

Annual report and review 2015

Nordic Cochrane Centre



Cochrane
Nordic

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Introduction

Updated systematic reviews of clinical research are essential for rational decision making in health care and for guiding the planning of new research. The Cochrane Collaboration is a registered charity, founded in 1993. It's major product, The Cochrane Library, contains more than 6,000 regularly updated systematic reviews of interventions in health care.

It is a fundamental right that information that is important to the citizens is transparent and available. Few things are more important than having access to reliable information about the benefits and harms of interventions for preventing and treating diseases. Half of the world's population has free access to Cochrane reviews and the other half has free access to abstracts of Cochrane reviews. Our ultimate aim is to provide free access to Cochrane reviews for everyone; currently, our economy has allowed us to provide free access to all Cochrane reviews 12 months after they have been published or updated.

Cochrane reviews are indexed in PubMed. The impact factor of the Cochrane Database of Systematic Reviews is 6.0 and the Database is ranked 13 of the 153 journals in the Medicine, General & Internal category.

The Cochrane Collaboration engages over 30,000 people in over 100 countries. Its organisational structure is described at <http://www.cochrane.org/>.

We report here the main achievements of the Nordic Cochrane Centre for 2015 and the three review groups based in Denmark in relation to our Strategic Plan 2011-15. For general information about the centre, see <http://nordic.cochrane.org/>.

The Nordic Cochrane Centre is located at Rigshospitalet in Copenhagen. It was established on 13 October 1993, the same month the Cochrane Collaboration was launched. The work of the Centre is evaluated by the Cochrane Collaboration Steering Group. There are branches (in future called associate centres) in Finland, Norway, Poland and Russia, which perform similar work as the Centre but have less formal obligations. The branch in Russia is located in Kazan, Tatarstan, and it opened in 2015.

Six Cochrane groups are based in the Nordic countries: the Hepato-Biliary Group (Denmark), the Colorectal Cancer Group (Denmark), the Anaesthesia Group (Denmark), the Occupational Health Group (Finland), the Norwegian satellite of the Effective Practice and Organisation of Care Group (Norway), and the Cochrane Bias Methods Group (Denmark).

The Nordic Cochrane Centre and the three review groups based in Denmark are financed by the Danish Government. Other funders are listed in our Annual Reports (<http://nordic.cochrane.org/>). Like other Cochrane groups, we do not accept industry funding.

Citizens in Denmark, Iceland, Norway and Poland, and almost all physicians in Finland, have free Internet access to the Cochrane Library, which is often consulted in these countries.

Selected main achievements

The Nordic Cochrane Centre is internationally oriented. Over the years we have had employees from Armenia, Colombia, Denmark, the Faroe Islands, Finland, Germany, Iceland, India, Italy, Moldova, Nigeria, Norway, Pakistan, Spain, Sweden, the UK, and the USA. In addition, unpaid volunteers have helped us from China, Egypt, France, Japan, Netherlands, Poland, Portugal, and Russia.

In relation to the opening of the branch in Russia in December 2015, the Nordic Cochrane Centre's deputy director, Karsten Juhl Jørgensen, gave a lecture to the Tatarstan parliament on behalf of the Cochrane Collaboration, spoke at the opening ceremony and contributed to a full-day workshop.

The Centre has contributed substantially to the Cochrane Collaboration, particularly in research and IT development.

Research

The Centre is very strong in research and has published numerous papers in the “the big five” general medical journals (BMJ, Lancet, JAMA, Annals of Internal Medicine, and New England Journal of Medicine). For many years, we have published in one or more of these journals every year. Much of this research has a methodological component, which contributes to improving the quality and reliability of Cochrane reviews, randomised trials and other types of research and to knowledge translation, i.e. providing information to the public that is easy to understand.

We regularly update over 20 Cochrane reviews performed by staff members and also publish new reviews, focusing primarily on issues of major importance for public health or for rational use of health care resources. These reviews span many different topics, including screening for diseases or risk factors, infectious diseases, cancer, asthma, enzyme deficiency, liver disease, rheumatology, psychiatry, and the placebo effect.

Some of the biggest threats to evidence-based medicine and therefore also to the reliability of Cochrane reviews are flawed designs, flawed analyses, selective reporting of favourable results and omission of major harms in trials. It has been abundantly documented that published reports of drug trials are generally unreliable, and that this leads to much unnecessary and harmful treatment of patients and to a huge waste in drug expenditure. We continue to contribute importantly to this type of research, and we and others have demonstrated that not even the voluminous clinical study reports that drug companies submit to drug agencies for obtaining marketing approval for their drugs are reliable but tend to downplay or omit major harms of drugs.

We currently work with clinical study reports on antidepressants that we have obtained from European drug regulators. This has resulted in a PhD in 2015; another is on its way. So far, we have published three of our papers in BMJ.

We continue to expand our research collaboration with colleagues internationally, primarily with researchers in Canada, France, Italy, Norway, Sweden, the UK, and the USA. We co-author guidelines on standards for good reporting of research: CONSORT for trials, STROBE for

observational studies, PRISMA for systematic reviews and SPIRIT for protocols, which many top journals advise or require authors to adhere to when they submit manuscripts.

Value of the Centre for Denmark

The Nordic Cochrane Centre and the three Cochrane review groups based in Denmark have been funded by the Danish government since 2001. This investment has paid off handsomely. It has saved billions of Danish crowns, which we shall illustrate with three examples. Taken together, the three reports we produced have saved over 500 mio Danish crowns annually, which is about 100 times greater than our annual budget.

Mammography screening was carried out in Denmark in the 1990s in a limited geographical area, corresponding to 20% of the population in the relevant age group. In 1997, a report from the National Board of Health recommended it be introduced in the rest of the country, but the Danish Medical Association had doubts about its effects. We were asked to assess the trials in 1999, which took us just four weeks. Our conclusion was that we could not exclude the possibility that screening did more harm than good. Next, the National Board of Health funded a Cochrane review, which we published in 2001, with similar reservations. Mainly because of our research, the Danish regions decided to postpone the introduction of screening in the remaining 80% of the country, but were ultimately forced to introduce it by the government. From late 2007, the remaining regions gradually introduced screening although coverage was not complete even as late as in 2014 due to lack of staff. We have published many papers on mammography screening and a 388-page book and have explained why we are convinced that it does more harm than good and should be stopped. In all those years where we only had screening in 20% of the country, Danish taxpayers were spared around 200 mio Danish crowns every year. Our Cochrane review on mammography screening is in top ten for world-wide downloads of Cochrane reviews.

In 2008, a majority in Parliament wanted to reimburse alpha-1 antitrypsin for treatment of patients with lung disease who had this enzyme deficiency. However, the Health Committee asked the Nordic Cochrane Centre's director, Peter Gøtzsche, to assess the trials, and he delivered a report after four weeks. His conclusion was very clear: There was no good reason to use the treatment. The results of the two randomised trials showed no conclusive effect on lung function, and there was a lack of data on patient relevant outcomes, for example symptoms, quality of life, acute exacerbations, infections and survival. Two years earlier, the Danish Drug Agency had claimed that treatment with alpha-1-antitrypsin could reduce the loss of lung function and reduce mortality, but there was no reliable evidence for these claims, and the drug agency did not respond to Gøtzsche's request for documentation for these effects. Gøtzsche later wrote a Cochrane review of this treatment. Based on his initial report, reimbursement of the drug was declined, which has saved at least 100 mio Danish crowns annually.

General health checks are popular but we decided to do a Cochrane review to find out whether they worked. When we saw the results in 2011, we asked for a meeting with the Minister of Health and she abandoned the governments plans of introducing it, as the results were very convincing. There were almost 12,000 deaths in the trials but no effect on mortality whereas the intervention led to more diagnoses, which increase drug usage. It is therefore likely that health checks do more harm than good. Our review has saved over 200 mio Danish crowns annually.

Advocating for transparency in research

If science cannot be checked or repeated by others, independently from those who did the original research, science ceases to exist. Unfortunately, this is often the case in health care research, and we therefore continue to prioritise our work with opening up the unpublished data at drug agencies and elsewhere, e.g. at research ethics committees, and to advocate for sharing the raw, anonymised patient data.

Our biggest achievement was our breakthrough with the European Medicines Agency in 2010 (BMJ 2011;342:d2686). The agency refused to provide us access to unpublished clinical study reports and trial protocols, claiming it needed to protect the drug industry's commercial interests. It didn't impress the agency the least that we documented that this secrecy cost human lives, but after three years of battle the agency was forced by the European Ombudsman, to whom we had appealed, to open its archives and to change its policy from one of extreme secrecy to openness. 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.

However, the fight for open science, human rights and respect for the patients without whose altruistic contribution to research none of us would have any data, is a never ending battle. We have observed that the European Medicines Agency in many different ways tries to wind the clock back. We therefore collaborate with and support consumer organisations and other bodies, e.g. the Trans Atlantic Consumer Dialogue, the International Society of Drug Bulletins and the AllTrials campaign, and work actively with members of the European and other parliaments, the European Ombudsman, and many other decision makers.

As explained in our 2014 Annual Report, the Centre's director, Peter Gøtzsche, was very active at the political level in the European Parliament for several years as a scientific lobbyist, collaborating primarily with Margrete Auken, MEP for the Greens (Denmark), and David Hammerstein, previous MEP for Spain and representing the Trans Atlantic Consumer Dialogue. The EU Parliament succeeded in changing the European Commission's proposed revision of the Clinical Trials Directive completely, from being pretty poor and maintaining the secrecy around drug trial results to becoming pretty good. Rather detailed reports of all new drug trials will now become publicly available at a new EU Portal no later than 12 months after the trial is finished.

Dissemination of research

Dissemination of the results of Cochrane reviews and knowledge translation (which means providing information in a more easily understandable format than reviews) are important goals for the Collaboration. Cochrane reviews are being widely used in the Nordic area; in 2015, there were 308,839 downloads from the Cochrane Library in Denmark, Norway, Sweden and Finland.

Cochrane reviews are also being widely cited in the Nordic area, and we are contacted by over 100 different journalists every year who come to us because it is difficult to find experts in health care who do not have financial conflicts of interest or are biased in other ways. We established a partnership with the Journal of the Danish Medical Association many years ago, which means that published comments on Cochrane reviews have appeared regularly in that journal.

In the Danish Infomedia database, “Cochrane” appeared 544 times in 2015, of which 33 were in national newspapers. This list is not complete. For example, there were 9 listed appearances in radio or TV, which is far below the number of times researchers at the Centre actually appeared on national radio or TV. In addition to the national appearances, we give many interviews to the media in other countries, particularly in the UK, USA and Australia. We also write many newspaper articles and letters to the editors in scientific journals, and upload comments on PubMed abstracts when we find that published research is seriously misleading.

The Centre’s director, Peter Gøtzsche published an evidence-based book in 2013, "Deadly medicines and organised crime: How big pharma has corrupted health care." It has about 900 references that details the many flaws in drug trials, the widespread corruption of doctors, and the pervasive criminal activities in the drug industry, both in research and marketing. Gøtzsche published another evidence-based book in 2015, "Deadly psychiatry and organised denial," also with hundreds of references. There are many citations to important Cochrane work in the two books (“Cochrane” appears 90 and 131 times, respectively), and they are being widely translated, also into small languages like Finnish, Greek and Swedish. We have been contacted by more than 40 TV and film crews from seven countries for documentaries based on the books and have participated in numerous radio shows. We see the books as very important contributions to the goals of the Cochrane Collaboration, as they help the citizens to make more informed decisions about the drugs they are being offered by their physicians who rarely know much about drugs that goes beyond what the drug industry has told them. This is an important reason why our prescription drugs are the third leading cause of death after heart disease and cancer, and why psychiatric drugs alone also seem to be the third major killer. We must therefore do our utmost to demedicalise our societies and one way to do this is to inform our citizens that drugs are much more dangerous than think they are and very often don't have the benefits they are supposed to have.

We have conducted a series of PhD courses of relevance for production and understanding of Cochrane reviews and of the principles for evidence-based medicine. We also routinely involve medical students in our research.

We have an informal partnership with the National Board of Health. A previous PhD from our centre works full-time there with clinical guidelines and our deputy director works part-time as a methods consultant. This means that the guidelines have become more evidence-based and also that there are more reservations against the recommendations when the trial evidence is biased, which it virtually always is.

IT development

One of the Nordic Cochrane Centre's core contributions to Cochrane has been to produce two central software tools: RevMan and Archie. RevMan is the desktop application that gives Cochrane authors a user-friendly interface to write the complex structure of Cochrane reviews. Archie is the central web application where all Cochrane groups manage their members, reviews, documents and editorial workflows. Archie also handles the data delivery to the Collaboration's publisher and supports the Collaboration's monitoring responsibilities.

The Nordic Cochrane Centre's pivotal role in development of Cochrane software started in 1996 with the employment of MSc Rasmus Moustgaard. In 2015, the staff counted eight people whose

employment was transferred from the Centre to Cochrane's headquarters in the UK. This was a unilateral decision that was not motivated by poor performance or dissatisfaction with the work carried out in the foregoing 19 years. The Centre, which had invested more than 30 mio Danish crowns in software development during these years, asked the Cochrane Steering Group for financial compensation in relation to the takeover, but none was granted.

Review Groups in the Nordic region

Cochrane Hepato-Biliary Group

The group was registered on 29 March 1996 and is based in Copenhagen. In April 2016, the Cochrane Library contained 182 reviews and 128 protocols. For further information, see the Cochrane Library or <http://hbg.cochrane.org/>.

Cochrane Colorectal Cancer Group

The group was registered on 27 January 1998 and is based in Copenhagen. In April 2016, the Cochrane Library contained 108 reviews and 73 protocols. For further information, see the Cochrane Library or <http://cc.cochrane.org/>.

Cochrane Anaesthesia, Critical and Emergency Care Group

The Anaesthesia Group (CARG) was registered in February 2000 and is based in Copenhagen. In April 2016, the Cochrane Library contained 176 reviews and 74 protocols. For further information, see the Cochrane Library or <http://ace.cochrane.org/>.

Cochrane Work Group: Health & Safety at work

The Work Group was registered in July 2010 and is based in Kuopio. In April 2016, the Cochrane Library contained 23 reviews and 16 protocols. For further information, see the Cochrane Library or <http://work.cochrane.org/>.

Norwegian Satellite of the Cochrane Effective Practice and Organisation of Care (EPOC) Group

The Norwegian EPOC Satellite was launched in Oslo in November 2006. The aim of the satellite is to support review authors in low- and middle-income countries and reviews relevant to such countries, as well as supporting EPOC review authors in the Nordic area. For further information, see The Cochrane Library or <http://epoc.cochrane.org/>.

Cochrane Bias Methods Group

The Bias Methods Group moved its secretarial base from Ottawa in Canada to Odense in Denmark on 1 January 2016. The group's main aims are to undertake methodological research on how to identify and address potential biases in systematic reviews and meta-analyses; help to complete and co-ordinate systematic reviews of methods; to provide guidance to Cochrane

groups; and to update relevant sections of the Cochrane Handbook. For further information, see The Cochrane Library or <http://methods.cochrane.org/bias/>.

Nordic Cochrane reviews

Review production in the Nordic countries is very high (see Peter Gøtzsche, Britta Tendal and Mike Clarke. Review production in The Cochrane Collaboration – where is it happening and why? Cochrane Methods. Cochrane DB Syst Rev 2011 Suppl 1:16-9). Measured as number of reviews per 1 million inhabitants, Denmark was ranked 6, Norway 10 and Finland 11.

In issue 3, 2015 of The Cochrane Library, 185 reviews and 81 protocols were listed with a Nordic contact address:

Country	Reviews	Protocols
DENMARK	94	46
NORWAY	39	16
FINLAND	33	4
SWEDEN	11	9
RUSSIA	4	0
POLAND	4	6
Total	185	81

Advisory Board for the Nordic Cochrane Centre

The Advisory Board for the Nordic Cochrane Centre provides advice and support about the strategic direction for activities within the Centre. In 2015, the members were:

Douglas Altman, Professor of Statistics in Medicine, Oxford, UK

Gerd Antes, Director, German Cochrane Centre

Mike Clarke, former Director, UK Cochrane Centre

Sine Jensen, Senior Health Adviser, Danish Consumer Council

Cindy Mulrow, Editor, Annals of Internal Medicine

Maryann Napoli, Associate Director, Center for Medical Consumers, USA

Drummond Rennie, Editor, JAMA

David Tovey, Editor-in-Chief, The Cochrane Collaboration

Erick Turner, Department of Psychiatry, Oregon Health & Science University

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and institutions since the Centre was founded in 1993; see previous Annual Reports and Strategic Plans on <http://nordic.cochrane.org/>. Currently, the funders for the Centre or its projects are:

- Danish Government
- Laura and John Arnold Foundation
- Rigshospitalet
- University of Copenhagen

Awards

Peter C Gøtzsche:

Honourable Award, Consul General Ernst Carlsen's Foundation, Danish Medical Association.
Book of the Year, US Tributaries Radio, "Deadly Psychiatry and Organised Denial."

Publications by staff at the Nordic Cochrane Centre

PhD dissertations

Bello S. Blinding and the risk of unblinding in animal model experiments and randomised clinical trials. Defended 11 June at the University of Copenhagen, Faculty of Health. Own print 2015 (100 pages).

Krogsbøll LT. Benefits and harms of general health checks and screening with urinary dipsticks. Defended 22 June at the University of Copenhagen, Faculty of Health. Own print 2015 (288 pages).

Schroll JB. Unpublished data, particularly in relation to harms, in clinical trials. Defended 27 Feb at the University of Copenhagen, Faculty of Health. Own print 2015 (83 pages).

Books

Gøtzsche PC. Deadly psychiatry and organised denial. Copenhagen: People's Press; 2015.

Gøtzsche PC. Dødelig psykiatri og organiseret fornægtelse. København: People's Press; 2015.

New or updated Cochrane reviews and protocols

Johansen HK, Gøtzsche PC. Vaccines for preventing infection with *Pseudomonas aeruginosa* in cystic fibrosis. Cochrane Database Syst Rev. 2015;8:CD001399.

Krogsbøll LT, Jørgensen KJ, Gøtzsche PC. Screening with urinary dipsticks for reducing morbidity and mortality. *Cochrane Database Syst Rev.* 2015;1:CD010007.

Markova V, Norgaard A, Jørgensen KJ, Langhoff-Roos J. Treatment for women with postpartum iron deficiency anaemia. *Cochrane Database Syst Rev.* 2015;8:CD010861.

Journal articles and reports

Beck AM, Iepsen UW, Topperup R, Juhl Jørgensen K. Danish evidence-based clinical guideline for use of nutritional support in pulmonary rehabilitation of undernourished patients with stable COPD. *Clin Nutr ESPEN.* 2015;10(1):e33-e41.

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Jørgensen KJ. [Screening for colorectal cancer in Denmark – better prioritization and honest information is needed]. *Månedsskrift for Almen Praksis* 2015;496-503.

Jørgensen KJ (co-author/methods consultant): National Clinical Guideline for Treatment of ADHD in Adults – Published February 2015.

Jørgensen KJ (co-author/methods consultant): National Clinical Guideline for Treatment of Cervical Radiculopathy – Published May 2015]

Keen JD, Juhl Jørgensen K. Four Principles to Consider Before Advising Women on Screening Mammography. *J Womens Health* 2015 Oct 23.

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst Rev.* 2015;4:1.

Rasmussen KM, Schroll J, Gøtzsche PC, Lundh A. Under-reporting of conflicts of interest among trialists: a cross-sectional study. *J R Soc Med.* 2015;108:101-107.

Rasmussen JV, Olsen BS, Sorensen AK, Hróbjartsson A, Brorson S. Resurfacing hemiarthroplasty compared to stemmed hemiarthroplasty for glenohumeral osteoarthritis: a randomised clinical trial. *Int Orthop.* 2015;39(2):263-269.

Rugbjerg M, Iepsen UW, Jørgensen KJ, Lange P. Effectiveness of pulmonary rehabilitation in COPD with mild symptoms: a systematic review with meta-analyses. *Int J Chron Obstruct Pulmon Dis.* 2015;10:791-801.

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Other

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Boesen K, Lykkemark A, Jørgensen KJ. Replik: [Ugeskriftet should not bring drug commercials]. Ugeskr Læger 2015;25:2446.

Danborg PB, Simonsen AL, Hrobjartsson A, Gøtzsche PC. Risk of bias assessment in preclinical research supporting clinical practice. 2015. Abstract from The Inaugural REWARD/EQUATOR Conference, UK.

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