

Session 1 (ASK): Exercise sheet

Foundations of Clinical Research · Level 1 · Neudata · #ClearDataClearImpact · Week 1 · Saturday 31 October 2026 · online, 19:30–22:30

Name: _____

Department: _____

How to use this sheet. This sheet is sent by email before the session, as a Word file and as a PDF. Keep it open on your computer during the session and type your answers into the Word file, or print the PDF at home if you prefer to write by hand.

- Exercise 1: **whole class**, segment 1.2 (11 minutes). The trainer shares it on screen and types the class answers; you answer in the chat or the poll.
- Exercise 2: aim, objectives and hypothesis, **on your own** (segment 1.3, 7 minutes). Type your primary objective in the chat.
- Exercise 3: **your own** Proposal builder 1 (30 minutes), in the proposal template.
- Exercise 4: homework for next Saturday (synonym list).
- Extra practice (optional, at home): other scenarios and more FINER and hypothesis practice.

The answers are discussed in class. There is no mark.

The running example (for reference)

P: Population	Adults (18+) with septic shock in the ICU
I: Intervention	Restrictive fluid strategy
C: Comparison	Usual care (standard fluids)
O: Outcome	Death from any cause
T: Time	Within 28 days

Question: *In adults with septic shock in the ICU, does a restrictive fluid strategy, compared with usual care, reduce 28-day mortality?*

FINER check (slide): F (Feasible) is red: a mortality outcome needs well over a thousand patients, too many for one ICU.

The two course papers (in the course folder, [Course/Papers](#)):

- **Paper 1:** Boulet N, et al. Impact on fluid balance of an optimized restrictive strategy targeting non-resuscitative fluids in intensive care patients with septic shock. *Crit Care* 2024;28:429. A pilot randomised controlled trial (48 patients); main outcome cumulative fluid balance at day 5.
- **Paper 2:** Hyun DG, et al. Impact of a cumulative positive fluid balance during the first three ICU days in patients with sepsis. *Ann Intensive Care* 2023;13:105. A matched cohort from the Korean sepsis registry; main outcome 28-day mortality.

Exercise 1: Rescue the running example (whole class, 11 minutes, segment 1.2)

Our question fails F (Feasible). Here are three feasible versions.

Version	Idea
A (pilot trial)	Restrictive fluid protocol vs usual care; outcome: cumulative fluid balance at day 5
B (cohort)	Fluid-positive vs not by day 3; outcome: death by day 28
C (descriptive)	How many of our patients with septic shock are fluid-positive on day 3?

Poll: which version could our own ICU do within two years? ☐ A ☐ B ☐ C

Tips

- For an observational question, **I** becomes **E** (Exposure: something patients have or receive that we do not assign), giving **PECO**.
- A descriptive question (how many? how often?) may only need **P** and **O** (and **T**).
- Choose **one** primary outcome and say **when** it is measured.

For the version the class chooses:

Version chosen: ____	
P: who?	
I / E: what is given, or what are they exposed to?	
C: compared with what?	
O: which outcome?	
T: measured when?	

The question in one sentence:

Type of question (tick one): ☐ descriptive ☐ analytical (observational) ☐ analytical (experimental)

FINER (G = green: fine; A = amber: needs thought; R = red: must change)

Letter	Test	G / A / R
F : Feasible	Enough patients, time, money, skills, data?	
I : Interesting	To you, your team and readers?	
N : Novel	Confirms, refutes or extends what is known?	
E : Ethical	Could an ethics committee approve it?	
R : Relevant	Could the answer change practice, policy or research?	

H0 and H1 (or "descriptive: no hypothesis"):

H0: _____

H1: _____

Exercise 2: Aim, objectives and hypothesis (on your own, 7 minutes, segment 1.3)

Use the **pilot question (version A)**: *In adults with septic shock, does a restrictive fluid protocol, compared with usual care, reduce cumulative fluid balance at day 5?*

Aim (one sentence, starting "To compare..."):

Objectives (2, each with a measurable verb such as compare, estimate, describe, determine or measure; tick the primary one):

1. ☐ _____

2. ☐ _____

Hypothesis. Write **H0** (null: no difference) and **H1** (alternative: a difference) for your primary objective.

H0: _____

H1: _____

Then type your primary objective in the chat.

Exercise 3: Proposal builder 1 (on your own, 30 minutes)

First the trainer fills Part 1 of the template for the running example on screen (8 minutes). Then you write Part 1 of **your own** proposal, on a question from **your own department**, in the **Research**

Proposal template (Templates/Research_Proposal_Template.docx, sent by email). This sheet is your checklist. Anything unfinished is homework. The search, references, problem statement and working title come **next Saturday** (Session 2, Proposal builder 2).

Time	Task	Done
0–8 min	Watch the trainer model Part 1 on the running example	☐
8–25 min	1. Choose ONE problem from your own department (the questions saved from the welcome chat may help)	☐
	2. PICO(T) or PECO table and the research question in one sentence	☐
	3. FINER check: a colour for every letter; rewrite the question if any letter is red	☐
	4. Aim (one sentence), 2–3 objectives (measurable verbs; mark the primary), H0 / H1 (or "descriptive: no hypothesis")	☐
25–30 min	Two volunteers read their question and aim aloud; everyone suggests one improvement in the chat	☐

My question: _____

FINER: F ☐ I ☐ N ☐ E ☐ R ☐ (G / A / R)

Quality checks before you stop

- ☐ Every PICO box is filled, and there is only **one** primary outcome with a time point.
- ☐ The question, aim, primary objective and hypothesis all talk about the **same** outcome.
- ☐ No FINER letter is red.

Exercise 4: Homework (synonyms for next Saturday's search) (on your own, about 15 minutes)

PubMed searches in **English**. For each PICO word in **your own** question, write 2–3 English words or phrases that authors might use.

PICO element	My word	English synonyms (2–3)
P		
I / E		
O		

Example (running example): septic shock · sepsis · vasopressor-dependent sepsis; fluid restriction · restrictive fluid · conservative fluid.

Exit question (in the chat, or the 1-question form linked there; 2 minutes, before you leave)

1. Which FINER letter did our running example fail, and why?
2. Rewrite as an objective: "To understand fluid balance in our ICU".

Why we ask: it is not homework and not marked. It shows us what is still unclear. The trainers read every answer before next Saturday and open Session 2 with what they find.

Homework before next Saturday (Session 2)

- Finish **your own** Proposal Part 1 draft: question, FINER check, aim, objectives, H0/H1.
- Exercise 4 (synonym list).
- **Install Zotero (required):** Zotero desktop, the Zotero Connector for your browser and the Word plug-in, free from [zotero.org/download](https://www.zotero.org/download). Session 2 uses Zotero live. If you have problems, email the trainers before Friday.
- **Have ready next Saturday:** your PICO question, your synonym list, a computer with internet and Zotero.

Extra practice (optional, at home)

A. From scenario to PICO(T). Pick one scenario. Fill the PICO(T) or PECO boxes and write the question as one sentence.

- **Scenario A: Ventilator-associated pneumonia.** Your ICU raises the head of the bed to 30–45° for ventilated patients, but compliance is patchy at night. A colleague wonders whether a twice-daily nurse checklist would reduce ventilator-associated pneumonia.
- **Scenario B: Pressure injuries.** Several patients in your medical ward developed pressure injuries last quarter. Some staff turn patients every 2 hours, others every 4 hours. Nobody knows how often pressure injuries occur in your unit.
- **Scenario C: Delirium.** Older patients after hip-fracture surgery often become confused. The geriatric team suggests a daily non-drug bundle (glasses and hearing aids on, orientation, sleep protection, early mobilisation).
- **Scenario D: Stroke door-to-needle time.** Your emergency department wants to know whether a pre-hospital alert from the ambulance shortens the time from arrival to thrombolysis.
- **Scenario E: Medication errors.** Many errors happen when patients move from ICU to the ward. A pharmacist-led medication reconciliation at transfer is proposed.

B. Which FINER letter is the main problem?

1. "In all hospitalised adults in our country, does vitamin D supplementation reduce mortality over 10 years?" Main problem: _____
2. "In ICU patients with septic shock, does withholding antibiotics for 24 hours reduce resistance?" Main problem: _____
3. "Do nurses in our ICU wash their hands?" (already measured monthly by the infection-control audit for 5 years) Main problem: _____
4. "In adults with community-acquired pneumonia, does the colour of the drug chart affect 28-day mortality?" Main problem: _____

C. Write H0 and H1, or say why none is needed.

a) "In ventilated ICU adults, does early mobilisation, compared with usual care, shorten ICU length of stay?"

H0: _____

H1: _____

b) "What proportion of our septic shock patients have a positive cumulative fluid balance on day 3?"

H0 / H1 needed? ☐ yes ☐ no. Because: _____