

Special issues for addressing adverse effects

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Disclosure

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- I have no actual or potential conflict of interest in relation to this presentation

Review question

Approach	Description	Examples
Confirmatory (hypothesis testing)	Authors pre-specify adverse effects that are anticipated or already recognized to be associated with the intervention	<ul style="list-style-type: none">• Surgical intervention: wound infection• Anticoagulants: bleeding
Exploratory (hypothesis generation)	Authors do not pre-specify any particular adverse outcomes of interest	Any, or all, of the adverse event data found within the included studies
Hybrid approach	Confirmatory + exploratory approaches: anticipated and previously unrecognized adverse effects	

Eligibility criteria

Beneficial outcomes	Adverse effects	Advantages	Disadvantages
Condition A	Condition A	<ul style="list-style-type: none">• Easier to search and extract data• Least time-consuming	Omission of relevant data if the adverse effects are also observed when the intervention is given for other conditions
Intervention applied to any condition		Improve the detection of AEs	Increase complexity of the project: broader search strategies and more time-consuming screening

Study design

Beneficial outcomes	Adverse effects	Advantages	Disadvantages
RCTs	RCTs	<ul style="list-style-type: none">• Easier to search and extract data• Least time-consuming	<ul style="list-style-type: none">• RCTs are limited to detect AEs• Poor reporting of AEs in RCTs
RCTs	RCTs & Observational studies	Improve the detection of AEs	Increase complexity of the project: different search strategies, screening and RoB assessment

Data extraction and analysis

Analysis approach	Advantages	Disadvantages
Description of individual events	<ul style="list-style-type: none">● Detailed information● Relevant to decision-making	<ul style="list-style-type: none">● Add complexness● Increase noise
Grouping events according to organ system categories	<ul style="list-style-type: none">● Limit the number of comparisons● Increase power to detect signals	<ul style="list-style-type: none">● Lumping can bias the analysis● Reduce information on potential relevant events

Peryer G, Golder S, Junqueira D, Vohra S, Loke YK. *Chapter 19: Adverse effects*. In: Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). Cochrane Handbook for Systematic Reviews of Interventions version 6.0 (updated July 2019). Cochrane, 2019. Available from www.training.cochrane.org/handbook.

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Thank you!

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