Surgical Research Methodology
Part 1: Research Question
Part 2: Case Series
Part 3: Surveys

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Part 1: FORMING THE RESEARCH QUESTION
Forming the Research Question

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Starting your Research Project

• Is the question you are trying to answer in your research project clinically important or trivial?

• Distinction between the trivial and important questions is not that easy! The answer lies in scholarship
Starting your Research Project

- You have to be familiar with the **boundary of knowledge on the subject**

- To do this you have to first perform a **systematic review of the subject (i.e. thorough review of the literature)**
Reasons to Pursue a Research Question

• Intervention is novel
• Intervention consumes large health care resources.
• Controversy on the effectiveness of the novel procedure
• Large cost difference between 2 prevailing interventions.
Research is an Iterative Process
Initial Groundwork for Research
Question Formulation

1. Plausibility
2. Feasibility
3. Support
4. Resources
Plausibility

- Is the question answerable?
- Must have a thorough understanding of the anatomy, biology, physiology and prevalence of the problem.
Plausibility Example

• It is not plausible to examine the outcomes of reconstruction of the congenitally absent ear in a RCT comparing the Nagata technique with the “genetic engineering method”

• The genetic engineering methods are not advanced at this point in time to regenerate an acceptable ear
Feasibility

- Whether the study design we choose is one that can potentially answer the research question
- Best study design depends on the question asked
Feasibility Example

Research Question:

• Is the supramicrosurgical reconstruction with a periumbilical abdominal flap is superior to the deep inferior epigastric perforator (DIEP) flap in breast reconstruction?

Possible barriers:

• We don’t know how to transfer a flap with a 0.8 mm luminal diameter of the vascular pedicle
• We don’t have the required instruments
• QOL scales may not be sensitive enough
Feasibility

Choosing a Study Design

- **Simple Studies (i.e. Case series, Cohort)**
  - If little is known on the topic, or there are big gaps in knowledge

- **RCT**
  - When a novel surgical technique entered the main stream of surgery and challenges a prevailing one
Feasibility Example

Research Design:
• RCT to determine whether smoking affects the short-term survival of replanted digits

Barriers:
• Ethically, we cannot randomize patients to either Group A: continue smoking or Group B: non-smoking after replantation of digits.
• For questions of harm, appropriate study designs include case-control studies and cohort studies
Feasibility – Example

Research Design:

- RCT comparing the use of intermittent lower extremity pump vs. low molecular heparin in preventing fatal pulmonary embolism in cosmetic abdominoplasty.

Possible Barriers:

- Fatal pulmonary embolism in cosmetic abdominoplasty is a very rare event.
- As the frequency of the ‘end points” is a critical factor in the sample size calculation, the rarity of the target event means that the investigator will require a sample size measured in thousands of patients!
Resources

- Financial resources
  Think of the budget and the details that go with that!

- Choose a supervisor who has research coordinator support
<table>
<thead>
<tr>
<th>Item</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Research Assistant</strong></td>
<td><strong>$29203.20</strong></td>
<td><strong>$29203.20</strong></td>
<td>A research assistant is required to coordinate this project. Duties will include helping to screen and consent patients, ensuring that the case report forms are completed by participating surgeons, administering the quality of life questionnaires to patients, data entry, and assisting with the costing and analyzing of the data.</td>
</tr>
<tr>
<td>$26.00 / hour + 35% fringe benefits 16 hours / week for 2 years</td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Statistician/data analyst</strong></td>
<td><strong>$0.00</strong></td>
<td><strong>$3,750.00</strong></td>
<td>A statistician/data analyst is required to provide methodological consultation throughout the trial and to analyze the data at the end of the trial.</td>
</tr>
<tr>
<td>$50/hour for 75 hours</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Economist Consultation</strong></td>
<td><strong>$0.00</strong></td>
<td><strong>$1,000.00</strong></td>
<td>An economist is required to provide methodological consultation throughout the trial and to help cost the data at the end of the trial.</td>
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<tr>
<td>$50/hour for 20 hours</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Photocopying of case report forms and quality of life forms</strong></td>
<td><strong>$725.00</strong></td>
<td><strong>$725.00</strong></td>
<td>We will need to photocopy the case report forms and the quality of life forms.</td>
</tr>
<tr>
<td><strong>Office supplies</strong></td>
<td><strong>$250.00</strong></td>
<td><strong>$250.00</strong></td>
<td>We will require to following office supplies for this project: envelops, papers, folders, and CDs for data storage.</td>
</tr>
<tr>
<td><strong>Health Utilities Index</strong></td>
<td><strong>$4000.00</strong></td>
<td><strong>$0.00</strong></td>
<td>There is $4000 administration fee to use this questionnaire</td>
</tr>
<tr>
<td><strong>Mailing of quality of life forms</strong></td>
<td><strong>$200.00</strong></td>
<td><strong>$200.00</strong></td>
<td>We anticipate that we will need to mail multiple quality of life questionnaires to each patient to help ensure complete follow up.</td>
</tr>
<tr>
<td><strong>Total budget</strong></td>
<td><strong>$34,378.20</strong></td>
<td><strong>$35,128.20</strong></td>
<td></td>
</tr>
</tbody>
</table>
Forming the Research Question

- You have an idea, the necessary support and resources now you need to transform your research idea into a well built clinical question
Background Questions

• Ask for general knowledge about a surgery problem

• Have two essential components:
  1. A question root (who, what, where, when, how, why) with a verb
  2. A disorder, or an aspect of a disorder

i.e. What complications can occur with the ECTR?
Foreground Questions

• Ask for specific knowledge about managing patients with a surgery problem

5 essential components:

Patient or problem

Intervention

Comparison intervention (if relevant)

Outcomes

Time
Well Built Clinical Question

- **Population** (patient)
- **Intervention**
- **Comparison** (this is optional)
- **Outcome**
- **Time Horizon**
Population (Patients)

• How would I describe a group of patients similar to mine?
  – Be brief and precise

i.e. All patients with clinical evidence of carpal tunnel syndrome confirmed with EMG and nerve conduction study
Intervention

• Which main intervention, prognostic factor or exposure am I considering?
  – Be specific

i.e. In ECTR, the Agee or the Chow technique or extrabursral or intrabursal
Comparative Intervention

• What is the main alternative to compare with the intervention?

  – Be specific

  i.e. In OCTR, short incisions and long incisions, as these incisions allow one to visualize the median nerve
Outcome

• What can I hope to accomplish, measure, improve or affect?
  – Be specific

  i.e.
  – Pain control
  – Return to work, ADL
  – Improve Quality of Life (QOL)
  – Quality Adjusted Life Years (QALYs)
Outcomes

• How will you measure them?
• Who will measure them (think of bias introduction)
• How often will you measure them?
Time Horizon

- Appropriate time to measure outcome
  - 1 month post-op
  - 6 months post-op
  - 1 year post-op
  - Long term >5 years
  - For the patient’s life?
- Short, intermediate, long term follow-up
Time Horizon

Example:

- Population = chronic osteomyelitis of tibia patients
- Intervention = free muscle flap
- Comparison = free cutaneous flap
- Outcome = no drainage of pus from tibia
- Time Horizon = 2 years
### Framing the Clinical Problem

<table>
<thead>
<tr>
<th>Population</th>
<th>Patients who have clinical symptoms of CTS and confirmed with EMG and nerve conduction studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
<td>Any ECTR technique</td>
</tr>
<tr>
<td>Comparison</td>
<td>Any OCTR technique</td>
</tr>
<tr>
<td>Outcome</td>
<td>HRQL, cost (cost-effectiveness), Return to work, Pain</td>
</tr>
<tr>
<td>Time horizon</td>
<td>Short term (6 weeks), long term (3 years)</td>
</tr>
</tbody>
</table>
Final Well-Built Clinical Question

In Patients who have clinical symptoms of CTS and confirmed with EMG and nerve conduction studies is the ECTR technique more cost-effective than the OCTR technique?
Primary vs. Secondary Questions

Primary Questions:
• Provide definitive answer, as sample size calculations are based on the primary questions.

Secondary Questions:
• Answers are considered ‘hypothesis generating’
• Answers may need to be addressed in another study in which they become the primary questions.
Primary & Secondary Questions

• All the primary and secondary questions need to be asked “up front”

• Ensures questions are “hypothesis driven” = based on your predictions of what will happen

• Do not want questions to be “data driven” = made up after the study results are in, especially to “explain” findings that may well be simply the play of chance
Primary & Secondary Questions

• Tendency among clinical investigators to ask multiple questions in a clinical study

• Avoid asking multiple questions! Simplify!
DESIGNING CASE SERIES
What is a Case Series?

Case Report

- Uncontrolled, descriptive study involving a detailed description of an intervention and outcome in one patient

Case Series

- Expansion of the individual case report to include multiple patients with an outcome of interest
Problems with Case Series

- Cannot compare different treatments
- Limited to making causal inferences about the relationship between risk factors and the outcome of interest
- Subject to MANY biases
- Results not generalizable
- Lowest level of scientific evidence
- Unlikely to be published in a high impact journal
Why Perform a Case Series?

- You want to generate a hypothesis
- The disease/condition/event is rare
- Determine safety of new technique (i.e. complication rates)
- Lack of evidence (no published data about the topic)
- You have limited time and resources
Case Series Design

Patients → Inclusion Criteria → Exposed to same treatment

Exclusion Criteria

Poor Outcome

Good Outcome
Prospective Case Series

- Study protocol prepared in advance
- Patients with similar exposure
- Same inclusion and exclusion criteria
- Clearly defined follow-up examination
- Use same outcome scores
- Data analyzed at end of study – can only perform descriptive statistics
Retrospective Case Series

- Data collected from already treated/examined patients (i.e. medical records, office charts etc.)
- Patients with similar exposure
- Same inclusion and exclusion criteria

Problems:
- Missing/incomplete data
- No outcome data
- Variable data (if multi-center)

⇒ You many not be able to answer your question
DESIGNING SURVEYS

Key Reference:
A guide for the design and conduct of self-administered surveys of clinicians
KEA Burns, M Duffett, ME Kho, MO Meade, NKJ Adhikari, T Sinuff, DJ Cook, for the ACCADEMY Group
CMAJ 2008, 179(3):245-252
What is a Survey?

• A form of scientific inquiry with the aim of gathering reliable and unbiased data from a representative sample of respondents
Reasons to Conduct Survey Research

- Learn more about surgeon knowledge, attitudes and practice
- To generate or refine research questions
- To evaluate the impact of clinical research on practice
Types of Surveys

- **Descriptive** = reporting factual data
- **Explanatory** = drawing inferences between constructs or concepts
- **Informal**
- **Formal** (specific objectives and outcomes)
Steps in Survey Development

1. Determining the objective
2. Sample Selection
3. Item generation
4. Item reduction
5. Question formatting
6. Response formatting
7. Composition
8. Pre-testing
1. Determining the objective

- Refer back to research question presentation
- Specify of the topic, respondents, and primary (and secondary) research questions

- Important and interesting questions are more likely to attract the attention of the target audience and are more likely to complete the survey questionnaire
2. Sample Selection

1. Random (probability design)
   – Simple random sampling, systematic random sampling, stratified sampling and cluster sampling
   – Consult a statistician

2. Deliberate (nonprobability design)
   – Purposive sampling, quota sampling, chunk sampling and snowball sampling
   – Chosen when investigators cannot estimate the chance of a given individual being included in the sample
   – Such designs enable investigators to study groups that may be challenging to identify
3. Item Generation

Item Generation:
- Literature reviews
- In-depth interviews, focus-group sessions
- Combination of these methods

Following item generation:
- Group the generated items into domains
- Begin formulating questions within the domains
4. Item Reduction

Limit the number questions within domains to a manageable number

Methods

1. **Focus-Group Sessions**: Participants are asked to evaluate the relative merit of included items by ranking/rating items

2. **Statistically**: examine the relation between and among items within domains. This method requires data obtained through pilot testing.

- Most research questions are addressed with 25 or fewer items and at least 5 items in each domain
5. Question Formatting

**DO**

- Focus each question on a single construct
- Create questions with fewer than 20 words
- Create questions that are easy to understand and interpret and are nonjudgmental and unbiased
- Phrase questions in a socially and culturally sensitive manner
- Specify the perspective from which questions should be addressed

**DON’T**

- Use absolute terms - i.e. “always,” “none” or “never”
- Use abbreviations
- Use complex terminology
5. Question Formatting

Considerations:

- Language used influences the response formats used, which may affect the response rate.
- The wording of the question and the order of response categories can influence the responses obtained.
- The manner in which questions are synthesized and presented can influence potential respondents’ decisions to initiate and complete a questionnaire.
Develop succinct and unbiased response formats

1. Open = free text
2. Closed
   - Binary = Yes / No
   - Nominal = List of mutually exclusive, unordered, names or labels,
   - Ordinal = Likert scale
   - Interval and ratio measurements = continuous responses i.e. proportions

➢ Consult a statistician to ensure that response data required for analyses will be obtained
7. Composition

Cover Letter

- State the objective
- Highlight why potential respondents were selected
- Print on departmental stationery with signatures
- Personalize the cover letter to recipients
- Provide an estimate of the time required to complete the questionnaire
- Affirm that the recipient’s participation is imperative to the success of the survey
7. Composition

**Formatting and Appearance:**
- Font style and size should be easy to read (i.e. Arial 10–12 point)
- Use of coloured ink, bold type, shading and broad lines to direct respondents’ attention
- Questions should be numbered with response options on separate line

**Organization:**
- Place more interesting questions first
- Questions can be ordered on the basis:
  - Content (i.e. broad questions preceding specific ones)
  - Permutations in content (scenario-based)
  - Structure (based on the similarity of response formats)
8. Pre-Testing

- Ask people who are similar to prospective respondents to evaluate each question – should the question remain as is or does it need to be changed or removed?

- Determine if they interpreted questions in a consistent manner as you intended
Thank You!

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