# A Prospective, Randomized Trial to Compare the Fluid Capture Efficiency of the "Total Capture" Drape versus a Standard Drape for Hysteroscopy: Innovation for Improved Patient Safety and Surgical Care

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## I. Specific Aims:

a) To perform a comparative trial of the "Total Capture" hysteroscopy drape (TCD) versus the standard drape during patient surgeries to document improved, real-time determination of patient fluid absorption. Inaccurate detection of fluid absorption by a patient during hysteroscopy is a source of complications, morbidity and mortality from excessive patient fluid absorption. Pilot testing of a prototype design of the "Total Capture "drape versus the conventional hysteroscopy drape indicated remarkable improvement in fluid capture and accurate fluid deficit determination in a plastic pelvic model experiment. The interest from corporate producers of hysteroscopy fluid management systems and drape manufacturers is contingent upon demonstrating "proof of concept" with actual patient surgeries.

b) To evaluate the clinical usefulness of the TCD compared to the Standard drape for hysteroscopy with the standardized metrics of: 1) the Human Factors Surgical Drape Assessment and 2) The System Usability Scale. These metrics will allow us to quantitate clinical usefulness and usability of both the operating surgeons and operating room staff.

## II. Significance

Distention of the uterine cavity is necessary for visualizing the inside of the uterus during hysteroscopy. Continuous turnover of the medium is important to maintain adequate imaging by clearing debris and blood that accumulate during the surgical procedures. Systemic absorption of distention media is directly related to the surgical disruption of veins in the deep endometrium (lining of the cavity) and myometrium (uterine smooth muscle) during surgery. The absorption of media by the patient is directly proportional to the invasiveness of operative hysteroscopy and the distention medium pressure within the uterine cavity.

Patient hazards and complications from imprecise measure of fluid absorption: The safe conduction of hysteroscopic surgery requires precise monitoring of patient fluid absorption of the distending medium used to visualize the intrauterine cavity. The detection of the amount of fluid absorption depends upon the proper collection of the distention medium not absorbed by the patient. Serious patient complications, including hyponatremia (low serum sodium), heart failure, and pulmonary and cerebral edema, can result from over absorption of distending medium (1). Absorption of non-electrolytic distention medium (glycine, sorbitol) can cause an osmotic imbalance between extracellular fluid and brain cells causing life-threatening cerebral edema. Isotonic saline or Ringer's lactate, if absorbed in sufficient volume, have also been associated with fluid overload leading to right-sided heart failure and pulmonary edema (2, 3). These complications could lead to the requirement for intensive care unit monitoring, permanent disability, or even death of the patient.

The incidence of blood electrolyte disturbances following operative hysteroscopy that require monitoring has been estimated to be as high as 5%. The incidence of severe clinical complications of fluid overload associated with operative hysteroscopy has been estimated to be about 0.1% to 0.2% (4, 5). Unfortunately, as described, these complications for women undergoing hysteroscopy can produce serious morbidity or death. In fact, female sex steroids may inhibit enzymes that regulate blood electrolytes, which may explain why premenopausal women are 25 times more likely to die or have permanent brain damage from hyponatremic encephalopathy than men or postmenopausal women (6).

Loss of uncollected distention medium onto the floor and into operating room blankets creates other hazards to the patient and surgical team besides the significant patient risks of fluid absorption. Fluid standing on the operating room floor can pose a fall risk to surgical team members (7). The effluent fluid from the patient that is not collected contains blood and bodily fluids that expose the surgical team to the hazards of infectious disease and biological toxins. Significantly, fluid becomes an electrical hazard when it comes into contact with electrical equipment. Distention medium that escapes capture may come in contact with electrical outlets, switches, and surgical electrodes increasing the risk of burns, fires and damage to equipment.

Additionally, the inaccurate detection of the fluid deficit may pose a clinical dilemma for the hysteroscopic surgeon. Does the surgeon stop a procedure when the fluid management alarm indicates that a fluid deficit (approximate patient fluid absorption) exceeds the safe limit even though they see fluid on the floor? If the surgery proceeds, how long can it safely continue? Without accurate, real-time fluid absorption data, surgeries may be prematurely terminated because of erroneously reported high fluid deficits thus requiring a potentially unnecessary repeat surgery with a delay in cure, increased cost, and more patient risks. The surgical team and healthcare system would certainly be exposed to medico-legal risk if a fluid management alarm sounds, the procedure is continued and the patient suffers a complication of fluid overload.

## III. Guideline Recommendations for Fluid management During Hysteroscopy

Use of an automated fluid pump and monitoring system is advocated by both the American College of Obstetricians and Gynecologists and the American Association of Gynecologic Laparoscopists (8, 9). Guidelines for the threshold for acceptable fluid absorption by patients during hysteroscopy have been established by these groups. Most guidelines indicate that a threshold for safe absorption by patients is 500 to 750 mL for non-electrolytic media and 1000 mL for electrolytic medium such as normal saline. Data indicate that fluid absorption of greater than 1000 mL of electrolytic medium is associated with an increased risk of gas embolism (10). It has been shown with routine postoperative CT imaging of the brain that cerebral edema can occur with as little as 500 mL of non-electrolytic distension solutions (1). For other patients with cardiovascular disease or other comorbidities, the threshold for

safe absorption of medium should be reduced. An alarm can be set to sound a warning when a preset volume deficit is reached. Most operating rooms mandate a halt to the procedure following a warning alarm and, in some cases, special post-operative patient monitoring is required for patients to insure fluid and electrolyte normality, adequate pulmonary function, and hemodynamic stability.

## IV. A Design to Improve the Accuracy of Fluid Deficit Measurements During Hysteroscopy

The problem with current hysteroscopy drapes for fluid management: The actual measurement of the distension medium absorbed by patients is often inaccurate because fluid that is not absorbed into the patient's body is not adequately captured into the collection bag of the surgical drape for return to the fluid management system and deficit calculation. The method for real-time monitoring of patient fluid absorption involves subtracting the volume collected from the volume infused considering all sources from the hysteroscope outflow (11). The sources of outflow include: 1) the perineal collection bag which captures fluid spilled from the cervix but around the hysteroscopy sheath, and 2) the media not captured by the collection bag that spills on the floor or is absorbed into operating room blankets (see Figure 1). Problems are compounded if the person monitoring fluid balance has other duties in the operating room which increases the risk of errors. While conceptually simple, there are a number of difficulties encountered when attempting to collect media from all sources in the operating room environment.

**Standard Hysteroscopy Drape**

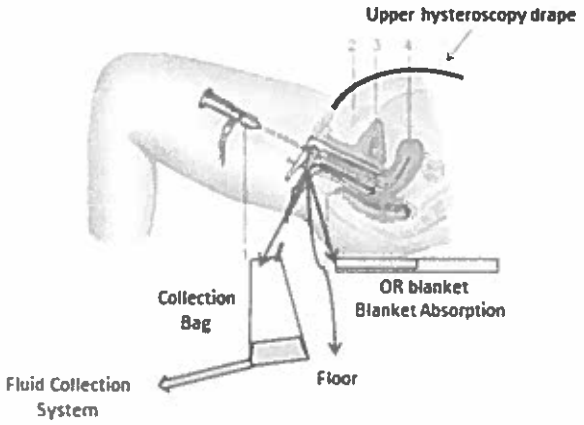



**Figure 1.**

A proposed solution to the problem: The "Total Capture" Drape (TCD) for hysteroscopy prevents the escape of fluid that would otherwise not be measured by the standard drape because the TCD design includes a continuous sheet of non-permeable plastic that extends above the collection bag (see Figure 2 below).

**"Total Capture" Hysteroscopy Drape**

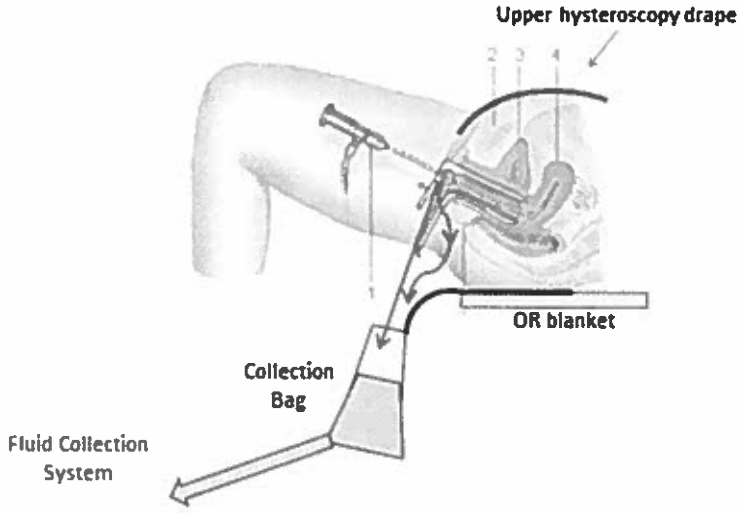



**Figure 2.**

Because of specially designed hand pouches under the sheet, the surgeon can situate the sheet beneath the patient's buttocks without violating sterile technique. The plastic extension sheet, which is continuous with the collection bag, has a "bowl" shaped design to funnel unabsorbed fluid into the collection bag while restricting its lateral flow to prevent fluid loss onto the floor and into blankets. The conventional hysteroscopy drape relies upon an adhesive strip to cause adherence of the drape to the patient's perineum. The conventional design fails because the moisture from unabsorbed fluid destroys the adhesive bond which creates a gap with loss of fluid between and around the buttocks as shown in Figure 1 above. We hypothesize the "Total Capture" Drape design provides an accurate recorded hysteroscopic fluid deficit in real-time so that patient safety and surgical parameters are optimized. The simple design of the TCD would add a very significant

improvement for patient safety and care with minimal cost for the estimated 200,000 hysteroscopies performed per year in the U.S.

## Experimental Trial with the TCD versus the Standard Hysteroscopy Drape in a Pelvic Model Simulation

We sought to document whether or not a prototype design of the "Total Capture" drape (TCD) would perform under replicated clinical conditions in a superior fashion compared to the currently marketed hysteroscopy drape. The experimental testing was performed with design assistance and prototype production of the TCD by Medical Murray Engineering and with technical help from Carolinas HealthCare System for access to an operating room suite, the hysteroscopy fluid management system, conventional Cardinal Health hysteroscopy drape, and the ZOE Gynecologic pelvic model. The pelvic model was configured so that all fluid introduced into the artificial vagina would not be absorbed by the model but would flow out of the artificial vagina. The fluid management system can accurately subtract the volume of fluid collected from the volume of inflow fluid introduced to calculate the fluid deficit which would indicate failure of fluid collection. The flow of fluid out the artificial vagina onto the perineum of the ZOE model could then be compared between drapes to determine the relative capture efficiency of fluid lost in this trial. (A video showing the experimental set-up and demonstration of the trial is available.)

### Data from Trial of Fluid Capture Efficiency of the TCD versus Conventional (Cardinal) Hysteroscopy Drape

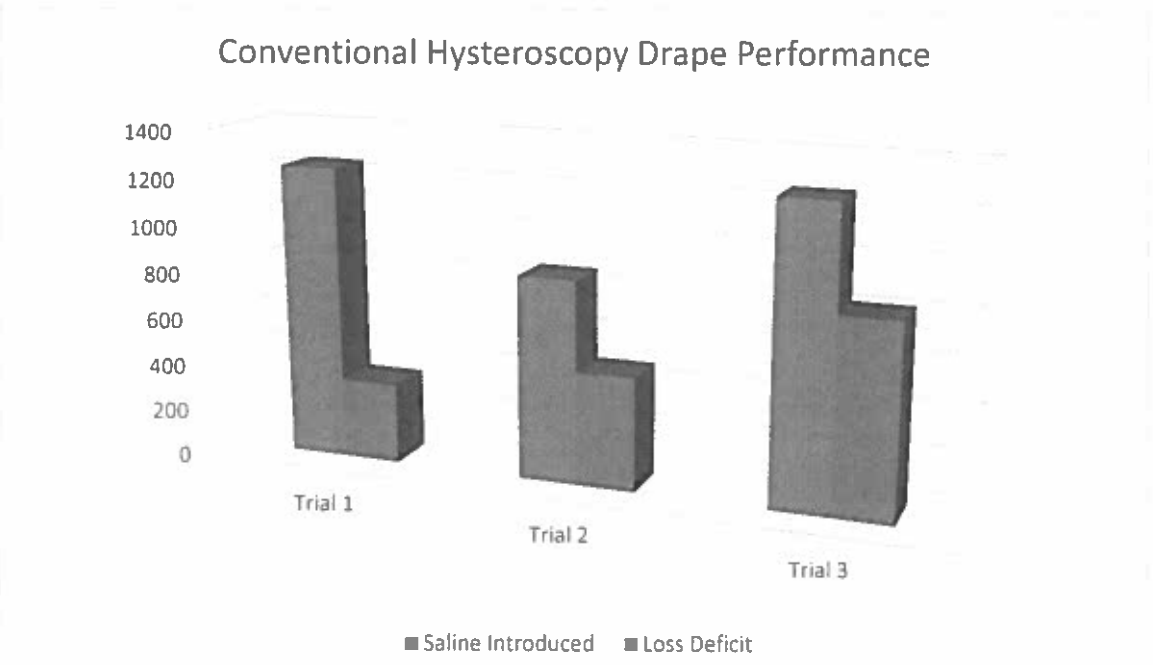
#### General Observations

A total of four trials per drape were conducted. The fluid loss (deficit) was calculated by subtracting the collected volume from the inflow volume by the fluid management system. This value should be 0 for all trials since the pelvic model was configured to have no absorption by the model and 100% of the fluid introduced would flow out of the artificial vagina. One trial from each product had procedural difficulties making results invalid. The first trial with the conventional hysteroscopy drape (Cardinal) was invalid because the pressure setting was too high (70 mm hg) instead of the standard 50

mm hg; the third trial of TCD was invalid because the saline bag became depleted in the middle of the trial.

**Conventional Hysteroscopy Drape Performance (Cardinal)**

| Cardinal | | | |
|---|---|---|---|
| Duration: 60 sec.<br>Pressure: 50 mmhg<br>Trial No. | Saline introduced (ml) | Loss (Deficit) (ml) | Comment |
| 1 | 1250 | 340 | NA |
| 2 | 862 | 482 | NA |
| 3 | 1260 | 820 | NA |



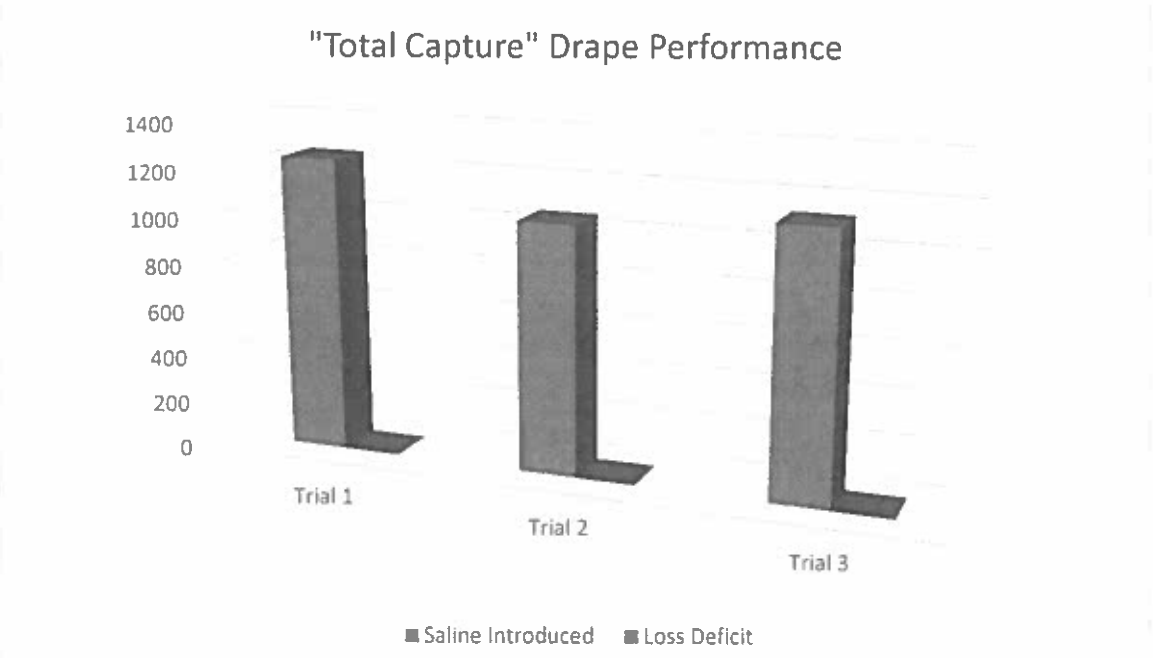

Observations:

- The proper functioning of the conventional drape (Cardinal) was dependent on the adhesion of double sided tape, around the inside lip of the fenestration to the perineum.
- The perineal region beneath the vaginal orifice found on the ZOE pelvic model was a best case scenario for the Cardinal product because the model has tacky elastomeric skin, and the model perineum was flat with no curves, clefts, or hair.

- Once the adhesive bond was broken, fluid ran down the perineum, behind the drape, not to be returned to the system – accounted for by the system as deficit. During the trials the adhesion did indeed fail and render the drape progressively less effective with each addition trial.

**"Total Capture" Drape Performance**

| Total Capture | | | |
|---|---|---|---|
| Duration: 60 sec.<br>Pressure: 50 mmhg<br>Trial No. | Saline introduced (ml) | Loss (Deficit) (ml) | Comment |
| 1 | 1255 | 0 | NA |
| 2 | 1059 | 0 | NA |
| 3 | 1131 | 0 | NA |




Observations:

- The Total Capture Drape did not rely on a skin-to-drape seal in order to function. With an extension flap underneath the patient, fluids running down the perineum were directed into the collection pouch and returned to the system.

- In four trials of the total capture drape, there was no deficit observed.

We concluded that no major design iterations would be required to move the TCD prototype to the next phase of development

## V. Comparative Trial for "Proof of Concept" Testing to Evaluate the Efficiency of the Total Capture Drape Compared to the Conventional Hysteroscopy Drape during Hysteroscopic Surgery

All women undertaking hysteroscopy are required to have a sterile surgical drape with a fluid capture pouch system to collect the distention media not absorbed by the patient to calculate fluid deficits. Both the TCD and the standard hysteroscopy drape possess the characteristics described above, although design features of the standard drape are deficient. The TCD has received 510(k) FDA determination to be "substantially equivalent" to the standard hysteroscopy drape.

a. Subject Recruitment: All women age 18 and older who are scheduled for an operative hysteroscopy at a CHS operating room facility are candidates for the trial. The research coordinator will be contacted by the physician of upcoming hysteroscopies. At that time, the coordinator will reach out to the patient to see if they are interested in participating. A consent will be emailed to the patient. Written consent will be obtained from patient in preop holding area.

b. Risks to the patient: It will explain that the TCD may not perform in the same manner as the standard drape. It will be shared that the TCD will have met sterilization standards and that there is no evidence that the TCD would substantially alter the surgical risks of the hysteroscopy.

c. Exclusions: Patients will be excluded if they are not acceptable candidates for a hysteroscopy procedure for any reason. Patients will be told that if they do not wish to participate in the trial that they will get the standard care that they normally would have received from their operating surgeon.

d. Benefits: Patients will be told that the drape for surgical use may or may not improve surgical outcome. The information gained from the trial may provide benefit to others undergoing hysteroscopy in the future.

e. Compensation: Participation in the study will not involve additional costs to the patient, nor will the patient receive any compensation for participation in the study. If complications of hysteroscopy occur during participation in the study, their physician will provide and arrange treatment as necessary, and medical expenses will be billed to the patient's insurance company in the usual manner. Patients will understand that they do not waive any legal rights by signing the study consent.

f. Withdrawal: It will be explained that the patient's participation in the study is completely voluntary, and that they should not feel under pressure to enter into the study. Withdrawal from the study will not harm their relation with their doctors or the Carolinas HealthCare System.

g. Confidentiality: The consent will specify that there is a small risk of loss of confidentiality, but the study data from the trial will be de-identified for collection and analysis. Any personal health information will be kept confidential and secure. No publication will reveal the identities of any patients.

h. Patient Information: In the consent form the patient will be provided the contact information for the principal investigator and that Institutional Review Board approval was required before the conduction of the study.

## Clinical Study Design

The primary outcome variable for the comparative trial will be the hysteroscopy fluid deficit (HFD) which can be precisely measured by the fluid management system by subtracting the outflow volume (OV) returned to the fluid management system from the inflow volume (IV). That is:

$$HFD = IV - OV$$

Secondary outcomes include uncollected fluid volume (UFV), occurrence of the alarm sounding for exceeding the fluid deficit limit, and procedure interruption. The UFV is defined as the difference of HFD between TCD and standard drape group. The UFV will be two components as determined by the circulating OR nurse in charge of the fluid management system. The first are the volume on the floor and the volume absorbed by the operation blankets and drapes. The second component is an estimate of any fluid loss from leaking hysteroscopy joints and gaskets not captured by the collection bag. In addition, the time required for procedures will be recorded.

Adverse events and serious adverse events will be captured along with relatedness and severity. We will classify event terms using Common Terminology Classification of Adverse Events version 4.03 (National Cancer Institute).

**Measures for Drape Usability, Quality, and Convenience**

We plan to objectively and subjectively evaluate the usability and usefulness of the TCD compared to the standard drape. Staff will be asked to complete the System Usability Scale (SUS) [section XVII SUS; Brooke, 1986] to evaluate their perceived clinical usefulness of the TCD and the standard drape. The SUS is a validated 10-item survey for assessing perceived usability that uses a 5-point Likert scale ranging from strongly disagree to strongly agree. To further subjectively and objectively assess the TCD a human factors and design researcher will observe the surgeries. The human factors researcher will attend the first surgeries to ensure consistent rating with design researcher who will subsequently observe the remaining surgeries until data saturation is reached. The human factors expert will attend any surgeries the design researcher cannot attend. Staff will be asked to speak aloud using the system, which the researcher will record. Further, the researcher will complete an objective human factors assessment tool (section XVII). Finally, enrolled surgeons will be provided the opportunity to participate in one-on-one feedback sessions or focus group sessions to provide suggestions on how they perceive usability of the drape can be improved. These sessions will be facilitated by the Principal Investigator and the design researcher or human factors expert. These metrics will allow us to quantitate clinical usefulness and usability of both the operating surgeons and operating room staff. These results will not only provide this assessment of the TCD compared to the standard hysteroscopy drape (which is used across ORs within CHS) but will also provide important information to improve the drape if deficiencies are identified.

Adverse events and serious adverse events will be captured along with relatedness and severity. We will classify event terms using Common Terminology Classification of Adverse Events version 4.03 (National Cancer Institute).

## VI. Randomization and Blinding

We will use standard randomization to allocate patients in a 1:1 allocation to the TCD or the standard hysteroscopy drape. The randomization lists will be generated by a study statistician within Dr. Zhao's team using SAS Enterprise Guide version 6.1. The assignments will be opaque envelopes which ensure allocation

concealment. Once a patient consents and is deemed eligible for the study, the study coordinator will provide the next envelope to the operation nurse who will open the envelope in privacy to learn the allocation. All study staff collecting and recording data for the trial will be masked to the drape that was used during the procedure.

## VII. Data Management

Case report forms will be developed by the OBGYN clinical research nursing staff in collaboration with Dr. Marshburn and Dr. Zhao. A REDCap database will be created for secure electronic data capture. The data flow will consist of paper data collection for eligibility assessment, baseline data, randomization, operational procedure, fluid measures, surgery outcomes, adverse events, and protocol deviations. The data will be entered into the electronic database within 3 business days of the enrollment.

## VIII. Statistical Methods and Sample Size Justification

The primary outcome for the study is the hysteroscopy fluid deficit (HFD) as determined by the fluid management system by subtracting the outflow volume (OV) from the inflow volume (IV) (HFD=IV-OV). Our null hypothesis is $H_o$: $\mu_{Standard}=\mu_{TCD}$ where $\mu$=mean fluid deficit. Our alternative hypothesis is $H_o$: $\mu_{Standard}>\mu_{TCD}$ due to the underestimation of the outflow volume created by the loss of outflow fluid to floors and blankets. If we assume the true absorption rates by the patients are the same between the groups due to randomization, by estimating and testing the difference HFD between the two groups we are estimating and testing a more accurate measure of the uncollected fluid volume (UFV) as shown below:

$$\begin{aligned}\mu_{Standard} - \mu_{TCD} &= (\mu_{Standard,\ true\ absorption} + \mu_{Standard,\ UFV}) - \mu_{TCD,\ true\ absorption} \\ &= (\mu_{true\ absorption} + \mu_{Standard,\ UFV}) - \mu_{true\ absorption} \\ &= \mu_{Standard,\ UFV}\end{aligned}$$

The primary analysis for the study will use a general linear model on the HFD with a fixed effect for study group (TCD versus Standard drape) controlling for surgeon and indication for hysteroscopy, the stratification factors for the randomization.

Secondary outcomes include estimated uncollected fluid volume from floor and blankets, occurrence of the fluid deficit alarm sounding, stopping of the operation due to concerns of overabsorption by the patient, and adverse events. Estimated uncollected fluid volume will be analyzed similar to the primary outcome. All other outcomes are categorical and will be compared using Chi-square analyses.

We will sample 10 procedures (or until data saturation) from each arm (TCD vs standard) to conduct qualitative assessments on Usability using the Human Factors

Assessment Tool for the surgeons and operating team members. Once data saturation is reached using the Human Factors Assessment Tool, enrolled surgeons will be provided a step-by-step video link orientation to the Total Capture Drape. For the SUS, we will collect data on attending physicians only on their first and fifth procedures (the study team may change it to 1st and 3rd if deemed appropriate). We will estimate means or medians with standard deviations (or interquartile ranges) for the items and total scores for the SUS. Both within (1st vs. 5th) and between arms (TCD vs. standard) comparison on totat scores of SUS will be conducted. We will compare the two groups using linear mixed models or generalized linear mixed models (depending on the distribution) with a random effect for the procedure to control for correlation of the measures among team members participating in the same procedure.

At this early stage of investigation, we have no prior data on HFD in patients to estimate the variability need for the sample size estimation. We have preliminary data from the simulated experiment showing a 100% recovering of loss deficit by the TCD. If we conservatively assume the loss deficit will decrease from 40% to 20% of the inflow volume, this would result in a clinically meaningful improvement with an approximate effect size of 0.92 based on the variability of loss deficit in the simulation. Given this, we are using effect size (relative to standard deviation) as the primary justification for the number of patients needed for the study. With a sample size of n=34 per arm, we would have 81% power to detect an effect size of 0.7 (0.7*standard deviation of the HFD) with a two sided, two sample t-test ($\alpha$=0.05). To account for potential missing data of 10%, we propose randomizing 76 women (n=38 per arm). With n=34 women in each group, we would also have 80% power to detect an absolute 33% reduction in the proportion of procedures with the alarm sounding due to fluid deficit threshold being reached assuming the proportion in the standard drape arm is 50%. This power was calculated using a Fisher's Exact test for testing proportions between two independent samples. The same power would apply for detecting differences in the proportion of procedures terminated.

## IX. Data and Safety Monitoring

The PI and the study team will meet bi- weekly to review the study procedures, enrollment (screening and randomization), implementation, protocol deviations, and data collection.

## X. Commercial applications

In 1999, the Institute of Medicine (IOM) released a report called *To Err is Human: Building a Safer Health System*. (12) The report highlighted a very large number of

hospital deaths that occurred from medical errors. The Quality Health Care in America committee believed it could not address the overall quality of medical care without first addressing a key component of quality; which was patient safety. (13)

The IOM believed that fundamental change for patient safety would require pressure and incentives from public and private purchasers of health care insurance, regulators (including the Food and Drug Administration), and licensing and certifying groups. (14) The Agency for Healthcare Research and Quality (AHRQ) was created to establish national safety goals and serve as a source of effective practices that would be shared broadly. Direct measures of surgical outcomes and complication rates demonstrated that "assumption is wrong" and improved performance was related to following checklists and protocols.

Safe equipment design and use depend on a chain of involvement and commitment that begins with the manufacturer and continues with careful attention to the vulnerabilities of a new device or system. Health care professionals should expect any new technology to introduce new sources of error, always alert to the possibility of unintended harm. New technologies should be tested with users and modify as needed before widespread implementation. The use of the "Total Capture" drape addresses a clear deficiency that prevents currently used drapes from achieving the necessary, real-time determination of patient fluid absorption during hysteroscopy. As outlined above, this problem poses preventable risks to both patients and operating room staff with the potential for considerable cost, personal injury, and liability.

Hospitals and operating room facilities are under a mandate to improve patient safety and care, minimize patient injury, and reduce cost. Agencies, such as the Premier, Inc. Healthcare Company, tracks databases on individual physicians and physician groups for procedural complications and costs of services (13). Clinicians who provide a lower value of patient care (quality divided by cost) would receive a disadvantageous ranking in a tier system which would lessen the opportunity for access to insured patient encounters. Clinical care facilities that fail to maintain "best practices" for patient safety, access, and quality care will suffer the repercussions of reduced reimbursements, decreased access for patient referrals, and removal of healthcare providers from insurance plans. The "Total Capture" Drape satisfies the goal for improving the quality of patient care by enhancing the accuracy of intraoperative information to optimize surgical outcomes and patient safety at minimal cost and inconvenience.

May attach the following sections as **Addenda.**

## XI. IP and licensing status

U.S. provisional patent application no. 61/867,757 was filed on May 30, 2013. U.S. non-provisional application no. 14/892,128 filed on November 18, 2015. CHS contracted Access Innovation, an NC-based intellectual property consultancy (acquired by Navigant consulting), to conduct a risk-assessment of the claims in the pending patent application and provide analysis of commercial opportunities.

## XII. Licensing discussions to date

The research and technology transfer team initiated conversations with several commercial partners including: Guardian OR, HVO, Smith and Nephew, and Hologic. Earlier this year, a third-party intellectual property consultant conducted a thorough risk-assessment of the claims in the pending patent application and provided analysis of commercial opportunities. The distribution channel for this product is tightly controlled by large manufacturers and distributors like Cardinal Health. A desirable licensee should have existing channel access and distribution relationships that will enable it to effectively market this product. Therefore, the assessment recommended: Microtek, Medline, 3M, Baxter, JNJ, Kimberly Clark, and Cardinal Health as good candidates for licensing discussions.

Members of Cardinal Health's Global Market Development team met with Dr. Paul Marshburn to view demonstrations of his patent pending drape. Based on the initial observations and discussions, Cardinal Health and Carolinas HealthCare System believe there may be commercial potential and agreed to collaborate on the proposed clinical study to further assess the technology.

## XIII. An overview of the proposed study

The milestones and associated costs remaining in the program are included in Attachment 3: *Contract Manufacturer Proposal for Remaining Work & Timeline.* An overview is included below:

- Design Optimization & Documentation, including:
  - Design Inputs
  - Drawings and Specifications
  - Packaging Design
  - Regulatory Assessment
  - Risk Analysis
  - Preclinical Test Protocols
- Procurement of Sample Materials

- Packaging and Packaging Process Formalization
- Sterilization Technical Assessment (Ethylene Oxide)
- Documentation, including:
  - Labelling
  - Instructions for Use
  - Manufacturing Instructions
- Procure Materials for Clinical Use
- Package Clinical Product
- Sterilization Validation
- Design Verification Testing, including:
  - Product Biocompatibility Testing
  - Packaging Validation and Transit Testing (at a later date)
- Design Review
- **Budget for Clinical testing is not included in the proposal from Medical Murray at this time, but can be previewed at a later date.

Clinical experience with the "Total Capture" drape would involve introducing the TCD directly into the outpatient setting for use in operative hysteroscopy. All patients receiving hysteroscopy require the use of a drape for maintaining a sterile operative field and for fluid management. Observational data will be collected to assess drape reliability and surgeon and OR staff satisfaction with regards to ease of use and obtaining real-time fluid management. A clear endpoint measure would be the number of cases in which the fluid deficit was precisely determined before surgical case completion.

An initial lot of the TCDs will be produced (approximately 50) with the consideration of discovering needed design iterations (expected to be minimal). A subsequent lot would employ these improvements learned during this observational experience to produce a final TCD design. This would fulfill the requirements for interested hysteroscopy drape and fluid management system producers for introduction directly into the market.

The cost of the above program is estimated in the $65,000 to $75,000 USD range. Timing to completion is estimated in the six to nine month range.

## XIV. Regulatory Status

The Total Capture Drape falls under Class II status, exempt from the 510k clearance process in consideration of FDA's approach to similar devices. If required, a third-party Assessment would be procured as part of the proposed activity.

<u>Regulation and Product Code for General Use:</u>
Title 21 – Food and Drugs

Chapter 1 – Food and Drug Administrations
Department of Health and Human Services
Subchapter H – Medical Devices

PART 878 – General and Plastic Surgery Devices
Subpart E – Surgical Devices
Sec. 878.4370 Surgical drape and drape accessories
Regulation Number: 21 CFR 878.4370
Product Code: KKX

(a) *Identification*. A surgical drape and drape accessories is a device made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination. The device includes a plastic wound protector that may adhere to the skin around a surgical incision or be placed in a wound to cover its exposed edges, and a latex drape with a self-retaining finger cot that is intended to allow repeated insertion of the surgeon's finger into the rectum during performance of a transurethral prostatectomy.
(b) *Classification*. Class II.

## XV. Value Proposition

With an estimated 200,000 hysteroscopies performed per year in the U.S. alone, a device such as the "Total Capture" drape addresses a large market associated with an unmet clinical need. Compared to current products on the market, the new drape design improves upon the safety and effectiveness of hysteroscopy procedures not only for the patient, but also for care providers. The Technology Enhancement Grant will allow for drape manufacturing leading to a patient use study combined with regulatory testing, with the intent of obtaining a licensing agreement at the conclusion of the project.

## XVI. References

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## XVII. Attachments

1. Invention diligence report (includes prior art search)
2. US patent application publication
3. Intellectual Property risk-assessment by Access Innovation
4. Human Factors assessment tool
5. Contract Manufacturer Proposal for Remaining Work & Timeline
6. Standard Usability Scale