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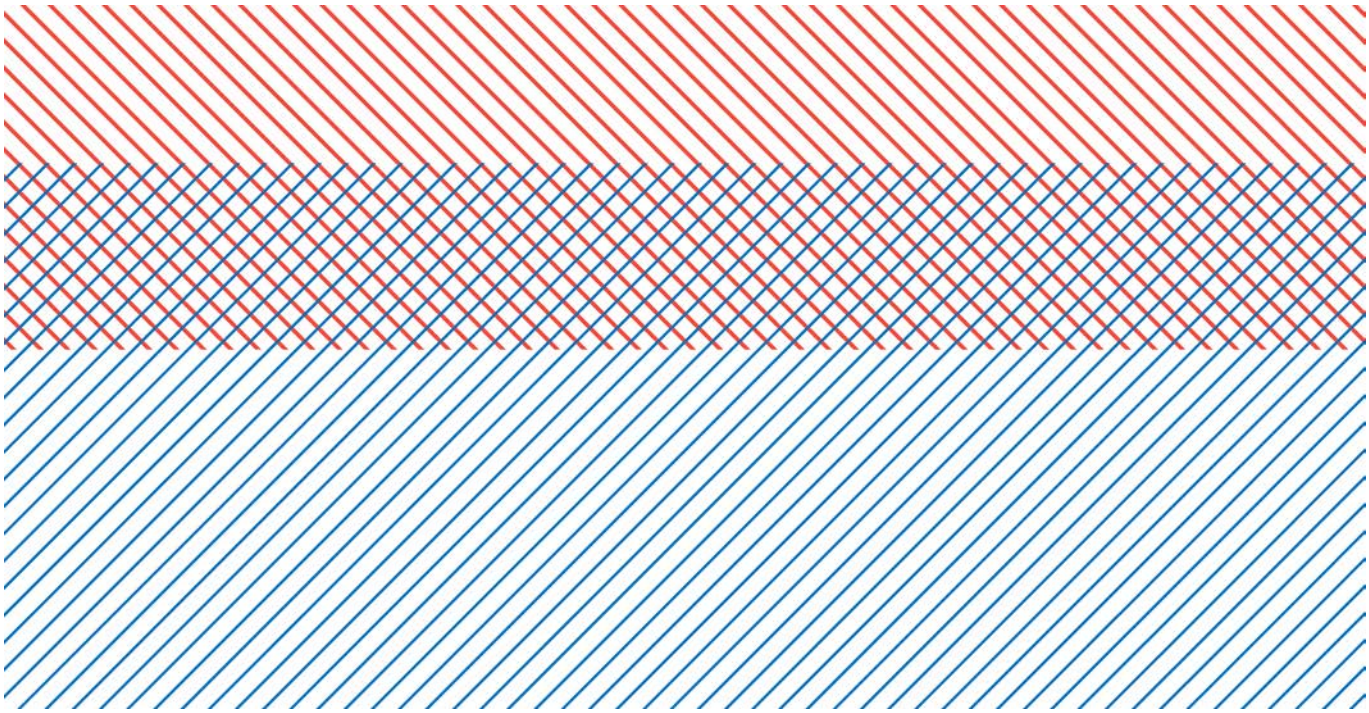
Evaluering af Nordic Cochrane Centre og Copenhagen Trial Unit



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Evaluering af Nordic Cochrane Centre og Copenhagen Trial Unit

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Forord

Sundheds- og Ældreministeriet har bedt VIVE om at gennemføre en evaluering af Nordic Cochrane Centre (NCC) og Copenhagen Trial Unit (CTU).

VIVE har valgt at designe evalueringen som en klassisk forskningsevaluering og har lagt det ud til et eksternt og uafhængigt evalueringspanel af internationale eksperter at udarbejde en evalueringsrapport for henholdsvis NCC og CTU.

VIVE har designet og organiseret evalueringen og har i alle evalueringens faser faciliteret evalueringspanelets arbejde. Afrapporteringsmæssigt adskiller evalueringen sig dog fra de fleste andre VIVE projekter ved, at det ikke er VIVE, der har draget konklusionerne og udarbejdet evalueringsrapporterne, men et evalueringspanel bestående af internationale eksperter.

I dette "forklæde" til det internationale evalueringspanels evalueringsrapporter præsenterer VIVE evalueringens formål og det valgte evalueringsdesign samt sammenfatter de konklusioner, som evalueringspanelet har draget. Evalueringspanelets fulde evalueringsrapporter (på engelsk) er optrykt i Bilag 3 (NCC) og Bilag 4 (CTU).

VIVE ønsker at sende en stor tak til de to centre og de tre tilknyttede Cochrane Review-grupper for det store arbejde, de har lagt i evalueringen og for et godt og konstruktivt samarbejde gennem hele evalueringen. Derudover skal der lyde en stor tak til de samarbejdspartnere og interessenter, som har stillet sig til rådighed for interview mv. i forbindelse med evalueringspanelets *site-visit* og i forbindelse med VIVEs supplerende kvalitative dataindsamling. Endelig skal lyde en særlig tak til evalueringspanelets medlemmer og ikke mindst panelets formand og næstformand for et stort, kompetent og engageret evalueringsarbejde.

Evalueringen er bestilt og finansieret af Sundheds- og Ældreministeriet.

Pia Kürstein Kjellberg
Forsknings- og analysechef for VIVE Sundhed
2019

Indhold

Sammenfatning og konklusion

Sundheds- og Ældreministeriet har bedt VIVE om at gennemføre en evaluering af Nordic Cochrane Centre (NCC) og Copenhagen Trial Unit (CTU). Denne rapport præsenterer evalueringens formål og design samt sammenfatter evalueringens resultater.

Hovedformålet med evalueringen har været at afklare, hvorvidt formålet bag finanslovsbevillingen til NCC og CTU er opfyldt, samt at undersøge omfanget af forskningsproduktionen og den forskningsmæssige kvalitet samt centrenes impact og eksterne samarbejdsrelationer.

VIVE har valgt at designe evalueringen som en klassisk forskningsevaluering og har i samarbejde med Danmarks Frie Forskningsfond nedsat et eksternt og uafhængigt evalueringspanel bestående af seks internationale eksperter, som har haft ansvaret for at udarbejde en evalueringsrapport for henholdsvis NCC og CTU.

Det internationale evalueringspanel har udarbejdet evalueringsrapporterne på grundlag af tre hovedkilder af data:

- Selvevalueringsrapporter fra de to centre
- Supplerede data og analyser fra VIVE
- Et tredages *site-visit* i København.

Evalueringsrapporterne indeholder et "executive summary" samt evalueringspanelets vurdering af de to centre inden for hvert af følgende fire evalueringstemaer:

1. Ledelse og organisering
2. Forskningsproduktion og kvalitet
3. Impact og relevans
4. Samarbejdsrelationer.

Evalueringspanelets fulde evalueringsrapporter er indsat som Bilag 3 og Bilag 4 i denne rapport.

Hovedkonklusion

For begge centre er evalueringspanelets overordnede konklusion, at formålet med finanslovsbevillingen er opfyldt.

I evalueringen af NCC fremhæver evalueringspanelet, at NCC har bidraget til at informere og kvalificere beslutninger inden for sundhedsområdet gennem tilvejebringelse og syntetisering af højkvalitets evidensbaseret viden, samt at dette er opnået gennem et betydeligt bidrag til at forbedre kvaliteten af den evidens, der er til rådighed for beslutningstagere, inklusive patienter og offentligheden. Dette er sket gennem udviklingen af robuste metoder og advokering for brug af disse gennem publicering i *high-impact* forskningstidsskrifter og gennem træning. Feedback fra interessenter peger endvidere på, at NCC har et godt omdømme baseret på kvaliteten, uafhængigheden og vigtigheden af centerets arbejde og ophænget til Cochranes overordnede mission. Evalueringspanelet ser dog også et behov for et tættere samarbejde mellem NCC og de i Danmark lokaliserede Cochrane Review-grupper samt en øget involvering af interessenter og for reetablering af et advisoryboard af medlemmer med tilknytning til den sundhedspolitiske dagsorden og kliniske dagsorden i Danmark.

I evalueringen af CTU fremhæver evalueringspanelet, at CTU, ifølge panelets vurdering, har indfriet centerets primære mål om at støtte, koordinere og gennemføre randomiserede kliniske forsøg, deltagelse i udviklingen af metoder til randomiserede kliniske forsøg og meta-analyser, uddanne studenter og forskere i evidensbaseret medicin, randomiserede kliniske forsøg, meta-analyser og sekventielle analyser; og støtte, koordinere og gennemføre systematiske reviews af litteraturen. Evalueringspanelet vurderer endvidere, at CTU har publiceret sin forskning i en vifte af *high-impact* forskningstidsskrifter, og at centerets studier har haft betydelig impact gennem indvirkning på klinisk praksis og stimulering af offentlig debat og diskussion.

Behov for at overveje muligheden for et ændret organisatorisk setup

Trods de to centres anseelige præstationer og den overordnede konklusion om, at formålet med finanslovsbevillingen er opfyldt, stiller evalueringspanelet for både NCC og CTU spørgsmålstegn ved bæredygtigheden af den nuværende organisationsmodel i lyset af centrenes begrænsede størrelse, afhængighed af ministeriel finansiering, placering på Rigshospitalet og komplekse styringsstruktur. Evalueringspanelet konkluderer således, at der for både NCC og CTU er et presserende behov for at overveje mulighederne for et ændret organisatorisk setup.

1 Baggrund og formål

Sundheds- og Ældreministeriet har bedt VIVE om at gennemføre en evaluering af Nordic Cochrane Centre og Copenhagen Trial Unit.

Baggrunden er, at Nordic Cochrane Centrr (NCC) og Copenhagen Trial Unit (CTU) hvert år modtager en finanslovsbevilling. I Finansloven for 2018 var den samlede bevilling til de to centre på 17,8 millioner kroner.

I finansloven står, at *"Aktiviteterne indenfor Cochrane området omfatter bl.a. udarbejdelse af systematiske oversigter over sundhedsvæsenets interventioner, forebyggelse af sygdomme, diagnostik, behandling og pleje. CTU understøtter og udfører videnskabeligt relevante kliniske forsøg, bl.a. som led i Cochrane-samarbejdet"* (Finansloven 2018, § 16.51.03.45).

Hovedformålet med evalueringen er at afklare, hvorvidt formålet bag finanslovsbevillingen er opfyldt, samt at undersøge omfanget af forskningsproduktionen og den forskningsmæssige kvalitet samt centrenes impact og eksterne samarbejdsrelationer.

Konkret sætter evalueringen fokus på følgende fire evalueringstemaer:

1. Ledelse og organisering
2. Forskningsproduktion og kvalitet
3. Impact og relevans
4. Samarbejdsrelationer.

Ud over NCC og CTU omfatter evalueringen også de tre Cochrane Review-grupper, som er lokaliseret i Danmark:

1. The Cochrane Colorectal Group (CCG),
2. The Cochrane Anaesthesia Group and the Emergency and Critical Care Group (ACE)
3. The Cochrane Hepato-Biliary Group (CHBG).

Evalueringen er designet som en klassisk forskningsevaluering. Heri ligger blandt andet, at evalueringen af de to centre og udarbejdelsen af evalueringsrapporterne er foretaget af et evalueringspanel bestående af internationale eksperter. Evalueringspanelet har udarbejdet en engelsksproget evalueringsrapport for henholdsvis NCC og CTU. Disse to evalueringsrapporter er indsat som Bilag 3 og Bilag 4 i denne rapport og indeholder begge et "executive summary" samt en vurdering af de fire evalueringstemaer.

Evalueringspanelets sammensætning og det samlede evalueringsdesign er nærmere beskrevet i kapitel 2,

2 Evalueringsdesign

Evalueringen af NCC og CTU anlægger en klassisk tilgang til forskningsevalueringer. Baseret på en kombination af kvantitative og kvalitativ data er der indsamlet viden om både forskningscentrenes videnskabelige produktion og dens kvalitet samt centrenes forskningsmæssige impact i samfundet.

Inden for forskningsevaluering er der en række forskellige tilgange og metoder, som hver især trækker visse elementer ved institutionen i forgrunden (Hansen, 2009; Garret-Jones, 2000). Forskningsevalueringer fokuserer typisk på enten forskningens indflydelse i det akademiske miljø eller i samfundet generelt. Indflydelse i det akademiske miljø undersøges via data om forskningsproduktionen, dennes impact og institutionens relationer i det akademiske miljø. Indflydelse i samfundet undersøges via data om deres nytte og betydning for samfundet, samt om hvordan institutionen indgår i samspil med omgivelserne.

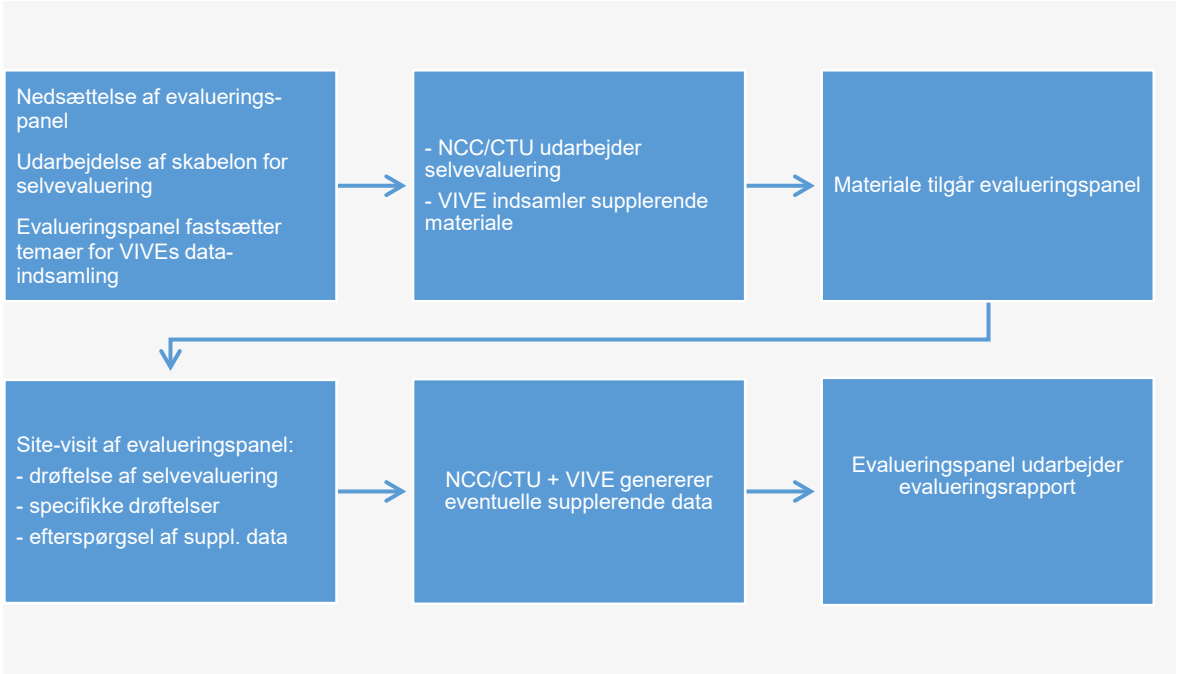
Det primære formål med et evalueringsdesign er, at det indhenter de data, der er relevante for evalueringens formål i egnet omfang og format. Data som ofte bruges til forskningsevaluering er kvantitative opgørelser over forskningsproduktionen gennem fx optælling af forskningsproduktion, brug af bibliometriske forskningsindikatorer og citationsanalyser (se fx Hidalgo og Espinar, 2017). Derudover anvendes også kvalitative data som fx interview og peer-review. Ofte kombineres disse metoder (Pedersen, 2017; Hansen 2009), hvilket også er denne evalueringsfremgangsmåde.

Evalueringen af NCC og CTU følger dermed den gængse fremgangsmåde for forskningsevaluering, og i evalueringsdesignet har VIVE lagt vægt på:

- at selve evalueringen foretages af internationale, uvildige eksperter på området, som sammensættes i et evalueringspanel
- at de to centre foretager en selvevaluering på baggrund af en skræddersyet evalueringsskabelon, udviklet og kvalitetssikret af VIVE
- at VIVE både selvstændigt og på forespørgsel af evalueringspanelet indhenter relevante data til at supplere selvevalueringerne
- at evalueringspanelet mødes på centrene (*site-visit*) og vurderer det materiale, som er indhentet om centrene
- at evalueringspanelet udarbejder evalueringerne på baggrund af selvevalueringerne, supplerede data og analyser udarbejdet af VIVE samt fra evalueringspanelets site-visit.
- at der udarbejdes selvstændige evalueringsrapporter for hvert af de to centre.

Den samlede evalueringsproces er illustreret i Figur 1.

Figur 1: Evalueringsprocessen



Hovedelementerne i evalueringsdesignet er beskrevet nærmere nedenfor

2.1 Evalueringspanel

For at sikre en uvildig og kvalificeret evaluering er nedsat et evalueringspanel bestående af internationale eksperter. Det er evalueringspanelet, der har udarbejdet den endelige evaluering, og det er panelet, som står som afsender af evalueringen. Evalueringspanelets rapport dækker følgende områder:

1. Ledelse og organisering
2. Forskningsproduktion og kvalitet
3. Impact og relevans
4. Samarbejdsrelationer.

Formanden for evalueringspanelet har i samarbejde med panelets næstformand haft det overordnede ansvar for evalueringspanelets arbejde og udarbejdelse af evalueringen.

Formanden for evalueringspanelet er blevet udpeget af Danmarks Frie Forskningsfond (DFF) efter indstilling fra VIVE. Ved indstillingen af formanden for evalueringspanelet er der blevet lagt vægt på, at denne skulle være en international anerkendt forsker inden for det kliniske område, have kendskab til det ledelsesmæssige og strategiske arbejde med forskningsinstitutioner på internationalt niveau samt have erfaring med at lede store, internationale forskningsprojekter og/eller forskningscentre. I valget af formand er endvidere lagt stor vægt på uvildighed i forhold til de to centre, og der er foretaget individuelle vurderinger af, om mulige kandidater til formandsposten har en tilpas distance til både de danske organisationer og disses internationale bagland.

VIVE har udpeget de øvrige medlemmer af evalueringspanelet efter indstilling fra DFF. VIVE bad DFF om at indstille tre internationalt anerkendte forskere fra det sundhedsvidenskabelige råd under DFF[1] og to internationalt anerkendte forskere fra det samfundsvidenskabelige råd under DFF[2]. Kandidaterne fra det sundhedsvidenskabelige råd skulle have indsigt i processer og metoder knyttet til brugen af randomiserede studier, systematiske reviews og erfaring med at vurdere kvaliteten og relevansen af sundhedsfaglig forskning. Kandidaterne fra det samfundsvidenskabelige råd skulle have indsigt i organisering og ledelse af forskningscentre på sundhedsområdet samt have indsigt i det danske sundhedsvæsens organisering og ledelse. For at sikre evalueringens uvildighed var det endvidere et vigtigt kriterium, at panelmedlemmerne ikke måtte have haft tæt samarbejde eller andre tætte relationer med de to centre eller deres internationale baglandsorganisationer de sidste fem år, som kunne give anledning til habilitetsproblemer i forhold til evalueringen af de to centre. I overensstemmelse med ligestillingsloven indstiller DFF både en mand og en kvinde til hver plads i evalueringspanelet.

Efter at DFF havde gennemført en proces med indstilling og udsendelse af invitationer til de indstillede, modtog VIVE en liste fra DFF med fem forskere fra det sundhedsvidenskabelige råd og to forskere fra det samfundsvidenskabelige råd. På grundlag af denne liste udpegede VIVE efter samråd med evalueringspanelets formand de øvrige medlemmer af evalueringspanelet. Baseret på en samlet vurdering af kandidaternes individuelle og komplementære kvalifikationer udpegede VIVE tre af de fem forskere, som havde accepteret invitationen fra det sundhedsvidenskabelige råd, og de to forskere, som havde accepteret invitationen fra det samfundsvidenskabelige råd. Alle panelmedlemmer er udpeget i kraft af deres personlige kompetencer. Sammensætningen af udvalget har været i høring hos NCC og CTU.

Evalueringspanelet består samlet set af seks medlemmer med komplementære kompetencer inden for sundhedsvidenskabelige reviews, klinisk forskning, *trials* samt ledelse og organisering af sundhedsforskning:

- Amanda Sowden (formand). Professor and Deputy Director and leader of the University of York's Centre for Reviews and Dissemination's research programme in public health, United Kingdom
- Terje P. Hagen (næstformand). Professor and Head at the Institute of Health and Society, University of Oslo, Norway
- Diederick Grobbee. Professor of Clinical Epidemiology and founder of the Julius Center, University Medical Center Utrecht, The Netherlands
- Eva Swahn. Professor at the Department of Medical and Health Sciences, Division of Cardiology, Linköping University & the Department of Cardiology, University Hospital, Linköping, Sweden
- Merete Osler. Clinical Professor at the Department of Public Health, University of Copenhagen & Consultant at the Center for Clinical Research and Prevention, Bispebjerg and Frederiksberg Hospital, Denmark
- Mickael Bech. Professor in healthcare leadership at Crown Prince Frederik Center for Public Leadership, Aarhus University, Denmark.

Dette internationale evalueringspanel har udarbejdet evalueringsrapporterne for henholdsvis NCC og CTU. Panelets arbejde med at evaluere de to centre har været baseret på en

[1] Danmarks Frie Forskningsfond | Sundhed og Sygdom
[2] Danmarks Frie Forskningsfond | Samfund og Erhverv (FSE)

evalueringsprotokol med konkrete evalueringsspørgsmål (se Bilag 1) og tre hovedkilder af data:

1. Selvevalueringsrapporter fra de to centre
2. Supplerede data og analyser fra VIVE
3. Et tredages *site-visit* i København.

Disse datakilder beskrives i de efterfølgende tre afsnit.

Evalueringspanelets arbejde har bestået dels af møder/site-visits, dels af vurdering af udsendt skriftligt materiale. Panelet har mødtes i København i forbindelse med site-visits, hvor der også har været afholdt arbejdsmøde. Panelet har fået tilsendt de to centres selvevaluering forud for mødet i København samt supplerede data og analyser fra VIVE.

2.2 Selvevalueringsrapporter

Selvevalueringsrapporterne har skullet give evalueringspanelet viden om centrene og en forståelse for deres nuværende situation og de udfordringer, som centrene står overfor. NCC og CTU har udarbejdet hver deres selvevalueringsrapport, baseret på en evalueringsskabelon udarbejdet af VIVE, og kommenteret og kvalitetssikret af formanden for evalueringspanelet. I udviklingen af evalueringsskabelonen er der blevet lagt vægt på, at den skulle indhente data, som er dækkende, systematiske og velunderbyggede. Hvert center har været ansvarlig for udarbejdelsen af deres selvevalueringsrapport, og de har selv afgjort, hvordan arbejdet med selvevalueringen skulle organiseres.

Den samlede skabelon for selvevalueringsrapporten er gengivet i Bilag 2 (på engelsk).

Selvevalueringsskabelonen indeholder i oversigtsform følgende hovedelementer:

Beskrivelse af centerets strategi, organisering, ledelse og økonomi

NCC og CTU skal her redegøre for deres vision og strategi, hvilke tiltag der er igangsat for realiseringen af vision og strategi, samt hvordan opfølgningen på de strategiske målsætninger sikres. Centrene skal beskrive, hvordan de er organiseret og ledet, hvorledes dette understøtter deres arbejde og realisering af strategi og vision. De skal foretage en beskrivelse af deres grundlæggende organisering, ledelsens opgaver og placering samt de forskellige støttefunktioner på centrene. De skal også fremlægge en redegørelse for deres økonomi, økonomistyring og deres evne til at tiltrække eksterne ressourcer fra fx forskningsråd, fonde og EU.

Forskningsproduktion og forskningskvalitet

Centrene skal her opgøre og kvalitetsvurdere deres forskningsproduktivitet. Opgørelsen omfatter en optælling af publikationer de seneste fem år fordelt på seks hovedtyper: peer-review artikler, Cochrane Reviews, Cochrane Protocols, bidrag til bøger, bidrag til konferencer og anden forskningsformidling (forskellige medier) for centrene. Som led i dette opgøres årlige gennemsnitstal af publikation pr. forsker og pr. bevilligede million kroner. Endvidere skal centrene redegøre for deres undervisningsaktivitet samt antallet af ph.d.-afhandlinger de seneste fem år, påbegyndte ph.d.-forløb, igangværende ph.d.-forløb, samt hvor ph.d.-kandidaterne har fået ansættelse.

For at vurdere kvaliteten af forskningen skal artikler publiceret de seneste fem år inddeles efter de forskningstidsskrifter, hvor de er publiceret, ligesom centrene skal redegøre for, hvilke forskningstidsskrifter de anser for at være top forskningstidsskrifter for publicering af centerets forskning.

Impact og relevans

Centrene skal her redegøre for, hvordan deres forskning og aktiviteter bruges og skaber nytte forskellige steder i det danske samfund. Det skal bl.a. bidrage til at vurdere relevansen af den forskning, som centrene bedriver. Redegørelsen skal dække følgende punkter:

- Eksempler på mulig indvirkning på behandlingspraksis og kliniske retningslinjer de seneste fem år
- Samarbejde med offentlige myndigheder de seneste tre år
- Samarbejde med sygehuse og sundhedspersonale de seneste tre år
- Deltagelse i rådgivning, kommissioner, nævn m.m. de seneste tre år
- Arrangør af konferencer, symposier og andre vidensdelende aktiviteter de seneste tre år
- Andre måder, som centerets forskning og aktiviteter er blevet brugt på, som har bidraget til værdi for det danske samfund inden for de seneste tre år.

Opgørelsen skal underbygges af dokumentation for impact og relevans.

Samarbejdspartnere – nationalt og internationalt

NCC og CTU skal her redegøre for, hvilke eksterne parter de har formelle samarbejdsaftaler med – både nationalt og internationalt. Redegørelsen skal angive typen af samarbejde, hvilken rolle centrene spiller i samarbejdsrelationerne, hvilket output samarbejdet har resulteret i, og hvordan samarbejdet har bidraget til realiseringen af centrenes målsætninger.

2.3 VIVEs indsamling af supplerende data og materiale

Efter dialog med formanden for evalueringspanelet har VIVE indsamlet yderligere data og foretaget supplerende analyser til evalueringspanelet inden for de fire overordnede temaer:

1. Ledelse og organisering
2. Forskningsproduktion og kvalitet
3. Impact og relevans
4. Samarbejdsrelationer.

Selvevalueringen giver et vigtigt input til evalueringen, men de supplerende data og analyser gør det muligt for evalueringspanelet at få et bedre og mere dybdegående grundlag for evalueringen.

Ledelse og organisering

For at sikre et relevant sammenligningsgrundlag i forhold til centrenes ledelse og organisering har VIVE for evalueringspanelet afdækket, hvordan udvalgte centre med sammenlignelige forskningsaktiviteter er organiseret og ledet. Der er blevet udvalgt to centre til sammenligning med NCC og to centre til sammenligning med CTU.

Forskningsproduktion og kvalitet

Som supplement til opgørelserne i selvevalueringsrapporten har VIVE foretaget en opgørelse af de to centres involvering i forskningsaktiviteten ved en citationsanalyse. Da begge centre primært publicerer i kliniske tidskrifter, opgøres de årlige antal af første-, med- og sidste forfatterskaber for centrene[3]. Dernæst opgøres antallet af citationer for publicerede artikler for de sidste fem år, hvilket vurderes at give et mål for relevansen af de publicerede artikler, da et højt citationsantal betyder, at andre forskere har brugt resultaterne i deres artikler og derfor finder forskningen relevant. I forlængelse heraf udregnes to forskellige indikatorer for, om artiklen er citeret mere eller mindre end gennemsnittet for de valgte forskningstidsskrifters artikler. Som sidste del opgøres de bibliometriske forskningsindikator point (BFI-point) for de publicerede artikler.

Impact og relevans

For at afdække, hvordan eksterne parter, som offentlige myndigheder og sygehuse, vurderer betydningen af centrenes arbejde, har VIVE foretaget interview med relevante samarbejdspartnere. Disse er blevet udvalgt, så der er sikret en bred repræsentation af forskellige aktører og samarbejdsparter.

Samarbejdsrelationer

Med afsæt i de samarbejdspartenere og samarbejdsrelationer, som er fremgået af selvevalueringen, har VIVE foretaget en nærmere analyse af, hvem der samarbejdes med, typen af og indholdet i samarbejdet. Dette er blevet gjort ved at foretage kvalitative interview med to til fire af de samarbejdspartnere, centrene har peget på i deres selvevaluering med henblik på at få deres perspektiv på samarbejdet.

2.4 Site-visit og møde i København

Efter at have fået tilsendt selvevalueringsrapporterne og det supplerende materiale fra VIVE, har evalueringspanelet den 20.-22. maj 2019 været på et tredages *site-visit* i København. I programmet var der afsat en dag pr. center til besøg. Besøget skulle give evalueringspanelet mulighed for at få et generelt indtryk af centrene og samtidig have mulighed for at drøfte selvevalueringen med centrene.

Programmet for evalueringspanelets besøg på centrene omfattede følgende punkter:

- Introduktion og rundvisning
- Møde med centrenes ledelse/evalueringsgruppe om selvevalueringen
- Interview med udvalgte medarbejdere
- Interview med eksterne samarbejdspartnere
- Interview med repræsentanter for Cochrane Review-grupper.

Herudover omfattede programmet for evalueringspanelets tre dage i København et interview med Rigshospitalets ledelse, et Skype-møde med direktøren for den internationale Cochrane organisation, Mark Wilson, samt en række arbejds- og planlægningsmøder internt i evalueringspanelet eller mellem VIVE og evalueringspanelet.

[3] Dette er indikatorer for involveringen i forskningsproduktiviteten, da førsteforfattere typisk er primær skriver på artiklen, medforfattere har bidraget i varierende grad og sidste forfatterskab typisk er seniorforsker (lektor eller professor). Første- og sidste forfatter vurderes at være de mest prestigefyldte pladser i forfatterrækkefølgen i medicinsk litteratur (Caminiti 2015).

2.5 Høring af evalueringspanelets udkast til evalueringsrapport

I perioden efter besøgsdagene i København har evalueringspanelet foretaget en samlet vurdering af evalueringsdataene fra selvevalueringsrapporter, supplerende materiale fra VIVE og site-visit og har på grundlag af dette udarbejdet et udkast til evalueringsrapport for henholdsvis NCC og CTU. Disse udkast er herefter blevet sendt til høring hos de to centre, de tre tilknyttede Cochrane Review-grupper samt Sundheds- og Ældreministeriet. Efter at have modtaget høringssvarene og forholdt sig til disse har evalueringspanelet udarbejdet de endelige evalueringsrapporter.

Evalueringspanelets endelige evalueringsrapporter er gengivet i Bilag 3 (NCC) og Bilag 4 (CTU).

Bilag 1 Evalueringsprotokol

Dette bilag indeholder projektets evalueringsprotokol, dvs. de evalueringsspørgsmål, som har været styrende for evalueringspanelets arbejde med at evaluere de to centre. Evalueringsprotokollen er udarbejdet af VIVE i samarbejde med evalueringspanelets formand.

Evaluation protocol

Evaluation of The Nordic Cochrane Centre and Copenhagen Trial Unit

The Nordic Cochrane Centre (NCC) and Copenhagen Trial Unit (CTU) receive each year a grant under the National Finance Act. According to the Finance Act, the activities at the Cochrane Centre include production of systematic reviews of health care interventions, prevention of diseases, diagnostics, treatment and care, and that CTU supports and conducts scientifically relevant clinical trials. The main purpose of the evaluation is to assess whether the purpose of the National Finance Act grant is fulfilled, to evaluate the scale of the research production and its research quality as well as the societal impact of the centres and their external collaborations and partnerships. Accordingly the evaluation both include formative elements focusing on broadening the understanding of the institute's characteristics for the purpose of continuous improvement and summative elements focusing on accountability to the entity that funds the running of the centre.

Specifically, the evaluation must address the following topics:

- Management and organization of the centres
- Research production and quality
- Impact and relevance of the centres' activities
- Collaborations and partnerships

An external evaluation panel carries out the evaluation. The members of the panel are acknowledged national and international experts within medicine and evaluation of research. The basis for the evaluation include the following:

- Self-evaluation reports by NCC and CTU
- Site-visit by the evaluation panel
- Documentation and additional data collected by VIVE – The National Centre for Social Science Research.

The result of the evaluation is presented in separate reports for each of the two institutions. The purpose of the evaluation is not to compare the two institutions but to give individual assessments of each centre.

In the following, the topics of the evaluation are described further.

Management and organization

The evaluation panel is asked to give a general description and assessment of the governance structure and the management and organizational structure of the centre. The description and assessment should address the following:

- An overall description and assessment of the governance structure of the centre, including reflections on the governance structures ability to hold the management of the centre accountable

- A reflection on the strategy of the centre in relation to the purpose and mission of the centre
- A description and assessment of the management and organizational structure of the centre, including reflections on the organizational and management structures adequacy for accomplishing the centre´s purpose and strategy, and the expediency of the decision-making structure and the division of labor between the different sections of the centre
- An assessment of the organizational support for researchers
- An assessment of the centre's ability to attract external resources from research councils, research funds, EU etc.
- A reflection on the expediency of governance structure, the management and organizational structure compared to similar type of institutions.

Research production and quality

The panel is asked to give an assessment of the quantity and quality of research from the centre. The assessment should include the following elements:

- A count of publications over the past five years divided into main types of publications
- The average number of annual publications per researcher for the centre at large
- An assessment of the quality of research based on bibliometric indicators
- Reflections on the level and quality of output compared to economic resources
- An assessment of the centres' production of PhD candidates, including reflections on the centres' involvement in PhD programs
- An overall assessment of the productivity of the centre and the importance and quality of the research.

Impact and relevance

The evaluation panel is asked to give its assessment of the impact and relevance of the centre's activities for the Danish society. The assessment should include the following elements:

- An assessment of the impact of the centre on clinical practice and clinical guidelines.
- Reflections on how the centres research and other activities create value in various parts of the Danish society
- Reflections on the centres' impact on the public debate in Denmark

Collaborations and partnerships

The evaluation panel is asked to give its assessment of the centres national and international collaborations and partnerships. The assessment should include the following elements:

- An assessment of the level of national and international collaboration of the centre, including reflections on the level of national vs. international collaborations, and the role of the centre in the collaborations
- An assessment of the output of the collaborations
- Reflections on importance of the collaboration for accomplishing the centre´s purpose and strategy.

Bilag 2 Skabelon for selvevalueringsrapport

Dette bilag indeholder den skabelon for selvevalueringsrapport, som de to centre har brugt i udarbejdelsen af deres respektive selvevalueringsrapporter. Selvevalueringsskabelonen er udarbejdet af VIVE i samarbejde med evalueringspanelets formand.

Self-evaluation report template

Evaluation of The Nordic Cochrane Centre and Copenhagen Trial Unit

Guidelines for the self-evaluation report

It is the centre's responsibility to draw up the self-evaluation document based on the guidelines given in this guide. The centre is responsible for establishing the mechanisms for collecting information on the centre needed to cover the themes mentioned in the guide, and to provide the requested documentation. The centre is free to increase the amount of evidence with the aim of broadening the scope of information provided and thereby improve the evaluation.

The self-evaluation report is a key part of the evaluation and together with the site-visit, the main evidence for the external review process. The drawing up of the self-evaluation document by the centre must enable the external review panel to know about and understand the centre's standing. The report should be complete and rigorous, include evidence and documentation, systematic and detailed, and balanced.

The self-evaluation report should cover the following themes:

- Management and organization
- Research production and quality
- Impact and relevance
- Collaborations and partnerships.

Use the centre's own word-template for the report and structure the report according to this self-evaluation template. Use Times New Roman 12 and single-spaced text. Include a front page and an index at the start of the report.

1. Strategy, organization, management and economy

1.1 History and governance structure

1.1.1 Overview of the history of the centre

Please give a brief overview of the history of the centre, including a description of when, how and why the centre was established and the most important changes in the organisational setup and basic funding since the establishment.

1.1.2 The overall governance setup of the centre

Please describe which authority holds the contract for the centre and the centre's contractual relationship with this authority

1.1.3 How does the centre seek advice and support about its vision/mission and strategy?

1.1.4 Does the centre have and use a board[1]?

If the centre has a board or similar structure, please provide information about:

- *a) The role of the board*
- *b) The election of members, their obligations, their compensation*
- *c) How and how often the board is involved in the centre's activities (i.e. through regular meetings, ad-hoc consultations etc.)*
- *d) One or more example(s) illustrating the role of the board for the centre.*

If the centre does not have a board, please provide reflections upon this choice.

1.1.5 Does the centre have and use an advisory board[2]?

If the centre has an advisory board or similar structure, please provide information about:

- *a) The role of the advisory board*
- *b) The election of members, their obligations, compensation*
- *c) How and how often the advisory board is involved in the centre's activities (i.e. through regular meetings, ad-hoc consultations etc.)*
- *d) One or more example(s) illustrating the role of the advisory board for the centre.*

If the centre does not have an advisory board, please provide reflections upon this choice

1.1.6 The governance structure's ability to hold the management of the centre accountable

[1] Board or 'board of directors' is a group of individuals formally elected by shareholders to oversee or manage an organization

[2] An advisory board is a group of individuals that provides non-binding strategic advice to the management of an organization.

Please elaborate on the ways in which the described governance structure enables accountability.

Please reflect: Which opportunities for improvement do you see?

1.1.7 Relevant documents and additional information

Please provide documents and information that you consider relevant for the evaluation of the centre's governance structure.

1.2 Management and organization

1.2.1 Describe the centre's organizational and economic relationship to each of the following organizations:

a) The hosting organization, The Copenhagen University Hospital ('Rigshospitalet')
b) The other of the two centres
c) The three Danish Cochrane Review Groups
d) The Cochrane Organization

1.2.2 Which managerial positions exist at the centre and what are their tasks and responsibilities?

Please provide a description of all managerial positions of the centre, including the following topics:
a) Title and managerial position
b) Primary task(s)
c) Staff responsibility (yes/no), If yes: number of staff members

1.2.3 How is the centre organized?

Please provide organizational diagram and/or description of the hierarchical structure of the centre, illustrating the organization's division of labour.

1.2.4 How does the centre provide organizational support for its researchers?

Please describe the support functions for researchers available within the organization.

Please describe the support functions for researchers made available by the centre outside of the organization.

1.3 Vision and strategy

1.3.1 What is the centre's vision, mission and/or goals?

Please describe the centre's vision, mission and/or goals of the centre

1.3.2 What is the centre's strategy?

Please describe the centre's strategy, as well as the development process resulting in the formulation of the centre's strategy and the time period of the strategic plans and how frequently are they assessed

1.3.3 How are the vision and strategy anchored in the centre's activities?

Please describe the organizational activities specifically conducted to reflect upon, develop or adjust the centre's achievements of goals and strategy

1.3.4 Relevant documents and additional information

Please provide documents and documentation relevant to review the centre's vision/mission and strategy, including but not limited to annual reports for the last five years

1.4 Economy and budget

1.4.1 How is the centre funded?

Please provide information about funding sources for the last five years, including both government funding and other sources.

Please report in million DKK in 2018-prices with two decimals. Use figures from final accounts if available. For years, where final accounts are not available, use budgets and mark the year with a 'B'.

In the first table, please exclude any funds for Danish Cochrane Review Groups affiliated with the centre

Table 1.1. The Centre's revenues 2014-2018 (excluding Cochrane Review Groups affiliated with the centre)

Million DKK 2018 prices \ *year*	2014	2015	2016	2017	2018
Government grant (National Finance Act)					
Research councils and research funds					
EU					
The Copenhagen University Hospital ('Rigshospitalet')					
Other revenues (including reimbursement of wage expenses by external collaboration partners)					
Total revenues					

Please describe the source of the most important “other revenue” sources

Please provide the same information for the Danish Cochrane Review Groups affiliated with the centre

Table 1.2. Revenues for Danish Cochrane Review Groups affiliated with the centre

Million DKK 2018 prices \ *year*	2014	2015	2016	2017	2018
Government grant (National Finance Act)					
Research councils and research funds					
EU					
The Copenhagen University Hospital (‘Rigshospitalet’)					
Other revenues (including reimbursement of wage expenses by external collaboration partners)					
Total revenues					

Please provide information about the distribution of expenditures for the last five years, including both wage costs and other operating costs.

Please report in million DKK in 2018-prices with two decimals. Use figures from final accounts if available. For years where final accounts are not available use budgets and mark the year with a ‘B’.

In the first table, please exclude expenditures for Danish Cochrane Review Groups affiliated with the centre

Table 1.3. The Centre’s expenditures 2014-2018 (excluding Cochrane Review Groups affiliated with the centre)

Million DKK 2018 prices \ *year*	2014	2015	2016	2017	2018
Wage expenses:					
Researchers, including management (excluding PhD’s)					
PhD’s					
Administrative functions					
Other employees					

Reimbursement for employees on sickness leave or maternity/parental leave (revenue)					
Total wage expenses					
Operating expenses:					
Premises (rent, utility expenses for water, heating etc.)					
Office expenses (IT equipment, printers, paper etc.)					
Conferences and other academic activities					
Other operating expenses					
Total operating expenses					
Total expenditures (wages and operating expenses)					

Table 1.4. Expenditures 2014-2018 for Cochrane Review Groups affiliated with the centre

Million DKK 2018 prices \ *year*	2014	2015	2016	2017	2018
Wage expenses:					
Researchers, including management (excluding PhD's)					
PhD's					
Administrative functions					
Other employees					
Reimbursement for employees on sickness leave or maternity/parental leave (revenue)					
Total wage expenses					
Operating expenses:					
Premises (rent, utility expenses for water, heating etc.)					
Office expenses (IT equipment, printers, paper etc.)					

Conferences and other academic activities					
Other operating expenses					
Total operating expenses					
Total expenditures (wages and operating expenses)					

Please report the number of employees *(Full Time Equivalents/FTE)* at the centre for the last five years.

In the first table, please exclude employees at Danish Cochrane Review Groups affiliated with the centre

Table 1.5. Employees (FTE) at the centre (excluding employees at Danish Cochrane Review Groups affiliated with the centre)

Full Time Equivalent/FTE \ *year*	2014	2015	2016	2017	2018
Researchers, including management (excluding PhD's)					
PhD's					
Administrative functions					
Other employees					
Total number of employees (FTE) excluding Danish Cochrane Review Groups affiliated with the centre					

Table 1.6. Employees (FTE) at Danish Cochrane Review Groups affiliated with the centre

Full Time Equivalent/FTE \ *year*	2014	2015	2016	2017	2018
Researchers, including management (excluding PhD's)					
PhD's					
Administrative functions					
Other employees					

Total number of employees (FTE) at Danish Cochrane Review Groups affiliated with the centre					

1.4.2 How successful is the centre in attracting funds?

Please provide a list of fund applications from the last five years, including the name of the fund/organization, the applied for amount, status (rejected/granted), and if relevant, the amount granted.

1.4.3 How is the use of resources linked to the centre's vision/strategy?

Please describe how the centre allocates resources. Include a description of how it is prioritized which clinical fields are to be the subject of reviews to be conducted in the coming year(s). If relevant, describe how the resource allocation is related to the centre's goals and to the dimensioning of workload (Full Time Equivalent/FTE).

1.4.4 How is the financial management of the centre organized and linked to the centre's vision/strategy?

Please describe how the financial management of the centre is organized. If relevant, describe how the resource allocation and financial management is related to the centre's goals and to the dimensioning of workload (Full Time Equivalent/FTE).

1.4.5 Relevant documents and additional information

Please provide documents and information that you consider relevant for the evaluation of the centre's budgetary and financial accountability.

2 Research production and quality

2.1 Research production

2.1.1 The centre's publication list for the last seven years.

In addition, to the accounts of publications below, please provide a full list of all publications for the past seven years (01.01.2012-31.12.2018) for VIVEs analysis of citations. The list should be based on PURE, and exported from PURE in CSV file. It is expected that all publications are available in PURE for each researcher. If the publications are not found in PURE, they are not counted in the final evaluation.

2.1.2 The centre's research production for the last five years?

Please count the yearly scientific output of PURE publications for the last five years in the main categories of publications presented in the table below. Please provide the count for each year from 2014-2018.

In the first table, please exclude publications by Danish Cochrane Review Groups affiliated with the centre

Table 2.1 Number of publications (excluding publications by Danish Cochrane Review Groups affiliated with the centre)

Publication type \ year	*2014*	*2015*	*2016*	*2017*	*2018*	*Total*
Peer-reviewed journal articles						
New Cochrane Reviews						
Updated Cochrane Reviews						
Cochrane Protocols						
PhD/doctoral dissertations						
Contributions to books (books and book chapters)						
Conference contributions						
Other publications and none-peer-reviewed dissemination of research (reports, letters, comments etc.)						
Total (excluding publications by Danish Cochrane Review Groups affiliated with the centre)						

Table 2.2 Number of publications by Danish Cochrane Review Groups affiliated with the centre

Publication type* \ *year	*2014*	*2015*	*2016*	*2017*	*2018*	*Total*
Peer-reviewed journal articles						
New Cochrane Reviews						
Updated Cochrane Reviews						
Cochrane Protocols						
PhD/doctoral dissertations						
Contributions to books (books and book chapters)						
Conference contributions						
Other publications and none-peer-reviewed dissemination of research (reports, letters, comments etc.)						
Total (by Danish Cochrane Review Groups affiliated with the centre)						

2.1.3 Number and type of studies in Cochrane Reviews

If relevant, please reflect upon trends over the last five years in the number and the type of studies included in each Cochrane Review as well as the overall complexity of the reviews.

2.1.4 Prioritizing of Cochrane Reviews

Please provide information about how Cochrane Reviews are prioritised and who is involved in setting the review questions

2.1.5 Teaching activities

If relevant, please account for teaching activities of researchers at the centre over the last five years

2.1.6 Training activities

If relevant, please account for training activities at the centre over the last five years

2.1.7 Publication productivity

For the centre at large, please provide the average number of publications per researcher and the average number of publications per million of the budget for the last five years. Please use the information on total publications in Table 2.1 *divided with the number of researchers from* Table 1.5 *and the funding from government grant and total funding in* Table 1.1.

In the first table, please exclude publications, employees and budgets of Danish Cochrane Review Groups affiliated with the centre

Table 2.3 Average number of publications per researcher and per million DKK (excluding publications, personnel and budgets of Danish Cochrane Review Groups affiliated with the centre)

	2014	*2015*	*2016*	*2017*	*2018*
Average number of publications per employed researcher (FTE), including management					
Average number of publications per 1 million DKK of government grant					
Average number of publications per 1 million DKK of total funding					

Please provide the same information for Danish Cochrane Review Groups affiliated with the centre, based on the information on total publications in Table 2.2*, the number of researchers from* Table 1.6 *and the funding from government grant and total funding in* Table 1.2*.*

Table 2.4 Average number of publications per researcher and per million DKK for Danish Cochrane Review Groups affiliated with the centre

	2014	*2015*	*2016*	*2017*	*2018*
Average number of publications per employed researcher (FTE), including management					
Average number of publications per 1 million DKK of government grant					
Average number of publications per 1 million DKK of total funding					

2.2 Research Quality

2.2.1 Journals of publication

Please provide a list of the peer-reviewed journals in which the centre's researchers have published articles in the last five years and count the number of articles published in each of these journals for each of the last five years in a table like the one below.

In the first table, please exclude publications of Danish Cochrane Review Groups affiliated with the centre

Table 2.5 Number of published peer-reviewed articles by journal (excluding publications of Danish Cochrane Review Groups affiliated with the centre)

Journal name \ year	*2014*	*2015*	*2016*	*2017*	*2018*	*Total for all years*
Journal 1 [name of journal]						
Journal 2 [name of journal]						
…						
Journal N [name of journal]						
Total number of peer-reviewed articles						

Please describe which international journals you consider as the top journals for the centre's research and provide information on potential strategies underlying the distribution of articles in the table above and/or for future publications in peer-reviewed journals.

Please provide the same information for publications by employees at Danish Cochrane Review Groups affiliated with the centre

Table 2.6 Number of published peer-reviewed articles by employees at Danish Cochrane Review Groups affiliated with the centre

Journal name \ year	*2014*	*2015*	*2016*	*2017*	*2018*	*Total for all years*
Journal 1 [name of journal]						
Journal 2 [name of journal]						
…						
Journal N [name of journal]						
Total number of peer-reviewed articles						

2.2.2 Authorship order as indicator of involvement in research production

In health sciences, the first and last authorships are often considered the most prestigious. Please reflect whether this sort of reasoning is reflecting the way the authors are listed in the peer-reviewed articles published by your centre or other principles of authorship order are prominent.

2.3 PhD. activity

2.3.1 Phd Supervision responsibility

Please provide information whether the centre is expected to provide supervision for PhDs and if so, how this supervision is provided

2.3.2 The number of PhD. projects that are initiated, ongoing, and defended dissertations

Please count the activity of PhDs for the last five years according to the three categories: PhDs that have been initiated, PhDs that are ongoing and PhDs that are publicly defended (dissertations). Please provide the number for each year in a table like the one below.

Table 2.7 PhD projects (excluding Danish Cochrane Review Groups affiliated with the centre)

Category \ year	*2014*	*2015*	*2016*	*2017*	*2018*	*Total*
PhDs initiated						
PhDs ongoing						
PhD Dissertations						
Total						

2.3.3 Affiliation of PhD fellows following the dissertation

Please provide the number of PhD fellows that are employed at the centre following the public defence and PhDs that are no longer affiliated with the centre. This should be provided in table as the one below. Please also provide a list of the specific affiliations of the PhDs that are not affiliated at the centre after the PhD defence.

Table 2.8 Affiliation of PhD fellows (excluding Danish Cochrane Review Groups affiliated with the centre)

Category \ year	*2014*	*2015*	*2016*	*2017*	*2018*	*Total*
PhDs employed at the centre following the defence						
PhDs employed other places following the defence						

Table 2.9 Employment of PhD fellows not affiliated with the centre after the Ph.D. defence (excluding Danish Cochrane Review Groups affiliated with the centre)

Name of employment place following the public defence

3 Impact and relevance

3.1.1 Who are the centre's primary audiences/target groups in the Danish society?

Please list the organizations that the centre considers its primary target group.

3.1.2 Please describe the ways in which the centres' research and activities are used by and creates benefits in various parts of *the Danish society.* Include at least the following topics:

- Examples of potential impact on clinical practices and clinical guidelines within the past five years
- Collaborations with public authorities within the past three years
- Collaboration with hospitals and healthcare professionals within the past three years
- Participation in consulting, commissions, boards etc. within the past three years
- Organization of conferences, symposiums or other knowledge sharing initiatives within the past three years
- Other ways the centres' research and activities are used by and creates benefits in the Danish society within the past three years

For each of these topics please provide examples or documentation.

3.1.3 Visitors, secondments etc. at the centre in the past three years?

Please provide information on the number of visitors, secondments etc. at the centre in the past three years.

3.1.4 Web hits, downloads of Cochrane reviews and media activity

Please provide information on

- *the number of web hits for your centre per year in the past three years*
- *the number of Cochrane reviews, that have been downloaded by Danish IP-addresses (.dk) in the past three years*
- *the number of times employees at the centre have been cited in Danish media in the past three years*

3.1.5 User-friendly summaries of reviews and other tailored research knowledge

Please reflect upon the centre's policy for making user-friendly summaries of reviews or other tailored written versions of publications to communicate research knowledge to the primary target groups in the Danish society

3.1.6 The centre's impact on the public debate in Denmark?

Please reflect upon the centre's impact on the public debate in Denmark and give examples

4 Collaborations and partnerships

4.1 National collaborations and partnerships[3]

4.1.1 The centre's formal collaborations and partnerships in Denmark

Please list the centre's national collaborations during the last five years.

Please describe the role(s) of the centre in each of its national collaborations.

Please describe the achieved output of each of the national collaborations.

4.2 International collaborations and partnerships

4.2.1 The centre's formal collaborations and partnerships internationally

Please list the centre's international collaborations during the last five years

Please describe the role(s) of the centre in each of its international collaborations.

Please describe the achieved output of each of the international collaborations.

4.3 Own assessment of national and international collaborations

4.3.1 How does the centre's collaborations cohere with the centre's goals/vision and strategy?

Please reflect upon the importance of the centre's collaborations for accomplishing the centre's goals/vision and for succeeding with its strategy.

Please reflect upon which areas of improvement you see, e.g. should the balance between national/international be changed; should output, focus, size of collaborations be different?

[3] Collaborations and partnerships refer to arrangements where there is a formalized written agreement on e.g. the content of the collaboration, the division of labor and the duration of the collaboration.

Bilag 3 Evaluation Report Nordic Cochrane Centre

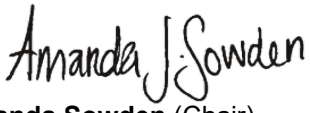
Dette bilag indeholder den evalueringsrapport, som det internationale evalueringspanel har udarbejdet for det Nordiske Cochrane Center (NCC).

Ud over evalueringspanelets evaluering af det Nordiske Cochrane Center indeholder evalueringsrapporten også panelets evalueringsperspektiver på de to danske Cochrane Reviewgrupper, som er tættest knyttet til det Nordiske Cochrane Center:

- The Colorectal Group (CCG),
- The Anaesthesia Group and the Emergency and Critical Care Group (ACE).

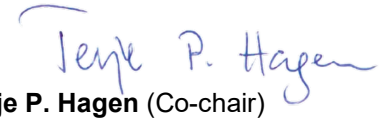
Evaluation of the Nordic Cochrane Centre

Final Report



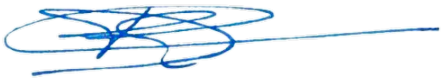
Amanda Sowden (Chair)

Professor and Deputy Director and leader of the University of York's Centre for Reviews and Dissemination's research programme in public health, United Kingdom



Terje P. Hagen (Co-chair)

Professor and Head at the Institute of Health and Society, University of Oslo, Norway



Diederick Grobbee

Professor of Clinical Epidemiology and founder of the Julius Center, University Medical Center Utrecht, The Netherlands

Eva Swahn

Professor at the Department of Medical and Health Sciences, Division of Cardiology, Linköping University & Department of Cardiology, University Hospital, Linköping, Sweden

Merete Osler

Clinical Professor at the Department of Public Health, University of Copenhagen & consultant at the Center for Clinical Research and Prevention, Bispebjerg and Frederiksberg Hospital, Denmark

Mickael Bech

Professor in healthcare leadership at the Crown Prince Frederik Center for Public Leadership, Aarhus University, Denmark

September 2019

Table of Contents

Executive summary

Background of the evaluation

The Nordic Cochrane Centre (NCC) and the Copenhagen Trial Unit (CTU) receive funding from the Ministry of Health via the National Finance Act. This funding has been in place since 1993 and, until now, no formal evaluation of the work of the Centres has taken place. Such an evaluation was requested by the Ministry of Health and was organised and overseen by VIVE, the Danish Center for Social Science Research. The aim of the evaluation was to assess whether the purpose of the two centres as stated in the National Finance Act grant has been fulfilled. The Finance Act states:

> *"The activities in the Cochrane area include preparation of systematic reviews of health care interventions, prevention of diseases, diagnostics, treatment and care. CTU supports and performs scientifically relevant clinical trials, i.a. as part of the Cochrane Collaboration."* (the National Finance Act 2018, translation by VIVE).

An international Panel of six people carried out the evaluation. The evaluation focused on i) management and organisation of the centres; ii) research production and quality; iii) impact and relevance of the centres' activities and iv) collaborations and partnerships.

The results of the evaluation are presented in separate reports for each of the two centres. This report presents the results of the evaluation of the NCC. The report also includes perspectives on the Cochrane Anaesthesia, Cochrane Emergency and Critical Care and Cochrane Colorectal Groups, which are also funded under the Finance Act.

Conclusions of the Evaluation Panel

The Panel concludes that the NCC's overall purpose of informing health care decision-making through the provision of high-quality synthesised evidence has been fulfilled. The Panel notes the significant contribution made to improving the quality of evidence available to decision-makers, including patients and the public. This has been achieved by developing robust methods and advocating for their use through publication in high-impact journals and through training. The NCC's work is of clear relevance to Danish health care practices and there are examples of significant influence on policy.

Some of the NCC's work has received considerable media interest and has without doubt informed public debate in Denmark and internationally. In turn, this is likely to bring benefits to society by helping to drive science and clinical practice forward. Stakeholder feedback suggests that the NCC has a good reputation, which is based on the quality, independence and importance of its work and its anchoring to Cochrane's overall mission. The Panel notes the controversy surrounding some of the scientific and public debates, which have split the opinions of policy-makers and the research community. The Panel see that there is a need for increased engagement with stakeholders and to re-establish the Advisory Board, with a refreshed membership, to include people engaged with the health policy and practice agenda in Denmark.

Active collaboration with researchers nationally and internationally has resulted in high-quality publications and outputs, notably reporting standards, Cochrane reviews, and clinical

guidelines. By comparison, collaboration with the Denmark-based Cochrane Review Groups (CRGs) appears to be very limited. Given the increasing complexity of Cochrane methods, the need to adhere to methodological standards and editorial processes, and to ensure stakeholder involvement in priority setting, the Panel concludes that the NCC and the Denmark-based CRGs should develop closer working relationships, with opportunities for shared learning as a priority.

Despite the NCC's considerable achievements, the Panel questions the sustainability of its current operating model, given its small size, dependence on Ministry funding, positioning in Rigshospitalet and complex governance structures. The Panel concludes that there is an urgent need to consider the options for a revised governance structure that would strengthen the NCC's current position and facilitate its future growth. Closer alignment with a university would seem desirable, in bringing further potential for collaboration and increased opportunities to secure research funding and recruit PhD students, as well as signalling its national scope, while maintaining the research integrity and independence that is central to its operation and strategy.

1 Introduction

1.1 Background

The Ministry of Health has asked VIVE, The Danish Center for Social Science Research, to evaluate the Nordic Cochrane Centre (NCC) and the Copenhagen Trial Unit (CTU).

The NCC and CTU receive a grant each year through the National Finance Act. In the National Finance Act for 2018, it is stated:

> *"In 2018, DKK 17.8 million were allocated for financing of the Cochrane and Copenhagen Trial Unit (CTU). The activities in the Cochrane area include preparation of systematic reviews of health care interventions, prevention of diseases, diagnostics, treatment and care. CTU supports and performs scientifically relevant clinical trials, i.a. as part of the Cochrane Collaboration. The allocated funds from 2009 onwards include DKK 0.5 million for the financing of free access for all to the Cochrane Library"* (the National Finance Act 2018, translation by VIVE).

According to information from the centres, the 17.8 million DKK in 2018 were distributed as follows:

- The Nordic Cochrane Centre: 7,335,000 DKK
- Copenhagen Trial Unit, including the Cochrane Hepato-Biliary Group: 7,735,000
- The Cochrane Review Groups: 2,730,000 DKK
    - Herlev Hospital: 1.316.000 DKK (The Cochrane Anaesthesia and Cochrane Emergency and Critical Care Groups)
    - Bispebjerg Hospital: 1,413,000 DKK (The Cochrane Colorectal Group).

1.2 The evaluation

The results of the evaluation are presented in separate reports for each of the two centres. This report presents the results of the evaluation of the Nordic Cochrane Centre (NCC). In addition to the NCC, the report includes perspectives on the Cochrane Anaesthesia and Cochrane Emergency and Critical Care Groups and the Cochrane Colorectal Group.

The main aim of the evaluation is to assess whether the purpose of the National Finance Act grant has been fulfilled, by evaluating the scale of research production and its quality as well as the societal impact of the centres and their external collaborations and partnerships. Accordingly, the evaluation includes both formative elements focusing on broadening the understanding of the institute's characteristics for the purpose of continuous improvement and summative elements focusing on accountability to the entity that funds the running of the centre.

Specifically, the evaluation addresses the following four topics:

- Management and organisation of the centres
- Research production and quality
- Impact and relevance of the centres' activities
- Collaborations and partnerships.

These topics are presented in further details below.

1.3 The evaluation panel

An international evaluation panel has carried out the evaluation and is responsible for writing this report. The appointment of the chair of the evaluation panel was done by The Independent Research Fund Denmark [Danish name: Danmarks Frie Forskningsfond, DFF] based on a nomination by VIVE. VIVE appointed the additional members of the evaluation panel based on nominations by DFF. VIVE requested DFF to nominate three internationally well-acknowledged researchers from the medical sciences council under DFF and two researchers from the social science council under DFF. The candidates from the medical sciences council were to have insight into the processes and methods of randomised studies, systematic reviews and experience with assessing the quality and impact of health care research. The candidates from the social sciences council under DFF were to have insight into the Danish health care system and management and organisation of health research. In order to ensure the impartiality of the evaluation, a basic criterion in the nomination of candidates, in addition to the professional skills, was that they must not have had collaborations or other close relations with the NCC, CTU or their international counterparts in the last five years. DFF, in accordance with the Danish Gender Equality Act, nominates at least one male and one female candidate for each seat in the panel. After a process of nomination and invitation of nominees by DFF, VIVE received a list from DFF of five researchers from the medical sciences council and two researchers from the social sciences council, all of whom accepted the invitation. The appointment of the additional members was done by VIVE, after consulting the chair of the evaluation panel. Based on an overall assessment of the individual and complementary qualifications, VIVE appointed three of the five researchers who accepted the invitation from the medical sciences council and the two researchers that accepted the invitation from the social sciences council. All panel members were appointed in their own personal capacity. The composition of panel members has been subject to a hearing by the NCC and the CTU.

The panel consists of six members with complementary competencies in reviews in public health, clinical research, trials and management, and organisation of health research:

- Amanda Sowden (Chair). Professor and Deputy Director and leader of the University of York's Centre for Reviews and Dissemination's research programme in public health, United Kingdom
- Terje P. Hagen (Co-chair). Professor and Head at the Institute of Health and Society, University of Oslo, Norway
- Diederick Grobbee. Professor of Clinical Epidemiology and founder of the Julius Center, University Medical Center Utrecht, The Netherlands
- Eva Swahn. Professor at the Department of Medical and Health Sciences, Division of Cardiology, Linköping University & the Department of Cardiology, University Hospital, Linköping, Sweden
- Merete Osler. Clinical Professor at the Department of Public Health, University of Copenhagen & consultant at the Center for Clinical Research and Prevention, Bispebjerg and Frederiksberg Hospital, Denmark
- Mickael Bech. Professor in healthcare leadership at Crown Prince Frederik Center for Public Leadership, Aarhus University, Denmark.

1.4 Evaluation protocol

The evaluation protocol elaborated by VIVE and the chair of the panel covers four topics:

- Management and organisation
- Research production and quality
- Impact and relevance
- Collaborations and partnerships.

The protocol contains the questions guiding the evaluation panel's assessment and is presented in further detail below.

Management and organisation

The evaluation panel was asked to give a general description and assessment of the governance structure and the management and organizational structure of each of the two centres. The description and assessment were to address the following:

- An overall description and assessment of the governance structure of the centre, including reflections on the governance structure's ability to hold the management of the centre accountable
- A reflection on the strategy of the centre in relation to the purpose and mission of the centre
- A description and assessment of the management and organizational structure of the centre, including reflections on the organizational and management structures' adequacy for accomplishing the centre´s purpose and strategy, and the expediency of the decision-making structure and the division of labour between the different sections of the centre
- An assessment of the organizational support for researchers
- An assessment of the centre's ability to attract external resources from research councils, research funds, EU etc.
- A reflection on the expediency of governance structure, the management and organizational structure compared to similar types of institutions.

Research production and quality

The panel was asked to give an assessment of the quantity and quality of research from each of the two centres. The assessment was to include the following elements:

- A count of publications over the past five years divided into main types of publications
- The average number of annual publications per researcher for the centre at large
- An assessment of the quality of research based on bibliometric indicators
- Reflections on the level and quality of output compared to economic resources
- An assessment of the centres' production of PhD candidates, including reflections on the centres' involvement in PhD programmes
- An overall assessment of the productivity of the centre and the importance and quality of the research.

Impact and relevance

The evaluation panel was asked to give its assessment of the impact and relevance of each of the two centres' activities for the Danish society. The assessment was to include the following elements:

- An assessment of the impact of the centre on clinical practice and clinical guidelines.
- Reflections on how the centres' research and other activities create value in various parts of the Danish society
- Reflections on the centres' impact on the public debate in Denmark

Collaborations and partnerships

The evaluation panel was asked to give its assessment of each of the two centre's national and international collaborations and partnerships. The assessment was to include the following elements:

- An assessment of the level of national and international collaboration of the centre, including reflections on the level of national vs. international collaborations, and the role of the centre in the collaborations
- An assessment of the output of the collaborations
- Reflections on importance of the collaboration for accomplishing the centre´s purpose and strategy.

1.5 The evaluation process and methods

The evaluation of the two centres was carried out in parallel and is based on both quantitative and qualitative data. The data include:

- Self-evaluation reports by the NCC and CTU
- Site-visit by the evaluation panel in Copenhagen 20th to 22nd May 2019
- Documentation and additional data collected by VIVE

Both the self-evaluation reports, and the documentation and additional data collected by VIVE, provide information on each of the four topics of the evaluation. The site-visit included meetings with management, employees and a selected number of stakeholders of each centre as well as a meeting with the management of the hosting organisation, The Danish National Hospital – 'Rigshospitalet' and a teleconference with the Chief Executive Officer of Cochrane.

2 Management and organisation

This section provides a brief overview of the history of the Nordic Cochrane Centre (NCC), its current position and funding arrangements, its purpose and strategy, and its organizational and governance structures.

2.1 Background, current position and funding

The NCC was established in 1993 by Professor Gøtzsche at Rigshospitalet in Copenhagen. The international Cochrane Collaboration (now Cochrane) was itself founded in the same year. Cochrane is an international organisation, with over 13,000 members from more than 130 countries, whose mission is to promote evidence-informed health decision-making by producing high-quality, relevant and accessible systematic reviews and other forms of synthesised research evidence.

The NCC was originally funded via the organisation Hovedstadens Sygehusfællesskab (HS: The hospital community of the Capital Region). As part of the 2006 structural reforms in Denmark, the organisation HS was merged into one of five regions, Capital Region of Denmark, and the financial support for the NCC was transferred to the national Danish Finance Act, which has continued to provide funding. In 2018, the amount of funding from the Danish Government was DKK 7.335 million. Funding from other sources (e.g. research councils and research funds) for 2018 amounted to DKK 0.71 million. In 2018, funding from the Danish Government comprised 87% of the NCC's total budget. In earlier years, this percentage ranged from 58 (2014) to 99 (2017).

Several Associate Centres have been set up, which are directly affiliated with the NCC. A Norwegian Branch was established in 1997, and in 2017 Polish and Russian Branches were established. Cochrane Finland was established in 1997, and Cochrane Sweden in 2017. In addition, several Cochrane groups also refer to the NCC:

- the Cochrane Hepato-biliary Group (DK)
- the Cochrane Colorectal Group (DK)*
- the Cochrane Anaesthesia Group (DK)*
- the Cochrane Emergency and Critical Care Group (DK)*
- the Occupational Health Group (Fin)
- the Norwegian Satellite of the Effective Practice and Organization of Care Group (No)
- the Cochrane Bias Methods Group (DK).

Three of these groups* are funded via the Danish Finance Act. In 2018, this funding amounted to DKK 2.729 million, which is in addition to the funding for the NCC.

The NCC operates as a research department within Rigshospitalet, and all financial actions go through the finance office and administrative issues through the Human Resources Department at Rigshospitalet. Payments by the Danish Government are made directly to Rigshospitalet. Funding for the three* Cochrane groups is administered by Herlev Hospital and Bispebjerg Hospital, which host the editorial bases for these groups.

The NCC and the Copenhagen Trial Unit (CTU) are connected through their collective government funding and are housed next door to each other at Rigshospitalet, but their

activities are completely independent of each other. The CTU hosts the editorial base of the Cochrane Hepato-Biliary Group, including its Co-ordinating and Managing Editors and Information Specialist (see Evaluation of the Copenhagen Trial Unit – Report).

Also based at Rigshospitalet, and co-located with the NCC, is a small group who are part of Cochrane's Informatics and Technology Services. This service is centrally managed via the Cochrane Central Executive team based in London, UK.

2.2 Purpose and strategy

The overall aim of the NCC is "to help citizens, patients, health care professionals and payers of health care services to choose – or to avoid use of – interventions rationally, in an evidence-based fashion, and with a focus on benefits, harms and costs." [1] This aligns with Cochrane's *Strategy to 2020*[2], which aims to put Cochrane evidence at the heart of health decision-making all over the world and has the following goals:

1. **Producing evidence –** to produce high-quality, relevant, up-to-date systematic reviews and other synthesised research evidence to inform health decision-making.
2. **Making our evidence accessible –** to make Cochrane evidence accessible and useful to everybody, everywhere in the world.
3. **Advocating for evidence –** to make Cochrane the 'home of evidence' to inform health decision-making, build greater recognition of our work, and become the leading advocate for evidence-informed health care.
4. **Building an effective sustainable organisation –** to be a diverse, inclusive and transparent international organisation that effectively harnesses the enthusiasm and skills of our contributors, is guided by our principles, governed accountably, managed efficiently and makes optimal use of its resources.

The NCC has five main areas of work, as set out in their *Strategic Plan 2016-2020*: [1]

1. **Research** – priority is given to research that makes a difference to many people. Specific areas of interest are psychiatric drugs and screening. Methodological research that aims to elucidate the sources of bias is also a priority. Work will continue to improve the reliability of clinical and observational studies and to develop and update reporting guidelines.
2. **Dissemination of research results** – priority is given to the translation of review findings into understandable formats, including for patients and the public.
3. **Associate centres and review groups** – the focus is on providing support to and close working with affiliated centres and groups (currently in Denmark, Norway, Finland, Sweden, Russia and Poland).
4. **Partnerships** – priority is given to informal partnerships to ensure full academic freedom.
5. **Workshops and courses** – priority is given to supporting individuals in Denmark, Sweden, Norway, Poland and Russia to complete Cochrane protocols and reviews.

[1] Taken from *Strategic Plan 2016-2020: Nordic Cochrane Centre.*
[2] Taken from *Strategy to 2020 (Cochrane).*

2.3 Organisation and management

Full-time research positions are currently held by the Acting Director and a Senior Researcher. In addition, the NCC employs a communications consultant, an administrator and a secretary, plus four full-time PhD students and early career researchers, and two PhD students who are shared with the Centre for Evidence-based Medicine (CEBMO) at the University of Southern Denmark and Odense University Hospital. In addition, the Centre hosts visiting scholars and students. NCC staff view their core strengths as being research synthesis and methodological expertise.

In order to supervise PhD students and contribute to teaching, it is necessary for one or more members of NCC staff to have a university affiliation. The PhD students are employed at the NCC and they are enrolled in university PhD programmes. The former Director was affiliated with the University of Copenhagen, through a Professorship and had the overall responsibility for the NCC-funded PhD students. None of the NCC's senior staff currently have a university affiliation. Interim arrangements for the current PhD students are in place.

2.4 Governance arrangements

Cochrane – The NCC holds the status of a 'Cochrane Centre'. Cochrane and the NCC have signed a Collaboration Agreement which sets out the terms and conditions for both parties and commits the NCC to support Cochrane's mission, principles, organisational strategies and goals, as defined by Cochrane's Governing Board, and to fulfil the core functions of a Cochrane Centre, as set out in *"Implementing Strategy to 2020: Cochrane Centres, Branches & Networks – New functions and Structures"*. The Cochrane Governing Board is responsible for overseeing the development and implementation of Cochrane's strategic direction. The Acting Director of the NCC is an elected member of the Cochrane Governing Board.

Cochrane Centres are directly accountable to the CEO of Cochrane to ensure adherence to Cochrane's overall strategy, and Centre Directors meet quarterly with Cochrane's CEO to review progress in relation to their own strategic plans.[3] Centres have coordinating responsibility for national (and sometimes regional) work plans, and the NCC represents Cochrane in the Nordic countries. The groups and affiliated centres in the Nordic Region report directly to the NCC.

NCC – The Centre is characterised by an informal culture, partly due to its small size, and decisions about work plans are made in dialogue with individuals, rather than through formal meetings or pre-allocation of resources based on full-time equivalents (FTEs). Prioritisation of research activity is in line with the direction set out in the centre's *Strategic Plan 2016-2020*, but ultimately it is the Director who decides which projects to initiate.

The NCC does not have a board of directors, as the Cochrane Governing Board sets the agenda for the organisation overall. The NCC does have an advisory board; members are consulted infrequently and on an ad hoc basis.

Danish Government – The NCC is funded through the Danish Finance Act via the Ministry of Health. The Danish Finance Act does not pose any requirements in terms of governance or

[3] NCC's Strategic plan 2015-2020 is available here - https://nordic.cochrane.org/strategic-plan

accountability. Since its inception in 1993, the NCC has not been formally evaluated, beyond the monitoring of annual scientific and financial reports.

Rigshospitalet – The NCC is hosted by Rigshospitalet and is organised as a hospital research department. Rigshospitalet ensures formal rules and regulations are met, but no explicitly defined governance structure is in place and the NCC is not accountable to Rigshospitalet for its activities or decision-making.

University of Copenhagen – The NCC had an affiliation with the University through the former Director's Professorship**.** The affiliation was a prerequisite for the centre to supervise PhD students. None of the senior staff currently have affiliations with the University, and senior researchers outside the NCC (with University affiliations) act as the main supervisors for current PhD students.

2.5 The Panel's assessment of the overall management and organisation

The NCC's overall purpose to inform health care decision-making through the provision of high-quality synthesised evidence has been fulfilled. The Centre has made a significant contribution to the quality of evidence available to decision-makers, including patients and the public, by developing robust methods and advocating for their use through publication in prestigious journals and through training.

Given the small size of the NCC, its achievements are impressive. Currently, there are two senior researchers to develop, lead, oversee and manage the work of the Centre and its staff. The Panel noted that due to its positioning in Rigshospitalet, the NCC appears to be relatively isolated from the academic community and this, coupled with its small size, may be disadvantageous for PhD students and early career researchers, who appear to have limited opportunities to engage in wider academic pursuits or for career development. Although, it is noted that PhD students can visit Cochrane Centres and partnering research units in other countries. PhD students are formally enrolled at the University of Copenhagen, but there seem to be few interactions with other academic environments. The Panel suggests that a more formal affiliation with the University of Copenhagen, and/or with the CEBMO at the University of Southern Denmark, would enhance possibilities for collaboration and joint working. The Panel notes that Cochrane Centres in other countries are often based in or affiliated with Universities and therefore benefit from wider academic engagement and collaboration.

The Panel notes that the NCC is almost exclusively dependent on funding from the Danish Ministry, which could threaten its future sustainability – particularly if, at any point, this grant is reduced or removed. Additional research grants have been secured, but for relatively small amounts compared with the Ministry funding. The success in attracting external funding seems to vary, and the NCC does not appear to have a strategy for actively pursuing research income.

The NCC's governance arrangements appear intricate, with differing levels of accountability to Cochrane, Rigshospitalet and the Ministry of Health. The NCC's affiliation to the University of Copenhagen (via a Professorship) creates an additional complexity. The Panel's impression was one of a somewhat vague governance structure, lacking in accountability and with weak organisational anchoring. The NCC is answerable to Rigshospitalet for the legal use of the government grant, but no formal evaluation of its work and activities has been made beyond the annual monitoring of accounts and scientific outputs. Discussions have taken place

between the Chief Executive Officer (CEO) of Cochrane and the Acting Director of the NCC about the governance structure, and both acknowledged that clear lines of accountability and regular communication are important and necessary. In a meeting with the Panel, Rigshospitalet highlighted the importance of a clear and strong governance structure, while noting the need for a Cochrane Centre to be an independent entity, which led them to conclude that an alternative governance structure was needed.

Although the NCC has an advisory board, the Panel felt that the full potential of this group to influence and shape the Centre's activities has not been realised. The Panel questioned whether the membership of the advisory board was sufficiently close to, and engaged with, the health policy and practice agenda, in Denmark, and whether membership could be refreshed.

3 Research production and quality

This section provides an overview and assessment of the research production and quality. Various bibliometric indicators were used to inform the assessment. The indicators capture the involvement and productivity of the NCC in any of the peer-reviewed publications, as well as the performance of the publications. The analyses are restricted to publications from 2012/14 to 2018 and include only publications indexed in the Web of Science (WoS) database.

This section also includes an overview of the NCC's involvement in PhD supervision.

3.1 Research production and impact of publications

From 2014 to 2018, the NCC has registered 140 publications, of which 55 (39% of total publications) are journal articles and 18 (12% of total publications) are Cochrane articles (Table 3.1).

Table 3.1 Number and publication classification of the publications from NCC

WoS -Classification	2012	2013	2014	2015	2016	2017	2018	2014-2018 Total	2012-2018 Total
	No.	No.	No.	No.	No.	No.	No.	No.	No.
Article	20	12	21	10	10	8	6	55	87
Cochrane	2	6	6	4	5	3	0	18	26
Editorial	1	3	2	2	3	0	3	10	14
Letter	6	16	5	14	9	5	4	37	59
Review	4	5	4	3	6	5	2	20	29
Total	33	42	38	33	33	21	15	140	215

Abbreviations: WoS: Web of Science, No.: Number of observations.

Des: The table shows the NCC's publications from 2012 to 2018, divided into the five publication categories used in the analysis.

Between 2014 and 2018, NCC staff had 60 (43% of total publications) first authorships, 77 (55% of total publications) last authorships and 51 co-authorships (data not shown in tables).

Comparing the citations received by the publications to those of the average article published in the field of clinical medicine, publications from the NCC received 2.93 times more citations than the average publication (MNCS Clinical Medicine range 1.71 to 3.62, for individual years). A similar result is found when the NCC publications are compared to an average publication in all the WoS fields. NCC publications receive 2.88 times more citations than the average article in all WoS fields (MNCS All fields range from 1.68 to 2.64, for individual years; Table 3.2).

Table 3.2 Number of citations and normalised citation score for publications from the NCC

	Number	TC	Mean TC	Median TC	Max TC	MNCS Clinical Medicine	MNCS All fields	Missing Publi-cations
2014	38	1603	42.18	5.5	608	3.62	3.64	0
2015	27	765	28.33	5	571	3.22	3.25	6
2016	29	298	10.28	4	66	1.71	1.68	4
2017	18	112	6.22	3	42	2.46	2.30	3
2018	15	38	2.53	2	7	3.54	3.27	0
All years	127	2816	22.17	4	608	2.93	2.88	13

Abbreviations: TC: Total number of citations for the period, MNCS: mean normalised citations score of the publications of a unit

Des: The table shows the number of publications included in the analysis. For each publication year, the total, mean, median and maximum number of citations of the publications in that year are shown. The table further shows the mean MNCS Clinical medicine and MNCS All fields scores, which indicate whether the publications received more (scored above 1) or fewer (scored less than 1) citations than the average publications in the relevant field in the given publication year. It was not possible to obtain citation data for all the NCC publications, for which reason there are missing data. The most frequent missing publication type is Cochrane protocols.

Note: We apply weights based on the publication's classification for both MNCS scores. Articles, Cochrane articles and reviews are given a weight of 1 in the analysis, whereas letters, comments and editorials are given a weight of 0.25

When focusing on articles from the two publication categories 'articles' and 'Cochrane articles (excluding reviews, letters and editorials)', there are 69 publications, which on average have a MNCS Clinical Medicine score of 4.5 (MNCS Clinical Medicine range 2.81 to 5.73, for individual years) and a MNCS All fields score of 4.44 (MNCS All fields range 2.75 to 5.77, for individual years). Both results imply that the publications from the NCC receive more than twice as many citations as an average publication in the two fields of WoS. The MNCS scores are slightly higher than the scores obtained using all publications categories, which might be explained by the exclusion of letters and editorials, which do not receive many citations.

3.2 PhD supervision

The NCC considers PhD supervision and mentoring to be a necessary obligation of any research centre. In their self-evaluation report, the NCC recorded seven PhD students as being registered in the period 2014-18. In the same period, one PhD Fellow was employed by the NCC following their defence.

3.2 The Panel's overall assessment of research productivity and quality

The Panel concluded that the NCC has produced an impressive number of outputs, with many judged to be of high quality, as evidenced by publication in high-impact journals, including *BMJ*, *Lancet*, *Ann Intern Med*, *JAMA*, and *J Clin Epidemiol*. Based on the number of employees at the NCC (FTE), ranging between 2.4 and 2.77 over the five-year period, this equates to approximately 20 outputs (all) per year, per researcher (FTE), or approximately five peer-reviewed journal articles per year, per researcher (FTE).

Many of the publications report methodological research, with the aim of expanding existing, or developing new, approaches and methods for systematic review – for example, the inclusion of clinical study reports from drug regulatory authorities. Publications include major reporting

guidelines, such as CONSORT for randomised trials and PRISMA for systematic reviews, developed as part of international collaborations. The NCC has played an important role in developing the methods that underpin research synthesis and this is notably one of their main strengths, as well as being a central aim of their overall strategy.

Of the 17 Cochrane reviews in production over the past five years, five are judged by the NCC as being 'complex'. Reviews are considered complex if they differ from standard systematic reviews in terms of the nature and sources of data and the processes used for synthesis and interpretation. These reviews often require a multidisciplinary review team with a particular skill set, especially highly skilled methodological and statistical expertise.

Although the NCC does not have a specific remit to supervise PhD students, the importance of doctoral research and students was highlighted. Over the five-year period, seven PhD students were registered. In addition, staff contributed to PhD training at the University of Lund in Sweden and to courses in evidence-based medicine at the University of Copenhagen, as well as to workshops and events in Denmark and beyond. The Panel agreed that the NCC potentially had more to offer with regard to boosting systematic review capacity, through increased supervision of PhD students.

4 Relevance and impact

This section describes and assesses the relevance and impact of the NCC's activities in the context of Cochrane's overall mission as an international organisation, whose combined activities have a worldwide focus, which benefits many countries. As such, Danish society benefits from Cochrane activities carried out in other countries, not just those undertaken in Denmark.

4.1 Primary audiences and target groups (stakeholders)

The NCC's primary audiences and target groups include patients, carers and their families; health professionals; policy-makers and other decision-makers; and researchers and academics, guideline producers, journalists, professional societies and librarians. Within Cochrane itself, Danish authors and editors, and affiliated entities, are key target groups.

4.2 Setting priorities

Working with stakeholders to set priorities for systematic reviews is essential; not only to ensure that important questions are addressed, but also to provide a foundation for knowledge translation. The NCC's overarching aim is to work in areas that affect many people, because this is where research can have the most value. The NCC states that their research agenda is set locally and developed with national and international collaborators. Examples of systematic reviews that have addressed important questions with national and international relevance include:

- Screening for breast cancer with mammography. This review was requested by the Danish Ministry of Health and has been updated regularly, most recently in 2013. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD001877.pub5/full
- Treatment for women with post-partum iron deficiency anaemia. This review was undertaken with Danish clinicians, who identified a clinically important question. Most recent update; 2015. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010861.pub2/full
- General health checks in adults for reducing morbidity and mortality from disease. This review was undertaken because of its potential societal impact, and the findings were discussed with the Danish Minister of Health. Most recent update: 2019. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD009009.pub3/full
- Screening for reducing morbidity and mortality in malignant melanoma. This review was initiated because of its potential societal impact. Published in June 2019. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD012352.pub2/full

4.3 Activities that lead to impact

The NCC has been active in a range of activities that are considered important in achieving impact ('pathway to impact'). These activities include advocating for better quality evidence; making evidence accessible to Danish audiences (now coordinated by a communications consultant); promoting the use of evidence in decision-making; and working with public authorities to develop clinical guidelines, using the best available research evidence. National

and international guidelines can have a direct impact on healthcare practices and affect the lives of thousands of patients. Recent examples of NCC involvement in the development of national clinical guidelines include:

- The national clinical guidelines project initiated by the Danish Health Authority (2014). The NCC was instrumental in developing the underpinning methodology.
- Physiotherapy and Ergotherapy for Children with Cerebral Palsy, March 2014.
- National Clinical Guideline for Rehabilitation in patients with COPD, May 2014.
- National Clinical Guideline for Treatment of ADHD in Adults, February 2015.
- National Clinical Guideline for Treatment of Cervical Radiculopathy, May 2015.
- National Clinical Guideline for Non-pharmacological Interventions for Depression, May 2016.
- National Clinical Guideline for Surgical Interventions for Obesity, January 2017.

In addition, the NCC has played a key role in developing and promoting the methods of evidence-based medicine in Denmark and beyond. International collaborations have resulted in reporting guidelines, including the CONSORT statement for randomised trials; STROBE for observational studies; PRISMA for systematic reviews and SPIRIT for study protocols, which are used globally. Of particular note is the work to gain access to clinical study reports from the European Medicines Agency, which led to full disclosure of clinical trial data in Europe. The next step is to explore the inclusion of study reports in systematic reviews, and this is a priority for Cochrane.

4.4 Contributions to public debate

The NCC reports that they receive frequent requests to evaluate the quality of the evidence on a specific research topic, and this is related to their reputation of independence. They view this as an important contribution to advancing the call for better evidence to inform decision-making and to improve health information for the general public. The NCC gives several examples:

- In 2017, the NCC was requested by journalists from the Danish Broadcasting Corporation to evaluate the evidence behind the promotional claim that the pain medications Tramadol and Tapentadol were rarely addictive. This resulted in a series of TV documentaries, which were reported on national TV news. The TV programmes raised awareness about opioid use in Denmark and led to new regulations ensuring that both Tramadol and Tapentadol were regulated in the same way as other opioids. The Danish Ministry produced a new report on adverse reactions to Tramadol, and recent data show that the use of Tramadol has fallen.
- In 2018, the NCC was requested to review the evidence for the effectiveness of an intervention for childhood obesity, which resulted in articles in a national newspaper about the drug's limitations.
- The NCC's research on screening, particularly mammography screening, has informed public policy and debate over many years. This has initiated an intense debate between the NCC and the Danish Cancer Society and, although opinions have been diverse, it is plausible that the debate will help drive science forward and encourage more investigation of the beneficial effects and potential harms of screening. This work has also had impact outside Denmark, most notably in France and Switzerland, with both countries re-evaluating their recommendations on mammography screening.
- More generally, the NCC has advocated for transparency and better documentation on the efficacy and safety of healthcare interventions and conflicts of interest. This has

contributed to new regulations governing postgraduate training of doctors in collaboration with the pharmaceutical industry, and rules for conflicts of interest among members of the Medical Council. The NCC's agenda on this has been articulated in Danish medical journals and major newspapers (see, for instance: http://ugeskriftet.dk/debat/laegemiddelstyrelsen-og-laegemiddelindustrien-ligner-et-lukket-kredsloeb,
https://finans.dk/erhverv/ECE11496437/chefer-i-laegemiddelstyrelsen-ejer-aktier-i-novo-nordisk-nu-skal-det-stoppes/?ctxref=forside
https://laegemiddelstyrelsen.dk/en/news/2019/danish-medicines-agency-strengthens-its-policy-on-conflicts-of-interest/).

4.5 The Panel's overall assessment of relevance and impact

The NCC's work is of clear relevance to Danish health care practice and policy, and there are examples of significant influence on policy. These include the Centre's contributions to national clinical guidelines covering a range of topics, such as depression and obesity, plus the Centre's work on general health checks, which influenced the Government's decision not to introduce them. The findings from this review have been promoted internationally, and their implications are being discussed in other countries, including the UK.

As noted in Section 4.4, some of the NCC's work has received considerable media interest and widespread coverage and has without doubt informed public debate in Denmark and beyond. In turn, this is likely to bring benefits to society by helping to drive science and practice forward. Public opinion on some of the NCC's work has been diverse, and the depth of feeling has been played out in the public domain, leading the Panel to question whether this has been potentially detrimental to the organisations involved and the role of the NCC's governing structures.

Stakeholder feedback suggests that the NCC has a good reputation, largely due to the quality, independence and importance of its work and to the central mission of Cochrane. There was strong support for re-establishing the Advisory Board, and for increased engagement with stakeholders, to help determine research priorities. The Panel concurred that having stronger stakeholder engagement and a refreshed Advisory Board would be beneficial.

5 Collaborations and partnerships

This section provides a short overview of the NCC's collaborations and partnerships with other organisations, together with the Panel's reflections on these, and of the NCC as a representative of Cochrane entities in the Nordic countries and as a contributor to the international Cochrane organisation.

The Panel notes that the NCC states that they are independent of any political interests and institutions, and have full academic freedom. This underpins their approach to collaboration and partnerships outside of Cochrane.

5.1 Overview of national and international collaborations and partnerships

The NCC has highlighted three national partners: the Danish Health Authority; the Centre for Evidence-based Medicine Odense (CEBMO) and the Section for General Practice at the University of Copenhagen.

Collaboration with the Danish Health Authority is long-standing and focuses on the production of national clinical guidelines, where NCC staff have served as methods consultants and contributed to national screening committees. Collaborations with researchers based in the CEBMO and the Section for General Practice at the University of Copenhagen involve supervision and mentoring of PhD students, as well as joint working on individual projects, particularly on bias in research, the impact of conflicts of interest and screening.

The NCC has highlighted its collaboration with the international *Preventing Overdiagnosis* initiative. This initiative supports the development of a community of clinicians, researchers, policy-makers and citizen advocates with an interest in overdiagnosis, organises international conferences and encourages the generation of research. The NCC is leading a project involving 30 researchers from institutions worldwide to develop an evidence-based approach to re-evaluation of existing screening interventions. This aligns closely with the NCC's ongoing interests in screening.

NCC staff are currently exploring options to contribute to EVIPNet, a network established by WHO to promote the systematic use of research evidence in health policy-making across Europe.

Evidence presented in other sections of this report is relevant here, as many of the achievements highlighted are dependent on successful collaboration.

5.2 Cochrane partnerships

The NCC serves as the local representative for Cochrane in Denmark and in the countries where affiliated centres or groups exist. Staff from the NCC and Cochrane Sweden contribute to PhD training in systematic reviews at the University of Lund, and these courses are available to Danish PhD students. Workshops in systematic reviews are provided by NCC staff to affiliated centres in Sweden, Norway, Poland and Russia. All Denmark-based Cochrane Review Groups (CRGs) are invited to research meetings at the NCC.

NCC staff worked with the Cochrane Editorial Unit in London to establish new coordinating editors for two of the CRGs based in Denmark: Cochrane Colorectal Group and Cochrane Anaesthesia, Critical and Emergency Care Group.

5.3 The Panel's overall assessment of collaborations and partnerships

The NCC has actively engaged in developing collaborations and partnerships within Denmark, the other Nordic countries and internationally. These have mainly been with individual researchers, as opposed to wider organizational collaborations. Collaborations have resulted in high-quality research and publications, notably reporting standards, Cochrane reviews, methodological development and other important outputs, such as clinical guidelines.

The NCC contributes to a range of Cochrane training activities, notably with Cochrane Sweden. The Panel agreed that the NCC potentially had more to offer with regard to enhancing systematic review capacity in Denmark and other Nordic countries, but that the relatively small number of senior staff might be a restricting factor.

Collaboration with the CRGs based in Denmark appears to be limited, with the exception of the Cochrane Bias Methods Group where a range of activities are ongoing, including joint supervision of PhD students. The Panel noted that the CRGs appear to work independently of the NCC and of each other. The NCC expressed their desire to the Panel to re-introduce regular meetings with the CRGs and to establish closer working relationships. The Panel concurred that stronger collaborations between the NCC and the Denmark-based CRGs would be beneficial. In light of the increasing complexity of Cochrane methods, and the need to adhere to methodological standards, opportunities for support and shared learning should be actively pursued.

6 Options for organising Cochrane activities

6.1 Summary of the evaluation

The Panel concluded that the NCC has achieved its main aims and objectives: it has i) contributed to the overall goals of Cochrane; ii) pursued the activities outlined in its own strategic plan (2016-2020) and iii) met the objectives set out in the contract with the Ministry of Health ("*The activities in the Cochrane area include preparation of systematic reviews of health care interventions, prevention of diseases, diagnostics, treatment and care").* However, given the lack of specificity in the contract with the Ministry, it is challenging for the Panel to make precise assessments regarding the degree to which the NCC is meeting the expectations of its core funding.

In considering the value of core funding, the Panel agreed that it provides a platform to:

- Support and co-ordinate Cochrane activities in Denmark and other Nordic countries
- Promote the work of Cochrane and the NCC and the value of evidence-informed health-care
- Engage with policy-makers, practitioners, patients and other stakeholders to identify, define and address important research priorities in Denmark
- Undertake high-quality, impactful research, underpinned by longer-term methodological development
- Build research capacity and expertise, and provide a unique source of advice and bespoke training
- Generate additional research income that expands the work of the Centre and contributes to future sustainability.

Despite the NCC's considerable achievements, the panel questions the viability of its current operating model:

- The NCC is small in size and seems isolated, given its positioning in Rigshospitalet. These limitations might affect the NCC's ability to secure additional research funding, which is necessary to foster growth and reduce dependency on the ministry grant. An organisational affiliation that facilitates collaboration beyond the local academic community should increase opportunities as well as bringing other benefits, especially for early career researchers.
- The NCC's governing structure is complex and lacks clear lines of accountability. A clearer governance structure should improve the transparency of decision-making and clarify to whom and how the NCC is accountable for its national grant and activities. In light of Rigshospitalet's steer to the Panel that an alternative governance structure is needed, clarification around future arrangements requires urgent consideration.

6.2 Options

The Panel concludes that there is a need to consider the options that would strengthen the NCC's current position and facilitate its future growth. Closer alignment with a university would seem desirable, bringing further potential for collaboration, and increased opportunities to secure research funding and recruit PhD students.

Option 1 – The NCC was previously affiliated with the University of Copenhagen (through its Professorship) and hosts several PhD students enrolled at the University of Copenhagen. One option is to align the NCC within a cognate Department or Faculty at the University of Copenhagen to provide potential synergy. The national funding from the Finance Act would be an earmarked grant to the University, which would allow Cochrane activities to continue at the current level. This could be supplemented by research grants and possible investment from the University to foster growth, which should improve academic sustainability while maintaining the research integrity and independence that is central to the NCC's operation and strategy.

Option 2 – The NCC works collaboratively with the Centre for Evidence-based Medicine Odense (CEBMO) at the University of Southern Denmark, through joint supervision of PhD students and via the Cochrane Bias Methods Group. Another option would be to align NCC with existing research groups working in the area of evidence-based medicine or in the National Institute of Public Health at the University of Southern Denmark. As outlined in Option 1, funding would be from an earmarked grant from the Ministry, which could be supplemented by research grants and possible investment from the University of Southern Denmark. Again, this should improve academic sustainability while maintaining the research integrity and independence that is central to the NCCs operation and strategy.

Given existing collaborations, either option seems viable, and both options would offer opportunities to build critical mass and for cross-fertilisation of ideas with researchers working in cognate areas. Either option would signal the national scope of the NCC, which, given its funding source, is important. Similar arrangements are in place in other countries.[4]

[4] See VIVE supplementary data and materials: The Nordic Cochrane Centre.

7 Cochrane Review Groups (CRGs)

This section provides a short overview of the history of the CRGs funded under the grant from the Ministry of Health, their organizational arrangements (including links with the NCC), research productivity and the Panel's overall reflections.

7.1 History and background

Three Cochrane review groups, based in Copenhagen, are funded via the grant from the Ministry of Health. These are:

1. **The Colorectal Group**

   The Colorectal Cancer Group was registered as a Cochrane Review group in 1998. The coordinating editor of this group is Jacob Rosenberg, Professor and Director of the Center for Perioperative Optimizaton (CPO) at Herlev Hospital in the greater Copenhagen area. Rosenberg was appointed coordinating editor in 2018 and is currently working on re-establishing an infrastructure and new strategic direction for the group.[5] The group is now known as the Cochrane Colorectal Group (CCG).

2. **The Anaesthesia Group and the Emergency and Critical Care Group (one group until 2018)**

   The Anaesthesia, Critical and Emergency Care Group was established in 2000 at Bispebjerg Hospital, in Copenhagen.[6] Since 2014, the Group has been based at Herlev Hospital in Copenhagen. Professor Ann Merete Møller has been Coordinating Editor of both groups for 20 years, until 2018. Now, Andrew Smith from the Royal Lancaster Infirmary, UK, is the coordinating editor of the Anaesthesia Group and Harald Herkner, Medical University of Vienna, Austria, is coordinating editor of the Emergency and Critical Care Group. Both groups are affiliated with the anaesthetic research unit at Herlev Hospital, Capital Region, Denmark. For the purposes of this report, the two groups will be considered as a whole (ACE).

3. **The Cochrane Hepato-Biliary Group**

   The Cochrane Hepato-Biliary Group was formed in 1996, and the coordinating editor is Christian Gluud, director of the Copenhagen Trials Unit (CTU) in Copenhagen. This Group is discussed in more detail in the Evaluation Report for the CTU.

[5] Further details about the history of the Colorectal Group can be found on the Cochrane website: https://colorectal.cochrane.org/more-about-us

[6] Further details about the Anaesthesia Group and the Cochrane Emergency and Critical Care Groups can be found on the Cochrane website: https://community.cochrane.org/news/news-cochrane-anaesthesia-critical-and-emergency-care-group

7.2 Organizational arrangements

The financial accounting for the Colorectal Group (CCG), the Anaesthesia Group and the Emergency and Critical Care Group (ACE) takes place at the host hospitals:

- The Cochrane Review Groups: TOTAL 2,730,000 DKK per year
    - ACE: 1,316,000 DKK
    - CCG: 1,413,000 DKK

ACE: the managing editor, information specialist and administrative co-ordinator (0.2 full-time equivalent) are paid directly from the Danish Ministry grant. Editors and reviewers contribute on a voluntary basis.

CCG: the managing editor and administrative co-ordinator are paid directly from the Danish Ministry grant. Editors and reviewers contribute on a voluntary basis. A few non-profit organisations have provided funds over the past ten years.

The remit of these groups is to prepare and update Cochrane reviews. Review production is managed within each group by co-ordinating and managing editors. In 2018, Cochrane implemented its 'CRG Transformation Programme' with the aim of creating a more sustainable review production system.[7] The Programme introduced Cochrane networks and new governance structures for CRGs. Each CRG is nested within one of eight networks and the networks are led by a Senior Editor. The CRGs work with their Senior Editor to ensure consistent quality of reviews and efficient editorial processes. CRGs are accountable to the editor-in-chief of the Cochrane Library via their senior editor. Each CRG is required to sign a Memorandum of Understanding, every five years, with the editor-in-chief, which describes the expectations and responsibilities of Cochrane and the CRG. Senior Editors and the editor-in-chief are responsible for ensuring that accountability is aligned with any requirements of the funder.

7.3 Research production

CCG

From 2014 to 2018, the CCG registered 56 publications, of which 54 (96% of total publications) are Cochrane articles and two (4% of total publications) are reviews (Table 7.1). There was no information on 22 (39% of total publications) publications from 2014 to 2018 in WoS databases (mostly Cochrane protocols).

[7] Further details are available at: https://community.cochrane.org/organizational-info/resources/resources-groups/crg-networks-portal/crg-network-resources

Table 7.1 Number and publication classification of the publications from CCG

WoS -Classification	2012	2013	2014	2015	2016	2017	2018	2014-2018 Total	2012-2018 Total
	No.	No.	No.	No.	No.	No.	No.	No.	No.
Article	0	0	0	0	0	0	0	0	0
Cochrane	33	14	4	7	14	16	13	54	101
Editorial	0	0	0	0	0	0	0	0	0
Letter	0	0	0	0	0	0	0	0	0
Review	0	0	0	0	0	2	0	2	2
Total	33	14	4	7	14	18	13	56	103

Abbreviations: WoS: Web of Science, No.: Number of observations.

Des: The table shows CCG's publications from 2012 to 2018, divided into the five publication categories used in the analysis.

The 34 publications by CCG gained 253 citations from 2014 to 2018. Most citations were for articles published in 2014 and 2015, which is expected as articles from those years have had longer exposure time than articles published in 2017 or 2018. The average article received seven citations for all years (Mean TC range is 0 to 47, for individual years).

Table 7.2 Number of citations and normalised citation score for publications from CCG

	Number	TC	Mean TC	Median TC	Max TC	MNCS Clinical Medicine	MNCS All fields	Missing Publications
2014	2	94	47	47	52	4.08	4.10	2
2015	4	53	13	15	19	1.52	1.53	3
2016	4	42	11	8	20	1.93	1.89	10
2017	14	63	5	2	31	1.83	1.71	4
2018	10	1	0	0	1	0.20	0.19	3
All years	34	253	7	2	52	1.46	1.40	22

Abbreviations: TC: Total number of citations for the period, MNCS: Mean Normalised Citations Score of the publications of a unit.

Des: The table shows the number of publications included in the analysis. For each publication year, the total, mean, median and max. number of citations the publications in that year are shown. The table further shows the mean MNCS Clinical medicine and MNCS All fields scores, which indicate whether the publications received more (scored above 1) or fewer (scored less than 1) citations than the average publication in the relevant field in the given publication year. It was not possible to obtain citation data for all the CCG publications, for which reason there are missing data. The most frequent missing publication type is Cochrane protocols.

Note: We apply weights based on the publication's classification for both MNCS scores. Articles, Cochrane articles and reviews are given a weight of 1 in the analysis, whereas letters, comments and editorials are given a weight of 0.25.

When comparing the citations received by the 34 publications to those of the average article published in the field of clinical medicine, publications from CCG received 1.46 times more citations than the average publication in the field of clinical medicine (MNCS Clinical Medicine range is 0.20 to 4.08, for individual years). In other words, they received more citations than an average publication in the field. Similarly, when CCG publications are compared to an average publication in all the WoS fields, the CCG publications received 1.40 times more citations than the average article in all WoS fields (MNCS All fields range is 0.19 to 4.10, for individual years, see Table 7.2).

ACE

From 2014 to 2018, ACE registered 399 publications, of which 160 (40% of total publications) are journal articles and 231(58% of total publications) are Cochrane articles (Table 7.3). There was no information on 42 (10% of total publications) publications from 2014 to 2018 in WoS databases (mostly Cochrane protocols).

Table 7.3 Number and publication classification of the publications from ACE

WoS -Classification	2012	2013	2014	2015	2016	2017	2018	2014-2018 Total	2012-2018 Total
	No.	No.	No.	No.	No.	No.	No.	No.	No.
Article	11	5	24	27	34	35	40	160	176
Cochrane	18	30	44	48	61	39	39	231	279
Editorial	0	1	0	0	1	0	0	1	2
Letter	0	0	0	0	0	0	0	0	0
Review	1	1	1	0	1	1	4	7	9
Total	30	37	69	75	97	75	83	399	466

Abbreviations: WoS: Web of Science, No.: Number of observations.

Des: The table shows ACE's publications from 2012 to 2018, divided into the five publication categories used in the analysis.

Note: There are an unknown number of reviews in the Article category.

The 357 publications by ACE gained 3,846 citations from 2014 to 2018 (Table 7.4). Most citations were for articles published in 2014 and 2015, which is expected as articles from those years have had a longer exposure time than articles published in 2017 or 2018. The average article received 10.77 for all years (Mean TC range is 1.04 to 21.13, for individual years).

Table 7.4 Number of citations and normalised citation score for publications from ACE

	Number	TC	Mean TC	Median TC	Max TC	MNCS Clinical Medicine	MNCS All fields	Missing Publica-tions
2014	68	1,437	21.13	12	140	1.84	1.85	1
2015	68	1,137	16.72	11	120	1.92	1.94	7
2016	84	808	9.62	6	51	1.76	1.72	13
2017	61	385	6.31	2	68	2.57	2.40	14
2018	76	79	1.04	0	7	2.12	1.96	7
All years	357	3,846	10.77	4	140	2.02	1.95	42

Abbreviations: TC: Total number of citations for the period, MNCS: Mean Normalised Citations Score of the publications of a unit.

Des: The table shows the number of publications included in the analyses. For each publication year, the total, mean, median and maximum number of citations in the publications in that year are shown. The table further shows the mean MNCS Clinical medicine and MNCS All fields score, which indicate whether the publications received more (score above 1) or fewer (score less than 1) citations than the average publication in the relevant field in the given publication year. It was not possible to obtain citation data for all the ACE's publications, for which reason there are missing data. The most frequent missing publication type is Cochrane protocols.

Note: We apply weights based on the publication's classification for both MNCS scores. Articles, Cochrane articles and reviews are given a weight of 1 in the analysis, whereas letters, comments and editorials are given a weight of 0.25.

When comparing the citations received by the 357 publications to the average article published in the field of clinical medicine, publications from ACE receive 2.02 times more citations than the average publication in the field of clinical medicine (MNCS Clinical Medicine range is 1.76 to 2.57, for individual years). In other words, they receive more than twice as many citations as

an average publication in the field. A similar state of affairs is seen, when ACE publications are compared to an average publication in all of the WoS fields, which shows that the ACE publications receive 1.95 times more citations than the average article in all WoS fields (MNCS All fields range 1.72 to 2.40, for individual years; Table 7.4).

7.4 The Panel's overall reflections on Cochrane Review Groups (CRGs)

As can be seen from the tables above, there are differences between CRGs in the number of reviews published over the period. Several factors need to be considered when assessing productivity. The breadth of the research question usually impacts on the number of studies to be included in the review, meaning that the effort and resource required to produce reviews is not evenly distributed. The complexity of the review question is also a factor: some reviews are methodologically challenging to conduct and require advanced statistical and reviewing skills, which are not always immediately available within the team. Another factor is the importance and relevance of the review question to stakeholders. Reviews will only be used if they address meaningful questions, and therefore priority setting is an important aspect of review production. Quality is a key factor, and Cochrane has documented the inconsistent quality of its reviews, and its new strategy focuses on 'fewer, better reviews'.[8]

The Panel notes that the CRGs appear to work independently of each other and of the NCC. There appears to be enthusiasm for re-introducing regular meetings and for working together more closely. In light of the increasing complexity of Cochrane methods, the need to adhere to methodological standards and to ensure stakeholder involvement in priority setting, the Panel strongly supports the need for closer working and shared learning between all Cochrane entities in Denmark. This aligns with the new arrangements and governance structures that Cochrane has recently implemented.[9] As part of these new arrangements, all CRGs sign a Collaboration Agreement with Cochrane, which outlines expectations, requirements and responsibilities. Each CRG needs to be re-accredited every five years to ensure that core functions, including review production, editorial activities organisational and collaboration are carried out.

[8] Further details are available: 'The structure and function of Cochrane Review Groups'. https://community.cochrane.org/sites/default/files/uploads/inline-files/The%20Structure%20and%20Function%20of%20Cochrane%20Review%20Groups_16Aug17_2.pdf

[9] Further details are available: https://community.cochrane.org/organizational-info/resources/resources-groups/crg-networks-portal/crg-network-resource

Bilag 4 Evaluation Report Copenhagen Trial Unit

Dette bilag indeholder den evalueringsrapport, som det internationale evalueringspanel har udarbejdet for Copenhagen Trial Unit (CTU).

Ud over evalueringspanelets evaluering af Copenhagen Trial Unit indeholder evalueringsrapporten også panelets evalueringsperspektiver på den danske Cochrane Review-gruppe, som er tættest knyttet til Copenhagen Trial Unit:

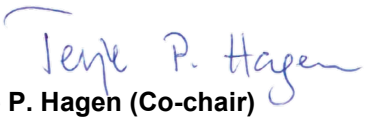
- The Cochrane Hepato-Biliary Group (CHBG).

Evaluation of the Copenhagen Trial Unit

Final Report

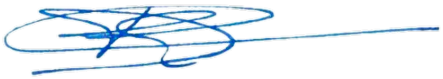
Amanda Sowden (Chair)

Professor and Deputy Director and leader of University of York's Centre for Review and Dissemination's research programme in public health, United Kingdom



Terje P. Hagen (Co-chair)

Professor and Head at Institute of Health and Society, University of Oslo, Norway



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September 2019

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Executive summary

Background of the evaluation

The Nordic Cochrane Centre (NCC) and the Copenhagen Trial Unit (CTU) receive funding from the Ministry of Health via the National Finance Act. This funding has been in place since 1993 and, until now, no formal evaluation of the work of the Centres has taken place. Such an evaluation was requested by the Ministry of Health and was organised and overseen by VIVE, the Danish Centre for Social Science Research. The intent of the evaluation was to assess whether the purpose of the two centres as stated in the National Finance Act grant has been fulfilled. The Finance Act states:

> *"The activities in the Cochrane area include preparation of systematic reviews of health care interventions, prevention of diseases, diagnostics, treatment and care. CTU supports and performs scientifically relevant clinical trials, i.a. as part of the Cochrane Collaboration."* (the National Finance Act 2018, translation by VIVE).

An international Panel of six people carried out the evaluation. The evaluation focused on i) management and organisation of the centres; ii) research production and quality; iii) impact and relevance of the centres' activities and iv) collaborations and partnerships.

The results of the evaluation are presented in separate reports for each of the two centres. This report presents the results of the evaluation of the CTU. The report also includes perspectives on The Cochrane Hepato-Biliary Group (CHBG), which is also funded under the Finance Act.

Conclusions of the Evaluation Panel

In the Panel's view the CTU has achieved its main goals: support, coordinate and conduct randomized clinical trials; participate in the development of methods for randomised clinical trials and meta-analyses; educate students and researchers in evidence-based medicine, randomised clinical trials, meta-analyses and trial sequential analysis; and support, coordinate, and conduct systematic reviews of the literature.

Furthermore, the CTU has published its research in a range of high impact medical journals. The impact has been substantial as CTU-studies have influenced clinical practice and stimulated public debate and discussion.

Despite the CTU's considerable achievements, the Panel questions the sustainability of the current operating model, given its small size, dependency on Ministry funding, positioning in Rigshospitalet and complex governance structures. The Panel concludes that there is an urgent need to consider the options for a revised governance structure. The Panel has discussed several alternatives, including reorganising the CTU as a regional trials unit, incorporating the CTU into a university environment and creating a broader Center for Biostatistics and Epidemiology.

In light of the increasing complexity of Cochrane methods, the need to adhere to methodological standards and to ensure stakeholder involvement in priority setting, the Panel suggest a closer collaboration and shared learning between all Cochrane entities in Denmark.

This aligns with the new arrangements and governance structures that Cochrane has recently implemented.

1 Introduction

1.1 Background

The Ministry of Health has asked VIVE, The Danish Center for Social Science Research, to evaluate the Nordic Cochrane Centre (NCC) and the Copenhagen Trial Unit (CTU).

The NCC and CTU receive a grant each year through the National Finance Act. In the National Finance Act for 2018, it is stated:

> *"In 2018, DKK 17.8 million were allocated for financing of the Cochrane and Copenhagen Trial Unit (CTU). The activities in the Cochrane area include preparation of systematic reviews of health care interventions, prevention of diseases, diagnostics, treatment and care. CTU supports and performs scientifically relevant clinical trials, i.a. as part of the Cochrane Collaboration. The allocated funds from 2009 onwards include DKK 0.5 million for the financing of free access for all to the Cochrane Library"* (the National Finance Act 2018, translation by VIVE).

According to information from the centres, the 17.8 million DKK in 2018 were distributed as follows:

- The Nordic Cochrane Centre: 7,335,000 DKK
- Copenhagen Trial Unit, including the Cochrane Hepato-Biliary Group: 7,735,000
- The Cochrane Review Groups: 2,730,000 DKK
    - Herlev Hospital: 1,316,000 DKK (The Cochrane Anaesthesia and Cochrane Emergency and Critical Care Groups)
    - Bispebjerg Hospital: 1,413,000 DKK (The Cochrane Colorectal Group).

1.2 The evaluation

The results of the evaluation are presented in separate reports for each of the two centres. This report presents the results of the evaluation of the Copenhagen Trial Unit (CTU). In addition to the CTU, the report also includes perspectives on the Cochrane Hepato-Biliary Group.

The main aim of the evaluation is to assess whether the purpose of the National Finance Act grant has been fulfilled, by evaluating the scale of research production and its quality as well as the societal impact of the centres and their external collaborations and partnerships. Accordingly, the evaluation includes both formative elements focusing on broadening the understanding of the institute's characteristics for the purpose of continuous improvement and summative elements focusing on accountability to the entity that funds the running of the centre.

Specifically, the evaluation addresses the following four topics:

- Management and organisation of the centres
- Research production and quality
- Impact and relevance of the centres' activities
- Collaborations and partnerships.

These topics are presented in further details below.

1.3 The evaluation panel

An international evaluation panel has carried out the evaluation and is responsible for writing this report. The appointment of the chair of the evaluation panel was done by The Independent Research Fund Denmark [Danish name: Danmarks Frie Forskningsfond, DFF] based on a nomination by VIVE. VIVE appointed the additional members of the evaluation panel based on nominations by DFF. VIVE requested DFF to nominate three internationally well-acknowledged researchers from the medical sciences council under DFF and two researchers from the social science council under DFF. The candidates from the medical sciences council were to have insight into the processes and methods of randomised studies, systematic reviews and experience with assessing the quality and impact of health care research. The candidates from the social sciences council under DFF were to have insight into the Danish health care system and management and organization of health research. In order to ensure the impartiality of the evaluation, a basic criterion in the nomination of candidates, in addition to the professional skills, was that they must not have had collaborations or other close relations with the NCC, CTU or their international counterparts in the last five years. DFF, in accordance with the Danish Gender Equality Act, nominates at least one male and one female candidate for each seat in the panel. After a process of nomination and invitation of nominees by DFF, VIVE received a list from DFF of five researchers from the medical sciences council and two researchers from the social sciences council, all of whom accepted the invitation. The appointment of the additional members was done by VIVE, after consulting the chair of the evaluation panel. Based on an overall assessment of the individual and complementary qualifications, VIVE appointed three of the five researchers who accepted the invitation from the medical sciences council and the two researchers that accepted the invitation from the social sciences council. All panel members were appointed in their own personal capacity. The composition of panel members has been subject to a hearing by the NCC and the CTU.

The panel consists of six members with complementary competencies in reviews in public health, clinical research, trials and management, and organisation of health research:

- Amanda Sowden (Chair). Professor and Deputy Director and leader of the University of York's Centre for Reviews and Dissemination's research programme in public health, United Kingdom
- Terje P. Hagen (Co-chair). Professor and Head at the Institute of Health and Society, University of Oslo, Norway
- Diederick Grobbee. Professor of Clinical Epidemiology and founder of the Julius Center, University Medical Center Utrecht, The Netherlands
- Eva Swahn. Professor at the Department of Medical and Health Sciences, Division of Cardiology, Linköping University & the Department of Cardiology, University Hospital, Linköping, Sweden
- Merete Osler. Clinical Professor at the Department of Public Health, University of Copenhagen & consultant at the Center for Clinical Research and Prevention, Bispebjerg and Frederiksberg Hospital, Denmark
  Mickael Bech. Professor in healthcare leadership at Crown Prince Frederik Center for Public Leadership, Aarhus University, Denmark.

1.4 Evaluation protocol

The evaluation protocol elaborated by VIVE and the chair of the panel covers four topics:

- Management and organisation
- Research production and quality
- Impact and relevance
- Collaborations and partnerships.

The protocol contains the questions guiding the evaluation panel's assessment and is presented in further detail below.

Management and organisation

The evaluation panel was asked to give a general description and assessment of the governance structure and the management and organizational structure of each of the two centres. The description and assessment were to address the following:

- An overall description and assessment of the governance structure of the centre, including reflections on the governance structure's ability to hold the management of the centre accountable
- A reflection on the strategy of the centre in relation to the purpose and mission of the centre
- A description and assessment of the management and organizational structure of the centre, including reflections on the organizational and management structures' adequacy for accomplishing the centre´s purpose and strategy, and the expediency of the decision-making structure and the division of labour between the different sections of the centre
- An assessment of the organizational support for researchers
- An assessment of the centre's ability to attract external resources from research councils, research funds, EU etc.
- A reflection on the expediency of governance structure, the management and organizational structure compared to similar types of institutions.

Research production and quality

The panel was asked to give an assessment of the quantity and quality of research from each of the two centres. The assessment was to include the following elements:

- A count of publications over the past five years divided into main types of publications
- The average number of annual publications per researcher for the centre at large
- An assessment of the quality of research based on bibliometric indicators
- Reflections on the level and quality of output compared to economic resources
- An assessment of the centres' production of PhD candidates, including reflections on the centres' involvement in PhD programmes
- An overall assessment of the productivity of the centre and the importance and quality of the research.

Impact and relevance

The evaluation panel was asked to give its assessment of the impact and relevance of each of the two centres' activities for the Danish society. The assessment was to include the following elements:

- An assessment of the impact of the centre on clinical practice and clinical guidelines.
- Reflections on how the centres' research and other activities create value in various parts of the Danish society
- Reflections on the centres' impact on the public debate in Denmark

Collaborations and partnerships

The evaluation panel was asked to give its assessment of each of the two centre's national and international collaborations and partnerships. The assessment was to include the following elements:

- An assessment of the level of national and international collaboration of the centre, including reflections on the level of national vs. international collaborations, and the role of the centre in the collaborations
- An assessment of the output of the collaborations
- Reflections on importance of the collaboration for accomplishing the centre´s purpose and strategy.

1.5 The evaluation process and methods

The evaluation of the two centres was carried out in parallel and is based on both quantitative and qualitative data. The data include:

- Self-evaluation reports by the NCC and CTU
- Site-visit by the evaluation panel in Copenhagen 20th to 22nd May 2019
- Documentation and additional data collected by VIVE

Both the self-evaluation reports, and the documentation and additional data collected by VIVE, provide information on each of the four topics of the evaluation. The site-visit included meetings with management, employees and a selected number of stakeholders of each centre as well as a meeting with the management of the hosting organisation, The Danish National Hospital – 'Rigshospitalet' and a teleconference with the Chief Executive Officer of Cochrane.

2 The Copenhagen Trial Unit – management and organisation

This section provides a short overview of the historical background of the Copenhagen Trial Unit (CTU) and its affiliated Cochrane review group: the Cochrane Hepato-Biliary Group (CHBG). The CHBG focuses on interventions for patients with liver and biliary diseases. This section also provides a description and assessment of the current organizational arrangements and the governance structure of the CTU.

2.1 Background, organizational placement and funding

The CTU was established following a decision by the Copenhagen City Council in October 1994. The decision marked the end of a long process in which several alternatives for increasing the quality of the clinical research in Denmark were considered. At the same time, the Copenhagen Health Services were transformed into The Hospital Association of the Capital (Hovedstadens Sygehusfællesskab) with the aim of running health care services targeting the population in the City of Copenhagen and the City of Frederiksberg. On June 1, 1995, Christian Gluud, was appointed Head of the CTU. On January 1, 1996, after a phase of planning and preparation, the CTU was up and running. After four years at The Municipal Hospital (Kommunehospitalet), the CTU moved to The National Hospital (Rigshospitalet) in 2000.

During 1995 to 2006, the CTU received funding from Hovedstadens Sygehusfællesskab. In 1996, the first year of full activity, the funding was about DKK 2.5 million (approximately DKK 6.85 million in currently). Following the structural reorganisation of Danish municipalities and regions in 2007, the governance of the CTU was transferred to the Capital Region of Denmark. At the same time, the Danish state initiated an earmarked grant to the Capital Region for the CTU's running costs. During 2018, funding from the Danish State amounted to DKK 7.735 million. Additional to state funding, the CTU received limited funding from user fees.

The CTU is collaborating with Cochrane in preparing, maintaining and disseminating systematic reviews of the effects of health care interventions. The Editorial Team of the CHBG is hosted by the CTU. The CHBG grew in parallel with the CTU and has functioned as an integrated part of the CTU, providing expertise in systematic reviewing and literature searching.[1] The CTU and the Nordic Cochrane Centre (NCC) are connected through their collective government funding and are situated next door to each other at Rigshospitalet. Their activities are completely independent of each other, however. For further information, see the accompanying NCC Evaluation Report.

The CTU operates as a department within Rigshospitalet. The economic relationship with Rigshospitalet is headed by the Chief Financial Department at the Capital Region of Denmark and according to the rules and regulations of this department. The Capital Region has strict and specific procedures for the use of grants of the Capital Region of Denmark, who control the Danish state grant to the CTU and the CHBG, and other revenue based research grants from both domestic and foreign investigators, including EU grants. Although the CTU is organised as a department under Rigshospitalet, and refers to the vice-president of Rigshospitalet in administrative and financial matters, there is no regular meeting structure or

[1] Further details of CTU's and CHBG's history can be found on the organisations' websites: http://www.ctu.dk/ and https://hbg.cochrane.org/

explicitly defined governance requirements for the CTU. According to both the CTU and Rigshospitalet, the interaction is ad hoc, and the CTU does not have regular meetings with Cochrane. However, the CHBG signed a five-year collaboration agreement with Cochrane in June 2018, which defines the goals, including the responsibilities (commitment to produce evidence), requirements to adhere to Cochrane policies and standards for reviews, ensuring that the products are accessible and that the group is sustainable. In 2021, the CHBG's work will be assessed in detail based on this agreement.

The CTU does not have a regular board as such but had an advisory board in the period 1996 to 2006. According to the CTU's self-evaluation, the members of the advisory board provided good advice and recommendations, especially regarding strategic and tactical matters. Over time, the vision, mission and strategy of the CTU became clearer and the experience of the team more extensive, and the advice offered by the advisory board was not necessarily timely. Therefore, the CTU chose to approach the members of the advisory board on an ad hoc basis. Gradually, this approach made the annual meetings less necessary. The members of the advisory board were elected by the CTU among the researchers of Hovedstadens Sygehusfællesskab (H:S) with the greatest experience in conducting randomised clinical trials.

2.2 Purpose and strategy

The CTU presents itself as a non-specialty-oriented clinical intervention research unit. The centre offers collaboration at all stages of clinical research as well as education in organising clinical trials. The CTU's overall mission is to strengthen Danish clinical research in order to improve patients' prognosis and to contribute to creating credible and reliable clinical research. The CTU's aims are to:

- Support, coordinate and conduct randomised clinical trials in the primary and secondary health-care sectors. The trials focus on prevention, diagnosis, therapy and health care
- Participate in the development of methods for randomised clinical trials and meta-analysis
- Educate students and researchers in evidence-based medicine, randomised clinical trials, meta-analyses and trial sequential analysis
- Support, coordinate and conduct systematic reviews of the literature using meta-analysis, and participate in the international Cochrane Collaboration.

The Copenhagen Trial Unit's strategy is primarily based on the following activities directed at:

- reducing the risk of testing the wrong questions in randomised clinical trials by conducting systematic reviews
- reducing the risk of systematic error (bias) by conducting trials at low risks of bias;
- reducing the risk of random error (play of chance) by conducting trials sufficiently large to answer the questions posed
- reducing the risks of other design errors or other errors in research by employing proper PICOT (participants; intervention; control; outcomes; time points); IT infrastructure; SOPs for clinical trials and systematic reviews; detailed statistical analysis plans; data management plans; and transparency regarding plans and data
- increasing the knowledge and understanding of systematic reviews and randomised clinical trials.

2.3 Organisation and management

The CTU employs approximately 20 people, including student assistants on a part-time basis. Twelve to fourteen people constitute the core staff. They work as trialists, epidemiologists, statisticians and information-technology specialists.

The CTU's main activities are anchored in the individual steering committees for the randomised clinical trials or the author teams for the individual systematic reviews. These core products undergo continuous and systematic quality improvement according to the pertinent SOPs and relevant strategies. Projects as well as other work issues are discussed at the once-a-week staff meetings of the CTU and the CHBG. The usual topics for discussion include: randomised clinical trials, systematic reviews and IT.

When initiating a new collaboration with researchers, the CTU arranges a series of meetings and outlines a contract stating the responsibilities of each of the collaboration partners. This includes randomisation, data management etc. The CTU prefers to participate as a research partner and have a seat in the research project's steering committee.

Ten years ago, the CTU received funding to carry out network activities. For example, the centre is a member of the Nordic Trial Alliance and ECRIN. The CTU is still involved in these activities (for example as scientific board members), but on an un-funded basis.

2.4 The Panel's assessment of the overall management and organisation

The CTU was established to strengthen the quality of Danish clinical research. As will be emphasised later in this report, this has been achieved. The CTU has played an important role in Danish clinical research by developing and implementing standards for clinical trials and by offering relevant educational courses.

The organisation of the CTU was changed following the structural reform of Danish municipalities and regions in 2007. As a consequence of the reform, the responsibility for the CTU was transferred from Hovedstadens Sygehusfællesskab to The Capital Region. However, at the same time the central state initiated an earmarked grant to the CTU. Though not unusual, earmarked grants, in the view of the Panel, break with the fundamental principle of the Danish municipal and regional block grant funding system. The earmarked grant has provided stability in funding over time, but it may also have reduced the integration of the CTU into a broader regional context. The Panel noted that the CTU is heavily dependent upon the earmarked grant from the central state and that this may threaten long-term sustainability if the grant is reduced or removed. The CTU has managed received additional funding but few major grants from other funders.

That CTU no longer has a working advisory board, and there is no regular meeting structure between Rigshospitalet, which is the CTU's governing administrative body. This further strengthens the Panel's impression of a loosely coupled organizational system. Loosely coupled organisations may strengthen local autonomy but may also reduce the organisations' ability to reach overarching goals and to cooperate with other relevant parts of the wider hospital or regional organisation.

The Panel notes that the CTU is quite small and accentuates that the organisation is different from the organisation of similar units in Denmark as well as in others countries. The trend in other Danish regions, and also in the other Scandinavian countries, has been to build methodological support units for clinical research that offer a broad set of methodological approaches. Such units are often bigger than the CTU, may be organised in cooperation with universities and hospitals and, as a reflection of these features, may have greater capacity than the CTU to engage in applications for larger grants and projects, for example at the EU-level. The CTU's current host, Rigshospitalet, in meetings with the Panel also emphasised the need for an alternative governance structure, preferably outside the hospital's organisation.

3 Research production and quality

The following subsections provide an assessment of the research production and impact of the CTU and its affiliated Cochrane review group – CHBG.

We base the assessment on various bibliometric indicators used to assess research production and the quality of research centres. The five indicators capture the involvement and productivity of the centre in any of the peer-reviewed publications, as well as the performance of the publications. The analyses are restricted to publications from 2012/2014 to 2018 and include only publications indexed in the Web of Science (WoS) database.[2]

3.1 Research production and impact – the CTU

From 2014 to 2018, the CTU registered 365 publications, of which 199 (55% of total publications) are journal articles and 78 (21% of total publications) are Cochrane articles (Table 3.1). The numbers of articles peaked in 2015 followed by a slight decline. The decline in publications coincided with an increase in the Cochrane articles.

Table 3.1 Number and publication classification of the publications from the Copenhagen Trial Unit

WoS Classification	2012	2013	2014	2015	2016	2017	2018	2014-2018 Total	2012-2018 Total
	No.	No.	No.	No.	No.	No.	No.	No.	No.
Article	27	37	40	48	44	39	28	199	263
Cochrane	11	11	14	16	15	15	18	78	100
Editorial	0	4	0	0	2	2	4	8	12
Letter	5	6	8	4	7	3	7	29	40
Review	4	2	7	5	8	20	11	51	57
Total	47	60	69	73	76	79	68	365	472

Abbreviations: WoS: Web of Science, No.: Number of observations.

Des: The table shows CTU's publications from 2012 to 2018, divided into the five publication categories used in the analyss.

When assessing the author order, the CTU had 41 (11.3% of total publications) first authorships, 132 (36.2% of total publications) last authorships, and 284 co-authorships (data not shown in tables).

Comparing the citations received by the publications to those of the average article published in the field of clinical medicine in general, publications from the CTU receive 2.25 times more citations than articles in general. A similar result is obtained when comparing the CTU publications to an average publication in all of the WoS fields. CTU's publications receive 2.19 times more citations than the average article in all WoS fields (Table 3.2).

[2] For further description of the methods, see the VIVE working paper «The research production and quality of Copenhagen Trial Unit and its affiliated Cochrane review group".

Table 3.2 Number of citations and normalised citation score for publications from CTU

	Number	TC	Mean TC	Median TC	Max TC	MNCS Clinical Medicine	MNCS All fields	Missing Publica-tions
2014	65	2,039	31.37	11.00	335	2.68	2.69	4
2015	59	1,305	22.12	14.00	179	2.53	2.55	14
2016	68	736	10.82	5.50	69	1.94	1.90	8
2017	69	453	6.57	4.00	64	2.55	2.38	10
2018	56	46	0.82	0.00	6	1.46	1.35	12
All years	317	4,579	14.44	5.00	335	2.25	2.19	48

Abbreviations: No.: Number of observations, TC: Total number of citations for the period, MNCS: Mean Normalised Citations Score of the publications of a unit.

Des: The table shows the number of publications included in the analysis. For each publication year, the total, mean, median and maximum number of citations in the publications in that year are shown. The table further shows the mean MNCS Clinical medicine and MNCS All fields score, which indicates whether the publications received more (score above 1) or fewer (score less than 1) citations than the average publication in the relevant field in the given publication year. It was not possible to obtain citation data for all the CTU publications. The most frequent missing publication type is Cochrane protocols.

Note: We apply weights based on the publications' classification for both MNCS scores. Articles, Cochrane articles and reviews are given a weight of 1 in the analysis, whereas letters, comments and editorials are given a weight of 0.25.

When focusing on articles from the two publication categories 'articles' and 'Cochrane articles' (excluding reviews, letters and editorials), there are 232 publications, which have an average MSCN Clinical Medicine score of 2.34 and a MNCS All fields score of 2.29. Both results imply that the publications from the CTU receive more than twice as many citations as an average publication in the two fields of WoS.

3.2 Research production and impact – CHBG

From 2014 to 2018, CHBG registered 197 publications, of which 180 (91% of total publications) are Cochrane articles and 3 (0.2% of total publications) are journal articles (Table 3.3).

Table 3.3 Number and publication classification of the publications from CHBG

WoS Classification	2012	2013	2014	2015	2016	2017	2018	2014-2018 Total	2012-2018 Total
	No.	No.	No.	No.	No.	No.	No.	No.	No.
Article	0	2	2	1	0	0	0	3	5
Cochrane	36	44	33	45	26	39	37	180	260
Editorial	0	2	0	0	1	0	0	1	3
Letter	0	0	1	1	0	0	1	3	3
Review	2	3	3	2	3	0	2	10	15
Total	38	51	39	49	30	39	40	197	286

Abbreviations: WoS: Web of Science, No.: Number of observations.

Des: The table shows CHBG's publications from 2012 t0 2018, divided into the five publication categories used in the analysis.

The 97 publications by the CHBG gained 784 citations from 2014 to 2018 (Table 3.4). Most citations are for articles published in 2014 and 2015, which is expected as articles from those years have had longer exposure time than articles published in 2017 or 2018. The average article receives eight citations for all years (Mean TC range 1-15 for individual years).

Table 3.4 Number of citations and normalised citation score for publications from CHBG

	Number	TC	Mean TC	Median TC	Max TC	MNCS Clinical Medicine	MNCS All fields	Missing Publica-tions
2014	27	403	15	9	91	1.29	1.29	12
2015	17	151	9	7	26	0.97	0.97	32
2016	13	104	8	6	26	1.47	1.44	17
2017	24	108	5	3	18	1.83	1.71	15
2018	16	17	1	0	8	2.17	2.00	24
All years	97	783	8	4	91	1.54	1.48	100

Abbreviations: No.: Number of observations, TC: Total number of citations for the period, MNCS: Mean Normalised Citations Score of the publications of a unit.

Des: The table shows the number of publications included in the analysis. For each publication year, the total, mean, median and maximum number of citations of the publications in that year are shown. The table further shows the mean MNCS Clinical medicine and MNCS All fields score, which indicates whether the publications received more (score above 1) or fewer (score less than 1) citations than the average publications in the relevant field in the given publication year. It was not possible to obtain citation data for all the NCC publications. The most frequent missing publication type is Cochrane protocols.

Note: We apply weights based on the publications' classification for both MNCS scores. Articles, Cochrane articles and reviews are given a weight of 1 in the analysis, whereas letters, comments and editorials are given a weight of 0.25.

When comparing the citations received by the 97 publications to those of the average article published in the field of clinical medicine, publications from CHBG receive 1.54 times more citations than the average publication in the field of clinical medicine (MNCS Clinical Medicine range 0.97-2.17 for individual years). In other words, they receive more citations than an average publication in the field. A similar state of affairs is seen when CHGB publications are compared to an average publication in all of the WoS fields, which shows that the CHGB publications receive 1.48 times more citations than the average article in all WoS fields (MNCS All fields range 0.97-2.00 for individual years). According to the CTU's self-evaluation, works by the CHBG have been cited over 100 times in more than 30 international guidelines.

3.3 PhD candidates and the CTU's involvement in PhD programmes

One of the CTU's main goals is to educate students, candidates and researchers in evidence-based medicine, randomised clinical trials, meta-analyses and trial sequential analysis. Supervising PhD students is viewed as a way to achieve this goal. Table 3.5 shows the number of PhD students.

Table 3.5 Official supervision by members of Copenhagen Trial Unit staff of PhD projects (excluding personnel by the CHBG)

Category per year	2014	2015	2016	2017	2018	Total
PhDs – initiated	4	3	0	1	1	9
PhDs – ongoing	4	5	7	3	3	22
Defended PhD dissertations	4	3	1	4	1	10

From 2014 to 2018, no PhD fellows were employed at the CTU after their defence. However, the CTU has maintained collaboration with a large number of the PhDs, carrying out joint research and publishing in a broad range of topics, sometimes outside the topic of the PhD thesis.

3.4 The Panel's overall assessment of research productivity and quality

In the Panel's view, the CTU is characterised by high productivity of original research and review publications. Thus, each year (2014-2018) the CTU has published 10-14 publications per employee, or per 1 million of the government grant. Around 30% of the publications include CTU employees as the first or senior author. The CHBG has mainly published systematic reviews but also with a high productivity of above 20 publication per year per employee.

The original papers have been published in a range of medical journals, several in high impact journals. CTU staff have been actively involved in PhD supervision, both as main and co-supervisors, and have lectured on PhD courses at the University of Copenhagen. The CTU has been involved in a large number of courses and symposia. Most of these have been abroad and targeted at international audiences.

Additionally, the CTU has participated in several important research projects that have influenced treatment of patients worldwide, for example in coronary heart disease and sepsis treatment.

Although research quality and method development within clinical research are part of the mission of the CTU, the centre has relatively few publications on theory or methodology. Many of the teaching activities have been conducted abroad, and the CTU has not been responsible for PhD courses in, for instance, RCTs, clinical epidemiology or GCP in Denmark.

4 Impact and relevance

This section describes and analyses the CTU's and CHBG's impact and relevance. The description is based on a broad range of sources, including the CTU's self-evaluation and the Panel's impressions from the site visits.

The impact of the CTU and CHBG can be measured along several dimensions. The Panel has concentrated on trials and interventions with significant relevance in the public debate.

4.1 Target groups and examples of trials with significant relevance

As a reflection of the CTU's aims, it has had a broad audience and range of target groups since 1995. In relation to conducting randomised clinical trials and systematic reviews, the audience and target groups are health researchers from academia and industry. Moreover, they are from different educational backgrounds and specialities, such as physicians, nurses, physiotherapists and engineers. The trials have covered various diseases, from foot warts to schizophrenia. Supported researchers are primarily from the capital region (75%), with some collaborations with researchers from the other regions (12%) in Denmark and internationally (21%). The regional distribution of collaborators may at least partly be representative for the regional distributions of trials.

According to the self-evaluation report, the CTU prefers to do clinical research with the joint efforts of academic researchers at Danish universities and university hospitals, as well as small private start-ups. According to statements from the CTU members during the site visits, the experience with development plans involving pharmaceutical or medical device industries, or where these industries were involved as sponsors have not always been positive because of their unwillingness to choose the most valid methods for the systematic reviews and lack of transparency of data.

Examples of methodological developments with CTU participation:

- Development of thresholds for statistical and clinical significance in randomised trials and systematic reviews
- Trial Sequential Analysis as a tool for handling imprecision and risk of random errors in randomised trials and systematic reviews
- Risk of bias and systematic review methodology
- Development of OpenClinica software for trials: this includes improving system stability and speed, and adding functionality for randomisation, monitoring and various self-service capabilities.

Examples of potential impact on clinical practices and clinical guidelines in the past five years include (listed from the CTU's self-evaluation):

- The CLARICOR trial published in the BMJ (clarithromycin versus placebo for patients with stable coronary artery disease) showed, surprisingly, that clarithromycin increased mortality even at the 10-year follow-up. Since the first published results in 2005, the CTU has repeatedly informed the authorities of the possible adverse reactions of clarithromycin (meetings at European Medicines Agency (EMA), London and Danish Medicines Agency; Copenhagen). At the time of the first publication of the results, the United States Food and

Drug Administration (FDA) issued a safety alert. In 2018, the FDA added a new warning to clarithromycin's label, advising prescribers to choose other antibiotics in patients with coronary artery disease. This happened after FDA had conducted a large observational study confirming CLARICOR's results. In the same period, the Danish and European medicines agencies have changed nothing in their recommendations for the use of clarithromycin.

- The 6S trial (hydroxyethyl-starch versus placebo infusion to septic patients) published in NEJM (49) and the subsequent systematic review in BMJ has contributed to EMA and the 'Surviving Sepsis Campaign' recommending not using hydroxyethyl-starch to septic, burned and critically ill patients. Also, the EMA recommends monitoring perioperative patients receiving hydroxyethyl-starch products for kidney problems for at least 3 months after infusion of starch. Twice, the EMA Pharmacovigilance Risk Assessment Committee (PRAC) and the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) (http://www.hma.eu/352.html) have endorsed the recommendation to suspend the marketing authorisations of hydroxyethyl-starch solutions for infusion across the European Union, but twice the European Union has opposed such a definite withdrawal.
- The TTM-1 trial (cooling to 33 to 34 degrees Celsius versus 36 degrees Celsius to patients with out-of-hospital cardiac arrest) published in NEJM has led the ICU department at Rigshospitalet to cool unconscious patients to 36 degrees Celsius rather than the previously recommended 33-34 degree Celsius. Several other ICUs in Europe and Australia have also adopted this strategy. The TTM-2 trial, presently randomising patients, aims to determine whether unconscious patients with out of hospital cardiac arrest should be cooled at all if the temperature is lower than 37.8 degrees.
- The TRISS trial (patients in the intensive care unit (ICU) who had septic shock and a haemoglobin concentration of 9 g per decilitre or less to receive 1 unit of leukoreduced red cells when the haemoglobin level was 7 g per decilitre or less (lower threshold) or when the level was 9 g per decilitre or less (higher threshold) during the ICU stay), published in NEJM and the subsequent systematic review published in BMJ, has contributed to the 'Surviving Sepsis Campaign' guidelines (51) recommending not to transfuse septic patients before the haemoglobin was 7.0 g/dl or less.
- The SUP-ICU trial (patients admitted to the ICU for an acute condition (i.e. an unplanned admission) who were at risk of gastrointestinal bleeding received 40 mg of intravenous pantoprazole (a proton-pump inhibitor) versus placebo daily during the ICU stay) published in NEJM and the subsequent systematic review in Intensive Care Medicine has led the ICU department at Rigshospitalet not to use proton pump inhibitors prophylactic for all patients at risk of gastrointestinal bleeding, but to reserve this intervention for patients exhibiting signs of gastrointestinal bleeding.

4.2 Interventions in the public debate

According to the self-evaluation, the CTU strives to base its research on a 'results-driven' approach rather than a 'hypothesis-driven' approach. This chosen approach rules out the intention to deliberately impose or dictate pre-specified opinions, and in many cases the conclusion from the research is that there is not enough evidence to either support or refute a given intervention. Such findings are important to the scientific eye but seldom create public debate. In some cases, high quality evidence accumulates, and reliable estimates of the long-term balance of risks and benefits of a given intervention can be reached. At times, these

research findings have been controversial. The CTU lists several examples in its self-evaluation report:

- In February 2017, the CTU published a systematic review on selective serotonin reuptake inhibitors (SSRIs) (62). The study concluded that SSRIs might have statistically significant effects on depressive symptoms. However, SSRIs were also associated with significantly higher risks of both serious and non-serious adverse events, and the potential small beneficial effects seem to be outweighed by harmful effects. These findings triggered a substantial public debate in several media channels.
- Another example of the impact of the CTU on the public debate involves the findings on vitamin and mineral supplements, which raises doubts about the common beliefs that vitamin and mineral supplements are necessary for good health. Christian Gluud participated in the BBC Horizon documentary on the matter: BBC Horizon 25.10.2018: Trial – Vitamin Pills: Miracle or Myth?
- The systematic reviews on methylphenidate for children and adolescents have been used in another BBC documentary, called 'The Doctor Who Gave Up Drugs' (BBC One) by Dr Chris van Tulleken.
- In March 2017, the CTU published a systematic Cochrane review on the effects of direct-acting antivirals (DAAs) for hepatitis C. This was the first systematic review assessing the clinical effects of DAAs. The results from the Cochrane review and the BMJ article discussing the review results, received tremendous attention, both in Denmark (interview in national radio, several articles etc.) and internationally.

4.3 The Panel's assessment of the impact of the centre on clinical practice and clinical guidelines

The CTU's work has comprised an important resource for many clinicians, mainly at hospitals in the Capital Region, by providing high quality assistance in planning, conducting and analysing clinical trials. Results from several of the CTU-studies have also influenced clinical practice worldwide. Important examples include the CLAROCOL and 6S trials.

Some of the systematic reviews on vitamins and antidepressants have received considerable media attention and discussion. The latter has initiated a heated debate between the CTU and Danish psychiatrists, and the work has been turned down by the Danish Medical Agency. Although public opinions on some of these matters have been diverse, it is plausible to believe that the debate will help drive science forward by encouraging more researches and doctors to investigate the relationship between the beneficial and harmful effects of interventions. The Panel questions whether some of the debates could have been played out within the medical society before entering the public sphere. This raises questions related to the governing structure of the CTU, which the Panel will return to later in the report.

The CTU has contributed to the training of students and researchers in conducting RCTs and in methodological development in general. This may have an impact on the quality of future research.

5 Evaluation of collaborations and partnerships

The section provides a short overview of the CTU's and CHBG's collaborations and partnerships with other organisations over the past five years, as well as the Panel's evaluation.

5.1 Overview of collaborations and partnerships

The CTU lists 70 collaborators and partnerships in the past 5 years, of which most (59%) are national. Most of CHBG's 23 collaborations and partnerships (70%) are international (Table 5.1).

Table 5.1 Collaborators ad partnerships by organisation, last 5 years*

Organisation	National	International	Total
CTU	41	29	70
CHBG	7	16	23
Total	48	45	93

* Summary statistics based on TBU's and CHBG's self-evaluation.

Important collaborators include the Centre for Research in Intensive Care (CRIC: http://www.cric.nu/). The CTU has a 5-year contract with CRIC and the Innovation Fund Denmark to undertake four large multicentre trials (SUP-ICU, HOT-ICU, AID-ICU and CLASSIC-II) in intensive care. The cooperation has included the carrying out of systematic reviews of the existing evidence, both before and after these trials were completed. This collaboration has also included several international organisations participating in the trials and systematic reviews.

Other important collaborations include the European Clinical Infrastructures Network (ECRIN) and Nordic Trial Alliance (NTA), with the aim of improving and harmonising conditions for doing multinational and multicentre clinical research in Europe and Scandinavia.

Some of the collaborations have led to long-lasting national and international collaborations to improve and harmonise clinical research in cardiology, endocrinology, neurosurgery, intensive care medicine, perioperative medicine, pain research, psychiatry and obstetrics.

The CHBG has extensive collaborations, mainly international, which reflects the work of Cochrane. The CHBG Editorial Team office staff collaborate with more than 2180 people around the world (more than 70 countries), and the role include peer reviewer, translator, consumer, review author, statistician and editor.

5.2 Assessment of collaboration and partnerships

The Panel notes the extent of the collaborations and partnerships across Denmark and internationally. The CTU has assisted in and initiated high quality, multicentre randomised clinical trials in multiple medical research fields – among critically ill patients, cardiology patients and children – and has improved the methods and infrastructure of these trials.

International cooperation is essential for reaching evidence-based recommendations on the use of interventions in all specialties of clinical medicine, and the CTU has engaged in the

development of such collaborations both within and outside Cochrane. International cooperation is important because it raises the methodological quality and statistical power to detect or reject clinically relevant intervention effects on patient centred outcomes, as well as on all-cause mortality, serious adverse events and health-related quality of life. International collaborations will probably become more important in future years as the effects of interventions might diminish in size.

6 Options for organising the activities of the CTU and the CHBG

6.1 Summary of the assessment

In the Panel's view, the CTU has reached its main goals: support, coordinate and conduct randomised clinical trials; participate in the development of methods for randomised clinical trials and meta-analyses; educate students and researchers in evidence-based medicine, randomised clinical trials, meta-analyses, and trial sequential analysis; and support, coordinate and conduct systematic reviews of the literature.

Furthermore, the CTU has been highly productive in carrying out original research and systematic reviews and publishing original papers in high impact medical journals. The impact has been substantial, as the CTU-studies have influenced clinical practice and stimulated public debate and discussion.

However, the Panel questions whether the current organizational and financial model is sustainable:

- The earmarked grant under the Financial Act breaks with the fundamental principles of municipal and regional funding. There is a discrepancy in the CTU's funding from the Financial Act and their primary collaboration with clinical researchers in the Capital Region of Denmark, while other equivalent units in other parts of the country are paid by the hosting regions and/or universities.
- The governing structure of the unit is ambiguous and lacks legitimacy in, for instance, Rigshospitalet, the CTU's host organisation, and Rigshospitalet has indicated that CTU should not be organised as part of the hospital.
- The CTU is relatively small in size, lacks professional statistical expertise and, compared to similar organisations in Denmark and other Scandinavian countries, offers a narrow selection of methodological approaches. These limitations will probably restrict the CTU's ability to participate and succeed in future research programmes of a certain size.

Taken together the Panel concludes that there is a need to discuss alternative arrangements for organising the CTU and the CHBG.

6.2 Options for the CTU

Several alternatives should be discussed:

Model 1: the CTU as a regional trial unit

The easiest model to implement would be simply to move the CTU to the regional level and allow its scope to broaden to cover all hospitals in the Capital Region. A CTU board would be necessary for setting priorities and developing strategic plans. While the model is simple to implement it will not solve all future challenges, including the problem related to lack of statistical expertise and, more generally, the need to sustain an attractive academic environment. The model can however be combined with increased collaboration with Copenhagen University, for example by personnel in joint CTU/university positions.

Model 2: the CTU as a university unit

Lack of statistical expertise can be handled by merging the CTU with the Section of Biostatistics or other cognate sections under the Department of Public Health, University of Copenhagen. The Section of Biostatistics conducts biostatistical research and development participates in medical research and offers biostatistical advice to PhD students and staff engaged in experimental and clinical medicine, public health and dentistry, in all disciplines under the Faculty of Health Sciences. However, the funding for this model could be controversial, since the capital region would need to fund university activity. This problem could be solved by letting CTU stay on the Finance Act. The size of the university overhead will also be an issue with this model.

Models 3: Copenhagen Center for Biostatistics and Epidemiology (CCBE)

This model would require Rigshospitalet and the University of Copenhagen to set up a joint centre integrating the activities of the Department of Public Health, the CTU and possibly other statistical units at Rigshospitalet. The CCBE would cover all aspects of biostatistics, methodological research, advanced supervision and advice in all areas of medicine and health-related research, from clinical and epidemiological research, to molecular biology and other basic medical sciences. The Centre will develop statistical methods and their application to the design, analysis and interpretation of biomedical, clinical and epidemiological studies and data as well as provide statistical and epidemiological advice and training for researchers and students of the Faculty of Health Science, Rigshospitalet and other hospitals in the capital region. The capital region will fund the organisation together with University of Copenhagen and Rigshospitalet.

6.3 Options for the CHBG

The Panel notes that the CHBG and other Cochrane entities in Denmark appear to work independently of each other and of the Nordic Cochrane Centre. In light of the increasing complexity of Cochrane methods, and the need to adhere to methodological standards and to ensure stakeholder involvement in priority setting, the Panel strongly supports the need for closer collaboration and shared learning among all Cochrane entities in Denmark. This aligns with the new arrangements and governance structures that Cochrane has recently implemented.[3]

[3] Further details are available at https://community.cochrane.org/organizational-info/resources/resources-groups/crg-networks-portal/crg-network-resources

Litteratur

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