

Part B: Experimental Design and Protocol
Human Subjects Protocol Application:

Title: Evaluation of Outcomes in the Post Anesthesia Care Unit at Boston Children's Hospital Waltham

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Please provide a brief summary or abstract of this research protocol.

Quality outcomes in the Post Anesthesia Care Unit (PACU) have always been a goal of hospital care at Boston Children's Hospital (BCH). A considerable number of metrics can be used to measure quality of outcomes in the PACU - such as the incidence of postoperative pain, the incidence and degree of emergence delirium, and number of patients who experience post-operative vomiting.

The purpose of this study is to collect a large amount of prospective, observational data to evaluate the quality of outcomes in the PACU at BCH Waltham including the incidence of severe pain, agitation/delirium, and emesis. We will also collect preoperative demographic and psychological profile data on patients as well as data on operative and anesthetic factors that may impact the quality of PACU outcomes. Data will be collected from several electronic data sources including PowerChart, SurgiNet, AIMS, and EPIC systems. All data will be pooled in a web-based relational database allowing analysis of correlation between factors and outcomes. Because BCH Waltham outpatient surgery patients are selected as having ASA health status 1 or 2, it is likely that the outcomes from their care will be dependent on these factors rather than their underlying pathology. We will also survey parents of these patients for their overall satisfaction with perioperative care.

We hypothesize that 1) A significant proportion of patients recovering at BCH Waltham experience significant pain, significant agitation, and emesis. 2) We further hypothesize that the quality of PACU outcomes will correlate with surgical technique, anesthetic drugs delivered, nerve blocks performed, and patient psychological profile. 3) That the rate of post-hospitalization behavior changes will vary and will be related to pre-existing temperament characteristics more than to operative care. 4) That parental satisfaction with care in the PACU at BCH Waltham will correlate with the quality of PACU outcomes.

1. Specific Aims /Objectives

Specific Aim 1: Evaluate the quality PACU outcomes at BCH Waltham in term of the incidence of postoperative pain, emergence delirium, vomiting, and postoperative behavior changes in children having outpatient surgery at BCH Waltham.

Specific Aim 2: Identify trends or correlations between modes of care (general anesthetic technique, nerve blockade, surgical type, patient psychological profile) and the quality of PACU outcomes.

Specific Aim 3: Determine if there is any relationship between the Quality of PACU outcomes and the existence of Post Hospitalization Behavior Changes.

Specific Aim 4: Determine the relationship between quality of PACU outcomes and the overall satisfaction that parents of patients express with their care at BCH.

2. Background and Significance

The quality outcomes involving pain, agitation, and vomiting in the Post Anesthesia Care Unit (PACU) bear greatly on the quality of care provided in the perioperative timeframe at Boston Children's Hospital (BCH). High quality PACU outcomes decrease the total workload for PACU nurses, decrease the chance of injury to patients, and increase satisfaction of patients, families, and care-givers. In addition, previous investigations by Kain and coworkers have found that PACU outcomes may impact on longer term behavioral, emotional and satisfaction outcomes for patients and families. [1-7] Other studies have linked the type of anesthesia delivered with various PACU outcomes. In particular, the use of total intravenous anesthesia has been associated with lower levels of nausea, vomiting, and emergence delirium when compared with inhaled anesthetic gases. [8-22]

Over the last 3 years, all of the perioperative information on BCH patients undergoing surgery and anesthesia has been migrated to electronic entry and storage. It is now possible to collect this information and place it into on large relational database allowing for ongoing evaluation of the quality of recovery at BCH. Additionally, since there is a large surgical load at BCH Waltham, it is possible to collect data on over 1000 patients/year – this that can ultimately inform outcomes for particular procedures with respect to the manner in which that procedure was performed. We propose a multidimensional, prospective, observational study that will be comprehensive in evaluating the quality of outcomes in the BCH Waltham PACU with a multidimensional approach. We will begin by codifying the nature of the emergence behaviors and side effects that occur in the BCH Waltham PACU. We will also collect data on specific elements of the preoperative assessment (age, sex, patient temperament issues, etc.) as well as the operative/anesthetic care of patients for each patient. This data, coming from various electronic sources, will be combined into one large relational web-based database. (Figure 1.) Using this database, we will then evaluate if correlations exist between pre-existing personality issues (or specific aspects of care in the operating room) and the quality of the recovery in the BCH Waltham PACU and post-hospitalization behaviors. We will also evaluate the patient behavior (per parent report) or stress (per youth report) two days and two weeks after the procedure to determine if there are any persistent (2 days or 2 weeks) behavior changes after the procedure. Ultimately we will investigate whether or not any elements of the pre-operative evaluation or operative care impact these late behaviors.

We believe that by looking at our primary outcomes – that of pain, emergence delirium, and vomiting in the Waltham PACU – with respect to patient factors and anesthetic management we will identify patients who are at particularly high risk for adverse Waltham PACU outcomes as well as anesthetic techniques that are associated with optimal Waltham PACU outcomes.

3. Preliminary Studies/Progress Report

We recently completed a version of this study at BCH Longwood. Reports generated include primary outcomes, as well as secondary outcomes and care variables. Relational analyses such as child temperament and anesthetic choice vs. outcome have been correlated. Please see Appendix 8 and 9 for reports of this work.

4. Design and Methods

a. Study Design

This will be a prospective observational study that will follow patients on the day of surgery from arrival in the BCH Waltham Day Surgery Unit, through surgery, and through their recovery in the BCH Waltham PACU. Subsequently we will evaluate post-hospitalization behavior changes at 2 days and 2 weeks after the surgery.

b. Patient Selection and Inclusion/Exclusion Criteria

We will enroll patients aged 2-6 years, who are undergoing the following qualifying surgeries at BCH Waltham:

- Eye muscle surgery
- Tonsil and/or Adenoid Removal

Enrollment will exclude those patients identified in their Pre-Anesthesia Record as having developmental delay or decisional impairment regardless of age.

These qualifying surgeries are performed on approximately 35 patients per week. Patients having these procedures have been identified as having high rates of pain and emergence delirium postoperatively by the BCH Waltham PACU nursing staff. In addition, review of anesthetic records reveals that there is significant variability in the nature of the general anesthesia, regional/local anesthetic, and adjunctive medications (type and amount of opioids, use of Total Intravenous Anesthesia (TIVA), ondansetron, decadron, acetaminophen, NSAIDS) used in the perioperative period for these patients. For example, there is approximately 20% use of some form of continuous intravenous anesthesia vs. 80 % exclusive inhaled anesthesia.

c. Recruitment Methods

We plan to offer participation to patients aged 2-6 years, who are scheduled for tonsillectomy/adenoidectomy, adenoidectomy only, tonsillectomy only, or eye muscle surgery at Boston Children's Hospital Waltham. Potentially eligible subjects will be identified through a review of the schedule of upcoming surgeries in Surginet, by age and scheduled procedure type. Potentially eligible patients will be sent a brochure describing our methodologies in lay language, 1 week prior to their scheduled surgery. This brochure will include a link to a web-based, informational Power Point presentation. Potential participating families will be encouraged to view the presentation. Prior to the scheduled surgery, we will contact each potential participant by telephone to gauge their interest in participation and answer any questions concerning participation and/or the informational video. If the family agrees to participate they will be asked to arrive 15 minutes before their scheduled pre-op time where a written consent form will be provided in the BCH Waltham Day Surgery Unit.

d. Description of Study Treatments or Exposures/Predictors

- Preoperative (Remote): We will identify potential participants from preoperative scheduling data available through the various surgical sections we will be working with for this study. Description of the study will be sent by mail to families 1 week prior to their scheduled surgery. These materials will include an electronic link to a Power Point presentation that describes the study benefit, design, enrollment, etc. On a day before scheduled surgery, we will contact each potential participant by phone to gauge their interest in participation and answer any questions that exist concerning participation. If the family agrees to participate in this study, a written consent form will be provided in the BCH Waltham Day Surgery Unit.

- Preoperative (Day of Surgery - Demographics): Demographic data on each patient will be collected – including age, weight, diagnosis, history of previous surgery (yes/no), and coexisting major medical problems. This data will be obtained from the electronic medical record after enrollment in the study on the day of surgery or in the preoperative clinic.

- Preoperative (Day of Surgery – Psychological Profile): On the day of surgery we will collect The Children’s Behavior Questionnaire-Very Short Form (CBQ-VSF), a parent reported behavioral inventory on each child that allows us to understand his/her developmental status and aspects of their emotionality and sociability. This will consist of a short survey of questions. This is presented in Appendix 1.[23]

We also will assess aspects of emotionality more broadly, specifically through use of the observational Yale Pre-Operative Anxiety Scale (YPAS-m).[25] This observational scale is one that the research coordinator will complete (i.e., it is not a self-report questionnaire that must be administered to patients or families) and has been validated for our proposed use with patients ages 2-12 to further assess pre-operative behaviors of interest for characterizing emotionality.

- Preoperative (Day of Surgery – Induction): Data on the nature of the induction of anesthesia will be collected by the study coordinator using the Induction Compliance Checklist (ICC) (Appendix 3.)

- Intraoperative: Data on the intraoperative care of each patient will be collected through the Automated Information System (AIMS) at Boston Children’s Hospital. The information will include use of inhalation agent (type and MAC level), propofol infusion (both as sole anesthetic agent and as adjunct to general anesthesia), dexmedetomidine (bolus or infusion), dexamethasone (dose), ondansetron (dose), and opioid analgesic.

- Postoperative (PACU Data): In the PACU recovery data on each patient will include:

1. Pain behavior information using the FLACC scale (Appendix 4.)[26] or Wong-Baker Faces Scale (Appendix 5)[27].
 2. Emergence agitation categorization through use of the Pediatric Anesthesia Emergence Delirium Scale (PAED) (Appendix 6.).
 3. Episodes of emesis will be recorded along with the total time the child spent in the PACU.
- These measures will be recorded by reporting the highest level of pain or agitation that occurred for every 15 minute interval. In addition, any time vomiting occurs – it will be recorded.

- Postoperative (Remote): The behavior of participants will be assessed using the Post-Hospitalization Behavior Questionnaire (PHBQ) (Appendix 7).[28] Follow up surveys will be administered by email through REDCap to be completed 2 days after surgery and 2 weeks after surgery. The follow-up surveys can also be completed on paper by request. In that case, each family will be given 2 copies of the questionnaire at the time of surgery along with an instruction sheet concerning when the questionnaire should be completed. A self-addressed, stamped envelope will be included. Families completing the questionnaires by email will be called to remind them to complete the 2 day questionnaire if we have not received it within 4 days after discharge, and 2.5 weeks after discharge if we have not received the 2 week questionnaire. Families completing the questionnaires on paper will be called to remind them to complete and return their questionnaires if we have not received them 2.5 weeks after discharge. They will be given the option to complete the questionnaire by phone.

- Postoperative (Remote): At the same time we collect the 2-Day PHBQ data, we will question the consenting parent on their satisfaction with the perioperative care of their child This will be done using four questions designed to elicit (1) satisfaction with recovery in the BCH Waltham PACU; (2) global satisfaction with the surgical care at Boston Children’s Hospital Waltham; (3) degree of confidence participants would have recommending surgical services at Boston Children’s Hospital Waltham to family and/or friends; and (4) indication of whether healthcare had to be sought at Boston Children’s Hospital Waltham or another health facility as a result of the surgical services provided. Answers to the first two questions will be solicited on a simple scale from 0 to 10 with 0 being ‘very bad’ and 10 being ‘excellent’. Answers to the first two questions will also be solicited on a simple scale from 0 to 10, with 0 being ‘not at all and 10

being ‘very strongly’. The fourth question is worded yes/no, and participants also will have the opportunity to explain qualitatively why they have answered either yes or no

A member of the study team will mail a follow-up thank-you postcard to all those participating families for whom all follow-up documentation has been completed and received back at Boston Children’s Hospital within two weeks of receiving completed follow-up materials.

Figure 1. Data Collection and Storage Scheme

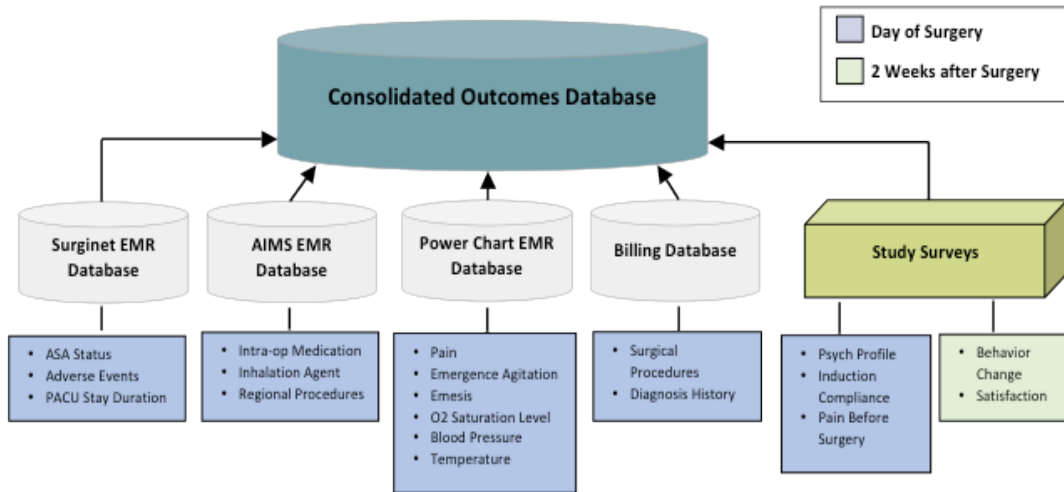
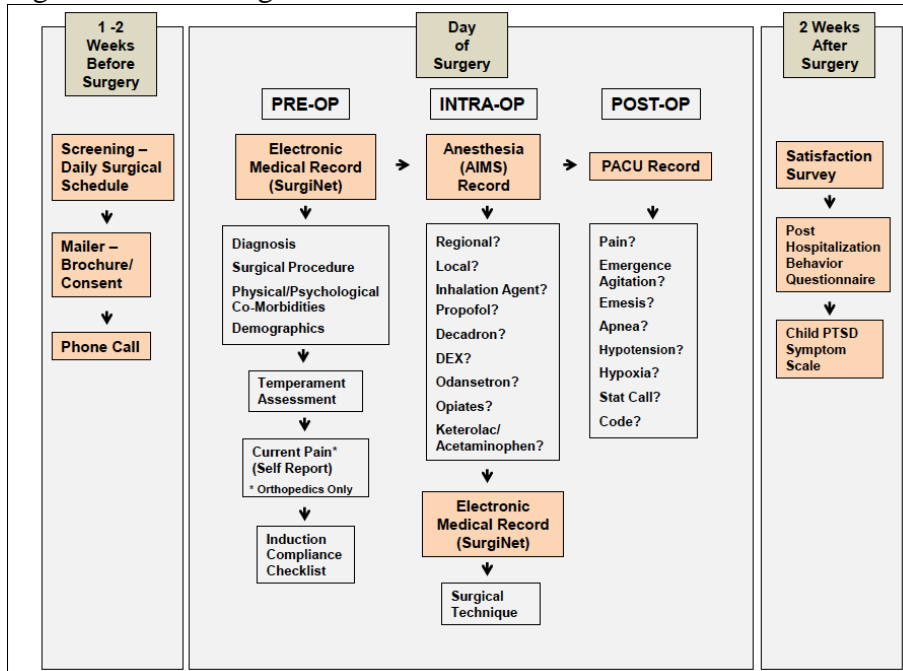


Figure 2. Flow Diagram for Data Collection



e. Definition of Primary and Secondary Outcomes/Endpoints

Primary outcomes:

1. Incidence of significant pain defined by pain behavior information from FLACC scale, Wong-Baker Faces scale– equal to or more than 5 on a scale from 0 to 10 at any time during the Waltham PACU stay.
2. Incidence of agitation using emergence agitation categorization with PAED scale equal to or more than 10 on this scale for more than 30 seconds during the recovery period.
3. Post-operative vomiting (POV) will be measured by episodes of vomiting or retching in Waltham PACU. This will be a binary outcome – either vomiting/retching occurred or it did not.

Secondary outcomes:

1. Parental satisfaction with perioperative care, as determined from a four-question satisfaction survey allowing participating families to rate their recovery experience, global surgical experience, and need for further care at another healthcare facility.
2. Post-hospitalization behaviors changes defined by development of 4 or more behavior changes on the Post Hospitalization Behavior Questionnaire (PHBQ)

5. **Data Management and Statistical Analysis**

a. Data Management Methods

Data will be collected from several sources:

1. Questionnaire data from the personality profiles performed in the preoperative venue will be entered directly into the Anesthesia Oracle database instance using a study tablet.
2. Data on pre-operative anxiety will be collected and entered into the Anesthesia Oracle database instance by the research coordinator.
3. Data on induction compliance will be collected and entered into the Anesthesia Oracle database instance by the research coordinator.
4. Data on demographics for each patient will be obtained from a review of the CHAMPS data on each patient and entered into the Anesthesia Oracle database instance.
5. Data on specific parameters of the intraoperative management will be collected and stored in the AIMS data system.
6. Data concerning PACU outcomes will be collected on the electronic PACU flow sheet and entered directly into the Anesthesia Oracle database instance.

Data from the PHBQ and Satisfaction surveys completed by participants via email using REDCap are stored in a corresponding REDCap database. Surveys completed on paper or over the phone will be recorded directly into the REDCap database by the study coordinator upon receipt. All data collected in REDCap will be securely transferred into the Anesthesia Oracle database instance using REDCap's REST API.

b. Quality Control Method

Data will be verified by investigators after being loaded into the database.

c. Data Analysis Plan

- Raw data on the number of children who emerge from anesthesia with severe pain as per FLACC/Faces readings will be recorded.
- The number of children who experience Emergence Delirium defined as a PAED score of 10 during their BCH Waltham PACU stay – will be recorded.
- The number of children who experience vomiting or retching without frank emesis will be recorded.

- Time required to meet BCH Waltham PACU discharge criteria will be recorded.
- Outcomes will then be analyzed with respect to the pre-operative demographic and behavioral/psychological profiles that were collected on each patient
 - Further analysis will evaluate the impact of anesthetic technique metrics on the duration of BCH Waltham PACU stay, percentage of patients with pain scores reflecting severe acute pain in the BCH Waltham PACU; PAED scored reflecting emergence agitation, and rates vomiting. Specifically, the use of regional anesthesia will be evaluated. The use of a propofol infusion during the anesthetic as well as the amount (and type) of opiate used during the case will be evaluated. The administration of adjunctive medications such as dexamethasone, ketorolac, acetaminophen, or ondansetron will also be evaluated. Logistical regression analysis will be used to determine if any of the above is independent predictors of poor perioperative outcomes.
- Follow up data on behavioral outcomes will be obtained using the PHBQ . The rate of 4 or more new behavioral changes on the PHBQ will be evaluated with respect to patient demographic data (age, pre-existing diagnoses) and the data on primary outcomes during the Waltham PACU stay.

d. Statistical Power and Sample Considerations

This is an observational, longitudinal study. As such we are not performing a power analysis to determine required sample sizes. Given the current frequency of these surgeries we will enroll approximately 15-25 patients per week in this study. After 12 months we expect to have at least 520 patients in our database. After 24 months we expect to have 1000 patients in our database. The primary aim of this study is to use our specific metrics to determine the percentage of patients in our BCH Waltham PACU who have one or more of our primary outcomes. We will also determine the percentage of patients who have behavior changes at 2 days and/or 2 weeks after the procedure (PHBQ measures) and the overall parental satisfaction with our perioperative care as determined by the satisfaction outcome scores.

Our secondary aim is to assess the relationships between various patient and procedural characteristics and primary BCH Waltham PACU outcomes as well as the PHBQ outcomes. We will perform a univariate logistic regression analysis of potential predictor variables including patient psychological profiles, induction behaviors, and anesthetic management as well as the operative procedure itself. Using the results of this univariate analysis, we will develop multiple logistic regression models. Multiple logistic regression models will be evaluated manually in a stepwise fashion to determine characteristics associated with primary and secondary outcomes.

e. Study Organization

None

f. Data and Safety Monitoring Plan

All data that is to be released to investigators will be reviewed prior to release to ensure maintenance of confidentiality.

6. Risk and Discomfort

This is an observational study not involving greater than minimal risk. This research will not influence or change any treatment course.

7. Privacy Provisions

Patient privacy will always be respected in any study activity. For this study, this is limited to the process of behavioral evaluation in Waltham PACU and postoperative care unit.

8. Confidentiality Provisions

All paper records are kept in locked cabinet with access restricted to the investigators. The study tablet is encrypted, password protected, and compliant with Boston Children's Hospital policies. When not

in use it will be stored in a locked cabinet with access restricted to the investigators. No data will be stored directly on the device.

All identifying information such as dates of birth, names or medical record numbers, will be removed from the Anesthesia Oracle database instance. All patients will be assigned to an ID number that will be not linked to any patient identifying information. Research related data will not be entered in to patients' medical records. All data will be electronically secured in a private folder and password protected. Only research investigators and personnel affiliated with the study will have access to patient information.

A REDCap (Research Electronic Data Capture) database will be created to store data captured on case report forms and to collect remote survey data. REDCap is a secure, web-based application designed to support electronic data capture for research. Only authorized users are permitted access to the data files, and daily server back-up activities are executed to ensure data recovery.

Appendix 1.

Children's Behavior Questionnaire--Very Short Form

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Children's Behavior Questionnaire Version 1

Subject No. _____ Date of Child's Birth: ____ / ____ / ____
Today's Date _____ Sex of Child : M/F
Age of Child: _____
Years Months

Instructions: Please read carefully before starting:

On the next pages you will see a set of statements that describe children's reactions to a number of situations. We would like you to tell us what your child's reaction is likely to be in those situations. There are of course no "correct" ways of reacting; children differ widely in their reactions, and it is these differences we are trying to learn about. Please read each statement and decide whether it is a "true" or "untrue" description of your child's reaction within the past six months. Use the following scale to indicate how well a statement describes your child:

- | Circle # | If the statement is: |
|----------|--------------------------------------|
| 1 | extremely untrue of your child |
| 2 | quite untrue of your child |
| 3 | slightly untrue of your child |
| 4 | neither true nor false of your child |
| 5 | slightly true of your child |
| 6 | quite true of your child |
| 7 | extremely true of your child |

If you cannot answer one of the items because you have never seen the child in that situation, for example, if the statement is about the child's reaction to your singing and you have never sung to your child, then circle NA (not applicable).

Please be sure to circle a number or NA for every item.

My child:	Extremely untrue 1	Quite untrue 2	Slightly untrue 3	Neither true nor untrue 4	Slightly true 5	Quite true 6	Extremely true 7	N/A
1. Seems always in a big hurry to get from one place to another.	1	2	3	4	5	6	7	N/A
2. Gets quite frustrated when prevented from doing something s/he wants to do.	1	2	3	4	5	6	7	N/A
3. When drawing or coloring in a book, shows strong concentration.	1	2	3	4	5	6	7	N/A
4. Likes going down high slides or other adventurous activities.	1	2	3	4	5	6	7	N/A
5. Is quite upset by a little cut or bruise.	1	2	3	4	5	6	7	N/A
6. Prepares for trips and outings by planning things s/he will need.	1	2	3	4	5	6	7	N/A
7. Often rushes into new situations.	1	2	3	4	5	6	7	N/A
8. Tends to become sad if the family's plans don't work out.	1	2	3	4	5	6	7	N/A
9. Likes being sung to.	1	2	3	4	5	6	7	N/A
10. Seems to be at ease with almost any person.	1	2	3	4	5	6	7	N/A
11. Is afraid of burglars or the "boogie man."	1	2	3	4	5	6	7	N/A
12. Notices it when parents are wearing new clothing.	1	2	3	4	5	6	7	N/A
13. Prefers quiet activities to active games.	1	2	3	4	5	6	7	N/A
14. When angry about something, s/he tends to stay upset for ten minutes or longer.	1	2	3	4	5	6	7	N/A
15. When building or putting something together, becomes very involved in what s/he is doing, and works for long periods.	1	2	3	4	5	6	7	N/A
16. Likes to go high and fast when pushed on a swing.	1	2	3	4	5	6	7	N/A
17. Seems to feel depressed when unable to accomplish some task.	1	2	3	4	5	6	7	N/A
18. Is good at following instructions.	1	2	3	4	5	6	7	N/A
19. Takes a long time in approaching new situations.	1	2	3	4	5	6	7	N/A
20. Hardly ever complains when ill with a cold.	1	2	3	4	5	6	7	N/A
21. Likes the sound of words, such as nursery rhymes.	1	2	3	4	5	6	7	N/A

My child:	Extremely untrue 1	Quite untrue 2	Slightly untrue 3	Neither true nor untrue 4	Slightly true 5	Quite true 6	Extremely true 7	N/A
22. Is sometimes shy even around people s/he has known a long time.	1	2	3	4	5	6	7	N/A
23. Is very difficult to soothe when s/he has become upset.	1	2	3	4	5	6	7	N/A
24. Is quickly aware of some new item in the living room.	1	2	3	4	5	6	7	N/A
25. Is full of energy, even in the evening.	1	2	3	4	5	6	7	N/A
26. Is not afraid of the dark.	1	2	3	4	5	6	7	N/A
27. Sometimes becomes absorbed in a picture book and looks at it for a long time.	1	2	3	4	5	6	7	N/A
28. Likes rough and rowdy games.	1	2	3	4	5	6	7	N/A
29. Is not very upset at minor cuts or bruises.	1	2	3	4	5	6	7	N/A
30. Approaches places s/he has been told are dangerous slowly and cautiously.	1	2	3	4	5	6	7	N/A
31. Is slow and unhurried in deciding what to do next.	1	2	3	4	5	6	7	N/A
32. Gets angry when s/he can't find something s/he wants to play with.	1	2	3	4	5	6	7	N/A
33. Enjoys gentle rhythmic activities such as rocking or swaying.	1	2	3	4	5	6	7	N/A
34. Sometimes turns away shyly from new acquaintances.	1	2	3	4	5	6	7	N/A
35. Becomes upset when loved relatives or friends are getting ready to leave following a visit.	1	2	3	4	5	6	7	N/A
36. Comments when a parent has changed his/her appearance.	1	2	3	4	5	6	7	N/A

Please check back to make sure you have completed all items by marking a number or "NA".

Thank you very much for your help!

Appendix 2.

SELF-EVALUATION QUESTIONNAIRE STAI Form Y-1

Please provide the following information:

Name _____ Date _____ S _____

Age _____ Gender (Circle) **M** **F** T _____

DIRECTIONS:

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel *right* now, that is, *at this moment*. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

NOT AT ALL
SOMEWHAT
MODERATELY SO
VERY MUCH SO

- | | | | | |
|--|---|---|---|---|
| 1. I feel calm..... | 1 | 2 | 3 | 4 |
| 2. I feel secure | 1 | 2 | 3 | 4 |
| 3. I am tense | 1 | 2 | 3 | 4 |
| 4. I feel strained | 1 | 2 | 3 | 4 |
| 5. I feel at ease | 1 | 2 | 3 | 4 |
| 6. I feel upset | 1 | 2 | 3 | 4 |
| 7. I am presently worrying over possible misfortunes | 1 | 2 | 3 | 4 |
| 8. I feel satisfied | 1 | 2 | 3 | 4 |
| 9. I feel frightened | 1 | 2 | 3 | 4 |
| 10. I feel comfortable | 1 | 2 | 3 | 4 |
| 11. I feel self-confident..... | 1 | 2 | 3 | 4 |
| 12. I feel nervous | 1 | 2 | 3 | 4 |
| 13. I am jittery | 1 | 2 | 3 | 4 |
| 14. I feel indecisive..... | 1 | 2 | 3 | 4 |
| 15. I am relaxed | 1 | 2 | 3 | 4 |
| 16. I feel content | 1 | 2 | 3 | 4 |
| 17. I am worried | 1 | 2 | 3 | 4 |
| 18. I feel confused..... | 1 | 2 | 3 | 4 |
| 19. I feel steady..... | 1 | 2 | 3 | 4 |
| 20. I feel pleasant..... | 1 | 2 | 3 | 4 |

SELF-EVALUATION QUESTIONNAIRE

STAI Form Y-2

Name _____ Date _____

DIRECTIONS

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you *generally* feel. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe how you generally feel.

ALMOST NEVER
SOMETIMES
OFTEN
ALMOST ALWAYS

- | | | | | |
|---|---|---|---|---|
| 21. I feel pleasant..... | 1 | 2 | 3 | 4 |
| 22. I feel nervous and restless | 1 | 2 | 3 | 4 |
| 23. I feel satisfied with myself..... | 1 | 2 | 3 | 4 |
| 24. I wish I could be as happy as others seem to be | 1 | 2 | 3 | 4 |
| 25. I feel like a failure | 1 | 2 | 3 | 4 |
| 26. I feel rested | 1 | 2 | 3 | 4 |
| 27. I am "calm, cool, and collected"..... | 1 | 2 | 3 | 4 |
| 28. I feel that difficulties are piling up so that I cannot overcome them..... | 1 | 2 | 3 | 4 |
| 29. I worry too much over something that really doesn't matter..... | 1 | 2 | 3 | 4 |
| 30. I am happy | 1 | 2 | 3 | 4 |
| 31. I have disturbing thoughts | 1 | 2 | 3 | 4 |
| 32. I lack self-confidence..... | 1 | 2 | 3 | 4 |
| 33. I feel secure | 1 | 2 | 3 | 4 |
| 34. I make decisions easily | 1 | 2 | 3 | 4 |
| 35. I feel inadequate..... | 1 | 2 | 3 | 4 |
| 36. I am content | 1 | 2 | 3 | 4 |
| 37. Some unimportant thought runs through my mind and bothers me | 1 | 2 | 3 | 4 |
| 38. I take disappointments so keenly that I can't put them out of my mind | 1 | 2 | 3 | 4 |
| 39. I am a steady person..... | 1 | 2 | 3 | 4 |
| 40. I get in a state of tension or turmoil as I think over my recent concerns and interests | 1 | 2 | 3 | 4 |

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STAIP-AD Test Form Y
www.mindgarden.com

State-Trait Anxiety Inventory for Adults Scoring Key (Form Y-1, Y-2)

Developed by Charles D. Spielberger in collaboration with R.L. Gorsuch, R. Lushene, P.R. Vagg, and G.A. Jacobs

To use this stencil, fold this sheet in half and line up with the appropriate test side, either Form Y-1 or Form Y-2. Simply total the scoring **weights** shown on the stencil for each response category. For example, for question # 1, if the respondent marked 3, then the **weight** would be 2. Refer to the manual for appropriate normative data.

Form Y-1	NOT AT ALL SOMEWHAT MODERATELY SO VERY MUCH SO	4 3 2 1	3 2 1 4	2 1 4 3	1 4 3 2	Form Y-2	ALMOST NEVER SOMETIMES OFTEN ALMOST ALWAYS	4 3 2 1	3 2 1 4	2 1 4 3	1 4 3 2
1.	4	3	2	1		21.	4	3	2	1	
2.	4	3	2	1		22.	1	2	3	4	
3.	1	2	3	4		23.	4	3	2	1	
4.	1	2	3	4		24.	1	2	3	4	
5.	4	3	2	1		25.	1	2	3	4	
6.	1	2	3	4		26.	4	3	2	1	
7.	1	2	3	4		27.	4	3	2	1	
8.	4	3	2	1		28.	1	2	3	4	
9.	1	2	3	4		29.	1	2	3	4	
10.	4	3	2	1		30.	4	3	2	1	
11.	4	3	2	1		31.	1	2	3	4	
12.	1	2	3	4		32.	1	2	3	4	
13.	1	2	3	4		33.	4	3	2	1	
14.	1	2	3	4		34.	4	3	2	1	
15.	4	3	2	1		35.	1	2	3	4	
16.	4	3	2	1		36.	4	3	2	1	
17.	1	2	3	4		37.	1	2	3	4	
18.	1	2	3	4		38.	1	2	3	4	
19.	4	3	2	1		39.	4	3	2	1	
20.	4	3	2	1		40.	1	2	3	4	

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STAIP-AD Scoring Key
www.mindgarden.com

Appendix 3.



HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL



Boston Children's Hospital
Until every child is well™

Study ID#: _____

Date: ____/____/____

Completed By: _____

Reason Not Completed: _____

INDUCTION COMPLIANCE CHECKLIST

1. Crying, tears in eyes
2. Turns head away from mask
3. Verbal refusal, says “no”
4. Verbalization indicating fear or worry, “where’s mommy?” or “will it hurt?”
5. Pushes mask away with hands, pushes nurse or anesthesiologist with hands/feet
6. Covers mouth/nose with hands/arms or buries face
7. Hysterical crying, may scream
8. Kicks/flails legs/arms, arches back, and/or general struggling
9. Requires physical restraint
10. Complete passivity, either rigid or limp

Was a family member present? **No** **Yes** **(please circle)**

Which one? _____

Appendix 4.

Age-Appropriate Pain Scales

FLACC Scale:

	DATE/TIME						
Face 0 - No particular expression or smile 1 - Occasional grimace or frown, withdrawn, disinterested 2 - Frequent to constant quivering chin, clenched jaw							
Legs 0 - Normal position or relaxed 1 - Uneasy, restless, tense 2 - Kicking, or legs drawn up							
Activity 0 - Lying quietly, normal position, moves easily 1 - Squirming, shifting back and forth, tense 2 - Arched, rigid or jerking							
Cry 0 - No cry (awake or asleep) 1 - Moans or whimpers; occasional complaint 2 - Crying steadily, screams or sobs, frequent complaints							
Consolability 0 - Content, relaxed 1 - Reassured by occasional touching, hugging or being talked to, distractible 2 - Difficult to console or comfort							
TOTAL SCORE							

Appendix 5.

Wong-Baker FACES Pain Rating Scale



From Wong D.L., Hockenberry-Eaton M., Wilson D., Winkelstein M.L., Schwartz P.: Wong's Essentials of Pediatric Nursing, ed. 6, St. Louis, 2001, p. 1301. Copyrighted by Mosby, Inc. Reprinted by permission.

Appendix 6.

Pediatric Anesthesia Emergence Delirium Scale:

1. The child makes eye contact with the caregiver.
2. The child's actions are purposeful.
3. The child is aware of his/her surroundings.
4. The child is restless.
5. The child is inconsolable.

Items 1, 2, and 3 are reversed scored as follows: 4 = not at all, 3 = just a little, 2 = quite a bit, 1 = very much, 0 = extremely.

Items 4 and 5 are scored as follows: 0 = not at all, 1 = just a little, 2 = quite a bit, 3 = very much, 4 = extremely. The scores of each item were summed to obtain a total Pediatric Anesthesia Emergence Delirium (PAED) scale score.

Appendix 7.

Post Hospitalization Behavioral Questionnaire - PHBQ

Responding Parent: Mother _____ Father _____ Other: _____ (please state relationship)

Please answer the following questions about specific behaviors that may or may not have changed following your child's hospital experience. Please circle the number that best describes your child's current behaviors as *compared to how these behaviors were before* your child's hospital experience.

	Much less than before	Less than before	Same as before	More than before	Much more than before
1. Does your child make a fuss about going to bed at night?	1	2	3	4	5
2. Does your child make a fuss about eating?	1	2	3	4	5
3. Does your child spend time just sitting or lying and doing nothing?	1	2	3	4	5
4. Does your child need a pacifier?	1	2	3	4	5
5. Does your child seem to be afraid of leaving the house with you?	1	2	3	4	5
6. Is your child uninterested in what goes on around him (or her)?	1	2	3	4	5
7. Does your child wet the bed at night?	1	2	3	4	5
8. Does your child bite his (or her) finger nails?	1	2	3	4	5
9. Does your child get upset when you leave him (or her) alone for a few minutes?	1	2	3	4	5
10. Does your child need a lot of help doing things?.	1	2	3	4	5
11. Is it difficult to get your child interested in doing things (like playing games with toys)?	1	2	3	4	5
12. Does your child seem to avoid or be afraid of new things?	1	2	3	4	5
13. Does your child have difficulty making up his (or her) mind?	1	2	3	4	5
14. Does your child have temper tantrums?	1	2	3	4	5
15. Is it difficult to get your child to talk to you?	1	2	3	4	5
16. Does your child seem to get upset when someone mentions doctors or hospitals?	1	2	3	4	5

17. Does your child follow you everywhere around the house?	1	2	3	4	5
18. Does your child spend time trying to get or hold your attention?	1	2	3	4	5
	Much less than before	Less than before	Same as before	More than before	Much more than before
19. Is your child afraid of the dark?	1	2	3	4	5
20. Does your child have bad dreams at night or wake up and cry?	1	2	3	4	5
21. Does your child have irregular bowel movements?	1	2	3	4	5
22. Does your child have trouble getting to sleep at night?	1	2	3	4	5
23. Does your child seem to be shy around strangers?	1	2	3	4	5
24. Does your child have a poor appetite?	1	2	3	4	5
25. Does your child tend to disobey you?	1	2	3	4	5
26. Does your child break toys or other objects?	1	2	3	4	5
27. Does your child suck his (or her) fingers or thumbs?	1	2	3	4	5

Please check back to make sure you have completed both pages of the questionnaire.

Thank you very much for participating!

Appendix 8:

Creation of an Integrated Outcomes Database for Pediatric Anesthesia

S. Sinnott, E. Carpino, P. Sriswasdi, R. Lekowski, R. Blum, J. Cravero

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Introduction: Outcomes data are critical for process improvement in any medical field. Large national (1) and local (2) database models have been proposed to aid in improving patient care and outcomes. We describe the creation of an integrated quality outcomes database that includes all phases of anesthesia/operative care and allows a continuous assessment of perioperative outcomes in a large tertiary children's hospital. Data will be used to continuously analyze anesthesia practice vs. outcomes, thereby driving improvement in patient care and satisfaction through iterative data-driven changes.

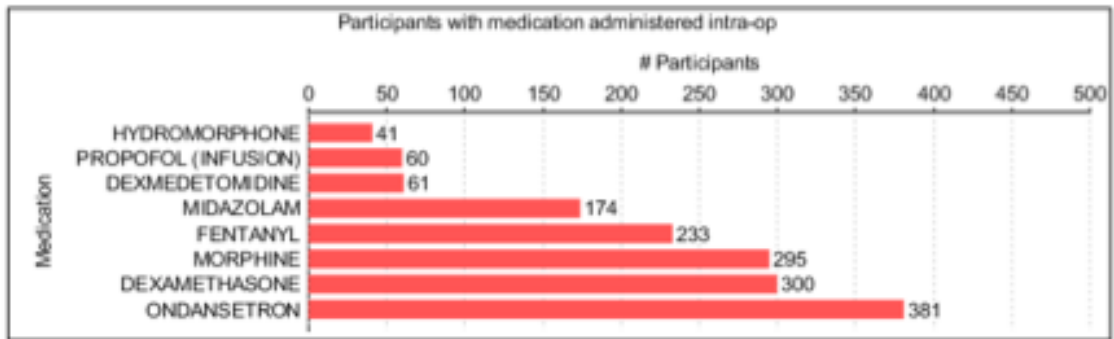
Methods: After IRB approval, we enrolled 430 patients undergoing a defined set of surgical procedures with a specific data collection/extraction strategy. We codified immediate postoperative outcomes related to anesthesia/surgery to include postoperative pain, agitation, and vomiting as well as physiological alert states for respiratory or cardiovascular systems. Late outcomes were defined as post-hospitalization negative behavior changes and family satisfaction levels. Possible factors that impact immediate and long-term outcomes were identified – including pre-existing child temperament, coexisting physical or psychological illness, induction compliance, surgical procedure/technique, and anesthetic technique. We developed a Java-Spring web-application on top of an Oracle database which would transform, validate, and consolidate data from a variety of distinct hospital database environments (Oracle, SQL Server, and Netezza). In addition to these automated processes the web application provides a user interface for manual cleaning of data entry for study specific data sources which are outside of the scope of normal clinical operations. This single consolidated database instance then provides a basis for rapid development of cross data source visualizations through Jasper Reports and custom data sets for analysis using Apache POI.

Results: Reports generated include primary outcomes, as well as secondary outcomes and care variables. Relational analyses such as anesthetic choice vs. outcome are possible. A brief example of primary outcomes and medication use is presented in Figure 1. Dashboard reports are available continuously for feedback to all members of the department for quality feedback.

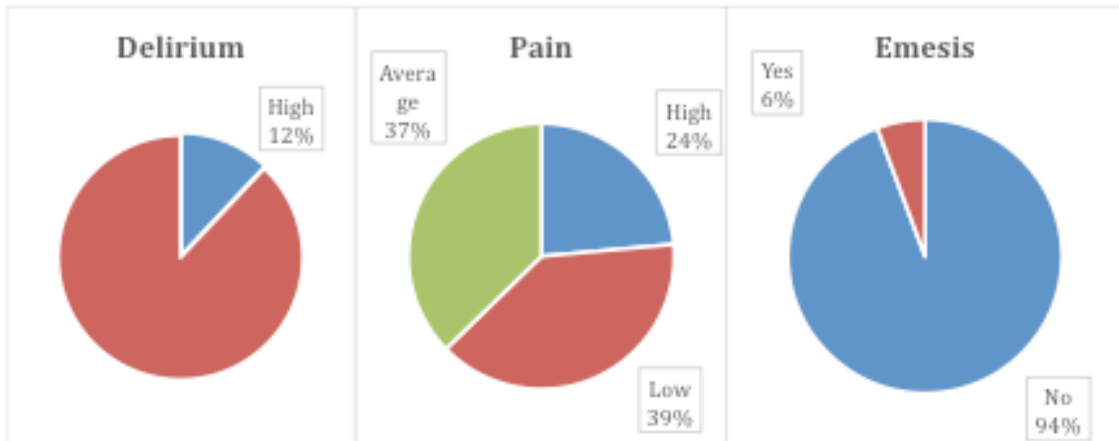
Conclusion: We present an integrated outcomes database for pediatric anesthesia that can be used for continuous process improvement based on outcomes data driven dashboard reports. The database will allow tracking of changes in technique in response to data feedback over time, improving post anesthetic care quality and creating a higher level of satisfaction for patients, families, and health care providers.

1. Bothner U. BJA, 2000
2. Kehlet H. Anesthesiology, 2012


Figure 1. Examples of Dashboard Data Feedback Output from the Database.



Post Anesthesia Outcomes




Appendix 9.



Child Temperament and Postoperative Behaviors – Integrated Analysis

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BACKGROUND

There are many factors that can influence behaviors after surgery and anesthesia. Previous studies have shown that approximately 54% of children experience negative behavioral changes such as nightmares, separation anxiety, eating problems and increased fear of physicians at a 2 week follow-up interval after surgery. Furthermore, 20% continued to show behavior changes at a 6 month follow up. (1) Many factors have been related to these changes including age, number of siblings and immediate preoperative anxiety(2). Researchers have documented that preoperative anxiety can be correlated with, among other factors, youth temperament – specifically children with low scores for Emotionality, Activity, Sociability, and Impulsivity were prone to having higher levels of anxiety in the preoperative holding area. (1) In this study we used a unique integrated outcomes database including personality inventories, demographic information, anesthesia delivery data, pain/behavior data collected from the Post Anesthesia Care Unit (PACU), and post-operative behavior ratings to evaluate whether specific temperament characteristics could be correlated with aspects of the operative experience and post-hospitalization behavior changes after surgery.

METHODS

614 participants age 2-29 were enrolled following IRB approval and consent/assent. Figure 1. Illustrates the timing of data collection. Data on patient temperament and demographics were obtained pre-operatively. Induction compliance and intraoperative anesthesia data were obtained in the operating room. Data on PACU outcomes including vomiting, pain, and agitation were collected from nursing records. Post-hospitalization behavior changes were surveyed by mail from parents or participants (ages 10 and over) at 2 days and 2 weeks after surgery. Measures: Five Rothbart temperament scales were administered: frustration, discomfort, soothability, fear, and sadness. Age appropriate versions of the scale (encompassing ages 3 – 30) were used, with variables generated to represent the domains across all ages. Induction behaviors were categorized by the Induction Compliance Checklist. Post-operative agitation was measured using the Pediatric Anesthesia Emergence Delirium Scale (PAED) and remote postoperative behaviors were measured using the Post Hospitalization Behavior Questionnaire (PHBQ). Pain was coded using the Numerical Rating Scale, Wong Baker Faces Scale, or FLACC scale depending on age and developmental status. Data Organization: All the temperament data were integrated with the demographic and outcomes data, then collated uniquely in a single SPSS database (version 22.0, SPSS Inc, Chicago, IL) for analyses.

RESULTS

Correlation

	Induction Compliance	Max PACU Agitation Score	Max PACU Pain Score	Frustration	Discomfort	Soothability	Fear	Sadness	phbq_DUM_tot_2days	phbq_DUM_tot_2wks	phbq_DUM_sep_anx_2days	phbq_DUM_sep_anx_2wks
Induction Compliance	1	0.125	0.076	0.111	0.204	0.093	0.098	0.124	0.048	0.162	0.100	0.163
Max PACU Agitation Score	-	1	0.402	0.275	0.152	0.163	0.212	0.245	0.200	0.149	0.239	0.14
Max PACU Pain Score	-	-	1	0.105	0.110	0.040	0.091	0.077	0.193	0.051	0.210	0.023
Frustration	-	-	-	1	0.546	-0.086	0.551	0.659	0.274	0.259	0.288	0.193
Discomfort	-	-	-	-	1	0.097	0.535	0.657	0.269	0.114	0.295	0.059
Soothability	-	-	-	-	-	1	0.173	0.138	0.150	0.034	0.147	0.054
Fear	-	-	-	-	-	-	1	0.577	0.155	0.230	0.224	0.266
Sadness	-	-	-	-	-	-	-	1	0.241	0.172	0.256	0.109
phbq_DUM_tot_2days	-	-	-	-	-	-	-	-	1	0.421	0.776	0.356
phbq_DUM_tot_2wks	-	-	-	-	-	-	-	-	-	1	0.432	0.818
phbq_DUM_sep_anx_2days	-	-	-	-	-	-	-	-	-	-	1	0.462
phbq_DUM_sep_anx_2wks	-	-	-	-	-	-	-	-	-	-	-	1

Bold values are statistically significant at 0.05 level

Regression: Temperament characteristics on Induction compliance

	Beta	Significance
Discomfort	0.213	0.009
Soothability	0.051	0.307
Fear	-0.024	0.637

Regression: Temperament predicting post-op agitation (emergence)

	Beta	Significance
Discomfort	-0.035	0.725
Soothability	0.181	0.021
Fear	-0.111	0.246
Frustration	0.242	0.019
Sadness	0.153	0.179

CONCLUSIONS

Analysis of behavioral outcomes in our integrated outcomes database reveals that there is significant correlation between specific temperament measures assessed across ages and important perioperative outcomes including pain, agitation, and, to a lesser extent, post-hospitalization behavior change.

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