Interventions & Comparisons

The **I** in PICO describes the intervention in a review or study which includes, treatments, adjunctive therapies, medications, diagnostic tests or recommendations for patients.

The **C** in PICO describes the comparison in a review or study which is the alternative or standard treatment to be compared to the experimental intervention. Most of the principles for annotating Comparisons are the same as those for Interventions.

- Materials or Procedures (interventions)
    - All drugs
    - Any intervention
    - Combination drug terms
- Delivery method, setting, rationale and provider modifiers
    - Dose, schedule and duration
    - Injections
- Classification categories
- New group/arm - how and when to use
    - Multi-arm study
    - Two-arm study
    - Studies split by review authors

Materials or Procedures (interventions)

All drugs

In many reviews authors include any drug within a specific drug category or categories.

- use the drug classification

    example: DrugCategory - Immunoglobulins

Any intervention

Sometimes the intervention will be stated as *any intervention.*

- omit the controlled vocab term
- annotate the intervention modifiers (if there are any)
- leave the classification heading blank/unselected if not specified

Combination drug terms

- Annotate with the two or more separate drugs or drug categories using AND

    example: Favipiravir Combined With Tocilizumab - Favipiravir AND Tocilizumab

- Exception: combination drugs where the combination is widely known as as single medication

    example: Lopinavir And Ritonavir which is known as Kaletra

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Delivery method, setting, rationale and provider modifiers

> ⓘ **Important!**
>
> Only annotate the modifiers when they are an important component of the review question. More often than not this information is not reported at Methods level.

In some reviews the interventions in I and C are identical but what differs is

1. the delivery method (e.g. intravenous vs. oral)
2. where it was delivered (e.g. home vs. hospital)
3. who delivered it (e.g. nurse or lay health worker)
4. the reason it was given (e.g. palliative)

The annotation model has incorporated some components of TIDieR. (This checklist was developed as an attempt to improve the quality of description of interventions in publications).

Dose, schedule and duration

If this information is not available or not required the fields remain empty.

Some review questions will focus on

- dose comparisons between different interventions and comparisons
- comparison of specific doses of the same drug

Dose	Schedule	Duration
• the dose can be given as a range - hit the double-headed arrow to the right of Dose. Enter the range as given e.g. 20-60 mg.	• while Dose is relevant for only drug interventions many non-drug interventions will use Schedule e.g. exercise, educational interventions	• as per Schedule, Duration is often required for non-drug interventions e.g. exercise, psychotherapy • if a minimum rather than absolute duration of treatment is given, do not annotate this
Available units: • IU=international unit • mg=milligrams • g=grams • meq=milliequivalent • µg=micrograms • ml=millilitre	Schedules as reported in reviews or studies: • (prn=as needed) • (qd=once daily) • (bid=twice daily) • (tid=three times daily) • (qid=four times daily)	

Injections

- choose *injection* as a delivery method modifier for the intervention
- use more specific injection terms in the delivery method modifier section if indicated in the review text

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Classification categories

For both the Intervention and Comparison components there is a 15 item classification of interventions from Davey et al.

This classification is built upon the Health Research Classification System developed by the UK Clinical Research Collaboration.

Behavioural
• Dietary interventions • Exercise • Lifestyle interventions • Nutrition

Cellular & Gene Therapies
• In-vitro fertilisation • Stem cell therapy • Tissue engineering

Complementary

- Acupuncture
- Hypnotherapy
- Homeopathy
- Herbal Medicine
- Massage

Complex

- Two or more classification categories combined

Educational

- Advice
- Education programmes
- Instruction
- Skills training

Medical Devices

- Dressings
- Implants
- Mobility aids
- Prostheses

No Active Treatment

- Placebo
- Sham
- (leave domain field blank if 'No treatment' is stated in review or study

Other

- Conservative supportive treatment
- Conventional care
- Fluid therapy
- Humidified air inhalation
- *Non-pharmacological Interventions*
- *Non-surgical Interventions*
- Normal monthly home visits
- Observation
- Oxygen therapy
- Phototherapy
- Routine care
- Standard care
- Standard surgery
- Surfactants
- Usual care

Pharmacological Interventions

- Analgesics
- Chemotherapy
- Drugs
- Medicated ointments
- Medicated gels/creams
- Oils (fish, olive etc)
- Vaccines
- Vitamins & nutritional supplements

Physical

- Cryotherapy
- Laboratory-controlled dietary interventions
- Managed exercise therapy
- Osteopathy
- Physiotherapy
- Speech therapy
- Warming of patient

Psychological

- Cognitive behavioural therapy
- Counselling

Radiotherapy

- Laser
- Phototherapy
- Ultrasound
- X-rays

Resources and infrastructure

- Costs
- Economic
- Duration of stay in hospital or ICU
- Hospital admission
- Health care provision
- Palliative care
- Training

Screening

- Screening
- Random drug testing
- Random alcohol testing

Surgical

- Blood sampling (venepuncture, heel lance etc.)
- Operations
- Organ & bone marrow transplants
- Surgery
- Surgical procedures
- Tissue grafts
- Transfusions

New group/arm - how and when to use

Some studies are designed to compare several interventions with one another so that there is no single Comparison. These studies are referred to as multi-arm studies and each "arm" of the study receives one of the interventions.

Multi-arm study

If authors of a review state no clear Comparison each of the arms should be annotated as a New Arm in the Intervention

- use the 'add new arm' function to indicate different interventions that are to be compared with one another
- Comparison should be left blank
- if a Comparison is <u>clearly identified</u> it should be annotated in the Comparison

Two-arm study

- There may not be a clearly identified Comparison but review authors may want to look at studies comparing two different interventions with one another
- Annotation is the same as for multi-arm studies

Studies split by review authors

- Typically there should be one study annotation for each included study in a given review
- Each row in the a review's PICO Characteristics of Included Studies table represents one study, however, some review authors have split up their description of a multi-arm trial into two or more rows

Where authors have split a multi-arm study into different rows

- only one of the rows needs to be annotated
- the data from the other arm(s) should be added to the one you are annotating

CD004217: Pain relief for neonatal circumcision

This was a 3-arm trial that the authors split into 2 rows in the Included Studies table. The Stang-1988A row describes arms 1 and 3 of the trial, and the Stang-1988B row describes arms 2 and 3 (these were the 2 relevant comparisons from the study that were used in the Review).

 In this example, either Stang-1988A or Stang-1988B could be annotated as a 3 arm trial and the other row left without an annotation. Stang 1988-A was annotated.

Stang 1988-A *RCT* *Blinding of randomization - can't tell* *Blinding of intervention - partial* *Complete follow-up - can't tell* *Blinding of outcome measurement - can't tell*	60 male NB; > 24 hr age; BW > 3000 g; 5 min Apgar > 7; uncomplicated delivery	0.8 ml 1% lidocaine DPNB (n=20) saline DPNB (n=20) no treatment control (n=20) 5 min WT *comparison is DPNB versus no treatment	% time cry, modal behavior state, plasma cortisol
Stang 1988-B *see Stang A*	see Stang A	*comparison is DPNB versus sham (saline) treatment	see Stang A

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