THE COCHRANE COLLABORATION'S CONTRIBUTION TO THE DEVELOPMENT OF PRINCIPLES OF INTEGRITY IN RESEARCH PRACTICE

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This article is one in a sequence of publications in the Journal of Medical Ethics focused on the integrity of healthcare research. Our first article in the series on integrity in modern biomedical science briefly reviewed the main stages of the global think tank development calling to attention of a wide range of specialists from local ethical committees, editorial boards of biomedical journals, and experts of scientific funds who determine the research priorities and fund studies. In this article, we concentrated on the specific contribution and pioneering function of the Cochrane collaboration in developing scientific research integrity principles.

Keywords: conflict of interest, integrity, medical research, systematic reviews, clinical practice guidelines, Cochrane, Cochrane Library

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ВКЛАД КОКРЕЙНОВСКОГО СОТРУДНИЧЕСТВА В РАЗВИТИЕ ПРИНЦИПОВ ДОБРОСОВЕСТНОСТИ ИССЛЕДОВАТЕЛЬСКОЙ ПРАКТИКИ

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Настоящая статья является продолжением серии публикаций в журнале «Медицинская этика» по проблеме добросовестности, или целостности — честности — порядочности исследовательской практики в здравоохранении. В нашей первой статье из серии статей о проблемах добросовестности в современной биомедицинской науке мы кратко представили основные этапы развития мировой научной мысли в этом направлении, обращая внимание широкого круга специалистов локальных этических комитетов, редакционных коллегий биомедицинских журналов, экспертов научных фондов, определяющих приоритеты и финансирование исследований. Здесь мы сконцентрировали внимание на конкретном вкладе и пионерской роли Кокрейновского сотрудничества в развитие принципов добросовестности научных исследований.

Ключевые слова: конфликт интересов, добросовестность, медицинские исследования, систематические обзоры, клинические рекомендации, Кокрейн, Кокрейновская библиотека

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The establishment of the Cochrane Collaboration has dramatically advanced research integrity in medicine, pharmacy and healthcare. Cochrane has always been at the forefront of the scientific thought within the health sciences around the globe. Cochrane's policies aim to clarify conflicts of interest (COI) and key aspects of their assessment. In addition, management of COI should become the main principle and a mandatory requirement for the integrity of research [1].

At Cochrane, a conflict of interest is a set of circumstances and conditions that creates a risk that professional judgment or actions regarding a primary interest (the patient's health, validity of the study) will be unduly influenced by a secondary interest (for example, financial).

Cochrane is committed to minimizing the impact of conflicts of interest. Thus, its work is internationally recognized as the benchmark for high-quality medical information.

Cochrane's systematic reviews and core values of independence, transparency, and research integrity are supported by its strict policies on reporting and managing potential conflicts of interest [2].

ADHERENCE TO CONFLICTS OF INTEREST POLICIES AT COCHRANE

Cochrane enforces a very strict Conflict of Interest (COI) Policy for the Cochrane Library Content. It requires a full disclosure of potential conflicts and prohibits individuals with certain conflicts from participating in review development and update [2].

The updated COI policy for Cochrane review authors and the Cochrane Library Content came into force on October 14, 2020. Many Cochrane reviews were already underway

before the date. As applying a new policy to already published Cochrane Reviews would be overly burdensome for editorial teams and unfair to existing authors, the 2014 Conflict of Interest Policy continues to apply to those Cochrane Reviews (and their updates) that had begun development before the 2020 policy was introduced [3].

Cochrane has established strict regulations and a comprehensive system of rules regarding COI for all its Groups. These rules and regulations were originally published in 2014 and updated in March 2022. They apply to Geographic groups (for example, Cochrane Russia, Cochrane China), Methods groups and Thematic groups, sites and evidence synthesis units. These groups are not allowed to accept funds from commercial sponsors or sources that have a financial interest in the areas covered by the Cochrane Library. Cochrane Groups that violate this policy may be deregistered by the Cochrane Governing Board [2–3].

MANAGEMENT OF COI AT COCHRANE

The funding sources of Cochrane Groups are monitored annually by the Cochrane leadership. The sources should be unconditionally consistent with Cochrane conflict of interest policies.

All queries about identifying and managing potential conflicts, implementation of rules, regulations, and conditions for using COI policies should be submitted to the Editorial Group dealing with research integrity and conflicts of interest. The group was created to impartially assess potential conflicts of interest and make timely recommendations [2].

STUDYING THE IMPACT OF COI IN COCHRANE SYSTEMATIC REVIEWS

Cochrane researchers have shown in a series of Cochrane reviews that the impact of conflicts of interest on research practice and presentation of research results is enormous. The first in the series Cochrane review about industry sponsorship and research outcomes, which was published in 2017 and translated into 13 languages, was used in four clinical guidelines. It has an All-metric score of 863 [4].

The review found that industry-sponsored (sponsored by manufacturers of medicinal products and medical devices) research of medical interventions such as drugs and devices is more likely to conclude that the product of the sponsor is effective than studies not funded by industry. This is due to bias that cannot be explained using standard Cochrane review methods or risk of bias assessment tools for bias or shift. It is important to note that the results of clinical trials of medicines and medical devices influence the decisions that doctors make when treating patients. Clinical trials are often funded by manufacturers of the tested products. Companies can also conduct the trials themselves. In the updated review, the authors were the first to study the impact of industry funding on clinical trials' conclusions [4–5].

The authors of this review carried out a comprehensive search for all relevant papers of studies published from 2010 to 2015 and included 75 studies with funding-related data [4].

On the basis of the synthesis of the results of included clinical trials, the review found that clinical trials funded by industry sponsors (manufacturers) reported product effectiveness more often with a risk ratio (RR) of 1.27 (95% confidence interval (CI) ranging from 1.17 to 1.37), without significant difference in harm, with favorable overall conclusions, and recorded risk ratio of 1.34 (95% CI ranging from 1.19 to 1.51). The results were compared with those from trials not funded by industry.

The authors of this review found no differences in standard methods that could increase the risk of bias between industry-funded and non-sponsored clinical trials, except for the blinding procedure. Industry-funded studies were more likely to report satisfactory blinding and showed less agreement between results and conclusions than non-industry funded studies (RR 0.83, 95% CI from 0.70 to 0.98).

Sponsored trials of medicinal products and medical devices equally showed a greater benefit for the sponsoring manufacturer's product and had certain methodological shortcomings. Thus, industry-sponsored studies tend to be biased in favor of the sponsor's products [4–5].

Systematic reviews have been considered the best way to present information about a set of clinical trials addressing a specific clinical or healthcare issue. The reviews significantly influence clinical decision-making and choosing the most effective interventions. Thus, reliability and confidence are crucial for the systematic reviews.

However, in some cases, systematic reviews are funded by pharmaceutical or other manufacturing companies with a financial interest in the review's results and conclusions when they produce the drug or device being tested. In other cases, systematic reviews are carried out by researchers having a personal financial interest in specific results or conclusions. It happens, for example, when the author consults the company that manufactures the product being tested in the review. Such financial conflicts of interest can impact development of systematic reviews and presentation of their results.

Cochrane researchers examined the issue in detail in the Cochrane review regarding financial conflicts of interest in systematic reviews: associations with results, conclusions, and methodological quality [6].

The research has found how often systematic reviews with financial conflicts of interest presented conclusions more favorable to the intervention (product) being studied than those without conflicts. They also assessed differences in methodological quality of systematic reviews with and without financial conflicts of interest.

Having compared systematic reviews with and without financial conflicts of interest (COI) from seven included trials, the authors discovered that systematic reviews with COI tended to have more frequent (almost twice as high) conclusions in favor of the product in conflict with RR of 1.98 (95% CI ranging from 1.26 to 3.11) as compared to those without COI. Using synthesized results of four studies, the authors of this Cochrane Review showed that the methodological quality in systematic reviews with financial conflicts of interest was lower [6].

Thus, authors of the Cochrane review have concluded that systematic reviews with financial conflicts of interest, often funded by industry funding or with industry authorship, tend to have lower methodological quality and present more favorable conclusions than those without such conflicts. Thus, the authors of the study recommend that users of systematic reviews — including patients, doctors, guideline developers, and researchers — prioritize the reviews that have no financial conflicts of interest of their authors.

Authors should be cautious when studying and interpreting systematic reviews, especially when only those with a COI are available.

CONFLICTS OF INTEREST IN CLINICAL PRACTICE GUIDELINES

Conflicts of interest are highly relevant for clinical trials, systematic reviews and clinical practice guidelines.

This problem was first studied in a Cochrane's Review entitled "Conflicts of interest in clinical guidelines, advisory committee reports, opinion pieces, and narrative reviews: associations with recommendations" [7].

Clinical practice guidelines can be presented in various documents. These can be individual clinical practice guidelines (recommendations) or published journal articles. Clinical practice guidelines represent a set of provisions and assertions that recommend how to diagnose, prevent and treat patients with a pathology. Clinical practice guidelines must be based on the best available evidence.

Unfortunately, healthcare professionals with a COI in relation to a certain product or intervention commonly act as authors of publications containing clinical guidelines. For example, an author of clinical practice guidelines can also consult the manufacturer of a medicinal product or a medical device. The conflict of interest can influence the content of the guidelines (recommendations).

Meanwhile, developers of clinical practice guidelines can have non-financial COI as they belong to certain medical professions or due to ambitious career-drive conflict of interest.

Authors of Cochrane methodological review that included 21 trials examined financial and non-financial COI and their relation to the suggestions from clinical practice guidelines, advisory committee reports, opinion pieces, and narrative reviews.

The authors have shown that financial COI are associated with positive recommendations. In other words, the clinical practice guidelines compiled by persons with financial COI more likely contained positive recommendations as compared to those made by experts without COI. The impact of non-financial COI on clinical practice guidelines was examined in one study only, and similar results were obtained confirming a shift towards positive or favorable recommendations in relation to certain interventions (technologies).

Authors of this review suggest that patients, doctors and people taking healthcare decisions should primarily use the clinical practice guidelines prepared up by experts without any conflict of interest [7–8].

CONCLUSIONS

Thus, modern healthcare, medical education and biomedical research practice come across more and more complex signs of undue practices in research and reporting of results while seemingly striving to use scientifically substantiated facts (evidence) with reference to meta-analyses and systematic reviews.

Widespread financial dependence on industry introduces a commercial bias in scientific data, medical education, and clinical practice. The bias results in exaggeration of benefit and underestimation of harm.

It is essential to differentiate between conflict and conflict-free biomedical experimental and clinical trials, meta-analyses, systematic reviews, and clinical practice guidelines targeted at medical practice. Cochrane systematic reviews are still regarded as the gold standard in research quality and research integrity.

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