

CHBG NEWSLETTER

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COCHRANE POLICY ON COMMERCIAL SPONSORSHIP OF COCHRANE REVIEWS AND COCHRANE GROUPS The numbering is a continuation from The CHBG Newsletter 2018; Vol. 22: Issue 2 and covers reviews published 8 of November 2018 through 10 of April 2019.

PUBLICATIONS ON THE COCHRANE LIBRARY (THE CLIB). FROM 10 OF APRIL TO 7 OF NOVEMBER 2018 (COCHRANE DATABASE OF SYSTEMATIC REVIEWS)

NEW REVIEWS

220. Physical exercise for people with cirrhosis. Luise Aamann, Gitte Dam, Anders R Rinnov, Hendrik Vilstrup, Lise Lotte Gluud. Cochrane Database of Systematic Reviews 2018, Issue 12. Art. No.: CD012678. DOI: 10.1002/14651858.CD012678.pub2.

221. Acetyl-L-carnitine for patients with hepatic encephalopathy. Arturo J Martí-Carvajal, Christian Gluud, Ingrid Arevalo-Rodriguez, Cristina Elena Martí-Amarista. Cochrane Database of Systematic Reviews 2019, Issue 1. Art. No.: CD011451. DOI:

10.1002/14651858.CD011451.pub2.

222. Transcatheter arterial chemoembolisation followed by three-dimensional conformal radiotherapy versus transcatheter arterial chemoembolisation alone for primary hepatocellular carcinoma in adults. Liming Lu, Jingchun Zeng, Zehuai Wen, Chunzhi Tang, Nenggui Xu. Cochrane Database of Systematic Reviews 2019, Issue 2. Art. No.: CD012244. DOI:

10.1002/14651858.CD012244.pub2.

223. Radix Sophorae flavescentis versus no intervention or placebo for chronic hepatitis B. Liang N, Kong DZ, Ma SS, Lu CL, Yang M, Feng LD, Shen C, Diao RH, Cui LJ, Lu XY, Nikolova D, Jakobsen JC, Gluud C, Liu JP. Cochrane Database of Systematic Reviews 2019, Issue 4. Art. No.: CD013089. DOI: 10.1002/14651858.CD013089.pub2.

UPDATED REVIEWS

86. Pharmacological interventions for acute hepatitis C infection. Maria Kalafateli, Elena Buzzetti, Douglas Thorburn, Brian R Davidson, Emmanuel Tsochatzis, Kurinchi Selvan Gurusamy. Cochrane Database of



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Trusted evidence. Informed decisions. Better health.

Systematic Reviews 2018, Issue 12. Art. No.: CD011644. DOI: 10.1002/14651858.CD011644.pub3.

87. Glucocorticosteroids for people with alcoholic hepatitis. Pavlov CS, Varganova DL, Casazza G, Tsochatzis E, Nikolova D, Gluud C. Cochrane Database of Systematic Reviews 2017, Issue 11. Art. No.: CD001511. DOI: 10.1002/14651858.CD001511.pub4

NEW OR MAJOR UPDATED PROTOCOLS

378. Deep neuromuscular blockade in adults undergoing an abdominal laparoscopic procedure. Moira H Bruintjes, Kim I Albers, Kurinchi Selvan Gurusamy, Maroeska M Rovers, Cornelis JHM van Laarhoven, Michiel C Warle.

https://doi.org/10.1002/14651858.CD013197

379. Exercise interventions for adults after liver transplantation. Èlia Pérez-Amate, Marta Roqué i Figuls, Miguel Fernández-González, Maria Giné-Garriga. https://doi.org/10.1002/14651858.CD013204

380. Induction immunosuppression in adults undergoing liver transplantation: a network metaanalysis. Kurinchi Selvan Gurusamy, Emmanuel Tsochatzis.

https://doi.org/10.1002/14651858.CD013203

381. Perioperative antioxidants for adults undergoing elective non-cardiac surgery. Jia Liu Stevens, Helen McKenna, Kurinchi Selvan Gurusamy, Jason Van Schoor, Michael PW Grocott, Gavin Jell, Daniel Martin.

https://doi.org/10.1002/14651858.CD013174.382

382. Antibiotic prophylaxis for people with cirrhosis and variceal bleeding. Beatriz Sanchez-Jimenez, Norberto C Chavez-Tapia, Janus C Jakobsen, Dimitrinka Nikolova, Christian Gluud.

https://doi.org/10.1002/14651858.CD013214

383. Medical interventions for prevention and treatment of hepatic encephalopathy in adults with cirrhosis: a network meta-analysis. Peter N Bjerring, Marsha Y Morgan, Hendrik Vilstrup, Sabrina M Nielsen, Robin Christensen, Lise Lotte Gluud.

https://doi.org/10.1002/14651858.CD013241

384. Biliary anastomosis using T-tube versus no T-tube for liver transplantation in adults. Jose Jeova de Oliveira Filho, Rachel Riera, Delcio Matos, Diego R Kleinubing, Marcelo Moura Linhares.

https://doi.org/10.1002/14651858.CD013289

385. Essential phospholipids for people with nonalcoholic fatty liver disease. Varganova DL, Pavlov CS,

Casazza G, Nikolova D, Gluud C. https://doi.org/10.1002/14651858.CD013301

FEEDBACK ON PUBLISHED PROTOCOLS OR REVIEWS

Further feedback has been received on the review protocol "Aluminum adjuvants used in vaccines. Snezana Djurisic, Janus C Jakobsen, Sesilje B Petersen, Mette Kenfelt, Sarah Louise Klingenberg, Christian Gluud. <u>https://doi.org/10.1002/14651858.CD013086</u> So far, we cannot provide a date when the review on aluminum will be published.

NEW REGISTERED TITLES

550. Computed tomography for the diagnosis of hepatocellular carcinoma in people with chronic advanced liver disease. Nadarevic T, Giljaca V, Colli A, Fraquelli M, Casazza G, Miletic D, Štimac D. 551. Immune checkpoint inhibitors for unresectable hepatocellular carcinoma. Abdel-Rahman O, Elsayed Z. 552. Contrast-enhanced ultrasound for the diagnosis of hepatocellular carcinoma in chronic advanced liver disease. Fraquelli M, Nadarevic T, Giljaca V, Colli A, Miletic D, Štimac D, Casazza G.

553. Granulocyte colony-stimulating factor with or without stem or progenitor cell infusion for people with advanced chronic liver disease. Colli A, Prati D, Fraquelli M, Casazza G.

554. Herbal interventions for non-alcoholic steatohepatitis. Koca Caliskan U, Balaban Y, Aka C. 555. Lactobacillus rhamnosus versus placebo for eradication of vancomycin-resistant Enteroccocus Feacium carrier-state. Rubin M, Halkjær SI, Pinholt M, Gluud LL, Petersen AM.

556. Associating liver partition and portal vein ligation for staged hepatectomy procedure versus conventional two-stage hepatectomy for colorectal liver metastasis. Shiraiwa DK, Riera R, Kleinubing D R, Linhares M Moura. 557. Thymosin-a1 for people with chronic hepatitis B. Htet NH, Naing C.

PAST EVENTS

CHBG EXHIBITION STAND DURING THE 70TH ANNUAL LIVER MEETING (AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES). 9 TO 13 NOVEMBER 2018, SAN FRANCISCO, CA, USA

Dimitrinka Nikolova and Goran Bjelakovic (CHBG editor) manned the CHBG stand. We thank our visitors.

FUTURE EVENTS

CHBG EXHIBITION STAND DURING THE INTERNATIONAL LIVER CONGRESS (EASL). 11 TO 13 APRIL 2019, VIENNA, AUSTRIA Place: Read Messe – Hall B. CHBG stand no. 337. Dimitrinka Nikolova, Sarah Louise Klingenberg, and Christian Gluud from the CHBG Editorial Team office will man the CHBG stand. We will be most happy to see you in person and met new people.

SYSTEMATIC REVIEW OF DIAGNOSTIC TEST ACCURACY. BASIC RESIDENTIAL COURSE – 12 HOURS You will find the programme for this very intensive course as well as registration details on the CHBG website (hbg.cochrane.org). Tutors are authors and editors of Diagnostic Test Accuracy Reviews.

EVIDENCE-BASED MEDICINE COURSE FOR PH.D. STUDENTS AND MEDICAL DOCTORS AT THE MEDICAL FACULTY IN NIS, SERBIA. 5 AND 6 JUNE 2019 Dimitrinka Nikolova and Christian Gluud are among the invited presenters. The course is planned as two parts: the first is more general, focusing on evidencebased medicine and clinical practice, designs in epidemiological research, estimation of bias in clinical research, and The Cochrane Library. The second part will focus on the CHBG, evidence-based hepatology, CHBG reviews, and liver diseases in pregnancy. The course will be free of charge and participants will be accredited (6 Continuing Medical Education (CME) points for participants and 12 CME points for lecturers).

CONGRESS OF INTERNAL MEDICINE (SERBIAN ASSOCIATION OF INTERNAL MEDICINE). 7 JUNE 2019. ZLATIBOR, SERBIA

Dimitrinka Nikolova and Christian Gluud are among the invited presenters. The presentations at this congress are to a large extend overlapping with the mentioned above, but the target audience is different. We thank Aleksandar Nagorni and Goran Bjelakovic, from Nish, Serbia, both CHBG authors, for organizing these activities.

VISITORS

Goran Bjelakovic, Serbia, visited the CHBG Editorial

team office from 27.02.2019 to 09.02.2019, to work on a review on vitamin A supplementation for primary and secondary prevention of mortality. We thank Goran for his visit and hard work.

STAY UPDATED

We kindly urge you to stay updated about recent changes and updates related to Cochrane and review preparation through the <u>cochrane.org</u> website. Updated are parts of the MECIR Standards <u>https://community.cochrane.org/mecir-manual</u>, and the Handbook <u>https://training.cochrane.org/handbook</u> You may find information on webinars at <u>https://training.cochrane.org/cll-webinars</u>) or series of online learning modules <u>https://www.cochrane.org/news/cochrane-</u>

interactive-learning) etc.

An official Cochrane policy. Last updated March 2014

COCHRANE POLICY ON COMMERCIAL SPONSORSHIP OF COCHRANE REVIEWS AND COCHRANE GROUPS See also information about the policy in the <u>Conflicts</u> of interest and Cochrane Groups section of the Cochrane Community site and in the <u>Conflicts of</u> interest and Cochrane Reviews section of the Editorial and Publishing Policy Resource. Prepared by: Cindy Farquhar, Sophie Hill, Lisa Bero, David Tovey. Date: 8 March 2014

Principles informing this policy

Whilst Cochrane has adopted the uniform requirements for declaration of conflicts of interests (CoI) framework produced by the International Committee of Medical Journal Editors, Cochrane and the Cochrane Database of Systematic Reviews differ from many journals in two ways: 1) certain types of sponsorship are forbidden and 2) we ask for disclosure of CoI at the beginning of a review process (title registration). Such declarations may be managed within the group processes or be referred to the Funding Arbiter for discussion and decision making.

Independence: Cochrane Reviews must be independent of conflicts of interest associated with commercial sponsorship and should be conducted by

people or organizations that are free of such bias Free from interference: The process for conducting Cochrane Reviews and the Cochrane Groups and contributors responsible for producing Cochrane Reviews should operate free from interference.

Assurance: Users of Cochrane Reviews should be assured that Cochrane Reviews are produced in an independent manner.

Definitions

'Commercial sponsor or source': any for-profit manufacturer or any other for-profit source with a real or potential vested interest in the findings of a specific review. This definition is not intended to include government departments, not-for-profit medical insurance companies and health management organizations, although clauses 6-8 below are relevant for all funders. Also not included are for-profit companies that do not have real or potential vested interests in Cochrane Reviews (e.g. banks). Appropriate 'Funder' of a Cochrane Review: a body which provides a grant, contract, gift, or other form of financial support for one, several, or all authors of a review (or the funding may go to their institution(s)) where the funder has no commercial or vested interest in the finding of the review. Conflict of Interest of a Cochrane author or editor: Conflict of interest is defined as "a set of conditions in which professional judgement concerning a primary interest (such as patients' welfare or the validity of research) may be unduly influenced by a secondary interest (such as financial gain) or may be perceived to be influenced by a secondary interest."

Policy affecting Cochrane Reviews and Groups Scope of policy

This policy affects the people who conduct Cochrane Reviews ('authors'), referees and editors, and all Cochrane Groups (Governing Board, Centres, Review Groups, Fields, Methods Groups, Consumer Network, and the Central Executive Team).

Commercial funding of reviews or authors The intent of clauses 1-5 is to ensure the independence of Cochrane Reviews by making sure there is no bias associated with commercial conflicts of interest in the conduct of Cochrane Reviews.

- 1. Cochrane Reviews cannot be funded or conducted by commercial sponsors or commercial sources with a real or potential vested interest in the findings of a specific review.
- 2. Individuals who are currently employed or where employed any time in the last three years by a company that has a real or potential financial interest in the outcome of the review (including but not limited to drug companies or medical device manufacturers); or who hold or have applied for a patent related to the review are prohibited from being Cochrane Review authors. In most cases, current or previous employment would be characterized by the affiliation statement made by the author at the title registration, protocol, or review stage of the review. Any questions about what constitutes "employment by a company with a financial interest" should be referred to the Funding Arbiter.
- 3. Authors who in the last three years have received financial support from commercial sponsors or sources who have a real or potential financial interest in the findings of the review, but who are not covered by the restriction above should declare these interests at the earliest possible stage in the editorial process. Such financial support may include remuneration from a consultancy, grants, fees, fellowships, support for sabbaticals, royalties, stocks from pharmaceutical companies, advisory board membership, or otherwise. In such cases, at the funding arbiter's discretion, and only where a majority of the review authors and lead author have no relevant Cols, it may be possible for an author who has a declared interest as listed in the previous sentence to be a Cochrane Review author.
- 4. Editors with conflicts of interest with a given product/drug/non-drug intervention should not undertake peer review or be a contact editor or provide sign-off on a review that involves that product, drug, non-drug intervention, or a competing intervention. Co-ordinating Editors with conflicts of interest should assign the

relevant review to another editor within their group. Editors are prohibited from being employees of a pharmaceutical company or medical device manufacturer.

5. Peer reviewers should be asked to declare Col using the ICMJE framework.

Disclosure of commercial conflicts of interest

The intent of clauses 6-7 is to ensure that all links between Cochrane authors and commercial sponsorship or sources are disclosed, so that Cochrane users have confidence in the process for the disclosure and management of potential commercial conflicts of interest.

6. At title registration stage, Cochrane authors should declare their conflicts of interest according to the relevant ICMJE criteria.

Commercial interests that should be declared include, but are not limited to: income from private clinical practice (if relevant to the topic), ownership of stocks related to industry, legal advice related to the topic, consultancies, honoraria, fellowships, speaker's fees, involvement in primary research in the subject area of their review, funding for primary research in the subject area of the review, and any other interests that others may judge relevant. Employment in a speciality relevant to the review should be declared in the interests of transparency, but this does not prevent an individual from being a review author, editor, or peer reviewer.

7.On receipt, the relevant Cochrane Review Group (CRG) will assess whether an author may have a Col that would prohibit them from participating in the review team. In making this assessment, it is important to consider how the reader would perceive the potential for conflict of interest. All potentially important conflicts (as described in the paragraphs above) should be referred to the funding arbiter unless it is clear, that the conflicts prohibit the author from further involvement.

At each stage of the review – title registration,

protocol publication, review publication, and updating the Col declarations should be updated and reviewed by the Managing Editor and Co-ordinating Editor as appropriate.

Cochrane authors who are also the authors of included studies

The intent of clause 8 is to ensure transparency of Cochrane authors who are authors of primary studies.

8. Cochrane authors who include primary studies (which they had conducted) in their review should declare this in the review in the Declarations of Interest section. The CRG should ensure that an editor checks the included data and interpretation against the study report and any available study registration details or protocol.

Funders of Cochrane Reviews

Cochrane Reviews are commonly funded by granting bodies. The intent of clauses 9-11 is to ensure that granting bodies do not interfere in the design and release of reviews and that funding is transparently declared.

9. Funders of Cochrane Reviews cannot interfere with the design or conduct of reviews.

10. Funders cannot delay or prevent the publication of a review or its update.

11. Funding for the review should be declared in the 'Sources of support' section of the review, which should include reference to the role of any sponsors.

Role of the Funding Arbiter

If there are questions about how this policy should be implemented, under what conditions the policy applies, if COIs are unclear, or there is no agreement between the parties, the matter will be referred to the Funding Arbiter Panel who will assess the potential conflict of interest and make a recommendation.

The Funding Arbiter Panel (FAP) is nominated by the Governing Board and contains 3-4 Cochrane contributors and one person external to Cochrane. In making an assessment, the FAP will consider the principles outlined above.

Removal of reviews not meeting policy

The intent of clause 12 is to enforce the policy.

12. Cochrane Reviews (whether new or updates) or protocols that do not meet the above requirements (1-8) from the inception of this policy will be withdrawn after consultation with the FAP and Editor in Chief.

Commercial sponsorship of Cochrane Groups

The intent of clause 13 is to ensure the independence of Cochrane Groups and their activities.

13. No Cochrane Groups are permitted to accept funds from commercial sponsors or commercial sources.

Cochrane Groups which violate this policy by accepting commercial funding may be de-registered,

following an investigation by the appropriate body.

Derivative products

The development of derivative products from Cochrane Reviews is the responsibility of Cochrane Trading Company, supported by the Editor in Chief, the and the Governing Board.

14. In developing derivative products, these bodies will adhere to the items above.

Royalties

15. Authors and CRGs should not receive royalties on sales of reprints of their reviews, since these sales are likely to have been made to commercial sources and might, therefore, be assumed to be equivalent to direct sponsorship of the review or Group. Therefore, the current policy that royalties on reprint sales go to Cochrane centrally, via the Collaboration Trading Company, will continue.

Audit

16. There will be an audit of compliance with the policy within six months and the policy will be revisited in two years.

The Cochrane Hepato-Biliary Group (The CHBG) Newsletter is written, edited, and published in electronic and paper format by Dimitrinka Nikolova and Christian Gluud at The CHBG Editorial Office in Copenhagen, Denmark. It is issued twice a year and it is also distributed for free world-wide to all people on The CHBG member list who have contributed, are contributing, or have shown interest in the work of The CHBG or in this CHBG Newsletter. The purpose with The CHBG Newsletter is to inform readers about activities of The CHBG. Editorial CHBG staff at The CHBG Editorial Office: Christian Gluud, Co-ordinating & Criticism Editor, E-mail: cgluud@ctu.dk; Dimitrinka Nikolova, Managing Editor, E-mail: dimitrinka.nikolova@ctu.dk; Sarah Louise Klingenberg, Information Specialist, E-mail: slk@ctu.dk **Postal address** The Cochrane Hepato-Biliary Group/The Copenhagen Trial Unit, **Centre for Clinical Intervention Research** Department 7812, Rigshospitalet, Blegdamsvej 9, Copenhagen Ø, DK-2100 Tel. +45 3545 7169 or +45 3545 7175 Fax +45 3545 7101 Web site: hbg.cochrane.org Visiting address Department 7812, Tagensvej 22, 2nd floor, Copenhagen N, DK-2200