randomized were included in 5/6 reviews.[2-7] The pair efficacy/effectiveness was - with exceptions[2 5] - included in four reviews.[2 3 5 7] The two pairs experimental/observational and analytical/descriptive were included – with exceptions[6] – each in two reviews [4 6] The review by Schwartz & Lellouch[2] included the pair of explanatory/pragmatic and discussed efficacy but not effectiveness. The CONSORT statement[5] included three pairs of terms but did not discuss the meanings of efficacy/effectiveness. The remaining reviews[3 4 7] included three but different pairs of terms. Our analysis of the studies confirmed the use of an experimental (RCT) design in 91%, the assessment of the primary endpoint in 29%, the assessment of efficacy in 14%, of effectiveness in 25%, and neither of these in 60%. In 6% the study was classified as a pragmatic trial.

Conclusions The most likely reason for the observed incongruence is a lack of a consensus on terms and methods for reporting the results of pragmatic clinical trials. All reviews expect pragmatic trials to describe effects under RWC but assess these effects under experimental but not real-world conditions (RCTs) resulting in a conflict between expected and observed outcomes. CONSORT includes two imprecise statements.[5] The review by Schwartz & Lellouch[2] does not use the term 'randomized' and cannot justify the new name of 'randomized pragmatic trial'.[5] Second, the aim of 2008 CONSORT is extension of its applicability to pragmatic trials. In fact, CONSORT changed 'pragmatic' into 'pragmatic randomised' and used an inappropriate reference[2] to justify this change. The benefit of this maneuver is the recommendation of a valid instrument for assessment of effectiveness, but it may result in harm from the resulting confusion and incongruence of guideline recommendations.

26 IS THE REVISED COCHRANE RISK OF BIAS TOOL RESEARCH READY FOR THE ERA OF OPEN SCIENCE AND PREREGISTRATION?

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10.1136/bmjebm-2019-EBMLive.34

Objectives Risk of bias (RoB) is an important to assess scientific evidence. Lack of detailed preregistration obfuscates reporting transparency and cast doubts about the required bijective relation between study protocol and the final scientific report of outcomes.

This contribution examines whether the lack of preregistration affects the judgments required for risk of bias assessment according to the RoB 2.0 tool and whether the tool can adequatly capture flaws in preregistration.

Method We examined the literature on RoB 2.0 and thoroughly evaluated the definition and criteria for the three different categories 'high risk of bias', 'low risk of bias', and some concerns of risk of bias'. Moreover, we investigated the literature on meta-science and performed a conceptual analysis of the epistemic merits and methodological benefits arising from various forms of preregistration. Accordingly, selective endpoint reporting, or endpoint modification raise serious and severe doubts about the scientific validity of biomedical randomized controlled trials (RCT) and preregistration is obligatory according to Article 35 of the Declaration of Helsinki of 2013.

Results The upcoming revised Cochrane handbook introduces RoB 2.0 as a new research tool for assessing the risk of bias of an RCT. RoB 2.0 requires a comparison between the prespecified analysis intentions and the reported analyses in order to assess potential selection bias of multiple outcomes or endpoints. In case a preregistered analysis plan is met, 'low risk bias' is assigned. 'High risk of bias' is assigned only if it is likely that reported outcomes have been selected based on the results, i.e. a deviation from the preregistered protocol is detected. If no information is available, RoB 2.0 suggests 'some concern'. Furthermore, in cases where preregistration is lacking, RoB 2.0 suggests the methods section of an article as a source of the analysis intentions. Therefore, the lack of preregistration does not by default lead to the evaluation of a 'high risk of bias'.

Conclusions Although lack of preregistration can lead to 'some concerns of risk of bias', there is by default no assignment of 'high risk of bias'even if a preregistration protocol is completely lacking. In light of the epistemic arguments in favour of preregistration, RoB 2.0 presents an untoward loophole in the risk of bias assessment with regard to selective outcome reporting or post hoc endpoint modification. Because any RoB 2.0 assessment is very effort-intensive and time-consuming, it is of utmost importance that all sort of biases are adequate considered and, thus, that future systematic reviews and meta-analysis benefit from risk of bias assessment tools that account for lack of preregistration as a source of 'high risk of bias' by default.

27 SEX AND GENDER REPORTING AND ANALYSIS IN COCHRANE REVIEWS: A CROSS-SECTIONAL METHODS STUDY. PRELIMINARY RESULTS

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10.1136/bmjebm-2019-EBMLive.35

Objectives Sex and gender health differences have been well established in the scientific literature. However, numerous studies present poor levels of inclusion of female participants and an insufficient sex/gender reporting and analysis. This lack of consideration of sex and gender in medical research reduces the applicability of findings and jeopardises its capacity to support informed decisions. Studies also suggest that women under-representation in science might be related to this deficient consideration of sex/gender in health research. This study aims to describe the degree of sex/gender reporting and analysis in Cochrane systematic reviews published in 2018 and investigate its association with gender of authorships.

Method Cross sectional study. We screened Cochrane reviews published in 2018. We removed reviews addressing sex-specific medical conditions and those that had been withdrawn by Cochrane. We collected data on gender and country affiliation of first and last authors, and review type. We documented the frequency of sex/gender terms used in each section of the reviews (abstract, methods, results, and discussion). In the