Questions to be completed by candidates for election to position of Co-Chair of the Cochrane Collaboration Steering Group

Statement from: Lisa Bero July 5, 2015

1. Please describe how you first became involved in The Cochrane Collaboration and your subsequent contribution to its work.

I have had a variety of roles in The Cochrane Collaboration. I first became involved in The Cochrane Collaboration in 1996 as a founder and Co-Director (with Drummond Rennie) of the San Francisco Cochrane Center, now the San Francisco Branch (which I direct) of the United States Cochrane Center. I was attracted to The Cochrane Collaboration because the rigorous systematic reviews produced seemed a logical and powerful way to influence health practice and policy. I also had a deep interest in innovating and improving scholarly publication and providing access to information on pharmaceuticals. Thus, the special task of the SFCC was to develop the on-line criticism management system for The Cochrane Library which was groundbreaking at the time.

In true Cochrane fashion, I wanted to see The Cochrane Library include systematic reviews on how to best use systematic reviews and other research to influence practice and policy. So, I was an editor of the Effective Practice and Organization of Care (EPOC) Group from 1996 until 2013. I was involved in methods development for these reviews which were the first in The Cochrane Library to include non-randomized studies. I was the contact editor for many reviews.

I served on the Cochrane Collaboration Steering Group for a total of 12 years (see question #3 for more detail).

I have also been involved in creating new roles in The Cochrane Collaboration which I have subsequently filled. My involvement in the development of the Commercial Sponsorship Policy led to the formation of the Funding Arbiter Panel. I was Chair of the Funding Arbiter panel from 2006 to 2010 and resigned as a panel member in January 2015.

I spearheaded the application for the Cochrane Collaboration to be an NGO in official relations with the World Health Organization (WHO). This was approved by WHO in January 2011. I have been The Cochrane Collaboration designated official (liaison) in collaboration with WHO since 2011 and Cochrane delegate to the World Health Assembly in 2011 and 2012 (see question #3 for additional information). I continue to be a main contact person with WHO and in the last year have been involved in the development of our renewal application.

In addition, I served as a Scientific Program committee member for several Colloquia and I have been a member of The Cochrane Library Oversight Committee from 2010 to 2014.

I was Professor of Clinical Pharmacy and Health Policy at the University of California, San Francisco (UCSF) from 1991 to 2014 and remain an adjunct professor. In August 2014, I moved to the University of Sydney to take the position of Chair of Medicines Use and Health Outcomes at the Charles Perkins Centre, University of Sydney where I lead a program in research integrity and science policy.

2. Have you helped to prepare or bring into practice a Cochrane Review? If so, what was your involvement?

I am an author of 3 Cochrane Reviews and 3 protocols (as well as one withdrawn review), 2 in EPOC, 1 in tobacco and 3 methodology reviews. I am the senior author on 5 of these. As such, I have been deeply involved in protocol preparation, data extraction, analysis and writing. I am currently updating 2 of these reviews.

I have also published extensively on the use, quality and methods of Cochrane reviews and other systematic reviews. For example,

- 1. Krauth, D, Woodruff, T and Bero, L. A Systematic Review of Instruments for Assessing Risk of Bias and other Methodological Criteria of Published Animal Studies. <u>Environmental Health</u> Perspectives. 2013; 121:985-992. http://dx.doi.org/10.1289/ehp.1206389.
- 2. Schroll, JB, Bero, L, Gotzsche, P. Searching for unpublished data for Cochrane reviews: Cross sectional study. <u>BMJ</u>. 2013; 346:f2231. DOI 10.1136/bmj.f2231 (published 23 April 2013)
- 3. Roseman, M, Turner, EH, Lexchin, J, Coyne, JC, Bero, LA, Thombs, BD. Reporting of conflicts of interest from drug trials in Cochrane reviews: cross sectional study. <u>BMJ</u> 2012;**345**:e5155.
- 4. Hart, B, Lundh, A and Bero, L. The effect of reporting bias on meta-analyses of drug trials: Reanalysis of meta-analyses. <u>BMJ</u>, 2011;343:d7202. doi: 10.1136/bmj.d7202
- 5. Odierna, D and Bero, L. Systematic reviews reveal an unrepresentative evidence base for the development of drug formularies for poor and nonwhite populations, <u>J Clin Epidemiol</u>, 2009; doi: 10.1016/j.jclinepi.2009.01.009.
- 3. Please describe leadership roles that you have held within The Cochrane Collaboration and in other relevant contexts, with examples of successful leadership.

I was a twice-elected member of the Cochrane Collaboration Steering Group (a total of 12 years).

From 2004 to 2010 (re-elected 2007), I was a member of The Cochrane Collaboration Steering Group. This period marked the evolution of The Cochrane Collaboration into a more structured organization with a publishing contract, editor-in-chief for The Cochrane Library, more detailed methodological standards, a commercial sponsorship policy, and formal training and mentoring initiative. In 2005, I became Chair of the Funding Arbiter Panel for the Cochrane Collaboration. This group develops and monitors Cochrane Collaboration policy on conflicts of interest. During this time, the Steering Group also became more strategic about spending funds to support the development of the organization. In 2008, I chaired of Priority Setting Grant Review Committee for Cochrane. The selected grants were productive and the findings were published as a special issue of the Journal of Clinical Epidemiology. I served as a member of the Center Director's Executive from 2009 to 2012 during which we developed more cohesive agendas and a more productive way of working among the Center Directors.

I first served on the Steering Group from 1996-2000. In 1997, I was elected Chair, Subgroup on Registration and Monitoring and oversaw the development of the earliest processes for monitoring entities within The Collaboration. I have been Co-Chair since October 2013.

An example of my leadership at UCSF has been my service as Vice Chair for Research in the Department of Clinical Pharmacy from 2000 to 2013. In this capacity, I developed a research mentoring program for junior faculty, a grant-writing program, an annual Spring Research Seminar, a research resources website and start-up fund. The number of faculty receiving investigator initiated grants doubled during this period.

At the University of Sydney, I developed and chair the Charles Perkins Centre Committee on Academic Industry Relations and I am a member of the Vice Chancellors special committee on Industry Partnerships. I am the leader of 2 research nodes at the Charles Perkins Centre: 1) bias and research integrity and 2) evidence synthesis.

4. What experience do you have of committee work, both within The Cochrane Collaboration and nationally and internationally (particularly at the policy-setting level)?

I am a real team player and good citizen of the research community. My numerous service activities for the university, professional and international organizations can be found in my curriculum vitae which I am happy to provide. I list some of the highlights below.

In 2010, I stepped down as Chair of the UCSF Chancellor's Advisory Committee on Conflicts of Interest after 11 years of service. This committee reviews faculty conflicts of interest and developed management plans. This was a high profile and sometimes controversial committee. We developed new policies for the university and implemented them across all faculty. I have also served on the Academic Senate Task Force on Conflicts of Interest and Clinical Trials and the Academic Senate Task Force on University Vendor Relations. I have served on many UCSF committee in the Schools of Pharmacy and Medicine, as well as campus-wide and Academic Senate committees, including the UCSF Strategic Planning Board and the Ethics and Compliance Board Steering Committee.

I have been an active contributor to National Academy of Science committees. I am currently a member of the Congressionally-mandated committee reviewing the Environmental Protection Agency's IRIS process for identifying hazardous chemicals. Our goal is to bring a more evidence-based systematic review approach to chemical hazard assessment. I am the primary author of one chapter of the report, and deeply involved in most other chapters. I was a member of the Institute of Medicine (IOM) Committee on Conflicts of Interest in 2008 through 2009. This committee produced a report on managing conflicts of interest in clinical care, research and education. I was appointed to the IOM Board on Health Care Services in 2009.

I am dedicated to my service activities that involve more collaboration with international researchers, particularly those in low resource settings. I spearheaded the application for the Cochrane Collaboration to be an NGO in official relations with the World Health Organization (WHO) which was approved January 2011. I am the Cochrane Collaboration designated official (liaison) in collaboration with WHO and Cochrane delegate to the World Health Assembly.

I have been a member of the WHO Essential Medicines Committee since 2005. This committee reviews applications for the WHO Essential Medicines List and has been steadily revising its processes to make the selection more evidence-based. The Essential Medicines list is used for setting medicines policy at the country level and planning supply and procurement in low resource settings. I chaired the committee in 2011, 2013 and 2015. Reaching consensus on this committee can be a challenge because, in addition to evidence of efficacy, safety, and cost, the committee also considers cultural norms, values and preferences.

In 2013 and 2015, I chaired the first meeting of the Pan American Health Organization Strategic Fund Selection Committee. Medicines listed in the Strategic Fund are purchased at bulk rates by PAHO for Latin American Countries participating in the fund.

I was appointed to the Advisory Committee on Health Research for the Pan American Health Organization (PAHO) in 2008.

From 2010 through 2014, I was a member of the World Health Organization Guideline Review Committee which reviews all protocols and final products of WHO guidelines. In 2011, I was cochair of the WHO Guideline Panel on Country Pharmaceutical Pricing Policies.

I served as a Member of the Study Session Drug Protocol Review Committee for Angezia Italiana del Farmaco (AIFA), Independent research on drugs funded by the Italian Medicines Agency in 2008 and 2009. The Italian Medicines Agency administered a novel program to fund drug trials that are not typically supported by drug companies. I was invited to participate in 2014 but was unable to do so due to other commitments.

In addition to the University of Sydney committees noted in the question above, I have served on 2 tenure review committees. In addition, I have been invited to join the NHMRC committee on systematic review methods for environmental hazards.

5. What do you think would make you an effective Co-Chair of the Steering Group?

As documented above, my extensive leadership experience, as well as my experience chairing international committees with participants from very diverse backgrounds, will make me an effective co-chair. I have an in-depth understanding of the history of the organization and have been personally involved in many of the changes we have seen in the last 20 years. However, my dedication to The Cochrane Collaboration should make me an outstanding co-chair. The Cochrane Collaboration gave me, as a new researcher many years ago, an instant network of like-minded collaborators, support to go after projects and ideas that were not the *status quo* in pharmaceutical or tobacco control research, and challenged my mind with innovative methods and an appreciation for other cultures and research communities. Today, as in 1996 when I was first involved in The Cochrane Collaboration, I believe that Cochrane Reviews are essential to promoting evidence-based health care and policy.

The Cochrane Collaboration is at a critical time where we need to encourage participation not only globally, but among more junior collaborators. Like my university, The Cochrane Collaboration is facing the challenge of succession planning. I feel I have the opportunity to give back to the organization that has given so much to me. I want to strive to ensure the future of the Cochrane

Collaboration by supporting and developing new collaborators who can reap the benefits of participation that helped many of us build the organization we have today.

6. Acting as Co-Chair of the Steering Group requires a consultative approach to decision-making. Please illustrate how you would do this.

The vast international composition of The Cochrane Collaboration makes consultation a challenge. The Steering Group and entity executives, as representatives of their entities, are the starting point for consultation and I plan to maintain contact with these groups on a regular basis. The Chief Operative Officer and Editor-in-Chief can also help facilitate communication. When consultation is sought from the broader Collaboration, written documents clearly describing the issues, options and decisions required should be circulated for comment. All comments should be carefully considered. Although I firmly believe there is no substitute for face-to-face discussions, the reality is that many collaborators cannot attend meetings. They should not feel that they are missing out or that their voices will not be heard. We should use all the technology available to us in terms of internet communication (webinars, social media, etc.) to facilitate consultation.

Historically, decisions have been reached by consensus on the Steering Group. I think this model should be maintained. In the event that consensus is difficult to achieve, a technique I have often used is to "step back... and look forward." The group is asked to reflect on the goal that is actually to be achieved (step back) and to think about where the options will bring us towards achieving that goal (look forward). This can help diffuse some of the arguments and distractions (if any) and refocus the group on the decision at hand.

7. How do you see The Cochrane Collaboration and/or the Steering Group developing or changing in the future (i.e. what is your 'vision'), and why?

With an Editor-in-Chief firmly in place and a Chief Operating Officer on board, I see the Steering Group moving away from day to day running of the Collaboration (which has sometimes been necessary in the past) to become more of the strategic and policy making body for the Collaboration. The CCSG will have the opportunity to propose solutions to some of our most pressing problems and develop plans for new directions. The Strategic Review and Cochrane Strategy 2020 consultation have confirmed that the mission and principles of The Collaboration will not change. Our primary purpose continues to be the production of high quality, up-to-date systematic reviews. My vision is to have the Steering Group address some of the challenges and opportunities facing The Cochrane Collaboration and to produce concrete options for moving forward on these issues:

- 1. Enhancing global participation in The Cochrane Collaboration and global use and relevance of Cochrane reviews.
- 2. Engaging and mentoring the future leaders and participants in The Cochrane Collaboration.
- 3. Supporting open access to data from individual studies.
- 4. Supporting open access to The Cochrane Library, while maintaining a financially viable organization.

8. As Co-Chair, you would be expected to solve problems and resolve conflicts. How would you approach this aspect of the role?

I have had extensive experience in conflict resolution in committee settings, as well as formal training in conflict resolution. Working to prevent conflicts should always be the first strategy. This is done by building relationships, engaging stakeholders, communicating clearly, aligning and clarifying goals, and carefully reviewing potential solutions in light of available data (see also question #6). If conflicts still arise, it may be necessary to involve a "third party" (who could be the co-chair) to review the steps leading to the conflict and offer a solution. Ultimately, the participants will be asked to reflect on what is best for the organization. In my first 2 years as co-chair, I have had to deal with a few individuals who have violated or ignored Cochrane policies. These conflicts have been resolved fairly and effectively.

9. In the role of Co-Chair, you would be expected to represent the Collaboration in a variety of settings; have you any experience of this or similar representation? In this context, please illustrate your ability to communicate successfully with a range of audiences.

Over the past 2 decades, I have represented various parts of the Cochrane Collaboration in a wide variety of settings. I have given numerous talks on aspects of the Cochrane Collaboration to academic and lay audiences all over the world. I have described above how I have represented the Cochrane Collaboration as an organizational representative on formal committees.

I believe that it is particularly important for researchers and Cochrane Collaborators to communicate their findings to the general public. I have designed and participated in workshops on evidence-based health care, including modules on systematic reviews, for journalists, consumer advocates, lawyers and federal judges. I am regularly interviewed by major print, internet, television and radio journalists about our research and The Cochrane Collaboration. I have been featured in two videos on Evidence-Based Medicine. I was featured in an October 2007 article in Discover Magazine entitled "Science under Siege" by Jennifer Washburn. I was interviewed for articles on my work published in The Economist, Science, The Scientist, spoke on public radio in various locations, appeared on Fox News television, and spoke at the Commonwealth Club. In 2012, I was featured in a profile in The Lancet.

I am very comfortable interacting with people all over the world. As noted above, the WHO Essential Medicines Committee presents both cultural and linguistic challenges which I have managed successfully for a number of years.

10. For individuals seeking <u>re-election</u> as Co-Chair: What do you think you have contributed to the work of the Steering Group during your previous two-year term of office?

In the last 2 years, I believe I have led the Steering Group and Cochrane Collaboration in making substantial progress towards:

- 1. Creating a more strategic steering group, through our development sessions and focus of the co-chairs on strategic issues
- 2. Governance reform through proposal for restricting the Steering Group
- 3. Structure and Function review of the entire organization
- 4. Providing central support for improving the quality of Cochrane reviews.

Our 3 biggest challenges are 1) financial sustainability, 3) maintaining enthusiasm and participation among collaborators and 3) communicating our efforts at change. To address these, we will 1) engage with outside consultants and perspectives to plan strategically for our financial future, and 2) work more closely with the communications team to not only improve our communications strategy but to improve the ways in which collaborators can contribute to our strategic thinking.

I have an excellent working relationship with the CEO, editor in chief and co-chair which enhances our ability to reach and implement decisions.

I confirm that I wish to stand for election to the position of Co-Chair of The Cochrane Collaboration Steering Group and that, if elected, I would be able and willing to commit the necessary time and attention to the role.

Signed:

Lisa Bero