Designing a multi-centre RCT: From initial good idea to team building and obtaining funding.

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I will also show this QR code at the end of the talk
Perspective

- Framed by information from the two top text books on the subject

- I am going to talk about my own experiences and beliefs
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Key lessons I have learned

1) Your research question must be important.
2) Know your Funding Agency.
3) Demonstrate your clinical expertise.
4) Demonstrate your research expertise.
5) Choose your team members wisely.
6) Your written grant must be clear and concise.
Choosing your research question
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When should you conduct a multi-centre RCT?
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When a single centre RCT cannot recruit enough patients fast enough.
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Maybe not the single best reason....
Choosing your research question
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Conducting a multi-centre RCT is *very complex*. 
Choosing your research question

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- Managing your friends in your ICU is difficult. In a multi-centre RCT, you must manage different colleagues from different sites, many of whom you don’t even know and who may be senior to you!
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This level of complexity makes multi-centre trials very expensive.
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*When should you conduct a multi-centre RCT?*

*Lesson #1. Your research question must be important.*
What is important?
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At work, your boss defines what is important!
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At work, your *boss* defines what is important!

- When planning your RCT, think of your Funding Agency as your boss!!
- Understand your Funding Agency’s priorities/agenda.
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- To be considered ‘important’, I must show the NHMRC my project will:
  1) Improve health and well-being and
  2) Change practice or policy.
What is important?

Lesson #2. At work, your Boss defines what is important.
Your Funding Agency is your Boss! Know your Funding Agency.
Example
2006-2010 **Doig GS**, Cooper DJ, Finfer SR, Simpson F, Solano T, Peake S and Davies A. Early parenteral nutrition vs. standard care in the critically ill patient: A Level I randomised controlled trial. **NHMRC Project Grant $1,812,750**
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We also present data showing that, despite this systematic review, 46.9% of eligible critically ill patients in ANZ do not receive early PN.

A database composed of 13 representative control hospitals, obtained from a recent 27 hospital Australian and New Zealand Intensive Care Society Clinical Trials Group (ANZICS CTG) Endorsed cluster randomised controlled (cRCT) trial of evidence-based ICU feeding guidelines conducted over a six-month period, identified 354 patients who would qualify for recruitment into the current trial. Of these potentially eligible patients, 166 (46.9%) did not receive enteral or parenteral nutritional support during their ICU stay, which averaged 4.7 ± 2.2 days. An additional

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- Finally, we explicitly express our commitment to *practice change*!!
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You may think that a highly-cited publication in a major journal is the end-deliverable for your project. Members of your Funding Agency may be more focussed on health change in the real world.

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  **Lesson #3. Publish to demonstrate your clinical expertise!**

  www.EvidenceBased.net
#4) Demonstrate your research expertise

Use methods papers to demonstrate knowledge of good RCT conduct.
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2010-2014 **Doig GS, Simpson F, Caterson I, Davies AR, et al.** Management of refeeding syndrome in critical illness: An AuSPEN endorsed multicentre RCT. NHMRC Project Grant $1,308,800


2006-2010 **Doig GS, Cooper DJ, Finfer SR, Simpson F, et al.** Early parenteral nutrition vs. standard care in the critically ill patient: A Level I RCT. NHMRC Project Grant $1,812,750

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Show your prior success. It predicts future success!
Or, show that you have been learning how to succeed!!!
Lesson #3. Demonstrate your clinical expertise on your research question.

Lesson #4. Demonstrate your research expertise in multi-centre RCTs.
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To ensure the success of your grant, you must assemble three teams:

1) An experienced grant writing team
   • This team must have clinical and research expertise.
   • Must include senior biostatistician or academic clinical trialist.
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To ensure the success of your grant, you must assemble three teams:

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To ensure the success of your grant, you must assemble three teams:

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2) A data management team
   • Collaborate with a recognised Data Management Centre.
     • Led by biostatistician or academic trialist who is named on your grant.

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To ensure the success of your grant, you must assemble three teams:

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To ensure the success of your grant, you must assemble three teams:

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3) A network of participating sites
   - This can be the most difficult aspect of a multi-centre RCT!
   - Make friends. Agree to help your friends in the future if they help you now!

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#5) Multi-center RCTs are a team sport

To ensure the success of your grant, you must assemble three teams:

1) An experienced grant writing team
2) A data management team
3) A network of participating sites

- These teams should be identified before you write your grant.
- Few people will be members of all three teams.
- Members should be selected because skills are appropriate for specific team.
- Do not make your teams too big.

**Lesson #5. Choose your team members wisely!**
#6) Your grant must be clear and concise

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4) Communicate that you and your team *can conduct* your multi-centre RCT.
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4) Communicate that you and your team can conduct your multi-centre RCT.

Start putting these elements together 2 to 3 years in advance of writing your grant!
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Good Luck!!!
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