
Plan Overview

A Data Management Plan created using DMPTool

Title: Patient Understanding of Anesthesia and Consent

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Funder: Digital Curation Centre (dcc.ac.uk)

Template: Digital Curation Centre

Project abstract:

The written anesthesia consent form has become a standard requirement throughout the United States of America. However, there has been little examination regarding the verbal aspects of anesthesia consent and of the value of the preoperative anesthesia discussion that should take place prior to surgery. Non-anesthesia medical studies have indicated that inadequate patient-physician communication and an inadequate patient-physician relationship will result in misunderstanding and an increased malpractice risk. Furthermore, a lack of understanding of the duties and responsibilities of anesthesiologists is damaging to the broader professional status of the field of anesthesiology. This study will utilize patient pre-anesthesia discussions and post-operative questionnaires to examine the degree of awareness that the patients and their families possess regarding general anesthesia, their understanding of the duties and responsibilities of the anesthesiologist, the role of the anesthesiologist within the operating room and their knowledge as to the specifics of what they are agreeing to when signing the consent form. This study examines the level of detail that is currently a part of the physicians' discussion, comparing it with an intervention discussion. The study will use this comparison to determine the need for a more structured and thorough pre-anesthesia discussion. If established, there will be substantial ramifications to the priority and importance given to pre-anesthesia discussions nationwide. Secondary benefits include positive influences on anesthesia residency training and malpractice actions against anesthesiologists. Improved patient satisfaction with the anesthesia experience is another potential secondary benefit.

Last modified: 10-04-2021

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Patient Understanding of Anesthesia and Consent

Data Collection

What data will you collect or create?

Data collected will be audio recordings of conversations between patients and operating staff about the informed consent process of anesthesia. Staff will meet with patients before the time of operation and inform them about the process of the patient's procedure. Staff will also inform the patients about what to expect from the anesthesia in terms of administration, maintenance, side effects, and other procedures that may occur while the patient is unconscious.

The recordings will be reviewed at a later time and will be analyzed using a scoresheet to evaluate what topics the anesthesia specialists or operating staff covered during the informed consent process.

How will the data be collected or created?

For the most part, we will use an Apple recording device (audio only). The files will be manually (not electronically) transmitted to another portable device (a laptop) where files will be stored. The device that stores the files will never leave campus and will be part of the JHMI network. All devices will be Apple devices to promote interoperability. We will name the files based on a deidentified numbering system and based on intervention vs. control group. Data will then be compiled and analyzed for statistical significance.

Documentation and Metadata

What documentation and metadata will accompany the data?

The anesthesia consent form.

Pre-operative interview checklist.

Post-operative questionnaire.

Ethics and Legal Compliance

How will you manage any ethical issues?

Patient and staff permission and consent will be obtained before recording the interaction.

How will you manage copyright and Intellectual Property Rights (IP/IPR) issues?

Question not answered.

Storage and Backup

How will the data be stored and backed up during the research?

A mobile Apple recording device will be used to record the audio of the interview. The files will then be transmitted onto an Apple brand laptop in order to promote interoperability.

How will you manage access and security?

The devices that store the data will never leave the campus and will be part of the JHMI network.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

The pre-operative scoresheets and their coinciding recordings should be preserved.

What is the long-term preservation plan for the dataset?

Question not answered.

Data Sharing

How will you share the data?

The files will be e-mailed to members that are part of the project.

Are any restrictions on data sharing required?

Files will *only* be shared with project group members.

Responsibilities and Resources

Who will be responsible for data management?

Question not answered.

What resources will you require to deliver your plan?

Question not answered.