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Cochrane – A sinking ship?

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By *Maryanne Demasi, PhD*

A scandal has erupted within the Cochrane Collaboration, the world's most prestigious scientific organisation devoted to independent reviews of health care interventions. One of its highest profile board members has been sacked, resulting in four other board members staging a mass exodus.

They are protesting, what they describe as, the organisation's shift towards a commercial business model approach, away from its true roots of independent, scientific analysis and open public debate.

There are concerns that Cochrane has become preoccupied with “brand promotion” and “commercial interests”, placing less importance on transparency and delivering “trusted evidence”.

It began as a simmering personality clash, between the CEO and a board member, but now has boiled over into a spectacular war of words, where the underlying issues of Cochrane have bubbled to the surface, with many insiders predicting the beginning of the end of Cochrane.

The dispute

A meeting of the Trustees of Cochrane was convened in an effort to resolve an ongoing dispute between the CEO of Cochrane Collaboration, Mark Wilson and one of the founding fathers of the Cochrane Collaboration in 1993, Director of the Nordic Cochrane Centre, Peter C. Gøtzsche.

It began with, what might be perceived as, fairly trivial issues. Wilson accused Gøtzsche of using Cochrane's letterhead on a complaint to the European Medicines Agency about its evaluation of possible harms of HPV vaccines and testifying in a court case without overtly declaring his expert testimony was expressing ‘personal’ not ‘Cochrane’ views.

Wilson alleged that it constituted a breach in the ‘Spokesperson Policy’, a claim denied by Gøtzsche. The dispute intensified after several people complained to the Board about Gøtzsche's ‘take no prisoners’ approach to critiques of industry-funded science.

Gøtzsche is well-known for his blunt criticisms over the harms of breast cancer screening programs, the overuse of psychiatric drugs, and has referred to the drug industry as ‘organised crime’. But his most recent article, with co-authors Lars Jørgensen and Tom Jefferson, was a stinging critique of the quality and methodology of Cochrane's HPV vaccines review. [1]

Immediate backlash ensued and the Cochrane leadership, accused Gøtzsche's team of causing reputational damage to the organisation, fuelling anti-vaxxers and risking “the lives of millions of

women world-wide by affecting vaccine uptake rates”, according to a complaint by the editor of the Cochrane group that published the HPV review.

Gøtzsche stood by his group’s paper, sparking an urgent, internal review at Cochrane. On 3 Sept 2018, Cochrane’s Editor in Chief, David Tovey, and his Deputy, Karla Soares-Weiser, issued a [statement](#) claiming that the criticisms of the HPV vaccine review had been ‘substantially overstated’ and ‘inaccurate and sensationalized.’

“People all over the world have interpreted the Cochrane editors’ criticism of us as being the ‘final word’” said Gøtzsche in frustration. “The editors did not even address our most important concern that the harms of the HPV vaccine had been greatly under-reported and that much of the clinical data is not included in the review”.

Legal Review

The Board of Trustees agreed to engage the services of an external law firm to independently assess the dispute between Gøtzsche and Wilson. In July 2018, Gøtzsche was presented with 400 pages of documents, containing allegations that he had breached Cochrane policies and damaged its reputation.

Gøtzsche retaliated by submitting a 66-page dossier outlining, in painstaking detail, allegations that Wilson’s leadership team was ‘destroying’ Cochrane by treating it like it was a “brand or product”, accusing Wilson of “serious abuse and mismanagement of Cochrane”, “tampering with meeting minutes” and “management by fear”.

The lawyers poured over the mountain of documents and were expected to deliver a verdict in time for the 13 Sept Governing Board meeting. Twelve hours before the meeting started, the Counsel’s report was delivered to the Board with a caveat that inadequate time was granted for a thorough review of all the issues.

Nonetheless, the report found that none of the serious allegations against the Cochrane executive could be substantiated, nor did it find that Gøtzsche had breached the Spokesperson Policy or had acted inappropriately in his role as Trustee.

The Board Meeting

Co-chair, Marguerite Koster, allowed Gøtzsche ‘five minutes’ to state his case. Witnesses in the room say Gøtzsche was constantly interrupted before being asked to leave the room while the other Board members discussed the situation. Gøtzsche was given no further opportunity that day to defend himself.

After more than 6 hours of deliberation, the remaining 12 Board members voted on whether Gøtzsche could remain as their 13th Governing Board member and continue to practice under the Cochrane license.

Five voted to remain, six voted to remove and one abstained. In the end, a ‘minority’ vote [6 out of 13] saw Gøtzsche vacated from his position and lose his Cochrane membership. After 25 years of

service to Cochrane and author of 17 Cochrane reviews, Gøtzsche would officially learn of his fate by an email.

“No clear reasoned justification has been given for my expulsion aside from accusing me of causing ‘disrepute’ for the organization”, claims Gøtzsche. “This is the first time in 25 years that a member has been excluded from membership of Cochrane”.

Several board members were shocked over the treatment of Gøtzsche.

“The legal assessment essentially exonerated Peter of breaching the Spokesperson Policy so his enemies spent the day inventing new excuses to get rid of him”, said one member. “To expel Peter is totally disproportionate,” said another of Gøtzsche’s supporters. “It was like looking for any behavioural pretext to fire him.”

The following day, 14 Sept 2018, four members resigned from the Governing Board in solidarity for Gøtzsche and because they felt something drastic had to happen in order to save the organisation.

[See here: Why we resigned](#)

“What should happen now, is that entire Board should resign and start again”, said one member after their resignation.

On 15 Sept 2018, a statement to Cochrane Directors, from the co-chairs of the Governing Board, mentioned that four members resigned and that changes to the board were afoot, but did not mention Gøtzsche’s expulsion from the Board.

“I don’t understand why they are sticking they’re head in the sand”, said one board member. “They should do something now to address everyone’s concerns”.

Cochrane’s sinking ship

The events that have unfolded in the last few days have consequences for Cochrane far beyond dealing with the public embarrassment of losing more than a third of its Governing Board.

Much of Gøtzsche’s scientific work at the Nordic Cochrane Centre, has focused on exposing the flaws in clinical trials and the undue influence of the drug industry on medical research.

In addition, there are the issues raised in a recent [editorial](#), co-authored by Dr Tom Jefferson from Centre for Evidence-Based Medicine, Oxford. It explains the problems behind the reliance of data from published journal articles, many of which are likely to contain ‘unfathomable bias’.

“We know that the biomedical journals publish articles which are neutral at best, but are mostly positive and tend to emphasize benefits and downplay or even ignore harms,” says Jefferson.

“What you end up within the medical journals is a shoe-horn version or a summarized version and you don’t know what criteria go into choosing which bits goes into the print version. So that introduces unfathomable bias”.

Jefferson's answer to whether we should ignore evidence from journal articles was 'probably' unless urgent steps aren't taken to address the issue of reporting bias: cherry picking and spin of research findings

This presents Cochrane with an enormous problem. The lifeblood of the organisation is in carrying out systematic reviews. The basic evidence, upon which these reviews are founded, is largely at risk of bias, especially for interventions where there is a huge market.

"The contention that Cochrane has been publishing reviews that are mainly beneficial to the sponsors of these interventions is probably a fact," says Jefferson. "If your review is made up of studies which are biased and in some cases are ghost written or the studies are cherry picked and you don't take that into account in your review, then its garbage in and garbage out – its just that the 'garbage out' is systematically synthesised with a nice little Cochrane logo on it".

As for the data behind the HPV vaccines, it's a question of whether anyone has seen the full data set. "The answer is no-one outside the vaccine manufacturers. Not the drug regulators and certainly not, independent scientists" says Jefferson. "So if you were to ask me what I think of HPV vaccines, I would say 'I don't know' because I haven't seen the full data set".

Furthermore, Gøtzsche says that Cochrane's policy regarding the conflicts of interest of the authors of reviews is inadequate. "I proposed a year ago that there should be no authors of Cochrane reviews that have financial conflicts of interests with companies related to the products considered in the reviews," says Gøtzsche "But Cochrane did nothing about it".

Currently, Cochrane allows up to half of the authors on a review to have conflicts of interest, a policy that is widely criticized by insiders, and largely unknown to the public.

So why hasn't Cochrane done anything about it?

"Cochrane has become too sensitive to criticism of the pharmaceutical industry", says one board member. Insiders say a 'possible concern' might be that Cochrane fears that Gøtzsche's criticism of the HPV vaccines review would negatively impact its sponsorship from the Bill & Melinda Gates Foundation.

Scientific censorship

Cochrane has been accused of 'scientific censorship' and is now in 'damage control' to contain the PR nightmare.

Publicly, Cochrane has always maintained it encourages debate about scientific issues, including controversial ones. "Cochrane values constructive criticism of its work and publicly recognises this through the Bill Silverman Prize ... with a view to helping to improve its work, and thus achieve its aim of helping people make well-informed decisions about health care", states Cochrane.

However, the reality is very different. "They don't believe in democratic plural science", said one outgoing board member. "Good governance of science always requires open debates. The prestige of a scientific institution has to do with its ability to manage critical debates, not censor them".

“Science needs to be challenged, it should not be politically correct, it is not consensus seeking,” says Gøtzsche. “You cannot call a public challenge to science ‘controversial’, it’s a pejorative term. It’s simply what our job as scientists requires of us”.

The future of Cochrane

Cochrane is in a moral crisis and many say it has lost a democratic leadership. “On dozens of issues, the Board can only vote yes or no with very little opportunity to amend or modify the executive team’s proposals,” says Gøtzsche.

The entire US Cochrane Centre has already closed down in the spring of 2018, in frustration over management and other centre directors are also contemplating leaving Cochrane. Whereas those who’ve been critical of Cochrane’s direction, have simply withdrawn, Gøtzsche spoke out publicly and has borne the consequences.

“A recovery from this dire situation would call for the dissolution of the present board, new elections and a broad-based participatory debate about the future strategy and governance of the organization”, says Gøtzsche.

The Annual General Meeting on Monday (17th Sept) might shed light on Cochrane’s future.

DISCLOSURE: *Maryanne Demasi is a science reporter and a researcher working with Prof Peter C. Gøtzsche, the Nordic Cochrane Centre, and was present in Edinburgh at the time of the meeting, but not present in the discussion room.*

Reference: [The Cochrane HPV vaccine review was incomplete and ignored important evidence of bias](#). BMJ Evidence-Based Medicine Published Online First: 27 July 2018. doi: 10.1136/bmjebm-2018-111012