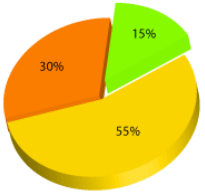


10 Common Mistakes of Beginning Researchers

Prof Barbara Anderson

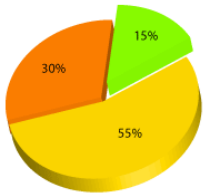
and Carmel Smart

ISPAD Science School for Health Professionals

ISPAD
International Society for Pediatric and Adolescent Diabetes

Objectives

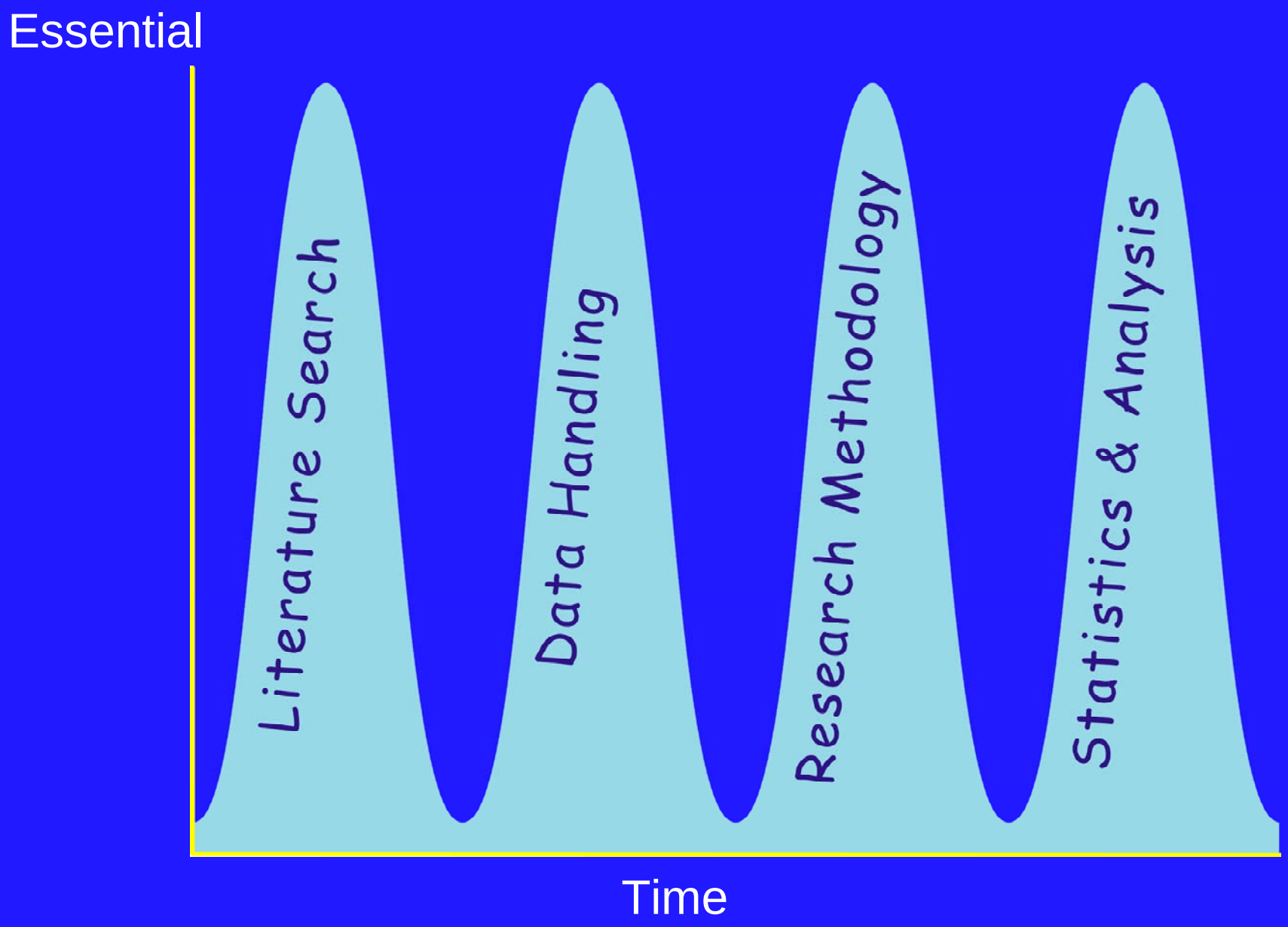
- To increase awareness of common mistakes made by beginning researchers and ways to minimise these.



- To explore examples of mistakes from the diabetes literature.

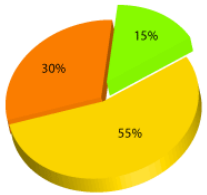
- To provide an insight into the clinical research process.

Personal plan: Assess Your Training Needs



Evidence Based Practice in Medicine

- Scientific research provides evidence.
- Use the best research evidence at the time of making clinical decisions.



"*Making the best use of*
the current best evidence
to make
the best decisions
to enable
the best care for patients."

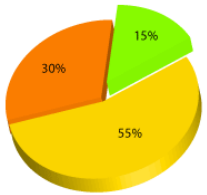
Adapted from Sackett. BMJ 1996;312:71-72

Opinion Based Practice
Biased

#1. Inadequate Literature Review

You have a question that you want to explore…

Can children with diabetes count carbohydrate?



Have other studies been done before?

Were they well conducted and what did they find?

Are there any gaps in the literature?

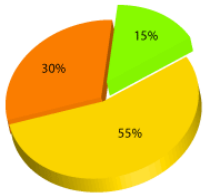
Is there a tool to assess carbohydrate counting accuracy?

How many children should we assess?

How is accuracy in carbohydrate counting defined?

Why Review the Literature?

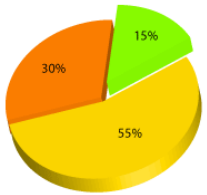
- Stops you re-inventing the wheel
- Helps you find the gap
- Provides background in the area of your study
- Helps formulate your research question
- Helps you find or develop research tools
- Provides information on sample size and effect size



#1. Inadequate Literature Review

Common mistakes in Literature Reviews…

- Failure to report core papers.
- Misquote a paper's findings from a secondary source.
- Skim only the abstract and not actually read and interpret the results.



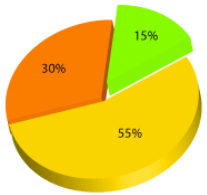
- Cite conclusions drawn from a Cochrane Review or Meta-analysis but do not read the original papers (may be type 1 and type 2 OR no studies on children).

First – Define Your Topic

Can children with diabetes count carbohydrate?

Clearly define the topic:

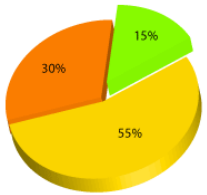
Can children and adolescents with type 1 diabetes on intensive insulin therapy count carbohydrate accurately?



Key-words: carbohydrate counting, diet-related knowledge, dietary behaviours and dietary adherence.

Where is the Evidence?

- Journals (Diabetes Care, Pediatric Diabetes, Diabetic Medicine, Diabetologia, discipline specific journals etc)
- Electronic databases (CINAHL, PUBMED)
- Cochrane Reviews
- National and International Guidelines (ADA, ISPAD, NHMRC Guidelines)
- Conference Abstracts
- Books



Protein restriction for diabetic renal disease (Review)

Robertson LM, Waugh N, Robertson A

THE COCHRANE COLLABORATION®

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2009, Issue 1

http://www.thecochranelibrary.com

WILEY
Publishers Since 1807

Cochrane review may not address your question

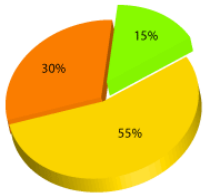
Studies are needed to examine:

The efficacy and safety of high protein, low carbohydrate diets in adolescent girls with type 1 diabetes trying to lose weight.

Lit Search Helps Further Define Your Topic

*Can children and adolescents with type 1 diabetes on intensive insulin therapy count carbohydrate **accurately?***

Definition of Accuracy is problematic but literature search helps explore possible definitions.



Accuracy: Within ± 10grams of true amount per day.

Estimates within 20% of actual meal CHO.

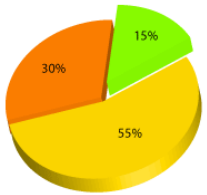
NO universally accepted definition for accuracy in CHO estimations

Critical Analysis of Papers

- **Clarity** - clear aims & methods
  - appropriate questions

- **Validity** - Sound methodology – appropriate study design
  - no bias
  - ethical

Does the method match the question?

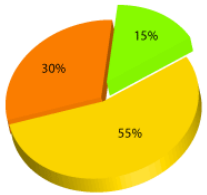


- **Reliability** - repeatable or chance result
  - data collection, stats, analysis

- **Applicability** - worthwhile, relevant, helpful,
  - practical,
  - benefit / harm

Managing Your References

- All references can be saved in files for later use by Reference Management Programs such as ENDNOTE, ProCite, Reference Manager, Refworks



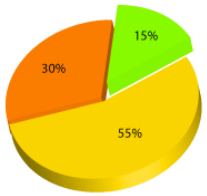
- The programs work with Microsoft Word and other word processing programs

- Referencing styles can be changed to suit particular journal types

In summary…

Has my literature review helped me to systematically collect and analyse information so that I am able to:

1. *define my particular research question?*
2. *examine what is known and what is not about my topic?*
3. *identify areas of controversies in the literature?*
4. *formulate questions that require more research?*



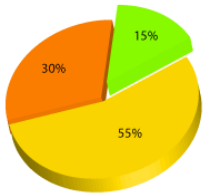
If yes, you are off to a good start!

#2. Lack of a testable research question

- 3 Foundation Steps:

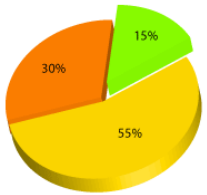
1. Begin with a clinical observation or idea that interests you

(Even though doctors tell parents that their child needs to be independent in managing their diabetes, young adolescents with T1DM who are in charge of their own diabetes management, seem to do worse than kids whose parents stay involved.)



#2. Lack of a testable research question

2. **Search the literature** to see if this idea has already been studied:



If no, is this an important area? Is it very difficult to study? To measure?

If yes, are there any unexplored aspects of this idea, any gaps in the literature that my study could fill, can I bring any innovation to this research area?

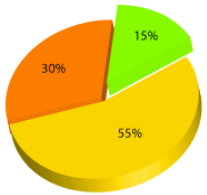
.

#2. Lack of a testable research question

- 3. **Sharpen your Research Question**

Include the specifics that can be measured about:

1. Independent Variable--the variable under study [Parent involvement in DM management]

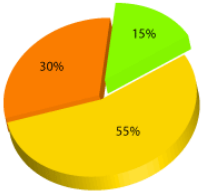


2. Dependent Variable--the outcome variable [young teen does better or worse]

3. The study population [young teens and their parents]

A vague research question

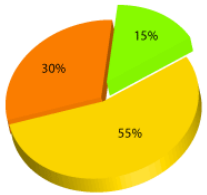
- **When parents help their young teen with diabetes tasks, does the teen do better or worse?**



- Some problems:
  - How will ‘parent help’ be measured?
  - Over what length of time is meant?
  - What does ‘doing better’ mean?

Sharpening your Research Question

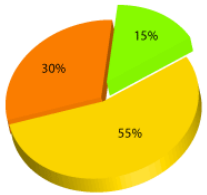
- Clarify which parent (one most responsible for diabetes) and age of teen (11 – 14 yrs.)
- ‘Parent help’ is defined by both parent and teen reporting about the extent of parent help in the family.



- Report on diabetes management over the past 3 months
- Teen ‘doing better’ is defined by HbAlc.

Evolution of your research question

- Idea=*(Doctors tell parents that their child needs to be independent in managing their diabetes, but young adolescents with T1DM who are in charge of their own diabetes management, seem to do worse than kids whose parents stay involved)*



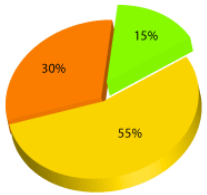
- Vague Question= When parents help their young teens with diabetes tasks, do the teens do better or worse?

- Testable Research Question = What is the relationship between parent involvement in the tasks of diabetes management (insulin, blood glucose checking, & food choices) over the past 3 months & the glycemic control of their 11-14 yr-old teen as measured by HbAlc?

#3. Overambitious measurement plan (response burden)

- Focus **only** on your variables of interest

- You can't measure everything!

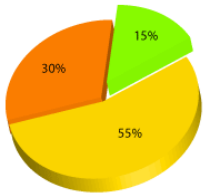


-Think about the expenses (money and time) involved in collecting your data.

-Think about the time demands on the participants in your research

3.Overambitious measurement plan

- **Research Question=*Relationship between parent involvement in diabetes tasks and HbAlc?***

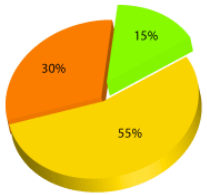


- How can I measure parent involvement?

- Many options: Interview parent /child; Self-report questionnaire; direct observation; clinician report (3rd party).

3. Overambitious measurement plan

- Direct observation usually most complex measurement strategy. Observe:
  - who decides it is time for insulin
  - who decides on insulin dose
  - who decides on injection site
  - who injects
  - who disposes needle/stores insulin



- How many injections need to be observed?
- Who does the observing? Where? When?
- What other tasks need to be observed? BGM, food choices, carrying supplies for low BG, etc?

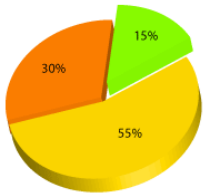
- Can observations be done reliably, unobtrusively>?

#3. Overambitious Measurement Plan

Best to use an existing measure.

Does a validated interview or survey exist to measure parent involvement in diabetes tasks?
If yes,

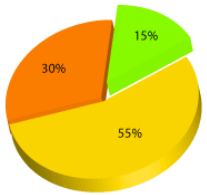
- Does is fit my research question?
- Does it have acceptable psychometric properties? (reliability, validity)
- Is it too long for parent to complete?
- Are questions 'appropriate' for all parents?



- **Too ambitious to develop new measure; this is a separate, different research question.**

#4. Inadequate Sample Size

Important to do a sample size calculation in the planning stages of your study to ensure you have:

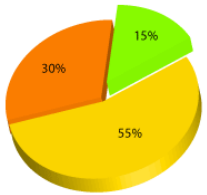


1. Access to a suitably large population (may need to collaborate!)
2. Sufficient power to determine whether or not there is a true effect from an intervention.
3. External validity - ability to generalize results.

What is Power?

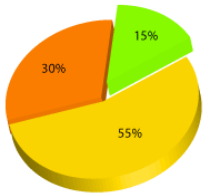
- Power refers to a study's strength to find a difference when a difference actually exists.

- When there is a significant difference in the population but we fail to find this difference (Type 2 error), our study is said to lack power.



Sample Size and Power Analysis

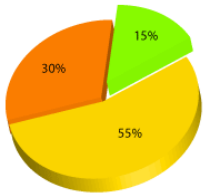
- Key idea is to know before a study what is the chance your intervention will have an effect.
- Sample size is a key driver of this.



- Can save wasted effort and disappointment if proper planning is carried out prior to the study.

Sample Size

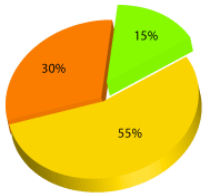
- Determining the sample size requires “educated assumptions” about effect size and p-value.



- Cannot just “leave it to the statistician” as you know the literature and the clinical significance of a difference or change from the intervention.

What size change is important?

- We need to estimate the size of the **effect** of an intervention on the dependent variable (BGLs, HbA1c, BMI, % time in target range)

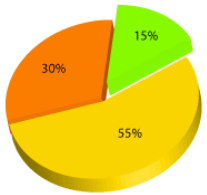


- To determine if the effect is clinically significant, base it on previous research or what you know from clinical care.

What size change is important?

Research Question:

In children using insulin pump therapy does an insulin dose for 60g carbohydrate (CHO) maintain glycaemic control if 50g or 70g CHO is ingested?



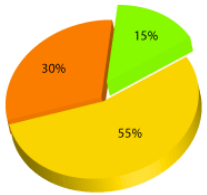
Method:

Three standardised lunches with variable CHO (50g, 60g and 70g CHO). CGMS used to measure postprandial response.

How many children do we need to enable us to find a difference in postprandial blood glucose levels if a difference actually exists?

What size change is important?

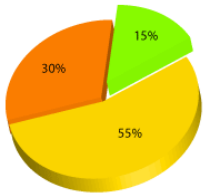
Based on previous research and clinical targets, a difference in glucose levels of 2 mmol/l at 120 mins post-prandially was determined to be a clinically significant effect.



Literature review and previous studies also provided info about variability (std deviation) in BG measurements.

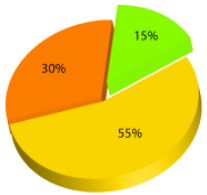
How many children do we need?

A sample size of 30 patients was determined to provide 80% power to detect a difference in glucose levels of 2 mmol/l at 2 hours between the 50g and 60g and the 60g and 70g carbohydrate meals.



#5. Unethical or Coercive Recruitment Methods

- **Unethical** to sign up subjects for study without informed consent that honestly reports:
  - Study approved by the IRB (Institutional Review Board) or Ethics Board of institution where researcher works
  - Who sponsors/pays for study (Drug company, Government)
  - Time required for research participation
  - The real purpose of study (avoid misleading pt.)
  - How study findings will be used
  - Risks of participation
  - Benefits, if any, of participation

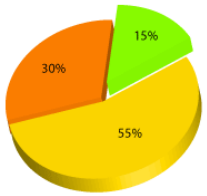


#5. Unethical or Coercive Recruitment Methods

- **Coercive** to

-Recruit a minor or 'vulnerable person' (prisoner, brain-damaged patient) without a guardian.

-Offer a large amount of money (over and above compensation for time, transportation costs or a small stipend). Most institutions have a maximum amount paid for research participation.



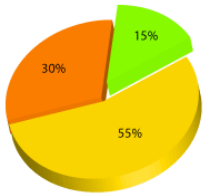
- Use personal power/status to recruit,

- Connect research participation to another service the subject needs (e.g. health care, police protection), so that subject feels if she does not consent to study, her doctor/the police will not take care of her.

#6. Bias in Sample Selection

- Select a sample that is not representative of the population to which you want your findings to apply.

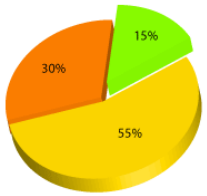
- Sample is collected in such a way that some members of the intended population are less likely to be included than others.



- A biased sample is a non-random sample. **But almost every sample is biased in some way, because it is practically impossible to ensure a perfectly random sample.** But if the degree of under-representation is small, the sample can be treated as a reasonable approximation to a random sample .

#6. Bias in Sample Selection

- The researcher's task is to minimize the bias in her research sample, as much as humanly possible.



- Avoid 2 common sample selection errors:
    1. **Recruitment Site/ Method Bias**
    2. **Self-selection Bias**

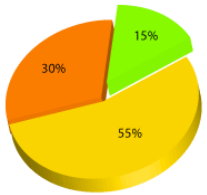
#6. Bias in Sample Selection

1.Recruitment site/method bias

You are studying the relationship between diabetes control and depression in youth with T1DM:

-Recruit from a diabetes camp

- Recruit from youth on a diabetes website



2.Self-Selection bias

You want to test the effectiveness of a new family-based intervention to help kids lose weight:

- Recruit from an ad in the newspaper

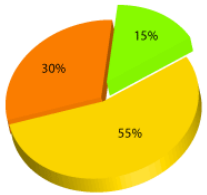
- Recruit using the internet

#7. Poor Outcome Measure

- **Inappropriate choice of outcome measure**

  - Outcome measure chosen is not a good measure of the effect of the intervention.

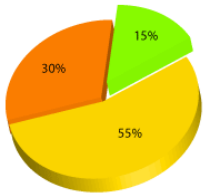
For example, in dietary intervention study investigating if there is an advantage of using the dual-wave bolus for High Protein - High Fat meals, HbA1c is chosen as the outcome measure.



Preferable to use a measure of postprandial control such as differences in glucose levels measured by Continuous Glucose Monitoring.

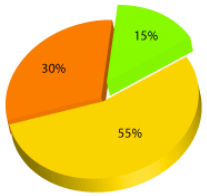
Outcome Measure

- **Validated Tools**
  - Be aware of the validated tools available to measure your outcome. (If there are any!)
  - The tool may or may not be suitable BUT you should be able to justify why you have not chosen to use it if you decide not to.
  - Creating your own validated tool is a whole new research project.



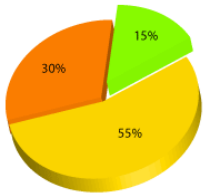
Outcome Measure

- **Measurement Bias**
  - Bias tends to produce results that depart systematically (i.e.not randomly) from the truth.
  - Bias can occur as a result of the way data is collected and analysed.



Measurement Bias

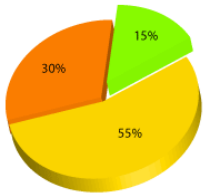
- Interviewer /investigator not “blinded” to:
  - Study hypothesis
  - Subjects intervention status (What group they are in)
  - *You have a strong belief that jellybeans are better for hypo treatment than juice. You are the person grading the BGL response and you know to which group the subject is assigned…*



Instrument Bias

A stadiometer may not reflect a child's height due to –

- Observer error
  - Health Professional measures inaccurately
- Subject error
  - Patient has hair pulled up
- Instrument error
  - Equipment error – Not calibrated regularly

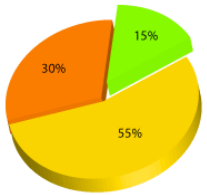


Another common piece of equipment to standardise is HbA1c analyser (Collect info on make, model and country of production).

If doing a collaborative study need to standardise equipment (food scales, lab tests, glucometer).

#8. Failure to Control for Confounders

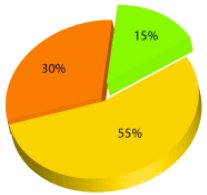
Imagine a study which aims to determine whether living close to takeaway food outlets is associated with obesity. BUT people who live close to takeaway food outlets also live in high-rise buildings and have less access to parks, bicycle paths and playing fields.



Therefore, risk of obesity may not be due to increased takeaway food consumption but due to the confounding effects of lack of physical activity.

Confounding

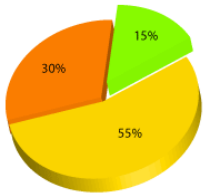
- Confounding occurs when other factors influence the study outcome. These factors are called confounders.



- A confounding variable *(access to physical activity)* distorts the apparent magnitude of the effect of the independent variable *(proximity to takeaway food)* on the dependent variable *(prevalence of obesity).*

Confounding

- A confounder is likely to be unequally distributed amongst the exposed and non-exposed and needs to be measured.

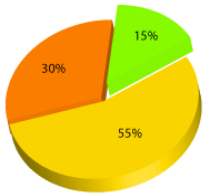


- *Think of all the factors that may be confounders in your study*. Try to control for them. Collect information on them to allow you to address with reviewers or in discussion.

- *Common confounders – age, gender, education level, socio-economic status, insulin regimen, time since diagnosis.*

Confounding

- If you know something affects your outcome then examine your study to see if it confounds (influences) your results.



- Measure it to see if it is evenly distributed in both groups.

- *The challenge is to think of all possible confounders BEFORE you start so you control for them or collect information on them.*

Table of Subject Characteristics

In published studies, a Table of Subject Characteristics allows us to check that *known confounders* (age, gender, BMI, insulin dose/kg) are *evenly distributed*.

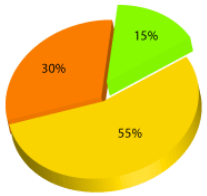


Table 2 Clinical characteristics of subjects by insulin therapy group (CSII and MDI)

	CSII	MDI
n	17	14
Age (years)	13.7 ± 2.1	12.9 ± 1.8
Sex (male/female)	7/10	7/7
Duration of diabetes (years)	5.9 ± 3.4	3.9 ± 2.1
HbA_{1c} (%)	7.8 ± 0.7	7.5 ± 0.7
BMI *z* score	0.6 ± 0.9	0.9 ± 0.8
Test meal insulin bolus (units)	7.3 ± 3.4	7.2 ± 3.7
Insulin : carbohydrate ratio (unit/g)	1:9.4 ± 3.7	1:9.0 ± 3.6

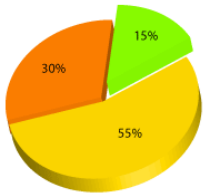
Data are presented as means ± SD.

BMI, body mass index; CSII, continuous subcutaneous insulin infusion; HbA_{1c}, glycated haemoglobin; MDI, multiple daily injections; SD, standard deviation.

In Reality…

- It is unlikely that you will be able to perform a research study without there being some confounders in your work.

- However, you need to collect information on potential confounders and tried to control for them, for example, by randomising the groups to the intervention.

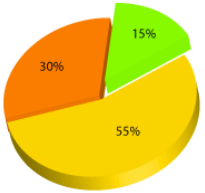


- Address potential confounders in the Discussion of your paper-

  “A possible confounder may be differences in the participants’ insulin sensitivity, as CHO variations may cause greater postprandial excursions in more insulin sensitive subjects. The current study was not powered to examine this issue. Further studies are needed.. ”

#9. Lack of sensitivity to culture and language differences

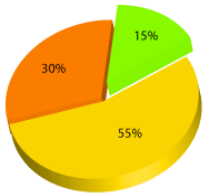
- 1. In recruitment methods



- 2. In research methods (measures), procedures, personnel

#9. Lack of sensitivity to culture and language differences

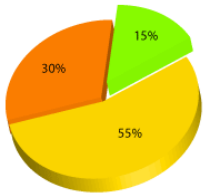
1. Lack of sensitivity to cultural differences in recruitment methods:
   - Images in recruitment ads (picturing only white persons)
   - Ethnicity/culture/language of person recruiting subjects for the study
   - Language of the recruitment ad (not translated into all languages represented in the population)



#9. Lack of sensitivity to culture and language differences

2. Lack of sensitivity to cultural differences in study methods and procedures:

-Research staff from one distinct cultural/ethnic group.



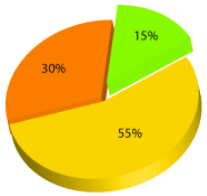
- Measures not translated for people represented in the population to whom you want to generalize.

- Questionnaires use words only familiar to one cultural/ethnic group; use pictures that represent only one cultural/ethnic group.

#10. Common errors in Grant and Ethics applications

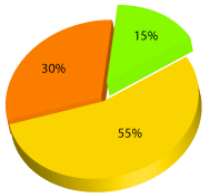
Grant applications

- Should contain a well developed research plan which includes:
  - *Why you are going to do the study (Significance and Background literature)*
  - *What you are going to do (Aims and Hypothesis)*
  - *Where you are going to do it (Setting)*
  - *How you are going to do it (Research design and method)*
  - *When you are going to do it (Time-line)*
  - *Who is responsible (Research team)*
  - *How much it will cost (Budget)*



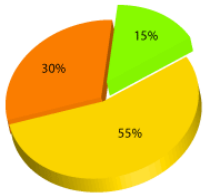
What Reviewers Look For…

- An interesting problem and clear direction to the work
- A clear well-written proposal with rationale for the methods chosen
- Attention to detail—spell it out!
- Preliminary studies
- Power analysis
- A qualified investigative team
- Realistic budget and timeline
- Acknowledgement of pitfalls, discussion of alternatives



Grant Writing

- Get critical feedback from colleagues
- Be familiar with all the specific requirements for the application
- Give yourself plenty of time to produce a quality application
- Don’t give up!
- Perseverance is required for success
- Respond to each of the critiques—go along with the reviewer whenever possible

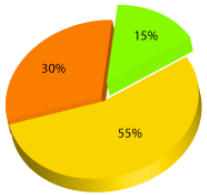


#10. Common errors in Ethics applications

- **Informed consent**

  - Information sheets and consent forms that are age appropriate
  - Detail how voluntary participation will be ensured.

- **Data analysis and storage**

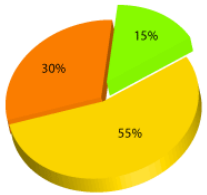


  - Early statistician input
  - De-identified records
  - Locked files and password protected computers

- **Appropriately trained staff to do the research**

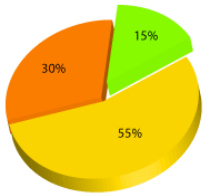
#10. Common errors in Ethics and Grant applications

- Allow time to do photocopying and gather signatures.
- Be prepared to make lots of changes particularly when you are learning.
- If you receive a grant *set aside the time separately to your clinical work.*
- Writing and developing grants and papers take time and thought (alone) - different from busy clinical workload with constant contact.



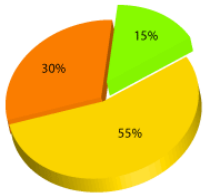
Summary: 10 Common Mistakes

1. Inadequate literature review
2. Research question not testable
3. Overambitious measurement plan (response burden)
4. Inadequate sample size
5. Unethical and/or coercive recruitment methods



Summary: 10 Common Mistakes

6. Biased sample selection
7. Poor choice of tool to measure outcome
8. Failing to control for confounders

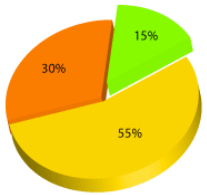


9. Insensitivity to culture & language differences
10. Common errors in ethics applications & grant proposals

Mistakes from the Diabetes Literature

In a study on disordered eating:

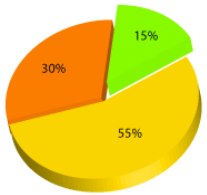
"Height and weight were measured during the clinic visit for the adolescents. The non-diabetic adolescents (controls) self-reported their height and weight."



Mistakes from the Diabetes Literature

In a study investigating the tolerance of a particular CGMS device:

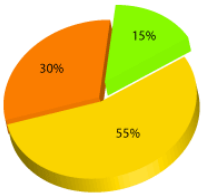
“Because of difficulty using the sensor, 5 of 32 subjects withdrew during the run-in phase. The remaining 27 subjects were included in the analysis.”



Mistakes from the Diabetes Literature

In a study investigating the effectiveness of treatments for hypoglycaemia:

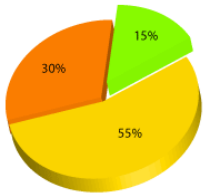
"Spontaneous hypoglycaemia was defined as a blood glucose < 4mmol/l."



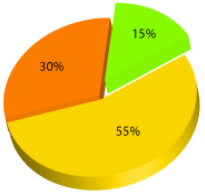
Mistakes from the Diabetes Literature

In a study investigating insulin administration for high protein meals:

“Compliance with the dietary intervention was assessed by the number of D-W boluses. We assumed this meant compliance with our dietary instructions in daily life.”



- Thank you for your attention!



- Questions?