Design Input Report

Device for the Controlled Reduction of Pediatric Intussusception

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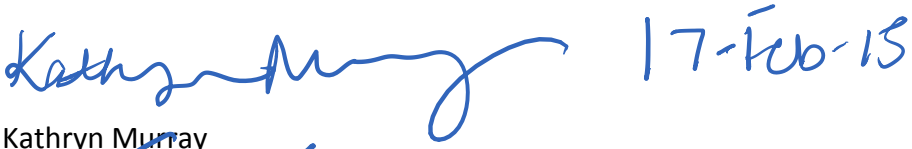

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Executive Summary

The goal of this project is to improve the procedure for reducing an intussusception, a condition where a portion of the bowel folds over itself, causing luminal as well as blood flow obstruction. Currently reduction is performed using a hand aneroid and an enema tip. The hand aneroid provides very little control over pressure, with pressure swings approaching 100 mmHg in under 1 second. In addition, there is a faulty seal between the enema tip and the child's anus, preventing a proper amount of air pressure from being maintained, forcing the radiologist to continually pressurize the bowel using the hand aneroid, and leading to physician fatigue. Furthermore, the nurse must attempt to maintain the seal by continuously squeezing the buttocks of the child together, giving rise to nurse fatigue. In moving towards designing a new device to improve upon and replace the current intussusception device, it has been necessary to evaluate the needs of the users and convert them into more objective metrics. These metrics will allow concepts and prototypes to be evaluated and selected. To form the basis of these metrics, the user needs were consolidated into five categories: pressure regulation, child-device interface, hands-off/ease of use, safety, and other. The specific metrics were taken from ISO specifications, ANSI specifications, FDA guidances, user interviews, and a review of the literature. A summary of the complete user needs and design inputs can be seen in the spreadsheet available on page 15 of this report.

Project Description

Problem Statement

Intussusception is a condition characterized by the invagination of one segment of the intestine into an adjacent segment, which typically presents in infants and toddlers between the ages of 6 months to 2 years. The first line of treatment for this condition is usually pneumatic reduction, in which the bowel obstruction is physically pushed back by pressurizing the intestine with air. This physically-demanding procedure requires the pediatric radiologist and assisting nurses to maintain pressure within the patient's bowel by manually pumping air into the intestine and holding the buttocks to create a tight seal for an extended amount of time. The multiple periods of physical exertion often lead to arm muscle fatigue in both physicians and their assistants, requiring these users to rotate positions through reduction attempts. In addition to experiencing physical exhaustion, the pediatric radiologists are constantly splitting their attention between multiple sources of information in the procedure room, including the fluoroscopy screen, the pressure gauge, the tubing from the pump, and the patient's physical cues. Overall, the quantity and physical nature of the tasks required to achieve a successful reduction create a chaotic and overwhelming environment prone to both error and stress. Based on this assessment, it is evident that any future solutions targeting this condition must focus on reducing the number of tasks the radiologist and nurses must perform as well as the physical exertion demanded by each task, since these factors might compromise the success of the reduction or the determination of bowel perforation.

Statement of Purpose

The primary goals of this project are to increase the automation within the procedure and to improve the patient-system interface as to reduce air leakage. These two improvements serve a dual purpose. By automating the pumping procedure and reducing leakage, the air will be delivered in a more controlled manner, allowing for greater pressure control and reducing a potential source of error. Additionally, these improvements will significantly reduce the amount of work required from the pediatric radiologists and the nurses, enabling them to be more

focused on the primary task. Thus, these modifications will result in a more controlled and efficient procedure benefiting the patients, radiologists, and nurses.

Functional Analysis

Before reduction is attempted, diagnosis must occur. Unless the patient fits certain exclusion criteria (such as perforation and ischemia), pneumatic reduction will be attempted. The patient will be placed on the fluoroscopy table, under a continuously imaging X-ray machine (Figure 1). An enema tip connected to a long tube is inserted into the patient's anus using the appropriately sized tip and is secured using tape before being connected to the air pumping device. The infant is then held down by a nurse, technician or parent while the pediatric radiologist continually squeezes and releases the hand aneroid pump to force air into the anus and attempt to maintain a pressure of 120 mmHg as measured by the gauge on the hand aneroid. The reduction attempt will continue for at least three minutes unless reduction is observed on the fluoroscopy screen. If air leakage occurs, the buttocks are held by another assistant to ensure a tighter seal. If a sudden pressure drop is observed on the pressure gauge, the physician will check for a sign of perforation or reduction on the fluoroscopy screen. If perforation has occurred, the patient will be rushed to surgery, and if reduction has occurred, the procedure will end. Otherwise, the reduction attempt will continue for at least three minutes. Reduction will be attempted at least three times before the procedure is deemed unsuccessful and the patient is recommended for surgery.

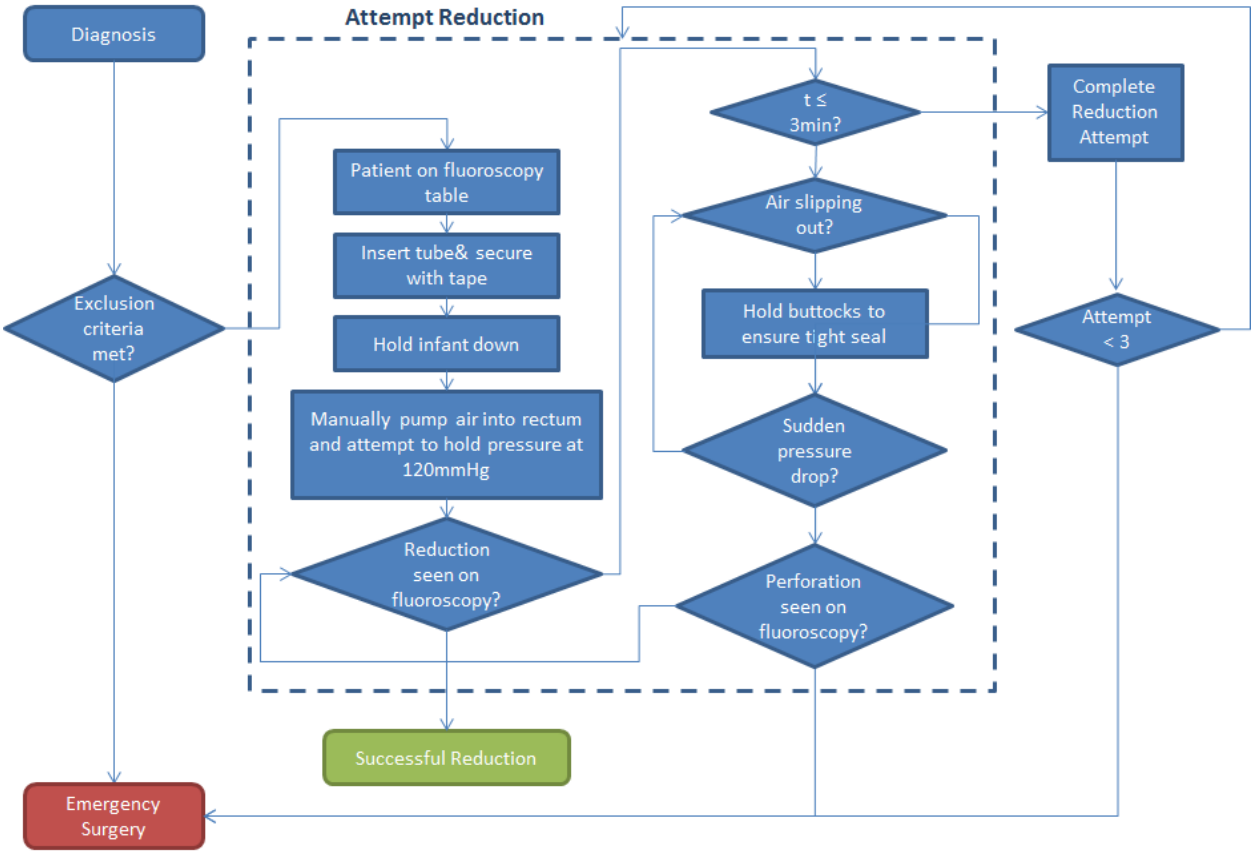


Figure 1. Functional analysis of the pneumatic reduction procedure. To achieve a successful reduction, pressure must be maintained at or near 120 mmHg during three 3-minute attempts or until reduction is observed on the fluoroscopy screen without inducing perforation.

External Device Interfaces

The predicate device itself is composed of a hand aneroid that interfaces with an enema tip. This interface between device parts can be achieved via a Luer lock adapter. Although the current device used for reduction does not interface with external objects, a device which utilizes air to pressurize the bowel could be designed to interface with the hospital air supply. Additionally, if the proposed device relied on electrical power, it must be able to interface with the standard 120 V power supply.

Value Statement

The proposed project will decrease the amount of physical exertion associated with the procedure while increasing the amount of control within it. This will make the procedure easier for the radiologist and the nurse and improve patient outcomes.

Users

The primary users are the physician and nurses. Secondary users are the patient and the patient's parents. The physician is responsible for directing the procedure, operating and monitoring the fluoroscopy equipment, and insufflating the intestine with air using the hand aneroid. The nurse is responsible for maintaining the seal between the patient's buttocks and the enema tip. The patient endures the procedure and suffers the consequences, while the parents are generally observing.

Operating Environment

The intussusception reduction procedure is performed in a fluoroscopy room, shown in Figure 2, where five to six people are present. The fluoroscopy machine blocks the radiologist from viewing the patient leaving only the two nurses, one on the fluoroscopy table top and one at the head of the table, to physically interact with the child. An additional one to two nurses are positioned around the room to assist the head physician, to rotate with the nurses at the child's feet and head, or to provide emotional support to the parents as needed.

Figure 2. Fluoroscopy room where pneumatic reduction is usually performed.

Market Information

The global incidence of intussusception is 74 cases per 100,000 children under 1 year of age (Jiang, 2013). The U.S. incidence of this condition is 30-60 per 100,000 infants (Jiang, 2013). This incidence rate merits the presence of reduction devices in every pediatric hospital, with most pediatric radiology wards possessing at least 2+ devices. The Shiels Device (shown in Figure 3a) consists of a hand aneroid pump, a pressure gauge, and an enema tip. The Shiels Device is only sold as such through GRI Medical and the bulb and gauge currently sells for approximately $200. The disposable portion of the device (the enema tip) is sold in bulk and currently sells for $225 per 10 units. Alternatively, the hand aneroids (one in Figure 3b) sold commercially to as part of blood pressure cuffs can be used instead. There are many variations in terms of the method of air delivery and depending on the degree of automation and overall quality of the product, the prices can range between $100 and 300 (Welch Allyn, 2015). Lastly, a group of researchers in India designed an air insufflation device for the reduction of intussusception (Figure 3c) that incorporates various features (Thomas, 2008). It is portable, relying on a rechargeable battery to pump air, has a release valve to relieve the excess pressure, and incorporates a pressure drop alarm to notify the users of a systematic leak. Based on these market considerations, it has been determined that the target price should be less than 350 USD for the capital item and between 20 and 30 USD for the enema tip.

Figure 3. Competitive devices and prior art. (a) A sketch from the patent for the Shiels Device, (b) a picture of the hang aneroid used by the pediatric radiologists at Children's Healthcare of Atlanta at Scottish Rite, and (c) a picture of the Thomas, et al. air insufflation device.

Potential FDA Product Classification and Regulatory Pathway

Throughout the process of reduction, two main parts of one system are used. The enema tip and tubing used to connect to the other part is considered an enema kit by the FDA. This is a Class I medical device and is exempt from the premarket notification procedures. By definition, the enema kit does not include a colonic irrigation system (FDA 876.5220).

The second part of the reduction device may be considered similar to a colonic irrigation system, which controls the pressure, temperature, or flow of water into the rectum in order to cleanse the lower colon. This also includes the fittings to connect to a water source and the ability to use electrical power (FDA 876.5210). As used for colon cleansing by medical professionals, a colonic irrigation system is a Class II medical device.

For optimal marketing and regulatory pathways, it is favorable to consider two separate FDA approvals for the two parts of the device, one for the enema tip and child interface and a second for the pressure controls system.

Design Inputs

Initial requirements established for an improved intussusception device revolve around the user's need for more control during the procedure. Pressure fluctuations, sources of air leakage, and a physically demanding environment created by the current procedure result in a lack of control and standardized settings. The proposed design inputs originate from these user needs and will be included throughout the conceptualization phase to ensure the final design solution incorporates all user needs. These needs fall under several broad categories which include pressure regulation, child-device interface, ease-of-use, and safety. The most critical of these metrics are described below sorted by the categories in which they fall. The complete listing of metrics are available on page 15 of this report.

Pressure Regulation

Pressure generation range: The device must be capable of generating between a pressure of 20 mmHg and 240 mmHg within the intestine. This is based on the standard procedure for using the Shiels reduction device, which calls for pressure generation between 40 mmHg and 120

mmHg, with a safety factor of 2 on both ends. The device will be analyzed for functional capability prior to fabrication and will be tested with a pressure gauge post construction.

Pressure delivery error: Fluctuations in pressure created with the current reduction procedure present a large problem when attempting to standardize this procedure and provide consistent, predictable outcomes for patients. After observing the reduction procedure at Scottish Rite Childrens' Hospital, it became clear how difficult it is to maintain a consistent pressure, with the hand aneroid used by the radiologist often measuring fluctuations in pressure of exceeding 100 mmHg. After speaking with radiologists, a pressure regulation error of ± 10 mmHg has been established as an acceptable range for this metric.

Pressure cutoff: The device must have a pressure cut off mechanism independent of all other components within the device. In the event that the system delivers more than 500 mmHg to the child, this device must equalize the device and child to external atmospheric pressure. Within current procedure, the pressure jumps as high as 260 mmHg during certain parts of the procedure; because it is not desirable for the pressure to be released unless the system has failed, the failure response point is set far above the expected operating pressure. This will be tested by intentionally inducing failure within the system, leading to an overpressure situation.

Child-Device Interface

Pressure retention in intestine: Retaining pressure in the intestine is critical for providing an uninterrupted pressure to the occluded portion of the bowel. For this, a sufficient seal must be created at the interface between the child and the device. The current approach of using an enema tip sized to the child is ineffective because the compliance of the anus changes after insertion and because the patient's anus relaxes over time. To ensure the proposed solution creates a sufficient seal, it will be tested in a test bed anus to ensure the device can seal to a pressure of 140 mmHg, 20 mmHg above the intended value.

Enema tip slip-out pressure: The enema tip must be able to withstand a certain pressure before slipping out of the anus and relieving the remaining pressure in the intestine. Having a consistent slip out pressure will allow radiologists to understand the limitations of the child-device interface and will provide an additional safety factor in the event of large, unanticipated

increases in pressure. The designated slip-out pressure is set at 500 mmHg to ensure the functional pressure range needed is well below the pressure at which the interface with the child fails.

Enema tip size: The size of the enema tip must be adjustable or have multiple configurations such that it can fit the full range of pediatric anus sizes. This requires a minimum of 24 and 40 French sizes, which are offered by the existing device.

Enema tip insertion length: The predicate enema tip is generally inserted up to 3 in into the patient's anus in order to properly deliver air to the intestines. The new device must be able to achieve this minimum insertion length through demonstration in a test bed anus that will be developed for multiple verification scenarios.

Ease-of-Use

Storage and portability: Because of the overwhelming and crowded nature of the operating environment, the device must not occupy more space than the predicate device's case (11in x 9in x 4in). Additionally, it must not burden the physicians, nurses or other staff who may be involved in moving the device. Thus, the device must not exceed 10lbs, roughly the same weight of a newborn infant, which most healthcare staff are comfortable carrying.

Compatibility with non-specified tips: The device must be compatible with other tips which are not specified for the device, radiologists currently use a variety of Foley catheters and other enema tips which are not specifically designed for intussusception reduction. In order for a new device to be easily integrated into existing workflows, it must be compatible with these other tips. To achieve this compatibility Luer Lock connectors will be used, as these are a standard connector within medical settings. The connector will be designed to ISO 594 and will be tested and inspected per ISO 594.

Reduction parameters: The device must have an equal or greater rate of reduction as well an equal or lesser average time to reduction when compared to the predicate device. Both of these parameters will be verified by comparing the parameters as outputs of a radiologist using the predicate device and the new device on the same test bed.

Glove compatibility: Because the device is used by a radiologist and nurses who are gloved, the device must be glove compatible. This will be verified by analyzing all components for compatibility with gloves and demonstrating full functionality with gloves.

Interfacing with hospital air source: In order to allow integration into the procedure setting, the device must interface with the hospital air source. This requires being compatible with NPT (ANSI B1.20.1), BPT (ISO 228) and barb fittings (ASME B16). This will be tested to the respective fitting specifications.

Status indicator: The design solution must incorporate a status indicator that can be read from a minimum of six feet away [IEC 60601-1-6 (usability of medical electrical equipment); ISO 9241 (ergonomics of human-system interaction)]. To ensure we have met these standards, we will conduct a survey amongst users to ensure the proposed solution better indicates status in comparison to the predicate device.

Safety

Device health indications: The design solution must include indications for device health to ensure the device is only used when fully functional and calibrated. Because the radiologist and nurse must focus on other tasks during the procedure, it becomes critical that the proposed design is able to assess its own ability to function and relay that information to the user. To establish that this design input has been met, system simulations will be conducted to ensure appropriate notification is delivered to the user if the system becomes dysfunctional.

Parameter indications: The design solution must incorporate indications that provide proper direction and instruction for understanding the parameters used by the device (pressure, leakage, time, on vs. off). User trials will be used to ensure the radiologist and nurse can follow device indications to accurately assess the system's parameters.

Emergency stop: It is necessary for the device to have an emergency stop button which will deactivate the device per industry standards (ISO 13850) and equalize the pressure between the intestine and exterior. This will be tested to comply with ISO 13850.

Aseptic catheter and enema tip: In order to be safe for insertion into the anus the enema tip and tube must be clean and aseptic. This will be performed per ISO 13408, which provides guidance on aseptic processing of healthcare devices. The device will be tested for bioburden and inspected for cleanliness.

Patient fluid backflow: In order to prevent cross contamination between uses of the device it is necessary for there to be no backflow from the child into the device. This will be verified by testing that no colored fluid, both liquid and vapor passes into the device at 500 mmHg (the maximum pressure which will exist). The device must meet or exceed some basic parameters of measuring success when compared to the existing device.

Biocompatibility: Because the enema tip will be coming into contact with the body of the child, it is important for it to be biocompatible. This will be achieved and verified by using materials which are either ISO 10993 or USP class VI certified.

Cleanability: In order to preserve cleanliness between operations, it is necessary for the device to be capable of being washed down. This capability will be verified by marking and contaminating the device exterior, cleaning the device, and verifying that there has been no damage to the device, no entrance of fluid, and no remaining bioburden or marking.

Perforation rate: The proposed device must have an equal or lesser rate of perforation compared to the predicate device. This parameter will be verified by comparing the parameter as an output of a radiologist using the predicate device and new device on the same test bed.

Project Deliverables

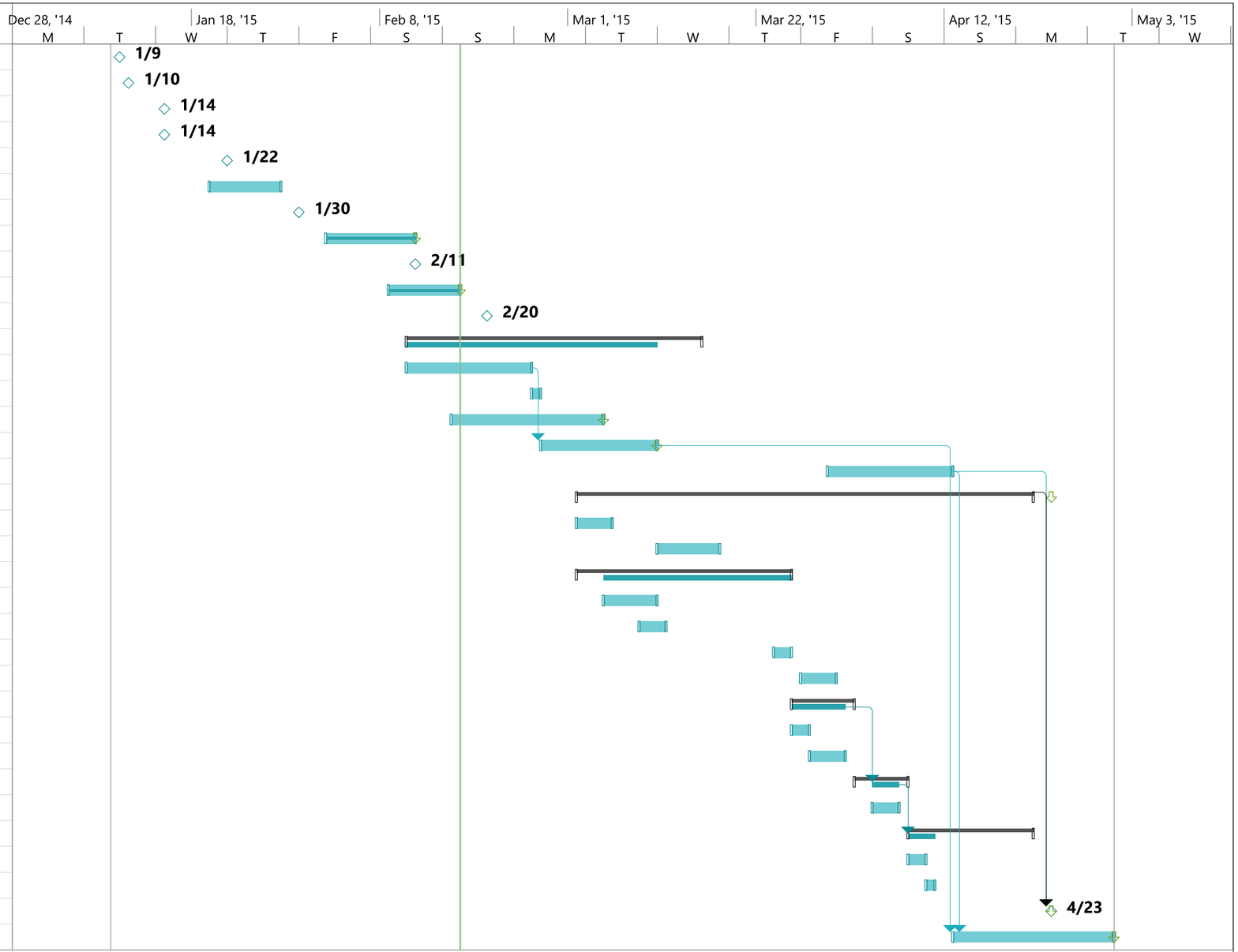
The upcoming milestones for the intussusception reduction device project is for group members to begin drawing and developing their design concepts followed by a group brainstorming meeting to discuss concepts. This will lead into the concepts and prior art presentation and paper due March 4th and March 10th. Following the designs concepts, prototyping will begin with filtering the concepts, CAD drawings, designing the test bed, and ordering necessary materials. Finally, the Design Expo is scheduled for March 23rd where the

poster and final functional prototype will be presented. A complete Gantt chart detailing the timeline is available on page 14 of this report.

In testing the device for the controlled reduction of pediatric intussusception, a test bed will be created to hold a porcine intestine that is expected to be available. The Shiels device will be directly compared against the controlled reduction device. In order to test the interface between the device and the anus, it will be necessary to build or purchase a device which can simulate a child's anus. It is possible that these two test beds will be combined into one.

Once the test equipment is constructed, prototypes will be tested on the test beds. Once a prototype proves viability, tests will be performed by a trained radiologist to aide in assessing the quality of the design.

ID	Task Name	Start	Finish
4	250 word summary	Fri 1/9/15	Fri 1/9/15
5	Project List	Sat 1/10/15	Sat 1/10/15
6	Team Composition	Wed 1/14/15	Wed 1/14/15
7	Team Contract	Wed 1/14/15	Wed 1/14/15
33	Scottish Rite visit	Thu 1/22/15	Thu 1/22/15
8	Project Charter	Tue 1/20/15	Tue 1/27/15
32	Scottish Rite visit 2	Fri 1/30/15	Fri 1/30/15
25	Formal Design Inputs Presentation	Mon 2/2/15	Wed 2/11/15
34	Intussusception case	Wed 2/11/15	Wed 2/11/15
3	Design Inputs Report	Mon 2/9/15	Mon 2/16/15
35	Egleston visit	Fri 2/20/15	Fri 2/20/15
26	**Design Concepts**	**Wed 2/11/15**	**Sun 3/15/15**
28	Individual concept creation	Wed 2/11/15	Tue 2/24/15
27	Brainstorming session	Wed 2/25/15	Wed 2/25/15
30	Concepts and Prior Art Presentation	Mon 2/16/15	Wed 3/4/15
29	Prior Art Report	Thu 2/26/15	Tue 3/10/15
1	Poster	Mon 3/30/15	Sun 4/12/15
9	**Prototyping**	**Mon 3/2/15**	**Tue 4/21/15**
10	Filter concepts	Mon 3/2/15	Thu 3/5/15
11	Design test bed	Wed 3/11/15	Tue 3/17/15
21	**Prototype 1**	**Mon 3/2/15**	**Wed 3/25/15**
24	CAD development	Thu 3/5/15	Tue 3/10/15
22	Order necessary controls equipment	Mon 3/9/15	Wed 3/11/15
23	3D print model for fit	Tue 3/24/15	Wed 3/25/15
14	Test prototype 1 in test bed	Fri 3/27/15	Mon 3/30/15
15	**Prototype 2**	**Thu 3/26/15**	**Wed 4/1/15**
17	Test prototype 1 in test bed	Thu 3/26/15	Fri 3/27/15
16	Redesign	Sat 3/28/15	Tue 3/31/15
12	**Prototype 3**	**Thu 4/2/15**	**Tue 4/7/15**
13	Test prototype 2 in test bed	Sat 4/4/15	Mon 4/6/15
18	**Prototype 4 - Functional**	**Wed 4/8/15**	**Tue 4/21/15**
20	Test prototype 3 in test bed	Wed 4/8/15	Thu 4/9/15
19	Radiologist prototype test	Fri 4/10/15	Fri 4/10/15
31	Design Expo	Thu 4/23/15	Thu 4/23/15
2	Final Report and Prototype Materials	Mon 4/13/15	Thu 4/30/15



Project: Semester schedule gan
Date: Tue 2/17/15

Task	Project Summary	Manual Task	Start-only	Deadline
Split	Inactive Task	Duration-only	Finish-only	Progress
Milestone	Inactive Milestone	Manual Summary Rollup	External Tasks	Manual Progress
Summary	Inactive Summary	Manual Summary	External Milestone

Design Inputs Intussusception Reduction Device

	Category	Parameter	Comment	Functional	Performance	Constraint	Physician	Nurse	Patient	Hospital	other	Metric	Critical	Need	Want	Reference	Test	Analysis	Demonstration	Inspection	Verification Description
				Product Requirements			User						Rating				Method of Verification				
A1	Pressure Regulation	pressure generation range	how much pressure do we need to generate in system	■			■		■			[20 mmHg, >=240 mmHg)		■		standard procedure used today goes to 120mmHg, this is double; (Shiels, 1993)	■	■			hook system up to gauge pressure indicator and read max pressure capable of being generated
A2		pressure delivery error	how much fluctuation?		■						■	estimate: +/- 10 mmHg	■			interviews suggest that fluctuations are large (as high as 100 mmHg). We hypothesize that smaller fluctuations will lead to better outcomes. This will require post prototype construction testing	■	■			hook system up to gauge pressure indicator and read error at various pressure settings
A3		pressure cut-off	what causes perforation? mechanical blowout valve; this is the worst case scenario; there should be 2 pressure safety systems in place before this safety feature will be reached	■			■		■			estimate: 500 mmHg		■		this will be a mechanical pressure blow out, which should only ever kick in if there is a failure mode. Shiels 1993 suggests that pressure should be <270 mmHg, so we increase the value for system failure	■	■			intentionally over-pressure system. Insure that system dumps pressure
B1	Rectal Device Interface	pressure retention in intestine	must be capable of holding/sealing against a pressure in intestine such that our flow rate can maintain pressure	■				■				should seal to 140 mmHg	■			standard procedure used today goes to 120mmHg, this adds a slight safety factor for spikes due to coughing, etc.. Some leakage above that pressure is acceptable; (Shiels, 1995), (Shiels, 1993), (Kaiser, 2007)	■				ensure that pressure is held in test bed intestine (ASTM D1456 - rubber elongation)
B2		enema tip size	must be insertable into rectum of child, should come in multiple sizes to satisfy patient diversity	■		■	■	■	■			at minimum 24 French and 40 French sizes		■		tips which satisfy B2 and B3 for the full range of infant anus sizes from 0-2 years old; prior art offers 24 and 40 French sizes (Grattan-Smith, 2015; Shiels, 1991)	■		■		ensure that tip can be inserted into test bed rectum and conforms to expected dimension
B3		enema tip/catheter slip-out pressure	how much pressure can be applied prior to tip/catheter slip out	■				■				500 mmHg	■			standard 140 mmHg + significant safety factor for tugging on line, child movement, Valsalva maneuver, etc... will require additional testing post prototype fabrication to determine exact value necessary (Shiels, 1995; Shiels, 1991; Mahaffey, 2015)	■				pressurize test bed rectum and ensure that tip stays inserted without user intervention
B4		enema tip insertion length	must be capable of being inserted at least 3 inches	■				■	■			>3 inches		■		current insertion length is generally 3 inches or less (Grattan-Smith, 2015; Mahaffey, 2015)	■	■			measure insertable length
C1	Physical Embodiment	storage and portability	must be capable of being stored and easily moved			■		■		■		weight is comfortable for transport by nurses (<10lbs); size is no more than prior art case (11inx9inx4in)			■	must be easy to use and fit in the same space as prior art. Interview with Grattan-Smith and visit to hospital allowed physical contact with Shiels device case (Grattan-Smith, 2015; Shiels, 1995)	■	■	■		will ensure size and weight are no larger than prior art case; will survey nurses for comfort level moving device
C2		compatiblity with non-specified tips	connectors out of pressure control system should be industry standard	■		■		■		■		luer lock compatible		■		ISO 594 (luer-lock)	■	■		■	inspection to ISO specifications
C3		visual intimidation	should minimize fear and intimidation		■		■	■	■			by survey would person (patient parent, physician, nurse) be less comfortable than with the predicate device			■	(Grattan-Smith, 2015; Mahaffey, 2015)			■		survey
E1	Environmental	environmental impact	should minimize impact on the environment			■				■	■	conform to ISO 14040 and ISO 14044 (Envirenmental Managment / Lifecycle analysis)			■	ISO 14040 and ISO 14044 (Envirenmental Managment / Lifecycle analysis)		■			process and design review
F1	Sterility	aseptic catheter/enema tip and tube	enema tip and tube should be clean			■				■	■	conform to ISO 13408 (asptic processing of healthcare products)		■		ISO 13408 (asptic processing of healthcare products)	■			■	bioburden, visual inspection
F2		flow back of liquid from patient	no fluid should return from the patient into the device with a pressure gradient up to 500 mmHg			■				■		zero flow of liquid water from patient into device at A3 pressure (500 mmHg)		■		dirty fluid is exiting the child, this must not be passed into the device and onto the next patient (Mahaffey, 2015)	■				will verify by colored water liquid and vapor being pushed through filter mechanism at A3 pressure
G1	Performance	reduction time	should be equivalent or better to current device when used on test bed		■		■	■	■	■		time to reduction of intussusception on device less than or equal to prior art when compared on our test bed		■		device must be better than the prior art; data will be comparative on test bed (Shiels, 1992)			■		have a trained physician perform reduction on test bed using existing device and new device compare time to successful reductions
G2		subjectively preferred by physicians	by survey of physicians, use is preferred by physicians on test bed		■		■					by survey physicians statistically prefer our device to the prior art when compared on a test bed	■			device must be better than the prior art; data will be comparative on test bed (Shiels, 1992)			■		user trial/survey
G3		subjectively preferred by nurses	by survey of nurses, use is preferred by nurses on test bed		■			■				by survey nurses statistically prefer our device to the prior art when compared on a test bed	■			device must be better than the prior art; data will be comparative on test bed (Shiels, 1992)			■		user trial/survey
G4		reduction rate	should have a higher rate of successful reduction than prior art		■		■	■	■	■		should have a higher rate of successful reduction than prior art		■		device must be better than the prior art; data will be comparative on test bed (Shiels, 1992)			■		have a trained physician perform reduction on test bed using existing device and new device compare number of successful reductions
H1	Safety	perforation prevelance	should not lead to increased perforations compared to current device; ideally would notify if a perforation does occur		■		■		■	■		mathematically, pressure should be delivered in a more controlled fashion; tests on test bed should show no increase in perforations when compared to previous art.		■		device must be better than the prior art; data will be comparative on test bed (Shiels, 1992)	■				have a trained physician perform reduction on test bed using existing device and new device compare number of perforations. Guarantee mathematically that the pressure we deliver is in no way more likely cause perforations
H2		emergency stop	drops air pressure to zero immediately after activation	■			■			■		compliant with ISO 13850 (emergency stops) / will depressurize intestine at system max exit flow rate; kill all power to system		■		ISO 13850 (emergency stops)	■				will measure pressure output from device, time to depressurize, proper electrical state
H3		parameter indications	clear indication of set parameters and easy adjustment of said parameters		■		■					easy for a new user to understand the set parameters	■			ISO 9241 (ergonomics of human-system interaction), ISO 11581 (symbols for computer interfaces)			■		user trials
I1	Reliability/Maintenance	device health indication	comparative testing using multiple sensors to ensure accurate sensor readouts. Self test solenoids		■		■	■		■		able to detect failure of critical components	■			the device should minimize the affects of relevant failure modes		■	■		verify that system has been designed in a way as to minimized affects of relevant failure modes. Test simulated failure modes.
I3		cleanability	should be sealed against wash-down			■		■		■		must be designed for cleanability			■	current ASTM WK31799 (medical device cleanability) is in progress; will have to develop in house method	■	■			contaminate and mark device surface; wash down device; Does any fluid enter the case? Is there any damage? Is there any remaining marking or bioburden?
J1	Life Span	disposable shelf life	disposable component should be able to last for 10 years			■				■		disposable component should be able to last for 10 years			■	current BARD catheter lifespan	■	■			accelerated aging
J2		capital device lifespan	primary device should be able to last for 10 years			■				■		primary device should be able to last for 10 years			■	based on Welch Allyn hand aneroid (competitive product) warranty period	■	■			accelerated aging combined with simulated cycles
K1	Packaging	packaging should not compromise device	it should be easy to open packaging and move straight to use. Should adequately protect device from mechanical and biological attack		■		■	■				conforms to ISO 11607 (packaging for terminally sterilized medical devices), including adequate protection for the device; also allows ease of use of packaging		■		ISO 11607 (packaging for terminally sterilized medical devices)	■		■		conformance to standard for protection and user testing for ease of use.
K2		labeling should allow intuitive use	easy to read, short instructions for use (IFU)		■		■	■				conforms to ISO 15223 (symbols for medical device packaging) standard with clear labeling		■		ISO 15223 (symbols for medical device packaging)		■	■		user trials and spec conformance
L1	Interfacing Devices	electro-magnetic interference (EMI)	conforms to IEC 6060; ensure electro-magnetic interference is at a safe level; does not interfere with fluoroscopy or other relevant devices in the fluoroscopy suite			■						conforms to IEC 60601 (guide for electronic medical devices)		■		IEC 6061 (guide for electronic medical devices)	■	■			will test per standard
L2		should interface with standard hospital air source	quick disconnect to interface with 1/4 NPT and barb for tube			■	■	■		■		must interface with 1/4 NPT and soft tube (barb fitting), ISO 228 (BPT) fitting		■		ANSI B1.20.1 (NPT), ISO 228 (BPT), ASME B16 (pipe fittings)	■	■			test against specifications
M1	User Experience	intuitive use	a standard trained radiologist should be able to figure out the interface with no instruction; we will allow a basic IFU on the device		■		■	■				conforms to standard practices for interface design; by survey (physicians statistically agreeing on device being intuitive to use)	■			ISO 11581 (symbols for computer interfaces); ISO 20282 (ease of operation of everyday devices); ISO 9241 (ergonomics of human-system interaction); IEC 62366:2007 (medical device usability); AAMI-HE75 (human factors for medical devices)		■	■		user trials/standard verification
M2		glove compatibility	minimize static touch interfaces, maximize tactile feedback		■		■					all systems must function fully with gloves		■		interviews suggest that all users are fully gloved and that the environment becomes very messy with bowel fluid exiting the patient (Grattan-Smith, 2015; Mahaffey, 2015)		■	■		intelligent design and user trials
M3		status indicator	should have clear status indicator which can be read from at least 6 feet, along with more detailed data up close		■		■					indicator which can be read from at least 6 feet	■			IEC 60601-1-6 (usability of medical electrical equipment); ISO 9241 (ergonomics of human-system interaction)		■	■		design for easy reading of status, survey users
M4		distractions	no alarms; no flashing		■		■	■		■		no alarms or flashing lights; simple notification of blow off		■		IEC 62366:2007 (medical device usability); AAMI-HE75 (human factors for medical devices); Kaye, 2000 (FDA)		■			design per standards
M5		physical work	currently physicians and nurses are required to exert themselves significantly to perform a successful reduction; this causes fatigue		■		■	■				should reduce physical exertion when compared with the predicate device	■			interview with nurse and physician indicated excessive physical exertion (Grattan-Smith, 2015; Mahaffey, 2015)			■		user trials on test bed comparing new and predicate device for fatigue
M6		tactile feedback	a way for the physician to make real the pressure via feedback and perhaps interact directly		■		■					should provide adequate tactile feedback, using ISO 9241 (ergonomics of human-system interaction) as guidance			■	ISO 9241 (ergonomics of human-system interaction)		■	■		analysis against standard practices along with user trials
M7		feedback for end states	the physician should easily know if rupture or reduction has occurred	■			■					will notify radiologist if an end state (reduction or perforation) has occurred			■	(Grattan-Smith, 2015; Mahaffey, 2015)	■				compare ability of device to predict end states to actual presence of end states
M8		instructions for use (IFU)	easily understood IFU			■	■	■				conforms to ISO 37 (IFUs), is easy for new users to use		■		ISO 37 (IFUs)		■	■		compatibility with specifications and user trial
N1	Regulatory	biocompatibility	general medical stuff			■			■		■	ensure materials are biocompatible over device lifespan		■		ISO 10993 (biological evaluation of medical Devices), USP VI (implantable materials)	■	■			analysis of known material properties and accelerated aging
N3		unique device identification (UDI) compliance	plan for upcoming UDI guidance implementation			■					■	every device uniquely identified per FDA guidance		■		FDA guidance on UDI		■		■	design in UDI and inspect
O1	Research	data storage capability	ability to plug in a USB drive and extract a csv file with pressure, duration, date and other relevant data	■			■			■	■	ability to plug in a USB drive and extract a csv file with pressure, duration, date and other relevant data			■	IEC 62680 (USB)			■		successfully place patient information less data onto standard USB storage device