Needs Analysis and Time Flow Study to Assess Endoscopic Ear Surgery

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REH1510 Thesis Proposal

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**Abstract:**

BACKGROUND: Transcanal endoscopic ear surgery (TEES) is a minimally invasive technique to operate inside the middle ear through the ear canal. Though the benefits of reduced length of hospital stay and patient morbidity are valued, ear surgeons have hesitated to adopt the technique. This is because it requires one-handed surgery and existing tools, designed for two-handed traditional invasive microscopic ear surgery, are not optimized for single-handed TEES.

OBJECTIVE: This study proposes to understand the specific needs, instrument limitations and technologic advancements required to facilitate TEES.

STUDY DESIGN: Part one of this study is to conduct a needs assessment survey, following a two-round Delphi method, where a questionnaire will be sent out to ear surgeons globally. This will aim to identify the current needs and technological limitations that surgeons experience in TEES. Part two will be a time flow study to record the duration of TEES steps to assess the current limitations of the tools and techniques employed. This data will be collated to develop requirements and criteria against which future instrumentation can be developed to facilitate TEES. During the time flow study, the surgeons will be practicing TEES resulting in motor learning to develop the one handed surgery technique. To characterize this, fMRI will be used to map the right and left hand region in the motor cortex to determine whether brain activation has changed as a result of motor learning while practicing TEES.

EXPECTED OUTCOMES: As a result of discussions with the primary investigator (an ear surgeon at SickKids hospital) and his colleagues, it is anticipated that the needs assessment survey will show that ear surgeons experience the following difficulties during endoscopic ear surgery: keeping the operative field clean, keeping the endoscope lens clean, cutting bone, single-handed surgery, reaching structures within the middle ear, and gripping structures. The two-round Delphi method will conclude this in a rigorous format, as it is an accepted survey technique in many other areas of surgery. The time flow analysis will identify the inefficiencies during different surgical steps where intervention is required, which may require redesign of existing instruments. It is expected that brain activation of the right hand region of the motor cortex is enhanced after the surgeon has practiced TEES maneuvers during the course of the time flow study. As well, it is expected that an experienced TEES surgeon, who has gone through extensive motor learning, would exhibit greater brain activation than a less experienced TEES surgeon, who is still under the phase of skill acquisition.

SIGNIFICANCE: These needs and limitations will yield criteria against which instrumentation should be developed. This will be addressing a knowledge gap in the field of endoscopic ear surgery. It will motivate industry and academic researchers to develop better instrumentation and training platforms, increasing the adoption of endoscopic ear surgery.

**Overview:**

This project’s goal is to design instrumentation to facilitate endoscopic ear surgery, a new, growing technique that is minimally invasive. The primary challenge with TEES is it requires one hand to hold the endoscope while the other hand performs the surgery single-handedly. In order to design the appropriate instrumentation, first a needs analysis study will be conducted to understand the needs of surgeons who employ TEES, then a time flow study will record the duration of steps during TEES to understand which steps require new instrumentation to facilitate specific hand maneuvers. Furthermore, before and after the time flow study, the left and right hand regions of the motor cortex will be imaged using fMRI to determine if practicing TEES during the time flow study caused motor learning within the brain and if there is a difference in motor cortex activation between surgeons with different levels of experience in TEES.

**Background and Literature Review:**

Middle ear surgery is traditionally performed through an external incision with visualization of delicate anatomical structures using a microscope. More recently, minimally invasive ear surgical techniques have been developed using endoscopes to access the middle ear through the ear canal without an external incision (1) (2). As with open microscope-guided surgery, TEES allows the surgeon to perform procedures such as ear drum reconstruction, skin growth removal and hearing bone repair (2) (3). The advantages of TEES are as follows: removing the need for an external incision and reducing postoperative morbidity (4), improving visualization for disease eradication (5) (6), reducing the rate of residual skin growth (5), and improving hearing by facilitating hearing bone preservation (4) (7).

Despite the enthusiasm of some ear surgeons (otologists), TEES has not yet been accepted by all practicing otologists (8). The principal challenge with TEES is that a one-handed surgical technique is required as the endoscope is held in the other hand. Ear surgery instruments were developed for two-handed microscope-guided surgery so they are not optimized for the TEES environment (2) (9). As otologists have been trained and gained experience in microscope-guided ear surgery, they have developed techniques with the according instruments and have become accustomed to a two-handed surgical approach. By learning different surgical techniques and gaining experience with the endoscope, most surgeons find that they can complete more cases endoscopically (2) (3) (9). The motor learning of both types of surgery are different as different muscles are recruited to perform tasks that are specific to the type of surgery. Since TEES primarily employs the right hand, then perhaps right hand motor learning has occurred to a greater degree than the left hand.

Neuroimaging of brain activity, via functional MRI (fMRI), in the left and right hand regions of the motor cortex will attempt to understand the extent of neurological changes associated with motor learning of TEES during the time flow study. Landau and D’Esposito from the University of California, Berkeley, conducted an fMRI study of motor expertise between pianists and nonpianists where both sets of participants were asked to press a certain key following a stimulus (20). They examined activation in primary sensorimotor regions, which are known to change with different amounts of practice. Experienced pianists showed greater activation, which they hypothesized was due to functional reorganization after years of motor learning via practicing piano. Similarly, it is expected that the TEES surgeon with ten years of experience will exhibit greater brain activation compared to an experienced traditional, microsopic surgeon who has only practiced TEES for one to two years.

The learning curve for TEES can be steep and frustrating. In the experience of the primary investigator (PI), technological advances in the design of the endoscope, camera, and suction dissection instruments have led to incremental stepwise jumps in this learning curve (10). There is a knowledge gap in the literature where it is not reported exactly why surgeons have not adopted the technique, and what technological and/or training advances would encourage greater adoption. It is proposed that in order to ease the technique of TEES, the needs of surgeons and current limitations of tools must be determined.

The following describes the use of surveys and time flow analyses in literature to assess: the needs of a field of surgery and the efficiency of a procedure, respectively. These methods will be used to assess the needs of surgeons and current limitations of instruments for TEES. This will attempt to understand how to improve TEES adoption among otologists.

Surveys are widely used to gain information regarding a specific topic by consulting a wide variety of experts in the field. They have been used to assess the challenges of endoscopic neurosurgery in Britain and the current status of endoscopic ear surgery in Canada (9) (11). The Delphi method has been employed internationally in the field of surgery where surveys are sent out to surgeons to form a consensus about varying surgical issues such as: treatment of the retraction pockets of the tympanic membrane, developing a core set of patient-reported outcomes in pancreatic cancer, and an international consensus for sepsis and septic shock definitions (12) (13) (14). A survey, sent to ear surgeons globally, will be conducted to identify the current needs of the TEES technique.

Time flow studies aim to analyze the efficiency of procedures, and have been used for many purposes in surgery, including MRI-guided angioplasty workflow and operating room setup dedicated for minimally invasive laparoscopic surgery (15) (16). This study will assess the feasibility and efficiency of endoscopic ear surgery using the same method.

**Research Question:** Why is TEES not widely adopted by otologists and what technological advances would encourage more frequent and broader use of TEES? Is there greater brain activation in an experienced TEES surgeon’s motor cortex due to a greater degree of motor learning? Does the right hand region of the motor cortex experience greater activation because it is more heavily used during TEES? **Hypothesis:** TEES is recognized for its potential and the investigators hypothesize that by conducting a needs analysis survey and a surgical time flow analysis, current limitations of TEES will be explored to develop criteria to ease the technique of TEES. As well, since the endoscope is in the left hand, it is hypothesized that the right hand, that performs all surgical maneuvers will exhibit greater activity and that a more experienced TEES surgeon will have greater brain activation due to enhanced motor learning. **Research Objectives:** In order to facilitate TEES the following must be understood: a) the reason surgeons are not adopting TEES by conducting a questionnaire for surgeons and b) limitations of existing tools by conducting time flow analysis. As well, differences in brain activity between experienced surgeons and the right and left hand will be studied to understand TEES motor learning.

**Specific Aims and Methods:**

**Part 1: Needs Assessment Survey:**

The aim of the needs assessment survey is to understand the reasons why ear surgeons are not using TEES and what would ease its use. A qualitative assessment of the challenges in TEES caused by limitations in current instrumentation will be completed by performing an online survey of otologists. The Delphi method will be followed to analyze the qualitative results of the survey.

The questionnaire is included in Appendix C, and requires the participants to rate their need for specific instrument functionalities. The rating scores, a number between 1 and 100, will be analyzed statistically to develop a list of requirements for improvements in instrument design. The survey was developed on RedCap, the SickKids research management software and the scale increments were worded as per research survey guidelines provided by Harvard and the University of Wisconsin (17) (18). Appendix A includes the explanation of the study and survey for the participants.

*Participant Recruitment:* The participants are otologists who will be invited to participate by email, by requesting ontological societies to send the survey to their members. Online surveys of surgical practice are frequently distributed by such societies. The societies of which the PI is a member will be contacted asking for permission to survey their members, for example: Canadian Society of Otolaryngology - Head and Neck Surgery and the International Working Group on Endoscopic Ear Surgery.

**Part 2: Time Flow Analysis:**

*Study Design (General Overview):*

The time flow analysis will be recorded by the MASc student during ear surgery. The surgery will be divided into steps, described in Appendix B. The type of instruments used during the different steps and the number of changes between instruments will also be noted. These observations will lead to an appreciation of the ergonomic requirements of the instruments and the design advantages of each for specific maneuvers. The time taken for five surgeons to perform ten surgeries each will be recorded. Each step for each surgeon will have a mean and standard error time, and statistical difference between surgeons for each step will be calculated. This will aim to determine the inefficiencies and address the steps where further instrument design would be beneficial. This would also provide a good benchmark against which to measure efficiency and feasibility of developing future tools.

*Participants*: The time flow study will include two kinds of participants: patients, who will be undergoing ear surgery, and surgeons, who will be performing the ear surgery.

*Participant Recruitment*: There will be two experienced TEES surgeons and three experienced traditional microscopic ear surgeons who have less experience in TEES. This will characterize the difference between experienced TEES and experienced traditional surgeons. Note, the experienced TEES surgeons are also experienced traditional otologists as they were trained in traditional surgery during their residency and fellowship; they have adopted TEES during their careers as staff surgeons.

*Inclusion criteria*: Patient participants: 50 surgical patients, who require skin growth removal surgery or ear drum reconstruction surgery. Surgeon participants: 5 surgeons with more than one year of experience in endoscopic ear surgery.

*Study intervention*: Each surgeon will be observed and recorded performing ten operations. The time and number of instruments changed will be recorded for the steps outlined in the Data Collection Form, included in Appendix B. Before the time flow study, the surgeon participants will undergo fMRI. The MRI will have a nonmetallic 3D printed endoscope, instruments and an anatomical model of the middle ear to serve as a mock surgical simulation. The anatomy model will be mounted in the MRI in a position similar to that during surgery. The surgeon will be asked to perform three sets of three predetermined common maneuvers inside the MRI to activate the regions of interest. This will occur before and after the completion of the time flow study, where the surgeons will have practiced ten surgeries. The fMRI results will determine whether these ten surgeries have increased the brain activity in the motor cortex, suggesting the occurrence of motor learning. This method stems from the method used in (19) and (20) where functional neuroimaging (fMRI) was used to image brain activity in pianists who were given nonmetallic keyboards and a mirror to help them play inside the MRI.

*Statistical analysis*: During the time flow study, the factor to be studied is the type of instruments used for each surgical step. The block is the surgeon. The response is the time required for the surgical step. Therefore, an ANOVA will be used to determine if there is a statistical difference in the time to complete a surgical step depending on the instruments used.

The fMRI data analysis will follow the same format as described by Landau and D’Esposito (20). The VoxBo analysis package would be used to postprocess the data to obtain a series of amplitude-scaled and time-shifted covariates. After this, SPM99 would be used to normalize each participant’s brain. The regions of interest (ROI) would be identified, as a result of the brain activation during specific tasks. For each trial, the mean parameter estimate from the ROI in each participant’s normalized activation map is taken. This is compared across participants. Before and after the time flow study, if there is a significant difference (p<0.05) between the parameter estimate, then this could be due to motor learning as a result of practicing TEES during the time flow study.

**Expected Outcomes:**

As a result of the PI’s personal experience and communication with his colleagues and ear surgeons who attended an Endoscopic Ear Surgery skills course in October, 2016, it is anticipated that the following difficulties will be revealed in the needs analysis survey: clearing blood from the operating field, keeping the endoscope lens clean, dissecting, gripping structures, accessing structures that are visible with the endoscope’s wide viewing angle, bone removal beyond certain anatomy, and difficulty with ear drum graft positioning. As well it is anticipated that understanding the needs for TEES and identifying the inefficiencies during surgery would provide a basis of what type of instrumentation should be optimized to facilitate the surgery.

This methodology will collect insight from a variety of surgeons to understand the spectrum of their opinions on TEES and how and/or if it can be improved. Although a potential limitation would be a low survey response rate, the creation of practical and innovative solutions to the challenges of endoscopic surgery is not dependent upon a high survey response rate due to the experience of the PI who has considerable insight into the current status of activity and opinions within the field of TEES and performs 80% of cases with TEES.

See Appendix D for timeline and dissemination plan.

It is expected that the right hand activity is greater than the left, as it’s been trained more as the only ‘operating hand’ and has developed more motor control. As well, the motor cortex activity of the experienced TEES surgeon will not change as they have already gone through the motor learning process for TEES. The experienced traditional surgeons will have significant changes in their right hand motor cortex as a result of the motor learning throughout the study. **<insert reference about practicing piano and how much you need to practice in order to motor learn>** Brain activation in the experienced TEES surgeon would differ from brain activation in an experienced traditional, microscopic otologist who has limited experience in TEES as the motor learning is different and the skills required are different because the surgery is single-handed, there is no ‘extra hand’ to hold suction, hold onto tissues and help perform maneuvers such as positioning an ear drum graft in the appropriate position.

**Significance and Conclusions:**

Therefore, it is anticipated that conducting a needs analysis survey and a surgical time flow analysis, current limitations of TEES will lead to the development of instruments with the functionalities identified in the results of the survey. It is anticipated that new TEES instruments will increase the range of ear procedures that can be completed minimally invasively and increase the speed and effectiveness of surgery, thereby aiming to improve its adoption among otologists. The design techniques and instruments created will also be applicable to other minimally invasive surgery in bony cavities such as sinus, nasal, spinal and arthroscopic surgery (21), (22), (23). It is envisaged that ultimately, virtual patient models could be used with rapid prototyping and fabrication to create patient specific specialist instruments extending the limits of minimally invasive surgery even further.

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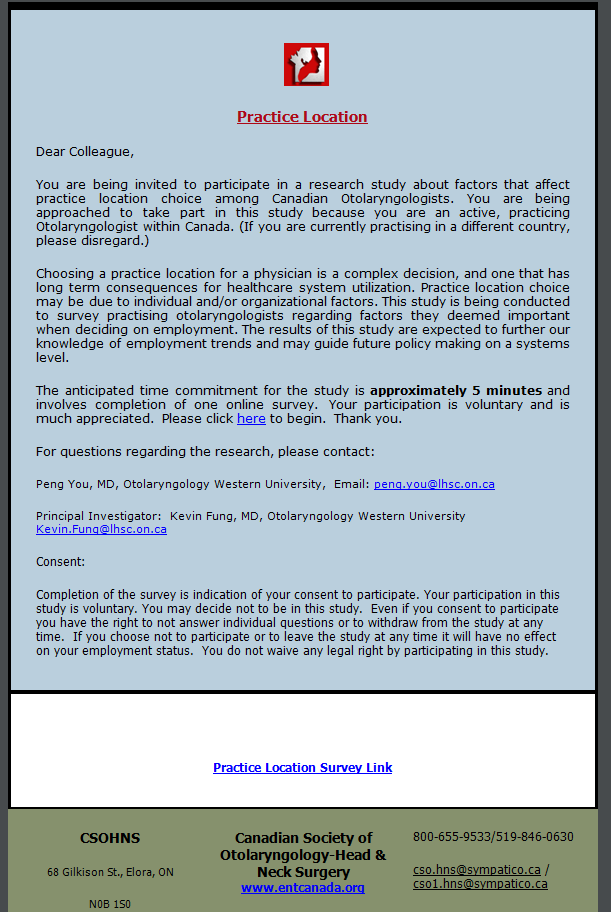
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**Appendix A: Needs Assessment Survey**

*This appendix outlines the details of the survey. V-1 27-Oct-2016*

The email and landing page of the survey describe the survey to the otologists who will be asked to fill it out. Implied consent is requested so the survey results remain anonymous. The figure below is of an invitation to participate in a survey sent to the PI. The language used is a guide used to describe our survey.



*Email:*

The email will contain the following email script:

“Dear Colleague,

You are being invited to participate in a research study to understand how to increase the adoption of totally endoscopic ear surgery. We would like to invite you to participate in this voluntary, anonymous online survey, because you are a practicing Otolaryngologist. This voluntary survey’s objective is to collect data to answer these research questions by surveying practicing otologists, and to publish the results in a research journal to fill this knowledge gap.

The approximate time to complete the survey is 5 minutes. Your participation or nonparticipation in this survey will be unknown and will not affect your professional status and/or integrity in any way. The survey is to aid in the research of understanding the current experience of endoscopic ear surgery and why it is not widely adopted. This study will be conducted using the two-round Delphi method. The responses of this survey will be collated to develop a second round of more specific questions, which will be sent out in another survey.

For questions regarding the research, please contact:

Arushri Swarup, MASc. Candidate, Institute for Biomaterials and Biomedical Engineering, University of Toronto, email: arushri.swarup@sickkids.ca

Principal Investigator: Dr. Adrian James, Paediatric Otorhinolaryngologist, SickKids Hospital, adrian.james@sickkids.ca

Consent:

By completing and submitting the survey, it will be implied that you consent to participating in the study. Your participation in this study is voluntary, anonymous and confidential. You may decide not to be in this study. Even if you consent to participate you have the right to not answer individual questions or to withdraw from the study at any time.

The survey is available by clicking on the link below:

<Link to survey>”

Landing Page of Survey:

“There is growing interest amongst otologists worldwide around the use of endoscopes in ear surgery. As most ear surgery instruments were developed for use with the microscope, it is possible that changes in instrument design for use with endoscopes may allow more procedures to be completed effectively with a totally endoscopic approach. This project is a not for profit initiative to stimulate the development of instrumentation optimized for endoscopic ear surgery. This survey aims to investigate the suitability of currently available instruments for use in endoscopic ear surgery and identify priorities for improvements in instrument design.

The approximate time to complete the survey is **5 minutes**. The survey will be conducted via a two-round Delphi method. The responses of this survey will be collated to develop a second round of more specific questions, which will be sent out in another survey. The results will then be analyzed and presented in a paper in an otology research journal.

By completing and submitting the survey, it will be implied that you consent to the researchers analyzing and presenting it. You may decide not to be in this study, and may withdraw at any time before submitting the survey.

This survey is completely **voluntary** and will remain confidential and **anonymous** to the researchers. This survey is purely for research purposes.

We thank you for your time. Please continue to begin.”

*Questionnaire:* Please refer to the questionnaire (Appendix C).

In the case that we do not receive any responses within two weeks, we will send out one follow-up email to the invited participants. The email will read:

“Dear Dr.\_\_\_\_\_\_\_\_\_\_,

This is a friendly follow up email to the request to participate in the voluntary survey, linked below, to gather information about why totally endoscopic ear surgery is not widely adopted and practiced. This will aid in a research study aiming to understand the answers to these questions.

It is important to note that this survey is completely voluntary and will remain confidential and anonymous to the researchers. There will be no way to identify the participant to their answers to the survey. As well, participation or nonparticipation in this survey will not affect your professional integrity in any way. This survey is purely for research purposes.

By answering the questions in the survey and submitting it, it will be implied that you consent to filling out your survey and the researchers using the anonymous data to analyze and present it.

We thank you for your time. Please click below to begin.”

<Link to survey>

**Appendix B: Data Collection Form for the Time Flow Study**

*Time Flow Study Data Collection Form V-1 27-Oct-2016*

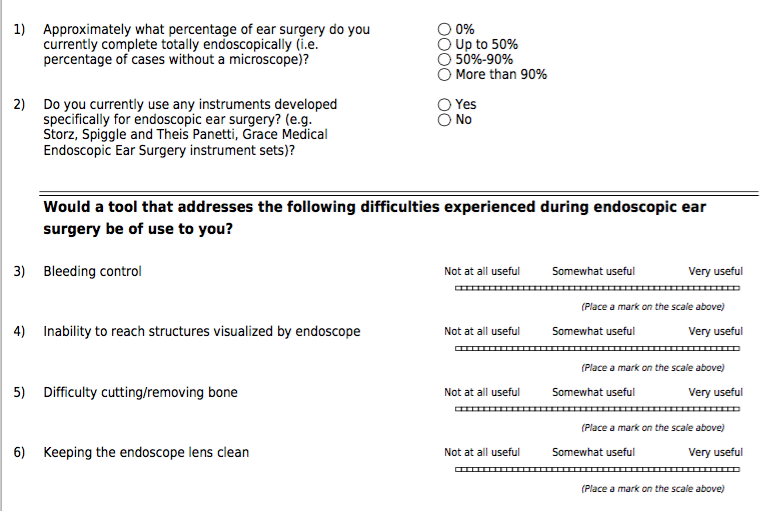
|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Surgery: |  | Study Number: XXXXX | | Study Number: XXXXX | |
| Tympanoplasty | Step | Date/notes | Time (min) | Date/notes | Time (min) |
|  | Cleaning Out Ear canal |  |  |  |  |
|  | Injecting Anaesthesia |  |  |  |  |
|  | Hair Trimming |  |  |  |  |
|  | Cleaning Edges of Perforation |  |  |  |  |
|  | Making Skin Incision |  |  |  |  |
|  | Raising Flap |  |  |  |  |
|  | Preparing Graft |  |  |  |  |
|  | Placing Graft |  |  |  |  |
|  | Replacing Flap |  |  |  |  |
|  | Packing Ear Canal |  |  |  |  |
| Surgery: |  | Study Number: XXXXX | | Study Number: XXXXX | |
| Cholesteatoma Removal | Step | Date/notes | Time (min) |  |  |
|  | Cleaning Out Ear canal |  |  |  |  |
|  | Injecting Anaesthesia |  |  |  |  |
|  | Hair Trimming |  |  |  |  |
|  | Cleaning Edges of Perforation |  |  |  |  |
|  | Making Skin Incision |  |  |  |  |
|  | Raising Flap |  |  |  |  |
|  | Preparing Graft |  |  |  |  |
|  | Placing Graft |  |  |  |  |
|  | Replacing Flap |  |  |  |  |
|  | Packing Ear Canal |  |  |  |  |

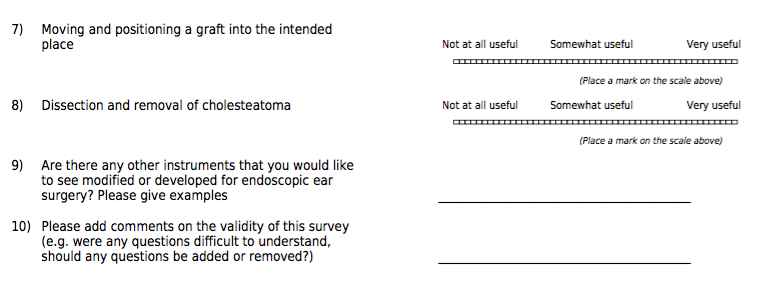
Note: The study number is a randomly generated 5-digit code.

**Appendix C: Questionnaire**

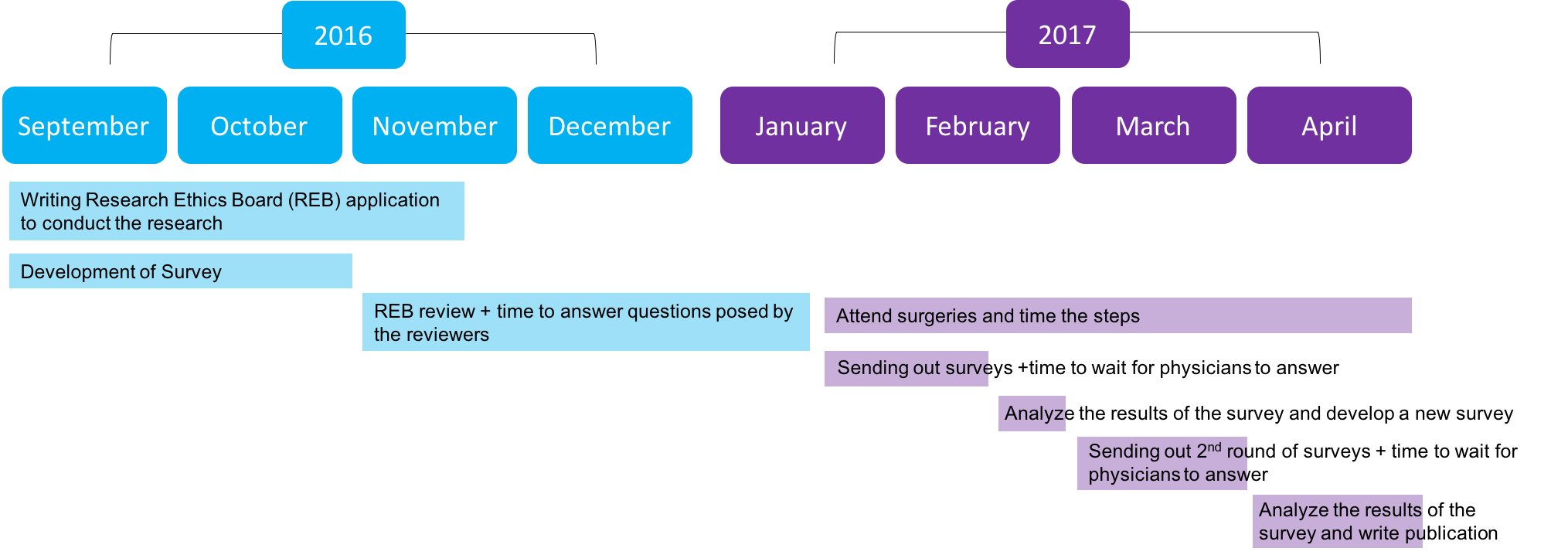
*The following outlines the questions asked in the Needs Assessment Survey V-1 27-Oct-2016.*

The questions are continuations from the current views of ear surgeons regarding transcanal endoscopic ear surgery in Canada (9).





Appendix D: Timeline & Dissemination Plan



Boxes show approximate length of time required to complete the tasks.

The needs assessment and time flow study results will be submitted to the 2nd World Congress on Endoscopic Ear Surgery by the International Working Group of Endoscopic Ear Surgery (IWGEES). http://www.sinuscentro.com.br/iwgees/index.htm