Writing a research proposal

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Objectives

- How to find a research project
- How to find a mentor
- How to write a proposal
 - What are the key elements in this proposal

Step 1

- An idea
- Do any of you have any research ideas?
- What if you do not have any ideas?
- Ask yourself
 - What am I interested in?

Step 1

- If you do not know exactly what you are interested in, then ask and look for ideas
- Where?
- MICH website- list of investigators
- Speak to residents, staff
- Ask the Program Director
- Ask around

Once you have the idea

Then you need to find a mentor and develop a specific research question

Research mentor

- What kinds of attributes do you think that they should have?
- Available
- Able to support you (time, knowledge)
- He or she needs to have skills
 - Knowledge of topic, research methodology
 - Track record of conducting research successfully
 - Ideally, successful in assisting trainee led research

Research mentor

- A good idea if the mentor has collaborators, who are experts in other domains- study design, statistics, analytic techniques
- If funds are going to be needed to do this research, is the mentor able to assist with finding these
- Able to set up a realistic timeline for conducting the project
- Available (2nd mention of this!)

Resident Research Committee

- Remember that there are members of the Department of Pediatrics and beyond the Department that can assist with your research project
- Most research is a strong team effort
- Do not feel shy about asking for assistance

Back to your idea

How are you going to refine this to be able to decide which study design, which population to study, what data to collect....?

Your idea

- Where do you start?
- Exploring the literature
- Discussing your idea with your mentor
- Discuss with Biostatistician (BCU-CHI)

- Do children with new onset hyperthyroidism have abnormal EEGs or a lowered seizure threshold?
- Are children with more impulsivity likely to be more influenced by food advertisements compared to those with low impulsivity
- Do formula fed infants need to receive infant vitamin D supplements
- Are adolescents whose parents smoke more likely to smoke than those with parents who do not

FINER

- F- feasible obtaining enough samples or patients
- I − *interesting* to you and others!
- N- *novel* is this new? Can it confirm?
- E- ethical do not pass 'GO' if not the case!
- R- relevant- will this influence practice, expand our understanding

How to take this to the next step?

- Specific research question
- For this you need to think about a question and then the best design to address this
- But it must also be ethical, feasible (sample size calculation)

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Your question

- You need to have a question
- Then- what is the population to be studied
- What is the intervention or exposure to study
- What is the timeframe
- What is the setting
- What is the method to do this?
- (who, what, when, where, why, how)

PICOT

- P- population- people or patients
- I intervention (may not apply)
- C- control or comparison
- O –outcome
- T- timeframe

Lets look at examples

- Adolescent smoking and do parents' smoking influence this?
 - What kinds of designs could you use to study this?
 - RCT? is this ethical?
 - Case control?
 - Cohort (observational)?

Adolescent smoking

- Cohort study
- Had longitudinal data from birth
- Have data on the families
- Asked adolescents to come for an interview
- (so a cohort study with a prospective observational study)
- Interviewed adolescents and adults on smoking behaviour

- Had a questionnaire (validated) looking at past and current smoking
 - For adolescents and parents
- Tool to asses nicotine dependence in the parents

Adolescents and smoking

- Did a logistic regression to determine the relationship between parental smoking and adolescent trajectory (i.e. early smoker, regular smoker)
- Adolescents exposed to parental nicotine dependence have an increased odds of more intense smoking pattern

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Adolescents and smoking

- How else could have designed this
- Just a plain questionnaire
- The cohort study provided researchers with families to contact to ask these series of questionnaires

- In Canada, breastfed infants are recommended to receive vitamin D 400IU/d
- The AAP is explicit that all infants need 400IU/d
- Not all formula fed infants consume 1 L of formula containing 400IU/L
- We have noted some infants drinking formula have rickets!

- So we wonder if this might be a problem
- We do a literature search and there is not much information
- So is this interesting, novel, relevant?
- (FINER)

- How could we study this?
- Study designs
 - Observational
 - Treatment- RCTs

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 - Case-control
 - Cross-sectional
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- How could we study this?
- Study designs
- Observational
 - Case-control- we do not currently have data re this
 - Cross-sectional
 - Cohort study

- How could we study this?
- Chart review- case series
 - How many infants presenting with rickets drank formula versus breast milk?
- Other ideas?

- How could we study this?
- Sample the blood of infants drinking formula and find out their 25(OH)D concentration
- (Cross-sectional observational study)

- What would we specifically examine?
- What is my research question?

- Are infants obtaining sufficient vitamin D when they consume fortified infant formula?
- Previous studies have suggested that 50 nmol/L 25(OH)D is needed to provide enough vitamin D for intestinal calcium absorption, blood calcium concentrations and bone mineralization

- PICOT
- (population, intervention, control, outcome, timeframe)
- Formula fed infants less than 1y of age
- (perhaps target infants 0-6mo)- they are less likely to be drinking 1 litre of formula
- Outcome- what percentage of infants reach the target of 50 nmol/L 25(OH)D

- How many infants do I need to sample?
 - Sample size calculation
 - In this instance, I will estimate what percentage do I think will be less than 50nmol/L and then determine the precision of my estimate
 - 30% deficient, n=40 (my choice)
 - Using 95%CI- 30% ± 15%

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 - If I used n=60 and 95%CI, 30% ± 10%

Vitamin D and formula

- FINER-
- now I have a specific question
- Is this novel?- not many people have studied this
- Is this relevant? By 6mo many infants are obtaining formula
- 20% of infants never receive breast milk
- Ethical- to take a sample of blood and do a questionnaire?

Vitamin D and formula

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- now I have a specific question
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- 20% of infants never receive breastmilk
- Ethical- to take a sample of blood and do a questionnaire?
 - This sees to be relevant
 - This is feasible and interesting (to me at least!)

Take these ideas

- Once you have the literature and you think that this will be novel, interesting and feasible
- Plan to write this all down as guide to how you will undertake your project
- (this is the 'proposal')

What are the elements?

1. Background- why is this important

- 1. Title!
- 2. Background- why is this important
 - a. What is your hypothesis?
- 3. Outline 'Aims' overall study question
- 4. Primary objective- your main study question
 - a. The sample size and statistical method for addressing this question is the core of the proposal

- 5. Specific study design (method)
 - a. What population will you study, where?
 - b. What material will you collect (blood, questionnaire)
 - c. Outline the study variables (outcomes)
 - d. How will you collect this information
- 6. Statistical analyses
- 7. Sample size calculation
- 8. Ethics
- 9. Study time line
- 10. Team involved in undertaking this project
- 11. How are you going to spread the news about your findings?

- Your mentor will assist with this
- Once you have written this, you have a clear idea of how to proceed
- You will need to have a review of this protocol by the REB –(Research Ethics Board)
- You can then obtain your data and analyze are per your proposal

What if problems with project?

- What are you going to do?
- What if your mentor is not working out?
- What are the resources available to you?

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- Speak to your mentor
 - Have already established typical time to reply to emails
 - Have already established with proposal what the timeline will be
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- Speak to your Program Director
- Speak to the Resident Research Committee members

References

- The Research Guide
 - Royal College, B Harvey et al, 2011
- Practical Epidemiology Primer
 - London School of Hygiene and Tropical Medicine