractions that cannot push the baby through the birth canal, or from the birth canal simply not being the right size or shape. There are also some potential medical causes such as the increased use of epidural

anesthesia leading to a reduced urge for the mother to push. Failed attempts at instrumental extraction, especially with vacuum extraction, can also further lodge the head within the pelvis. [1] Impaction rates are estimated to be even higher in low resource settings and have worse outcomes. Since experience plays an important role in management of impaction, when skilled physicians are not available C-section is only to be undertaken as a last resort, if at all, due to increased risk to mother and child. This reluctance to proceed to C-section (along with a deficit of tools to handle the complex procedure and its outcomes) further extends the second stage of labor, compounding the severity and frequency of complications.

Current Standard of Care

The preferred method to resolve impacted fetal head is via manual extraction known as the "pull method." Once the uterine incision has been made, the pull method requires the physician to grasp the feet of the baby as it is pulled out through the uterine incision. Sometimes another hand will also be inserted vaginally to provide a push up ("push method," see Figure 1). Although serious maternal and fetal complications can arise, the "pull method" is the most commonly practiced maneuver. [1]

Figure 1: "Push" and "Pull" methods of disimpaction.
Source: OBG Management, 2012

Several devices exist that aim to resolve cases of impacted fetal head by forcing vaginal delivery, but their use is waning. Metallic fetal head elevators such as the Coyne spoon and the Murless head extractor, mechanistically similar to the "shoe horn," assist in extraction of the fetal head. These instruments have been shown to cause deformation to the fetal head and are associated with significant maternal soft tissue trauma (i.e. severe perineal tears). Vacuum extractors including the Kiwi OmniCup and the Malmstrom metal cup conform to the fetal head and create negative pressure, assisting in maneuvering the fetal head vaginally. Vacuum extraction has been shown to be more effective, but with increased risk of newborn scalp injury, cephalohematoma and potentially fatal subgaleal hemorrhage. [4] These concerns were so great that in 1998, the Food and Drug Administration (FDA) issued a public health advisory calling for caution when using

vacuum-assisted delivery devices, citing a 5-fold increase in deaths and serious neonatal injury. [5] A thorough literature search indicates that there are no existing devices that allow the physician to elevate and displace the lodged fetal head during C-section.

CHAPTER 2: EPIDEMIOLOGY & COST ANALYSIS

Hypothesis

There is no reliable method for predicting impacted fetal head, and current solutions—including the use of forceps or an assisting physician's hand—are dangerous and ineffective. While the association between fetal head impaction and adverse outcomes is generally accepted, there is a lack of data regarding impaction's true societal cost in terms of maternal/fetal morbidity, mortality, and subsequent healthcare costs. We proposed to use multiple ICD-9 codes within the category of 'failure to progress' as a proxy for fetal head impaction, as these are potential risk factors for and strongly associated with fetal head impaction in cesarean section. The four codes of diagnoses of interest in this research study were prolonged second stage of labor (P2S), cephalopelvic disproportion (CPD), persistent occiput posterior (POCP), and failed forceps/instrumental delivery (FF). We hypothesized that these subtypes of failure to progress in second stage of labor are associated with significantly greater maternal and fetal morbidity, mortality, and costs.

Methods

We proposed to use multiple data sources in our analysis: 1) chart review of Parkland Hospital patients 2) aggregate national data from The Healthcare Cost and Utilization Project (HCUP) 3) background data from previously conducted literature search. A research plan was developed and submitted to the UT Southwestern Institutional Review Board (IRB), which determined that the project does not meet the definition of human subject research and thus does not require IRB approval or oversight.

The first analysis was conducted with the assistance of Dr. Scott Roberts, Director of High Risk Obstetrics at Parkland Hospital. Dr. Roberts selected five recent cases complicated by fetal head impaction. These patient cases were studied in an attempt to determine the cause of fetal head impaction, severity, method of resolution, morbidity, and associated costs. An obstacle to completing an effective analysis was the small sample size and lack of ICD-9 codes associated with diagnosis/conditions accounted for within the patient records. Accordingly, no meaningful and significant conclusions could be drawn from this dataset.

We redirected then to using HCUP, which is a group of databases created and maintained by the Agency for Healthcare Research and Quality. Our primary source was the National

Inpatient Sample database (NIS), the largest publicly available all-payer hospital inpatient care database in the United States. Researchers and policymakers use NIS data to identify, track, and analyze trends in health care utilization, access, charges, quality, and outcomes.

The 2012 National Inpatient Sample (NIS) was utilized to identify the frequency of ICD-9 codes associated with fetal head impaction. The incidence as a primary diagnosis and secondary diagnosis was determined. The NIS dataset was first queried to isolate pertinent cases, female patient admissions with associated neonatal data (neomat codes). The relevant dataset was then segmented by Diagnosis Related Group (DRG) 765 and 766, Cesarean Section with CC (complication and comorbidity) and Cesarean Section without CC. These two data sets were then analyzed to identify incidence of ICD-9 codes associated with impaction and to identify total hospital charges. Hospital-specific charge-to-cost ratios were used to convert total hospital charges to hospital costs for use in a cost-benefit analysis of a new intervention. A representation of the approach to isolating the cases of interest is represented in Figure 2 below.

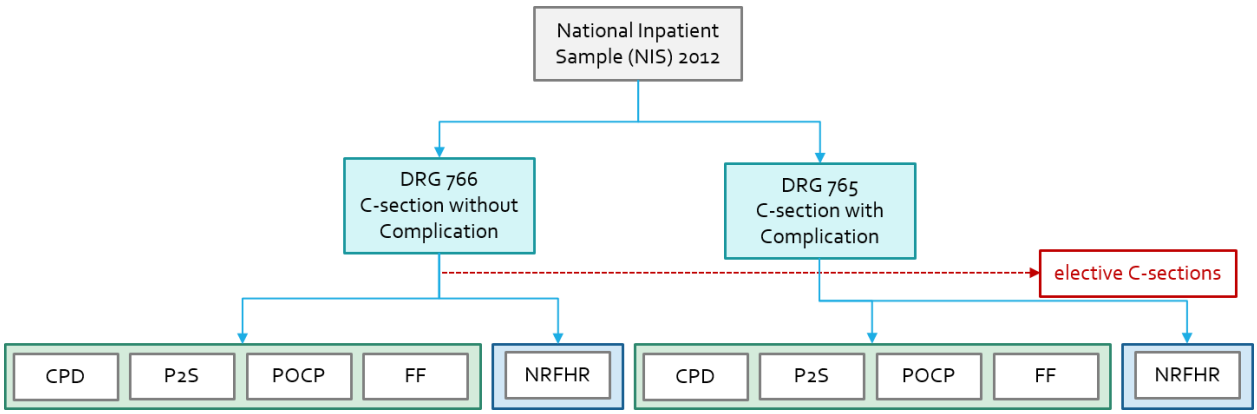


Figure 2: National Inpatient Sample segmented by DRG 766 and 765.

CPD: cephalopelvic disproportion, P2S: prolonged second stage of labor,

POCP: persistent occiput posterior, FF: failed forceps delivery, NRFHR: non-reassuring fetal heart rhythm

The complete National Inpatient Sample (NIS) 2012 data set was first stratified by DRG 766 and DRG 765, representing cases of C-section without complication and C-section with complication, respectively. These two DRGs represented approximately 1.25 million cases as coded, which approximates 1.3 million, the total number of C-sections in the U.S. in 2012 as reported by the Centers for Disease Control (CDC). After isolating by DRG group, we identified 93,416 cases of Cesarean Section with Complication/Comorbidity (DRG 765) and

157,476 cases of Cesarean Section without Complication/Comorbidity (DRG 766). Using the variable field variable, "elective," all cases of elective C-section was removed from both DRGs. This was done in an effort to exclude the large number of patients who have had prior c-sections, and the smaller number of patients who otherwise elect to have c-sections.

From a prior literature search, we had discovered that fetal head impaction presents primarily as failure to progress (FTP), the most common indication (35.4%) for primary cesarean section delivery [6]. Accordingly, we focused on ICD-9 codes associated with fetal head impaction as confirmed by literature search and OB/GYN physician interviews. These included cephalopelvic/fetopelvic disproportion (653.40-653.43), persistent occiput posterior (660.30-660.33), failed forceps delivery (660.70-660.73), and prolonged second stage (662.20-662.23). Cases of non-reassuring fetal heart rhythm (NRFHR) were also queried for use as a control. A comparison of incidence and cost was completed across both DRGs, with major takeaways reported in the following section.

Results

Incidence

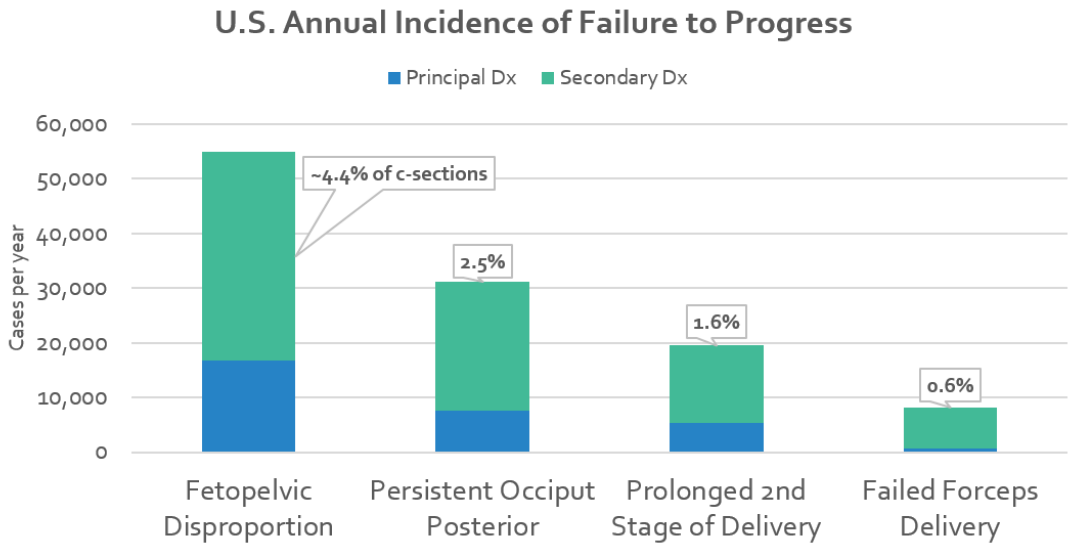


Figure 3: U.S. annual incidence of failure to progress by associated ICD-9 codes.

We determined the incidence of four ICD-9 codes determined to be closely associated with fetal head impaction via literature study. The incidence of CPD was approximately 55K, POCP was 30K, P2S was 20K, and FF was 8K. This represents approximately 4.4%, 2.5%, 1.6%, and 0.6% of all C-sections in the U.S. annually, respectively. Accounting for the potential co-incidence of these problems in a single case, this suggests that one of these four codes occurs in approximately 5% of all C-sections cases in the U.S. annually. This corresponds to approximately 25% of all cases of failure to progress.

Risk Analysis

ICD-9 diagnosis	Risk of complication
CPD	33%
POCP	37%
FF	42%
P2S	43%
NFHR	47%

Table 1: Risk of complication by individual ICD-9 diagnosis.

In order to determine relative risk of C-section resulting in complication, all patient cases of FTP were first categorized by ICD of interest (CPD, POCP, FF, P2S, and NRFHR). Subsequently, each category was divided by DRG, to assess for the number of cases that resulted in C-section without complication (DRG 766) and C-section with complication (DRG 765). As shown in the table above, of all cases of CPD, 33% resulted in complicated C-section. Of causes of FTP, prolonged 2nd stage appears to confer the highest risk, at 43% resulting in complicated C-section.

Charges & Costs

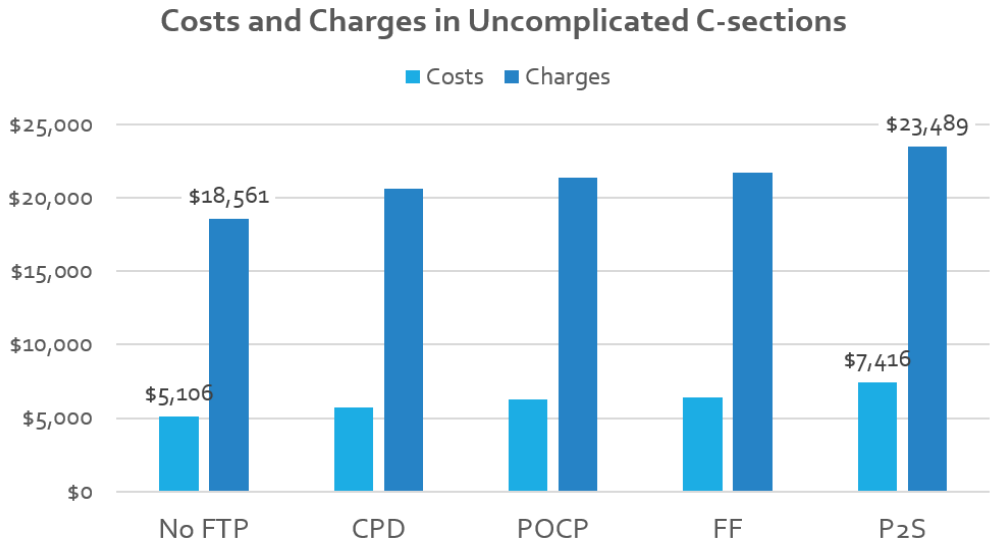


Figure 4: Hospital costs and charges associated with ICD-9 codes of interest in uncomplicated C-section.

In uncomplicated cases without failure to progress (collectively referring to CPD, POCP, FF, and P2S here), the total hospital charges and costs were lower than in cases with FTP. As represented above, within this subset, CPD cases had the lowest total charges and costs, and P2S had the highest total charges and costs. P2S, the most expensive FTP scenario in uncomplicated C-section, had an average of 27% higher hospital charges, and 45% higher costs than uncomplicated cases without FTP.

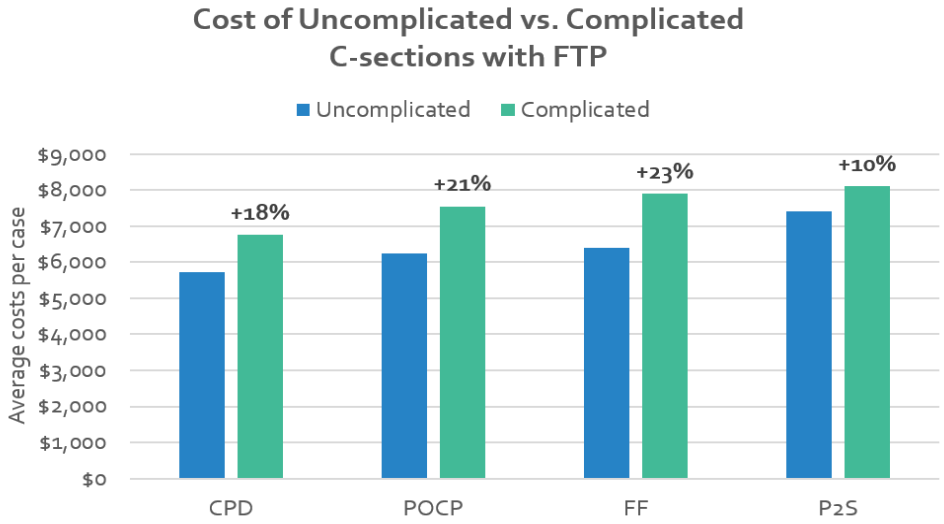


Figure 5: Hospital costs of uncomplicated versus complicated C-sections with failure to progress by associated ICD-9 code.

A cost comparison between uncomplicated and complicated cases of FTP shows that, not surprisingly, complicated cases have higher costs. However, in complicated cases of FTP, FF cases have the greatest increase in cost, with a 23% increase. Complicated cases of POCP have a 21% increase, CPD an 18% increase, and P2S only a 10% increase.

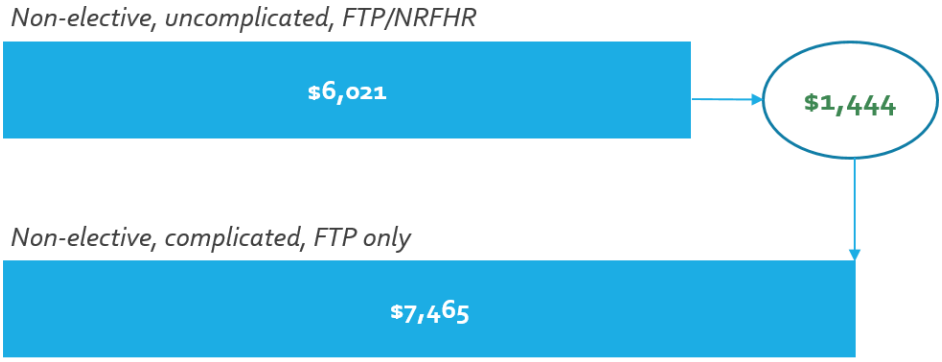


Figure 6: Cost difference in non-elective C-section with failure to progress, with and without complications.

Examining cost at a high-level, non-elective c-sections with FTP/NRFHR that result in uncomplicated C-section cost ~$6K as shown above. On the other hand, the same case scenario resulting in a complicated c-section costs ~$7.5K. Given these two scenarios, the added cost of complication in a C-section with FTP is ~$1,400. This cost differential does not however account for increased time and burden for physicians and the hospital, cost of subsequent morbidity for mother and baby, and changes to quality of life.

CHAPTER 3: SOLUTION DEVELOPMENT

Hypothesis

Literature review and interviews with practicing obstetricians suggested that the delayed disimpaction of the fetal head and the high pressures of manual disimpaction were the key drivers of increased mortality and morbidity in fetal head impaction. [15] As such, we hypothesized that a rapid, lower pressure disimpaction would be most able to reduce complications in impaction. We further hypothesized that this could be achieved via an inflatable transvaginal bladder, providing an increased contact area compared to an obstetrician's fingertips while maintaining sufficient disimpaction force. Figure 7 summarizes the relationship between pressure, force, and surface area.

$$\downarrow Pressure = \frac{Force}{\uparrow Surface\ Area}$$

Figure 7: Relationship between pressure, force, and surface area.

Proposed Solution

The Safe-C Pump is envisioned as a fetal head disimpaction device that uses a specially shaped balloon to gently dislodge the baby's head during a cesarean. It consists of three basic functional units: 1) a soft balloon or bladder on an adjustable stalk, 2) a plate to stabilize the device against the mother, and 3) an inflation control mechanism built into the handle (see Video 1 or Figure 8). In use, the deflated balloon is inserted into the vaginal canal, and a quick adjustment of the stalk allows the device to accommodate any mother and any delivery by bringing the deflated balloon against the baby's head. While holding the device against the mother, the operator inflates the balloon, allowing the pressure to gently lift the baby's head back into the uterus (see Video 2). This allows the cesarean delivery to be completed in just a few seconds.

This design is intentionally simple in its construction and operation in order to make it appropriate for use in an emergency C-section, as well as appropriate for potential use in low

resource settings (in which cost, complexity, and robustness are primary concerns).

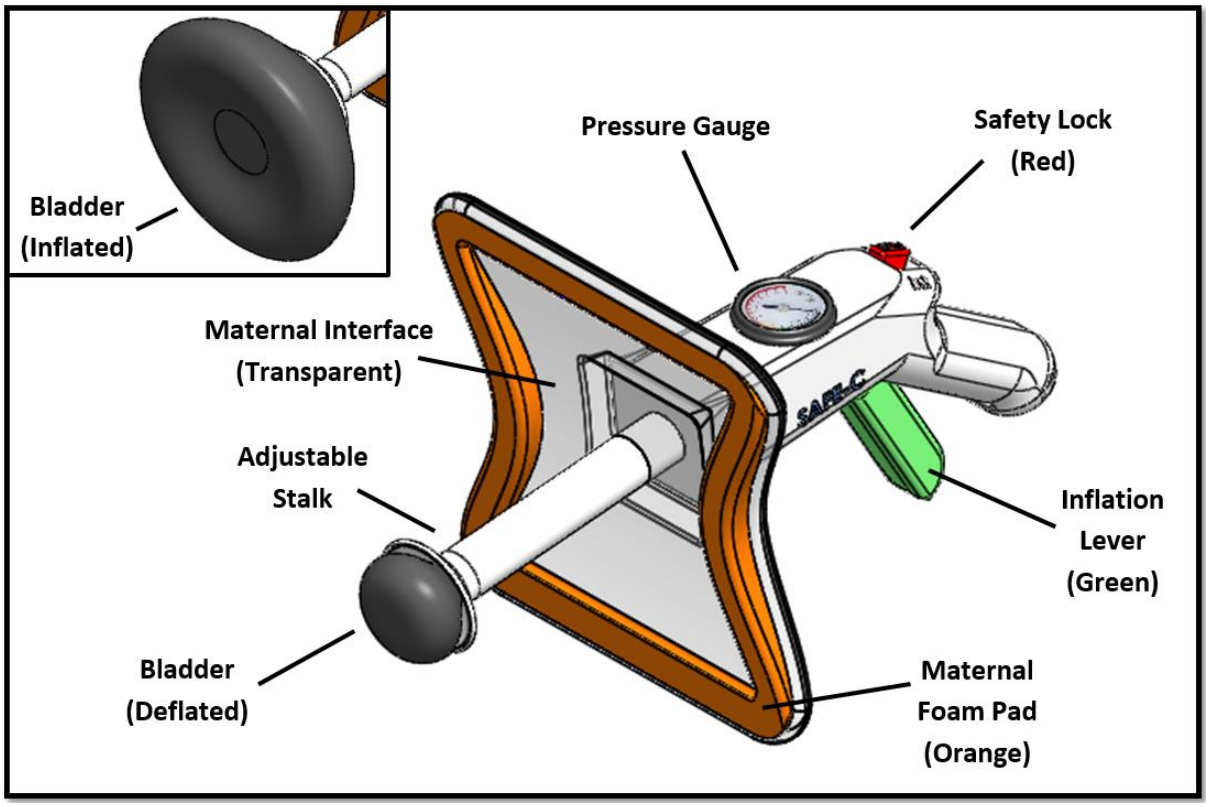


Figure 8: CAD model of envisioned Safe-C Pump.

Methods

Prototyping

An initial prototype of a transvaginal inflatable bladder was created using components of consumer goods (i.e. plastic molding from a margarita glass, the rubber bladder of a soccer ball, and the pump and pressure gauge from a sphygmomanometer; see Figure 9). This was tested on a wooden impaction model to demonstrate a primitive

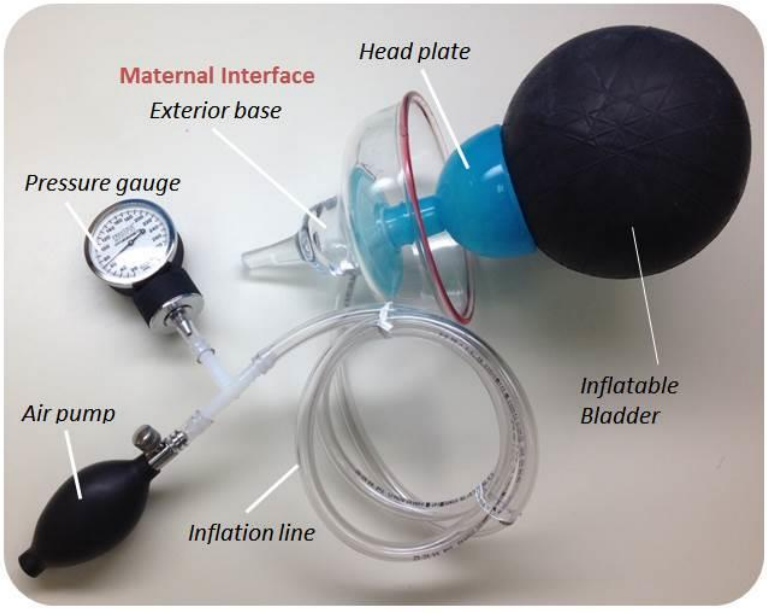


Figure 9: Initial Safe-C Pump Prototype.

proof-of-principle (see Video 3).

Encouraged by these results, we obtained a fetal head impaction simulator (the Adam,Rouilly AR58 Desperate Debra, Figure 12), and we created a revised prototype with input from practicing obstetricians and testing on the simulator. A number of possible materials, (including silicone, Mylar, PVC sheet, and latex) and shapes (such as pyramidal, conical, or round) for the bladder were investigated before settling on a multilayered, round, latex bladder. A hard plastic introducer directs the bladder into the birth canal and allows for manual bladder positioning. A flexible tubing connects the bladder to a hand pump via the introducer. A one-way piston hand pump, in the form of a commercial bike pump, was used to inflate the bladder, allowing for rapid inflation and a reusable design (see Figure 10). Other pump modalities (such as compressed gas, electric, or crank pumps) and inflation fluids (currently room air) have been envisioned as components in a clinic-ready model.

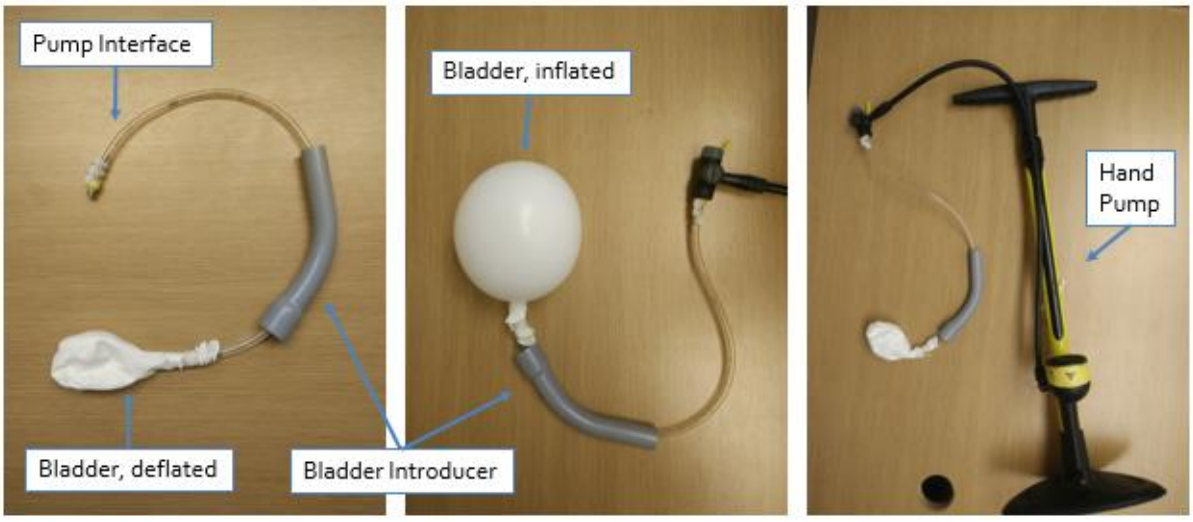


Figure 10: Revised Safe-C Pump prototype.

Finally, a computer-aided design (CAD) model was produced in SolidWorks CAD in order to illustrate the likely form and functions of a production device. Additional features include the incorporation of a hand pump within the device itself (allowing for one-handed operation), an integral pressure gauge and regulator, a transparent patient interface to allow visualization of the impaction, deployable sensors to monitor fetal orientation and wellbeing, and a bladder shaped to cup and guide the fetal head most quickly out of the cesarean incision. Figure 8 includes images of the one embodiment of the device, while Video 1 gives a

360-degree view. Alternative embodiments would be tailored to the environments in which the Safe-C Pump is to be deployed, allowing for sterile single-use portions of the device with a reusable base or adding or eliminating particular features.

Pressure

The comparison of applied pressure of the Safe-C Pump versus the current standard of care was obtained by first estimating the forces involved in disimpaction by an obstetrician's vaginal hand. A simulated fetal head was affixed to a modified postage scale (see Figure 11); UTSW obstetricians were then asked to simulate their "push" technique and typical disimpaction force upon the simulated head as forces were recorded. The contact area of four fingertips of an 80kg adult male was then measured and used with the average recorded force to estimate a manual disimpaction pressures.

Figure 11: Disimpaction force testing apparatus.

Next, pressure sensitive film (Tekscan PIF4LW Extreme Low pressure indicating film), selected on the basis of this estimate, was affixed to a wall. The Safe-C Pump prototype was inflated against the film and held steady for one minute; three- and four-fingertip manual disimpaction was simulated against an unexposed portion of the film and maintained for the same period of time. The film was allowed to develop and was then digitally scanned. Color area and degree of color change were each measured, corresponding to contact surface area and applied force, respectively. From this we obtained a comparison of applied pressure for a simulated Safe-C versus manual disimpaction.

Disimpaction Speed

Speed of disimpaction of Safe-C versus manual disimpaction was obtained using a small sample of UTSW Ob/Gyn residents (each a PGY1-4). Each clinician was allowed to familiarize themselves with the "Desperate Debra" simulator and practice disimpaction on the simulator's green, or "easy," impaction setting. Each clinician was timed for each of 3 individual attempts on the green ("easy"), yellow ("moderate"), and red ("difficult") impaction settings (see Figure 12). The impacted head was lubricated and reset into right occiput posterior position within the model pelvis between each attempt. Upon an unsuccessful attempt or one requiring greater than 1 minute to disimpact, the clinician's next attempts would be on the next easiest setting. The disimpaction testing was then repeated with the prototype Safe-C Pump, operated by a medical student volunteer. Testing proceeded from PGY4 to PGY1, with colleagues available to offer instruction on manual disimpaction.

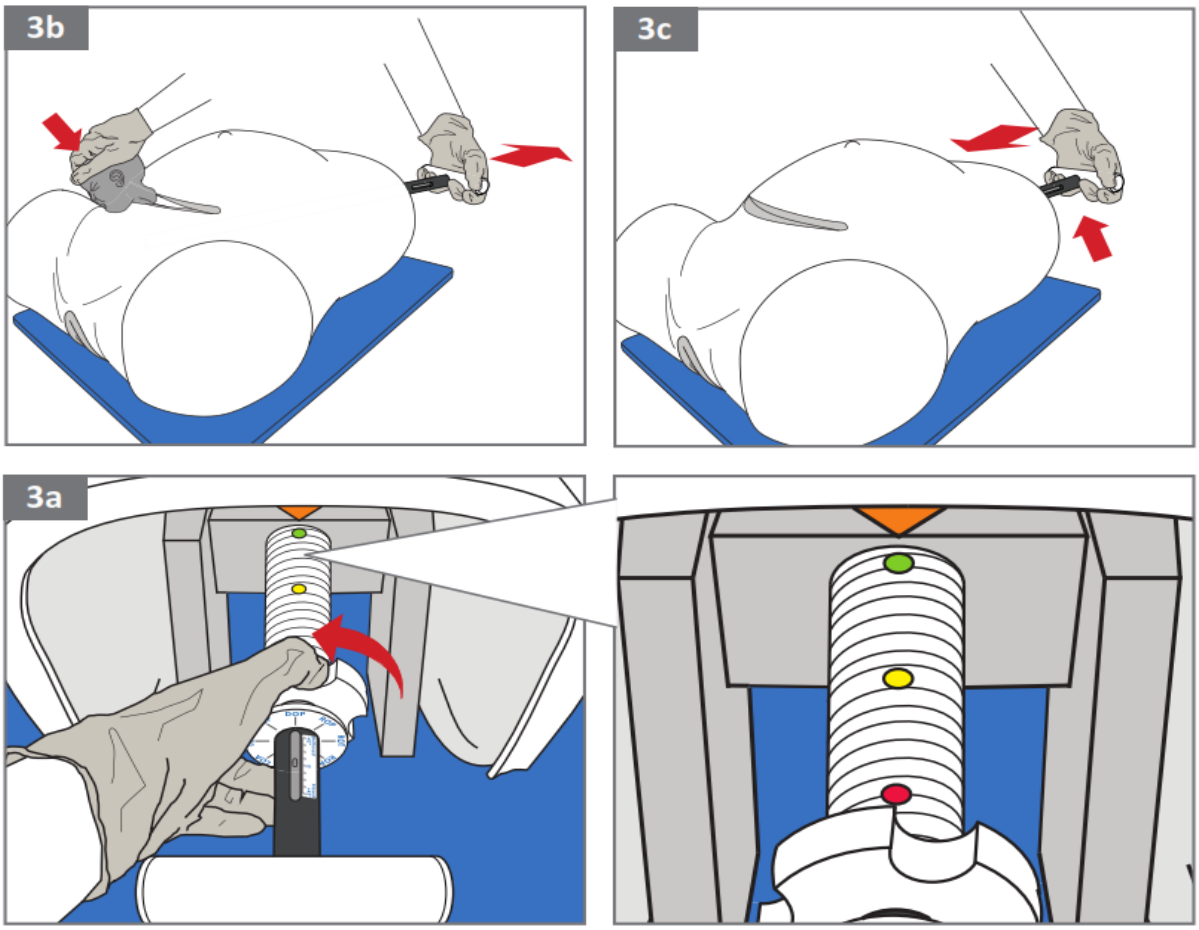


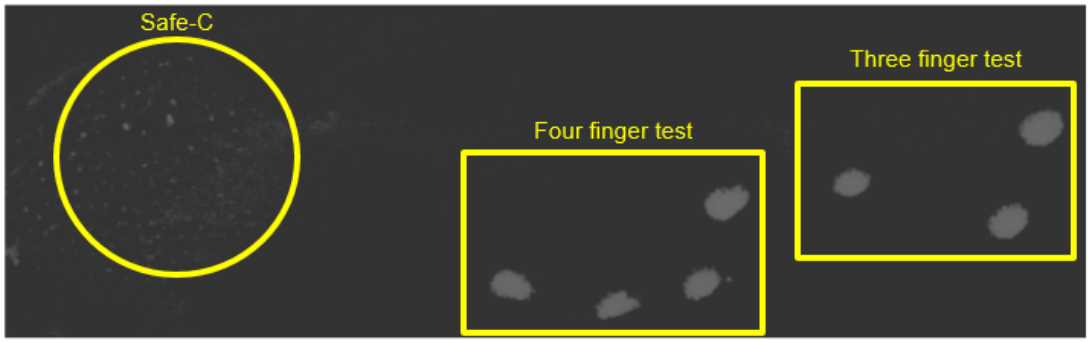
Figure 12: Desperate Debra fetal head impaction simulator with difficulty settings. From Adam,Rouilly AR58 Desperate Debra Manual.

Results

Pressure

In simulating the required force used by faculty obstetricians in disimpaction, we found that the average to be approximately 21.6 lbs. (range 19-24, n=4) of force using one hand unsupported. When allowed to gain leverage by holding onto a fixed object with his other hand, one faculty member generated as much as 45 lbs. of force. In interviews with faculty members, more than one pointed out that they simply try to exert as much force as they are physically able. Using an estimated 22 lhs of force over an approximately 2 sq. inch surface area, we estimated that clinicians generated about 11 PSI or 568 mmHg of pressure.

When comparison of manual versus Safe-C disimpaction force was obtained by use of the pressure film, a 19-fold decrease in pressure was found with the Safe-C device as compared to a three finger disimpaction. Full results are summarized in Table YY.



	Safe-C	Four finger test	Three finger test
Area (cm^2)	87.5	9.6	5.5
Force (lbs.)	40.5	48	63
Pressure (PSI)	0.46	6.6	8.7

Table 2: Comparison of applied forces by Safe-C Pump and three or four-finger manual disimpaction by use of pressure-sensitive, color-changing film.

Disimpaction Speed

Manual disimpaction of the "Desperate Debra" demonstrated difficulty in settings greater than "easy" and outright failure for the "difficult" impaction setting. There was an inverse proportionality between clinician experience and disimpaction speed, suggesting that manual

disimpaction is experience and technique-dependent. Use of the Safe-C device allowed for speedy disimpaction at all difficulty settings, even when used by an operator with limited experience.

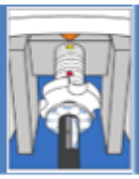
Average of 3 Trials	Easy 	Medium 	Difficult 
R1	45.4 sec	failed	failed
R2	18.1 sec	> 1 min	failed
R3	11.5 sec	> 1 min	failed
R4	9.6 sec	> 1 min	failed
Safe-C	5.9 sec	6.8 sec	8.0 sec

Table 3: Comparison of disimpaction speed between manual disimpaction by Ob/Gyn residents and Safe-C Pump on various simulated impaction difficulties.

Conclusions

Preliminary results of testing on the impaction simulator are promising and suggest that the Safe-C Pump might be able to offer a faster, safer, and less operator-dependent means for cesarean delivery in fetal head impaction. Disimpaction speed testing should be repeated with a larger sample of trainees and experienced obstetricians, and perhaps in pairs of obstetricians to better duplicate clinical practice. The Safe-C Pump could then be deployed as an alternative to the assisting obstetrician, facilitating rather than replacing manual delivery.

Finally, the key question of clinical efficacy remains unproven until the device can be deployed *in vivo*. Due to a lack of animal models for human birth (and specifically head impaction), a possible precursor to a clinical trial could be its use in cases of intrauterine fetal demise with impaction, allowing maternal safety to be established.

CHAPTER 4: BUSINESS ANALYSIS

Market and Customers

C-section delivery is the most common surgical procedure in U.S. hospitals, accounting for 33% of the 4 million births recorded in 2012 (U.S.). C-section rates, up from 21% in 1996, are projected to remain steady, if not rise, and are driven by many factors including labor induction, use of epidurals, and patient health risk factors. [7] Rising rates of C-sections performed at full dilation and/or during the second stage of labor further increase risk of impaction. Fetal head impaction may present in ~25% of C- sections, translating to ~320,000 cases annually in the U.S. [8]

The target customers for the Safe-C Pump are healthcare providers, specifically hospitals which perform Cesarean sections; as of 2013, there were ~5,000 registered community hospitals in the U.S. [9] The initial target segment will include Parkland Hospital (Dallas, TX) as a clinical market study to gain patient and clinician feedback prior to hard launch. Parkland has an annual addressable market of over $60,000 (considering cesarean delivery and fetal head impaction rates). This soft launch phase will culminate our proof of concept phase. Parkland Hospital, a partner of UT Southwestern hospitals, will be recruited to serve as a clinical research development partner in the evaluation of device efficacy against existing methods. The study will focus on ease of use, outcomes, morbidity and mortality, patient satisfaction, and cost efficiency for the hospital.

Financial Analysis

Device Economics

In the broader category of delivery assist devices, several options exist (e.g. forceps, vacuum extractors) that aim to alleviate impaction during vaginal delivery, but their use is declining due to safety and efficacy concerns (from 9.0% to 3.4% between 1990 and 2012). Although vacuum extraction devices also address fetal head impaction, they cannot be used in cesarean section. While they are not directly competing products, a strong parallel can be drawn between the market, target customers, and device economics. Vacuum extractors specifically are used in 8.1% of vaginal deliveries in the U.S., translating to ~215,000 cases

annually. [10] With a price per unit of $20-$40 for disposable vacuum extraction devices, annual revenues are estimated at $6-$9 million accounting for variability in sales mix, with gross margins of 60%. [11]

Initial unit cost will depend heavily on production volume. As such, we will focus on achieving target gross and net margins, taking into account wholesale and lower margin GPO-negotiated (group purchasing organization) contracts, rather than attempting to match retail price of comparable devices. The medical technology industry averages gross margins of ~40%, with the medical equipment sector at ~30%, diagnostic tools closer to 60%, and medical devices approaching 70% gross margins. [12] After considering the need for biocompatible components and the cost of comparable devices, we estimate the final disposable product cost at scale to be $20-40, and accordingly anticipate a retail price of $50-100 per unit. Accordingly, gross margins of 60% would provide ample cash flow for operations and reinvestment into the business, and allow for maintenance of receivables and profit sharing along the distribution chain.

Given an estimated 320,000 annual cases of impacted fetal head during C-section and a retail price of $50- $100, the Safe-C has an annual revenue potential of $16-$32 million. Our initial goal will be Texas market saturation ($2.5MM addressable market). We estimate negligible market penetration in year 1 (strategy including only Parkland Hospital, see above), 5-10% of the Texas addressable market by year 2, and 50% of the Texas addressable market by year 3. We conservatively estimate the Safe-C method to become the standard of care in 8 years at 80% penetration of the total addressable market if pursuing a non-partnering strategy. If successful in obtaining an equity investment or exclusive licensing agreement with an established medical device distribution partner, we anticipate 80% penetration in 5 years.

Beyond improving clinical outcomes, the Safe-C Pump would enable physicians and hospitals to see efficiency gains and more substantial savings from avoided cost of maternal and fetal damage. Vacuum extraction is included in the global reimbursement for labor and delivery by the Centers for Medicare and Medicaid Services (CMS), and additional reimbursement is not applied. Currently, the cost of the Kiwi vacuum is passed on to the patient, and we initially anticipate the same protocol for the Safe-C Pump.

Commercialization Strategy

Initial steps towards commercialization, with the assistance of a regulatory consultant, will be to establish the vacuum extractor (a FDA Class II device) as a predicate device. This will allow us to focus subsequent clinical studies on establishing substantial equivalence and to pursue a premarket notification (510(k)) approval.

After consulting with mentors at the Texas Manufacturing Assistance Center (TMAC) to finalize device design, we will do a short run production for use in a clinical research study. Research efforts will initially be focused on our home institutions, Parkland and UT Southwestern hospitals. We anticipate limited distribution of the device to select hospitals collaborating on research and development to1) gather rapid feedback on efficacy for 510(k) approval, 2) incent adoption of the new technology, and 3) support a more detailed cost-benefit analysis, enabling publication of a clinical study around which end-user awareness can be organized.

To sustain large-scale funding of clinical research and development activities, we aim to pursue a partnering strategy via a comprehensive collaboration agreement with an established medical device company. With an equity investment, a development partner would be able to directly finance ongoing R&D expenses and offer additional expertise in the regulatory process, manufacturing, and commercialization of our technology. After establishing sales in Texas, we aim to focus on reaching top-tier U.S. markets (by volume) through wholesale distribution.

As a contingency strategy, we will identify a full service contract manufacturing partner with order fulfillment capabilities. Once sales have been established in Texas, we will begin seeking exclusive licensing partners with established distribution partners. We have identified a potentially ideal manufacturer/distribution partner, Clinical Innovations, which produces a portfolio of obstetric devices including the Kiwi vacuum.

While device demand will be set at the level of physicians and hospitals, Group Purchasing Organizations (GPOs) and other distribution channels will largely determine access to demand. Since our device serves a niche market, establishing a relationship with

GPOs should be relatively less problematic, given that the Safe-C Pump would not be competing directly with or replacing a device in their portfolio. Though margins may be lower for GPO-negotiated contracts, distribution through GPOs will be the most effective way to achieve rapid market penetration and recurring, high-volume orders. As detailed in the *Device Economics* section of the proposal, we will ensure target gross and net margins are maintained despite discount sales.

Envisioned Impact

Impacted fetal head presents a considerable mortality and morbidity burden in both high and low resource settings. We believe that our device will help reduce incidence of adverse outcomes, improving obstetric practice in the developed world. In the developing world, the Safe-C truly has an opportunity to shine. Maternal and fetal mortality during childbirth due to labor complications represents a development barrier to these countries that is almost inestimable in productivity and life lost. [2] Our device will provide a safe, simple, and effective way to reverse impaction, ultimately improving maternal and fetal survival rates.

Next Steps

Next steps in this project include necessary steps for continued product development, demonstration of clinical efficacy, and securing partnerships for distribution and use. Device iterations are planned to meet the unique needs of developed and developing world markets, including fully reusable models vs razor-blade partially reusable versions. These designs will continue to be refined with clinician feedback as testing continues. Testing will necessarily advance beyond device use on a simulator, and we will work with our clinical mentors to design satisfactory trials for eventual first-in-woman use to establish clinical efficacy.

To this end, further grant funding (from such organizations as Savings Lives At Birth), business plan competitions, and private investors will enable us to support and run such a trial as well as fund clinic-ready device development and production. Intellectual property is key to attracting such investment, and a provision patent has been filed with a full U.S. utility patent filing planned this Spring. We hope that this project continues to be an incredible vehicle for our education and that the Safe-C Pump will one day be of benefit to our patients.

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ACKNOWLEDGEMENTS

Safe-C Team

- *Anupama Atluru*
- *Daniel Walk*
- *Adam Harris*
- *Elizabeth Carstens*
- *Sandeep Ganji, PhD*

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- *UT Southwestern Department of OB/GYN*
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- *UT Southwestern Office of Global Health*
- *VentureWell*

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VITAE

Anupama studied Business Honors, Finance, and pre-med at the University of Texas at Austin while applying her penchant for problem-solving to help cultural, service, and leadership organizations broaden their reach and impact. After graduation, Anu worked as a management consultant to help leading companies primarily in the technology and telecommunications industries to solve complex strategic problems, with a focus on corporate and competitive strategy and product / services pricing, distribution, and lifecycle management. Anu has worked to impart innovation as a mindset to students and to advance the platform for healthcare innovation for rising physicians. She will soon begin her residency in emergency medicine at Massachusetts General Hospital.

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