#### Special issues for addressing adverse effects

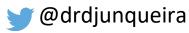
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#### **Disclosure**

 My work is supported by the Emergency Medicine Research Group (EMeRG) & the University of Alberta (salary and employee benefits)

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> <li>Surgical intervention: wound infection</li> <li>Anticoagulants: bleeding</li> </ul>
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> <li>Easier to search and extract data</li> <li>Least time-consuming</li> </ul>	Omission of relevant data if the adverse effects are also observed when the intervention is given for other conditions
Intervention 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><li>Easier to search and extract data</li><li>Least time-consuming</li></ul>	<ul> <li>RCTs are limited to detect AEs</li> <li>Poor reporting of AEs in RCTs</li> </ul>
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> <li>Detailed information</li> <li>Relevant to decision-making</li> </ul>	<ul><li>Add complexion</li><li>Increase noise</li></ul>
Grouping events according to organ system categories	<ul> <li>Limit the number of comparisons</li> <li>Increase power to detect signals</li> </ul>	<ul> <li>Lumping can bias the analysis</li> <li>Reduce information on potential relevant events</li> </ul>

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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