

Effectiveness of clinical decision support systems for managing drug therapy: a systematic review within the scope of a clinical evaluation of a medical device

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Background Clinical decision support systems (CDSS) are used to assist healthcare professionals in choosing the optimal therapy for their patients. Manufacturers of CDSS classified as medical devices need to subject their products to a clinical evaluation to comply with the Essential Requirements (ER) demanded by national and EU-standards.

Purpose To perform a systematic review of studies evaluating the effectiveness and safety of CDSS used by pharmacists and physicians to optimize the medication of their patients. As the review was part of a clinical evaluation, the overarching purpose was to evaluate the compliance of a specific CDSS device with the ER pertaining to safety and performance.

Method We searched PubMed and Cochrane Central Database of Controlled Trials databases for articles published in English or German between 2010 and February 2020. Studies were included if they (1) were randomized controlled trials, (2) reported quantitative effects of CDSS used by physicians and pharmacists on process of care or patient outcomes, (3) compared CDSS usage with 'usual care'. The study quality and relevance to the specific device was independently appraised by two authors using a substantially enhanced modification of the Cochrane Risk of Bias Tool and a self-developed scoring system. Interrater reliability was established using Cohen's Kappa. The structure and content of the review met the particular demands of the MEDDEV 2.7/1 guideline.

Findings Sixteen of 3876 identified RCTs met our inclusion criteria (> 63.641 patients). Most trials were performed in an ambulatory setting with physicians being more frequently involved as CDSS users than pharmacists. In nine (69.2%) of thirteen trials a significant positive impact was reported in the CDSS group on process of care outcomes pertaining to a reduction in medication errors and an improvement in prescribing quality. CDSS usage was associated with a significant positive effect on patient outcomes in one of three trials. No risks related to CDSS usage were reported either in terms of quantitative or qualitative data. The study quality and relevance to the device varied substantially. Interrater reliability of the appraisal was substantial ($\kappa=0,73$).

Conclusion Usage of CDSS appears to be effective in reducing medication errors and improving quality of prescriptions. Further studies are needed to generate more evidence of the effects on patient outcomes. As CDSS and their context of use differed from the particular device, limitations in transferability of the results had to be accepted. Based on the results and further criteria, compliance of the device with the ER was certified.