

CHBG NEWSLETTER

The Cochrane Hepato-Biliary Group (CHBG)

Volume 12, Issue 2 September 2008

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NEW PUBLICATIONS IN THE CLIB ISSUE 3 AND 4, 2008

NEW REVIEWS

- 87. Hepatitis B immunisation in persons not previously exposed to hepatitis B or with unknown exposure status. Mathew JL, El Dib R, Mathew PJ, Boxall EH, Brok J.
- 88. Preoperative biliary drainage for obstructive jaundice. Wang Q, Gurusamy KS, Lin H, Xie X, Wang C.
- 89. Early versus delayed laparoscopic cholecystectomy for biliary colic. Gurusamy KS, Samraj K, Fusai G, Davidson BR.
- 90. Methods of preventing bacterial sepsis and wound complications for liver transplantation. Gurusamy KS, Kumar Y, Davidson BR.

UPDATED REVIEWS

- 1. Day-case versus overnight stay for laparoscopic cholecystectomy. Gurusamy KS, Junnarkar S, Farouk M, Davidson BR.
- 2. Ursodeoxycholic acid for primary biliary cirrhosis. Gong Y, Huang ZB, Christensen E, Gluud C.

NEW PROTOCOLS

- 168. Antibiotic prophylaxis for leptospirosis. Brett-Major DM, Martinez LJ, Lipnick RJ.
- 169. Antibiotic prophylaxis for patients undergoing elective endoscopic retrograde cholangiopancreatography. Brand M, Bizos D, O'Farrell PJR.
- 170. Bariatric surgery for non-alcoholic steatohepatitis in obese patients. Chavez-Tapia NC, Tellez-Avila FI, Barrientos-Gutierrez T, Mendez-Sanchez N, Lizardi-



- Cervera J. Uribe M.
- 171. Immunosuppressive T cell antibodies for liver transplant recipients. Wilson CH, Asher JF, Manas DM.
- 172. Intra-peritoneal local anaesthetic instillation for laparoscopic cholecystectomy. Gurusamy KS, Guerrini GP, Zinnuroglu M, Davidson BR.
- 173. L-ornithine-L-aspartate for hepatic encephalopathy. Yuan W, Li J, Xu L, Zhang M, Lu Z, Feng S, Wang L.
- 174. Non-surgical interventions to decrease blood loss and blood transfusion requirements for liver resection. Gurusamy KS, Osmani B, Sharma D, Davidson BR.
- 175. Pentoxifylline for alcoholic hepatitis. Whitfield K, Gluud C, Rambaldi A.
- 176. Mycophenolate mofetil for liver-transplanted patients. Großmann K, Langer G, Saal S, Grothues D, Wienke A.
- 177. Pharmacological interventions to reduce ischaemia-reperfusion injury for liver resections performed under vascular control. Abu-Amara M, Gurusamy KS, Davidson BR.

NEW REGISTERED TITLES

- Pegylated interferon alpha 2b for chronic hepatitis C. Awad T, Thorlund K, Hauser G, Stimac D, Gluud C
- 2. Pegylated interferon alpha 2a for chronic hepatitis C. Awad T, Hauser G, Thorlund K, Stimac D, Gluud C.
- 3. Glucocorticosteroids for patients undergoing laparoscopic cholecystectomy. Malik AI, Tou S, Nelson RL.
- 4. Molecularly targeted agents for hepatocellular carcinoma. Oliveri RS, Gluud C.
- 5. Molecularly targeted agents for biliary cancer. Oliveri RS, Gluud C.
- 6. Molecularly targeted agents for hepatic metastases. Oliveri RS, Gluud C.
- 7. Fibrin sealants for hepatic resection. MA Thaha.
- 8. Pre-operative portal vein embolisation for primary and secondary liver tumours. Lochan R.
- 9. Ischaemic pre-conditioning for liver resections performed under vascular occlusion. Gurusamy KS, Kumar Y, Sharma D, Davidson BR.
- 10. Liver transplantation for hepatocellular carcinoma. Metrakos P.

PAST EVENTS

THE 22nd BI-ANNUAL CHBG MEETING AND EXHIBITION STAND DURING THE 43rd ANNUAL EASL MEETING

The CHBG held a bi-annual meeting in the morning of 23 of April 2008 in Milan, on the very first day when the EASL meeting started. We have not yet been successful in getting a better day and time for The CHBG meeting during the EASL meeting so that more people get the opportunity to attend it.

Our presence at the exhibition managed us to meet with people interested in our activities, discussed work with CHBG authors and other contributors. We also met new people, interested in knowing what we do and how they could join us.

We welcome all new members!

INTERNATIONAL CLINICAL TRIALS' DAY – ECRIN MEETING

More than 100 people attended the Brussels meeting on 19 and 20 of May. Discussions were focused on the themes of European Clinical Research Infrastructures Network (ECRIN) reaching across European borders and making it ready for starting on pilot projects in 2009.

FUTURE EVENTS

THE 16th COCHRANE COLLOQUIUM

October 3 to 7, 2008 Freiburg, Germany. The colloquium theme is 'Evidence in the era of globalisation'.

For detailed information visit http://www.colloquium.info

THE 23rd BI-ANNUAL CHBG MEETING AND EXHIBITION STAND DURING THE 59th ANNUAL AASLD MEETING

The CHBG will hold a meeting on November 2 from 6:30 pm to 8:30 pm. The meeting room is 'Pacific A' at San Francisco Marriott hotel. You can find the programme on the last page of this Newsletter or on The CHBG web site http://ctu.rh.dk/chbg

No registration is required and everyone is invited to attend it.

We were happy with the affluent attendance at The CHBG stand last year and we will man a stand this year too. At the stand you will also be able to meet authors of CHBG reviews. Please use the opportunity to meet us there.

The opening hours of the exhibition are:

Saturday, November 1 5:30 pm - 8:00 pm Sunday, November 2 9:30 am - 3:00 pm Monday, November 3 9:30 am - 3:00 pm

THE 59th ANNUAL AASLD MEETING

October 31 to November 4, 2008 San Francisco, CA, USA at Moscone West Convention Center For information, visit https://www.aasld.org

THE CHBG'S MONOTHEMATIC CONFERENCE ON SYSTEMATIC REVIEWS AND META-ANALYSES: FROM CLINICAL RESEARCH TO CLINICAL PRACTICE

We have planned to run a CHBG monothematic conference with six sessions on two days on 20 and 21 of April 2009 in Copenhagen, Denmark. Please consider this two-day opportunity to meet and discuss systematic reviewing when you are planningyuor travel to the 2009 EASL meeting in Copenhagen. The conference will be of interest to anyone using or producing evidence that is based on clinical research. The sessions will be on the evidence hierarchy, the randomised clinical trials, meta-analyses, Cochrane systematic reviews, risk of random and systematic errors in randomised clinical trials and in metaanalyses, and the history and achievements of The CHBG since March 1996. Details about time and place will be sent out to all CHBG members with email address in Archie as well as will be placed at The CHBG web site: http://ctu.rh.dk/chbg.

THE 24th BI-ANNUAL CHBG MEETING AND EXHIBITION STAND DURING THE 44th ANNUAL EASL MEETING

Details about the two planned activities in Copenhagen will be available in the first months of 2009.

THE 44th ANNUAL EASL MEETING

April 22 to 26, 2009 Bella Center, Copenhagen, Denmark For information, visit http://www2.kenes.com/livermeeting/Pages/Home.aspx

THE CHBG SYMPOSIUM 2009 AND EXHIBITION STAND DURING THE DDW 2009

The CHBG will run a symposium entitled: 'Evidence-based management of end-stage liver disease' in the afternoon of June 2 or 3, 2009 (the exact date and time are not fixed yet) during The Digestive Disease Week (DDW).

The programme covers topics on glucocorticosteroids and pentoxiphylline for alcoholic hepatitis; transarterial embolisation and transarterial chemoembolisation for hepatocellular carcinoma; nutrition for end-stage liver disease; and emergency sclerotherapy, banding, and medical interventions for bleeding oesophageal varices.

The symposium programme, similarly to The CHBG meeting programme at AASLD meeting 2008, will be distributed by e-mail, in the beginning of 2009, to all CHBG members with e-mail address in Archie as well as will be placed at The CHBG web site: http://ctu.rh.dk/chbg. We will appreciate if CHBG members keep their contact details on Archie up to date.

DDW MEETING 2009

May 30 to June 4, 2009 McCormick Place, Chicago, IL For information about the DDW meeting, visit http://www.ddw.org/wmspage.cfm?parm1=605

VISITS

Andrea Rambaldi, Italy, visited the Editorial Team Office in August 20 to 27, 2008. Andrea worked on the reviews: 'Milk thistle for alcoholic and/or hepatitis B or C virus liver diseases' and 'Glucocorticosteroids for alcoholic hepatitis'.

NEW CO-WORKERS

Tahany Awad, Egypt, is a new colleague of ours who came to Denmark in May 2008. She will spend at least a year with us, working mostly on preparation of Cochrane systematic reviews.

ACKNOWLEDGEMENTS

We would like to thank Kate Whitfield for all The CHBG work she did in the past months (September 2007 to August 2008). Now Kate is entirely dedicated to ECRIN work, but her enthusiasm to work on Cochrane Reviews remains. Sarah Klingenberg, The CHBG Trials Search Co-ordinator, is back from maternity leave and is resuming her contact with authors of reviews.

WORKING WITH REVIEW MANAGER 5 (REVMAN) AND ARCHIE

Here are some easy to follow instructions on how to work with the Cochrane Collaboration software. Users of Archie and RevMan can request a password or a reminder of their Archie user name as well as an Archie user account from the Archie login screen (http://archie.cochrane.org/).

Having logged into Archie, you can view and edit your contact details. As an author, you can view a copy of the latest version or any previous versions of your protocols and reviews. In order to work on the review, you will need to check it out of Archie into RevMan 5.

Open RevMan 5; go to 'File' and choose 'Check out'. A list of titles for all reviews for which you have permission to check out with their 'Availability' will be presented. A review title may come up with the following status: 'Checked out', which means that a co-author of the review team is working on the review; 'Locked' – you cannot access the latest version because, for example, it has been submitted for editorial approval. While the review is checked out, no one else can access it for editing.

To be on the safe side, use the 'save as' function and save the review on your computer drive. Check the review back in Archie when you have finished your work for the day. In this way, the most recent version will always be available on Archie, and you will be protected if something happens with your computer.

When you check in the file, you will be asked if you want to check it in as a 'draft' or for 'editorial approval'. For 'editorial approval' means that authors can no longer work on it.

If you or your team are still working on it, enter a description of the version (eg, XX reached outcome 3) for you and others to know how far in the process the review is. You will get a message saying it was successfully checked in. If you want to share the version with your co-authors, send them an e-mail to let them know they can now view your latest version in Archie. Please note that they can do this only if they have an Archie user account. If needed, a review can be shared among authors as a html or a word document exported from RevMan 5, but these formats may have a number of disadvantages for the review authors. Like graphs – the data are easily exported, but the graphs have to be copied and pasted into a document one at a time. It may be easier if you 'view' the graphs in Archie and then save them in a pdf format to send them to your co-authors.

If your team has finished working on the review and you want to check the review back into Archie for editorial approval, you should first complete the section on dates on the title page. Two dates need to be completed in RevMan when you submit a review; the date of the most recent literature search and the date assessed as up-to-date. These dates should be the same, unless a last minute literature search has been done, and the results are entered into 'waiting assessment' rather than being included in the current review under 'what's new'. Click on 'add event' and complete the 'description' – please ensure that you

indicate if the conclusions have changed or not, because this determines the label of the review in *The Cochrane Library*.

Proceed by doing the following in RevMan: Go to 'File' and choose 'Reports' and 'Validation report'. Run the validation check and try to fix all the 'errors' and 'warnings'. If the file contains 'errors', you cannot check the file into Archie for editorial processing. If there are errors you cannot resolve, contact us by e-mail, checking in the version onto Archie as a draft.

When submitting the review for editorial approval, describe the version (eg, 'your name' edits), select 'Submit for editorial approval' and enter text in the 'Message to Cochrane Review Group' box to communicate with us. However, a message sent to dnikolov@ctu.rh.dk will be answered sooner.

With the multiple check-ins and outs of a review, many versions are created on Archie. Some of them contain mostly minor changes. We may advise you to delete versions of documents that you no longer need. You can also delete several versions of a review at one time by using Shift-click and Ctrl-click to select multiple versions, and then click Delete. However, please note that a deleted version cannot be reinstated. To decide whether or not to delete a version, you may compare versions of the review. Go to 'History' tab in the Properties; click one of the versions you want to compare. Holding down the Ctrl key, click on the other version for comparison. Click Compare. You can print or save the 'comparison'.

If you only wish to view your review in RevMan, then you can download it and not check it out. When a review is 'downloaded', you cannot check it back into Archie. Closing RevMan without saving the downloaded version will make it disappear.

You may also read your review on Archie. Enter the title of your review in the 'Quick Search' box in the upper right hand corner of the opening screen to find your review. Click the second icon 'Search documents'. If there is more than one search result, double-click on the title to open its 'Properties'. If there is only one search result, the Properties screen will automatically open. Click the 'History' tab in the Properties where the current and previous versions of your review are listed. Click the latest version, and then click 'View'. The latest version is usually at the top of the list unless you have once in the past reverted

to an older version; then, the reverted older version indicating also the old version number, will be shown on the top.

Your contact details must be held updated on Archie and it is only you who know best your address. Your contact address can be read by everybody who has access to Archie unless you mark your contact details as private, which means that only the Review Group Co-ordinator and system administrators will be able to read your contact details. However, when your review is published in *The Cochrane Library* and if you are the Contact Person for the review, your main contact details (if you have more than one set of contact details) will be published fully. Your contact details will be published partially (ie, department, organisation, city, country) if you are a co-author but not the Contact Person for the review.

LICENCE TO PUBLISH FORM

Licence to Publish form is now required before submitting your protocol or review for publication in *The Cochrane Library*. The Licence to Publish form can be downloaded from 'File' and 'Reports', and 'Licence to publish form' in RevMan 5. It is the responsibility of the contact author to ensure that all co-authors have signed it and that it is received at the Editorial Team Office prior to the protocol or review publication.

IMPACT FACTOR FOR THE COCHRANE DATABASE OF SYSTEMATIC REVIEWS

Wiley-Blackwell (publishers of *The Cochrane Library*) has announced that the 2007 journal impact factors (JIF) have now been published by Thomson ISI. The *Cochrane Database of Systematic Reviews* has an JIF of 4.654 and is ranked 14 out of 100 in the ISI category Medicine, General & Internal. The 2007 JIF is calculated on the total number of cites in 2007 to articles published in 2006 (2442 cites) and in 2005 (2798 cites) -> total =5240 divided by the total number of articles published in 2006 (575) and 2005 (551) -> total = 1126.

To ensure Cochrane reviews are correctly tabulated, it is important that they are correctly cited as such in reviews and articles.

Citation example: Mathew JL, El Dib R, Mathew PJ, Boxall EH, Brok J. Hepatitis B immunisation in persons not previously exposed to hepatitis B or with unknown exposure status. Cochrane Database of Systematic Reviews 2008, Issue 3. Art. No.: CD006481. DOI: 10.1002/14651858.CD006481.pub2.

ASSESSMENT OF RISK OF BIAS IN INCLUDED STUDIES

The Cochrane Handbook for Systematic Reviews of Interventions was substantially updated in February 2008 (available from www.cochrane-handbook.org). The following is a standard summary text on assessments of risk of bias of included studies in reviews that we suggest to CHBG authors to use when they start working on the review protocol. The first five bias domains are obligatory to follow while assessment of the others should depend on the authors' judgements in regard to their review topic and relevance of the listed domains.

A great part of the following text is almost always present in CHBG protocols and reviews.

Assessment of risk of bias in included studies

Methodological quality will be defined as the confidence that the design and the report of the randomised clinical trial would restrict bias in the comparison of the intervention (Moher 1998¹).

According to empirical evidence (Schulz 1995²; Moher 1998¹; Kjaergard 2001³; Wood 2008⁴), the methodological quality of the trials will be assessed based on sequence generation, allocation concealment, blinding (of participants, personnel, and outcome assessors), incomplete outcome data, selective outcome reporting, and other sources of bias. Quality components will be classified as follows:

Sequence generation

- Low risk of bias (the methods used is either adequate (eg, computer generated random numbers, table of random numbers) or unlikely to introduce confounding).
- Uncertain risk of bias (there is insufficient information to assess whether the method used is likely to introduce confounding).
- High risk of bias (the method used (eg, quasirandomised trials) is improper and likely to introduce confounding).

Allocation concealment

- Low risk of bias (the method used (eg, central allocation) is unlikely to induce bias on the final observed effect).
- Uncertain risk of bias (there is insufficient information to assess whether the method used is likely to induce bias on the estimate of effect).
- High risk of bias (the method used (eg, open random allocation schedule) is likely to induce bias on the final observed effect).

Blinding of participants, personnel, and outcome assessors

- Low risk of bias (blinding was performed adequately, or the outcome measurement is not likely to be influenced by lack of blinding).
- Uncertain risk of bias (there is insufficient information to assess whether the type of blinding used is likely to induce bias on the estimate of effect).
- High risk of bias (no blinding or incomplete blinding, and the outcome or the outcome measurement is likely to be influenced by lack of blinding).

Incomplete outcome data

- Low risk of bias (the underlying reasons for missingness are unlikely to make treatment effects departure from plausible values, or proper methods have been employed to handle missing data).
- Uncertain risk of bias (there is insufficient information to assess whether the missing data mechanism in combination with the method used to handle missing data is likely to induce bias on the estimate of effect).
- High risk of bias (the crude estimate of effects (eg, complete case estimate) will clearly be biased due to the underlying reasons for missingness, and the methods used to handle missing data are unsatisfactory).

Selective outcome reporting

- Low risk of bias (the trial protocol is available and all of the trial's pre-specified outcomes that are of interest in the review have been reported or similar).
- Uncertain risk of bias (there is insufficient information to assess whether the magnitude and direction of the observed effect is related to selective outcome reporting).
- High risk of bias (not all of the trial's pre-specified primary outcomes have been reported or similar).

Baseline imbalance

- Low risk of bias (there was no baseline imbalance in important characteristics).
- Uncertain risk of bias (the baseline characteristics were not reported).
- High risk of bias (there was a baseline imbalance due to chance or due to imbalanced exclusion after randomisation).

Early stopping

- Low risk of bias (sample size calculation was reported and the trial was not stopped or the trial was stopped early by a formal stopping rule at a point where the likelihood of observing an extreme intervention effect due to chance was low).
- Uncertain risk of bias (sample size calculations were not reported and it is not clear whether the trial was stopped early or not).
- High risk of bias (the trial was stopped early due to an informal stopping rule or the trial was stopped early by a formal stopping rule at a point where the likelihood of observing an extreme intervention effect due to chance was high).

Academic bias

- Low risk of bias (the author of the trial has not conducted previous trials addressing the same interventions).
- Uncertain risk of bias (it is not clear if the author has conducted previous trials addressing the same interventions).
- High risk of bias (the author of the trial has conducted previous trials addressing the same interventions).

Source of funding bias

- Low risk of bias (the trial's source(s) of funding did not come from any parties that might have a conflicting interest (eg, a drug or a device manufacturer).
- Uncertain risk of bias (the source of funding was not clear).
- High risk of bias (the trial was funded by a drug or a device manufacturer).

Other sources of bias

- Low risk of bias (the trial appears to be free of other sources of bias).
- Uncertain risk of bias (there is insufficient information to assess whether other sources of bias are present).
- High risk of bias (it is likely that potential sources of bias related to specific design used, early termination due to some data-dependent process, lack of sample size or power calculation, or other bias risks are present).
- Schulz KF, Chalmers I, Hayes RJ, Altman DG. Empirical evidence of bias. Dimensions of methodological quality associated with estimates of

- treatment effects in controlled trials. JAMA 1995;273:408-12.
- 2. Moher D, Pham B, Jones A, Cook DJ, Jadad AR, Moher M, et al. Does quality of reports of randomised trials affect estimates of intervention efficacy reported in meta-analyses? Lancet 1998;352:609-13.
- 3. Kjaergard LL, Villumsen J, Gluud C. Reported methodologic quality and discrepancies between large and small randomized trials in meta-analyses. Annals of Internal Medicine 2001;135:982-9.
- Wood L, Egger M, Gluud LL, Schulz KF, Jüni P, Altman DG, Gluud C, et al. Empirical evidence of bias in treatment effect estimates in controlled trials with different interventions and outcomes: metaepidemiological study. BMJ 2008;336(7644):601-5.

CONVERSION OF CHBG PROTOCOLS AND REVIEWS INTO REVMAN 5 FORMAT

By November 2008, all Cochrane protocols and reviews must be converted into the new Review Manager 5 format! It is an easy process, and it is done 'automatically' when a protocol or review is checked out from Archie in the new version of RevMan.

We kindly ask all our authors to check out their review(s) and/or protocol(s) into RevMan 5 and to check it back into Archie after the conversion. Before cheching it in, make sure that the conversion went well and that everything is at the right place. In addition, the table with search strategies should be moved from Additional tables to Appendices. This can

be done with the copy-paste function after having added a new appendix. Remember to delete the old table and to adjust the text in the new table - from the Table menu choose both align left and align top -, and to change the link in the text of the review from 'Additional table xx' to 'Appendix xx'. Also remember to check that the names of the databases are written in full, to add the source of the database (platform used, web adress or similar), to enter the timespan including month and year of search, and make sure that the exact and complete strategies are reported. Use Toggle heading/cell function for the headings of the Search strategies table.

When the review or protocol is checked into Archie, make sure to choose 'Submit for editorial approval'. After having checked the conversion and checked in the review or protocol into Archie, please let us know by e-mail.

In case a more recent version of the review or protocol than the one in Archie exists with the authors in RevMan4 format, it will not be possible to open it in RevMan 5. In that case, please send the review or protocol to us by e-mail, and we will make sure it is converted into the new format.

If you experience any problems, please contact us and we will help you.

The bi-yearly Cochrane Hepato-Biliary Group (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 either 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.

Editorial CHBG staff at The CHBG Editorial Base

Christian Gluud, Co-ordinating & Criticism Editor, E-mail: cgluud@ctu.rh.dk; Dimitrinka Nikolova, Managing Editor and Review Group Co-ordinator, E-mail: dnikolov@ctu.rh.dk; Sarah Louise Klingenberg, Trials Search Co-ordinator, E-mail: slk@ctu.rh.dk; Nader Salas, IT Advisor and Web Master, E-mail: nader.s@ctu.rh.dk; Styrbjørn Birch, IT help E-mail: s.birch@ctu.rh.dk

Postal address: Cochrane Hepato-Biliary Group, Copenhagen Trial Unit,
Centre for Clinical Intervention Research
Department 33 44. Rigshospitalet, Blegdamsvej 9, DK-2100
Copenhagen Ø, Denmark,
Tel. +45 3545 7169 or +3545 7175, Fax +45 3545 7101,
E-mail: dnikolov@ctu.rh.dk
Web site: http://ctu.rh.dk/chbg

Visiting address: The Panum Institute, Department 3344, Blegdamsvej 3, Copenhagen.





THE 23rd COCHRANE HEPATO-BILIARY GROUP (The CHBG) BI-ANNUAL MEETING

DURING

THE 59th ANNUAL AASLD MEETING, San Francisco, CA – USA

PROGRAM

Date: 2nd November 2008.

Time: 6:30 pm to 8:30 pm.

Meeting room and place: Pacific A. San Francisco Marriott Hotel.

Chairs: Ronald L. Koretz and Christian Gluud.

6:30 pm – 6:35 pm	Welcome and presentation of the program.	C Gluud, Denmark.
6:35 pm – 6:55 pm	Pegylated interferon alpha 2a versus pegylated interferon alpha 2b for chronic hepatitis C.	T Awad, K Thorlund, G Hauser, D Stimac, C Gluud. Denmark.
6:55 pm – 7:15 pm	Terlipressin for hepatorenal syndrome.	K Christensen, LL Gluud, E Christensen. Denmark.
7:15 pm – 7:35 pm	Non-steroid anti-inflammatory drugs for biliary colics.	A Colli, D Conte, V Sciola, <u>M</u> <u>Fraquelli</u> . Italy.
7:35 pm – 7:55 pm	Antibiotic prophylaxis for patients undergoing elective laparoscopic cholecystectomy.	A Sanabria, E Valdivieso, G Gomez, <u>LC Dominguez</u> . Colombia.
7:55 pm – 8:15 pm	Diagnostic accuracy of the aspartate aminotransferase-to- platelet ratio index for the prediction of hepatitis C-related fibrosis: a systematic review.	AAM Shaheen, R Myers, Canada.
8:15 pm – 8:30 pm	Closing remarks and discussion.	RL Koretz, USA.