REB Form:

Complete Project Title:

Needs Analysis and Time Flow Study to Assess Endoscopic Ear Surgery

Short Title:

Needs Analysis for Endoscopic Ear Surgery

Lay Summary:

Endoscopic ear surgery is a new minimally invasive technique that differs from the traditional microscopic surgery due to differences in visibility and the need for one-handed surgery. This application seeks to shift current clinical practice in surgery for chronic middle ear disease by creating novel instrumentation that will facilitate the practice of endoscopic ear surgery by understanding surgeon’s needs. Practitioners of endoscopic ear surgery will be surveyed to reveal the barriers they face when adopting the technique, and that they continue to experience in endoscopic ear surgery. A comprehensive assessment of existing instruments, including surgeon surveys and intra- operative time-flow analysis, will be used to identify potential design limitations of currently available instruments. Innovative solutions to these barriers will be developed including on-line focus-group based discussions, concentrating on enhancing multi-functionality of instruments to be operated easily with one hand.

Objectives of the study:

The needs assessment will comprise two separate parts: (a) a time-flow analysis in the operating room of the PI and (b) a survey of endoscopic ear surgeons’ experience.

a) The time flow analysis will measure the duration of predetermined steps during the surgery as well as the number of changes between instruments. This will aim to measure the efficiency of current endoscopic ear surgery and provide areas where instrumentation redesign is required. The time flow analysis will be recorded by the MASc. student during ear surgery.

b) Survey.A qualitative assessment of the challenges in endoscopic ear surgery caused by limitations in current instrumentation will be completed by performing an on line survey of surgeons that perform endoscopic ear surgery. The Delphi method will be followed to analyze the qualitative results of the survey. A preliminary survey for local otolaryngologists will develop a questionnaire that will be sent to many otologists around the world and the answers will be analyzed to develop a third survey that will be sent out once again to the participants. This will attempt to develop a consensus of conclusions for the survey.

Inclusion criteria:

Time Flow Analysis:

Patient participants: -- 50 patients – 25 surgeries with current instruments and 25 surgeries with modified instruments at the end

Any patient undergoing middle ear surgery at Sick Kids or TGH for whom consent is received. Tympanoplasty (repair of ear drum perforation) and removal of cholesteatoma (skin growth with in the ear) are the principle cases of interest.

Surgeon participants:

Otolaryngologist with more than one year of experience with endoscopic ear surgery. Residents will not be included in this study as the speed of their surgery is influenced more by level of experience than instrument design. It would be inappropriate to put time pressure on their involvement.

Surgeon survey – 20 for survey development pragmatic sample size based on locally available surgeons and aim to recruit over a hundred participants for the final survey, in order to capture a wide range of opinions.

Otolaryngologist with any experience of ear surgery. Surgeons with and without experience of endoscopic ear surgery will be included to investigate how currently available instruments have influenced their uptake of endoscopic ear surgery. Residents will be invited to participate as their initial experience may provide valuable insight.

Survey will be conducted confidentially using surveymonkey or fluidsurveys

Email a consent form with the survey and explain that if they fill out the survey then it is implied that consent is given to publish results.

We will propose this consent form to the participants but it is not common practice to send a consent form with surveys. We will ask the REB if they will wave the requirement for the consent form for this case.

We will send the survey to otological societies such as the Canadian Society for Otolaryngology Head and Neck Surgery, the American Otological Society and the International Working Group on Endoscopic Ear Surgery.

Risks:

Probability and Magnitude of Risks:

Minimize the risk: consent form, timing experienced surgeons rather than trainees

* Surgeon may feel pressured as they are being timed during surgery, causing a potential risk for the safety and effectiveness of the surgery. Therefore, a consent form for both the surgeon and patient will be required to notify both participants about the potential risks

Benefits:

* Gain knowledge about the limitations of current tools

Funding?

Page 12: - does the study involve transfer of data? – does the survey count as transfer of data?

Page 17: Participants in the study:

Time flow – 50 patients

Survey – 100

Participants at SickKids

Budget – stipend 25000/yr + 10 000/year for disposables from otolaryngology sickkids

Perioperative service grant has been requested and if it doesn’t come through then we have departmental funds

Time flow

Survey

Page 18: Inclusion criteria – no age,

My role: co-investigator

Page 6:

Todo:

* RQRM
* Scientific Review – for Dr. Papsin and Dr. Cushing
* Budget

Reb only for time flow study – study of the patients, surgeons are a second group

Consent form: ask to use patient’s CT scans

When recording the data in the or record the study number on the piece of paper

Must remove the data using sickkids IT

Consent form: - description of research

1. Time flow – we want to record the duration of different parts of the operation to understand how to improve instruments in the surgery to increase efficiency of the surgery.
2. If your child has had a CT scan we would like to use this as part of the study to help us understand how surgical instruments can be designed to fit the shape of the ear better. To do this we would like to take a copy of the CT scan and use it to generate computer models and printed models of the shape of your child’s ear.

Talk with Ryan:

Survey – needs reb., surgeons are the research participants

* Provide
* For any questions that are N/A – just put N/A and add why it doesn’t apply to the study eg. How many research arms? – put N/A and why
* Explain data sources as to where we will get the mailing lists from -> give more information than just the mailing list
  + Need another avenue to obtain the emails e.g. request information from the society
  + Get the emails from publicly available emails – from a google search (from publicly available information
  + Put together the recruitment plan – don’t frame it as harassment or spam
  + Include the email script – it should give scope of study presented so it’s not made to seem coercive – if they don’t complete the survey it will not affect their professional integrity
    - They have option to not complete the study without profess or academic punishment
    - Its just for research
    - Send one email and then if necessary, a follow up email
    - Email will describe research study
    - When click on survey link – landing page that describes study in more depth – agreeing or disagreeing to take part in the study will not affect their professional standing, the study is voluntary it is being conducted because we want to know why the surgeons do EES, implied consent model (reading and completing the survey and submitting is implied consent)
  + Include the questionnaire, emails, landing page
  + Redcap system – held within network
  + Submit redcap survey printouts
  + Email addresses kept separate from study data

Time flow study – requires physician and patient consent form

Schedule a consultation with Ryan Singh after everything is ready to be submitted