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## Moral leadership crisis in the Cochrane Collaboration

There is something totally wrong with the leadership of the Cochrane Collaboration. Centralized management may ruin the entire network.

Peter C. Gøtzsche Professor and Director, Nordic Cochrane Centre

Medicines are a major expense for society, and it is often uncertain whether they work and what the harmful effects are. It is also often unclear whether new, expensive medicines are better than existing ones. The Cochrane Collaboration's main task is to find out if our treatments work and what harms they have. We do systematic reviews of randomised trials based on a comprehensive handbook. Cochrane reviews are considered to be of the highest standard for such reviews. There are over 10,000 reviews or protocols for upcoming reviews in the Cochrane Library, and the Danish government has ensured that all Danes have free access to them: <a href="https://www.cochranelibrary.com/">https://www.cochranelibrary.com/</a>. The government also funds the Nordic Cochrane Centre at Rigshospitalet, with DKK 5.6 million annually.

I was one of the founders of Cochrane Collaboration, which emerged as an idealistic grassroots movement in 1993, but have now been expelled as the first person ever, both from the Governing Board and as a member of the "party" (but I'm still the head of the centre). This action is not rationally justified, and only 6 of the 13 board members voted for the decision. The following day, four influential people from four countries resigned from the Board in protest over the obvious show trial that had taken place and the lack of strategic leadership.

There is a moral crisis in the Cochrane Collaboration. Our principles of transparency, openness and critical scientific debate are important to our credibility, but they have disappeared. My expulsion should be seen in this context.

A democratic deficit is also an issue. The role of the Governing Board has been radically diminished, and the Board has increasingly become a testimonial body that rubber-stamps highly finalized proposals with practically no ongoing in-put and exchange of views to formulate new policies. The growing top-down authoritarian culture focusing on "business", "brand" and "product" we have seen in recent years threatens the scientific, moral and social purposes of the organization. Many Cochrane centres have sustained negative pressure to conform with the leadership's wishes and there has been a lack of productive dialogue with the CEO and his staff in London. Upon alerting the Cochrane leadership of these worrisome tendencies that negatively affect the operability and the public's positive impression of Cochrane, the Nordic Cochrane Centre has received a number of threats to its existence. In the spring, my American colleagues closed the US Cochrane Center because they could no longer cooperate with the CEO. Several other centres are also considering closing or to become independent.

A year ago, I argued at a centre directors' meeting that Cochrane should be the world's moral leader in healthcare. However, Cochrane's management has totally failed in terms of its declared advocacy and political priorities. We do not hear anything about open data and scientific transparency, and Cochrane also refused to comment on the EU proposal to centralize medical technology assessment.

Resistance in the management against any of the members saying anything that could threaten the pharmaceutical industry's interests has also grown, and it has not been willing to avoid conflicts of interests among those who produce Cochrane reviews. I was elected to the Board a year and a half ago because there was a lot I wished to change for the better. It is very telling of the moral decline at the top of Cochrane that I received the most votes of all 11 candidates, although I was the only one who had dared criticize management. The Governing Board did not intend to publish the votes, but I demanded it with reference to the organization's principles of openness and transparency.

One of my first proposals was that we should not allow up to half of the authors of Cochrane reviews to receive financial support from the companies whose products they evaluate, which of course is detrimental to our credibility. Most of the Board members supported the proposal, and I was tasked with drafting a new policy in this area. It took me only an afternoon to rewrite the old policy from 2014, and I thought, a little naïvely perhaps, that we would then soon have a policy which we in decency could support.

That didn't happen. Six months later, Cochrane's Editor in Chief presented a very intricate plan for the Board. It described how we should work towards reaching a new policy. It was something about working groups and that everyone should be consulted and advised so that the more than 10,000 people contributing to Cochrane "could feel ownership of the project". A minority in the Board is external and I had persuaded a good friend and highly skilled lobbyist, former European Parliamentarian for Spain, to run as candidate for the Board, to which he was elected. We both protested saying that this is how you bury a good and necessary proposal. The Editor in Chief was very offended. During the discussion, he realised that I had done this little job six months earlier, but the co-chair of the Board, who directs the UK Cochrane Centre, had apparently not forwarded my proposal to him, probably because he did not support it.

Worst of all, the CEO introduced a Spokesperson Policy in 2015 as a direct response to a newspaper article I had written a year earlier in *Politiken* about ten harmful myths in psychiatry. Although he denies it, the CEO has used his policy to subdue freedom of speech to the great detriment for our work at the Nordic Cochrane Centre. His assertion is that we do not distinguish between whether our views are our own or whether they are official positions of the International Cochrane Collaboration. No one has ever been in any doubt about this, but people with industry interests have found that the CEO is their willing tool and therefore they routinely complain about us, e.g. about that we have used our own letterhead when writing letters or have mentioned in our articles that we work at the Nordic Cochrane Centre.

We dig very deeply and therefore often arrive at research results that are not popular in the industry or among specialist doctors. In the spring, there were two new complaints, which again were about my use of our own letterhead. As usual, the CEO opined that we had breached his Spokesperson Policy. I appealed to the Board, which has the task of making a decision when the CEO and a centre director disagree. However, the Board did not do this but initiated a legal investigation of everything I had done over the last 15 years, which was described in a folder of approx. 400 pages.

It was said that the investigation was "impartial", but Cochrane paid for it, which is clear from the report that praises Cochrane's leaders shamelessly. Nevertheless, the lawyer did not agree with the CEO that I had violated the Spokesperson Policy, and he also exonerated me of another strange accusation that had been construed, namely that I, as a member of the Board, was not allowed to write to the Board. It is hardly a coincidence that Cochrane has tried to keep Counsel's report secret.

But then our research on the HPV vaccines came to help the chairman of the Board. Although the Board denies it, it is a fact that this research played a key role in my expulsion from Cochrane.

In May 2018, the long-awaited, and highly prestigious, Cochrane review of the HPV vaccines was published. It is problematic. Contrary to Cochrane's rules, there were far too many researchers with financial conflicts of interest on the protocol for the review Cochrane had published, and after international protests, Cochrane had to throw out most of them.

My research group knows more about the topic than most people because we do research on the clinical study reports on the HPV vaccines we received from the European Medicines Agency. These reports can be of thousands of pages per trial, and they are far more reliable than the short papers the companies publish, especially with regard to harmful effects. We published our critique of the Cochrane review on July 27 in *BMJ Evidence-Based Medicine*. We demonstrated, among other things, that many studies and patients were missing in the Cochrane review. Our criticism was badly received by Cochrane's two chief editors, who thought it was exaggerated. It wasn't, and on September 17th, we published an even stronger criticism in the same journal after digging even deeper into the material. We demonstrated that important harms were missing, and that the first author had "forgotten" to declare that he had financial conflicts of interest in relation to the companies selling the vaccines. We expect to publish our own systematic review in the near future.

On August 30th, I sent my 66-page report (with 7 attachments) to Cochrane's lawyer, where I blankly rejected the 400-page charges against me. The following days several complaints were sent to the Board about me, including two from former Board chairmen, that were remarkably similar. They requested that I should be expelled from the Board because I had allowed myself to criticize a Cochrane review publicly in our own scientific article. This is, of course, what science is about: criticizing each other and making us all wiser. On top of this, the Spokesperson Policy encourages us to do this, and we also have an annual prize awarded to the one who, with constructive criticism, helps to make Cochrane's work better.

In our article in BMJ Evidence-Based Medicine, we also criticized Cochrane's PR, which cited people with conflicts of interest who were very positive towards the Cochrane review's findings.

We have good evidence for our suspicion that the chairman himself encouraged people to submit these new letters of complaint to him. However, it cannot reasonably be argued that a Board member or a person who has many Cochrane stripes on the shoulder, e.g. a centre director, is prohibited from criticizing Cochrane reviews publicly. Cochrane cannot survive that kind of censorship; it would kill the whole idea that created the Cochrane Collaboration.

At the board meeting on September 13, which ended with my expulsion, new accusations were fabricated against me, which I had not been informed about; nor was I allowed to defend myself against them. It was a genuine Kafkaesque process, where the verdict was that I had harmed the Cochrane Collaboration. In fact, I've contributed more than most people to the good reputation Cochrane has.

This happened during the annual Cochrane meeting, which took place in Edinburgh. We had a centre director's meeting three days later, where there was almost unanimous support among the 30-40 directors for me and my political strategy about preserving the freedom of speech. Several resistance groups were rapidly established, which had plans to overturn the rest of the Board with a vote of no confidence. However, the chairman held an animated speech that had the character of a 'hate speech', suggesting that I had done all sorts of things wrong without giving a single example. Now there was suddenly a focus on a third issue, namely a claim that I had been behaving badly for years. No one knew what this was about, myself included. A Cochrane editor from Finland asked the chairman twice to explain what it was about but did not get any answer.

The chairman of the Board was so manipulative with all his insinuations and untruthful statements that people went into shock by the obvious defamation of my instead of overturning the Board. It was cleverly done, but deeply shameful for the values the Cochrane Collaboration is based on.

The international reactions were pronounced, with articles in, for example, *Science*, *Nature*, *BMJ* and *Lancet*, which supported me. Nobody could understand why such a high-profile researcher was expelled from Cochrane.

A number of years ago, several Cochrane centres and editors received support from industry. I also led this battle against conflicts of interest, and I succeeded to put in place a total ban on this after a sharp confrontation between the two factions in Barcelona in 2003, mentioned in *BMJ* on 18 October that year.

The current affair is, of course, not about me but about something far bigger. I'm just the symptom that there is something totally wrong with Cochrane's leadership. Many senior executives in Cochrane had pinned their faith on me and had voted for me, but unfortunately, my career in the Board was short-lived and Cochrane's moral decline continues. Its credibility has suffered immensely, and it does not seem to stop.

The battle is far from over; it has just begun. We are several European Cochrane centres which have discussed whether we should become independent because we cannot defend the current direction of travel. By the way, we are not employed by Cochrane, but have obtained funds for our centres; e.g. the Nordic Cochrane Centre is on the government's budget. Therefore, we have always been very dissatisfied with the CEO acting as if he should decide everything we do - big and small. This pronounced centralized management may ruin the entire Collaboration, which is led by a man who does not understand science, but is trained as a journalist, with the Soviet Union and Eastern Europe as his special interests. This is clearly felt.

There is great and growing concern around the world over the course Cochrane has chosen under our new CEO, who joined us in 2012. Cochrane's moral crisis hurts, and its declining credibility has negative consequences for public health. The Cochrane Collaboration may well be the most important innovation in healthcare in the last century. We must continue the battle and get Cochrane back on track as the idealistic movement it was, until 2012.

Of course, I shall continue my work as usual, and I am still the head of the Nordic Cochrane Centre. I will also work on coming back to my organisation. Five new board members will be elected and there are other possibilities. It is not entirely black, but in these years, freedom of speech is threatened everywhere, also in Cochrane.

If you are interested in following the developments, you can do it via www.deadlymedicines.dk.