The importance of registry for systematic review and clinical trial

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Currently, many medical journals recommend that research, both conducted on humans and experimental animals and research review articles, should be registered before the research is published. These provisions are required to reduce publication bias, such as only publishing positive study results, and ensure that all clinical trials are publicly visible prior to subject recruitment. Registering systematic review and clinical trial also help other researchers and funders to understand how many trials are carried out and how the intervention studied is evaluated. In addition, registering trials allows other researchers to trace the study starting from the recruitment of subjects to the study completion and publication and minimize excessive duplication of trials.

One of the crucial elements of a high-quality systematic review is developing a protocol which includes main objectives and methods used to assess the risk of bias and analysis. Registering protocol information which was written in advance of the reviews can be done through the International Prospective Register of Ongoing Systematic Reviews (PROSPERO). A minimum data set that should be reported for a registry of systematic reviews includes a research question, such as patients and population, intervention or exposure, comparison, and outcome; inclusion and exclusion criteria; methods used to assess the risk of bias and analysis; anticipated start date; investigators; source of funding; competing interests of authors; and date of registration. Thus, registering the protocol of systematic reviews and reporting the results according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines are suggested to help the authors to improve their systematic reviews and meta-analyses reports and the journals’ peer-reviewers and editors to critically appraise the published systematic reviews.

Sometimes, changes between protocols and published reviews, such as adding or removing outcomes or modifying between primary and secondary outcomes, may result in review bias. In 2002, Silagy et al examined 47 reviews that the protocol had been published before. They found that almost all reviews had a major change compared to that published protocol with the greatest change was in the methods section, followed by the introduction section such as objectives narrowing, additional of comparison or new outcome measures, broadening of the inclusion criteria, and narrowing of the exclusion criteria.

The International Committee of Medical Journal Editors recommends that journals should only publish trials that have been previously registered. However, some journals sometimes do not follow this recommendation, including the high-impact journals. In this issue, the Medical Journal of Indonesia published two systematic reviews, namely Irawati et al and Irdam et al who conducted a systematic review based on the recommendations set in the PRISMA and Meta-Analyses statements. Unfortunately, those reviews were not prospectively registered at the PROSPERO. All searches of both reviews were conducted using PubMed, Google Scholar, and Cochrane. Irdam et al limited their review to studies published between 2010 and 2020 about animals or humans with diabetic erectile dysfunction and written in English. The intervention was mesenchymal stem cells injection with a comparison of subjects without intervention or receiving placebo, which was evaluated for their functional and structural outcomes. In addition, Irawati et al limited their review to studies of randomized controlled trials and observational studies reporting platinum chain and gold weight implants surgery for paralytic lagophthalmos patients published between 1990 and 2020 and written in English. Both reviews conducted data extraction with similar data variables,
namely first author's surname, year of publication, study design, and level of evidence.

In fact, a systematic review that is well conducted, reported according to the PRISMA guidelines, and prospectively registered in PROSPERO can be generally considered scientific evidence of high-caliber compared to individual trials in terms of making decisions for the benefit of clinical practice and health policy. We believe that registering a systematic review in advance will promote transparency, avoid bias, and improve methodological standards. Besides, registering a systematic review in advance only takes 30 min to complete of 22 questions.

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REFERENCES