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CHBG NEWSLETTER

The Cochrane Hepato-Biliary Group (THE CHBG) October 2011

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132. Routine drainage for orthotopic liver transplantation. Gurusamy KS, Naik P, Davidson BR.
133. Weight reduction for non-alcoholic fatty liver disease. Peng L, Wang J, Li F.
134. Probiotics for patients with hepatic encephalopathy. McGee RG, Bakens A, Wiley K, Riordan SM, Webster AC.
135. Methods of decreasing infection to improve outcomes after liver resections. Gurusamy KS, Naik P, Davidson BR.
136. Prostaglandins for adult liver transplanted patients. Cavalcanti AB, De Vasconcelos CP, Perroni de Oliveira M, Rother ET, Ferraz LJR.

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43. Propylthiouracil for alcoholic liver disease. Fede G, Germani G, Gluud C, Gurusamy KS, Burroughs AK.

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132. Bisphosphonates for osteoporosis in primary biliary cirrhosis. Rudic JS, Giljaca V, Krstic MN, Bjelakovic G, Gluud C.

133. Hormone replacement for osteoporosis in women with primary biliary cirrhosis. Rudic JS, Poropat G, Krstic MN, Bjelakovic G, Gluud C.
134. Nitazoxanide for chronic hepatitis C virus infection. Nikolova K, Afifi SA, Zayed N, Awad T, Hunter S, Amer A, Gluud C, Mabrouk M.
135. Bile acids for biliary colic. Veedfald S, Penninga L, Wettergren A, Gluud C.
136. Serological laboratory tests for diagnosis of human leptospirosis in patients presenting with clinical symptoms. Goris MGA, Boer KR, Bouman-Strijker M, Hartskeerl R, Lucas C, Leeflang MM.
137. Immunosuppressive T cell antibody induction therapy for liver transplant recipients. Penninga L, Wettergren A, Wilson CH, Steinbrüchel DA, Gluud C.

NEW REGISTERED TITLES

399. Pentoxifylline versus corticosteroids for alcoholic hepatitis. Gluud LL, Krag A, Thiele M.
400. Protease inhibitors in combination with pegylated interferon and ribavirin for chronic hepatitis C. Falck-Ytter Y, Yaseen AlSabbagh ME.
401. Mammalian target of rapamycin inhibitors for polycystic liver disease. Penninga L, Chavez-Tapia NC, Gluud C.
402. Histidine-tryptophan-ketoglutarate solution versus University of Wisconsin solution in liver preservation for transplantation. Li B, Liu F, Wei YG, Yan L, Wen T, C X.
403. Institut Georges Lopez-1 versus the University of Wisconsin preservation solution for liver transplantation. Wan Y, Zhang J, Zhou W.
404. Drug eluting beads TACE for unresectable hepatocellular carcinoma. Shao W, Song J.
405. De novo mTOR inhibitor immunosuppression versus calcineurin inhibitor immunosuppression for liver transplant recipients. Villaveces D, Cepeda M, Penninga L.
406.Preoperative physical exercise training for patients scheduled for major abdominal surgery. Nijhuis-van der Sanden MWG, Staal JB, Bonenkamp HJ, Voert JTer, Heusden-Scholtalbers L Van, van Goor H.
407. Surgical antibacterial prophylaxis in patients undergoing liver transplantation. Almeida RAMB, Hasimoto CN, Hasimoto EN, El Dib RP.
408. Methods to decrease blood transfusion requirements during liver resection. Gurusamy KS, Davidson BR.
409. Optimal surgical technique of laparoscopic cholecystectomy. Gurusamy KS, Davidson BR.
410. Preoperative education for laparoscopic cholecystectomy. Davidson BR, Gurusamy KS.
411. Surgical techniques to improve outcomes after liver transplantation. Gurusamy KS, Davidson BR.
412. Transarterial (chemo)embolisation for postoperative hepatocellular carcinoma. Ma T, Liu H, Zhang Q, Liang TB, Li Bai X, Chen W, Hu XJ.
413. Interventions to decrease ischaemia-reperfusion injury in liver transplantation. Gurusamy KS, Davidson BR.
414. Interventions to decrease ischaemia-reperfusion injury in liver resection. Gurusamy KS, Davidson BR.
415. Laparosocopic versus open cholecystectomy for acute cholecystitis. Coccolini F, Catena F, Lotti M, Pisano M, Ansaloni L.
416. Clevudine in patients with chronic hepatitis B virus infection. Campos JR, Cua IHY.
417. Isoprinosine versus other antiviral drugs for chronic hepatitis B. Njei B, Kumar S, Kenta-Bibi E, Zhao P, Kongnyuy EJ.
418. Terlipressin after paracentesis of tense ascites in patients with cirrhosis. Zhang H, Lv MH, Cao YL, Yang SM.

PAST EVENTS

THE 28TH BI-ANNUAL CHBG MEETING, APRIL 1, AND EXHIBITION STAND DURING THE 46TH ANNUAL MEETING OF THE EUROPEAN ASSOCIATION FOR THE STUDY OF THE LIVER (EASL), BERLIN, GERMANY, MARCH 30 TO APRIL 3, 2011

The CHBG meeting session was held in Hall 7 at the ICC Berlin (the EASL venue), on April 1, 2011 from 6:15pm to 8:15pm. The CHBG also had a stand during the EASL exhibition.

We thank both the meeting presenters and the audience for their engagement as well as visitors at the CHBG stand for their interest in the CHBG work. We look forward to seeing more people next year.

During the EASL meeting we had a chance to meet with EASL representatives and discuss the possibility that The CHBG could be given time for a meeting within the official EASL programme. Regrettably, The EASL Secretary General and The EASL Governing Board have later declined our request.

COCHRANE SYMPOSIUM DURING DDW 2011, MAY 7 TO 10, CHICAGO, USA

The Cochrane symposium 'Controversies and consensus: how Cochrane reviews guide therapy in inflammatory bowel disease' was run on May 9, 2011 at 4:00pm to 5:30pm.

INTERNATIONAL LIVER CANCER ASSOCIATION (ILCA) 2011 ANNUAL CONFERENCE, HONG KONG, SEPTEMBER 2 TO 4, 2011

Christian Gluud was invited to present 'Levels of evidence: from case series to systematic reviews' on September 3, 2011 at 1:30pm to 3:00 pm.

EUROPEAN CLINICAL RESEARCH INFRASTRUCTURES NETWORK (ECRIN) WORKSHOP, SEPTEMBER 22, 2011, PARIS, FRANCE.

On September 22, Maria Skoog, Jane Lindschou Hansen, and Christian Gluud from the Copenhagen Trial Unit, conducted a workshop for the European Correspondents from the European Clinical Research Infrastructures Network (www.ecrin.org) in Paris. The theme of the workshop was 'The randomised clinical trial and systematic reviews of such trials'. It included 11 sessions on topics such as, risk of random error and systematic error (bias) in randomised clinical trials and systematic reviews, as well as an introduction to the Cochrane Collaboration and The Cochrane Library.

FUTURE EVENTS

19TH COCHRANE COLLOQUIUM

The upcoming 2011 19th Cochrane Colloquium will be held in Madrid, Spain from 19 to 22 of October. The theme is 'Scientific evidence for healthcare quality and patient safety'. This provides a good opportunity to celebrate the Colloquium in conjunction with the VI International Conference on Patient Safety, organised by the National Agency for Health Care Quality at the Spanish Ministry of Health.

For information, check the web site (http://colloquium.cochrane.org/).

COCHRANE SYMPOSIUM DURING THE UNITED EUROPEAN GASTROENTEROLOGY WEEK (UEGW), STOCKHOLM, SWEDEN, OCTOBER 22ND TO 26TH, 2011

A representative from each of the four Cochrane Gastroenterology Groups will present at the Cochrane session.

The session will outline the strengths and limitations of systematic reviews and how Cochrane reviews can help resolve controversies in existing gastroenterology guidelines.

Peer Wille-Jørgensen, Co-ordinating Editor of The Colorectal Cancer Group and Christian Gluud from The CHBG will chair the session.

The program is:
Christian Gluud (DK). *Can you really believe systematic reviews?*

Brian Feagan, Co-ordinating Editor of the Inflammatory Bowel Disease and Functional Bowel Disorders Group (CA). *Crohn's disease guidelines: Europe versus the North America*.

Grigoris Leontiadis, Deputy Co-ordinating Editor of the Upper Gastrointestinal and Pancreatic Diseases Cochrane Group (CA). *Gastrointestinal bleeding guidelines.*

Richard L Nelson, Deputy Co-ordinating Editor of The Colorectal Cancer Group. *Clostridium difficile treatment guidelines.*

For current information, check the http://uegw11.uegf.org/.

THE 62ND ANNUAL AASLD MEETING NOVEMBER 4 TO 8, 2011, SAN FRANCISCO, CA, USA. CHBG EXHIBITION STAND. THE 29TH CHBG SYSTEMATIC REVIEW MEETING FOR PRACTITIONERS. NOVEMBER 7, 2011

The 29th bi-annual CHBG meeting will be run November 7, 2011 from 12:30 to 14:00 at Room Nob Hill CD, at Marriott Marquis Hotel, San Francisco, California, USA. The program is sent out with this Newsletter. No registration is required, but seats are limited to 100.

The CHBG exhibition stand during the AASLD meeting is booth number 238. We will be happy if you could come to se us there as well.

VISITS 2011

Mona H. Ismail, Saudi Arabia, worked at The CHBG Editorial Team Office from 21 June to July 17, 2011.
The aim of Mona's visit was to be trained in preparation of Cochrane systematic reviews based on meta-analyses of randomised clinical trials and on trial sequential analysis (http://ctu.dk/tsa). During her stay, Mona worked on two CHBG review protocols, ie, 'Entecavir for chronic hepatitis B' and 'Entecavir versus other antiviral drugs for chronic hepatitis B'.

Chavdar Pavlov, Russia, worked at The CHBG Editorial Team Office from July 8 to July 24, 2011. Chavdar continued his work on two diagnostic test accuracy systematic reviews, ie, 'Transient elastography for diagnosis of hepatic fibrosis in patients with alcoholic liver disease'; and 'Ultrasonography for diagnosis of hepatic steatosis or fibrosis in patients with alcoholic liver disease' (http://srdta.cochrane.org/welcome).

Ronald L. Koretz, USA, worked at The CHBG Editorial Team Office from 23 August to 8 September, 2011. In his capacity of a CHBG editor, Ronald prepared comments on a number of systematic reviews, considered for publication in The Cochrane Library as well as he worked, among other things, on updating the 'Interferon for interferon nonresponding and relapsing patients with chronic hepatitis C' review, which he going to present at the CHBG meeting on 7 of November 2011 in San Francisco, USA.

We thank all our visitors for their dedication and commitment to CHBG work.

NEWS OF IMPORTANCE TO AUTHORS

HOW TO WRITE RESPONSES TO COMMENTS FROM PEER REVIEWERS

We republish the text below as many new authors have started work on reviews. Besides, there is still more to be desired from CHBG authors already sending replies to comments, be it from peer reviewers or editors.

Authors of reviews and protocols are asked to submit a cover letter with point-to-point replies to the raised comments by the peer reviewers, contact editor, or editors, alongside with the revised version of the protocol or review. While the protocol or review is uploaded on Archie, the cover letter is usually sent by e-mail to the Managing Editor but addressed to the Contact Editor. The cover letter is a different document than the protocol or review checklists.

When you start preparing your cover letter, start with the title of the review and the names of the authors. Address the cover letter to the Contact Editor, writing also his or her name. Copy or retype the comments of all peer reviewers.

You shall start providing answers under each of the raised items by the peer reviewers. When you have made a change based on a comment or a suggestion, write for example: Thank you for the good comments. We have now written; or the sentence now reads, etc (and then you shall cite exactly the way the text reads in this new version of the protocol or review). When you decide to not make a suggested change, you shall justify why you think the change you are requested/suggested to make would not be appropriate. Continue in the same way. Be sure that you do not omit any raised point.

Usually, changing sentences and their structure, adding text, etc requires another global polishing of the whole review text, tables, figures, references, etc. Be sure that your text is grammatically sound. Print out and check before you submit. Please manually check for spelling errors and typos.

It could be that the Contact Editor has also made comments. You shall address these comments in the same cover letter. Finish your cover letter with your full name plus the names of the review authors who have contributed to the revision. Do

not forget to write the place and the date when you have written the letter.

You may also upload the cover letter on Archie within the Notes section of the protocol or review document. However, please do not forget to share it with the authors and the editorial team. Otherwise we cannot read it. The help function in Archie will guide you how to work with 'Notes'.

Do not forget to mark the protocol or review for 'Editorial Write Phase' when you check it back on Archie. This will create an automated e-mail to the Managing Editor.

We, of course, assume that the revision of the protocol or review is performed with the common efforts of the authors and that all review authors have approved of the revised version.

STANDARDISING OUTCOME MEASURES IN CHBG REVIEW PROTOCOLS

Following a CHBG Editors' telephone conference on February 14, the CHBG continues its efforts in standardising outcome measures in review protocols. Please read current recommendations.

1. In general, selection of review protocol outcome measures and their listing shall follow the Guidelines in Higgins JPT, Green S (editors). Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.0.2 [updated September 2009]. The Cochrane Collaboration, 2009. Available from www.cochrane-handbook.org.

In the Handbook on p.88 to p.90 you will read:

"5.4.2 Prioritizing outcomes: main, primary and secondary outcomes

Main outcomes

Once a full list of relevant outcomes has been compiled for the review, authors should prioritize the outcomes and select the main outcomes of relevance to the review question. The main outcomes are the essential outcomes for decision-making, and are those that would form the basis of a 'Summary of findings' table. 'Summary of findings' tables provide key information about the amount of evidence for important comparisons and outcomes, the quality of the evidence and the magnitude of effect (see Chapter 11, Section 11.5). There should be no more than seven main outcomes, which should generally not include surrogate or interim outcomes. They should not be chosen on the basis of any anticipated or observed magnitude of effect, or because they are likely to have been addressed in the studies to be reviewed.

Primary outcomes

Primary outcomes for the review should be identified from among the main outcomes. Primary outcomes are the outcomes that would be expected to be analysed should the review identify relevant studies, and conclusions about the effects of the interventions under review will be based largely on these outcomes. There should in general be no more than three primary outcomes and they should include at least one desirable and at least one undesirable outcome (to assess beneficial and adverse effects respectively).

Secondary outcomes

Main outcomes not selected as primary outcomes would be expected to be listed as secondary outcomes. In addition, secondary outcomes may include a limited number of additional outcomes the review intends to address. These may be specific to only some comparisons in the review.

For example, laboratory tests and other surrogate measures may not be considered as main outcomes as they are less important than clinical endpoints in informing decisions, but they may be helpful in explaining effect or determining intervention integrity (see Chapter 7, Section 7.3.4).

Box 5.4.a summarizes the principal factors to consider when developing criteria for the 'Types of outcomes'." (end of citation)

2. Review protocol outcome measures should include clinical outcome measures no matter the clinical outcome measures reported in the trials

one is going to include in the review. Trial culture shall never be the culture of systematic reviews, as most trialists, for example, select ten to fifteen outcomes but report only on a selected few.

3. Mortality should stand alone, and it should be the first primary outcome.

4. Morbidity from the disease should be the second primary outcome.

5. Adverse events should be included as a primary outcome unless the review topic or title formulation precludes the occurrence of an adverse event.

6. Quality of life, even that it is seldom reported, should be included as a primary outcome or as one of the secondary outcomes.

7. Surrogate outcomes (especially non-validated ones) should be included only as secondary outcomes.

8. Health economics. This outcome should preferably be the subject of a separate review, see Chapter 15 in the Handbook.

9. Composite outcomes. If trial authors have failed in reporting the separate components of composite outcomes in separate, it is up to the judgement of the review authors to meta-analyse them together or not.

We should continue to work on defining fixed outcomes depending on the review topic, eg, interventions for chronic hepatitis B, or chronic hepatitis C. This will help authors, consumers, and policy makers in preparing or using also overview of reviews, as well as preparation of 'Summary of findings' tables and their understanding, respectively.

Should you wish to share your opinion or comment on outcomes defined in published protocols after April 2011, please do not hesitate to contact staff at The CHBG Editorial Team Office.

AUDIT OF THE ABSTRACT, PLAIN LANGUAGE SUMMARY, AND SUMMARY OF FINDINGS TABLES IN PUBLISHED COCHRANE REVIEWS

The Cochrane Editorial Unit in Oxford, UK, based on the audit on abstracts of new Cochrane reviews, have prepared recommendations on how the abstract of an intervention review should be reported. Below are the recommendations which CHBG authors should follow and incorporate in their reviews.

1. The word limit of abstracts is now increased from 400 to an absolute limit of 1000 words; however, authors are encouraged to make abstracts no longer than 700 words.

2. There should be:
- Clear description of the question addressed by the review.
- Explicit description of the intervention(s) and comparisons.
- Inclusion of the date(s) and scope of search(es).
- Comment on the risk of bias of included trials.
- Description of the number of trials and participants in the review.
- Clear and consistent description of results for important outcomes, including a comment if no studies measured them.
- Absolute effects should be reported alongside relative effects in the abstract as they appear in other parts of the review (eg, Summary of Findings (SoF) tables or as natural frequencies/numbers needed to treat (NNTs) given in the text of the review).
- Full and consistent reporting of benefits and harms and overall conclusions across the abstract, plain language summaries (PLSs) and 'SoF tables.

As the abstract, PLS, and SoF tables contain the key information in Cochrane Reviews, it is expected that the above set of criteria will contribute to reporting guidelines for abstracts of systematic reviews being developed by Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (http://www.prisma-statement.org/).

ABSTRACT CHECKLIST BASED ON CRITERIA PROVIDED IN THE COCHRANE HANDBOOK (CHAPTER 11)

Before submitting a review for editorial approval, authors must check the abstract of the review against the following checklist:

1. In the background section, does the abstract explain the context or elaborate on the purpose and rationale of the review?
2. In the objectives section, does the abstract include the following information: intervention or comparison, type of people, disease or problem, and setting (if specified)?'
3. In the search methods section, does the abstract list the sources and the dates of the last search for each source?
4. In the selection criteria section, does the abstract include the following: type of study, intervention or comparison, and type of people, disease or problem?
5. In the data collection and analysis section, does the abstract include details of how many people extracted data?
6. In the main results section, does the abstract list the total number of studies included in the review?
7. In the main results section, does the abstract list the total number of participants included in the review?
8. In the main results section, does the abstract include brief details of the comparability of the studies, if applicable?
9. In the main results section, does the abstract include brief details of the risk of bias of the studies, if applicable?
10. In the main results section, does the abstract include the results of the primary outcome and no more than five other results?
11. In the main results section, does the abstract include whether or not adverse effects were identified, and if so, the findings?
12. In the main results section, is there an explanation of the size and direction of effect to accompany the numerical results?
13. In the main results section, are the summary statistics presented in a standard way, such as 'odds ratio 2.31 (95% confidence interval 1.13 to 3.45)'?
14. In the main results section, are risks of events (percentage) or averages (for continuous data) reported for both comparison groups?
15. Is the information in the main results and conclusions sections consistent with each other?
16. Does the abstract avoid making recommendations?
17. Is there a summary of findings table(s)?
18. Is the summary of findings table(s) in the appropriate format?
19. Is the PLS title a clear re-statement of the title and not a conclusion?
20. Are the findings reported in the PLS consistent with those of the abstract?

PLAIN LANGUAGE SUMMARIES

The Cochrane Collaboration now recommends that the titles of plain language summaries (PLSs) shall contain an absolute maximum of 150 characters (approximately 25 words) and that PLSs that have titles that are longer than this should be amended.

The rationale for requesting these changes now includes the extremely sub-optimal way that these summary titles will appear when presented on PubMed Health, a service from the US National Library of Medicine (NLM) aimed at the public, but the same holds true for the presentation on The Cochrane Library and also for the proposed new consumer portal on the Collaboration's own site.

Authors of PLSs shall avoid declarative titles as these are not supported and are contrary to Handbook guidance.

Though the current guidance on overall word count for PLSs is limited to 400 words, authors of PLSs may write the summary longer than that, as feedback from readers read that they would also like to find some background information on the question that is being addressed by the review, in addition to a description of the methods and results. Therefore, feedback is now to be taken into consideration and for longer summaries authors are strongly encouraged to break up the text into digestible sections by paragraph breaks and headings as appropriate.

Authors of PLSs shall ensure that PLSs are entirely consistent with the findings of the rest of the review.

THE COCHRANE CO-PUBLICATION POLICY

The Cochrane Policy Manual (http://www.cochrane.org/policy-manual/welcome) outlines the principles and processes for co-publishing Cochrane Reviews outside The Cochrane Library. The section of the manual that has been revised is 2.2.5 (http://www.cochrane.org/policy-manual/225-publication-versions-cochrane-reviews-print-journals). Appendix 2 contains the form to request co-publication.

The table listing the existing agreements with journals for co-publishing Cochrane Reviews is populated over time.

COPY-EDITING POLICY

The Cochrane Editorial Unit, Oxford, UK, now requires that all Cochrane protocols and reviews should be sent by the Cochrane Collaborative Group to Copy-editing Support Team. However, this does not mean that authors should submit their protocols or reviews for editorial consideration without following the Cochrane Collaboration Style Guidelines that you will find at http://www.cochrane.org/training/authors-mes/cochrane-style-resource or through RevMan help.

COCHRANE ONLINE LEARNING

All authors of intervention reviews may register and receive training online. To do this, visit the webpage - http://training.cochrane.org.

The Diagnostic Test Accuracy Working Group lists training events for authors of diagnostic reviews on their website (http://srdta.cochrane.org/workshops-and-events).

The Cochrane Hepato-Biliary Group (The CHBG) Newsletter is written, edited, and published in electronic and paper format by staff at The CHBG Editorial Base in Copenhagen, Denmark. It is issued twice a year and distributed for free in paper and electronic formats world-wide to all people on The CHBG members' list who have contributed, are contributing, or have shown interest in the work of The CHBG. The purpose with The CHBG Newsletter is to inform its readers about activities within The CHBG.

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The Cochrane Hepato-Biliary Group (The CHBG)

The 29th CHBG Systematic Review Meeting for Practitioners

Monday, November 7, 2011

Time: 12:30 to 14:00.

Location: Room Nob Hill CD, at Marriott Marquis Hotel, San Francisco, California, USA.

Chair: Christian Gluud, DK.

12:30 - 12:45.	Bariatric surgery for non-alcoholic steatohepatitis in obese patients. A Cochrane Hepato-Biliary Group systematic review.	Norberto Chavez-Tapia (MX), Felix Tellez-Avila (MX), Tonatiuh Barrientos-Gutierrez (MX), Nahum Mendez-Sanchez (MX), Misael Uribe (MX).
12:45 - 13:00.	Anti-thymocyte globulin for liver transplant recipients. A Cochrane Hepato-Biliary Group systematic review.	Luit Penninga (DK), André Wettergren (DK), Colin H Wilson (UK), Daniel A. Steinbrüchel (DK), Christian Gluud (DK).
13:00 - 13:10.	Lamivudine during pregnancy for preventing hepatitis B virus infection in newborns. A Cochrane Hepato-Biliary Group systematic review.	Khalid Mumtaz (CA), Umair Syed Ahmed (USA), Nadeem F Zuberi (PK), Sumaira Salamat (PK), Wasim Jafri (PK).
13:10 - 13:20.	Pegylated interferon for chronic hepatitis B. A Cochrane Hepato-Biliary Group systematic review.	Khalid Mumtaz (CA), Saeed Hamid (PK), Wasim Jafri (PK).
13:20 - 13:40.	Interferon for interferon nonresponding and relapsing patients with chronic hepatitis C. A Cochrane Hepato-Biliary Group systematic review.	Ronald L Koretz (USA), Maria Pleguezuelo (ES), Vasiliki Arvaniti (GR), Pilar Barrera Baena (ES), Ruben Ciria (ES), Kurinchi Selvan Gurusamy (UK), Brian R Davidson (UK), Andrew K Burroughs (UK).
13:40 - 13:50.	Antibiotics for prophylaxis of leptospirosis. A Cochrane Hepato-Biliary Group systematic review.	David M. Brett-Major (USA) and Robert J Lipnick (USA).
13:50- 14:00.	Antibiotics for leptospirosis. A Cochrane Hepato-Biliary Group systematic review.	David M. Brett-Major (USA) and Rodney Coldren (USA).

The Cochrane Collaboration is an international, independent, not-for-profit organization of over 28,000 contributors from more than 100 countries, dedicated to making up-to-date, accurate information about the effects of health care readily available worldwide.

The Editorial Team Office of The CHBG is in Copenhagen, Denmark. For information visit www.cochrane.org.