

WOMBAT

Perinatal Trials Toolkit

Formulating a research question (using PICO)

PICO

PICO is an acronym which stands for:

- Patient or Problem
- Intervention
- Comparator
- Outcome

It is used to translate a clinical problem into a structured question which identifies specific key concepts

Example 1: *Is progesterone a good thing for preventing preterm birth?*

Patient or Problem	Intervention	Comparator	Outcome
?	?	?	?

Participants - Define disease/condition

- Severity, stages of condition
- Setting (hospital, community)
- Age range, Gestation
- Other illnesses
- Exclusions?

Comparator - Specify the comparator

- Placebo
- Nothing
- Usual care
- Other intervention –best evidenced based alternative

Intervention - Define intervention

- Dose, duration, frequency, route
- Drugs- any in a class?
- Define optional and essential elements of the intervention (who must, how must it be done)

Outcomes

- What outcomes are important, and to whom?
- Have scales or measurement tools been validated?
- Use of surrogate outcome - related to the “real outcome”
- Primary vs secondary

Patient or Problem	Intervention	Comparator	Outcome
Women with a previous preterm birth <34 weeks, exclusions...	Vaginal progesterone, 100mgs daily, 20 weeks -34 wks	Placebo	Neonatal RDS, Safety, Maternal emotional well-being, Cost

Question as a testable hypothesis:

In women with a previous preterm birth less than 34 weeks (**P**), does antenatal administration of vaginal progesterone, 100mgs daily, from 20 to 34 weeks gestation (**I**), compared with placebo (**C**) reduce neonatal respiratory distress by 30% from 15% to 10% (**O**).

Example 2: How do we really know when to take a the best time to transfer a newborn from an isolette to an open cot?

Patient or Problem	Intervention	Comparator	Outcome
Preterm infants with a birthweight less than 1600gm	Transfer at 1600gm	Transfer at 1800gm	Weight gain, adverse events, length of stay

Question as a testable hypothesis:

In preterm infants with a birthweight less than 1600gm (**P**), does transfer at 1600gm (**I**), compared with 1800gm (**C**) results in similar weight gain, no increase in adverse outcome and shorter length of stay (**O's**).

How to write a problem statement

Basically think: "What is?" and "What should be?"

Example 1:

What is?

There is wide variation in practice in the care of women with preterm prelabour rupture of the membranes between 34 and 37 weeks gestation.

What should be?

We should know which care options are best for women with this problem.

Example 2:

What is?

Gum disease and periodontal disease may increase the risk of a women giving birth preterm. There has been minimal assessment of whether dental health preventative strategies during pregnancy may reduce the risk of preterm birth.

What should be?

These strategies require rigorous assessment.

This toolkit was prepared by Vicki Flenady and Rebecca Tooher.

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