Cochrane
Effective Practice and
Organisation of Care

Taking account of adverse effects in EPOC reviews

Adverse (undesirable) effects of interventions should always be considered in EPOC reviews. These can include adverse effects on

- Health or health behaviours
- Utilisation, coverage or access
- Quality of care
- Resource use
- Health care providers (e.g. stress, burnout or sick leave)
- Social outcomes (e.g. poverty measures, employment, education)
- Equity (i.e. increased inequities)

Consideration should be given in the background to how the intervention(s) might cause adverse effects.

Adverse effects should be included as a main (primary) outcome, unless there is a compelling reason for not doing so).

When relevant, suspected adverse effects should be identified under 'Types of outcome measures' in the protocol; i.e. outcomes should be specified for which there is a known mechanism by which the intervention might be expected to have an adverse impact on the outcome. These could be either primary (main) or secondary (other) outcomes. For example, the following unintended (adverse) effects were specified in an EPOC review of paying for performance: including motivating unintended behaviours, distortions (ignoring important tasks that are not rewarded with incentives), cherry-picking/cream-skimming (prioritising patients that are most profitable over those who release fewer financial rewards), gaming (improving or cheating on reporting rather than improving performance), increased inequities and dependency on financial incentives.

Review authors should look for reports of adverse effects in all included studies. When no adverse effects are reported, a distinction should be made between studies where adverse effects were investigated, studies where it is not clear whether adverse effects were investigated, and studies where it is clear that adverse effects were not investigated.

When appropriate, consideration should be given to including (and searching for) additional study designs for adverse effects that would be unlikely to be detected in the suggested study designs for EPOC reviews. Other relevant study designs might include, process evaluations linked to included studies, case studies, and descriptive studies. For example, several adverse effects of pay-for-

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performance have been identified in process evaluations, case reports and descriptive studies.[1] These studies do not provide a basis for estimating the magnitude of the adverse effects, but they provide evidence of the potential for these adverse effects to occur, and it is important for decision-makers to consider these potential adverse effects when deciding whether to use pay-for-performance and (if they do) how to design a pay-for-performance scheme to minimise potential adverse effects.

Review authors should report in the results section what evidence was found regarding adverse effects. When no evidence of adverse effects is found, they should clearly report whether adverse effects were investigated in the included studies.

Summary of Findings tables should, generally, include adverse effects (either as a generic outcome or specifying the most important potential adverse effects). As in the results section, if no evidence of adverse effects was found, it should be made clear in the Summary of Findings whether adverse effects were investigated in the included studies.

[1] Oxman AD, Fretheim A. An overview of research on the effects of results-based financing. Report No. 16-2008. Oslo: Norwegian Knowledge Centre for the Health Services 2008. Available at: http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.453.106&rep=rep1&type=pdf