Election of new internal members of the Cochrane Governing Board

Statement from Peter C. Gøtzsche, Professor and Director, the Nordic Cochrane Centre.

1. Do you have experience or expertise in one or more of the published list of essential areas of expertise for members of the Cochrane Board?

I have extensive experience and expertise in all of the listed essential areas.

Evidence-informed health care or policy

Since 2010, I have been active in the European Parliament as a scientific lobbyist, collaborating with influential MEPs and large consumer organisations like the Trans Atlantic Consumer Dialogue. My work has influenced policy setting in the EU Parliament. We succeeded in changing the European Commission's proposed revision of the Clinical Trials Directive completely, from maintaining the secrecy around drug trial results to becoming much more transparent.

In 2016, members of the EU Parliament tried to get me elected for a vacant post at the Management Board of the European Medicines Agency, but a political majority pointed at another candidate, an MEP.

I have held lectures in the EU Parliament, and in the UK, Dutch and Danish parliaments; I have spoken at two EU Commission meetings and have had a meeting with the Director for Research & Innovation DG at the Commission. I have also had meetings with people in the European WHO office in Copenhagen and in the WHO Uppsala Drug Monitoring Centre, and with the EU ombudsman, most recently in May 2016.

I collaborate with networks of like-minded people in order to change policies for the benefit of patients and healthy citizens, e.g. the Trans Atlantic Consumer Dialogue, the International Society of Drug Bulletins, and the Critical Psychiatry Network.

I have established a partnership with the Danish National Board of Health. A previous PhD from our centre works full-time there with national clinical guidelines and the Nordic Cochrane Centre's deputy director works part-time as a methods consultant. The result of this has been that the guidelines have become more evidence-based than previously and also that there are more reservations when the trial evidence is biased.

Editorial policy and publishing

I was an editor in the Cochrane Methodology Review Group 1997-2014 and have published many methodological research papers, which have helped improve the quality and relevance of Cochrane reviews. I have written four evidence-based books.

I was responsible for the establishment of the Placebo Methods Group and the Non-Randomised Studies Methods Group, both based at the Nordic Cochrane Centre. The Bias Methods Group moved its secretarial base from Canada to Denmark in January 2016.

Consumer engagement

I have always been an advocate for consumer engagement by strengthening an inclusive two-way dialogue with our consumers. It is therefore that I ,from the establishment of the Nordic Cochrane Centre in 1993, ensured that we had a consumer representative on our Advisory Board, who has

been very valuable for the development of the Centre's activities and our work. I have also involved the Danish Consumer Council in our work from 2001 for this reason.

In 2006, we criticised the content of invitations for publicly funded screening mammography in the *BMJ* and also published our own information leaflet, which was co-authored by a consumer and pretested among women. The US Center for Medical Consumers called it 'the first honest mammography information for women written by health professionals,' which is likely why volunteers have translated it into 15 languages. We updated it in 2012.

Currently, I collaborate with many patient organisations devoted to psychiatry. In 2014, I received the annual award from the National Society of Previous and Current Psychiatry Users 'LAP-prisen'). In 2015, psychiatric patients nominated me as the "Dane of the Year" because of my work with reducing the usage and harms of psychiatric drugs; I was among the 10 finalists for the title. In 2016, I was elected as Protector for the Hearing Voices Network in Denmark.

Systematic review conduct

We have held numerous workshops about writing Cochrane protocols and reviews and about evidence-based medicine. For example, in 2002 and 2003, I held two international workshops on Cochrane editing in Copenhagen, which were attended by editors from many Cochrane review groups.

I have authored 17 Cochrane reviews published in 11 different Cochrane review groups. Three of these Cochrane reviews, all of which I initiated, have saved Danish taxpayers an annual amount corresponding to about £50m, which is about 100 times the annual budget for our Centre. These reviews are: mammography screening, alpha-1 antitrypsin for treatment of patients with lung disease and general health checks.

Systematic review methodology

I am the co-author of CONSORT (Consolidated Standards of Reporting Trials), STROBE (Developing Standards of Reporting for Observational Studies in Epidemiology), PRISMA (Quality of reporting of meta-analyses) and SPIRIT (Standard Protocol Items for Randomised Trials).

In 1990, I defended my doctoral thesis "Bias in double-blind trials". This was the first thesis in the Nordic area, and perhaps in the world, that built on meta-analyses and had reviewed a whole therapeutic area (head-to-head comparisons of nonsteroidal anti-inflammatory drugs).

Knowledge translation and communication

The Nordic Cochrane Centre is highly active in disseminating the results of Cochrane reviews and research carried out at the centre to our key users. We work with the media which include local Danish media and international journalists on nearly a daily basis promoting Cochrane efforts and disseminating our research activities. As mentioned earlier, I work closely with policymakers and healthcare managers in enabling more evidence-informed decisions and improving healthcare to patients.

To ensure consistency in our efforts and support us at the Centre, I have recently employed a communications expert. Part of her responsibility is to support our Centre in using new media to expand our reach and create awareness of Cochrane to all our target audiences.

Financial management in the not-for-profit sector
I founded the Nordic Cochrane Centre in 1993 and I am still its director.

Organizational governance
See item 3 below.

2. How have you contributed to Cochrane's work during your time as a member?

See item 1 above and also below.

3. What experience do you have in leadership and governance roles within Cochrane and in other relevant contexts? Can you provide examples of successful leadership?

I was a co-founder of the Cochrane Collaboration, a member of the Cochrane Collaboration Steering Group 1993-1996, and I co-authored and was an editor of the first version of the Cochrane Handbook. I have been the director of the Nordic Cochrane Centre since I established it, for the last 14 years full-time.

I have facilitated the establishment of branches of the Nordic Cochrane Centre in Norway, Finland, Poland and Russia, and also chaired an exploratory meeting in June 2016 in Sweden, which we expect will lead to the establishment of a Swedish associate centre in early 2017.

I have chaired international exploratory meetings, which led to the establishment of the Cochrane Hepato-Biliary Group, the Cochrane Colorectal Cancer Group, the Cochrane Anaesthesia, Critical and Emergency Care Group, all based in Copenhagen, and the Cochrane Depression and Anxiety Group (currently called the Common Mental Disorders Group).

The Nordic Cochrane Centre has had a pivotal role in the development of Cochrane software, including Review Manager and Archie. It started in 1996 with the employment of MSc Rasmus Moustgaard. In 2015, the staff counted eight people whose employment was transferred from the Nordic Cochrane Centre to the Cochrane Executive Team (CET) in the UK. The Centre has invested more than what corresponds to £3m in software development during these years.

In 1996, I started negotiations with the Copenhagen Hospital Corporation, which led to the transferral of the Copenhagen Trial Unit from the Centre for Disease Prevention to the Nordic Cochrane Centre where it is still located under my leadership. This resolved a long-standing conflict between the leaders of the two units and ensured that the Copenhagen Trial Unit - whose leader is also the co-ordinating editor of the Cochrane Hepato-Biliary Group - prospered.

I have extensive experience with solving problems and resolving conflicts. I have helped many authors and editors and have brought some of these cases to the Cochrane funding or publication arbiters.

I have been founder and head, medical department, Astra-Syntex (1977-1983); founder and head, Nordic coordination office for AIDS trials (1987-1995); and was a co-founder of Council for Evidence-based Psychiatry, which had its inaugural meeting in the House of Lords in the UK in 2014 and which collaborates with a parliamentary committee on drug dependence. In 2016, I co-founded the International Institute of Psychiatric Drug Withdrawal.

I have been a Chairman at numerous congresses and international meetings including Cochrane Colloquia; chairman, Danish Society for Theory in Medicine (1992-1996), a member of

the Research Council and an examiner of PhD applications, Rigshospitalet (1993-2005) and a member of the Drug Committee, Rigshospitalet (1993-2010).

I was the first person in the world who obtained access to unpublished clinical study reports and trial protocols at the European Medicines Agency. This occurred in 2010, after a three-year long battle with the agency that involved a complaint to the European Ombudsman, to whom we had appealed (I described the process in BMJ 2011;342:d2686). The Ombudsman inspected the files at the agency and concluded that they didn't contain commercially confidential information, in contrast to the agency's claims. The Ombudsman then accused the agency of maladministration, which forced it to open its archives and to change its policy from one of extreme secrecy to openness.

4. What do you think would make you an effective member of the Board?

I believe I am highly result oriented with a sharp focus on avoiding wasting time. I am used to group work and have extensive experience with obtaining fruitful compromises. Being a full-time Cochrane Centre Director, I have no problems with allotting the necessary time for the work as a member of the Board.

The Cochrane Collaboration is about collaborating. Wide consultative processes have therefore been the norm where members can have their say before decisions were made. I believe it is important that this inclusive process continues, above all because so many people contribute many hours of voluntary unpaid work in evenings and weekends. Democracy, ownership and acceptance of decisions, and respect for diversity of opinion and of different cultures, are vital for this immense voluntary contribution, without which there wouldn't be much of a Cochrane Collaboration.

5. How do you see Cochrane developing or changing in the future (i.e., what is your 'vision'), and why?

I strongly believe we should always keep the first two of the ten guiding principles for the Cochrane Collaboration in mind:

1. Collaboration, by fostering global co-operation, teamwork, and open and transparent communication and decision-making.
2. Building on the enthusiasm of individuals by involving, supporting and training people of different skills and backgrounds.

Generosity, enthusiasm and a feeling of ownership of decisions are of utmost importance for continued survival and prosperity of the Cochrane Collaboration. I therefore feel it is essential that we continuously consider very carefully whether we have the right balance between what has always been essentially a bottom-up organisation and the recently introduced pyramidal management structure. Even after 23 years, I still see the Collaboration much more as an idealistic grassroots organisation than a business, and we could face deep trouble if we start losing some of our many thousands of unpaid volunteers.

I have talked to many people who have been active in the Cochrane Collaboration for many years and who have expressed concerns about recent developments in our organisation. Some of the criticisms are:

Although the officially registered name is still the Cochrane Collaboration, the word "Collaboration" has been dropped, both in internal and external communications. The Cochrane Collaboration is unique in that it builds on collaboration rather than competition and personal gains. Our collaboration involves generosity, a great deal of unpaid work, and a team spirit, which is virtually unknown in well-established specialist societies.

The CET should be serving those people who do the bulk of the work, above all the authors and editors of reviews, but also those working in centres and methods groups. It has been noticed, however, that the CET has assumed a much more directive role, which has had unfortunate implications for the collaborative spirit and potentially for essential future contributions from those who are the backbone of the Collaboration and are creating the royalties without which there would probably be no Collaboration. Although there was general agreement that more direction and uniformity in the quality of our output was needed, and also that the CET has contributed importantly to this, many people feel that the process has gone too far.

In line with this, people have wondered why so many of our resources go to salaries of centrally employed staff and they worry that volunteers may stop contributing their time for free when they see that people with similar tasks get a salary. This worry is particularly pronounced in the methods groups. People have also pointed out that the more employees there is at the CET and at affiliate offices, the more work they will create for themselves and others, which might not always be productive.

The Cochrane Collaboration is now run much more as a business with a brand than it was just a few years ago. Many see this as problematic, as it could lead to a lack of funding, e.g. from governments that might think we could do well on our own. The raison d'être for the Collaboration is research, not business, and this is also the reason why people still want to support us. Our brand has no value of its own, but derives its value from our research.

Some centre directors have argued strongly against the CEO's idea that it should no longer be a priority for centres to carry out methodological research or to be strong in research and thereby be good examples for others to follow. In my experience, one cannot be a good science educator without being a researcher oneself, and I believe this view is pretty universal, e.g. also at our universities.

Methodological research and development are at the heart of our collaboration; it is vital to keeping the work of the Cochrane Collaboration relevant and trustworthy and at the forefront of EBM. Without research being at the top of our agenda, our organisation might lose its ability to attract top researchers and it might also have negative implications for the willingness of governments to support Cochrane centres financially.

I agree with many of these pretty widespread concerns. One issue that has come up repeatedly is: Should the CET decide on what centre directors should be doing when it doesn't provide their salary and when the centres are on government finances, which come with expectations that might not always coincide with what the CET would want?

I believe we need to avoid that too much decisive power becomes concentrated at the CET and, if elected, I will work on refocusing on our central values and aims.

6. What do you see as the most important issues to be addressed by the Board during your term of office?

Although we are an evidence-based organisation, I feel that we have sometimes made decisions in the past without looking for or respecting the evidence. I also feel we are often too inward-looking when we make policies. One example is: If we asked the public whether they are happy that our current policy states that up to half of the authors on a Cochrane review are allowed to have financial conflicts of interest in relation to a drug company whose product is being evaluated, I am pretty certain what the answer would be. We are here to serve the public and I therefore feel we should be more outward-looking when we make policies.

Therefore, an important guiding principle for me if I should become elected will be: What does the public want from us? I believe it is a risk for all idealistic organisations that their policy making can become too consensus-based and too self-serving because growth and sustainability of the organisation may become a more prominent objective over time than the original one. There will always be influential people who will protest loudly if they fear their privileges might be taken away from them, particularly if these are pecuniary, and we have seen this happen several times in the Cochrane Collaboration when we tightened our commercial sponsorship policy. Conflicts are unavoidable but they can be used positively if handled professionally with a clear focus on our aims.

I believe Cochrane reviews generally have become too detailed, too cumbersome to carry out, and too difficult to read. In some reviews, there are more than 50 different outcomes, and the authors dutifully analyse and report all these outcomes despite the fact that we know that outcome reporting bias is very common, not least in published reports of drug trials.

If elected, I would advocate simpler reviews, with much fewer outcomes that focus on what is relevant and important for patients. A difference on an elaborate, composite scale rarely says much about whether the patients' lives have improved, particularly not when side effects are regarded as a separate issue and are very often downplayed or omitted altogether from published trial reports.

7. For individuals seeking re-election, how have you contributed to the Board during your previous term of office?

I am not seeking re-election.

8. Is there anything else you would like to say in support of your nomination?

No.

Conflict of interest declaration: Peter C. Gøtzsche

1. Financial interests

a) Received research funding: any grant, contract or gift, commissioned research, or fellowship from The Cochrane Collaboration or a related organisation (i.e. any organisation related to health care or medical research) to conduct research?
Yes, 2011 and 2012, The Cochrane Collaboration, for methodological research.

b) Had paid consultancies: any paid work, consulting fees (in cash or kind) from a related organisation?
No

c) Received honoraria: one-time payments (in cash or kind) from a related organisation?
No

d) Served as a director, officer, partner, trustee, employee or held a position of management with a related organisation?
No

e) Possessed share-holdings, stock, stock options, equity with a related organisation (excludes mutual funds or similar arrangements where the individual has no control over the selection of the shares)?
No

f) Received personal gifts from a related organisation?
No

g) Had an outstanding loan with a related organisation?
No

h) Received royalty payments from a related organisation?
No

2. Do you have any other competing interests that could pose a conflict of interest that would reasonably appear to be related to the primary interest?
No

Governing Board
The Cochrane Collaboration,
December 05, 2016

Nomination of Peter C Gøtzsche to the Governing Board of the Cochrane Collaboration

I am writing this letter to show my support for Peter Gøtzsche's wish to join the Governing Board of the Cochrane Collaboration. As the author of a short history of the Collaboration, I believe I have a privileged outsider's view of Cochrane, having spent a decade attending the annual Colloquia and then several years conducting interviews both inside and outside the organization. In the course of this research Dr. Gøtzsche was one of over 200 interviewees who shared with me a unique perspective of the organization, its history and its future.

I support this appointment because I think Peter brings not just an extensive knowledge of the practice of creating systematic reviews, but also a depth and breadth of experience in disseminating that knowledge to a broader audience. Dr. Gøtzsche's extensive and prolonged involvement in the Collaboration is unassailable. His enthusiasm for an international Collaboration was enshrined in quick action in 1993 when he pushed to create the Nordic Cochrane Centre, which, after the UK Centre in Oxford, was one of the first to fully commit to this international group.

I know Peter quite well and share with him his desire for Cochrane to produce the most rigorous and effective reviews possible. To this end, those reviews must be intelligible and useable by clinicians and patients. Over the course of writing my book I heard many criticisms of the Collaboration, one of the strongest being that the reviews did not serve patients' interests. I believe Peter's appointment to the Governing Board would be a vote for relevance and patient-centred reviews that address conditions important to patients. Peter is a fierce opponent to the way medicine has been infected by conflicts of interest and biased medical knowledge. He will, I'm sure he will continue to strongly voice those concerns as a member of the Governing Board.

Iain Chalmers told me that he thought one of the long-lasting legacies of the Collaboration was a "spirit of generosity." I believe that Peter understands, intrinsically, what motivates many of the thousands of volunteers around the globe and how they are the soul of Cochrane. I am confident that with Peter on the Governing Board, the organization will continue to grow and thrive, remembering its past, cultivating this spirit and ultimately remaining focused on the public interest.

Sincerely,

Alan Cassels

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To whom it may concern

Freiburg, 2016-12-12

Statement in support of Peter Gøtzsche's nomination as internal member of the Cochrane Governing Board

It is my pleasure to support the nomination of Prof Peter Gøtzsche **as internal member of the Cochrane Governing Board**.

Capacity in which I know Peter Gøtzsche

I have known Peter personally since 2010 when I first met him at the Center & Branch Directors' Meeting in Split, Croatia. Since then, we regularly met at the Center & Branch Directors' Meetings which take place at the Colloquia and the Mid-Year Meetings.

I do regard him very highly due to his thoughtful, sometimes critical input during these meetings and very much appreciate his expertise, experience, and vision with regard to any Cochrane-related matters.

In my view, Peter is one of the few "Cochrane" people who are widely known to the outside world. Through his extraordinary work Peter personally has and still is contributing a great deal to the good reputation Cochrane is benefitting from today.

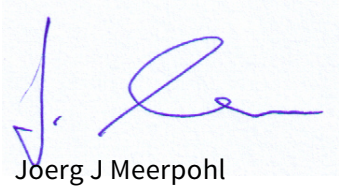
Why I consider Peter Gøtzsche to be an appropriate candidate in the light of the job description and the extent to which I think he has the necessary attributes

Peter has been involved with the Cochrane Collaboration from the very beginning as one of the most active and highly respected researchers, systematic review authors and as founding director of the Nordic Cochrane Centre. Peter is very passionate about the Cochrane Collaboration and has dedicated his career to his work at the Nordic Cochrane Center, which is one of the most successful and productive Centers within the Collaboration. He is author or co-author on more than a dozen Cochrane reviews and was a contributor to the 1st version of the Cochrane Handbook.

Peter has extensive managerial expertise and served on many high-level national as well as international committees or boards including the Cochrane Steering Group back in 1993-96. Peter was instrumental in setting up and supporting various other Cochrane Entities, such as the Branches of the Nordic Cochrane Centre and methods groups including the Non-randomized Methods Group. Peter also successfully hosted and led the Cochrane IMS team, which developed Archie and RevMan.

Peter's most outstanding achievement is in my view his perseverance with the European Medicines Agency (EMA) including a complaint to the EU ombudsman that eventually led EMA to grant – for the first time ever - access to clinical study reports and trial protocols. Peter's advocacy and contribution very positively impacted on the European Clinical Trials Directive.

Peter's intricate knowledge of the widespread activities within Cochrane, and his very strong commitment to the goals of Cochrane, combined with his long-standing, successful expertise in leadership and advocacy make him a very strong candidate for the position of an internal member of the Cochrane Governing Board.



Joerg J Meerpohl

Co-Director Cochrane Germany

Member, Cochrane Governing Board