Preoperative survey to evaluate patient allergy list, type of response to listed medication, and its relevance to perioperative care

NCT05670756

May 3, 2023

NATIONWIDE CHILDREN'S HOSPITAL
SHORT PROTOCOL (Waiver of Consent or Verbal Consent)

PROTOCOL TITLE: Preoperative survey to evaluate patient allergy

PROTOCOL TITLE:
Preoperative survey to evaluate patient allergy list, type of response to listed medication, and its relevance to perioperative care

PRINCIPAL INVESTIGATOR:
Joseph D. Tobias, MD
Department of Anesthesiology & Pain Medicine
614-722-4200
Joseph.Tobias@nationwidechildrens.org

VERSION NUMBER/DATE:
Ver. 2/May 3, 2023

Revision History

Revision #	Version Date	Summary of Changes	Consent Change?
1	5/3/2023	Adding OU as a relying site.	No

PROTOCOL TITLE: Preoperative survey to evaluate patient allergy

1.0 Study Summary

Study Title	Preoperative survey to evaluate patient allergy list, type of response to listed medication, and its relevance to perioperative care
Study Design	Anonymous, patient survey
Primary Objective	To determine allergies listed by patient and type of response which resulted in the allergy determination
Secondary Objective(s)	To determine the impact of the allergy list on anesthetic care
Study Population	Patients neonate to 21 years of age presenting for anesthetic care
Sample Size	1000
Study Duration	3 years

2.0 Methods

2.1 Although perioperative hypersensitivity reactions including anaphylaxis are rare, they may result in significant morbidity and mortality. The incidence of perioperative hypersensitivity reactions to medications, surgical equipment, and biological substances varies widely. Studies using large databases from France, Australia, and the United Kingdom (UK) have reported a significant variation in incidence ranging from 1:1361 to 1:20,000. Neuromuscular blocking agents (NMBAs), latex containing products, and antibiotics are identified as the agents most commonly responsible for perioperative hypersensitivity reactions. Newer NMBAs such as rocuronium may be associated with more frequent allergic reactions compared to older NMBAs, while the incidence of hypersensitivity to latex is decreasing as a result of its elimination from the perioperative environment and identification of at-risk patients.

2.2 Part of the routine preoperative evaluation is identification of previous allergies and avoidance of those medications during the perioperative period. For the purpose of our routine anesthetic care, we rely on the electronic medical record and the list of allergies provided. Although this is generally effective, it may be that allergies are erroneously listed and not based on good medical practice. For example, apnea following administration of an opioid such as fentanyl or diarrhea with the administration of Augmentin may be listed as allergies. The purpose of the current study is to evaluate allergies listed in the electronic medical record (EMR) of patients presenting for surgery and determine through a brief interview of the parent or guardian when that allergy was identified

and the exact symptomatology that resulted in determination of the allergy.

2.3 In addition to acute and chronic issues associated with substance abuse, these medications and substances can impact the perioperative care of patients and interact with anesthetic agents. Preoperative screening for these issues is now undertaken by an on-line preoperative questionnaire sent to the parents to complete prior to anesthetic care. Given the nature of such concerns and these issues, it is likely that there is under-reporting of these problems for various reasons.

2.4 Regardless of the history that is provided by the parents, no change in the allergy listing will be made and no specific change in the anesthetic plan mandate. The study will only involve identification of the listed allergies from the EMR and investigation into the symptoms that prompted this allergy listing. The purpose is to evaluate demographics and prevalence of allergies in patients presenting for surgery, evaluate the medical decision making process behind allergy identification, and determine its potential impact on perioperative care. For example, when patients are labelled as penicillin-allergic, it may be decided not to use cefazolin for prophylaxis of surgical site infections. Instead other antibiotics with a greater adverse effect profile such as vancomycin or clindamycin may be used.

2.5 The participants will be asked to complete a survey in REDCap using an iPad during the visit.

2.6 The information collected will include only demographic data including age, weight, gender, race and ethnicity. Survey data will be coded and will not include patient information. Completion of the survey will take approximately 10-15 minutes. Explanation of the study, its confidentiality, and the purpose will take approximately 5-10 minutes.

2.7 OU will be a relying site since one of their medical students will be collecting data for the study. All patients and data will come from NCH and all work on the study will be done at NCH.

3.0 Data Banking

3.1 All data collected during this study will be stored in a secure location, and only the collaborators directly involved with this research project will have access to this information. In addition, all electronic files will be stored on a secure, password-protected network. No data will be shared with OU.

3.2 Data will be stored for 6 years after the study is completed.

3.3 Data will not be stored for future use.

4.0 Inclusion and Exclusion Criteria

4.1 *Inclusion:* Patients 0-21 years of age presenting for surgery or procedure requiring anesthesia.

4.2 *Exclusion:* Patients who are not able cognitively to complete the computerized survey due to physical or intellectual impairment or communication issues related to non-English speaking patients.

5.0 Vulnerable Populations

5.1 This research involves children but does not involve greater than minimal risk under 21 CFR §50.51/45 CFR §46.404.

5.2 All data collected during this study will be stored in a secure location, and only the collaborators directly involved with this research project will have access to this information. In addition, all electronic files will be stored on a secure, password-protected network.

5.3 The subjects will not be exposed to greater than minimal risk.

5.4 Parents/legal guardians will be asked to give verbal consent and children will provide assent.

6.0 Number of Subjects (Records)

6.1 1000.

7.0 Recruitment Methods

7.1 Patients will be identified using the operating room schedule. The study coordinator, PI, or sub-investigators will screen and identify appropriate participants. Screening participants will occur according to the protocol defined inclusion and exclusion criteria under the auspices of a partial waiver in accordance with the HIPAA privacy rule.

7.2 Potential subjects will be approached in the pre-op area on the day of surgery by a member of the research team. The study will be explained to the patient and parents/guardians and they will be provided a copy of the consent form to review.

8.0 Withdrawal of Subjects

8.1 Patients may withdraw from the study at any time.

8.2 There are no anticipated circumstances under which subjects will be withdrawn from the research without their consent.

9.0 Data Management and Confidentiality

9.1 All data collected during this study will be stored in secure password protected computer files to which only trained members of the research team and collaborators directly involved with this research project will have access.

9.2 The data will be stored for the duration of the study and retained for 6 years after the study is completed per NCH as this meets both HIPAA and OHRP regulations.

9.3 No data will be transmitted to or from external institutions.

9.4 Subjects will be assigned a study identification number and no identifiers will be entered into REDCap. Names and MRNs will not be recorded.

10.0 Provisions to Protect the Privacy Interests of Subjects

10.1 Subject information will not be given to any other investigators. Subjects and their information will be closely monitored and guarded by study staff; there will be limited access to patients and their information by trained study staff; and subject information will only be shared and discussed between study staff specific to this study.

10.2 Only the absolute minimum information necessary for this study will be collected from the patient's records. Access to the patients' charts will be limited to only the research team who have completed all the necessary training.

10.3 We will only be publishing de-identified research information.

11.0 Economic Burden to Subjects

11.1 There will be no costs to subjects and subjects will not receive any compensation.

12.0 Consent Process

12.1 The consent process will begin in the preoperative surgery unit on the day of surgery, by PI, Sub-Investigators, Study Coordinators, and/or trained research staff.

12.2 The study will be thoroughly explained to the patient and their family. There will be ample time allotted for questions and answers. An explanation of voluntary participation will take place, and the family will be asked if they are interested in participating in the study. The patient will then be enrolled in the study with the understanding that they can elect to stop the study and be withdrawn from the study at any time.

12.3 Potential subjects will be provided a written information sheet and verbal consent will be obtained.

13.0 Setting

13.1 Potential subjects will be identified from the surgery schedule in Epic and recruited from the pre-op area of the surgery unit. Surveys will be completed via REDCap on iPads in the pre-op area.

14.0 Resources Available

14.1 The research team is comprised of 2 PhD research scientists, a research nurse, a research coordinator, two research associates, and two research interns. All team members will meet with the PI, co-investigators, and the research team for a study start up meeting for training about the protocol, research procedures, and their duties and functions.

15.0 Protected Health Information Recording

1.0 Indicate which subject identifiers will be recorded for this research.

☒ Name
☐ Complete Address
☐ Telephone or Fax Number
☐ Social Security Number (do not check if only used for ClinCard)
☒ Dates (treatment dates, birth date, date of death)
☐ Email address , IP address or url
☐ Medical Record Number or other account number
☐ Health Plan Beneficiary Identification Number
☐ Full face photographic images and/or any comparable images (x-rays)
☐ Account Numbers
☐ Certificate/License Numbers
☐ Vehicle Identifiers and Serial Numbers (e.g. VINs, License Plate Numbers)
☐ Device Identifiers and Serial Numbers
☐ Biometric identifiers, including finger and voice prints
☐ Other number, characteristic or code that could be used to identify an individual
☐ None (Complete De-identification Certification Form)

2.0 Check the appropriate category and attach the required form* on the Local Site Documents, #3. Other Documents, page of the application. (Choose one.)

☐ Patient Authorization will be obtained. (Include the appropriate HIPAA language (see Section 14 of consent template) in the consent form OR attach the HRP-900, HIPAA AUTHORIZATION form.)
☒ Protocol meets the criteria for waiver of authorization. (Attach the HRP-901, WAIVER OF HIPAA AUTHORIZATION REQUEST form.)
☐ Protocol is using de-identified information. (Attach the HRP-902, DE-IDENTIFICATION CERTIFICATION form.) (Checked "None" in 1.0 above)

PROTOCOL TITLE: Preoperative survey to evaluate patient allergy

☐ Protocol involves research on decedents. (Attach the HRP-903, RESEARCH ON DECEDENTS REQUEST form.)
☐ Protocol is using a limited data set and data use agreement. (Contact the Office of Technology Commercialization to initiate a Limited Data Use Agreement.

*Find the HIPAA forms in the IRB Website Library, Templates.

Attach the appropriate HIPAA form on the "Local Site Documents, #3. Other Documents", page of the application.

3.0 How long will identifying information on each participant be maintained? Identifying information on each participant will be retained for 6 years after the research is complete which meets both HIPAA and OHRP regulations.

4.0 Describe any plans to code identifiable information collected about each participant. Subjects will be assigned a study identification number and no identifiers will be entered into REDCap. Names and MRNs will not be recorded.

5.0 Check each box that describes steps that will be taken to safeguard the confidentiality of information collected for this research:
☒ **Research records will be stored in a locked cabinet in a secure location**
☒ **Research records will be stored in a password-protected computer file**
☐ **The list linking the assigned code number to the individual subject will be maintained separately from the other research data**
☒ **Only certified research personnel will be given access to identifiable subject information**

6.0 Describe the provisions included in the protocol to protect the privacy interests of subjects, where "privacy interests" refer to the interest of individuals in being left alone, limiting access to them, and limiting access to their information. (This is not the same provision to maintain the confidentiality of data.) Subject information will not be given to any other investigators. Subjects and their information will be closely monitored and guarded by study staff; there will be limited access to patients and their information by trained study staff; and subject information will only be shared and discussed between study staff specific to this study

Confidential Health Information

1.0 Please mark all categories that reflect the nature of health information to be accessed and used as part of this research.

PROTOCOL TITLE: Preoperative survey to evaluate patient allergy

- ☒ Demographics (age, gender, educational level)
- ☐ Diagnosis
- ☐ Laboratory reports
- ☐ Radiology reports
- ☐ Discharge summaries
- ☐ Procedures/Treatments received
- ☐ Dates related to course of treatment (admission, surgery, discharge)
- ☐ Billing information
- ☐ Names of drugs and/or devices used as part of treatment
- ☐ Location of treatment
- ☐ Name of treatment provider
- ☐ Surgical reports
- ☐ Other information related to course of treatment
- ☐ None

2.0 Please discuss why it is necessary to access and review the health information noted in your response above.
It is necessary to review the above health information to enable us to describe our patient population, ensure they meet the study inclusion specifications and evaluate our study outcomes.

3.0 Is the health information to be accessed and reviewed the minimal necessary to achieve the goals of this research? ☒ Yes ☐ No

4.0 Will it be necessary to record information of a sensitive nature? ☒ Yes ☐ No

5.0 Do you plan to obtain a federally-issued Certificate of Confidentiality as a means of protecting the confidentiality of the information collected? ☐ Yes ☒ No