ACTFAST

PI: Michael Avidan
IRB ID #: 201603038

Project Details

1. Demographics

1.1 Project Title:
Anesthesiology Control Tower: Feedback Alerts to Supplement Treatments (ACTFAST)

1.2 Short Title (required):
ACTFAST

1.3 Project is primarily:
Biomedical

1.3.a Does this study require review under ICH-GCP?
No

1.4 Type of Study:
Other Interventional

1.4.a Is your research study one in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes (NIH clinical trial definition).
No

1.5 Select how you plan to obtain consent:
- No consent process (waiver of consent)

2. Source(s) of Support

2.1 Source(s) of Support

Type/Source	Grant Title	Name of PI on Grant	Status
Departmental			
Federal Agency Agency for Healthcare Research & Quality (DHHS)	Anesthesiology Control Tower: feedback Alerts to supplement Treatment	Michael S. Avidan	AWARDED

Attachment Name	Category	Version	Date Attached
ApplicationFINAL_Redacted.pdf	Grant from funding source or private foundation/association	1	04/03/17

3. Research Team

3.1 Principal Investigator

Name	E-mail	Title	Sch
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3.2 Team Members

Research Team Members

Role	Name	Role Desc	Student	Email	Title	School	Department	Cont
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Team Member Financial Interest

Name	Financial Interests
Michael Avidan, MD	none
Joanna Abraham, PHD	none
Amrita Aranake-Chrisinger, BA, MD	none
Umeshkumar Athiraman, MD	none
Arbi Ben Abdallah, DES, PHD	none
Mara Bollini, BA, BSN, MHA	none
Thaddeus Budelier, MD, MSF	none
Yixin Chen, PHD	none
Bradley Fritz, MD	none
Stephen Gregory, MD	none
Daniel Helsten, MD	none
Bernadette Henrichs, PHD	none
Thomas Kannampallil, PHD	none
Christopher King, MD, PHD	none
Lecheng Kong, MS	none
Alexander Kronzer, BA	none
Dingwen Li, MS	none
Hao Liu, BS	none
Sherry McKinnon, BS, MS, CCRP	none
Alicia Meng, BA	none
Melissa Milbrandt, High School	none
Arianna Montes de Oca, MD	none
Teresa Murray-Torres, MD	none
Sarah Perez, MSN, CRNA, MS	none
Andrea Reidy, MD, 30071728	none
Pratyush Sontha, BA	none
Brian Torres, MS, DNP, CRNA	none

Sandhya Tripathi, PHD	none
Troy Wildes, MD	none
Rachel Wolfe, PharmD	none
Bing Xue, BS, MS	none

4. Other Institutional Reviews/Requirements

4.1 Do any of the objectives of this study involve the diagnosis, prevention, screening, evaluation, treatment or support of cancer patients?
No

4.2 Are more than 30% of the patients involved in this study likely to have an active cancer diagnosis?
No

4.3 Will any subject be asked to undergo a radiation therapy procedure (including external beam therapy, brachytherapy, or radiopharmaceutical therapy)?
No

4.4 Does your study involve the administration of non therapeutic radiopharmaceuticals (radioactive drugs) for research purposes?
No

4.5 Will any participant be asked to undergo any of the following:

- a standard radiology procedure involving ionizing radiation (includes X-rays, fluoroscopy, DEXA, CT)
  OR
- a standard nuclear medicine examination with FDA-approved radioactive drugs (including bone scans, radionuclide ventriculogram (RVG or MUGA), myocardial perfusion imaging, FDG-PET)
- **DO NOT include a nuclear medicine examination performed with the investigational radioactive drug(s) listed above in Question 4.4.**
- DO NOT include MRI or ultrasound

No

4.6 Will the study involve <u>any</u> of the following activity **PROSPECTIVELY** at WUSM or any BJC hospitals, even if subjects or their insurance will not be billed for the item or service, and regardless of the study funding source (including studies with departmental or no funding)?

- Procedures, tests, examinations, hospitalizations, use of Pathology, Laboratory, Cardiology, or Radiology services, use of clinic facilities or clinical equipment, or any patient care services, including services conducted in the Clinical Research Unit; or
- Physician services or services provided by non-physicians who are credentialed to bill (ARNPs, Physician Assistants, etc.)

Yes

4.6.a Will any of the prospective activities **EVER** use clinic facilities or clinical equipment **OUTSIDE** of a Designated Research Area? A Designated Research Area is one which does not schedule, order, or result/document via Epic. No insurance information is collected from subjects in a Designated Research Area.

Examples of Designated Research Areas:

- CTRU (Clinical & Translational Research Unit)
- CLCS (Core Laboratory for Clinical Studies)
- ID-CRU (Infectious Disease-Clinical Research Unit)
- NCRU (Neuroclinical Research Unit)
- ADRC (Alzheimer's Disease Research Center)
- CCIR (Center for Clinical Imaging) *Studies that request or require a professional radiology read be done and documented in Epic, this question must be answered "Yes".*

No

4.7 Does this study involve administration of recombinant or synthetic nucleic acids (gene therapy or mRNA vaccines) or microorganisms?
No

4.8 Does this study involve the use of human embryonic stem cells or human induced pluripotent stem cells?
No

4.9 Does this study involve research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero?
No

4.12 Will a Certificate of confidentiality be used for this research?
No

4.13 Does this project need to be registered on ClinicalTrials.gov?
Yes

4.13.a Who is the Responsible Party for registering this study in ClinicalTrials.gov?
Principal Investigator

4.14 Title that should appear in Epic (and will be visible in the patient medical record):

ACTFAST

4.15 Select one person from the study team that should appear in Epic as the contact person for this study:
Sherry McKinnon

4.16 Do you want to request that an ordering tool be built for your study in Epic?
No

4.17 Would you like to submit a request for the Epic team to consider your study for the use of BPA (Best Practice Advisory) in Epic?
No

4.18 Would you like to submit a request for the Epic team to build your questionnaires in Epic for the purposes of recruitment?
No

4.19 Will any external monitors require access to this study in Epic?
No

4.21 Mark all that apply to your study:

1. Protocol

1.1 Is there a separate, written protocol that will be submitted in addition to this form? (Note: a grant application is not considered to be a protocol)
No

1.2 Select up to three key words below that best describe this research study:
- Anesthesiology

1.3 Provide a short summary/abstract of the purpose and procedures of the study proposed in this IRB application.

- DO NOT include information on studies not proposed in this application.
- Use LAY terminology only. This must be easily understandable by IRB community members and nonscientists.
- DO NOT cut and paste technical abstracts from source of support applications that may not be understood by a general audience.

The purpose of this study is to implement an Anesthesiology Control Tower (ACT). This pilot study will employ the existing information technology infrastructure at Barnes Jewish Hospital to create a remote monitoring and alerting system for the operating rooms. Similar to “telemedicine” methods employed in critical care, the ACT will support operating room clinicians in adhering to best-practice principles.

The proposed study will logically build on our previous work and utilize the already established infrastructure and resources of the SATISFY-SOS registry study, the intra-operative electronic medical record and the AlertWatch® evidence-based alerting system. In conceptualizing this pilot study, as well as a larger follow-up trial focused on clinical outcomes, we have been mindful of challenges put forward to investigators by the National Institutes of Health, which seek to support low-cost, pragmatic, patient-centered randomized controlled trials (82). Specifically in relation to ACTFAST, (1) the highly developed, specialized IT infrastructure limits the investment required for embarking on this study; (2) the study will be conducted entirely within the context of routine clinical care, negating the need for dedicated trial-related visits; (3) access to registries with granular data on complications and patient-reported outcomes obviates the need for a new and costly infrastructure to track patient outcomes; (4) inclusion of large numbers of broadly representative patients in this study will be highly efficient with a waiver of informed consent (82). The design for this pilot proof-of-concept study will be a randomized clinical effectiveness trial of two years duration. It will include a 3 month pre-intervention period during which time the ACT will be staffed but no alerts will be sent. This will allow for the training of controllers, refinement of alerts, and optimization of processes for obtaining and filtering information from diverse electronic sources. This will also allow for the determination of baseline event rates for the outcomes of interest. Following this period, the trial will begin and run for 21 months. On a daily basis during the study period (weekdays from 7am to 5pm), each operating room at Barnes-Jewish Hospital where anesthesiology services are provided will be eligible for randomization, which will occur daily at the level of the operating room using computer-generated assignment. The experimental arm will receive the additional support of the Anesthesiology Control Tower in the form of control-tower alerts to the attending anesthesiologist that complement the AlertWatch® system. Some of these alerts will use video conference calling for communication between the clinician in the control tower and the clinicians in the operating room. The outcomes of interest in this pilot study will be the usability and usefulness of the ACT, clinician adherence to recommendations for monitoring, documentation and therapeutic interventions, key physiologic variables such as temperature and blood pressure, and patient outcomes including duration of postoperative hospital stay, incidence of postoperative morbidity (myocardial infarction, surgical site infection), functional recovery, and postoperative quality of life. All of the alerts included in this study will be chosen because they follow best intraoperative management practice and are in line with national metrics for quality and safety (83-85).

Outcome data will be collected on a group level to see if when the control tower provided information and intervention followed.

1.4 Specify your research question(s), study aims or hypotheses:
Specific Aim 1: To determine the usefulness and usability of an Anesthesiology Control Tower (ACT) for the operating suite.
- We hypothesize that the ACT will be usable and will be perceived as useful by the anesthesia team.
Specific Aim 2: To determine whether the ACT improves:
a. Clinicians’ compliance with standards of practice for treatment, documentation, and monitoring.
b. Surrogate measures of patient outcomes.
- We hypothesize that the ACT will result in (a) better clinician compliance (e.g., timely administration of antibiotics, rigorous documentation, and regular blood pressure and neuromuscular monitoring) and (b) improvement of key physiological parameters (e.g., temperature and blood pressure).
Specific Aim 3: To explore whether the ACT improves postoperative patient outcomes.
- We hypothesize that when the ACT provides feedback to clinicians, there will be a trend towards improved patient outcomes (e.g., fewer readmissions, improved quality of life) in this pilot trial.

1.5 Background and significance and/or Preliminary studies related to this project:

A.1. Opportunity for information and communication technology to improve perioperative care

Most of the >200 million people (1) who undergo elective surgery and other procedures around the world every year choose to do so because they believe that the surgery will cure a condition or improve their quality of life.(2) However, in recent years research conducted at Barnes-Jewish Hospital (BJH) and around the world has revealed that the incidence of adverse outcomes after surgery is disturbingly high. Following in-patient surgeries, the estimated 30-day mortality is between 1% and 5% (3-11), and by 90 days to 1 year postoperatively, between 5% and 10% of these patients have died (5, 6, 9, 12). Furthermore, about 10% to 20% of surgical patients experience major complications, such as heart attacks, unremitting pain, infections and blood clots, in the weeks to months following their procedures (7, 10, 11, 13). We are currently embarked on a major quality improvement initiative at BJH, called SATISFY-SOS (Systematic Assessment and Targeted Improvement of Services Following Yearling Surgical Outcomes Surveys - NCT02032030), in which we are systematically tracking the health and well-being of surgical patients postoperatively. This is a unique initiative enrolling 10,000 patients a year that will allow us to gauge outcomes that are important to patients, such as duration of debility, postoperative quality of life, and the timeline for return to work and to full functionality. Additionally, we have partnered locally with the American College of Surgeons' National Surgical Quality Improvement Program (NSQIP) and the Society of Thoracic Surgery (STS) database in order to enhance the granularity of the measured outcomes. Given the increased availability of information and communication technology at our hospital, and our current ability to track patients' postoperative trajectories, we believe that the next priority in our quality improvement agenda should be to leverage information and communication technology to implement perioperative evidence-based practices that positively impact patients' outcomes.

A.2. Information and communication technology can aid implementation of evidence-based care

The disturbing frequency of medical errors and patient harm has been well publicized (14). Unfortunately, increases in public and clinician recognition of errors, and the resulting movements in research and health care policy, have failed to decrease the rate at which harm occurs (15). In addition to directly committing errors, clinicians continue to contribute to harm by failing to implement evidence-based standards of care. This failure has been documented repeatedly and in a variety of settings (16, 17); whether in internal medicine (18) or critical care (19), clinicians do not follow even well established guidelines. Possibly of most concern is the lack of clinician awareness of these failures; many clinicians believe that they are in compliance with guidelines when in reality they are not (20). Overall, it is clear that the pursuit of quality in the healthcare system still has much to achieve and many barriers to overcome. Appropriate integration of information technology (IT) to provide decision support and meaningful alerts could potentially overcome barriers to the implementation of evidence-based care (21-23).

A.3. IT-driven decision support can impact outcomes

Despite major advancements in the safety of anesthetic techniques and therapeutics, the risk of patient morbidity and mortality related to surgery persists. Some of this risk is unavoidable and is either inherent to the nature of the surgical procedure itself, or is attributable to a characteristic of the patient that is not in an immediate way modifiable (10, 24, 25). There are, however, factors that do fall under the control of the anesthetic team that have been shown to affect the patient's immediate and long term health (26-29), including the appropriate management of hyperglycemia (30), proper administration of prophylactic antibiotics (31, 32), maintenance of normothermia (33), the avoidance of excessively large tidal volumes with mechanical ventilation (34, 35), administration of sufficient anesthesia (36-39), and appropriate thresholds for blood transfusions (40, 41). IT-driven decision support has been shown to optimize management of these factors, leading to improvement in physiological measures, such as blood pressure stability (42) and glucose control (43, 44) We have demonstrated that an IT-based solution can improve appropriate repeat dosing of antibiotics during surgery, although there remains opportunity for further improvement. We have also shown through large pragmatic clinical trials that IT-driven decision support can impact clinically relevant outcomes, such as preventing patients from experiencing intraoperative awareness (37). More generally, there is emerging evidence that perioperative management practices guided by IT solutions are likely to have lasting and long-term effects on patient outcomes (12). Leaders in perioperative quality improvement and patient safety must therefore develop pragmatic, technology-driven methods to implement such practices into the routine management paradigm.

A.4. Need for empowering and unobtrusive IT-based solutions

Information overload is a major barrier to implementation of evidence-based practice in the operating room. Anesthesiologists, like all medical practitioners, have multiple known limitations in their cognitive and decision making abilities (45-47). There is a limited amount of data that physicians can process per unit of time(48), and the mismatch between human decision making ability and excess information is a source of medical errors (49). In the realm of anesthesiology, the operating room environment is a source of numerous stimuli that can at times overwhelm a single clinician, who is often inundated with alarms and alerts. Practitioners may see alarms as frequently as every 3 minutes—even more frequently during induction of anesthesia and emergence from anesthesia—and while the majority of alarms might appear to be clinically irrelevant, a small percentage do require immediate intervention (50). Less experienced practitioners are likely to have the most difficulty and require the most assistance in these circumstances. However even the performance of senior physicians can suffer from the cognitive workload involved in patient care, particularly when supervising inexperienced trainees (51). Further information overload through intrusive or overwhelming IT-based decision support is likely to be unappreciated and even counter-productive. Given the known limits of human cognitive abilities, there is therefore a pressing need for empowering and unobtrusive perioperative information-technology based systems that support critical decision-making without inundating the clinician with unfiltered and often irrelevant information (52, 53).

A.5. Innovative information-technology based solution for the OR

The advancement of information technology and clinician decision support systems is being championed in the demand for quality in health care (54, 55), and in recent years, anesthesiology departments have increasingly embraced this development. Eight years ago, only 16% of the academic anesthesiology departments in the country employed anesthesia information management systems in their ORs (56); now, they are used in more than 75% of anesthesia departments in the United States(57). Since their inception, the functionality of anesthesia information management systems has increased remarkably, and they have been used to improve documentation compliance (58), to increase adherence to guidelines for prophylactic perioperative antibiotics (59, 60) and post-operative nausea and vomiting prophylaxis (61), and also to assist in the intraoperative management of hypotension and hypertension (42). Unfortunately, adherence has been shown to drop off over time (61). Data from remote electronic monitoring and support studies in the ICU strongly suggest that the addition of "telemedicine" may be a method for improving and maintaining adherence to established best practices (62, 63). On the strength of these compelling data, there has been widespread adoption of remote monitoring centers for intensive care units that provide back up to clinicians on the ground (64). Surprisingly, this control center model has not been evaluated for intraoperative care despite the fact that major perturbations in physiology (e.g., hemorrhage, shock, hypothermia, arrhythmias, hypoxemia, acid-base derangements) are probably more commonly encountered in the operating room than in the intensive care unit. By the time such derangements are recognized in the OR and rescue measures are initiated, damage to organ systems may have already occurred. There is therefore a gap in the field with an urgent need to assess the potential utility of a remote IT-based control center for the OR to anticipate and prevent injury and to improve quality of care generally. The insights yielded by the proposed ACTFAST (Anesthesiology Control Tower: Feedback Alerts to Supplement Treatments) pilot study will be highly informative to future research seeking to clarify the potential for health IT to promote evidence-based perioperative care.

B. Theoretical Framework for this Health IT Intervention Project

B.1 Anesthesiology Control Tower (ACT) Concept

The key innovative concept underlying this proposed health IT intervention project is that an Anesthesiology Control Tower (analogous to an air traffic control tower) can improve medical care for patients in the OR. Similar IT interventions have been developed in the critical care environment (65-67). These systems provide integrated information at the point of care, thus facilitating individualized care at the bedside and serving as platforms for broad quality improvement initiatives (68, 69). In the OR, this approach is now made possible at our hospital by technological advances in clinical monitoring and display systems. Such advances include real-time access to the hospital's electronic information systems, treatment guidelines, and protocols for care, as well as the availability of AlertWatch® (Ann Arbor, MI) in all ORs. Importantly, the perioperative electronic medical record, all hospital information systems, and the AlertWatch® dashboard are accessible remotely on any secure device with Internet connection (see figures 1a and 1b). This provides the opportunity to monitor patients remotely, and when necessary to institute ancillary support and even timely rescue interventions. AlertWatch® is an FDA cleared (Kl3O4Ol) patient monitoring and alerting system that provides integrated information similar to those systems developed in critical care. The crucial feature of AlertWatch® that is being used in this study is the availability of information via a secure Internet connection to clinicians at any physical location in the world. This allows for the creation of the remote Anesthesiology Control Tower (ACT). Just as an air traffic control tower monitors each aircraft and delivers additional information and alerts to the pilot and co-pilot, this ACT will engage with each team of anesthesia clinicians in a similar fashion to assist them in providing safe, effective, and efficient care for their patients. Also, just as a pilot may not be in the cockpit with the co-pilot for the entire flight, supervising anesthesiologists are not continuously present in the ORs. In our analogy, these physicians will be alerted by the supplementary ACT when undesired events are occurring or have the potential to occur, enabling the supervisors ("pilots") to return and provide appropriate support to the clinicians ("co-pilots") in the OR. The processing of electronic data by physician "controllers" in the ACT is a key component of the ACT, as it is expected that they will filter and prioritize information in order to improve the quality of alerts and to limit false alarms to the clinicians in the OR. This conceptualization of the ACT could allow it to decrease the burden from false and intrusive alarms in the OR, and instead provide an empowering and unobtrusive IT-based decision support solution to clinicians.

B.2. Overcoming challenges in the implementation of a health IT solution

The ACT concept provides a practical and innovative solution to the challenge of implementing evidence-based quality improvement in the operating room. It is abundantly clear that the deficiency of evidence-based practice in medicine is not due to lack of evidence; dozens of research studies are published every day and over 800,000 studies are available in the Cochrane Register of Controlled Trials (70). A gap between knowledge and performance is highlighted by the fact that increased awareness of areas of poor performance in patient care unfortunately may not lead to improvements in this care, as recently shown for hospitals enrolled in NSQIP. Participation in this quality-reporting program was not associated with any improved surgical outcomes in either of two rigorous studies (71, 72). In response to the known deficiency of evidence-based care, clinical decision support systems and similar technologies have been recommended by a number of organizations (23, 54, 73) as a method to help align clinical decisions with best practices, through the provision of relevant, evidence-based information and information management tools at the point of care (22). Encouragement is provided by a recent proof-of-concept study demonstrating that implementation of the AlertWatch® infrastructure in the ORs at the University of Michigan led to desirable intraoperative glycemic management behavior (44). Still, clinicians may fail to make use of decision support resources (74), and benefits from computerized decision support fade with time (18). Research performed in the intensive care field has repeatedly demonstrated that the addition of real-time, in-person (75, 76) or near-real time (77) prompting of clinicians improves adherence to best practices and furthermore improves patient outcomes. The ACT concept will provide similar real-time prompting based on data contained in AlertWatch® and other electronic health information systems, thus maximizing the potential to achieve individualized, evidence-based patient management in the operating suite.

B.3. Behavioral and organizational considerations

Genuine interest from key decision makers is an established facilitator to implementing new information technology in the healthcare setting (78, 79). With the strong support of the departmental chair, the residency director, and the department's anesthesiologists and residents, the ACT concept is primed for success. Fifteen attending anesthesiologists have already volunteered to spend fifteen days each a year as the "controller" in the ACT as part of their non-clinical allotment, and the residency curriculum will be revised to allow each senior resident the opportunity to gain invaluable experience as the "deputy controller" in the ACT. Given the continual, substantial increase in requirements for surgical procedures, a projected shortage of anesthesiologists, and financial constraints in healthcare, it will be infeasible for anesthesiologists to provide the level of supervision that is currently standard in the United States (e.g. one anesthesiologist for every one to four operating rooms) (80). However, current education of anesthesiologists largely emphasizes management of individual patients. There is little training on multi-tasking, on the supervision of anesthesia care teams, and on process management; yet anesthesiologists are already expected to be skilled in all of these areas, and the expectation will become increasingly manifest. Future anesthesiologists will be required not only to be competent in the development and implementation of individual anesthetic plans for patients who are presenting with ever-more complex medical conditions (81), but also in the management and direction of several concurrent plans delivered by residents or non-physician anesthetic clinicians. Resident participation in the staffing of the ACT will be a formative clinical experience that introduces trainees to the ever-expanding leadership roles that they will need to fill following graduation.

B.4. Likelihood for ACTFAST to generate insight

The ACTFAST study will make use of the highly granular perioperative electronic medical record to generate insight into surrogate perioperative measures (e.g., temperature, glucose, blood pressure management) that are likely to be associated with meaningful patient outcomes. Furthermore, this study will benefit from the extensive collaborative infrastructure that has been established over the last three years under the auspices of the Institute of Quality Improvement, Research and Informatics at Washington University. Despite the vast number of inpatient surgeries that take place in the United States (approximately 50 million each year), it is currently not routine to systematically track patients' postoperative outcomes after hospital discharge. At Washington University, approximately 25% of surgical patients have participated through structured questionnaires in the SATISFY-SOS initiative since 2012, through which we are tracking surgical outcomes up to one year postoperatively using electronic health information and patient-reported outcome measures. Patient reported outcomes tracked include health-related quality of life (Veteran's Rand-12), medical complications, falls, functional status (Barthel Index), cognition (PROMIS Cognition), pain, and intraoperative awareness (Modified Brice Interview). In order to augment outcomes tracked, we are enriching the SATISFY-SOS registry with extensive data from the electronic health record as well as from the local NSQIP and STS databases. The ACTFAST pilot study will therefore be well positioned to explore the association between intraoperative management and patient outcomes up to one year postoperatively, with minimal additional cost to the proposed project.

1.6 Literature cited/references (if attaching a grant enter N/A):

1. Weiser TG, Regenbogen SE, Thompson KD, Haynes AB, Lipsitz SR, Berry WR, Gawande AA. An estimation of the global volume of surgery: a modelling strategy based on available data. Lancet. 2008;372(9633):139-44. doi: 10.1016/S0140-6736(08)60878-8. PubMed PMID: 18582931.

2. Oresanya LB, Lyons WL, Finlayson E. Preoperative assessment of the older patient: a narrative review. JAMA : the journal of the American Medical Association. 2014;311(20):2110-20. doi: 10.1001/jama.2014.4573. PubMed PMID: 24867014.
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1.7 Describe EACH of your participant populations

- Include description of any control group(s)
- Specify the Inclusion/Exclusion criteria for EACH group

On a daily basis during the study period (weekdays from 7am to 5pm), each operating room at Barnes-Jewish Hospital where anesthesiology services are provided will be eligible for randomization, which will occur daily at the level of the operating room using computer-generated assignment. The experimental arm will receive the additional support of the Anesthesiology Control Tower in the form of control-tower alerts to the attending anesthesiologist that complement the AlertWatch® system. Some of these alerts will use video conference calling for communication between the clinician in the control tower and the clinicians in the operating room.

1.13 Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.

Describe study populations separately if they will be participating in different procedures

DESCRIBE:

- Control populations, if applicable
- Any randomization, if applicable
- What participants will be asked to do/what happens in the study (in sequential order)
- The time period over which procedures will occur
- Long-term follow-up and how it occurs

The study is being conducted with a waiver of consent. On a daily basis during the study period (weekdays from 7am to 5pm), each operating room at Barnes-Jewish Hospital where anesthesiology services are provided will be eligible for randomization, which will occur daily at the level of the operating room using computer-generated assignment. The experimental arm will receive the additional support of the Anesthesiology Control Tower in the form of control-tower alerts to the attending anesthesiologist that complement the AlertWatch® system. Some of these alerts will use video conference calling for communication between the clinician in the control tower and the clinicians in the operating room.

1.14 Will participants be randomized?
Yes

1.15 Will any of the following be used to collect information from the participant or others?

- Screening questions or screening/eligibility questionnaires
- Surveys
- Questionnaires
- Stimuli
- Any other written assessments

No

1.16 Does this project involve creating any audio, video, or photographs?
No

1.17 Does the study include any form of deception (e.g., providing participants with false information, misleading information, or withholding information about certain study procedures)?
Examples:

- Procedure includes a cover story that provides a plausible but inaccurate account of the purposes of the research.
- Participants will be provided with false information regarding the particular behaviors of interest in the research.
- Procedures include a confederate pretending to be another participant in the study.
- Participants will be told that the research includes completion of a particular task, when in fact, that task will not be administered.
- Study is designed to introduce a new procedure (or task) that participants are not initially told about.

No

1.18 Indicate any payments or reimbursements to participants (check all that apply)

- None - subjects not paid/reimbursed

1.19 Does this study have a plan to have an individual or committee review combined data from all participants on a periodic basis (such as summary or aggregate safety and/or efficacy data)?
No

1.20 What have you done to minimize any risks?

- No forseeable risks

1.21 What are the potential benefits related to this project for:

- the participant (if any)
- benefits to society (if any)

There is a possible benefit to participants (patients) as they could benefit from extra monitoring from the ACT.

This work could have a major impact on healthcare if it demonstrates that successful implementation of an ACT promotes quality improvement and enhances surgical patient safely, while simultaneously increasing efficiency.

1.22 Provide a summary of the analysis methods you will use, including, if applicable, the data points or outcomes you will analyze.
The baseline data on compliance metrics, surrogate measures of outcomes and clinical outcomes from the 3-month calibration period will be presented using standard descriptive statistics. Once the ACT intervention is implemented, we anticipate a possible contamination (or learning) effect over time in the control group. Clinicians may become sensitized to the standards of practice and the surrogate measures of outcome, leading to “overlapping” improvements in these measures in both study groups over the course of the study. This learning effect might manifest most strongly among physicians who spent time as “controllers” and “deputy controllers” in the ACT. Furthermore, with the knowledge that clinicians are being observed, there is a high likelihood of a robust Hawthorne effect (109, 110). The baseline data will be useful in assessing the extent of these effects. We will analyze results from the interventional period in 3-month time bins (with baseline data for reference) to evaluate the extent, potential increase over time, and potential durability of the contamination and Hawthorne effects. The behaviors and objective physiological variables measured under Specific Aims 2a and 2b might prove useful in quantifying the contamination and Hawthorne effects over time, although these effects could be difficult to distinguish from each other. Comparisons between groups during the randomized pilot study will be with parametric and non-parametric statistical tests, according to the distributions of the measures of interest. Fisher’s exact or Chi-square test will be used (1) to assess whether there is a difference between groups in the proportion of times that administration of antibiotics

is >30 minutes before or after surgical incision; (2) to evaluate whether or not the ACT alerts improve the compliance with 5-minute interval blood pressure measurement and with the use of EEG monitoring when indicated; and (3) to ascertain whether or not the alerts are associated with improved documentation of neuromuscular function. Contingency statistical tests will be used to compare occurrence of hypotension and hypothermia between groups, and unpaired t-test or Mann-Whitney U test, as appropriate, will be used to compare these durations between groups. Similar statistical approaches will be used for the exploratory outcomes, all of which will be regarded as hypothesis generating. ANCOVA or non-parametric ANCOVA might be helpful in detecting (and potentially controlling for) patterns of contamination or a Hawthorne effect (111). The results obtained in this pilot trial will be used to estimate appropriate sample sizes for follow-up outcomes studies. By convention, statistical significance will be based on a two-sided p value <0.05. All statistical testing will be with SAS® version 9.4 (SAS Institute Inc., Cary, North Carolina, USA).

1.23 Provide the rationale or power analysis to support the number of participants proposed to complete this study.
This pilot study will be carried out in all operating rooms at Barnes-Jewish Hospital (BJH, South Campus), St. Louis, MO, where AlertWatch® has been installed since 2014 and the electronic perioperative medical record has been in place since 2009. BJH is a 1,252 bed academic university affiliated and adult tertiary care hospital, performing about 19,000 inpatient surgeries a year (86). On average, 125 surgeries take place every business day of the week. To be conservative, we estimate that information on 50 to 100 surgeries per day will be collected for this pilot study. We therefore anticipate a total sample size of about 3,000 surgeries during the pre-intervention period, and about 21,000 surgeries during the trial period with 10,500 surgeries in each arm. We estimate that we will have comprehensive outcomes data for approximately 8,000 of the 21,000 patients included in the pilot study.

1.24 Indicate below only the sources of your data or specimens that you are requesting to obtain under a WAIVER OF CONSENT:

Type	Source	# records/samples	Any identifiers (check all that apply)?
Data - Retrospective Records created between: Earliest: 4/1/16 latest: 11/26/19	• Repository/Registry • Research Data Core (RDC) (collection of vital status and date of death)	15158	• Names • Medical record numbers • Account numbers • Any elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older. • A unique identifying number or code that can be linked to identifiers
Data - Retrospective Records created between: Earliest: 4/1/2016 latest: 12/14/17	• Medical Records (Metevision, Clinical Desktop, alertwatch, EPIC) • Collected Under an Approved IRB Study (201203088, 201506017, Division of Cardiothoracic Surgery's Cardiac Surgery Quality assurance surgical database) • Other (On a daily basis during the study period (weekdays from 7am to 5pm), each operating room of (BJH) will be eligible for cluster randomization, which will occur at the level of the operating room.)	21000	• Medical record numbers • Account numbers • A unique identifying number or code that can be linked to identifiers • Names • Any elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
Data - Prospective/Ongoing	• Medical Records (Metevision, Clinical Desktop, alertwatch, EPIC) • Collected Under an Approved IRB Study (201203088, 201506017, Division of Cardiothoracic Surgery's Cardiac Surgery Quality assurance surgical database) • Other (On a daily basis during the study period (weekdays from 7am to 5pm), each operating room of (BJH) will be	21000	• Medical record numbers • Account numbers • Names • A unique identifying number or code that can be linked to identifiers • Any elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.

Type	Source	# records/samples	Any identifiers (check all that apply)?
	eligible for cluster randomization, which will occur at the level of the operating room.)		
Data - Prospective/Ongoing	• Repository/Registry • Research Data Core (RDC) (collection of vital status and date of death)	15158	• A unique identifying number or code that can be linked to identifiers • Any elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older. • Medical record numbers • Account numbers

Attachment Name	Category	Version	Date Attached
Variable_Definitions_Targeted_Pancreatectomy_150101.pdf	Listing of Data/Specimen Data Points	1	12/13/17
doc027411201505290952 46(1).pdf	Listing of Data/Specimen Data Points	1	12/13/17
Variable_Definitions_Targeted_Thyroidectomy_150101.pdf	Listing of Data/Specimen Data Points	1	12/13/17
Variable_Definitions_Classic_150101.pdf	Listing of Data/Specimen Data Points	1	12/13/17
Variable_Definitions_Targeted_VentralHerniaRepair_150101.pdf	Listing of Data/Specimen Data Points	1	12/13/17
Variable_Definitions_Targeted_Proctectomy_150101.pdf	Listing of Data/Specimen Data Points	1	12/13/17
Variable_Definitions_Targeted_AIEndo_150101.pdf	Listing of Data/Specimen Data Points	1	12/13/17
Variable_Definitions_Targeted_AIOpen_150101.pdf	Listing of Data/Specimen Data Points	1	12/13/17
Variable_Definitions_Targeted_Appendectomy_150101.pdf	Listing of Data/Specimen Data Points	1	12/13/17
Variable_Definitions_Targeted_CarotidEndo_150101.pdf	Listing of Data/Specimen Data Points	1	12/13/17
Variable_Definitions_Targeted_Hepatectomy_150101.pdf	Listing of Data/Specimen Data Points	1	12/13/17
Variable_Definitions_Targeted_LEOpen_150101.pdf	Listing of Data/Specimen Data Points	1	12/13/17
Variable_Definitions_Targeted_LEEndo_150101.pdf	Listing of Data/Specimen Data Points	1	12/13/17
RDC data points 12.6.19.docx	Listing of Data/Specimen Data Points	1	12/06/19
Variable_Definitions_Targeted_CarotidOpen_150101.pdf	Listing of Data/Specimen Data Points	1	12/13/17
Variable_Definitions_Targeted_Colectomy_150101.pdf	Listing of Data/Specimen Data Points	1	12/13/17
WUSM DataCollectionForm v2_81 (custom).docx	Listing of Data/Specimen Data Points	1	12/13/17
Variables List_5.3.18.docx	Listing of Data/Specimen Data Points	3	05/09/18
Chapter 4 Hysterectomy PT 1-1-15(1).pdf	Listing of Data/Specimen Data Points	1	12/13/17

Chapter 4 Reconstruction PT 1-1-15.pdf	Listing of Data/Specimen Data Points	1	12/13/17
Variable_Definitions_Targeted_AAAEndo_150101.pdf	Listing of Data/Specimen Data Points	1	12/13/17
Variable_Definitions_Targeted_AAAOpen_150101.pdf	Listing of Data/Specimen Data Points	1	12/13/17
Worksheet_Targeted_Jan_2015(1).pdf	Listing of Data/Specimen Data Points	1	12/13/17
Data points 201603038.docx	Listing of Data/Specimen Data Points	3	12/14/17

1.24.a Does your data include **protected health information (PHI)**?
Yes

1.24.b What is the plan for participant identifiers?
Identifiers will be destroyed at the earliest opportunity, consistent with the conduct of the research.

1.24.c Does the research team agree that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the study, or for other research for which the use or disclosure of the requested information would be permitted by the HIPAA Privacy Rule?
Yes

1.25 Will any data from this project be stored for use in future research studies?
No

1.26 Does this project involve the collection or use of biological samples or genetic data?
No

1.27 Are you requesting institutional certification to contribute human data or samples to a repository or database for broad sharing (public or restricted access)?
No

2. Participants

2.1 Will there be any adult participants?
Yes

2.1.a How many adult participants do you expect to consent or enroll under a waiver for this project?
21000

2.1.b What is the age of the youngest adult participant?
18.0

2.1.c What is the age of the oldest adult participant?
No age limit

2.2 Will there be any minor participants?
No

2.3 Will there be any emancipated minor participants?
No

2.9 Is this project about pregnant women?
No

2.10 Will this project involve fetuses?
No

2.11 Does this project involve the use of fetal tissue from any source?
No

2.13 Does this project involve prisoners as participants?
No

3. Performance Sites

3.1 Indicate type of site(s) where research will occur (check all that apply):
- Hospital

- Academic Institution

3.2 Where will project procedures take place (check all that apply)?
- School of Medicine
- Barnes Jewish Hospital (BJH)

3.3 Is this project also being conducted by other researchers at their own sites (e.g. a multi-site collaborative project)?
No

5. Privacy & Confidentiality

5.1 Indicate your plans to protect the privacy interests of the participants during the conduct of the study (check all that apply):
- Only the minimum necessary private information is collected for the purposes of the study
- Any procedures or interventions conducted as part of the study will be conducted in private setting to the extent possible

5.3 Project uses paper or hard copy consents, surveys, data collection forms, research subject binders, or other hard copy materials (check all that apply):
No

5.4 Project collects, stores and/or transmits electronic data on mobile devices, desktop computers, servers including cloud servers, email, or any other information in electronic form (check all that apply):
Yes
- Password protected
- Access is limited to research team only
- Data are encrypted
- Transmitted using recognized security for electronic submission

5.5 Project collects or uses biologic specimens (check all that apply):
No

5.6 Identify any additional protections in place for data and or samples (check all that apply):
- No additional protections