Utvärdering av den kliniska forskningens kvalitet vid de landsting som omfattas av ALF-avtalet

Vetenskapsrådet 2018

UTVÄRDERING AV DEN KLINISKA FORSKNINGENS KVALITET VID DE LANDSTING SOM OMFATTAS AV ALF-AVTALET

VETENSKAPSRÅDET

BOX 1035

SE-101 38 STOCKHOLM

VR1804

ISBN 978-91-7307-362-2

Utvärdering av den kliniska forskningens kvalitet vid de landsting som omfattas av ALF-avtalet

Diarienummer

3.2-2018-1020
3.2-2016-7225
3.2-2016-7077
3.2-2016-7078

FÖRORD

Denna rapport är en gemensam redovisning av de två regeringsuppdragen U2016/02935/F och U2016/04203/F till Vetenskapsrådet att utvärdera den kliniska forskningens kvalitet vid de landsting som omfattas av ALF-avtalet.

Det huvudsakliga syftet med utvärderingarna är att identifiera, lyfta fram och premiera goda exempel i form av ALF-regioner som utmärker sig nationellt genom sitt kvalitetsarbete och därmed kan fungera som kvalitetsdrivande förebilder. Dessutom kommer resultaten av utvärderingarna att ligga till grund för den fördelningsmodell för ALF-ersättningen som, enligt 9 § ALF-avtalet, ska användas från och med 2019 och som innebär att 20 procent av ALF-ersättningen för klinisk forskning ska fördelas baserat på den kliniska forskningens kvalitet.

Vetenskapsrådet har, på uppdrag av regeringen, tidigare utvecklat och föreslagit en modell för fördelning av ALF-ersättningen som innebär att en del av ersättningen fördelas på basis av regelbundna utvärderingar av den ALF-finansierade kliniska forskningens kvalitet. Förslagen finns redovisade i Vetenskapsrådets två rapporter *Transparens och kvalitet - en modell för uppföljning och utvärdering av klinisk forskning finansierad av ALF-medel* (8:2010) och *En utvecklad modell för kvalitetsutvärdering av klinisk forskning finansierad av ALF-medel* (2:2013). Dessa förslag utgjorde ett av underlagen för det nya ALF-avtalet som trädde i kraft 2015, inklusive den nya fördelningsmodellen för ALF-ersättning som ska gälla från 2019.

Utgångspunkterna för utvärderingarna har, i enlighet med ALF-avtalet, arbetats fram och beslutats av den partssammansatta nationella styrgruppen för ALF, som består av ledamöter från landstingen och svenska staten. Enligt dessa utgångspunkter ska utvärderingarna genomföras av externa och oberoende internationella expertpaneler. I processen med att vidareutveckla och implementera utgångspunkterna har vi presenterat och diskuterat arbetet med utvärderingarna vid styrgruppens möten och mellan dessa möten även inhämtat synpunkter från styrgruppens arbetsgrupp för utvärderingarna. Parallellt med Vetenskapsrådets uppdrag att utvärdera forskningens kvalitet har Socialstyrelsen haft i uppdrag att utvärdera universitetssjukvården vid de landsting som omfattas av ALF-avtalet (S2016/06247FS). Vi har därför även samrått med Socialstyrelsen kring omfattning och avgränsning av de båda myndigheternas delvis överlappande uppdrag.

Det är första gången Vetenskapsrådet gör denna typ av utvärdering och vår ambition har varit att lära av processen och ta till oss synpunkter, erfarenheter och lärdomar inför nästa omgång. Då någon pilotomgång av utvärderingsmodellen inte har genomförts har justeringar av upplägget fått ske längs vägen. Exempelvis bjöd vi tillsammans med Socialstyrelsen in de berörda landstingen och universiteten till ett dialogmöte under våren 2017 för att informera, diskutera och få deras synpunkter på förslagen om hur utvärderingarna skulle genomföras. Vi har lyssnat på alla synpunkter och gjort överväganden för att se till så att systemet blir rättssäkert, relevant och rättvisande och att systemet ska kunna bidra till regionernas eget arbete med kvalitetsutveckling.

Resultatet av utvärderingarna bygger på sakkunniggranskning av olika underlag – bibliometriska analyser, publikationer, självvärderingar, hearings och statistik som Vetenskapsrådet hämtat in om respektive region, inom ramen för de tre olika utvärderingarnas olika behov. De internationella experterna som genomfört granskningarna har enats om omdömen och indelning i kategorier och Vetenskapsrådet har därefter fattat slutgiltigt beslut om kvaliteten på regionernas kliniska forskning. Sammantaget kan vi konstatera att svensk klinisk forskning generellt håller god kvalitet med flertalet goda exempel, men att det finns utrymme för kvalitetshöjande åtgärder i samtliga utvärderade regioner.

Vi vill rikta ett varmt tack till alla ledamöter i de internationella expertpanelerna som genomfört utvärderingarna och som med sin kunskap och sitt engagemang även gjort viktiga bidrag till det fortsatta utvecklingsarbetet.

I och med denna rapport överlämnar Vetenskapsrådet resultatet av utvärderingarna till Regeringskansliet (Utbildningsdepartementet).

Sven Stafström
Generaldirektör

Ann Fust
Rådsdirektör

INNEHÅLL

SAMMANFATTNING

Vetenskapsrådet har i enlighet med regeringsuppdragen U2016/02935/F och U2016/04203/F utvärderat den kliniska forskningens kvalitet vid de landsting som omfattas av avtalet mellan den svenska staten och vissa landsting om samarbete om utbildning av läkare, klinisk forskning samt utveckling av hälso- och sjukvården, ALF-avtalet [1]. Då landsting och universitet har ett gemensamt ansvar för den kliniska forskningen inkluderas all klinisk forskning som bedrivs av båda parter i utvärderingarna. Landsting och universitet benämns gemensamt som en ALF-region. Denna rapport sammanfattar resultatet av utvärderingarna och utgör redovisningen av dessa regeringsuppdrag.

Det huvudsakliga syftet med utvärderingarna är att identifiera, lyfta fram och premiera goda exempel i form av ALF-regioner som utmärker sig nationellt genom sitt kvalitetsarbete och därmed kan fungera som kvalitetsdrivande förebilder, så att det långsiktiga målet att främja hela nationens kliniska forskning på sikt kan uppnås. Dessutom ska, enligt 9 § ALF-avtalet, en ny fördelningsmodell användas från och med 2019. Denna modell innebär att 20 procent av ALF-ersättningen för klinisk forskning ska fördelas baserat på de utvärderingar av den kliniska forskningens kvalitet, som Vetenskapsrådet fått i uppdrag att utföra.

Utgångspunkterna för utvärderingarna har beslutats av den partssammansatta nationella styrgruppen för ALF, som består av ledamöter från landstingen och den svenska staten. Enligt dessa utgångspunkter ska utvärderingarna omfatta tre huvudområden och genomföras av tre externa och oberoende expertpaneler:

1. den vetenskapliga produktionens kvalitet (panel 1)
2. forskningens kliniska betydelse och samhällsnytta (panel 2)
3. forskningens förutsättningar (panel 3).

Varje expertpanel har, oberoende av de andra panelerna, gjort en sammanvägd bedömning av underlagen och grupperat ALF-regionerna i en av följande kategorier:

- undermålig kvalitet
- god–hög kvalitet
- mycket hög kvalitet.

De ALF-regioner som placerats i kategorin *mycket hög kvalitet* för något av de utvärderade huvudområdena lyfts här fram som goda exempel. Den nationella styrgruppen har beslutat att varje panel ska placera minst en och högst tre regioner i kategorin *mycket hög kvalitet*. Bedömningarna motiveras med ett skriftligt omdöme.

Panelernas bedömningar och rapporter ligger till grund för Vetenskapsrådets beslut om den kliniska forskningens kvalitet i respektive ALF-region, vilket sammanfattas i tabellen nedan. Panelernas fullständiga rapporter redovisas i del 2.

Tabell 1. Vetenskapsrådets beslut om den kliniska forskningens kvalitet i de olika ALF-regionerna

ALF-region	Den vetenskapliga produktionens kvalitet	Forskningens kliniska betydelse och samhällsnytta	Forskningens förutsättningar
Stockholm	Mycket hög kvalitet	God–hög kvalitet	God–hög kvalitet
Västra Götaland	Mycket hög kvalitet	God–hög kvalitet	Mycket hög kvalitet
Skåne	God–hög kvalitet	Mycket hög kvalitet	Mycket hög kvalitet
Uppsala	God–hög kvalitet	God–hög kvalitet	God–hög kvalitet
Västerbotten	God–hög kvalitet	God–hög kvalitet	Mycket hög kvalitet
Östergötland	God–hög kvalitet	God–hög kvalitet	God–hög kvalitet
Örebro	God–hög kvalitet	Undermålig kvalitet	God–hög kvalitet

[1] ALF-avtalet, U2014/07551/F

Sammanfattningsvis, visar utvärderingarna att svensk klinisk forskning generellt håller hög kvalitet. Alla ALF-regioner visar på styrkor inom olika forskningsområden och detta återspeglas även i urvalet av publikationer som granskats. Utvärderingarna visar även att det finns utrymme för förbättringsåtgärder i samtliga ALF-regioner. Exempelvis anser panelerna att fler och större samarbeten inom vissa forskningsområden samt större samordning mellan de olika kvalitetsregistren skulle kunna höja kvaliteten på svensk klinisk forskning ytterligare.

SUMMARY

In accordance with its Government Mandates U2016/02935/F and U2016/04203/F, the Swedish Research Council has evaluated the quality of clinical research at the county councils covered by the agreement between the Swedish Government and certain county councils concerning cooperation on medical education, clinical research and development of health services, the ALF agreement [2]. As county councils and universities have joint responsibility for clinical research, all clinical research carried out by both parties is included in the evaluations. County councils and universities are jointly referred to as an ALF region. This report summarises the result of the evaluations, and constitutes the report on these Government mandates.

The main purpose of the evaluations is to identify, highlight and reward good examples of ALF regions that are nationally outstanding and therefore can serve as good examples for the other ALF regions, so that the long-term goal of enhancing clinical research throughout the country can eventually be achieved. According to Section 9 of the ALF agreement, a new allocation model shall also be used as from 2019. This model entails 20 per cent of the ALF funding for clinical research being allocated on the basis of the evaluations of the quality of clinical research, which the Swedish Research Council has been tasked to conduct.

The starting points for the evaluations have been decided by the National ALF Steering Committee, consisting of members from the county councils and the Swedish state. According to these starting points, the evaluations shall cover three main areas and be conducted by three external and independent international expert panels:

1. the quality of the scientific output (ALF panel 1)
2. the clinical significance and societal impact of the clinical research (ALF panel 2)
3. the prerequisites for clinical research (ALF panel 3).

Each expert panel has carried out a weighted assessment of the documentation independently of each other, and grouped the ALF regions into one of the following categories:

- inferior quality
- good–high quality
- very high quality.

The evaluations are justified in a written statement. The ALF regions placed in the category *very high quality* for any of the evaluated main areas are highlighted as good examples. The National ALF Steering Committee, has decided that each panel should place at least one and at most three regions in the *very high quality* category.

The panels' evaluations and reports form the basis for the Swedish Research Council's decision on the quality of clinical research in each ALF region, which are summarised in the table below. The full reports of the panels are shown in Part 2.

[2] ALF-avtalet, U2014/07551/F

Table 1. The Swedish Research Council's decision on the quality of clinical research in the ALF regions

ALF region	The quality of the scientific output kvalitet	The clinical significance and societal impact of the clinical research	The prerequisites for clinical research
Stockholm	Very high quality	Good–high quality	Good–high quality
Västra Götaland	Very high quality	Good–high quality	Very high quality
Skåne	Good–high quality	Very high quality	Very high quality
Uppsala	Good–high quality	Good–high quality	Good–high quality
Västerbotten	Good–high quality	Good–high quality	Very high quality
Östergötland	Good–high quality	Good–high quality	Good–high quality
Örebro	Good–high quality	Inferior quality	Good–high quality

In summary, the evaluations show that Swedish clinical research generally holds high quality. All ALF regions show strengths in different research areas, which is reflected in the selection of publications reviewed. The evaluations also show that there is room for enhancement measures in all ALF regions. For example, the panels consider that more and larger research collaborations as well as greater coordination between the different quality registers could further enhance the quality of Swedish clinical research.

INLEDNING

ALF-avtalet [3], är ett avtal om samarbete om utbildning av läkare, klinisk forskning och utveckling av hälso- och sjukvården, som är upprättat mellan den svenska staten och vissa landsting. Landstingen är huvudmän för hälso-och sjukvården medan staten är huvudman för universiteten och därmed ansvarig för den utbildning och forskning som bedrivs vid de berörda universiteten. Genom ALF-avtalet har de båda parterna kommit överens om att gemensamt främja hälso- och sjukvårdens utveckling genom samarbete inom utbildning, forskning och utveckling. Parterna har, genom ALF-avtalet, även enats om att tillsätta en partssammansatt nationell styrgrupp för ALF [4]. Styrgruppen ska följa avtalets tillämpning och vid behov föreslå justeringar i avtalet. Det nationella avtalet kompletteras av regionala avtal mellan berörda landsting och universitet. I denna rapport benämns landsting och universitet gemensamt som en ALF-region (tabell 2).

ALF-avtalet reglerar bland annat den ersättning som staten ger landstingen för att medverka i utbildning av läkare, klinisk forskning och utveckling av hälso- och sjukvården, den så kallade ALF-ersättningen. Avtalet reglerar även hur denna ersättning ska fördelas mellan landstingen. ALF-ersättningen för klinisk forskning uppgick under 2015 till ca 1 700 miljoner kronor.

Tabell 2. ALF-regioner, landsting och universitet som omfattas av ALF-avtalet. Notera att Region Örebro län inte omfattades av ALF-avtalet före 2015.

ALF-region	Landsting	Universitet	Andel av ALF-medel för klinisk forskning (2015)
Stockholm	Stockholms läns landsting	Karolinska institutet	27 %
Västra Götaland	Västra Götalandsregionen	Göteborgs universitet	21 %
Skåne	Region Skåne	Lunds universitet	20 %
Uppsala	Region Uppsala	Uppsala universitet	12 %
Västerbotten	Västerbottens läns landsting	Umeå universitet	11 %
Östergötland	Region Östergötland	Linköpings universitet	8 %
Örebro	Region Örebro län	Örebro universitet	2 %

Uppdraget

Regeringen har gett Vetenskapsrådet två uppdrag att utvärdera den kliniska forskningens kvalitet vid de landsting som omfattas av ALF-avtalet. Dessa båda uppdrag redovisas gemensamt i denna rapport.

Det första uppdraget beslutades av regeringen i juni 2016 och innebär att Vetenskapsrådet ska utvärdera den kliniska forskningens vetenskapliga kvalitet utifrån den vetenskapliga produktionens kvalitet.[5] I uppdraget anges att utvärderingen ska genomföras efter samråd med den nationella styrgruppen för ALF. I oktober 2016 beslutade regeringen att även ge Vetenskapsrådet i uppdrag att utvärdera den kliniska forskningens vetenskapliga kvalitet avseende forskningens kliniska betydelse och samhällsnytta samt forskningens förutsättningar.[6] I uppdraget anges att Vetenskapsrådet ska inhämta synpunkter från den nationella styrgruppen för ALF under arbetets gång. Parallellt uppdrogs åt Socialstyrelsen att utvärdera universitetssjukvården vid de landsting som omfattas av ALF-avtalet.[7] Vetenskapsrådet och Socialstyrelsen ska enligt uppdragen samråda och samverka vad gäller datainsamling.

3 ALF-avtalet, U2014/07551/F (Länk till ALF-avtalet).

4 ALF-avtalet 15 §. Styrgruppen ska bestå av högst 14 ledamöter varav landstingen utser högst sju och svenska staten utser högst sju. Ordförandeskapet alterneras mellan landsting och stat.

5 Regeringsbeslut U2016/02935/F Uppdrag att utvärdera den kliniska forskningens vetenskapliga kvalitet. (Länk till uppdraget).

6 Regeringsbeslut U2016/04203/F Uppdrag att utvärdera den kliniska forskningens kvalitet avseende forskningens kliniska betydelse och samhällsnytta samt forskningens förutsättningar. (Länk till uppdraget).

7 Regeringsbeslut S2016/06247FS Uppdrag att utvärdera universitetssjukvård. (Länk till uppdraget).

En bakgrund till regeringens uppdrag till Vetenskapsrådet finns i det förnyade ALF-avtalet som trädde i kraft 2015. Enligt 9 § ALF-avtalet ska en ny fördelningsmodell användas från och med 2019, som innebär att 20 procent av ersättningen för klinisk forskning ska fördelas baserat på utvärdering av den kliniska forskningens kvalitet. Vidare anges att modellen ska innefatta expertbedömning av forskningens förutsättningar, forskningens kliniska betydelse och en bibliometrisk utvärdering. Enligt 15 § ALF-avtalet, ska den nationella styrgruppen för ALF lämna förslag på utformning och genomförande av återkommande utvärderingar av den kliniska forskningens kvalitet.

Det huvudsakliga syftet med den nya fördelningsmodellen för ALF-ersättningen och utvärderingarna av den kliniska forskningens kvalitet är att identifiera, lyfta fram och premiera goda exempel i form av ALF-regioner som utmärker sig nationellt genom sitt kvalitetsarbete och därmed kan fungera som kvalitetsdrivande förebilder, så att det långsiktiga målet att främja hela nationens kliniska forskning på sikt kan uppnås.

Relaterade uppdrag

Vetenskapsrådet har i två tidigare utredningar [8] på regeringens uppdrag utvecklat och föreslagit en modell som innebär att en viss del av ALF-ersättningen fördelas på basis av regelbundna utvärderingar, baserade på sakkunniggranskning, av den ALF-finansierade kliniska forskningens kvalitet. Dessa förslag utgjorde ett av underlagen för det förnyade ALF-avtal som trädde i kraft 2015, och har också varit ett av underlagen för det förslag till utvärderingsmodell som sedermera har tagits fram av den nationella styrgruppen för ALF, vilken inrättades som en konsekvens av det förnyade ALF-avtalet.

Uppdragets genomförande

Genomförandet av regeringsuppdragen till Vetenskapsrådet baseras på den modell för utformning och genomförande av utvärdering av den kliniska forskningens kvalitet som den nationella styrgruppen har arbetat fram. Styrgruppens utvärderingsmodell, och regeringsuppdragen, innebär att den kliniska forskningens kvalitet ska utvärderas utifrån följande tre huvudområden:

1. den vetenskapliga produktionens kvalitet
2. forskningens kliniska betydelse och samhällsnytta
3. forskningens förutsättningar.

Utvärderingarna har genomförts av tre oberoende internationella expertpaneler.

I regeringsuppdragen anges dessutom att Vetenskapsrådet ska samråda och inhämta synpunkter från den nationella styrgruppen samt att Vetenskapsrådet och Socialstyrelsen ska samråda och samverka vad gäller datainsamling. Därför har Vetenskapsrådet presenterat arbetet med utvärderingarna vid styrgruppens möten (som äger rum 4 ggr/år) och mellan dessa möten även inhämtat synpunkter från styrgruppens arbetsgrupp för utvärderingarna. Vidare har Vetenskapsrådet och Socialstyrelsen samrått kring omfattning och avgränsning av de båda myndigheternas delvis överlappande uppdrag. Samverkan kring datainsamling har också gjorts så långt det varit praktiskt möjligt.

Under våren 2017 bjöd Vetenskapsrådet och Socialstyrelsen in de berörda landstingen och universiteten till ett gemensamt dialogmöte för att informera, diskutera och få deras synpunkter på förslagen om hur utvärderingarna skulle genomföras.

Dessutom har, i enlighet med förordning 1982:668 om statliga myndigheters inhämtande av uppgifter från näringsidkare och kommuner, samråd skett med Sveriges Kommuner och Landsting (SKL) för insamling av underlag för utvärderingarna av forskningens kliniska betydelse och samhällsnytta samt forskningens förutsättningar.

[8] Se Vetenskapsrådets rapporter Transparens och kvalitet (8:2010) och En utvecklad modell för kvalitetsutvärdering av klinisk forskning finansierad av ALF-medel (2:2013).

Internt på Vetenskapsrådet har arbetet med att utforma och genomföra utvärderingarna genomförts av tre projektgrupper och en intern styrgrupp. För utvärderingen av forskningens förutsättningar inrättades även en extern rådgivande grupp. (Länk till information om gruppernas sammansättning).

Rapportens disposition

Rapporten redovisar gemensamt Vetenskapsrådets två uppdrag att i tre separata utvärderingar utvärdera den kliniska forskningens kvalitet vid de landsting som omfattas av ALF-avtalet. Detta är i enlighet med den nationella styrgruppens utvärderingsmodell som anger att de tre expertpanelerna ska arbeta oberoende av varandra och lämna över resultaten till Vetenskapsrådet som sammanställer en samlad slutrapport.

Rapporten består av två delar. Den första delen är skriven på svenska och beskriver inledningsvis uppdragens utgångspunkter följt av de samlade resultaten och Vetenskapsrådets beslut. Därefter följer kapitel med beskrivningar av respektive utvärderings förutsättningar och genomförande. Del två är skriven på engelska och inleds med en kort beskrivning av ALF-avtalet och utvärderingarna generellt. Därefter följer de tre expertpanelernas fullständiga rapporter, som utgör grunden för Vetenskapsrådets beslut. I dessa rapporter framgår panelernas motiveringar till kategoriseringen av ALF-regionerna och vilka regioner som placerats i kategorin *mycket hög kvalitet* och därmed lyfts som goda exempel. Rapporterna lyfter också fram andra goda exempel från olika ALF-regioner, som en/någon panel vill framhäva vid sidan av sin övergripande bedömning. Dessutom innehåller expertpanelernas rapporter identifierade utvecklingsområden samt rekommendationer för förbättringar.

UTGÅNGSPUNKTER FÖR UTVÄRDERINGARNA

Utgångspunkterna för de tre utvärderingarna har beslutats av den nationella styrgruppen för ALF.[9] Utvärderingarna ska i enlighet med dessa utgångspunkter och regeringens uppdrag till Vetenskapsrådet genomföras av tre externa och oberoende internationella expertpaneler utifrån följande huvudområden:

1. den vetenskapliga produktionens kvalitet (panel 1)
2. forskningens kliniska betydelse och samhällsnytta (panel 2)
3. forskningens förutsättningar (panel 3).

Då landsting och universitet har ett gemensamt ansvar för den kliniska forskningen har Vetenskapsrådet inkluderat all klinisk forskning som bedrivs av båda parter i utvärderingarna. Landsting och universitet benämns gemensamt som en ALF-region. Klinisk forskning definieras i detta sammanhang, i enlighet med 7 § ALF-avtalet, som ”sådan forskning som förutsätter vårdens strukturer och resurser och har som mål att lösa ett ohälsoproblem eller att identifiera faktorer som leder till ökad hälsa”.

Den nya fördelningsmodellen för ALF-ersättningen för klinisk forskning, som ska användas från och med 2019, innebär att 20 procent av ersättningen ska fördelas baserat på utvärdering av den kliniska forskningens kvalitet[10]. Enligt den nationella styrgruppen ska resultatet av utvärderingarna viktas så att den kliniska forskningens vetenskapliga kvalitet ska ligga till grund för fördelningen av 50 procent av fördelningspotten[11] och utvärderingarna av forskningens kliniska betydelse och samhällsnytta samt forskningens förutsättningar ska ligga till grund för en fördelning av vardera 25 procent av fördelningspotten. Dessutom har den nationella styrgruppen beslutat att varje expertpanel, oberoende av varandra, ska göra en sammanvägd bedömning och gruppera ALF-regionerna i följande tre kategorier:

- **Undermålig kvalitet**
  I denna kategori förväntas endast i undantagsfall någon ALF-region placeras. Denna klassificering ges om utvärderingen av det samlade underlaget visar på en undermålig prestation utifrån de tilldelade ALF-medlen, och/eller om den aktuella ALF-regionen underlåtit att fullt ut medverka i utvärderingen (t.ex.genom att prestera undermåliga/ej bedömningsbara självvärderingar eller i övrigt leverera ofullständiga underlag.). Den/de ALF-regioner som hamnar i denna kategori får ej del av fördelningspotten som är knuten till respektive huvudområde.
- **God–hög kvalitet**
  En majoritet av ALF-regionerna antas bli placerade i denna kategori. Denna klassificering ges om utvärderingen av det samlade underlaget visar på en prestation som är förväntad utifrån de tilldelade ALF-medlen. Dessa ALF-regioner får en garanterad tilldelning ur fördelningspotten som är knuten till respektive huvudområde. Fördelningen ska vara proportionell till grundbeloppet[12].
- **Mycket hög kvalitet**
  I denna kategori placeras de ALF-regioner (enligt den nationella styrgruppens beslut minst en och högst tre) som presterat mer än vad som kan förväntas utifrån de tilldelade ALF-medlen och som utmärker sig som nationella föredömen inom respektive panels område. Dessa ALF-regioner får en större tilldelning ur fördelningspotten som är knuten till respektive huvudområde än regionerna i kategorin *god–hög kvalitet*. Fördelningen är proportionell till storleken på grundbeloppet.

9 För mer information om den nationella styrgruppens beslutade utgångspunkter hänvisas till Vetenskapsrådets hemsida (www.vr.se/alf).
10 9 § ALF-avtalet.
11 Med fördelningspott avses de 20 procent av ALF-ersättningen för klinisk forskning som ska fördelas baserat på resultatet av utvärderingarna.
12 Med grundbelopp avses de grundbelopp som är fastslagna i ALF-avtalet (totalt 80 procent av ALF-ersättningen för klinisk forskning).

Varje expertpanel motiverar bedömningen med ett skriftligt omdöme för respektive ALF-region. I enlighet med den nationella styrgruppens utgångspunkter presenteras de 1–3 ALF-regioner som har placeras i kategorin *mycket hög kvalitet* i någon av de tre utvärderingarna som goda exempel vilka övriga ALF-regioner kan lära av.

Mer information om förutsättningar och genomförande finns i de kapitel som beskriver respektive utvärdering.

UTVÄRDERINGARNAS SAMLADE RESULTAT

Panelernas bedömningar och rapporter ligger till grund för Vetenskapsrådets beslut om den kliniska forskningens kvalitet i respektive ALF-region. Beslutet sammanfattas nedan (tabell 3). Panelernas fullständiga rapporter redovisas i del 2.

De ALF-regioner som har placerats i kategorin *mycket hög kvalitet* för något av de utvärderade huvudområdena lyfts som goda exempel. Dock har dessa begränsats till minst ett och högst tre per huvudområde, enligt den utvärderingsmodell, som beslutats av den nationella styrgruppen.

Tabell 3. Vetenskapsrådets beslut om den kliniska forskningens kvalitet i de olika ALF-regionerna.

ALF-region	Den vetenskapliga produktionens kvalitet	Forskningens kliniska betydelse och samhällsnytta	Forskningens förutsättningar
Stockholm	Mycket hög kvalitet	God–hög kvalitet	God–hög kvalitet
Västra Götaland	Mycket hög kvalitet	God–hög kvalitet	Mycket hög kvalitet
Skåne	God–hög kvalitet	Mycket hög kvalitet	Mycket hög kvalitet
Uppsala	God–hög kvalitet	God–hög kvalitet	God–hög kvalitet
Västerbotten	God–hög kvalitet	God–hög kvalitet	Mycket hög kvalitet
Östergötland	God–hög kvalitet	God–hög kvalitet	God–hög kvalitet
Örebro	God–hög kvalitet	Undermålig kvalitet	God–hög kvalitet

Sammanfattningsvis, visar utvärderingarna att svensk klinisk forskning generellt håller hög kvalitet, vilket framgår av ett flertal goda exempel. Alla ALF-regioner visar på styrkor inom olika forskningsområden och detta återspeglas även i urvalet av publikationer som granskats. Något som expertpanelerna också noterat är att vissa forskningsområden är starka i flera ALF-regioner och att svensk klinisk forskning därför skulle gynnas av fler och större nationella samarbeten inom dessa områden. Expertpanelerna lyfter även fram Sveriges goda förutsättningar att bedriva klinisk forskning tack vare vår tillgång till olika kvalitetsregister och biobanker samt att större samordning mellan kvalitetsregistren skulle kunna höja kvaliteten på den kliniska forskningen ytterligare.

Nedan redovisas översättningar av panelernas sammanvägda bedömningar av respektive ALF-region. För fullständiga rapporter hänvisas till del 2.

ALF-region Stockholm

Den vetenskapliga produktionens kvalitet

Mycket hög kvalitet

ALF-region Stockholm tilldelades 27% av ALF-medlen för klinisk forskning år 2015. Denna andel motsvaras av antalet publikationer (97) som regionen har valt ut för sakkunnigbedömning, där varje publikation har bedömts av 3 av de 31 granskarna och 18 panelmedlemmarna. Bedömningen av den vetenskapliga produktionens kvalitet och den kliniska relevansen baserades på sakkunnigbedömning av dessa publikationer.

Sakkunnigbedömningen visar att den vetenskapliga kvaliteten och kliniska relevansen för de publikationer som lämnats in varierar från ”mycket bra” till ”enastående” på den sjugradiga skala som använts. Sakkunnigbedömningen visar på utmärkt kvalitet när det gäller vetenskaplig tillförlitlighet och stringens, betydelse för forskningsfältet i stort samt nytänkande och originalitet. Dessutom anser panelen att Stockholm presterar exceptionellt bra när det gäller den bibliometriska profilen, och bättre än förväntat i förhållande till andelen ALF-medel. Detta illustreras genom styrkor som bedömdes vara ”utmärkta” till ”enastående” för samtliga forskningspublikationer och resulterade i panelens slutsats att placera Stockholm i kategorin *mycket hög kvalitet*.

Forskningens kliniska betydelse och samhällsnytta

God–hög kvalitet

Panelens omdöme för regionen är *god–hög kvalitet* för implementering och genomslag. Stockholm har betydande styrkor inom forskning och är en vetenskaplig ”motor” för Sverige; nästan hälften av landets högkvalitativa forskning utförs i Stockholmsregionen sett till volym. Regionen har ett internationellt konkurrenskraftigt forskningskluster som är viktig för att attrahera industri samt såväl nationella som internationella investeringar och samarbeten till Sverige. Dock befinner sig flera av aktörerna i regionen i en tidig fas av ett stort omvandlingsprogram där de arbetar tillsammans för att förstärka implementeringsprocesserna och säkerställa att högkvalitativ klinisk forskning får maximal samhällsnytta. Om det lyckas förväntas detta ambitiösa program att ge betydande vinster under de kommande åren.

Forskningens förutsättningar

God–hög kvalitet

I ALF-region Stockholm har kliniska forskare möjlighet att få tillgång till världsledande infrastruktur. Regionen verkar ha en god ekonomi, väl etablerade och förankrade strategier, en bred representation i strategiska styrelser och formella avtal på plats mellan i sammanhanget viktiga samarbetspartners. På högsta nivå pågår ett systematiskt arbete med att förbättra den kliniska forskningsmiljön, och ett av de viktiga verktygen för att göra detta är forskarskolorna.

Dock verkar samordningen inom regionen vara otillräcklig utifrån ett ”bottom-up”-perspektiv. Den strategiska enigheten på toppnivån avspeglas inte genomgående på lägre nivåer. Det finns variationer mellan avdelningar, kliniska områden och institutioner när det gäller det praktiska arbetet med att förbättra den kliniska forskningsmiljön. Dessa variationer avspeglas i olika inställningar till hur tid ska allokeras till forskning och hur åtkomst till infrastruktur ska optimeras. Landstingets ledning skulle tydligare kunna understryka att klinisk forskning med samarbete mellan hälso- och sjukvårdsenheter (avdelningar och mottagningar) och universitet är en viktig prioritet för alla hälso- och sjukvårdsleverantörer (dvs. både allmänna och privata) inom regionen. Dessutom, som den främsta forskningsregionen i landet, finns det en möjlighet att inta en mer aktiv och central roll inom samordning och maximering av användningen av forskningsinfrastrukturer inom hela landet, och därigenom förstärka samarbetet på nationell nivå.

Vidare, karriärvägarna skulle kunna vara mer flexibla, och man skulle i högre grad kunna uppmuntra medicinska specialister som befinner sig i ett senare skede av karriären att påbörja doktorandstudier. Den nya organisationsstrukturen som ska införas vid universitetssjukhuset erbjuder möjlighet att förbättra samarbetet på lång sikt, men kan också utgöra en utmaning, eftersom förändringen kan vara energikrävande under implementeringsfasen.

Även om det finns betydande styrkor i processer och strukturer för åtkomst till forskningsinfrastruktur, i den sammanlagda strategin för att stödja forskare under alla stadier av deras yrkesliv och i att säkerställa tid för forskning, så identifierade panelen några svagheter när det gäller att dels implementera strategierna längre ner i organisationen, dels säkerställa bästa utnyttjandet av de tillgängliga resurserna, och dels i arbetet med att samordna utnyttjandet av tilldelad forskningstid. Sammantaget bedömdes ALF-region Stockholm därmed vara av *god–hög kvalitet*.

ALF-region Västra Götaland

Den vetenskapliga produktionens kvalitet

Mycket hög kvalitet

ALF-region Västra Götaland tilldelades 21% av ALF-medlen för klinisk forskning år 2015. Denna andel motsvaras av antalet publikationer (74) som regionen har valt ut för sakkunnigbedömning, där varje publikation har bedömts av 3 av de 31 granskarna och 18 panelmedlemmarna. Bedömningen av den vetenskapliga produktionen och den kliniska relevansen baserades på sakkunnigbedömning av dessa publikationer.

Bedömningen av publikationerna och bibliometrin från Västra Götaland visar på forskning av mycket hög kvalitet, i synnerhet inom områdena diabetes, fetma och kirurgisk behandling av fetma, samt studier av mikrobiota, men även inom flertalet andra områden. Ett stort antal studier imponerar av följande anledningar: de angriper viktiga problem och omfattar studiepopulationer av mycket god storlek med bra uppföljningstid; de hanterar terapeutiska frågeställningar med väl utformade storskaliga studier som inkluderar samarbete med flera aktörer; eller de identifierar nya och viktiga biologiska mekanismer. Dessa aspekter visar på styrkor som panelen vill lyfta och som skulle kunna förstärkas ytterligare genom fler/större samarbeten, inklusive ett ökat antal internationella forskningssamarbeten. Panelen anser också att en mer samordnad användning av biobanker och register skulle bidra till att stärka forskningen ytterligare. En del studier visade på metodmässiga svagheter, som t ex avsaknad av kontrollpopulation, eller ej randomiserade studieupplägg.

Expertpanelen värderade denna region högt inom alla tre kriterier vetenskaplig kvalitet, klinisk relevans och bibliometrisk profil. Den vetenskapliga produktionen är internationellt konkurrenskraftig och visar på forskning av hög kvalitet inom ett stort antal ämnesområden. Sakkunnigbedömningen av de inlämnade publikationerna resulterade i mycket positiva utlåtanden när det gäller vetenskaplig tillförlitlighet och stringens, betydelse för forskningsfältet i stort samt nytänkande och originalitet. Baserat på bibliometriska volymoberoende indikatorer så ligger regionen i topp för andelen av publikationer inom topp-1%, och är näst högst för andel publikationer inom topp-10%.

Panelen var överens om att placera Västra Götaland i kategorin *mycket hög kvalitet*. Det finns dock potential för att prestera ännu bättre i en framtida ALF-utvärdering, då några prospektiva randomiserade studier och öppna kohort-studier var från enstaka centrum. Detta gör resultaten mindre pålitliga pga ett litet antal deltagare, eller ofullständiga data.

Forskningens kliniska betydelse och samhällsnytta

God–hög kvalitet

Panelens omdöme för Västra Götalands-regionen är *god–hög kvalitet*. Regionen har stark forskningskompetens och närvaro av forskningsutbildad personal inom den kliniska verksamheten. Strukturer och processer som främjar interdisciplinärt och intersektoriellt samarbete har etablerats, i synnerhet inom innovations- och livsvetenskapsområdena. Regionen har uttalade strukturer och processer för att ta fram regionala riktlinjer och HTA-rapporter (Health Technology Assessment), men den kliniska betydelsen kan fortfarande förbättras. Ett viktigt förbättringsområde är att etablera en strategi för uppföljning och utvärdering av implementeringen av kliniska riktlinjer. Potentialen för att utnyttja Registercentrum för att följa upp och utvärdera implementeringsbehoven behöver klargöras. Panelen noterade att den kliniska forskning som utförs i regionen har ett betydande och tydligt genomslag utanför akademin.

Forskningens förutsättningar

Mycket hög kvalitet

Samarbetet mellan Göteborgs universitet och Västra Götalandsregionen fungerar utmärkt. Hälso-sam är en gemensam och beprövad styrkommitté, som fattar beslut om övergripande strategi, budget och det slutgiltiga godkännandet av FoU-projekt. Den övergripande styrstrukturen är transparent och har fullt stöd inom de berörda organisationerna.

Det finns en tydlig målsättning med fokus på att skapa en kritisk mängd av klinisk forskning av hög kvalitet som leder till förbättrad hälsa. Forskningsansökningar och -projekt upprättas i samförstånd mellan forskare och avdelningschefer, vilket ofta fokuserar på problem som identifierats på kliniken. Ledningen skapar och sprider självförtroende och entusiasm. Forskare på alla nivåer anger att ledningen stöder dem och tillhandahåller bra villkor för att bedriva forskning.

Regionen har mycket relevant, tillgänglig och väl fungerande infrastruktur och goda förutsättningar för klinisk forskning på plats. Det finns ett tydligt fokus på jämställdhet, tvärvetenskaplig forskning och internationalisering. Sammanlagt har detta banat väg för forskning av hög kvalitet som leder till förbättrad hälso- och sjukvård. Större delen av ALF-bidragen fördelas ”bottom-up”, och utlyses i öppen konkurrens, samtidigt som det finns tydliga samordnade processer på alla nivåer för att garantera att medel fördelas enligt den övergripande strategin.

Regionen har under senare år genomfört en övergång från en produktionsorienterad inriktning till att numera betona värdet av klinisk forskning av hög kvalitet inom de kliniska avdelningarna. Stödet som täcker alla nivåer inom yrkeslivet, från student till professor i kombinerad tjänst, är utmärkt, och säkerställandet av tid för forskning fungerar bra. De flesta kliniska avdelningschefer har en akademisk bakgrund, vilket säkerställer fokus på forskning.

Med tanke på regionens genomarbetade processer och strukturer för åtkomst till forskningsinfrastruktur, styrkan av den sammanlagda strategin för att stödja forskare under alla nivåer av deras yrkesliv och samordningen av att tid för forskning garanteras, bedömdes ALF-region Västra Götaland att vara av *mycket hög kvalitet*.

ALF-region Skåne

Den vetenskapliga produktionens kvalitet

God–hög kvalitet

ALF-region Skåne tilldelades 20% av ALF-medlen för klinisk forskning år 2015. Denna andel motsvaras av det antal publikationer (70) som regionen har valt ut för sakkunnigbedömning, där varje publikation har bedömts av 3 av de 31 granskarna och 18 panelmedlemmarna. Bedömningen av den vetenskapliga produktionen och den kliniska relevansen baserades på sakkunnigbedömning av dessa publikationer. Baserat på sakkunnigbedömning av de utvalda publikationerna och den bibliometriska profilen för regionen placerades Skåne i den övre delen av kategorin *god–hög kvalitet*.

Sammantaget bedöms den vetenskapliga kvaliteten och kliniska relevansen av de forskningspublikationer som lämnats in från Skåne ligga över genomsnittet för alla ALF-regioner. I internationell jämförelse producerar Skåne ett brett spektrum av klinisk forskning, med onkologi, folkhälsa, endokrinologi och kardiologi runt genomsnittsvärdet för världen. Vissa specialiteter, som t ex klinisk neurologi och internmedicin, ligger väl över det internationella genomsnittet enlig den bibliometriska analysen. Exempelvis har en forskningsgrupp som arbetar med diabetes producerat enastående arbeten kring regleringen av insulinutsöndring i patienter med typ 2-diabetes samt kartläggning av gener associerade med förändrad funktion av öceller i pankreas. Flera grupper använder nationella befolkningsbaserade register av hög kvalitet, inom reumatologi, t ex psoriasis och systemisk skleros, psykiatri, t ex bipolär rubbning och schizofreni, samt i hematologiska maligniteter och hepatocellulär cancer. Flera av de publikationer som fick ett positivt utlåtande presenterar resultat från väl utförda randomiserade studier som hanterar viktiga kliniska frågeställningar.

Internationella samarbeten har lett till forskningsresultat av hög kvalitet, och i flera fall där forskare i Skåne samarbetat med andra regioner inom Sverige, som t ex inom kardiologi och medicin, resulterade det i vetenskapliga publikationer av mycket hög kvalitet. Skåne är den näst största ALF-regionen när det gäller volym, med mer än 3 700 publikationer (fraktionerat) under utvärderingsperioden. Sammantaget är den bibliometriska profilen för Skåne mycket bra.

Panelen menar att den kliniska relevansen av de utvalda publikationerna är lägre för Skåne än för andra regioner. Panelen menar att förbättringar kan göras, i synnerhet inom områden med stor forskningsproduktion, som t ex inom onkologi, folkhälsa och endokrinologi. Ett angreppssätt skulle kunna vara att ingå i fler samarbetsprojekt med svenska regioner med liknande expertis; detta borde kunna förbättra kvaliteten och vara till förmån för alla regioner.

Forskningens kliniska betydelse och samhällsnytta

Mycket hög kvalitet

Panelen var överens om att Skåne utgör ett gott exempel för andra regioner, i synnerhet när det gäller den imponerande implementeringen av klinisk forskning i den kliniska verksamheten. Hanteringen av HTA och avvecklingsprogram (disinvestment) är ett utmärkt exempel. Skånes målsättning är att personal inom hälso- och sjukvård och i administrativa stödfunktioner ska vara forskarutbildade, vilket är ambitiöst och lovande. Samarbetet mellan universitetet, universitetssjukhuset och primärvår-

den fungerar bra, och Centrum för primärvårdsforskning lyftes fram som ett initiativ av enastående kvalitet. De tre fallstudierna om implementering och de tre fallstudierna av genomslag som finns med i självvärderingen ansågs alla utgöra mycket bra exempel på evidensbaserad medicin med stor klinisk och samhällelig betydelse. Panelen var därför överens om att implementering och genomslag av klinisk forskning i Skåne skulle få omdömet *mycket hög kvalitet*.

Forskningens förutsättningar

Mycket hög kvalitet

Samarbetet mellan Lunds universitet och Region Skåne är etablerat sedan länge, och fungerar utmärkt. De strategier och beslut som fattas av styrgruppen för ALF får stöd på alla nivåer inom organisationerna. Det sätt som ALF-resurserna fördelas på är transparent, funktionellt och beprövat.

Den övergripande strategin är att tillhandahålla den bästa möjliga miljön för klinisk forskning av hög kvalitet och att hjälpa fram nästa generation av kliniska forskare, för förbättrad diagnostik, förebyggande och behandling av sjukdom. Kliniskt relevant forskning stimuleras genom öppna utlysningar ”bottom-up”, men det finns också utlysningar med inriktning på specifika kliniska områden som bedöms vara viktiga. Ledningen skapar och sprider självförtroende och entusiasm. Forskare på alla nivåer anger att ledningen stöder dem och tillhandahåller bra villkor för att bedriva forskning. Forskare inom båda organisationerna har likvärdig och lätt åtkomst till relevanta forskningsinfrastrukturer av hög kvalitet.

Karriärstegen med sju steg, som har fungerat som modell för hälso- och sjukvårdsvårdsregioner i Sverige, fungerar bra. Rekryteringen till forskningsbefattningar är mycket konkurrensutsatt, men uppfattas som rättvis. Det finns ett tydligt fokus på jämställdhet, tvärvetenskaplig forskning och internationalisering. De flesta kliniska avdelningschefer har en akademisk bakgrund och har ett stort fokus på forskning. De processer som finns på plats för att avsätta tid för forskning på klinikerna fungerar bra. Sammantaget har detta lett till att säkerställa forskning av hög kvalitet som leder till förbättrad hälso- och sjukvård.

Med tanke på den gemensamma strategiska visionen hos parterna, de genomarbetade processerna och strukturerna för åtkomst till forskningsinfrastruktur, styrkan i den sammanlagda strategin för att stödja forskare under alla stadier i deras yrkesliv och samordningen av att tid för forskning garanteras, bedömdes ALF-region Skåne att vara av *mycket hög kvalitet.*

ALF-region Uppsala

Den vetenskapliga produktionens kvalitet

God–hög kvalitet

ALF-region Uppsala tilldelades 12% av ALF-medlen för klinisk forskning år 2015. Denna andel motsvaras av det antal publikationer (42) som regionen har valt ut för sakkunnigbedömning, där varje publikation har bedömts av 3 av de 31 granskarna och 18 panelmedlemmarna. Bedömningen av den vetenskapliga produktionen och den kliniska relevansen baserades på sakkunnigbedömning av dessa publikationer.

De publikationer som Uppsala lämnat in rör huvudsakligen klinisk forskning (t ex kardiovaskulära sjukdomar, onkologi och pediatrik), med ett mindre antal inom translationell forskning/grundforskning (t ex proteomik, biomarkörer).

Sammantaget har Uppsala placerats i den övre delen av kategorin *god–hög kvalitet*. Panelen anser att denna region presterar bra när det gäller vetenskaplig kvalitet, klinisk relevans och bibliometri. I allmänhet anser panelen att den vetenskapliga kvaliteten och kliniska relevansen av de publikationer som lämnats in varierar från ”bra” till ”utmärkt” på den sjugradiga skala som använts vid sakkunnigbedömning av de individuella publikationerna. Dessutom avspeglar andelen av normaliserade citeringar (12%) den tilldelade andelen av ALF-medel (12%) och av publikationer (13%) och andelen av normaliserade citeringar (12%).

Panelen noterade att det finns mer potential och utrymme for internationella samarbeten och bedömde att den kliniska relevansen är låg för några av de publikationer som lämnats in.

Forskningens kliniska betydelse och samhällsnytta

God–hög kvalitet

Panelens omdöme för denna ALF-region är *god–hög kvalitet*. Uppsala har många styrkor och få svagheter när det gäller forskningskompetens. Regionen har också många styrkor och ett internationellt perspektiv på samarbete. Uppsala arbetar systematiskt med att utöka samarbetet med industrin och har aktivt samarbete mellan universitetssjukhuset och de andra sjukhusen och andra vårdgivare inom sjukvårdsregionen. Ett förbättringsområde är dock att förstärka det *dubbelriktade* samarbetet inom regionen. Mini-HTA-formatet är intressant, men ännu har ingen formell utvärdering gjorts av formatet. Ett förbättringsområde är att utveckla ett gemensamt system för att utvärdera regionens insatser för att införa nya processer för evidensbaserat arbetssätt i hela hälso- och sjukvårdssektorn.

Forskningens förutsättningar

God–hög kvalitet

ALF-region Uppsala har många starka forskningsmiljöer, bland annat kardiologi, onkologi, kvinnors hälsa, antibiotikaresistens, och strålterapi. Kommunikationen och relationen mellan universitetet och landstinget verkar vara varierande på den högsta ledningsnivån. För att kunna finansiera vissa dyrare infrastrukturer samt Gullstrandsprogrammet, används 25 procent av ALF budgeten på den strategiska ledningsnivån. Den övriga ALF budgetens finansieringsbeslut om 75 procent fattas inom de 23 forskningsråden för forskning, utbildning och utveckling. Det verkar saknas en gemensam strategi för prioriteringar och långsiktiga mål. Även om en del av infrastrukturen är av världsklass och också av nationell betydelse, så verkar tillgängligheten till dem variera en hel del. Behovet att införskaffa ytterligare lokala infrastrukturer parallellt med centralt finansierade infrastrukturer, visar på ett inte optimalt utnyttjande av tillgängliga centrala infrastrukturer.

Det varierar också mellan olika avdelningar när det gäller tyngdpunkten på forskning, vilket också reflekteras i den tid som allokeras till forskning. Det finns visst stöd till yngre kliniska forskare, postdoktorer och yngre självständiga forskare men även här görs koordineringen på avdelningsnivå och i mindre grad på sjukhusledningsnivå. Det finns också öronmärkta ALF-medel för doktorander i närliggande yrkesgrupper som sjuksköterskor och fysioterapeuter. Gullstrandstjänsterna fyller några av luckorna när det gäller steget mellan postdoktor och permanenta forskartjänster.

Trots att forskningsmiljön i Uppsala många gånger är excellent, så finns det en tydlig potential för att ytterligare förbättra en mer koordinerad approach från universitet och landstinget. Även om vissa aspekter i processen att tillgängliggöra infrastrukturer är bra, så borde processen förbättras på vissa områden för att underlätta tillgängligheten. Vidare gäller också, att även om en del styrkor identifierades när det gäller stöd till forskare i alla steg i karriären och i koordineringen av den allokerade tiden till forskning, så finns det svagheter när det gäller att utnyttja tillgängliga resurser på bästa sätt. Av den anledningen bedömdes ALF region Uppsala vara av *god–hög kvalitet*.

ALF-region Västerbotten

Den vetenskapliga produktionens kvalitet

God–hög kvalitet

ALF-region Västerbotten tilldelades 11% av ALF-medlen för klinisk forskning år 2015. Denna andel motsvaras av det antal publikationer (38) som regionen har valt ut för sakkunnigbedömning, där varje publikation har bedömts av 3 av de 31 granskarna och 18 panelmedlemmarna. Bedömningen av den vetenskapliga produktionen och den kliniska relevansen baserades på sakkunnigbedömning av dessa publikationer.

Västerbotten har placerats i kategorin *god–hög kvalitet*. I sakkunnigbedömningen av de inlämnade publikationerna bedömdes 30% som ”mycket bra” till ”utmärkta” när det gäller vetenskaplig kvalitet på den sjugradiga skala som använts vid bedömningen av de individuella publikationerna. Den kliniska relevansen av de inlämnade publikationerna bedöms dock vara av lägre kvalitet, och en förbättring av detta borde vara en prioritet för framtiden.

Västerbotten bidrar på ett bra sätt till kvaliteten på klinisk forskning i Sverige. Den sammanlagda bibliometriska profilen är bra, men heterogen, med en låg andel högt citerade publikationer (topp-1%). Panelen uppmuntrar Västerbottenregionen att stärka sitt internationella samarbete, och att stärka den kliniska relevansen av sina publikationer.

Forskningens kliniska betydelse och samhällsnytta

God–hög kvalitet

Panelen gav Västerbotten omdömet *god–hög kvalitet*. Sammantaget var panelen överens om att regionen presterade mycket bra inom forskningskompetens, och kompenserade väl för sina geografiska förutsättningar och sin begränsade befolkningsmängd. Samarbetet inom regionen var också mycket framgångsrikt, såsom samarbetet mellan sjukhus och andra aktörer inom vårdsystemet. Dessutom fanns ett mycket bra samarbete mellan patienter/medborgare och landstinget. Dock föreföll implementeringen av evidensbaserad praxis sakna ett systematiskt angreppssätt. Den förlitade sig på individer som bestämt sig för att bevaka och utvärdera nationella kvalitetsregisterdata.

Forskningens förutsättningar

Mycket hög kvalitet

Storleken, det geografiska läget och demografin i regionen utgör unika utmaningar men också en del möjligheter för forskning som adresseras systematiskt av ALF-region Västerbotten. ALF-regionen har tillgång till en population om ca 1 miljon invånare och samarbetar nära med Östersund, Sunderby (Luleå) och Sundsvalls lokala sjukhus. Dessa sjukhus är integrerade i den övergripande forskningsstrategin genom allokering av akademisk personal och lokala forskartjänster.

Det finns excellenta regionala forskningsinfrastrukturer såsom Wallenberg Centre for Molecular Medicine, The Molecular Infection Medicine Institute, The Centre for Medical Tehcnology and Radiation Physics, Chemical Biology Centre, The SciLife Laboratory, samt 6M-byggnaden för translationell forskning vid sidan av en etablerad struktur för forskning inom primärvården. Dessa är lättillgängliga för forskare.

Västerbotten har en stark och sammanhängande strategi för att säkra kapaciteten för att kliniska forskare ska kunna använda sin tid till forskning. Västerbotten har dessutom två parallella anställningsvägar för forskare, en akademisk som är ett flexibelt och sammanlänkat kliniskt vetenskapligt spår baserad på universitetet, och ett kliniskt forskarspår baserat på sjukhuset, vilket är unikt och en utmärkt strategisk åtgärd som uppmuntrar unga forskare att välja en akademisk karriär i ett tidigt skede. Avtalen mellan sjukhuset och universitetet har fattats på en strategisk nivå, och därigenom underlättat unga forskares tillgång till resurser.

En tydlig strategi för att etablera och stödja excellenta infrastrukturer samt välorganiserade karriärvägar kompenserar för eventuella rekryteringsproblem, även om frågan om hur man behåller duktiga kliniska forskare kommer att vara en avgörande faktor under de närmaste åren. Genom att fortsätta det strategiska arbetet med att stödja karriärvägar, ytterligare förstärkning av infrastrukturer och att utveckla samarbetet mellan fakulteterna på universitetet så borde man övervinna dessa utmaningar.

Genom det omfattande sättet för att tillgängliggöra forskningsinfrastrukturer, styrkan i den övergripande strategin och samarbetet mellan landstinget och universitetet att stödja forskare i alla steg i karriären, och samordningen för att allokera tid till forskning, bedömdes ALF-region Västerbotten vara av *mycket hög kvalitet*.

ALF-region Östergötland

Den vetenskapliga produktionens kvalitet

God–hög kvalitet

ALF-region Östergötland tilldelades 8% av ALF-medlen för klinisk forskning år 2015. Denna andel motsvaras av det antal publikationer (29) som regionen har valt ut för sakkunnigbedömning, där varje

publikation har bedömts av 3 av de 31 granskarna och 18 panelmedlemmarna. Bedömningen av den vetenskapliga produktionen och den kliniska relevansen baserades på sakkunnigbedömning av dessa publikationer.

Panelen har placerat Östergötland i kategorin *god–hög kvalitet*, detta baserat på sakkunnigbedömningen av de utvalda publikationerna och på den bibliometriska profilen för regionen. Panelen anser att Östergötland presterar på en nivå som är jämförbar med många av de andra regionerna, och att kvaliteten på den kliniska forskningen är mycket bra. Den vetenskapliga produktionen och kliniska relevansen bedömdes som mycket bra, men med några svagheter. Flera publikationer når viktiga resultat genom att tillämpa ett nytänkande angreppssätt och/eller genom att studera intressanta nischämnen. När det gäller den bibliometriska profilen presterar Östergötland strax över världsgenomsnittet gällande citeringsgenomslag, vilket visar på regionens sammanlagda styrka.

Regionen producerar mycket bra vetenskapliga publikationer inom ett brett urval av forskningsämnen. Denna bredd kan ses som positiv och indikerar mångsidighet inom forskningsproduktionen. Den kan dock också ses som en potentiell svaghet eftersom den kan tyda på en brist på fokus inom vissa expertområden. Östergötland bör överväga att anta en tydligare och mer fokuserad forskningsstrategi. Panelen föreslår att Östergötland prioriterar klinisk forskning inom områden där man har befintliga styrkor och ytterligare potential.

Forskningens kliniska betydelse och samhällsnytta

God–hög kvalitet

Panelen gav denna region omdömet *god–hög kvalitet*. Östergötland har en sammanhållen struktur för forskning och implementering av forskningsresultat i klinisk praxis; från den politiska nivån, via det regionala ALF-avtalet, till regionala medicinska programgrupper, och systematisk återrapportering till nationella kvalitetsregister.

Östergötland försöker att dra fördel av den väl fungerande hälsovården i Sydöstra sjukvårdsregionen som enligt regionens ledning och vissa nationella statistiska källor har några av de mest välfungerande landstingen och sjukhusen i Sverige. Det finns ett väletablerat samarbete mellan ALF-regionen och sjukvårdsregionen som tar ett gemensamt ansvar för ALF-avtalet och för klinisk forskning inom regionen.

Sammantaget är Östergötland en liten region, både när det gäller befolkning och finansiering av forskning inklusive ALF-finansiering. De kompenserar dock för detta genom ett väletablerat karriärutvecklingsprogram, en sammanhållande plan för forskning och implementering och med ett mycket starkt förhållningssätt till samarbete. Östergötland har antagit bra planer och bra processer, men håller fortfarande på att implementera dem.

Forskningens förutsättningar

God–hög kvalitet

Mellan fakulteterna för medicin och teknik finns en lång tradition av givande samverkan. Den kliniska forskningsmiljön i regionen och vid Linköpings universitet är kollegial och öppen, med en ledning som är lätt tillgänglig för övrig personal. En gemensam tvärvetenskaplig forskningsstrategi, som stöds av hela regionen och inkluderar hälso- och sjukvårdspersonalen, är grundstenen för regionens kliniska forskningsprofil.

Efter en forskningsutvärdering år 2014 har stödtjänsterna för infrastruktur och forskning utökats för att förenkla genomförandet av kliniska studier. Aktiv rekrytering av internationella forskare i toppklass har hjälpt till att bygga upp världsledande centrum inom relevanta områden och dessa kan därmed inkluderas i den kliniska forskningsinfrastrukturen i regionen.

Universitetet har dessutom aktiverat karriär- och stödprogrammet ”Student till Docent”, som banar väg för en forskarkarriär för läkarstudenten såväl vid sjukhuset som inom primärvården. Dessutom erbjuds motsvarande möjligheter för annan hälsovårdspersonal. Dock arbetar få kliniska forskare utomlands, och detta minskar möjligheterna för internationellt samarbete.

Den gemensamma forskningsstrategin är fullt förankrad hos båda parterna. Emellertid är organisationsstrukturen invecklad, vilket kan utgöra ett hot. Det decentraliserade systemet för att fördela tid

för forskning kan också utgöra ett hot, i synnerhet på mindre avdelningar där fokusen på forskning kan vara svagare. Allmänt verkar tidsutrymmet för forskning variera mycket mellan avdelningar, och verkar vara starkt beroende av avdelningscheferna.

Även om det finns betydande styrkor i processer och strukturer för åtkomst till forskningsinfrastruktur, i den sammanlagda strategin för att stödja forskare under alla stadier av deras yrkesliv, och i samordningen av utnyttjandet av fördelad forskningstid, så identifierade panelen några svagheter när det gäller att säkerställa bästa utnyttjandet av de tillgängliga resurserna. Sammantaget bedömdes ALF-region Östergötland därmed vara av *god–hög kvalitet*.

ALF-region Örebro

Den vetenskapliga produktionens kvalitet

God–hög kvalitet

ALF-region Örebro tilldelades 2% av ALF-medlen för klinisk forskning år 2015. Bedömningen av den vetenskapliga produktionen och kliniska relevansen baserades på sakkunnigbedömning av 10 publikationer, där varje publikation har bedömts av 3 av de 31 granskarna och 18 panelmedlemmarna.

Panelen har placerat Örebro i kategorin *god–hög kvalitet*. Denna bedömning är baserad inte bara på sakkunnigbedömning av de inlämnade publikationerna, utan också på den bibliometriska analysen av produktion inom regionen under 2012–2015. Panelen är medveten om att Örebro har en ovanlig situation när det gäller ALF-finansiering, eftersom regionen bara har varit del av ALF-avtalet sedan 2015. Panelen har tagit hänsyn till detta så att det inte utgjorde en nackdel för regionen i bedömningsprocessen.

Som en nybliven självständig forskningsenhet i ALF-sammanhang bedömdes Örebro utföra forskning av god kvalitet. Den sammanlagda bibliometriska profilen för regionen är mycket bra när det gäller antal publikationer och högciterade publikationer. Det innebär att Örebro överpresterar i förhållande till nivån på tilldelade ALF-medel.

Örebro skulle kunna använda sin nya status som ALF-region för att utvidga de stora kliniska samarbetsstudier där man har dokumenterat goda resultat. Det skulle också vara en fördel om Örebro deltog mer i internationella samarbeten.

Forskningens kliniska betydelse och samhällsnytta

Undermålig kvalitet

Örebro har helt nyligen fått ALF-finansiering, men i jämförelse med andra regioner verkar man inte ha använt denna inledande period för att skapa välinformerade strategier som skulle kunna användas för att stödja uppföljning och utvärdering av progress, prioritering av samarbeten eller för att driva förbättrad implementering och verksamhet av klinisk betydelse. De personer från regionen som deltog vid panelmötet förklarade att regionen hade valt att inrikta ALF-finansieringen på att skapa fler utbildningsplatser för att läkare, och för att utöka regionens forskningskapacitet. Dock var uppdraget för panel 2 att specifikt utvärdera den kliniska betydelsen och samhällsnyttan av forskning i regionen, vilket inkluderade att i detalj studera genomförandet och planerna för samarbete och implementering.

Regionen har en stark tradition av HTA, och har producerat en del bra forskning som har förbättrat allmänhetens hälsa. Regionen beskrev dock inte någon tydlig strategi för att demonstrera en harmonisering och koordination mellan akademi, sjukhus och landsting, inte heller för hur man avser att driva samarbete eller implementering i regionen. För närvarande avvaktar regionen för att se vad som är framgångsrikt snarare än att prioritera specifika områden.

Örebro är en liten region, med fördelen att beslut kan fattas snabbt, och att forskarna är väl insatta i regionens och patienternas behov. Det var dock en besvikelse att regionens deltagare i mötet inte svarade mer övertygande vid panelens intervju. Panelen ansåg att självvärderingen var förhållandevis svag i jämförelse med de andra regionernas. Även om panelen i sin sammanvägda bedömning till fullo beaktat den information som kom fram vid mötet med regionen, så är slutsatsen att den kliniska forskningens implementering och genomslag i Örebro får omdömet *undermålig kvalitet*.

Forskningens förutsättningar

God–hög kvalitet

Även om klinisk forskning har bedrivits i Örebro i många år, så har fakulteten för läkarutbildningen bara nyligen etablerats. Örebro har av studenterna fått det bästa betyget i Sverige för sin läkarutbildning, men behovet av att utveckla och etablera en ny läroplan har inledningsvis inneburit att majoriteten av uppmärksamheten har lagts på att säkra kvaliteten och leveransen av läkarutbildning. Under de senaste åren har dock Örebro utvecklat en strategi och gjort infrastrukturinvesteringar för att bygga upp en forskningsprofil. Det finns utmärkta och sammanhängande länkar mellan regionen och universitetet. Det är ofrånkomligt att givet detta sammanhang, och genom en lägre grad av extern finansiering än andra regioner, så är miljön för klinisk forskning i ett mycket tidigare utvecklingsskede än i motsvarande mer etablerade centra. Det finns dock ett nyetablerat kliniskt forskningscenter som fungerar effektivt, och det finns också internationellt erkända forskargrupper. Samordningen av stöd för forskarkarriärer och allokering av tid till forskning fungerar generellt bra. Trots det relativt tidiga utvecklingsskedet i Örebro, har man åstadkommit ett tydligt momentum och forskningsmiljön borde kunna förbättras över de kommande åren så länge som finansiering av forskningskapaciteten upprätthålls.

Även om betydliga styrkeområden har identifierats när det gäller hur man tillgängliggjort infrastrukturer, den övergripande strategin för att stödja forskare under alla steg i deras karriärer, och koordineringen av deras tid till forskning, så är regionen fortfarande i ett tidigt utvecklingsskede. Av den anledningen bedömdes ALF-region Örebro att vara av *god–hög kvalitet*.

UTVÄRDERING AV DEN VETENSKAPLIGA PRODUKTIONENS KVALITET – PANEL 1

Utgångspunkter

Utgångspunkterna för utvärderingen av den vetenskapliga produktionens kvalitet har formulerats av nationella styrgruppen för ALF. I enlighet med dessa ska en internationell expertpanel bedöma den *övergripande kvaliteten och omfattningen av den vetenskapliga produktionen* samt *den vetenskapliga profilen avseende klinisk relevans och kvalitet* för ALF-regionerna. Bedömningen av den övergripande kvaliteten och omfattningen av den vetenskapliga produktionen ska baseras på bibliometriska analyser medan den vetenskapliga profilen avseende klinisk relevans och kvalitet ska bedömas genom sakkunniggranskning av ett representativt urval av respektive regions vetenskapliga publikationer.

Panelens uppdrag är att göra en sammanvägd bedömning av ALF-regionerna och placera dem i en av tre kategorier (undermålig kvalitet; god–hög kvalitet; eller mycket hög kvalitet).

För ytterligare detaljer om utvärderingen finns följande länkade dokument till denna rapport:

- bedömningskriterier
- instruktioner till externa granskare
- instruktioner till panelen
- principer för datafångst (bibliometri)
- bibliometriskt underlag.

Expertpanelen och externa granskare

Utvärderingen har genomförts av en internationell expertpanel och externa granskare. Dessa personer är utsedda av Vetenskapsrådet efter nomineringar från ALF-regionerna, från råd och kommittéer inom Vetenskapsrådet[13] samt från projektgruppen. För sammansättningen av panelmedlemmar och externa granskare har följande kriterier beaktats: erfarenheter av utvärderingsarbete; representation av många kliniska forskningsdiscipliner; jämn könsfördelning samt geografisk spridning. Dessutom har Vetenskapsrådet jävspolicy följts och alla ledamöter i den internationella panelen samt de externa granskarna har uppmärksammats på och erhållit Vetenskapsrådets jävspolicy. Alla panelmedlemmar och externa granskare har intygat att ingen jävsituation föreligger. Professor Hugh McKenna utsågs till ordförande för panelen med totalt 19 internationellt erkända experter inom relevanta forskningsområden (tabell 4). För sakkunniggranskningen av publikationer rekryterades ytterligare 31 externa granskare.

[13] Ämnesrådet för medicin och hälsa, Kommittén för klinisk behandlingsforskning och Kommittén för kliniska studier

Tabell 4. Expertpanelen – ALF-panel 1

Namn	Organisation	Land	Vetenskapligt huvudområde
Hugh McKenna (ordförande)	Ulster University	Storbritannien	Hälsovetenskap/ forskningsutvärdering
Per Bakke	Universitetet i Bergen	Norge	Lungmedicin
Alexandra Durr	Institut du Cerveau et de la Moelle épinière	Frankrike	Neurovetenskap
Keith AA Fox	University of Edinburgh	Storbritannien	Kardiologi
Jan Frystyk	Odense universitetshospital	Danmark	Endokrinologi och metabolism
Robin Grant	University of Edinburgh	Storbritannien	Neurovetenskap
Per Ole Iversen	Universitetet i Oslo	Norge	Hematologi
Christine Katlama	Hôpital La Pitié Salpêtrière	Frankrike	Infektionsmedicin
Paulus Kirchhof	University of Birmingham	Storbritannien	Kardiologi
Tina Lavender	University of Manchester	Storbritannien	Reproduktionsmedicin och gyne-
kologi			
Marjatta Leirisalo-Repo	Helsingfors universitets-centralsjukhus	Finland	Reumatologi
Valerie Lund	University College London	Storbritannien	Oto-rhino-laryngologi
Brigitte Malgrange	University of Liège	Belgien	Neurovetenskap
Helle Prætorius	Aarhus universitet	Danmark	Urologi och njurmedicin
Jon Rhodes	University of Liverpool	Storbritannien	Gastroenterologi och hepatologi
Susan Smith	Royal College of Surgeons in Ireland	Irland	Vårdvetenskap
Peter Tyrer	Imperial College London	Storbritannien	Psykiatri
Cornelis van de Velde	Leiden University Medical Center	Nederländerna	Onkologi
Hannele Yki-Järvinen	Helsingfors universitet	Finland	Endokrinologi och metabolism

Utvärderingsprocess och bedömningskriterier

Övergripande kvalitet och omfattning av den vetenskapliga produktionen

Bedömningen av den vetenskapliga produktionens övergripande kvalitet och omfattning baseras på bibliometriska analyser av vetenskapliga publikationer från åren 2012 till 2015, vilka sammanställts av Vetenskapsrådet. Statistiken är baserad på data från Web of Science (Clarivate Analytics), i enlighet med principerna för datafångst som beslutats av den nationella styrgruppen för ALF (länk till principer för datafångst). Inför bedömningarna instruerades panelen att överväga följande indikatorer:

- totalt antal publikationer
- totalt antal publikationer i relation till andel ALF-medel
- citeringsgenomslag
- citeringsgenomslag i relation till andel ALF-medel
- medelcitering
- andel av högt citerade publikationer.

I materialet var även statistik över samarbets- och ämnesprofiler inkluderad som bakgrundsinformation, men inte avsedd att ingå i bedömningarna.

Vetenskaplig profilen avseende klinisk relevans och kvalitet

För bedömning av den vetenskapliga profilen avseende klinisk relevans och kvalitet ombads ALF-regionerna att göra ett urval av deras bästa publikationer från tidsperioden 2012 till 2015. Totalt inkluderades 360 publikationer i utvärderingen, motsvarande en procent av alla vetenskapliga publikationer inom klinisk forskning som publicerades av regionerna under tidsperioden 2012 till 2015. Varje ALF-regions andel av dessa 360-publikationer motsvarar dess andel av den totala ALF-finansieringen för forskning för år 2015 (tabell 5) Regionerna erhöll riktlinjer från Vetenskapsrådet för att underlätta urvalet av publikationer och fick tre månader på sig för att välja ut sina publikationer (länk till bedömningskriterier).

Tabell 5. ALF-regioner, landsting, tillhörande universitet och deras andel av ALF-finansiering samt antal publikationer utvalda från varje region. Observera att Region Örebro län inte fick ALF-finansiering före 2015.

ALF-Region	Landsting	Universitet	Andel av ALF-medel för klinisk forskning 2015	Antal publikationer
Stockholm	Stockholms läns landsting	Karolinska institutet	27 %	97
Västra Götaland	Västra Götalandsregionen	Göteborgs universitet	21 %	74
Skåne	Region Skåne	Lunds universitet	20 %	70
Uppsala	Region Uppsala	Uppsala universitet	12 %	42
Västerbotten	Västerbotten läns landsting	Umeå universitet	11 %	38
Östergötland	Region Östergötland	Linköpings universitet	8 %	29
Örebro	Region Örebro län	Örebro universitet	2 %	10

Sakkunniggranskningen av de 360-publikationerna genomfördes både av de 31 externa granskarna och av de 18 panelledamöter (förutom ordförande). Var och en av de 360 publikationerna bedömdes av tre granskare med kompetens inom ämnesområdet. Granskarna instruerades att bedöma publikationerna på en skala från ”undermålig” till ”enastående” och att ge skriftliga motiveringar, på två bedömningskriterier (länk till instruktioner till externa granskare):

- vetenskaplig kvalitet (inklusive nytänkande)
- klinisk relevans

Bedömning av publikationerna (inklusive motiveringar) sammanställda per region, och den bibliometriska analysen distribuerades till panelen den 1 december 2017. Panelen hade även tillgång till de 360 inlämnade publikationerna under hela bedömningsprocessen.

Panelmöte

Ett panelmöte ägde rum i Stockholm den 24 till 26 januari 2018. Under mötet diskuterades bedömningsresultaten, ALF-regionerna delades in i de tre olika kategorierna och ett utkast till panelrapporten skrevs. Samtliga panelmedlemmar deltog vid detta möte. Diskussionerna och skrivprocessen leddes av ordföranden med assistans av representanter för Vetenskapsrådet.

Medlemmarna i panelen är gemensamt ansvariga för de slutliga bedömningarna och för panelens rapport. I rapporten (se del 2) framgår panelens motiveringar till kategoriseringarna. Rapporten betonar också goda exempel på speciella aspekter av någon ALF-region, som panelen vill framhäva, vid sidan av den övergripande bedömningen. Dessutom finns identifierade utvecklingsområden samt rekommendationer till förbättringar.

UTVÄRDERING AV FORSKNINGENS KLINISKA BETYDELSE OCH SAMHÄLLSNYTTA – PANEL 2

Utgångspunkter

Utgångspunkterna för utvärderingen av forskningens kliniska betydelse och samhällsnytta har formulerats av den nationella styrgruppen för ALF. I enlighet med dessa ska utvärderingen genomföras av en panel bestående av internationella experter och den ska utgå från bedömning av olika underlag, inklusive självvärderingar och hearings. Det övergripande syftet är att höja den kliniska forskningens kvalitet.

Utvärderingen avser två huvudfrågor:
- Hur arbetar ALF-regionen med implementering av forskningsresultat i sin kliniska praktik?
- Vad är den kliniska betydelsen och samhällsnyttan av ALF-regionens kliniska forskning?

Fyra bedömningskriterier används:
- forskningskompetens
- samverkan
- implementering av forskningsresultat i klinisk praktik
- genomslag av klinisk forskning utanför akademin

Panelens uppdrag är att göra en sammanvägd bedömning av ALF-regionerna och placera regionerna i en av tre kategorier (undermålig kvalitet, god–hög kvalitet, eller mycket hög kvalitet). Enligt utgångspunkterna från den nationella styrgruppen ska 1–3 av ALF-regionerna placeras i kategorin mycket hög kvalitet och utgör därmed goda exempel. Därutöver lyfter panelen fram ytterligare goda exempel i fråga om vissa aspekter, oavsett den sammanvägda bedömningen av ALF-regionerna. Panelen identifierar också utvecklingsområden och ger rekommendationer för förbättringar.

Instruktionerna till ALF-regionerna inför deras självvärdering, instruktionerna till panelen samt schema för hearingarna återfinns under följande länkar:
- instruktion till självvärdering
- instruktion till panelen
- schema för hearing

Expertpanelens sammansättning

Utvärderingen har genomförts av en internationell expertpanel tillsatt av Vetenskapsrådet utifrån förslag från ALF-regionerna, från ämnesråd och kommittéer inom Vetenskapsrådet[14] samt från projektgruppen. Panelen består av åtta ledamöter (tabell 6) som tillsammans representerar kompetens och erfarenhet avseende klinisk forskning, implementering av forskning i praktik, utvärdering av genomslag av forskning utanför akademin samt perspektiv från myndigheter, industri och patientorganisationer. Vid sammansättningen av panelen har även jämn könsfördelning och geografisk spridning eftersträvats.

Vid rekryteringen har Vetenskapsrådet jävspolicy följts och alla ledamöter i den internationella panelen har uppmärksammats på och erhållit Vetenskapsrådets jävspolicy. Alla panelmedlemmar har intygat att ingen jävsituation föreligger.

[14] Ämnesrådet för Medcin och Hälsa, Kommittéen för kliniska studier, Kommittéen för klinisk behandlingsforskning, Enheten för kliniska studier.

Tabell 6. Expertpanelen – ALF-panel 2

Namn	Organisation	Land
Lisbeth Tranebjaerg (ordförande)	Rigshospitalet och Københavns Universitet	Danmark
Henning Beck Nielsen	Odense Universitetshospital och Syddansk Universitet	Danmark
Elizabeth Bergsten Nordström	Bröstcancerföreningen	Sverige
Anders Blanck	Läkemedelsindustrins branschorganisation (LIF)	Sverige
Kåre Birger Hagen	Diakonhjemmet Sykehus och Universitetet i Oslo	Norge
Charlotte Hall	Statens beredning för medicinsk och social utvärdering (SBU)	Sverige
Anne Sales	University of Michigan and VA Ann Arbor Healthcare System	USA
Ian Viney	Medical Research Council (MRC)	Storbritannien

Kriterier

Utvärderingsfrågor

Utgångspunkterna för panelens arbete är de två huvudfrågorna för utvärderingen:

- Hur arbetar ALF-regionen med implementering av forskningsresultat i sin kliniska praktik?
- Vad är den kliniska betydelsen och samhällsnyttan av ALF-regionens kliniska forskning?

Detta innebär att varje ALF-region utvärderas med avseende på sitt arbete med att implementera egna och andras forskningsresultat i sin kliniska praktik och avseende sitt arbete med att åstadkomma klinisk betydelse och samhällsnytta av sin egna kliniska forskning.

Bedömningskriterier och indikatorer

Utvärderingen fokuserar på följande fyra bedömningskriterier som specificeras genom indikatorer.

Forskningskompetens:

- hög närvaro av forskarutbildad (PhD) personal i klinisk praktik
- betydande och kontinuerligt bidrag av forskarutbildad (PhD) personal till samhället

Samverkan:

- samarbete mellan medicinsk expertis och icke-akademiska parter
- multidisciplinärt samarbete
- lämplig strategi och tydligt definierade målgrupper för kunskapsspridning

Implementering av forskningsresultat i klinisk praktik:

- lämpliga metoder och strategier för att hålla den egna kliniska praktiken i linje med den bästa evidensen inom relevanta forskningsområden
- lämpliga metoder och strategier för utvärdering av insatser för att hålla den egna kliniska praktiken i linje med den bästa evidensen
- lämpliga metoder och strategier för användning av resultat från utvärdering enligt ovan

Genomslag av klinisk forskning utanför akademin:

- genomslag utanför akademin, det vill säga räckvidd och betydelse av genomslaget (t.ex. hur frekvent forskningsresultat har påverkat relevanta intressenter och hur stark påverkan har varit, t.ex. hur viktig effekten har varit för berörda aktörer)
- underliggande forskning, det vill säga i vilken utsträckning ALF-regionens forskning kan anses ha utgjort ett väsentligt och tydligt bidrag till det beskrivna genomslaget

- nyckelprocesser och nyckelfaktorer, det vill säga i vilken utsträckning ALF-regionens processer och strategier kan anses ha bidragit till genomslag utanför akademin. Genomslag kan ofta inte tillskrivas specifika publikationer. Exempelvis kan externa processer som underlättar genomslag samt kontextuella faktorer som ligger utanför forskningsmiljön vara avgörande. Dessutom kan det vara en betydande tidsfördröjning mellan publicering av forskningsresultat och genomslag utanför akademin. Viktiga nyckelprocesser och nyckelfaktorer kan exempelvis omfatta ALF-regionens egna implementeringsprocesser och strategier samt kontextuella bidragande faktorer.

Definition av genomslag av klinisk forskning utanför akademin

Genomslag av klinisk forskning utanför akademin kan avse effekter på lokal, regional, nationell och/eller internationell nivå på ett eller flera områden t.ex. ekonomi, samhälle, politik, offentlig förvaltning, hälsa, produktion, miljö eller livskvalitet. Genomslag utanför akademin kan manifesteras på många olika sätt och avse olika typer av mottagare (individer, organisationer, samhällen, regioner eller andra enheter). Det kan t.ex. innebära effekter på produkter, processer, beteenden, politik, praxis, undvikande av skada eller slöseri med resurser.

I denna utvärdering avses två olika slags genomslag utanför akademin - klinisk betydelse och samhällsnytta.

Klinisk betydelse

Med klinisk betydelse avses effekter som sker i den kliniska praktiken, det vill säga effekter på patienters vård och hälsa. Klinisk betydelse omfattar t.ex. ny lokal praxis för behandling eller diagnos av en viss sjukdom, jämlik hälsovård, modifiering av rekommendationer eller riktlinjer för behandling eller avveckling av redundanta metoder. Ytterligare exempel på klinisk betydelse är bättre beslutsfattande i kraft av mer anpassat ledarskap, tydligare definierade roller och ansvarsområden eller nya delegationsordningar. Tidsbesparande innovationer kan också utgöra exempel på klinisk betydelse.

Samhällsnytta

Med samhällsnytta avses effekter som uppstår på andra ställen än i den kliniska praktiken. t.ex. inom andra delar av ekonomin, samhället, offentlig förvaltning, produktion eller miljö. Exempelvis kan det röra påverkan på nationella riktlinjer, förbättrad folkhälsa genom av spridning av kunskap till patientorganisationer och förbättrad kommunikation mellan sjukhus och den sociala sektorn. Ytterligare exempel är lönsamma spin-off företag, ökad tillväxt för industripartners eller regional tillväxt. Ett mer jämställt hälso- och sjukvårdssystem är en annan potentiell samhällspåverkan.

Bedömningsprocess

Panelens sammanvägda bedömning baseras på följande underlag:

- självvärdering från respektive ALF-region inklusive SWOT-analys[15] och fallstudier som visar på genomslag utanför akademin
- offentlig statistik om personal, baserad på data från Statistiska centralbyrån (SCB)
- data om kliniskt genomslag genom referenser till forskningsresultat i t.ex. kliniska riktlinjer, baserad på data från Minso Solutions AB[16] och Web of Science (Clarivate Analytics)
- hearings, där panelen intervjuade representanter i ledningsposition från varje ALF-region.

Självvärderingar och hearings utgör de viktigaste informationskällorna för panelens bedömningar. Som bakgrund till uppdraget informerades panelen av Vetenskapsrådet om ALF-finansieringens omfattning och om ALF-regionernas ungefärliga populationsstorlek och geografiska omfattning.

---

[15] SWOT-analys ("Strengths", "Weaknesses", "Opportunities" och "Threats") är ett planeringshjälpmedel där man försöker finna styrkor, svagheter, möjligheter och hot vid en strategisk översyn.

[16] http://ci.minso.se/en/

Självvärdering inklusive fallstudier

En mall för självvärdering (länk till självvärdering) skickades tillsammans med instruktionerna till panelen (länk till instruktion) ut till ALF-regionerna den 16 maj 2017. Sista dag för inlämning av de ifyllda självvärderingarna var den 15 september 2017. Självvärderingen består av följande avsnitt:

A. Bakgrundsdata

Antal kliniska studier[17] godkända av regional etikprövningsnämnd, där ALF-regionen är forskningshuvudman. Denna uppgift bedöms inte i sig utan bidrar endast till kontexten.

B. Forskningskompetens

Beskrivning av processer och strategier för att säkerställa en hög närvaro av forskarutbildade (PhD) yrkesverksamma inom klinisk praktik på lång sikt. Möjlighet att kommentera den offentliga personalstatistiken.

C. Samverkan

Beskrivning och förklaring av ALF-regionernas viktigaste samarbeten med icke-akademiska parter och vetenskapliga multidisciplinära samarbeten för att säkerställa forskningens kliniska betydelse. Beskrivning av aktiviteter och målgrupper för spridning av forskningsresultat till berörda intressenter utanför den egna organisationen, med goda exempel.

D. Implementering av forskningsresultat i klinisk praktik

Strategier, processer och aktuella exempel (från de senaste fyra åren) på implementering av forskningsresultat i klinisk praktik i ALF-regionen. De relevanta forskningsresultaten kan ha producerats både inom och utanför ALF-regionen. Denna del av självvärderingen är indelad i fem avsnitt:

- beskrivning av processer för att hålla klinisk praktik i linje med den bästa evidensen inom relevanta forskningsområden
- beskrivning av hur det säkerställs att dessa processer är lämpliga, uppdaterade och att de implementeras
- beskrivning av huruvida dessa processer utvärderas och hur det säkras att utvärderingsresultaten används
- beskrivning av ett till tre exempel på framgångsrika processer för implementering av kliniska forskningsresultat (egna och andras) i klinisk praktik i ALF-regionen, inklusive referenser till relevanta dokument och/eller namn på berörda aktörer för verifikation
- SWOT-analys (styrkor, svagheter, möjligheter och hot) för implementering av forskningsresultat i klinisk praktik.

E. Genomslag av klinisk forskning utanför akademin – fallstudier

Beskrivning av 1–3fall där klinisk forskning som utförs i den egna ALF-regionen har bidragit till positiv inverkan i klinisk praktik och/eller i andra delar av samhället. Fallstudierna innehåller tre avsnitt:

- Beskrivning av själva fallet, vad det är som har inträffat, antingen av klinisk betydelse eller av betydelse för samhället i vidare mening. Vem eller vad som har gynnats eller påverkats, hänvisning till referenser som kan bekräfta fallet. Genomslaget av forskningen ska ha inträffat under de senaste fyra åren.
- Beskrivning av den underliggande forskningen med 1–10 referenser till publikationer från ALF-regionen som visar på att forskningen har bidragit på ett väsentligt och tydligt sätt. Den ska innehålla en kort beskrivning av huvudinnehållet i dessa publikationer och en förklaring till varför denna forskning är väsentligt för det beskrivna fallet. Publikationerna ska vara från 1997 eller senare. Av instruktionerna till självvärderingen framgår hur publikationer som gjorts i samarbete med författare från olika instanser ska hanteras.
- Beskrivning av nyckelprocesser och nyckelfaktorer som anses ha bidragit väsentligt för att underlätta den kliniska forskningens genomslag utanför akademin.

[17] Klinisk studie avser en undersökning på människor för att studera effekten av ett läkemedel eller behandlingsmetod.

Statistik om avhandlingar och anställningar

Officiell personalstatistik per ALF-region beställdes från Statistiska centralbyrån (SCB). Dessa data skickades till ALF-regionerna 23 augusti 2017 med möjlighet att kommentera dem i självvärderingen. Statistiken för alla ALF-regionerna sammanställdes därefter av Vetenskapsrådet i en PM [18] som underlag för panelen och skickades till ALF-regionerna för kännedom den 27 oktober 2017.

Den presenterade statistiken innehöll information om

- antal avhandlingar, där personen har en yrkesexamen inom medicin och hälsa, vid universitet som ingår i respektive ALF-region (medel för år 2014–2016)
- i vilken utsträckning anställda[19] i landstinget i respektive ALF-region har doktorsexamen (medel för år 2014–2015)
- i vilken utsträckning anställda vid varje universitetssjukhus har doktorsexamen (medel för år 2014–2015)
- antal anställda med dubbel anställning och lön från både landsting och universitet (medel för år 2014–2015).

Könsfördelningen redovisades genomgående.

Kliniskt genomslag med hjälp av bibliometri

Ytterligare ett underlag för panelen utgörs av en studie av kliniskt genomslag. Studien består av en bibliometrisk analys av hur vetenskapliga publikationer citeras i kliniska riktlinjer, eller motsvarande. Resultatet presenterades för panelen och för ALF-regionerna i en PM [20] den 27 oktober 2017. Vetenskapsrådet tillhandahöll dessa data genom Minso Solutions AB [21] och Web of Science (Clarivate Analytics).

Hearings

Självvärderingar, personalstatistik och bibliometriska data avseende genomslag i kliniska riktlinjer låg till grund för de hearings som panelen hade med fem till sex representanter på ledningsnivå från landsting och universitet i varje ALF-region. Dessa tvåtimmars-hearings hölls i Stockholm den 20–22 november 2017. Panelen identifierade generella och specifika frågor att diskutera. Frågorna sändes till ALF-regionerna en vecka innan respektive hearing. Schema och deltagare vid hearingarna finns under denna länk.

Panelmöten

Panelen har träffats vid två tillfällen. Vid det första panelmötet, den 27–28 april 2017, presenterades syftet med utvärderingen och processen för utvärderingen, självvärderingsmallen samt bedömningskriterier och indikatorer diskuterades och modifierades något. Vid det andra mötet, den 19–24 november 2017, i samband med nämnda hearings, enades panelen om sina huvudsakliga slutsatser. Dessutom har två telefonkonferenser hållits, den 13 november 2017 för att diskutera preliminära intryck av underlagen och förbereda hearings samt den 16 januari 2018 för att komma överens om panelens slutliga rapport och bedömning. Samtliga panelmedlemmar har tagit del av allt underlag för bedömning av de sju ALF-regionerna och har aktivt deltagit vid hearings med företrädare för ALF-regionerna[22].

Medlemmarna i panelen är gemensamt ansvariga för de slutliga bedömningarna och för panelens rapport. I rapporten (se del 2) framgår panelens motiveringar till kategoriseringarna. Rapporten betonar också goda exempel på speciella aspekter av någon ALF-region, som panelen vill framhäva, vid sidan av den övergripande bedömningen. Dessutom finns identifierade utvecklingsområden samt rekommendationer till förbättringar.

---

[18] Data on human resources from Statistics Sweden (SCB) – to be used by ALF expert panel 2 in the evaluation of clinical significance and societal impact of clinical research in Sweden. Swedish Research Council 2017-10-04. Vetenskapsrådet Dnr 3.2-2016-7078.

[19] Med legitimationsyrken inom hälso- och sjukvård.

[20] Clinical impact – references to scientific publications in clinical guidelines – to be used by ALF expert panel 2 in the evaluation of clinical significance and societal impact of clinical research in Sweden. Swedish Research Council 2017-10-27. Vetenskapsrådet Dnr 3.2-2016-7078.

[21] http://ci.minso.se/en/

[22] Med ett undantag, Charlotte Hall deltog ej vid hearingen med ALF-region Örebro.

UTVÄRDERING AV FORSKNINGENS FÖRUTSÄTTNINGAR – PANEL 3

Utgångspunkter

Utgångspunkterna för utvärderingen av forskningens förutsättningar har formulerats av den nationella styrgruppen för ALF. I enlighet med dessa ska utvärderingen genomföras av en panel bestående av internationella experter. Den ska utgå från bedömning av olika underlag, inklusive självvärderingar och hearings. Det övergripande syftet är att höja den kliniska forskningens kvalitet. Panelens uppdrag är att göra en sammanvägd bedömning av kvaliteteten på den kliniska forskningens förutsättningar i ALF-regionerna och att gruppera dem i en av tre kategorier (undermålig kvalitet, god–hög kvalitet eller mycket hög kvalitet).

Enligt utgångspunkterna som formulerats av den nationella styrgruppen för ALF ska den kliniska forskningens förutsättningar utvärderas med avseende på kritiska framgångsfaktorer för att stärka den kliniska forskningen. Vetenskapsrådet har, med utgångspunkt i underlaget från styrgruppen, fokuserat på följande kritiska framgångsfaktorer, i utvärderingen kallade komponenter, för att utvärdera den kliniska forskningens kvalitet:

1. forskningsinfrastrukturer
2. tid till forskning
3. nästa generations forskare (utbildning)
4. karriärmodeller för klinisk forskning.

Inledningsvis fanns en ambition att också finansiering av klinisk forskning skulle ingå som utvärderingskomponent. Då det idag saknas bra metoder för att ta fram jämförbar finansiell statistik från landstingen och universiteten i ALF-regionerna har finansiell information endast utgjort bakgrundsinformation i denna utvärdering.

Instruktionerna till ALF-regionerna inför självvärdering och instruktionerna till panelen samt schema för platsbesök och hearings återfinns under följande länkar:

- bedömningsmatris
- självvärdering
- enkät till forskningsgruppsledare
- instruktion till förutvärdering
- schema för platsbesök.

Expertpanelens sammansättning

Utvärderingen har genomförts av en panel bestående av internationella experter tillsatta av Vetenskapsrådet utifrån förslag från ALF-regionerna, från ämnesråd och kommittéer inom Vetenskapsrådet [23] samt från projektgruppen. Panelen består av tolv ledamöter (tabell 7) med mångårig erfarenhet av att leda och organisera klinisk forskning och forskarutbildning. Ledamöternas profilområden är: organisation, ledarskap, finansiering av forskning, prioritering av forskning, meritsystem, forskarutbildning och praktik, mentorskap, forskningsinfrastrukturer samt kvalitetssäkringsstrukturer. Utöver sina profilområden har alla ledamöter ämnesexpertis inom olika relevanta områden. Vid rekryteringen har Vetenskapsrådet jävspolicy följts och alla ledamöter i den internationella panelen har uppmärksam-

[23] Kommittén för Klinisk behandlingsforskning (KKBF), Kommittén för Kliniska Studier (KKS), Ämnesrådet för Medicin och Hälsa vid Vetenskapsrådet (MH), Nationella styrgruppen för ALF, Regionala nämnder vid universitetssjukhusen i Sverige (RN).

mats på och erhållit Vetenskapsrådets jävspolicy. Alla panelmedlemmar har intygat att ingen jävsituation föreligger.

Vid sammansättningen av panelen har jämn könsfördelning och geografisk spridning eftersträvats.

Tabell 7. Expertpanelen – ALF-panel 3

Namn	Organisation	Land
Stig Arild Slørdahl (ordförande)	Helse Midt-Norge	Norge
Jaap Bonjer	VU University Medical Center Amsterdam	Nederländerna
Erik Fosse	Oslo universitetssykehus, Universitetet i Oslo	Norge
Björn Gustavsson	Norges teknisk naturvitenskapelige universitet	Norge
Ian Hall	Nottingham University	Storbritannien
Nina Langeland	Universitetet i Bergen	Norge
Marite Rygg	Norges teknisk-naturvitenskapelige universitet	Norge
Janna Saarela	FIMM, Institute for Molecular Medicine Finland	Finland
Lars Bo Svendsen	Rigshopsitalet,	Danmark
Marja Riita Taskinen	Helsingfors universitet	Finland
Inger Thune	Universitetet i Oslo	Norge
Rein de Vos	Academisch Medisch Centrum	Nederländerna

Kriterier

Utvärderingen av den kliniska forskningens förutsättningar utgår från fyra komponenter:

1. **Forskningsinfrastrukturer**, avser tillgängligheten till ALF-regionens forskningsinfrastrukturer, strategier för finansiering, underhåll och uppgradering, teknisk personal för underhåll och stöd vid användning, prioritering av infrastrukturer etc.
2. **Tid till forskning**, avser hur ALF-regionerna säkerställer att det ges tillräcklig tid till forskning i klinikens vardag, hur man på bästa sätt kombinerar klinisk anställning och klinisk forskning etc.
3. **Nästa generations forskare (utbildning)**, handlar om hur ALF-regionen arbetar för att göra det attraktivt att bli klinisk forskare i ALF-regionen, och hur tvärdisciplinära och tvärvetenskapliga forskningsområden stimuleras, etc.
4. **Karriärmodeller för klinisk forskning**, avser hur ALF-regioner utvecklat karriärvägar för kliniska forskare som möjliggör klinisk forskning och kliniskt arbete parallellt, samt hur klinisk forskning premieras i karriären, etc.

Komponenterna bedöms avseende hur de är implementerade i de sju ALF-regionerna när det gäller att skapa förutsättningar för klinisk forskning. För att bedöma hur dessa komponenter har implementerats och utvecklats har en bedömningsmatris tagits fram (länk till bedömningsmatris). Det som bedöms är hur varje ALF-region har utvecklat respektive komponent avseende organisationen i verksamheterna och med avseende på strukturer, processer och resultat.

Bedömningsmatrisen har också legat till grund för den datainsamling som gjorts, dels med en självvärdering till ledningarna för de sju ALF-regionerna, dels med en enkät som skickats till forskningsledare i respektive ALF-region.

Bedömningsprocess

Utvärderingen har genomförts i tre steg:

1. förutvärdering av ALF-regionerna baserat på regionernas självvärderingar och på enkätsvar från en enkät riktad till forskningsgruppledare i ALF regionerna (länk till instruktion)

2. lokala platsbesök och utfrågning om verksamheten i de sju ALF-regionerna (länk till schema för platsbesök)
3. samlade diskussioner och bedömningar där panelen slutligen placerat ALF-regionerna i någon av de tre kategorierna undermålig kvalitet, god–hög kvalitet eller mycket hög kvalitet.

Utvärderingen har gjorts med hjälp av följande underlag:

- självvärdering från respektive ALF-region
- resultaten av enkäten till forskningsgruppsledarna
- platsbesök inklusive hearings.

Som bakgrund till uppdraget informerades dessutom panelen av Vetenskapsrådet om ALF-finansieringens omfattning och om ALF-regionernas ungefärliga populationsstorlek och geografiska omfattning.

Självvärdering

En mall för självvärdering skickades tillsammans med instruktioner ut till ALF-regionerna den 6 september 2017 (länk till självvärdering). Sista dag för inlämning av självvärderingarna var den 18 oktober 2017. Vid självvärderingen ombads ledningsorganen för respektive ALF-region att redovisa hur de arbetat med att implementera och utveckla de fyra olika komponenterna som ingår i bedömningen med avseende på strukturer, processer och resultat.

Enkät till forskningsgruppsledare

En enkät skickades ut till forskningsgruppledare, som identifierats av ALF-regionerna själva, den 6 september 2017 (länk till enkät). Sista dag för inlämning av svaren var den 27 september 2017. Enkäten innehåller frågor om forskningsledarens bakgrund som forskare, om personens medicinska profession, om mobilitet, om tid till forskning samt ett antal bedömningsfrågor som utgår ifrån den bedömningsmatris som också använts för frågor i mallen för självvärderingen. I nedanstående tabell anges svarsfrekvensen för enkäten i respektive region.

Tabell 8. Svarsfrekvens på enkäten till forskningsgruppledare i respektive ALF-region

ALF-region	Utsända enkäter	Respondenter	Svarsfrekvens
Stockholm	775	482	62%
Västra Götaland	265	218	82%
Skåne	681	330	48%
Uppsala	185	129	70%
Västerbotten	296	188	64%
Östergötland	237	176	74%
Örebro	148	117	79%

Platsbesök

Då det är organisatoriska komponenter som ska bedömas och för att möjliggöra för panelen att få en lokal bild av respektive ALF-region samt att träffa så många företrädare för regionerna som möjligt genomfördes platsbesök i varje region. Panelen delades upp i tre grupper som träffade de olika ALF-regionerna under perioden 15–17 januari 2018, enligt tabell 9 (länk till schema för platsbesök).

Tabell 9. Panelens gruppindelning för platsbesöken

Gruppl	Grupp 2	Grupp 3
	ALF-regioner	
Östergötland och Stockholm	Umeå, Uppsala och Örebro	Skåne och Västra Götaland
Stig Slørdal	Nina Langeland	Lars Boo Svendsen
Marite Rygg	Erik Fosse	Inger Thune
Jaap Bonjer	Ian Hall	Rein de Voos
Marja-Riitta Taskinen	Janna Saarela	Björn Gustafsson

Bedömning

För att genomföra sin bedömning använde panelen inledningsvis en fyrgradig bedömningsskala för varje komponent och aspekt. Syftet med att använda en fyrgradigskala som ett första steg var att säkerställa att bedömningen av forskningens förutsättningar i de sju olika ALF-regionerna baseras på samma grunder och att det framgår vad det är som utgör god kvalitet. Skalan som panelen inledningsvis använde har följande gradering:

1. nybörjare (beginning)
2. under utveckling (developing)
3. etablerad (accomplished)
4. exemplarisk (exemplary).

Bedömningen genomfördes enligt följande upplägg och enligt de tre stegen som redovisats ovan.

Steg 1

Innan panelen träffades i Stockholm genomfördes en förutvärdering av varje ALF-region baserad på självvärderingarna och svaren på enkäten till forskningsgruppledarna. Panelledamöterna gjorde individuella bedömningar, genom att använda den fyrgradiga skalan ovan, av hur väl respektive ALF-region har implementerat de strukturer, processer och resultat som de redovisat för varje komponent. Panelledamöterna instruerades att använda skalan så att varje grad motsvarar samma bredd och djup genom alla bedömningar och att ange betyg, motivering och kompletterande frågor för varje ALF-region.

När panelen träffades i Stockholm inför platsbesöken kalibrerades bedömningarna för att säkerställa att bedömningsskalan använts på samma sätt och med samma betydelse av samtliga panelledamöter. De kompletterande frågorna från ledamöterna sammanställdes och presenterades för panelen inför platsbesöken.

Steg 2

I nästa steg genomfördes platsbesök, då panelen fick möjlighet att ställa kompletterande frågor till ledningen för ALF regionen, till verksamhetsansvariga och till forskare och doktorander inom klinisk forskning. Utfrågningarna utgick från de fyra komponenterna i avsikt att komplettera och förtydliga det underlag som lämnats i form av självvärderingarna. I samband med platsbesöken och utfrågningarna formulerades en sammanfattande bedömning för respektive komponent, samt ett preliminärt omdöme för hela ALF-regionen avseende helheten för forskningens förutsättningar. När panelens tre grupper åter träffades, efter att platsbesöken var genomförda, diskuterades resultaten för att kalibrera och gemensamt enas om en sammanvägd bedömning av alla ALF regioner.

Steg 3

I det sista steget omvandlades resultatet som panelen arbetat fram, enligt den fyrgradiga bedömningsskalan, till de tre kategorier som ALF-regionerna ska grupperas i (undermålig kvalitet, hög-god kvalitet eller mycket hög kvalitet). Då enades panelen om ett sammanfattande omdöme som motiverar

kategoriseringen. Panelen sammanfattade även sina generella reflektioner över förutsättningarna för klinisk forskning i Sverige i de sju ALF regionerna.

Avsikten med ovanstående process har varit att på bästa sätt skapa en tydlig och transparent utvärdering av den kliniska forskningens förutsättningar i de sju ALF-regionerna, så att varje region bedöms utifrån sina förutsättningar på en likvärdig skala.

Panelmöten

Expertpanelen träffades i Stockholm i anslutning till platsbesöken den 14–19 januari 2018. Efter platsbesöken genomfördes diskussioner för att kalibrera och gemensamt enas om en sammanvägd bedömning av alla ALF-regioner. Samtliga panelmedlemmar har tagit del av alla underlag för bedömning av de sju ALF-regionerna och har aktivt deltagit vid hearings med företrädare för ALF-regionerna i de tre grupperna som redovisats ovan.

Medlemmarna i panelen är gemensamt ansvariga för de slutliga bedömningarna och för panelens rapport. I rapporten (se del 2) framgår panelens motiveringar till kategoriseringarna. Rapporten betonar också goda exempel på speciella aspekter av någon ALF-region, som panelen vill framhäva, vid sidan av den övergripande bedömningen. Dessutom finns identifierade utvecklingsområden samt rekommendationer till förbättringar.

REFERENSER

Socialdepartementet, *Uppdrag att utvärdera universitetssjukvård*, 6 oktober 2016, Dnr S2016/06247FS.

Utbildningsdepartementet, *ALF-avtalet*, september 2014, Dnr U2014/07551/F.

Utbildningsdepartementet, *Uppdrag att utvärdera den kliniska forskningens vetenskapliga kvalitet*, 22 juni 2016, Dnr U2016/02935/F.

Utbildningsdepartementet, *Uppdrag att utvärdera den kliniska forskningens kvalitet avseende forskningens kliniska betydelse och samhällsnytta samt forskningens förutsättningar*, 6 oktober 2016, Dnr U2016/04203/F.

Vetenskapsrådet, *Transparens och kvalitet – En modell för uppföljning och utvärdering av klinisk forskning finansierad av ALF-medel*, 2010, Rapport 8:2010.

Vetenskapsrådet, *En utvecklad modell för kvalitetsutvärdering av klinisk forskning finansierad av ALF-medel*, 2013, Rapport 2:2013.

DEL 2 / PART 2
REPORTS FROM THE THREE EXPERT PANELS

INTRODUCTION

The ALF agreement[24] regulates the compensation from the Government to certain county councils for participating in medical education, clinical research and development of health services, i.e. "ALF funding". In 2015, the total amount of ALF funding for clinical research was approximately 1 700 million SEK. Regional agreements between the county councils and the universities providing medical education complement the national ALF agreement. In this report, the county council and the university are jointly referred to as an "ALF region" (Table 10).

Table 10. The ALF regions, county councils and universities that are subject to the ALF agreement. Note that Region Örebro did not receive ALF funding before 2015.

ALF region	County Council	University	Share of total ALF funding for clinical research (2015)
Stockholm	Stockholms county council	Karolinska institutet	27 %
Västra Götaland	Region Västra Götaland	University of Gothenburg	21 %
Skåne	Region Skåne	Lund University	20 %
Uppsala	Region Uppsala	Uppsala University	12 %
Västerbotten	Västerbottens county council	Umeå University	11 %
Östergötland	Region Östergötland	Linköping University	8 %
Örebro	Region Örebro county	Örebro University	2 %

Evaluation of clinical research

The current ALF agreement came into effect in 2015. One of the additions in the current agreement is a quality-based model for allocating a percentage of the ALF funding. This model entails that as from 2019, 20% of the ALF funding will be allocated based on the results of evaluation of the quality of the clinical research. The main purpose of the new allocation model and evaluation of the clinical research is to identify good examples of ALF regions that may serve as role models for the other ALF regions, in order to enhance the overall quality of clinical research in Sweden.

The Government has therefore commissioned the Swedish Research Council to evaluate the quality of the clinical research conducted in the county councils that are subject to the ALF agreement.[25] The results of the evaluations will be used in the new model for allocating ALF funding.

According to the ALF agreement, clinical research is defined as research that requires access to the structures and resources of the health services, and for which the aim is to solve a problem of ill health, or identify factors that lead to improved health.[26] Clinical research in the county councils is conducted both by the county councils and the universities, and often in collaboration between the two. Thus, the evaluations include all clinical research conducted by both the county council and the university, jointly referred to as an "ALF region" (Table 10).

The National ALF Steering Committee has decided on the starting points for the evaluations. Accordingly, three international expert panels have been appointed to perform the evaluations of:

- the quality of the scientific output (ALF panel 1)
- the clinical significance and societal impact of the clinical research (ALF panel 2)
- the prerequisites for clinical research (ALF panel 3).

[24] U2014/07551/F National ALF agreement

[25] U2016/02935/F Uppdrag att utvärdera den kliniska forskningens vetenskapliga kvalitet. (Commission to evaluate the scientific quality of clinical research); U2016/04203/F Uppdrag att utvärdera den kliniska forskningens kvalitet avseende forskningens kliniska betydelse och samhällsnytta samt forskningens förutsättningar (Commission to evaluate the quality of clinical research in terms of clinical significance and social benefit, as well as prerequisites for research).

[26] Section 7, National ALF agreement

According to the National ALF Steering Committee, the results of the evaluations should be weighted, so that the results from ALF panel 1 accounts for the distribution of 50% of the allocation pool, and the results from ALF panels 2 and 3 account for the allocation of 25% of the allocation pool respectively. Each panel should provide an overall assessment and group each ALF region into one of three categories.

- **Inferior quality**
  ALF regions are only expected to be placed in this category in exceptional cases. This category is used if the evaluation of the collected documentation indicates an inferior performance in relation to the share of allocated ALF funding, and/or the ALF region in question has failed to fully contribute to the evaluation (for example by producing inferior/non-assessable self-evaluation or otherwise delivering incomplete data, etc.). Any ALF region that ends up in this category will not be included in the panel's allocation pool.
- **Good–high quality**
  A majority of the ALF regions are expected to be placed in this category. This category is used if the evaluation of the collected documentation indicates a performance at a level that is to be expected based on the share of allocated ALF funding. The ALF regions in this category are guaranteed allocation of funds from the panel's allocation pool.
- **Very high quality**
  This category is used for the ALF regions that have performed better than expected, based on the share of allocated ALF funding. According to the National ALF Steering Committee, this category should consist of the 1–3 ALF regions that excel and set a national example within each panel's area. These ALF regions receive a premium of a larger share of the allocation pool than the ALF regions placed in category 2.

The three panel reports are summarised into a joint evaluation report by the Swedish Research Council, and delivered to the Government at the latest on 31 March 2018.

Each panel report begins with a description of the appointment of the panel and the evaluation process followed by the panel's reflections and overall comments. The panel's full assessments and justifications for each ALF-region are found last in each panel report.

EVALUATION OF THE QUALITY OF THE SCIENTIFIC OUTPUT – REPORT FROM ALF PANEL 1

The starting points for the evaluation were formulated by the National ALF Steering Committee. Accordingly, an international expert panel shall assess *the overarching quality and extent of the scientific output*, *and the scientific profile in terms of clinical relevance and quality*, of the ALF regions. The assessment of the overarching quality and extent of scientific output shall be based on bibliometrics, while the scientific profile in terms of clinical relevance and quality shall be assessed by means of peer review of a sample of the top scientific publications of each ALF region.

Based on these assessments, the panel shall sort the ALF regions into one of three categories (inferior quality, good–high quality, or very high quality).

For further details of the evaluation, the following documents are linked to the report:

- assessment criteria (sent to the ALF regions)
- instructions to reviewers
- instructions to the panel
- bibliometrical statistics for the ALF regions.

The expert panel and external reviewers

An international expert panel and external reviewers were appointed by the Swedish Research Council based on nominations from the ALF regions and from several councils and committees within the Swedish Research Council [27]. The following criteria were taken into consideration for the compilation of panel members and external reviewers: experience of evaluation work; a broad range of clinical research disciplines; gender balance; and geographical spread. Professor Hugh McKenna from Ulster University was appointed panel chair, and, in total, the panel consisted of 19 internationally renowned experts in relevant areas of research (Table 11). For the peer review process, an additional 31 external reviewers were involved. All panel members and external reviewers have ensured that they have no conflict of interest when participating in the evaluation.

[27] The Scientific Council for Medicine and Health, the Committee for Clinical Therapy Research and the Committee for Clinical Studies

Table 11. The ALF panel 1 members

Name	Affiliation	Country	Main area of expertise
Hugh McKenna (chair)	Ulster University	N. Ireland (UK)	Health Sciences/Research assessment
Per Bakke	University of Bergen	Norway	Respiratory System
Alexandra Durr	Institut du Cerveau et de la Moelle épinière	France	Neurosciences
Keith AA Fox	University of Edinburgh	Scotland (UK)	Cardiac & Cardiovascular Systems
Jan Frystyk	Odense University Hospital	Denmark	Endocrinology & Metabolism
Robin Grant	University of Edinburgh	Scotland (UK)	Neurosciences
Per Ole Iversen	University of Oslo	Norway	Hematology
Christine Katlama	Hôpital La Pitié Salpêtrière	France	Infectious Diseases
Paulus Kirchhof	University of Birmingham	England (UK)	Cardiac & Cardiovascular Systems
Tina Lavender	University of Manchester	England (UK)	Obstetrics & Gynecology
Marjatta Leirisalo-Repo	Helsinki University Hospital	Finland	Rheumatology
Valerie Lund	University College London	England (UK)	Otorhinolaryngology
Brigitte Malgrange	University of Liège	Belgium	Neurosciences
Helle Prætorius	Aarhus University	Denmark	Urology & Nephrology
Jon Rhodes	University of Liverpool	England (UK)	Gastroenterology & Hepatology
Susan Smith	Royal College of Surgeons in Ireland	Ireland	Health Care Sciences
Peter Tyrer	Imperial College London	England (UK)	Psychiatry
Cornelis van de Velde	Leiden University Medical Center	The Netherlands	Oncology
Hannele Yki-Järvinen	University of Helsinki	Finland	Endocrinology & Metabolism

The evaluation process and assessment criteria

Overarching quality and extent of the scientific output

The overarching quality and extent of the scientific output were assessed based on bibliometrical analyses of publications from 2012 to 2015 compiled by the Swedish Research Council. The bibliometrics was based on data from Web of Science (WoS) (Clarivate Analytics), in accordance with the principles of data capture as decided by the National ALF Steering Committee (principles of data capture).

The panel was instructed to consider the following bibliometrical indicators for the assessment of each ALF region:

- overall volume of publications
- overall volume of publications in relation to the share of ALF funding
- citation impact
- citation impact in relation to the share of ALF funding
- average citation rate
- share of highly cited publications.

Additional statistics on collaboration and subject profiles were also included in the material as background information.

The scientific profile in terms of clinical relevance and quality

For the assessment of the scientific profile in regards to clinical relevance and quality, the ALF regions were asked to select a number of their top publications published in 2012–2015. In total, 360 publications are included in the evaluation, corresponding to one per cent of all health science publications

from all the regions published in the time span 2012 to 2015. The number of publications selected by each ALF region is proportional to their share of ALF funding for research for the year 2015 (Table 12).

The regions were provided with guidelines rom the Swedish Research council and were allowed a time period of three months for the selection of publications (assessment criteria).

Table 12. ALF region, county council and university, share of ALF-funding, and number of publications selected from each region. Note that Örebro Region did not receive ALF funding before 2015.

ALF Region	County Council	University	Share of ALF funding for clinical research 2015	Number of publications
Stockholm	Stockholms county council	Karolinska institutet	27%	97
Västra Götaland	Region Västra Götaland	University of Gothenburg	21%	74
Skåne	Region Skåne	Lund University	20%	70
Uppsala	Region Uppsala	Uppsala University	12%	42
Västerbotten	Västerbotten county council	Umeå University	11%	38
Östergötland	Region Östergötland	Linköping University	8%	29
Örebro	Region Örebro	Örebro University	2%	10

The peer review of the 360 publications was performed by the panel members and the external reviewers. Each publication was assessed by three reviewers with expertise within the field of the publication.

The reviewers were instructed to assess the publications on a 7-grade scale ranging from poor to outstanding[28], and to provide explanatory comments, on two assessment criteria (instructions for reviewers).

- scientific quality (including novelty)
- clinical relevance

The assessments of the publications, compiled for each region, and the bibliometrics were distributed to the panel on 1 December 2017 (instructions to the panel). The panel also had access to the 360 submitted publications during the whole evaluation process.

Panel meeting

A panel meeting was held in Stockholm on 24–26 January 2018. During this meeting, the assessment results were discussed, the categorisation of the ALF regions was done and a draft of the panel report was written. The panel members are jointly responsible for the final assessment and the panel report. The discussions and the writing process were led by the chair and guided by representatives of the Swedish Research Council.

The panel report provides explanations for the categorisations and points out the ALF regions that excel, and from which other regions can learn. The report also emphasises good examples of particular aspects of all ALF region, regardless of the overall assessment of that region. In addition, identified areas of development as well as recommendations for improvements are provided for all regions.

Project organisation

The project team at the Swedish Research Council consisted of Karin Tegerstedt (project manager), Sten Söderberg (assistant project manager), Malin Eklund (assistant project manager), Andreas Augustsson, Peter Lundin, Gustav Petersson, Carole Desmoulins and Emma Bergström.

[28] The 7-grade scale is the same as is normally used for the assessment of applications by the Swedish Research Council

The panel's overall reflections and general comments

Introduction and Background

Thirty-one reviewers and eighteen panel members were appointed by the Swedish Research Council to evaluate the research papers submitted by the seven regions in Sweden that benefit from ALF funding and where the basic education of medical doctors takes place. Our goal was to assess the scientific quality of clinical research in these regions. The full details of the assessments can be found in the section "Assessments of the individual ALF-regions".

The panel members came from eleven different countries and represented a range of health care and medical specialists. All of the reviewers were high profile scientists with many years' experience in their fields. All were skilled in assessing the quality of scientific work, either through grant review or through appraising research quality for regional, national and/or international research organisations. There was a 50-50 split in the male–female make-up of the panel and there was a good balance of expertise across quantitative and qualitative research methodologies.

This was the first time that peer review and bibliometrics were used to determine the allocation of a percentage of the ALF funding. All reviewers and panel members have ensured that they have no conflict of interest when participating in the evaluation. The overall goal of our panel was to contribute to an enhancement in the quality of clinical research in Sweden.

The Process

During the Stockholm meeting, the assessment results were discussed and the categorisation of the ALF regions was agreed and confirmed. The panel report was drafted in sub-groups and agreed to by all panel members.

The reviewers and panel members did not have access to any other information pertaining to the regions' research environments such as infrastructure, staffing, research strategies, author contributions, PhD completions, researchers' esteem indicators, non-ALF research funding sources or how the 1% of publications was selected by each region.

The regions where asked to select their best 1% of publications with respect to Scientific Quality and Clinical Relevance over the period 2012 to 2015. This represented 360 publications and the reviewers and panel members assessed these papers. The panel was aware that there may have been other high quality papers in each region that were not submitted as part of this exercise.

The reviewers and panel members assessed the quality of the papers on a scale ranging from poor to outstanding; the reviewers also provided explanatory comments. In the peer review of scientific quality, there were examples of good to outstanding publications. In peer reviewing the clinical relevance across all the regions, it was noted that some papers were better than others, and again a mixture of good to outstanding quality was noted. In essence, the panel was impressed with the overall quality of the submitted work and identified some excellent examples of research with impact that has already shaped science and/or clinical practice.

We were particularly interested in the originality/novelty, significance and the rigour of the papers. Three different reviewers assessed each of the 360 publications for scientific quality and clinical relevance. In addition, the panel received and assessed a bibliometric analysis for each region, which took into account volume-dependent and volume-independent indicators, including citations. The bibliometric material also included a range of national and international comparators and publication collaborations. This latter information was not assessed as such but was used by the panel as contextual background.

One exception in the assessment process is the Örebro region, which, unlike the other six regions, only received ALF funding from 2015. The panel took account of this and ensured that it was not disadvantaged in the review process.

The Results

In most instances, there was very good agreement in the assessment of publications across the three reviewers. The section of each region's panel report provides explanations for the categorisations and points out where each ALF-region excels, and bodies of work from which other regions can learn. Specifically, the report emphasises good examples of research quality from all seven ALF-regions, regardless of their overall categorisation. In addition, areas of development as well as suggestions for improvements are provided.

The results show that none of the seven regions were judged to be in the 'Inferior Quality' category. The panel maintains that this reflects the quality of publications that were submitted in this ALF exercise and signifies the strength that exists in Swedish research. Two regions, Stockholm and Västra Götaland were judged by panel members to be in the 'Very High Quality' category. The other five regions were assessed as being in the 'Good to High Quality' category. While they shared the same category, these five regions varied in the quality of their profiles with Skåne and Uppsala in the top end of this category.

Table 13. Overall assessments for the ALF regions

ALF region	Inferior quality	Good-high quality	Very high quality
Stockholm			X
Västra Götaland			X
Skåne		X	
Uppsala		X	
Västerbotten		X	
Östergötland		X	
Örebro		X	

Exemplars of good practice

While representing only a small sample of all the papers that were reviewed, the following exemplars are worthy of comment and hold important lessons for clinical research in other regions specifically and in Sweden generally.

Stockholm

In the Stockholm region, outstanding research was found in the fields of cardiology, clinical neurology, nephrology and urology. There was a strong focus on translational studies and these often demonstrated strong links between basic biology and applied science, leading to great potential for clinical impact. In particular, the panel noted good instances of clinical relevance in oncology, psychiatry, cardiology, and rheumatology.

The panel also noted the efficient and effective use of large databases and health registries, a specific strength in this region and one that other regions could benefit from replicating and collaborating.

The Stockholm region had the highest proportion of collaborations with international centres of excellence among the regions submitted in this exercise. The panel considers this a key strength of the Stockholm region and one that other regions would do well to reproduce.

Västra Götaland

This region submitted papers on a broad range of topics showing very high quality in observational and cohort studies with notable basic science and randomised controlled trials. A substantial number of the outstanding papers were related to some aspect of diabetes, obesity, bariatric surgery and microbiota. There was a very strong emphasis on interdisciplinary partnerships involving several different subject areas. This is a specific strength of the Västra Götaland region. It would be beneficial for other regions to do similar work, as the panel believes that it is only through international interdisciplinary research that major global problems will be adequately addressed.

The panel also noted a very good trend in the production of outstanding publications in gastroenterology, neurology, oncology, surgery, and obstetrics and gynecology. The panel was impressed by the novelty of some studies and their potential for future development.

Skåne

The panel observed that certain specialities such as clinical neurology and internal medicine were well above international norms. Researchers in Skåne used highly regarded national population-based registries in rheumatology, psychiatry, haematological malignancy and hepatocellular cancer. Important scientific and clinical research in paediatric cancer has demonstrated a link between intra-tumoral genome diversity and risk of metastatic spread and ultimately prognosis. Notable research was also noted in molecular profiling in melanoma and CSF biomarker analysis in Parkinson's disease.

From the bibliometric analysis, the region has several areas that contribute to excellent scientific quality; these include neurosciences, paediatrics, obstetrics and gynaecology. They are amongst the leaders in Sweden in building up excellent international research collaborations and this is reflected in many of the papers that were submitted for assessment.

Uppsala

The panel was impressed by the scientific research ongoing in the Uppsala region. The publications submitted reflected rigorous and systematic studies within the field of oncology, cardiovascular diseases, proteomics and pediatrics. Novelty was also noted in many studies. Clinically, these hold great potential for enhancing practice. As with the scientific quality, the panel noted that clinical relevance was excellent in pediatrics, cancer and cardiovascular disease.

Västerbotten

The panel commended this region for its excellent research in the fields of public, environmental and occupational health. Its focus on disease prevention and health promotion is crucially important for population health and the Västerbotten region could take the lead in widening this expertise across the other regions. While highly rated research was noted in clinical neurology, Västerbotten could benefit from greater collaboration with researchers in other regions and with increasing research partnerships with neuroscientists.

Östergötland

In this region, the panel noted high quality basic science research, cohort studies and several strong health economic analyses performed by the department in Linköping. The emphasis on health economic analysis of cost-effectiveness was commendable and could be shared with other regions. The panel also commented on the broad range of clinical topics covered in the papers, including innovative approaches to research and exploration of interesting and unique "niche" areas of clinical research. For example, a study examining an intervention to prevent anterior cruciate ligament injury in female footballers would be of value in other groups of sportsmen and women. Given the potential for generalisability nationally and internationally, this could be an area for collaboration with other regions.

Örebro

The Örebro region is the smallest in terms of the number of publications submitted and this reflects their current share of the ALF funding. Nonetheless, the panel noted that they used patient cohorts and databases very expertly and resourcefully. There was excellent work undertaken in cardiovascular and surgical research, which has great potential for being further developed and supported.

Conclusions

The panel noted that there were research strengths across all seven regions in specific clinical areas, but occasionally it appeared that they were working in isolation or in competition with each other. Examples include oncological, diabetic and cardiovascular research. If these regions collaborated on

these topics, they could enhance their world leading research expertise and further raise Sweden's clinical research profile globally.

In summary, the panel identified outstanding research in the publications from each of the seven regions. We believe that a greater focus on their existing strengths and better national and international collaboration could lead to Sweden's clinical research being among the most outstanding worldwide.

Assessments of the individual ALF regions

ALF region Stockholm

Overall assessment

Very high quality

The Stockholm region received 27% of ALF funding and this was reflected in the number of publications (97) submitted for assessment. The assessment of the scientific output and clinical relevance was based on peer review of these papers where three people from among the thirty-one reviewers and eighteen panel members assessed each publication.

In general, the outcome of the peer review process showed that the scientific quality and clinical relevance of the submitted publications ranged from very good to outstanding on the seven-grade scale used. The peer review of the submitted publications showed excellent quality in terms of rigor, significance and originality/novelty. In addition, the panel considers that this region performs exceptionally well in terms of its bibliometric profile and the region performs better than expected in relation to the level of ALF funding. This illustrates excellent to exceptional strengths across the assessed research publications and ensured that the Stockholm region was placed in the category "Very high quality".

Scientific quality (including novelty) based on peer review of the submitted publications

Based on the reviews of the submitted publications, there are particular strengths that are worthy of comment. Examples include, excellence in medicine (including experimental), cardiology, clinical neurology, nephrology and urology.

The submitted publications were on a range of topics and the researchers employed a variety of robust methodologies. Individual reviewers assessed the publications highly for scientific quality, with most of the papers being judged to be very good to outstanding. In particular, the panel commended those publications that demonstrated high originality/novelty, rigour and significance. While incomplete, the following represents a small sample of papers showing strengths that merit specific mention:

- The role of stem cells in the propagation of cancer was investigated and this work has the potential to influence the entire field, internationally.
- A study that exemplifies the high status of research in the Stockholm region is in relation to self-harm in schoolchildren. Two of the papers from the Stockholm group related to this cluster-randomised trial involving over 11,000 schoolchildren across ten European countries. This illustrates the addressing of a major public health problem that is increasing in frequency, excellent international collaboration coordinated from a Swedish centre, high-class methodology and analysis of data, as well as important results that have high clinical relevance.
- In a related field, an additional problem of great clinical importance is the need for medication for attention deficit disorder in adult life. Whilst there is good evidence for the effectiveness of medication in young people, there has been concern over the benefits of continued treatment. There is evidence that criminality was reduced when medication was being taken for this condition in adult life (and increased when medication was not taken). This represents good use of the Swedish case register for a problem that is very difficult to address in other ways.
- In the cardiology field, there is an example of the use of large-scale registry programmes between

countries. There was a publication in a highly regarded international journal comparing the outcomes after myocardial infarction in Sweden and the UK and demonstrating differences. This has the potential to improve practice in the comparator country.

Overall, the Stockholm region's submission included outstanding publications. There was a strong focus on translational studies and these often demonstrated good links between basic biology and applied science.

While the overall scientific quality of the papers is very high in terms of methodology and innovation, a proportion of the evaluated papers related to clinical trials had less novelty, but with potential for clinical relevance.

Clinical relevance based on peer review of the submitted publications

Studies from a broad range of topics were included in the submission from the Stockholm region, with a large proportion judged to have high clinical relevance. Most were assessed as having clinical impact now or in the future. We noted especially, good examples in oncology, psychiatry, cardiology, and rheumatology. More than 50% of submitted publications were judged as very good or outstanding in terms of clinical relevance using the seven-grade scale used during the peer review of the individual publications. This is clearly a great strength in the Stockholm region. Large databases and health registries were used effectively and productively.

Bibliometrics – an assessment of the quality and extent of the total scientific output within the WoS Health Sciences

The Stockholm region is the largest region in terms of volume with over 6.800 publications (fractional counting) during the evaluation period. The region's share of ALF funding is 27%, but its share of publications is 33% and its share of the field normalised citations is 36%. In addition, the Stockholm region represents 39% of the top 10% publications and 39% of the top 1% publications. Therefore, the Stockholm region is over-performing in relation to ALF funding, in terms of both publications and citations.

Regarding volume independent indicators, the Stockholm region also scored highly. The average field normalised citation rate of 1.22 is well above the world average and above other ALF regions. The Stockholm region is also the best among all the regions submitted in this exercise regarding the share of top 10% publications (13.3%). A similar trend can be seen with regard to their share of the top 1% of cited publications. Their share is 1.2% compared to 1.0% across all the ALF regions. However, for one other region this was 1.5% and so the Stockholm region lies second for this metric.

The analysis shows an impressive strength and depth across a range of subject areas. In 16 out of 20 subject areas, the share of the top 10% of publications exceeded the world average (0.10). In the following subject areas, the share was substantially higher than the world average with medicine general and internal medicine scoring highest (0.30). The following subject areas exceeded a threshold of 0.15 (world average 0.10): medicine general and internal, clinical neurology, cardiac and cardiovascular systems, surgery, rheumatology, urology and nephrology, hematology, medicine research and experimental biochemistry & molecular biology, pharmacology and pharmacy, peripheral vascular disease, and psychiatry.

Overall, the bibliometric profile of the Stockholm region ranges from very strong to exceptionally strong. Based on their allocation of ALF funding, the region performs beyond that anticipated. The performance was equal with or above most of the Nordic comparisons, but not above those of certain high profile international comparators.

Reflections on collaboration

The bibliometric data also provide information on collaborations between the Stockholm region and other regions and countries. The panel did not score this, but used the information as contextual background.

Stockholm had the highest proportion of international collaborations among the seven regions. A substantial proportion of the submitted papers included national and international collaborators. The panel considers this to be a key strength of the Stockholm region.

The following is just one example of many concerning the Stockholm region's collaborations with centers in Sweden and internationally. It is a study examining the outcomes of pregnancy after bariatric surgery. This study led by a group from the Stockholm region, and other studies in the cardiovascular field, have influenced practice internationally and could not have been undertaken without collaboration between excellent researchers in different centres in Sweden.

ALF region Västra Götaland

Overall assessment

Very high quality

The region received 21% of ALF funding and this was reflected in the number of publications (74) submitted for assessment. The assessment of the scientific output and clinical relevance was based on peer review of these papers. Three people from among the thirty-one reviewers and eighteen panel members assessed each publication.

The review of the publications and bibliometrics from the Västra Götaland region shows evidence of very high quality research. This is particularly strong across the areas of diabetes, obesity and its surgical treatment, and the role of the microbiota. However, there is also evidence of very strong performance across many other disciplines. A substantial number of studies are particularly impressive for the following reasons: they address an important problem with a very well sized population and good length of follow-up; they have addressed a therapeutic question with a well-designed large study with collaboration across many sites; or they identify novel and important biological mechanisms. These aspects are to be commended and could be enhanced still further by even greater collaboration, including increasing international research partnerships. The panel also thought that greater collaborative use of biobanks and registries would be helpful. Some studies had methodological weaknesses such as lack of control population or non-randomised interventions.

The expert panel members rated this region highly in all three categories of scientific quality, clinical relevance and bibliometrics. Outputs were frequently internationally competitive and there was evidence of high quality research across a good range of scientific topics. The peer review of the submitted publications resulted in very high assessments for their rigour, significance and originality/novelty. Based on volume-independent indicators of citation impact, the region is top among all the submitted regions for the share of top 1% publications and around the second highest for the share of top 10% publications. On all these criteria it was agreed that the Västra Götaland region should be placed in the category "Very High Quality". However, there is the potential to perform even better in a future ALF exercise by taking into account the following: some prospective randomised or open cohort studies were from single centres, making results less reliable due to a small number of participants or incomplete data.

Scientific quality (including novelty) based on peer review of the submitted publications

The reviewed publications were judged to be very good. None was less than good and many were excellent on the seven-grade scale used during the peer review of the individual publications. In addition, the scientific community has noted many of the publications quite quickly. They include several register-based trials with new or confirmatory results. A very broad scope of specialties scored highly with several very good papers from each. Many publications reflected the use of a range of very good observational and cohort studies plus good basic ~~scienc~~e and randomised controlled trials. Other papers were assessed as groundbreaking and of international importance. A substantial number of these related to some aspect of diabetes, obesity, bariatric surgery and microbiota and there was evidence of very strong interdisciplinary interactions involving several research groups. There was also a good

spread of outstanding publications across other areas including gastroenterology, neurology, oncology, obstetrics and gynecology, and surgery.

The panel particularly commended those publications that demonstrated high originality/novelty, rigour and significance. While incomplete, the following represents a small sample of papers showing strengths that necessitate specific comment:

- A study in over 3000 obese patients and controls showing that bariatric surgery reduces markedly the subsequent development of type 2 diabetes over 15 years – an impressively large and important study with exceptionally long-term follow-up.
- A study based on patients in the Swedish National Diabetes Register followed up for 8 years showing striking and dose-related impacts of diabetes control on all-cause mortality.
- A controlled trial conducted in over 1000 patients across 30 hospitals showing that laparoscopic surgery for rectal cancer was similarly effective to open surgery in respect of tumour clearance and overall survival.
- A large study showing that the faecal microbial genetic expression profile is highly specific for type 2 diabetes and different from country to country.
- A study reporting tumour mutations in a key DNA regulator gene from over 500 tumour genomes across 14 cancer types – with implications for better understanding of cancer biology.
- A study showing that components of the gut bacteria regulate bile acid metabolism – a novel physiological mechanism.

Clinical relevance based on peer review of the submitted publications

The publications submitted by the Västra Götaland region were assessed as having high clinical relevance, placing this region among the highest of the seven regions. There were particularly strong clinical implications for studies across a range of fields including obesity/bariatric surgery, diabetes, treatment of urinary infection, microbiology, neurology, psychiatry, laparoscopic surgery, and uterine transplantation. There were also useful insights into new genetic disease mechanisms and metabolic mechanisms of disease across different areas.

Bibliometrics – an assessment of the quality and extent of the total scientific output within the WoS Health Sciences

The Västra Götaland region has produced over 3,300 publications (fractional counting) during the evaluation period. The region represents 17% of all citations and 16% of all top 10% publications. Compared to its share of ALF-funding of 20%, the region has slightly underperformed. However, with regard to the number of highly cited publications, where Västra Götaland represents 23% of all top 1% publications, the region performs beyond expectation.

The bibliometric profile is very strong. The analysis shows a strength and depth across a range of subject areas. The average field normalised citation rate of 1.19 is well above the world average and above the average of all seven ALF-regions. High proportions of publications in the top 10% came from a broad range of subject areas including dentistry (oral surgery and oral medicine), endocrinology and metabolism, clinical neurology, surgery, gastroenterology and hepatology, orthopaedics, general & internal medicine, and obstetrics and gynecology.

Reflections on collaborations

The bibliometric data also provided information on collaborations between the Västra Götaland region and other regions and countries. The panel did not score this, but used the information as contextual background.

Many of the submitted publications included examples of very good national and international collaborations. Specifically, it had a very high proportion of international collaborations. The panel considers this to be a strength of the Västra Götaland region and one which should be enhanced, especially pursuing targeted collaborations with international centres of excellence.

ALF region Skåne

Overall assessment

Good-high quality

The region received 20% of ALF funding and this was reflected in the number of publications (70) submitted for assessment. The panel identified the Skåne region at the top end of the category "Good-high quality", but it did not reach the highest category of "Very high quality". This categorisation is based on peer review of the scientific quality and clinical relevance of the submitted publications and on the assessment of all publications within the health sciences using bibliometric analysis. Three reviewers assessed each of the submitted papers.

In general, the scientific quality and clinical relevance of the research papers submitted from the Skåne region were considered as being above the average of the other ALF regions. Compared with international norms, it produced a broad spectrum of clinical research with oncology, public health, endocrinology and cardiology around world average level. Certain specialities such as clinical neurology and internal medicine are well above international norms. A research group working with diabetes produced outstanding work on the regulation of insulin secretion in type 2 diabetes and mapping genes associated with islet dysfunction in the pancreas. Several groups used high quality national population-based registries in rheumatology, e.g. psoriasis and systemic sclerosis, psychiatry e.g. bipolar disorder and schizophrenia and in haematological malignancy and hepatocellular cancer. Several of the highly assessed papers report outcomes of well-executed randomised trials addressing clinically important issues.

International collaborations led to high quality research and where scientists in the Skåne region collaborated with other regions within Sweden, such as in cardiology or medicine, the scientific output was of a very high quality. The Skåne region is the second largest region in terms of volume with over 3,700 publications (fractional counting) during the evaluation period. Overall, the bibliometric profile of Skåne was very good.

In general, the panel found that, compared with other regions, the clinical relevance was lower. The panel suggests that improvements can be made, particularly in its high volume areas, such as oncology, public health and endocrinology. One approach would be to undertake more collaboration with regions of similar expertise within Sweden; this should improve the quality and benefit all regions.

Scientific quality (including novelty) based on peer review of the submitted publications:

Overall, the panel assessed the scientific quality of submitted papers to be above the average of the seven ALF regions and some of the papers were at the level of the highest assessed regions. While it did not reach the "Very high quality" category, the panel considered the Skåne region to be at the top end of the "Good-high quality" category.

The Skåne region is amongst the leaders in Sweden in building up excellent international research collaborations and this is reflected in many of the papers that were submitted for assessment. Oncology research represented the largest contribution of the scientific publications. In the peer review of the submitted individual publications, 40% were assessed as being very good to excellent on the seven-grade scale used, particularly in the fields of cardiology, haematology, and paediatrics.

They also show strength across a wide range of areas, especially molecular biology, cardiology and diabetology. Other papers were of mixed quality with some good to excellent work being noted in epidemiological studies, basic research, and prognostic markers in malignancies.

Clinical relevance based on peer review of the submitted publications:

The panel judged clinical relevance as being towards the lower end of the comparative ALF regions, but noted very good or excellent clinically relevant studies in cardiology, haematology, and paediatrics. For example, the Skåne group performed an important randomised controlled study in the very clini-

cally difficult setting of unconscious survivors of out of hospital cardiac arrest, showing that cooling the patient to 33 degrees did not confer any benefit compared with 36 degrees.

In cancer, the Skåne region is particularly well regarded in the field of melanoma molecular profiling. The region has also produced excellent work on national psychiatric cohort studies in bipolar disorders and schizophrenia. Furthermore, there are examples of high scientific and clinical excellence in diabetes, which is of a world-class standard. These highlight ground-breaking scientific research and randomised clinical trials with clear clinical endpoints.

The panel rated highly the international collaboration study led by Lund authors in researching muscle metabolism in diabetes and cardiac arrest. The cardiac work should specifically have very good impact through clinical management guidelines.

However, many of their other areas of research were without a clear strong clinical focus and this may have implications for clinical relevance. For instance, there are relatively few randomised controlled studies among the submitted papers. In Sweden, there are magnificent registry databases that have international relevance in addressing questions of global relevance in elderly and co-morbid populations. The panel believes that the Skåne region could benefit from more collaboration with the other regions, such as in partnering in randomised controlled trials.

There are some areas within cancer research, neurosciences and cardiovascular research where the basic science does not seem to have immediate translational or clinical implications. Closer clinical collaboration may improve quality and relevance.

Bibliometrics – an assessment of the quality and extent of the total scientific output within the WoS Health Sciences

The Skåne region is the second largest region in terms of volume with over 3,700 publications (fractional counting) during the evaluation period. Skåne represents 18% of all publications and 17% of all citations and top 10% publications; however, its share of ALF-funding is 20%.

In terms of volume independent indicators, Skåne performs well above the world average and around the average of the seven ALF regions, although the share of highly cited papers is lower than expected (Share of top 1% is 0.7%). In the bibliometric overview of subject areas, most areas score around or above the world average (0.1). In the following areas, the share of top 10% publications exceeded the threshold of 0.15: clinical neurology, medicine, general and internal, neurosciences, pediatrics and obstetrics and gynecology.

Overall, Skåne has a very good bibliometric profile regarding average citation impact. As for the number of publications and the number of highly cited publications in relation to ALF-funding, the region is slightly underperforming.

Reflections on collaboration

The bibliometric data also provide information on collaborations between the Skåne region and other regions and countries. The panel did not score this, but used the information as contextual background.

The Skåne region had a high number of collaborations with international centres in several areas of basic science and clinical sciences. This included randomised studies in diabetes that had highly significant relevance. While the bibliometric data support this relatively high frequency of international collaborations (57%, share of whole counts), there was a relatively low frequency of collaborations with other regions within Sweden.

The Skåne region has a high scientific production in terms of number of publications in the Web of Science subjects; oncology, public, environmental and occupational health, endocrinology and metabolism and cardiac and cardiovascular systems. Nonetheless, they should consider methods to improve further the quality of research in these areas, which may include an increase in national and international collaborations.

ALF region Uppsala

Overall assessment

Good-high quality

The assessment of the scientific output and clinical relevance was based on peer review of the submitted publications from the Uppsala region. Three people from among the thirty-one reviewers and eighteen panel members assessed each publication.

The submitted papers from Uppsala are mainly within clinical science (e.g. cardiovascular diseases, oncology and pediatrics), with fewer within the translational/basic sciences (e.g. proteomics, biomarkers).

Overall, the Uppsala region is placed within the top end of the category "Good-high quality". The panel considers that this region performs well in terms of scientific quality, clinical relevance and bibliometrics. In general, the panel found the scientific quality and clinical relevance of the publications to range from good to excellent on the seven-grade scale used during the peer review of the individual publications. Therefore, overall the Uppsala region was approaching the best ALF regions. Moreover, its performance seems to reflect well its allocated share of the ALF-funding (12%) with the share of publications (13%) and the share of normalised citations (12%).

The panel noted that there is greater potential and scope for international collaborations and that some of the submitted papers appear to have minor clinical relevance.

Scientific quality (including novelty) based on peer review of the submitted publications

Overall, the panel assessed the scientific quality of submitted papers to be above the average of the seven ALF regions and some of the papers were at the level of the highest assessed regions. Although the amount of groundbreaking science is not particularly high, the researchers in the Uppsala region should be commended for executing several well designed randomised controlled trials to examine in a solid way clinically important questions.

The Uppsala region's contribution also includes a number of studies originating from registries, all performed at a very high scientific standard. In particular, researchers within the field of oncology, cardiovascular diseases, proteomics and pediatrics have published important contributions in their respective fields.

The panel particularly commended those publications that demonstrated high originality/novelty, rigour and significance. While incomplete, the following represents a small sample of papers showing strengths that are worthy of note:

- The well-conducted paediatric papers studying nutrition and neurodevelopment in large samples.
- The mapping of the human proteome in tissues.
- The clinical cancer studies including the biomarker discoveries in cancer patients.
- The important clinical studies in patients with various cardiovascular diseases.

Clinical relevance based on peer review of the submitted publications

The panel found the vast majority of the submitted papers to range from very good to excellent with regard to clinical relevance. In general, many of the clinical papers were considered by the panel to either have or will have an important clinical impact. In particular, this seems to be the case in publications relating to pediatrics, cancer and cardiovascular disease. However, the panel noted that there were other studies that were best designated as descriptive in nature and thus with limited clinical implications.

Bibliometrics – an assessment of the quality and extent of the total scientific output within the WoS Health Sciences

Uppsala has produced over 2,600 publications (fractional counting) during the evaluation period. Most bibliometric measures match the proportion of ALF-funding (12%). In other words, the Uppsala region has performed as could be expected from the funding provided through ALF.

In terms of volume independent indicators, Uppsala performs well above the world average and around the average of the seven ALF regions. In the bibliometric overview of subject areas, most areas score around or above the world average (0.1). In the following areas the share of the top 1% publications exceeded the threshold of 0.15: these included general- and internal medicine; cardiac- and cardiovascular systems; radiology, nuclear medicine and medical imaging; and nursing.

Overall, Uppsala has a very good bibliometric profile regarding citation impact. It is performing as can be anticipated from the amount of ALF-funding provided, placing the region just below the best performing ALF regions.

Reflections on collaborations

The bibliometric data also provide information on collaborations between the Uppsala region and other regions and countries. The panel did not score this, but used the information as contextual background.

Based on the submitted papers, the panel noted that a substantial fraction of the research collaborations involved Nordic partners, but with a limited contribution from other high rank and high profile international research institutions. While it is laudable that regional collaborations are so strong, the panel believes that partnering with international centres of excellence would yield future benefits.

ALF region Västerbotten

Overall assessment

Good-high quality

The region received 11% of ALF funding and this was reflected in the number of publications (38) submitted for assessment. The assessment of the scientific output and clinical relevance was based on peer review of these papers. Three people from among the thirty-one reviewers and eighteen panel members assessed each publication.

The Västerbotten region has been placed into the "Good-high quality" category. In the peer review of the submitted individual publications, 30% were assessed as being very good to excellent regarding scientific quality on the seven-grade scale used during the peer review of the individual publications. However, the clinical relevance of the submitted publications was less highly assessed and its improvement should be a priority for the future.

The Västerbotten region contributes well to the quality of clinical research of Sweden. The overall bibliometric profile is good but it is heterogeneous with a low share of highly cited publications (top 1%). The panel encourages the Västerbotten region to enhance its international collaboration, and to broaden and deepen the clinical relevance of their publications.

Scientific quality (including novelty) based on peer review of the submitted publications

Among the 38 publications, around 30% were assessed as being very good to excellent. The panel particularly commended those publications that demonstrated high originality/novelty, rigour and significance. While incomplete, the following represents a small sample of papers showing strengths that merit specific comment:

- The panel members were impressed by the outstanding findings in the genome editing field. Indeed, a new tool based on a bacterial CRISPR-associated protein-9 nuclease (Cas9) from Streptococcus pyogenes has opened worldwide avenues. This novelty already revolutionises the field of animal model generation and therapeutic insights.
- By performing a controlled trial to assess safety and effective delivery, researchers established one of the first RNAi therapy targeting a disease-causing gene (i.e. transthyretin in amyloidosis).

The panel members also found work in clinical neurology that was assessed as being very impressive; the panel members think that this research would benefit from increasing collaboration, especially in the neuroscience field.

Clinical relevance based on peer review of the submitted publications

Only a small number of submitted publications was assessed as being at the top end with very good to excellent scores with regard to clinical relevance. Many of these papers were linked to the public health domain and had been assessed highly with regard to their scientific quality.

The panel members were surprised that oncology and cardiology had not benefitted more from collaboration with the active public health department. The Västerbotten region could consider increasing its research using patient registries, especially in collaborations between the university and the clinical settings in Umeå.

Bibliometrics – an assessment of the quality and extent of the total scientific output within the WoS Health Sciences

Västerbotten has produced over 1,600 publications (fractional counting) during the evaluation period. The overall volume of publications and the number of field normalised citations is low in relation to its share of ALF-funding: the share of ALF-funding is 11%, whereas the share of publications is 8% and the share of normalised citations is 7%.

In terms of volume independent indicators, the region performs around the world average; however, the share of top 1% publications is lower than expected. The bibliometric overview of subject areas indicating strengths in several, where the share of the top 10% publications is above the world average.

Overall, the citation profile of Västerbotten is good and comparable to the average of all regions, but with a lower proportion of highly cited publications.

Reflections on collaborations

The bibliometric data also provide information on collaborations between the Västerbotten region and other regions and countries. The panel did not score this, but used the information as contextual background.

The national and international collaborations are good. However, these are mainly European and the region would benefit from having more collaborations with non-EU international centres of excellence. The panel believes that this would enhance the Västerbotten region's performance in future ALF assessments.

ALF region Östergötland

Overall assessment

Good-high quality

The region received 8% of ALF funding and this was reflected in the number of publications (29) submitted for assessment. The assessment of the scientific output and clinical relevance were based on peer review of these papers. Three people from among the thirty-one reviewers and eighteen panel members assessed each publication.

The panel has placed the Östergötland region in the category of "Good-high quality". This categorisation is based on peer review of the scientific quality and the clinical relevance and an assessment of all publications within health sciences using the bibliometric profile for the region. The panel's judgement is that it performs at a level that is comparable to many of the other regions in Sweden with the quality of clinical science being very good. The scientific outputs and the clinical relevance were judged to be very good with some weaknesses. Several papers used innovative approaches and/or studied interesting niche topics with important findings. In terms of bibliometrics, the Östergötland region performs just above world averages, illustrating the overall strength of the region.

The region produces very good scientific publications on a broad range of research topics. This variety can be seen as positive and indicates versatility in research capacity. However, it can also be seen as a potential weakness in that it lacks focus in particular areas of expertise. It may be appropriate for the Östergötland region to consider adopting a clearer and more concentrated research strategy. The

panel suggests that the Östergötland region consider prioritising clinical research in areas where they have existing strengths and with further potential.

Scientific quality (including novelty) based on peer review of the submitted publications

With respect to the assessment of the submitted publications, there was consensus among panel members that the Östergötland region had mixed performance in terms of scientific quality, including novelty. There was a range of topics and study designs reflected in the publications, with an impressive number of randomised controlled trials. There was also high quality basic science research, cohort studies and several strong health economic analyses performed by the department in Linköping.

The panel particularly commended those publications that demonstrated originality/novelty, rigor and significance. While incomplete, the following represents a small sample of papers that are worthy of comment:

- There was a good broad range of subject areas including musculoskeletal injuries, analyses of the impact of the gut microbiome on allergy, interventions for diabetes and cardiovascular disease and studies examining long-term outcomes for some common conditions such as myocardial infarction.
- There were also novel studies in genetics and an excellent study examining the potential for MRI scanning to replace post-mortem examination.

We also noted the health economic expertise in Linköping University and suggest that this could be exploited further. For example, formal health economic analysis of cost-effectiveness might have strengthened the musculoskeletal trials. The strengths at the basic science end of the spectrum includes an interesting focus on the gut microbiome and its potential impact in paediatric allergies.

Clinical relevance based on peer review of the submitted publications

The Östergötland region has generated an impressive number of quality publications illustrating high potential impact. Based on the peer review of the top publications, the clinical relevance was judged to be very good. The panel was very positive about the broad range of clinical topics covered in the papers, including innovative approaches to research and the exploration of interesting and unique areas of clinical research. For example, in the area of musculoskeletal health, there was a study examining an intervention to prevent anterior cruciate ligament injury in female footballers. This was an impressive cluster randomised controlled trial and further work examining this type of intervention, including its potential cost effectiveness, would be of value in other groups of sportsmen and sportswomen. This could be an area for international collaboration given that its finding are generalisable to other countries.

Other, strong research areas were in the fields of cardiovascular diseases and metabolic disorders. The region managed to generate excellent papers based on collaboration within large trials. It made use of that information through important secondary analyses, drawing on the local expertise in health economics.

The focus on the potential impact of the gut microbiome was also noted to be topical and of potential future clinical relevance across many domains and for all ages of patients. Some of the basic science papers reported findings that may prove to have high clinical relevance in future years. An example of this is the paper describing the presence of brown fat in human infants, which may have implications for the future treatment of obesity, a serious world-wide public health concern.

Bibliometrics – an assessment of the quality and extent of the total scientific output within the WoS Health Sciences

The region competes in a country with a good infrastructure and track record for meaningful clinical research. The overall volume of publications (above 1,600 fractional counting), number of field normalised citations and number of highly cited publications match the proportion of ALF-funding; therefore, Östergötland has performed as could be expected from the amount of ALF-funding provided.

Overall, Östergötland has a very good bibliometric profile regarding citation impact. In terms of volume independent indicators, Östergötland performs at the world average. However, it is below the

average of all ALF regions for average field normalised citation rate and its share of top 10% publications. The share of top 1% publications is in line with the average of all ALF regions.

Reflections on collaborations

The bibliometric data also provide information on collaborations between the Östergötland region and other regions and countries. The panel did not score this, but used the information as contextual background.

In terms of proportions of whole counts, 12% of its publications are within its own region, which is comparable to other Swedish regions. The panel interprets this as a sign of a good collaborative culture of clinical research in Sweden. The Östergötland region has slightly more national collaborations than other regions though a lower proportion of international collaborations. The research outputs would benefit from more targeted collaborations with global centres of excellence. Peer review of the papers also highlighted the potential for more international collaboration. Accepting this, good examples of international collaborations were noted with different institutions in the Netherlands, with one institution in Australia, and a collaboration with a Chinese university.

ALF region Örebro

Overall assessment

Good-high quality

The region received 2% of ALF funding in the year 2015. The assessment of the scientific output and clinical relevance was based on the peer review of 10 papers. Three people from among the thirty-one reviewers and eighteen panel members assessed each publication.

The ALF panel has identified the Örebro region as being in the category "Good-high quality". This judgement is based, not only on the peer review of the submitted papers, but also on the bibliometric analysis of outputs produced in the region between 2012–2015. The panel recognises that this region is in an unusual situation with regard to ALF funding, having only received one allocation during the period assessed. The panel took account of this and ensured it was not disadvantaged in the review process.

As a recently independent research entity in terms of ALF funding, the Örebro region was assessed as performing good quality research. The overall bibliometric profile of the region is very good in terms of number of publications and top cited publications. This means it is over-performing with regard to the level of ALF funding received.

The Örebro region could use its new status as an ALF region to expand on the large collaborative clinical studies, for which it has a good record of accomplishment. It would also be beneficial if the Örebro region increased its collaboration internationally.

Scientific quality (including novelty) based on peer review of the submitted publications

The scientific quality of the papers submitted from the region is overall sound. Many of the studies represent safer research questions and thus, show moderate novelty and significance. There are few basic science papers in the submitted publications. However, it is unclear if this reflected the paper selection process adopted by the region or if it was due to limited local research infrastructure for translational science. Nevertheless, it must be noted that there is a broad range of topics in the submitted papers, some of which are of very high quality.

The panel particularly commended those publications that demonstrated originality/novelty, rigour and significance. While incomplete, the following represents a sample of papers that are worthy of note:

- A study originating from the Örebro region on thrombus aspiration during ST elevation myocardial infarct, with an impressive cohort of over 7,000 patients.
- A landmark paper originating from the Örebro region on radical prostatectomy versus watchful waiting in early prostate cancer. This addressed the question of whether to operate or follow up the

patients without surgery. The study, with a long-term follow up, has changed the treatment strategy of prostate cancer globally.

Clinical relevance based on peer review of the submitted publications

Impressively, the overall evaluation of the selected papers demonstrated high clinical relevance in comparison to some of the other regions. The Örebro region is using their patient cohorts and databases effectively and resourcefully. We note that there is a strong cardiovascular and surgical research profile, which has the potential for further development and support. In particular, the research portfolio includes several highly assessed publications, showing significant impact on clinical practice worldwide.

Bibliometrics – an assessment of the quality and extent of the total scientific output within the WoS Health Sciences

The Örebro region has produced over 600 publications (fractional counting) during the evaluation period (2012–2015). It must be noted that it is a smaller region and thus, more susceptible to bibliometric variation than the larger regions. In addition, the bibliometrics are from a period when the region did not have ALF funding. Therefore, they must be treated with a degree of caution but is likely to change positively in the future. In 2015, Örebro´s share of ALF-funding was 2%, whereas the share of publications, field normalised citations and highly cited publications, over the evaluation period, was 3%.

The Örebro region has a very good bibliometric profile. The average citation rate and share of 10% publications shows performance that is above the world average, but below the average of all the ALF regions. The share of the top 1% of publications is equal to the average of all ALF regions (1%).

Reflections on collaborations

The bibliometric data also provide information on collaborations between the Örebro region and other regions and countries. The panel did not score this, but used the information as contextual background.

This region mainly collaborates within Sweden and throughout the Nordic countries with a few collaborations outside this geographical area. The region's scientific profile demonstrates a strong emphasis on multicentre and registry studies and the panel recognises the strengths of the Örebro´s use of Scandinavian health registries. The region would benefit from more targeted collaborations with international centres of excellence.

EVALUATION OF CLINICAL SIGNIFICANCE AND SOCIETAL IMPACT OF CLINICAL RESEARCH – REPORT FROM ALF PANEL 2

The evaluation, performed by an international expert panel, was based on assessments of several data sources, including self-evaluations and hearings. The starting points for the evaluation of clinical research quality were formulated by the National ALF Steering Committee. The overall goal was to increase the quality of clinical research in Sweden. The main objective of the evaluation was to provide assessments and place the ALF regions into one of three categories (inferior quality, good–high quality or very high quality).

There were two main questions for the evaluation:
- How does the ALF region work to implement research results into its clinical practice?
- What is the clinical significance and the societal impact of the research performed in the ALF region?

Four assessment criteria were applied:
- research competence
- collaboration
- implementation of research results into clinical practice
- impact beyond academia of the clinical research

The expert panel was instructed to evaluate each ALF region for the four criteria and provide an overall assessment of each ALF region. One to three of the ALF regions that excel and set a national example was to be categorised as very high quality. In addition, the panel was invited to point out good examples of certain aspects of some ALF regions, regardless of the overall category placement of that region, and provide recommendations for improvements.

The instructions to the ALF regions as well as the instructions for the panel and the schedule for the hearings can be found via the following links:
- instructions for self-evaluation
- instructions for the panel
- schedule for hearings.

The expert panel

The evaluation was performed by an international expert panel, appointed by the Swedish Research Council based on nominations from the ALF regions and from several councils and committees[29] and from the project team. Together the eight members of the panel comprised competences and experiences relating to clinical research, implementation of scientific evidence into practice, and impact evaluation as well as perspectives from government agencies, industry and patient organisations. All panel members were asked to affirm that they had no conflict of interest.

[29] Scientific Council for Medicine and Health, Committee for Clinical Studies, Committee for Clinical Therapy Research, The Office for Clinical Studies – all within the Swedish Research Council.

Table 14. The ALF panel 2 members

Name	Affiliation	Country
Lisbeth Tranebjaerg (chair)	University Hospital and University of Copenhagen	Denmark
Henning Beck Nielsen	University Hospital and University of Southern Denmark	Denmark
Elizabeth Bergsten Nordström	The Swedish Breast Cancer Association	Sweden
Anders Blanck	The Swedish Association of the Pharmaceutical Industry (LIF)	Sweden
Kåre Birger Hagen	Diakonhjemmet Hospital Oslo and University of Oslo	Norway
Charlotte Hall	Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU)	Sweden
Anne Sales	University of Michigan and VA Ann Arbor Healthcare System	USA
Ian Viney	Medical Research Council (MRC)	UK

Assessment criteria

Evaluation questions

The starting points for the panel's work were the two main questions for the evaluation:

- How does the ALF region work to implement research results into its clinical practice?
- What is the clinical significance and the societal impact of the research performed in the ALF region?

This means that each ALF region was evaluated in terms of its efforts to implement its own and others' research results in its clinical practice, as well as on its efforts to achieve clinical significance and societal impact of its own clinical research.

Assessment criteria and indicators

The evaluation focused on the following four assessment criteria further specified by indicators:

Research competence:

- high presence of research trained (PhD) professionals in clinical practice
- substantial and continuous supply of research trained (PhD) professionals to society

Collaboration:

- collaboration between medical expertise and non-academic stakeholders
- multidisciplinary collaboration
- appropriate strategy and clearly defined target groups for knowledge dissemination

Implementation of research results in clinical practice:

- appropriate practices and strategies for keeping the own clinical practice in line with the best evidence in the relevant research fields
- appropriate practices and strategies for the evaluation of efforts to keep the own clinical practice in line with the best evidence
- appropriate practices and strategies for the utilisation of findings from the evaluation above

Impact beyond academia of clinical research:

- Impact beyond academia: The reach and significance of the impact. The spread or breadth of influence, for instance how frequently research results have made an impact on relevant stakeholders, and the intensity of the influence, e.g. how important the impact has been to the stakeholders concerned.

- Underpinning research: The extent to which the research of the ALF region may be considered to have made a substantial and distinct contribution to the impact described.
- Key processes and factors: The extent to which the processes and strategies of the ALF region may be considered to have contributed to the impact in the described context. Impact can often not be attributed exclusively to specific publications. For instance, processes to facilitate impact as well as contextual factors that are external to the research environment may be essential. Also, a substantial amount of time may pass between the publication of research results and the occurrence of impact. Important processes and key factors may include, for instance, the ALF region's own implementation processes and strategies as well as contextual contributing factors.

Definition of impact beyond academia of clinical research

Impact beyond academia refers to clinical research that has provided local, regional, national and/or international benefits to one or more of the following areas: economy, society, public policy and services, health, production, environment, or quality of life. Impacts can be manifested in a wide variety of ways, including the many types of beneficiary (to individuals, organisations, communities, regions and other entities) and imply impacts on products, processes, behaviours, policies, practices, and also the avoidance of harm or the waste of resources.

In this evaluation, two different kinds of impact beyond academia were recognised: clinical significance and societal impact.

Clinical significance

Clinical significance refers to impacts on patient care and health that arise in clinical practice. Clinical significance encompasses, for instance, new local practices for treatment or diagnosis of a particular disease, health care equality, modifications of recommendations or guidelines for treatment, or modifications of guidelines for phasing out redundant methods (disinvestment). Another example of clinical significance is better decision making in the form of more adaptive leadership, more clearly defined roles and responsibilities, or new delegation policies. Time-saving innovations may also be important examples.

Societal impact

Societal impact refers to impact arising in other locations than clinical practice, for instance in other parts of the economy, society, public policy and services, production, and environment. One example would be the influence on national guidelines. In addition, improved public health through the dissemination of knowledge to patient organisations may be of importance, as well as improved communications between hospitals and the social services sector. Other examples are new viable spin-off companies, increased growth for industrial partners or regional growth. A more equal health care system is another important potential societal impact.

The evaluation process

The panel assessed each ALF region in terms of the clinical significance and societal impact of the clinical research. In addition, each ALF region was categorised into one of the three quality categories (inferior quality, good–high quality or very high quality). According to the instruction from the National ALF Steering Committee, one to three of the ALF regions should be ranked in the category very high quality, thus serving as good examples. In addition, the panel pointed out good examples of particular aspects of ALF regions, regardless of the overall category placement of that region, identified areas of development and provided recommendations for improvements.

The panel's overall assessments were based on the following sources of data:

- Self-evaluation by each ALF region including SWOT-analysis and impact case studies.

- Official statistics on staff[30]. Data from Statistics Sweden (SCB).
- Data on clinical impact by means of references to research results in e.g. clinical guidelines. Data provided by Minso Solutions AB[31] and Web of Science (Clarivate Analytics)
- Hearings, where the panel interviewed five to six representatives in management position from each ALF region.

The self-evaluation and the hearings constitute the main sources of information for the panel´s assessments.

In addition, the panel was informed by the Swedish Research Council about the amount of ALF funding, estimated population sizes and geographical extension of the ALF regions as background information.

Self-evaluation including impact case studies

A self-evaluation template developed by the Swedish Research Council was filled out by each ALF region (instructions for self-evaluation). The document with the instructions to the panel was distributed to the ALF regions at the same time as the instructions for their self-evaluation on 16 May 2017 (instructions for the panel). The deadline for submitting the filled-in self-evaluations was 15 September 2017. The self-evaluation consisted of the following sections:

A. Background data

Data on the number of clinical studies[32], approved by the regional ethical review board and hosted by the ALF region was presented as background information. This data was not assessed per se, but contributed to set the context.

B. Research competence

Description of processes and strategies to secure a high presence of research-trained (PhD) professionals in clinical practice in the long term. Possibility to comment on the official statistics on the staff.

C. Collaboration

Description and explanation of the ALF region's most important collaborations involving non-academic partners and scientific multidisciplinary collaborations to secure clinical significance of their clinical research. Description of activities and target groups for dissemination of research findings to concerned stakeholders outside their own organisation and examples of knowledge dissemination and the benefits of it.

D. Implementation of research results in the clinical practice of the ALF region

Strategies, practices and examples of recent time (last four years) of implementation of research results in the clinical practice in the ALF region. The relevant research results may have been produced either within or outside the ALF region in question. This part of the self-evaluation was divided into five sections:

- A description of practices for keeping the clinical practice in line with the best evidence in the relevant research fields.
- A description of how it is ensured that these practices are implemented, appropriate and updated.
- A description of whether these practices are evaluated and how it is ensured that the evaluation findings are utilised.

[30] With an ID profession exam that is an exam needed for registered professional qualification in the area of medicine and health

[31] http://ci.minso.se/en/

[32] Clinical studies refers to a research study using human subjects to evaluate biomedical or health-related outcomes, intended to add to medical knowledge. In this context, only clinical studies which have passed ethical vetting (Etikprövningsnämnd, EPN) are referred to.

- Description of one to three examples of successful processes of implementation of clinical research results (own or others) into clinical practice in the ALF region, including references to relevant documents and/or names of the stakeholders concerned for verification.
- A SWOT-analysis (strengths, weaknesses, opportunities and threats) for implementation of research results in clinical practice.

E. Impact beyond academia – impact case studies

Description of one to three cases where clinical research performed in the own ALF region has contributed to beneficial impact in clinical practice and/or in other parts of society. The impact case studies include three sections:

- First, a description of the case – including the type of clinical significance or wider societal impact that has occurred, who or what has benefitted, been influenced or acted upon and references to confirm the impact. The claimed impact of the research should have been recent, during the last four years.
- Second, a description of the underpinning research with references to one to ten publications from the ALF region in question that provide evidence of the substantial and distinct contribution this research has made to the impact case. A brief description of the key content of these publications and explanation of why this content was essential to the impact. The underpinning research publications should have been published in 1997 or later. Instructions on how to handle author contribution in publications made in collaboration are included in the self-evaluation template.
- Third, a description of the key processes and key factors that are considered to have contributed substantially to facilitate the impact beyond academia of the clinical research.

Statistics on dissertations and employments

Data on each ALF region's staff from Statistics Sweden (SCB), ordered by the Swedish Research Council, was provided to the individual ALF regions on 23 August 2017 with an option to comment upon it in the self-evaluations. The statistics for all ALF regions was compiled in a memorandum[33] for the panel. This memorandum was also provided to the ALF regions on 27 October 2017. The statistics presented included information on:

- Number of dissertations, where the person has an ID profession exam has an exam needed for registered professional qualification in the area of medicine and health, at the universities associated with each ALF region (average for year 2014–2016).
- The percentage of employees in the county councils in each ALF region holding a PhD (average for year 2014–2015).
- The percentage of employees at each university hospital holding a PhD (average for year 2014–2015).
- Numbers of staff with dual employment, receiving salary from both a county council and a higher education institution (average for year 2014–2015).

The gender distribution was reported throughout.

Clinical impact using a bibliometric approach

Results from a study on clinical impact through bibliometric studies of scientific literature cited in clinical guidelines and alike was an additional data source for the panel, and also provided as information to the ALF regions in a memorandum on 27 October 2017[34]. The Swedish Research Council provided this data by using Minso Solutions AB[35] and Web of Science (Clarivate Analytics).

33 Data on human resources from Statistics Sweden (SCB) – to be used by ALF expert panel 2 in the evaluation of clinical significance and societal impact of clinical research in Sweden. Swedish Research Council 2017-10-04. Dnr 3.2-2016-7078.

34 Clinical impact – references to scientific publications in clinical guidelines – to be used by ALF expert panel 2 in the evaluation of clinical significance and societal impact of clinical research in Sweden. Swedish Research Council 2017-10-27. Dnr 3.2-2016-7078.

35 http://ci.minso.se/en/

Hearings

The data provided in the self-evaluations, as well as the statistics on staff and the bibliometric data on clinical impact provided the basis for the panel's two-hour hearings with five to six representatives at management level from both the university/faculty and the county council/health care provider from each ALF region. The hearings were held in Stockholm on 20–22 November 2017. The panel identified general and specific questions to be discussed, which were sent to the ALF regions one week in advance of the hearing. The schedule and participants at the hearings can be found here.

Panel meetings

At the first panel meeting on 27–28 April 2017, the purpose and the process of the evaluation were presented, and the self-evaluation template as well as assessment criteria and indicators were discussed and slightly modified. At the second meeting on 19–24 November 2017, the panel met in connection with the hearings and agreed upon their main conclusions. In addition, two telephone conferences were held, on 13 November 2017 to prepare for the hearings, and on 16 January 2018 to agree on the panel report and final assessments.

The panel members are jointly responsible for the final assessments and the panel report. All panel members have partaken of all the assessment material from the seven ALF regions, including taking active part in the hearings with representatives of the ALF regions[36].

Project organisation

The project team at the Swedish Research Council consisted of Maud Quist (project manager), Andreas Augustsson (assistant project manager), Peter Lundin, Frida Mowafi, Gustav Petersson and Ulrica Horwath. Initially, Bo Sandberg was the project manager (October 2016 to March 2017).

Reflections and overall comments

The expert panel observed that Life Science research, development and translation is a high priority in Sweden[37]. The panel learned about a wide variety of clinical research that had been successfully translated into practice and has led to positive economic and societal impact both in Sweden and with international reach. The panel was tasked to assess regions on the basis of their strengths and weaknesses mainly in two areas; i) the implementation of research results into clinical practice and ii) the clinical significance and the societal impact of the research performed in the seven ALF regions. In addition the task was also to include assessment of research competence and collaboration.

The panel had contributed to the shaping of the process for this evaluation and were impressed with the attention to detail and efficient implementation of the review by the Swedish Research Council. However, it is important to note that this was the first time that such an evaluation had been conducted in this way in Sweden, and there will be opportunities to improve the process for its next iteration.

The panel agreed that all regions had both areas of strength and areas with room for improvement. It was encouraging that where the panel agreed there was room for improvement in a region, potential solutions could be found in the way other regions had approached the problem. The panel wished to highlight the benefit of greater collaboration and sharing of knowledge between regions.

Overall the panel agreed that Skåne should be singled out for excellent strengths in both areas assessed. The management of health technology assessments and the phasing out of old methods (disinvestment) are noteworthy examples. The collaboration between the university, the university hospital and primary care is working well and the Centre for Primary Health Care Research was highlighted as a particularly high quality initiative.

[36] With one exception, Charlotte Hall did not participate at the hearing with ALF region Örebro.

[37] Sweden's ten-year government strategy for science provides increased appropriations for research and development and highlights Swedish strengths in life sciences http://www.government.se/press-releases/2016/11/collaborating-for-knowledge--for-societys-challenges-and-strengthened-competitiveness/

The panels´ overall assessments for respective ALF region regarding the clinical significance and societal impact of clinical research are shown in the table below.

Table 15. Overall assessments for the ALF regions

ALF region	Very high quality	Good–high quality	Inferior quality
Stockholm		X	
Västra Götaland		X	
Skåne	X		
Uppsala		X	
Västerbotten		X	
Östergötland		X	
Örebro			X

Implementation

The panel was tasked to assess the processes for achieving, monitoring, evaluating and improving implementation of clinical research into practice. Some regions had well established approaches that had delivered excellent results, while others reported more or less developed plans to secure improved implementation. Important aspects of implementation included compiling the best available evidence concerning the benefit of new interventions, as well as utilizing information from quality registers and national data on healthcare performance.

Health Technology Assessment

The panel looked for the way that the region managed the compilation of the best evidence available for new clinical interventions, which usually involved a formal health technology assessment (HTA) process.

The Skåne HTA group's report on thrombectomy in ischaemic stroke, and action taken in the region to disinvest from certain pharmaceuticals for breast cancer treatment were highlighted by the panel as outstanding examples of successful implementation of HTA. It is not necessary for a region to run its own HTA process and the panel noted the decision by Uppsala to utilise the HTA unit in Örebro, but to first consult the national HTA network, and if necessary run a mini-HTA process.

Quality registers

The panel noted the importance of quality registers in all regions, to support implementation. Quality registers are often established by individual investigators, but many have extensive coverage of the Swedish population[38]. Quality registers are particularly important for the monitoring and evaluation of implementation in the Swedish context and their development is supported by a network of six registry centres[39]. However, the panel noted variation in the way that these registers were managed, as well as differences in coverage across disease areas and access to the data. In the best examples registers had excellent coverage of the population, were updated with data of high quality on a regular basis and were extensively used. In other examples users relied on annual reports produced by the registries, and the panel agreed that with a year lag it was difficult to adjust practice in a timely way. An example of the impact of quality registers was the use of the SWEDEHEART register in the TASTE trial[40] reported by Uppsala. The panel noted the advantage of using the infrastructure of population-based registers to recruit to a randomized controlled clinical trial, an approach which may provide Sweden with an international competitive advantage in the conduct of high quality trials.

[38] Review of 103 Swedish Healthcare Quality Registries J Intern Med. 2015 Jan;277(1):94-136. doi: 10.1111/joim.12303 https://www.ncbi.nlm.nih.gov/pubmed/25174800

[39] Quality Registry Centre, Stockholm (one of six regional Swedish QR Centres) http://qrcstockholm.se/om-qrc/

[40] Thrombus Aspiration during ST-Segment Elevation Myocardial Infarction N Engl J Med (2013); 369:1587-1597 DOI: 10.1056/NEJMoa1308789 http://www.nejm.org/doi/full/10.1056/NEJMoa1308789#t=article

Data on healthcare performance

Sweden has national mechanisms for gathering patient satisfaction feedback on healthcare performance (1177)[41]. There was evidence that regions scrutinize this information on a regular basis and have strategies to work on improving their performance. For example, the panel noted in Östergötland that there was a coherent structure for research and implementation of research results in clinical practice: from a political plan, via the regional ALF agreement, to Regional Medical Program groups, systematic reporting into national quality registers, as well as reference to the 1177 data.

Uppsala highlighted Abdominal Aortic Aneurysm (AAA) screening, a programme initially targeting 65-year-old men started in 2006, which had reached nationwide coverage in 2015. The panel noted that the AAA screening programme had prevented a considerable number of deaths. Västra Götaland highlighted that the knowledge gained from a longstanding project on obesity: the Swedish Obese Subjects (SOS) study on effects of bariatric surgery had substantial clinical significance and societal impact, both nationally and internationally over thirty years.

Research impact

The production of impact case studies was an important aspect of the self-assessment reports, illustrating strong examples of implementation and clinical impact, and the panel appreciated the care and attention regions had taken to compile these. The panel looked for evidenced and measurable impact clearly linked to a regional research programme. With the opportunity to submit up to three of these case studies, it was interesting to learn from the regional representatives how these had been selected. Some regions explained that they had wanted to illustrate the diversity of impacts achieved from their region's research; others had focused on research recognized nationally and internationally as the highest quality.

The panel wanted to encourage regions in the future to maintain interest in a wide variety of impacts, and to pay attention to longer term impact. The panel noted that some health areas occurred multiple times across different region impact cases, and that this suggested research strengths shared across regions (prostate cancer, thrombectomy, anticoagulation therapy). The expert panel agreed that this demonstrated potential for stronger collaboration across ALF regions in these areas.

Two impact cases from Stockholm illustrated the positive effect of medical research on society. Medical abortion with a combination of the progesterone receptor modulator mifepristone and a prostaglandin analogue was first invented by researchers in Stockholm and developed in collaboration with the World Health Organization (WHO). The safe and effective procedure is now increasingly administered by midwives in primary care, but can be administered by women themselves via telemedicine to allow improved access. In Sweden 97 % of abortions are now via the medical method. The national trial Swedescreen was instrumental in demonstrating that molecular screening for HPV gave better results than cytological tests for cervical cancer[42]. Swedish research also contributed to establishing the effectiveness of vaccines for prevention of HPV-associated cancers. The building up of comprehensive quality registers containing information on all Swedish vaccinations and screening invitations plus sample biobanks made Sweden a country of choice for phase III vaccine trials, and the resulting vaccines have been introduced into national programmes. The vaccination of 80 % of girls in Sweden from 2012 has been estimated to prevent about 530 invasive cancer cases per year[43], and the recent recommendation to extend this to boys has the potential to prevent a further 120 cases each year.

Two pre-requisites were highlighted by the panel as being crucial to generating clinical research impact; the clinical research capacity of the region (including incentives for research training, career development and recruitment) and approaches to collaboration.

---

41 The national 1177 Care Guide brings together advice, information and e-services for health and care available to the general population (in Swedish Vården i siffror – "Care in numbers").

42 https://www.ncbi.nlm.nih.gov/pubmed/24435414

43 https://www.folkhalsomyndigheten.se/contentassets/a56471aacod144c291cc3e61928790b8/health-economic-evaluation-universal-hpv-vaccination-swedish-national-vaccination-programme-children.pdf

Research competence

Regions employ a range of mechanisms to support researchers at all stages of their career, including careers for non-physicians and professions allied to medicine. It is challenging to train clinicians to be active in research, to address skill shortages, and to maintain a cadre of research leaders and supervisors. Regions have found ways to provide clear and flexible career pathways for clinical researchers. Some regions had succession plans for senior clinical researchers nearing retirement, and all had taken steps to improve gender balance in the workforce. Examples of success include Västerbotten which was found to have a strong focus on attracting and retaining talent, and an ambitious career programme for young clinical researchers. Today 70 % of students stay for internships, and of these 90 % stay for specialist training. This is in part because there are clear incentives for researchers to return to the region if they pursue studies and training outside the region. Västra Götaland has introduced measures to facilitate the recruitment of specialists from outside Sweden to address skill shortages, including offering Swedish language training.

Östergötland researchers have pioneered the development of inter-professional learning (IPL). A specific model for IPL – the Linköping Model – has been developed building on three compulsory steps and with students from 4–7 healthcare programmes participating. Linköping University is now coordinating the national and Nordic development plan for IPL in the medical doctors' programmes.

Collaboration

The panel was interested in incentives employed to encourage collaboration. Knowledge and skill transfer and the involvement of users, beneficiaries and policy makers are known to be important to achieve translation, implementation into practice and clinical impact. Regions reported collaborations across scientific disciplines and clinical specialities, across sectors (involving patients, public, industrial stakeholders), institutions (universities, hospitals, county councils and the private sector), and geographies (across the health region, between regions and internationally). The range of different approaches used across regions demonstrated success to varying degrees. The panel noted that ALF funding could be used to incentivise collaboration, if it was prioritized for projects that actively brought together different research disciplines, different organizations and sectors, or institutions with different strengths and facilities. In this way it could also be used to strengthen collaboration across regions and between regions.

Stockholm described an impressive 4D programme[44], a county-wide research programme aimed at improving healthcare for patients with arthritis, breast cancer, type II diabetes or heart disease. The collaborative work involves researchers in both primary care and hospitals.

Östergötland presented a strong example of industry collaboration and commercialization; the Centre for medical imaging science and visualization (CMIV). CMIV was founded in 2002 at the Linköping University Hospital through a joint initiative by Linköping University, the county council and the Linköping-based company Sectra. CMIV has pioneered 3D colour images derived from computer tomography data of humans. This has been applied to heart examinations, virtual autopsies and deep vision in brain surgery. The strongest impact internationally has been made with the so-called visualization table, which was commercialized by Sectra in 2013. The table is now used internationally both in medical practices and for educational purposes.

Recommendations for good implementation of clinical research to optimize societal impact

The panel has some general reflections on aspects of good practice:

- Clearly expressed ambitions and transparent and systematic procedures to adjust clinical practice, by extensive use of available registers
- Good collaborative relationship between university, university hospital and county authorities
- Ongoing involvement of patient organizations in developing the best practice for treating different

[44] http://ki.se/medarbetare/program-4d

disorders, and developing information material, available web sites, focus days for selected disorders, and other activities directed to the public
- Collaboration across regions on clinical research and intensify the existing quality registers in such work
- Encourage inter-professional teaching and training in order to secure collaborative attitudes between different groups of health personnel

Assessment of ALF region Stockholm

Overall assessment

Good-high quality

Overall the region was rated as "good-high quality" with respect to implementation and impact. Stockholm has significant research strengths and is a scientific "power house" for Sweden with almost half of the volume of high quality research carried out in the nation. The region contains an internationally competitive research cluster that is important for attracting industry, inward investment and international collaboration to Sweden. However, institutions in the region are in the early stages of a large programme of change, working together to strengthen implementation processes and to ensure that high-quality clinical research has maximum societal impact. If successful, this ambitious programme is expected to return substantial benefit in the coming years.

Research competence

The ALF region Stockholm, containing Karolinska Institute and the Karolinska University Hospital, has a very strong research presence and competence. The average number of PhD dissertations in medicine and health is the highest of all the ALF regions, and the number of physician dissertations averages 33 % of the total produced across all seven regions. An analysis of the citation of Swedish papers in Swedish clinical guidelines showed that 37 % of citations corresponded to publications with Stockholm authors[45]. Stockholm receives 27 % (2015) of the total ALF research funding. The balance between men and women researchers throughout the career pathway compares favourably with the other regions, and Stockholm has implemented various approaches to improving equality such as "unconscious bias" training. The average age at dissertation, for both physicians and other health professionals is close to the average across all regions. The percentage of physicians with PhDs employed by the county council is higher than for most other regions, while the percentage of other health professionals with PhD degrees employed by the county council is in the upper group of regions. Stockholm reports targeted training provided to staff to develop research leaders.

It is important to note that the region is undergoing a substantial change programme including a new University Hospital building, and complete reorganization of clinical structures. It is too early to assess whether this reorganization will result in improved implementation and/or improved patient experience and outcomes.

Collaboration

There is little reference to collaboration with hospitals in the region, other than the University hospital, in the Stockholm self-evaluation. However, during the hearing, this issue was raised and assurances were given that the ALF research funding is used across the hospitals within the region, not just at Karolinska University Hospital, and that ALF research funding is used among different professional groups. ALF research funding is distributed via open competition, and professionals at hospitals other than the University Hospital compete and are awarded funding. There is considerable funding from sources other than ALF funding, which represents just 10 % of the research funding available in the

[45] Data from Web of Science (Clarivate Analytics) and MINSO Solutions AB.

region. Most of the other funding, other than that coming from the county council, is in the form of research grants awarded to specific principal investigators and groups, a large proportion of which goes to principal investigators at Karolinska Institute.

Collaboration within the region goes beyond the ALF research funding to collaborative clinical practice and research among the different organizations. There are five emergency hospitals besides Karolinska University Hospital, 12 other hospitals, and 206 primary care practices. Many of these other institutions are privately operated, with support from the county council. The county council convenes monthly meetings, at which many issues among the hospitals and/or primary care groups are discussed.

The 4D programme is county-wide, and includes primary care as well as hospitals. The digital steering cards which are a primary programme of the region are used for forty "patient flows". These are diagnostic groupings of patients within the region who are followed comprehensively from their initial contact with the health care system, usually through primary care, through diagnosis, treatment and follow-up. These efforts are in accordance with the principle of "value-based health care". The region, in close collaboration with Karolinska Institute and Karolinska University Hospital, is developing a rich, clinical database of all patients (the VAL database[46]) which allows them to follow patients comprehensively across different care providers in the region. While this is very important for clinical care, it also has important implications for clinical research.

In their self-evaluation, Stockholm discussed collaboration with patient organizations in detail. At the hearing they discussed the extent to which patients are involved in producing information relevant to patients, to public education and dissemination, and other important approaches. Patient collaboration is facilitated by extensive interaction with patient organizations, including the involvement of "specialty patients", who have experienced highly specialized and sometimes rare diseases, and their input into the patient flow processes and to some extent clinical research. The region highlighted "oval table" meetings that included patient representatives. The panel wished to highlight the excellent arrangements in Stockholm for engaging and involving patient organizations in research.

Implementation of research results in clinical practice

The representatives from the region acknowledged that there was not a strong tradition of implementation, and stated that this is an area that they plan to strengthen. In the context of describing what they might do if ALF funding were increased, they stated that they would use an increase in funding to support a Center for Implementation Research. Exactly how this Center, if funded, would improve their implementation of research evidence into practice was not explored.

As mentioned above the region has ambition to transform the way that patients are treated and is part way through a substantial change programme. Automation will significantly expand the information available in the health system, which will bring its own practical challenges to storing data and gaining benefit from using evidence. Technology is not the entire solution to these problems, people and behaviour change must be at the centre of the implementation programme.

Details of implementation work in the region self-evaluation response were limited, although this was expanded upon in the discussion during the hearing. Attendees explained that they made use of national and some regional quality registries to monitor performance against clinical quality indicators, and the VAL database is useful to monitor outcomes. They do not have a systematic approach to monitoring and using quality data to improve performance overall. Changing practice, especially when there is evidence of poor or suboptimal performance, is usually left to the discretion of department or division heads with responsibility for clinical practice.

Impact beyond academia of the clinical research

The case studies provided by Stockholm were intended to cover broad societal impact (medical abortion); specific preventive care (HPV vaccination); and interaction between society and tertiary care

[46] VAL – Vårdanalysdatabasen; Stockholm regional health care data warehouse.

(out of hospital cardiac arrest). The three case studies are carefully documented, and provide varied and interesting cases of impact beyond academia, including considerable change in clinical practice in all three areas.

Of the three case studies, while all three have significant strength, the societal impact is variable, particularly when viewed internationally. The first case study of medical abortion has important impact in both Uganda and other international areas. For the second, HPV vaccination, the impact in Sweden is clear; but taking an international perspective, it was difficult to determine how much this contributed by the research at the Karolinska, and whether there has been adoption of these findings in national vaccination programmes (differences between the UK and the US are noted). For the third (out of hospital cardiac arrest), the societal impact is potentially important, but still being worked through. Overall, the case studies were considered strong.

Assessment of ALF region Västra Götaland

Overall assessment

Good-high quality

The panel´s grade for Västra Götaland region is *"good-high quality"*. The region has a strong research competence and presence of research trained personal in clinical practice. Structures and processes to promote inter-disciplinary and cross-sectoral collaboration have been established, especially within the field of innovation and life sciences. The region has explicit structures and processes for drawing up regional guidelines and Health Technology Assessment reports, but the clinical impact can still be improved. An important area for improvement is to establish a strategy for follow-up and evaluation of implementation of clinical guidelines. The potential for utilizing the Centre of Registers for monitoring and evaluation of implementation needs to be clarified. The impact beyond academia of the clinical research performed in the region was noted as significant and clearly evidenced.

Research competence

The region has a strong research competence and presence of research trained personal in clinical practice. The proportion of physicians with a PhD degree at the university hospital is slightly lower than the average of Swedish university hospitals (29 % vs 34 %), however the proportion of physicians with a PhD employed by the county council (including the university hospital) equals the average across all ALF regions (16 %). The share of dissertations in the region (2014-2016) as a proportion of the total from all ALF regions is 21 % (all professions) and 20 % (physicians), which corresponds well to the share of the ALF budget for Västra Götaland (21 %). The citation of publications from Västra Götaland in clinical guidelines is joint second highest out of the seven regions (16 %).

The county council and the University of Gothenburg have a common strategy and vision, as well as processes and strategies to secure a high presence of research trained professionals in clinical practice. The panel noted evidence that this had been put into practice with positive effect. This strategy includes to some extent non-university hospitals as well as health care professions allied to medicine. The ambition that unit managers, senior physicians and others in management positions at the university hospital shall have scientific competence is not yet entirely achieved. The attendees from the region noted during the hearing problems in recruiting clinical researchers from specialties in short supply in Sweden. To compensate for this, Västra Götaland has an active strategy for international recruitment and offers special language education programmes to meet the needs of clinical work.

Collaboration

Several structures and processes to promote inter-disciplinary and cross-sectoral collaboration have been established in the region. The panel agreed that there was a clear ambition and strong focus on innovation and collaboration with the life science industry in the region. Collaborations with other academic institutions (Chalmers University of Technology and the University of Borås) regarding

innovation in the medical technology area were noted. A structure for supporting the commercialization of research results was established in 1995 (GU Venture), and this has been ranked among best university-based incubators in Europe[47].

Västra Götaland has a clear vision ("Knowledge for a good life") and strategy ("VG2020 – Strategy for growth and development 2014–2020). Multidisciplinary collaboration is a prioritized area in this strategy which has seen SEK 300 million allocated to establish research centers with a focus on global social challenges. The Centre for Ageing and Health and the Centre for Antibiotic Resistance Research have been established with this funding, and are examples of encouraging multidisciplinary research and collaboration over subject and faculty boundaries.

Citizens, patients and relatives are identified as primary target groups for dissemination of research results. The Centre for Antibiotic Resistance Research[48] was used as a good example of disseminating research which has impacted on practice and policy both nationally and internationally.

Implementation of research results in clinical practice

Västra Götaland has pioneered central funding for the implementation of regional medical guidelines (RMR), and has explicit criteria for how (guideline for guidelines) and when (disease burden, variation in practice etc.) to implement a RMR. A regional impact assessment is undertaken before decisions on implementation are taken. 25 sector councils across all health areas act as local guideline committees and advise on implementation. Although three strong examples of successful implementation were provided in the self-evaluation, the panel considered that implementation was still an area that could be improved.

The Centre of Registers and several regional registries provide an infrastructure for evaluation of implementation of evidence-based practice. Although some hospital departments utilize the registries in their quality improvement work, no strategy or systematic structure has been set up at a regional level.

Impact beyond academia of the clinical research

Three strong examples of impact beyond academia were provided in the self-evaluation. The examples cover a broad range; a conceptual framework within neuropsychiatry and neurodevelopmental disorders (ESSENCE), solid evidence for the benefits of bariatric surgery, and a new advanced therapy for acute myeloid leukemia. In particular, the panel highlighted that the knowledge gained from the Swedish Obese Subjects (SOS) study on effects of bariatric surgery had substantial clinical significance and societal impact, both nationally and internationally. The fact that the study has been ongoing for 30 years and the availability of sample collections and linking with national registers has made the study globally unique. The results of long-term effects of bariatric surgery, on sustained weight loss, mortality and co-morbidities have had impact on clinical guidelines and most likely clinical practice in Sweden as well as internationally.

Assessment of ALF region Skåne

Overall assessment

Very high quality

The panel agreed that Skåne sets a good example for other regions, especially when it comes to the impressive implementation of clinical research into clinical work. The management of health technology assessments and the disinvestment programme are excellent examples. Skåne aims for research training of all healthcare professionals as well as administrators, which is ambitious and promising. The collaboration between the university, the university hospital and primary care is working well and the Centre for Primary Health Care Research was highlighted as a particular initiative of outstanding qu-

[47] GU Holdings was cited in the top 10 European University Business incubators in 2014/15 by UBI Global http://ubi-global.com/rankings/
[48] https://care.gu.se/education

ality. The three cases of implementation and the three cases of impact provided in the self-evaluation response were all considered very good examples of evidence-based medicine with great clinical and societal implications. The panel therefore agreed that clinical research implementation and impact in Skåne should be graded *"very high quality"*.

Research competence

Overall, the panel agreed that the research competence in Skåne region was strong. Skåne receives the third highest level of ALF funding (20 %, closely behind Västra Götaland at 21 %, numbers from 2015). Skåne delivers 17 % of the total PhD dissertations from the regions[49], and has the highest focus on training clinically qualified graduates with 68 % of the region PhDs being clinically qualified. The region graduates around the expected number of clinically qualified PhDs (21 % of the total), and papers from the region are equally well cited in clinical guidelines as the output from Västra Götaland.

The long-term aim in the region is that nearly all medical doctors will have a PhD degree. While the panel agreed that this measure may improve implementation of clinical research into clinical practice, panel members considered that this may not be a realistic target. Similarly, attendees from the region outlined that at present the majority of administrative leaders already have a PhD degree, but the future goal is that this should be mandatory.

Attendees from the region reported that higher number of female early career researchers had left academia, compared to men. The region has taken steps to address this gender imbalance, with 54 % of the approved ALF grants of the past years being awarded to female research applicants.

In response to a shortage of nurses Skåne has set up a special programme focusing on postdoctoral positions for nurses combining clinical work with research. It is hoped that this will provide an incentive for nurses to remain in the region.

Skåne has established a committee which acts as a "one-stop-shop" for the approval of clinical studies to improve the attractiveness of the region for clinical trials.

Collaboration

Attendees from the region highlighted direct collaboration between patients and healthcare professionals and also multidisciplinary academic collaborations as areas of strength in the region. The self-evaluation included three good examples of collaborative work; "The metabolic centre for obese type 2 diabetic patients" focuses on healthcare, patient-centred research and involvement of patient organizations, "Forum South" supports effective centralized clinical trial approval and the "WHO Collaborating Centre" supports international collaboration. Yet another important and specific achievement by Skåne is the "Medicon Bridge" a collaborative platform to initiate, facilitate and promote increased research collaboration between the health care sector, industry and academia in southern Sweden.[50]

Skåne University Hospital has sites in both Malmö and Lund[51] and runs the healthcare trust with several other centres and Lund University. Researchers and healthcare professionals are represented on all principal governance boards, including the board of directors and in the management teams of the clinical departments.

Infrastructure is shared across faculties, e.g. collaborations with the Faculty of Engineering at Lund University, and access to the MAX-lab[52]. Furthermore, there was evidence of close collaboration with hospitals and the University in Copenhagen. Skåne has a clear strategy for life sciences and considers it important to provide support creative ideas that may lead to improved processes or greater clinical impact. The panel agreed that the collaboration between Malmö and Lund seems to works well.

Although AstraZeneca has closed its research and development facility in Lund, there are now many

49 Data from Statistics Sweden.

50 http://mediconbridge.se/in-english/

51 The separate University Hospitals of Malmö and Lund merged in 2010 to form Skåne University Hospital.

52 The MAX-lab is the Swedish synchrotron facility https://www.maxiv.lu.se/about-us/

small companies based there, and employment in the life science sector is greater than before. Skåne considers there to be a thriving life science industry presence in the region. A life science innovation board has been created to promote innovation and run courses in entrepreneurship for PhD students. A compulsory course on innovation will be introduced next year for PhD students.

Implementation of research results in clinical practice

Skåne has several formalised bodies that act in concert to manage effective implementation of clinical research into clinical practice. For example, the region's corporate office has a strategic implementation group, which is responsible for implementation of national and international guidelines; the strategic group for research management and implementation (SRMI).

The self-evaluation from the region included three excellent examples of successful implementation; the Skåne Health Technology Assessment (HTA) group's report on thrombectomy in ischaemic stroke, early detection and treatment of sepsis, and disinvestment of certain pharmaceutical compounds in breast cancer. The thrombectomy and stroke work was conducted in Skåne and the report is now used across Sweden, and the panel was particularly impressed by the work to manage disinvestment effectively. All three areas have great clinical importance nationally and internationally.

The representatives from Skåne pointed out that staffing and money are always limiting, but that the amount of funding from the region for healthcare systems, including the ALF funding, has been maintained over the past decade. Approximately one third of the funding for research and development funding comes from ALF and the reminder from the healthcare region. Of course inflation means that the real value of this funding has declined and so, Skåne continues to work strategically to maximise the use of this support. One of the approaches important to this is evidence-based medicine including health economics.

Some of the opportunities to stimulate implementation mentioned by the region are use of health registries, national tertiary care and research infrastructure. Skåne is contributing to in the process of setting up the national tertiary care system, which is to start up in 2018. Furthermore, joint ventures have been created to maximise the use of biobanks, and joint programmes established between industry and academia.

The Centre for Primary Health Care Research was established in 2008 and conducts primary care research[53]. Examples of impact from this work include two clinical trials in mindfulness and one on anticoagulants. The Centre is financed partly by US NIH (National Institute of Health) and partly by the Swedish Research Council. This is an example of good collaboration across the region, and the result of prioritising funding to an area of clinical importance which was previously weak. The county council provides funding and the university provides professorships to the Centre.

Overall the region noted that economic conditions are challenging. Construction of a major new hospital complex in Malmö is a significant focus for the region, but there was good evidence that resources were being put successfully to implementing clinical research into practice.

Impact beyond academia of the clinical research

Skåne is active in disseminating research to the public via a magazine, webpage and events such as seminars. Patient forums are organised monthly, e.g. on prostate cancer, and a special division in the hospital is responsible for contacts and events.

Three examples of strong clinical impact beyond academia were provided: Cardiac arrest outside hospital, was systematically registered and monitored with respect to measuring hypothermia versus keeping normal body temperature with respect to survival and prognosis, and the impact has spread internationally.; secondly, a primary care management care programme for knee osteoarthritis which had also achieved international impact, and thirdly, an impressive diagnostic work-up for dementia has been initiated and implemented from Skåne, also with wide impact.

53 2016 Annual report for the Centre for Primary Health Care Research. https://issuu.com/cpf_report/docs/yearbook_cpf_kcp_2016_web

Assessment of ALF region Uppsala

Overall assessment

Good-high quality

The panel´s grade for this ALF region is *"good-high quality"*. Uppsala has many strengths and few weaknesses in research competence. The region also has many strengths and an international perspective on collaboration. Uppsala is working systematically to expand collaboration with industry and has active collaboration between the university hospital and the other hospitals and other care providers in the health region. However, an area of improvement is to strengthen the *two-way* cooperation with the broader region. The mini-HTA format is interesting, but no formal evaluation has yet been undertaken of the format. An area for improvement is to develop an overall system for evaluating the implementation efforts.

Research competence

Uppsala receives 12 % of the total ALF funding, and research from the region is well represented in terms of the proportion of research publications cited in clinical guidelines (14 %). The region has some world leading experts, e.g. in cardiology, some forms of oncology and in some specific subareas of research based on patient/health registers. The fact that Uppsala university hospital raises more than 2 billion SEK annually from providing health care to other regions on the open market is an indication of the high quality of services available. Research strengths are concentrated at the Uppsala University hospital.

Uppsala has similar strategies to other regions in terms of procedures and strategies for research trained professionals in clinical practice, but specifically attendees from the region highlighted strategies for encouraging multi-disciplinary approaches. Regarding multi-professional development it is noteworthy that Uppsala has Professorial positions in nursing and physiotherapy. Also, Uppsala has dedicated training programmes for professions allied to medicine and there are now twelve such PhD students.

Uppsala has a strategy to increase the proportion of female physicians that have employment contracts with both the county council and a university, and progress has been made with more women than men being employed in these combined positions during the last year. Research programmes and ear-marked funding must be open for both genders but incentives have been found to shift and maintain the balance in the clinical environments at the university hospital, and more women are now recruited to senior positions.

As opposed to most other regions, no part of the ALF-funding is distributed in open-competition across the region. For example, PhD-students at hospitals other than the Uppsala university hospital cannot access ALF funding.

Collaboration

Uppsala is similar to other regions in terms of non-academic partners, but highlighted collaboration with patients and the life science industry in its self-evaluation. Regarding multi-disciplinary collaboration, Uppsala highlighted international cooperation and exchanges with universities abroad. The panel formed the impression that cooperation was often built on personal expertise, not on formal structures or procedures.

Examples of target groups for dissemination of research results were described in the hearing and highlighted in the examples and cases from activities. An example on digitalization and public health included new self-help programmes which have been introduced in close collaboration with patient organizations. Further examples of patient involvement in development of care and research were presented in gynecology and diabetes. The diabetes example highlighted the importance of involving patients at an early stage. The development of a "virtual outpatient clinic" for young persons with diabetes was first designed by health professionals and IT people. However, when presented to young diabetes patients, they rejected the concept. Working in close cooperation with the patients, the project was entirely redesigned. The panel´s impression was that patient involvement in the region is increasing, but from a modest initial level.

Uppsala has recently decided to focus on collaborating with industry. Uppsala is part of the EIT Health initiative[54], a consortium of 140 partners from 14 European countries, promoting entrepreneurship and developing innovations in healthy living and active ageing.

There is collaboration between the university hospital and other hospitals in the health care region, such as Falun and Västerås. PhD students graduate at the local hospitals. Uppsala has also established a closer collaboration in specific clinical areas, where the local hospitals have the function of a research node. An area of improvement is to strengthen the two-way cooperation between the university hospital and the other hospitals in the health care region, from a situation where there the emphasis is on referrals from other health care providers to the university hospital only.

Collaboration between Uppsala University and the hospital provides access to advanced research and technology in other areas than medicine, e.g. nuclear physics.

Implementation of research results in clinical practice

There is a standardized pathway for decision on and introduction of new interventions at Uppsala University Hospital, but no overall strategy for implementation across the region. Implementation in Uppsala differs from other regions in using a "mini" health technology assessment (HTA) process and choosing not to have a full HTA process of its own. Instead Uppsala collaborates with the HTA unit in Örebro, Centre for Assessment of Medical Technology (CAMTÖ) to conduct full HTAs. The mini HTA is a structured way to start thinking about implementation of research in clinical practice. The mini HTA procedure considers impact at the departmental level, but also impact across the rest of the hospital and includes 24 questions, which are considered simple to complete. The process implies that the questionnaire will go back and forth between the hospital management and the department, before any decision is taken. Most often more information is given in each iteration. Each mini-HTA is followed up at 12 months. No formal evaluation of the mini-HTA process has been undertaken, but Uppsala has refined the questions and process, in light of experience. The decision not to set up a regional HTA unit had been thoroughly considered and was based on the view that Sweden had a number of these units and each was under-utilised.

Uppsala university hospital has chosen to adopt a "value-based" care approach. What is meant by value-based can vary from organization to organization, however the representatives from Uppsala explained that the patient should see "one hospital", not a series of different departments. Despite departments still being based on the traditional clinical specialties, this approach should provide a better match between research and clinical practice.

The example of Abdominal Aortic Aneurysm (AAA) screening, initially targeting 65-year-old men was started in 2006, and reached nationwide coverage in 2015 and the prophylactic results of the AAA project has strong clinical impact.

The strengths (cooperation, organization) and threats (recruitment, economics) of Uppsala are similar to other regions.

Areas of improvement identified included increasing the number of patients involved in clinical research and the availability of health economics as a resource in decision making. A dependence on patients from other parts of Sweden was also noted; Uppsala university hospital is a big hospital in a mid-sized region.

An impression formed by the panel is that implementation of research to clinical practice is built on individuals (e.g. department heads) and on PhD-students from the health region spending at least one year at the university hospital to learn practices, not on formal structures or procedures.

Impact beyond academia of the clinical research

Case studies of impact covered anticoagulants in atrial fibrillation, self-sampling cervical smears for HPV testing and delayed umbilical cord clamping. The cases reflect the high standard of clinical research that Uppsala is capable of. Uppsala has good track record for industry sponsored clinical trials, and ambition to further expand this work.

54 http://www.uu.se/eithealth/about

Assessment of ALF region Västerbotten

Overall assessment

Good-high quality

The panel gave Västerbotten the grade "good- high quality". Overall, the panel agreed that the region is performing very well in research competence, compensating well for their geography and small population. They are also very successfully collaborating across the region, with other hospitals and components of the health system, very well with patients/citizens, and with the county council. However, implementation of evidence based practice appeared to lack a systematic approach. It relied on individuals deciding to undertake monitoring and evaluation of national quality registry data.

Research competence

The research capacity of the Västerbotten was considered to be good, given the fact that the region faces significant geographical and demographical challenges. There is a strong focus on attracting and retaining talent, and there is ambitious career programme for young clinical researchers. Today 70 % of students stay for internship, and of these 90 % stay for specialist training, a very high proportion. This is in part because there are clear incentives both to continue studies and training outside the region, but also to return. One important approach is that clinicians are paid specialist salaries as they are attaining specialist credentials, not only after these are completed. They are very clear that their strengths in clinical research are in neuroscience, cancer, metabolic diseases and infection biology.

There are two systems for career advancement – Clinical researcher and Academic clinician-scientist - with clear tracks for both arms. Their ambition is to have more doctors reaching the PhD level faster and earlier. They provide financing to all young researchers, and use external review for all scientist positions. The articulation of the dual career tracks is a significant strength of the region, and it demonstrates the close collaboration between the University and the County Council. While not all heads of clinical departments have PhDs, many do, and the region aspires to enable all clinical heads in the hospital to have PhDs.

The gender balance for physicians with a PhD is more even than most other regions, which may be evidence of incentives to retain female researchers working in the region. Attendees from the region mentioned efforts to train PhD students in disciplines allied to medicine.

Research in the region was agreed to be well organized; 1 central hospital (Umeå University Hospital) acted as a hub to 3 regional "nodes" (hospitals outside of the central hub), with research activities taking place at all of these. Each node has a head for research and education, at least at associate professorship level. PhD students are supported at the nodes, not only at Umeå University Hospital.

The region has successfully exploited and developed telemedicine as a means to tackle the geographical distances between clinics and remote populations, and has active research programmes in telemedicine. This research is leading in Sweden.

Collaboration

The panel noted that collaboration was working well across the entire region. The collaboration between Umeå University and Umeå University Hospital was notably strong. Decision making committees include academic department heads as well as heads of clinical departments, and joint decision-making is assured.

Patients in Västerbotten are highly supportive of their regional health service and interested in taking part in clinical trials. A high percentage of the population has participated in research projects. They trust the system, and have high confidence in health care and pride in Umeå University hospital. Many research programmes include patient representatives, and information materials are produced in collaboration with patients. The panel noted that information is provided to the public about all clinical studies, ensuring that they "close the loop" with patients who have participated and have an interest in the results.

Collaboration takes place with many different stakeholders, but the common denominator is county councils and municipalities, the latter for primary and elder care.

Industrial collaboration is promoted in the region with initiatives such Biotech Umeå[55]. An attractive feature of the region is the ability to reach a population of over 850,000 through a single highly performing hospital trust[56].

From the collaborative perspective the panel noted the clear strategy to involve the entire region and population in research.

Implementation of research results in clinical practice

Implementation is primarily monitored through the use of quality research registers. Both uptake and outcomes are recorded in these registers. Where there is the ability to provide online feedback to the quality research registry this establishes a useful way of recording implementation. However, no standard procedures for monitoring and evaluating implementation were described. Instead the region relies on individual decisions from clinical department heads.

An important priority for the region is to focus on how outcomes are improved by clinical research. Professorial level clinical positions were seen as important to this.

The example of antibiotic stewardship (monitoring the use of different kinds of antibiotics and providing feedback when inappropriate antibiotics are used) was considered to be a good example of the use of quality research registers.

Impact beyond academia of the clinical research

The region provided strong cases in important areas, focusing on clinical rather than societal impact.

According to the information given at the hearing, the self-evaluation response was written to highlight different types of cases/studies, and not necessarily those with the highest impact. The panel agreed that all three cases were interesting and important topics. However, it was not clear in all three how clinical care has been affected; some of the examples described work still largely in the research realm, such as the molecular structure of protein aggregates in progression of neurodegenerative disease, a frontline research area with great future potential for leading to personalized medical care, even if this has not been obtained. The work on deep brain stimulation in movement disorders and adjuvant use of radiotherapy in prostate cancer appears to have had clinical impact, and in the case of prostate cancer, 15 year follow up has been performed. The panel appreciated that in the case of prostate cancer treatment, multi-professional collaboration was highlighted, with leadership by a nurse researcher in parts of the work.

55 http://www.biotechumea.se/biotech-umea

56 In 2014 *Dagens Medicin* ranked Umea University Hospital as the best performing in Sweden. http://viavasterbotten.se/2014/01/the-university-hospital-of-umea-voted-the-best-hospital-in-sweden/

Assessment of ALF region Östergötland

Overall assessment

Good-high quality

The panel gave this region the grade *"good- high quality"*. Östergötland has a coherent structure for research and implementation of research results in clinical practice: from a political plan, via the regional ALF agreement, to Regional Medical Program groups, and systematic reporting into national quality registers.

Östergötland is trying to capitalize on the well-performing healthcare in the South-East Healthcare Region which, according to senior management and some nationwide statistical sources, have some of the best performing county councils and hospitals in Sweden. There is a well-established collaboration between the ALF region and the Healthcare Region, and there is a shared responsibility for the ALF agreement and clinical research across the ALF region.

Overall, Östergötland is a small region, both in terms of population and funding for research, including ALF funding. However, they compensate this through well-established career development programme, a coherent plan for research and implementation, and with a very strong collaborative approach. Östergötland has adopted good plans and good processes, but are still in the process of implementing them.

Research Competence

Östergötland has a clearly stated research policy, which includes both structural conditions for enhancing competence in research and development within the region as well as providing incentives at the individual level in the form of salary increments for completed half-time seminar, PhD dissertation and Assistant professor competence.

The region described a well-established career development programme – 'From student to Assistant Professor' - where healthcare personnel can apply for funds for research protected time at various academic levels. This programme is jointly funded from the county council, Linköping University and ALF money.

To ensure knowledge and awareness of clinical research issues at leadership level, Östergötland has established a mandatory course for department heads within the region. A course in Good Clinical Practice is also a part of the PhD training programme for healthcare professionals.

Östergötland receives 8 % of the ALF funding (2015), and produces more or less the expected share of dissertations, including clinically qualified PhDs (28 PhDs, 6 % of the total).

Senior managers emphasized that the region has increased the number of research professors during the last 8 years. Information was also given that Östergötland graduates 150-200 medical doctors each year, but that this number will have risen to over 260 within a couple of years. 2/3 of the students come from outside of Östergötland. Of the graduated medical doctors 70 % stay in the region.

Collaboration

The importance of collaboration was highlighted both in the region's self-evaluation and by senior managers. There seems to be well-established collaborations with many different stakeholders: healthcare, patients/patient groups, Government agencies and the Life Science-industry. Overall the region is strong on collaboration and there is a deliberate strategy to build on the traditions of working collaboratively to improve research and healthcare in the larger South-East Healthcare Region.

The collaborative approach influences most parts of the region's work, and gives strengths in inter-disciplinary research, and inter-professional learning. It also leads to a strong collaboration between Linköping University, the Linköping University Hospital and other parts of healthcare in the three county councils that form the South-East Healthcare Region.

The most important partnership for Östergötland is the well-established healthcare collaboration across the wider South-East Healthcare Region (comprising of Östergötland, Jönköping County and

Kalmar County). This provides for a coherent healthcare system of 1 million inhabitants as well as for collaboration with Linköping University in clinical research, medical education and development of healthcare, and with Linköping University Hospital as a highly specialized academic centre.

There is a shared responsibility for the ALF agreement and clinical research across the ALF region.

Matters on clinical research, ALF funding and university health care are jointly decided by a Committee including the University and all three counties. In addition to ALF, there is a joint research council of South-eastern Sweden (FORSS) which provides funding for applied, patient-oriented research projects and research time for clinical PhD students and postdocs.

Linköping University and the county council jointly support 'Strategic Research Areas' (SRAs) as a common platform for interdisciplinary research, and with the purpose to promote collaboration between various faculties at Linköping University and the county council. The objective is to stimulate internationally competitive clinical research that leads to innovation in healthcare and stimulates development of new research leaders. Senior managers emphasized that SRAs have formed attractive research environments for recruitments to the large programme initiatives where Linköping University and the county council – together with national research funds such as the K&A Wallenberg Foundation and the Swedish Research Council – jointly fund e.g. the Wallenberg Centre for Molecular Medicine and the Center for Social and Affective Neuroscience.

Senior managers also highlighted collaborations with national agencies as important, and cited examples such as an interaction with the National Board of Health and Welfare on priority making in healthcare, with the National Board of Forensic Medicine (which has several adjunct positions at Linköping University) and the Social Insurance Agency (which funds research at Linköping University on e.g. medical rehabilitation and work environment and health).

According to senior managers, collaboration with patients is well developed in several areas, such as breast cancer, rheumatology and cardiology. Östergötland wants to promote patient participation also in the design of clinical research and thus make them become co-designers in research. Östergötland has a number of communication initiatives directed towards patients and the general public. Among these are focused lectures on selected topics that are held together with patient organizations, and a medical science research lecture series which also is addressing a national audience.

In Östergötland interaction with Life Science companies are becoming more important for the development of both research and healthcare. The South-East Healthcare Region has put a structure in place – 'Forum Sydost' - to facilitate both researcher-initiated and industry-initiated clinical studies, and there are clinical trial units at the larger hospitals. Senior managers point to the collaboration with Sectra at the Centre for medical imaging science and visualization (CMIV) as an example of successful industry collaborations which has resulted in solutions with numerous medical and educational applications, as well as great commercial potential.

Implementation of research results in clinical practice

The regional ALF agreement draws up general guidelines for university healthcare units to follow and implement new knowledge regarding diagnostics and treatments, with a system for evidence-based and managed introduction of methods, phasing out of old methodologies and promotion of innovations.

Procedures for securing implementation of evidence-based development work have been formalized, and there are a number of Regional Medical Program Groups (RMPG) with expert representatives from Linköping University and the three counties in the South-East Healthcare Region. In addition to RMPGs a number of different groups have been set up to promote evidence-based healthcare, such as the Regional Method Council, the Medical Products Committees and the National Center for Priority Setting in Healthcare. The RMPGs' role is to compile healthcare guidelines for different diagnoses. The RMPGs consist of both academic and healthcare staff, who jointly determine how the implementation should take place in practice. RMPGs also are responsible for the implementation of national guidelines into regional guidelines.

Senior managers outlined that there are formal procedures in place for securing implementation of evidence-based medicine at all levels of healthcare. The operational descriptions to the production

units enforce that all departments should be linked to relevant quality registers and use them to run improvement work.

The implementation of research results in clinical practice, as well as medical results/outcomes, are primarily monitored through following the results at each department in quality registers and the nationwide database 'Healthcare by numbers'. According to senior managers, actions are taken when deviations from desirable results are noted. This exercise is done regularly, not just adjusting on the basis of the annual reports.

Impact beyond academia of the clinical research

The region submitted three impact case studies showing an interesting mix. According to senior managers, Östergötland wanted to highlight not only the quality, but also the breadth, of the research and collaborations that the region is capable of.

The first case study presented an example of impact through industry collaborations and commercialization in the field of imaging and visualization. The Centre for medical imaging science and visualization (CMIV) was founded in 2002 at the Linköping University Hospital through a joint initiative by Linköping University, the county council and the Linköping-based company Sectra. CMIV pioneered in making 3D colour images from computer tomography data of humans. This has led to a number of applications in imaging such as heart examinations, virtual autopsies and deep vision in brain surgery. The strongest impact internationally has been made with the so-called visualization table, which was commercialized by Sectra in 2013, and the table is now used broadly internationally both in medical practices and for educational purposes.

The second case study was an example of impact through collaboration with the Swedish Football Association and an insurance company to prevent knee injuries in young soccer players. The background was that many soccer-playing girls every year suffer from severe knee injuries that cause suffering and cost a great deal of care. Prevention of injuries therefore could give great benefits to society. A large study was conducted at Linköping University, in collaboration with the insurance company Folksam, the Swedish Football Association, and a large number of football clubs in Sweden. The large study showed that many serious knee injuries can be prevented with a simple 15 minute warm-up programme: 'Knee Control', giving 64 percent lower risk of severe knee injuries. The results have had a broad national and international impact in recent years.

The third case was an example on impact through an inter-professional learning programme. The Faculty of Medicine at Linköping University has been a pioneer in the development of inter-professional learning, and is one of the few universities internationally with a coherent inter-professional learning programme (IPL). A specific model for IPL – the Linköping Model – has been developed building on three compulsory steps and with students from 4–7 healthcare programmes participating. The Linköping Model has become internationally renowned and is in Sweden seen as state-of-the-art for inter-professional learning. Linköping University is now coordinating the national and Nordic development plan for IPL in the medical doctors' programmes.

Assessment of ALF region Örebro

Overall assessment

Inferior quality

Örebro has only recently gained ALF funding, but in comparison with other regions did not appear to have used this initial period to draw up informed strategies that would usefully support monitoring and evaluation of progress, prioritise collaborations and drive improved implementation and clinical impact. Attendees to the panel meeting explained that the region had focused ALF funding on creating more places for educating doctors, and expanding the region's research capacity. However, the task for panel 2 was to specifically assess the clinical significance and societal impact of research from the region, which included looking in detail at evidence of and plans for collaboration and implementation.

The region has a strong tradition for health technology assessment, and has produced some good quality research that has made a positive difference to the health of the public. However, the region did not outline a clear strategy to demonstrate alignment and co-ordination between academia, hospital and county council, collaboration, or implementation in the region. At present the region is looking to see what thrives, rather than being guided by prioritisation of specific areas.

Örebro is a small region with the advantages that decisions can be taken quickly, and researchers know the region and patient needs well. However, it was disappointing that the attendees to the hearing from the region did not respond more convincingly to the review. The panel found the self-evaluation quite weak in comparison to other regions and, although the panel fully considered information provided at the hearing in reaching its overall assessment, it concluded that clinical research implementation and impact in Örebro should be graded *"inferior quality"*.

Research competence

Örebro University gained the right to award medical degrees in collaboration with Örebro University Hospital in 2010, becoming Sweden's newest medical school. A common board (Rådet för Medicinsk kunskapsstyrning, RMK) has been established across the county council, university and university hospital.

The region reports that roughly 10 % of first degree graduates secure a research position. From 2015 Örebro has received a small amount of ALF funding (2 % of the total ALF funding to regions in 2015), and produced the expected share of dissertations including clinically qualified PhDs (13 PhDs, 3 % of the total)[57].

The region is in the early stages of implementing support for clinical careers, and its main policy is to offer incentives to physicians to be research active, decrease the mean age for obtaining a PhD, encourage graduates into postdoc studies, and to build a larger cohort of PhD supervisors.

ALF funding is awarded to PhD students and competitively to projects. PhD students are all funded if they pass mid-term dissertation. Approximately 80 % of projects in the initial round were supported, which was noted as a very high success rate. In response to questions attendees at the hearing explained that the expectation is that this will become more competitive in the future.

ALF funding is being used to build basic research programmes that will support strengths in the clinic (e.g. projects to look for biomarkers to support work on enhanced care, company collaborations on medical devices to support surgery). The clinical research seems to be driven by individual scientists. Senior managers emphasized the region had an established track record in clinical research, but weaknesses in basic and translational sciences. The panel could find no evidence of any clear strategy aimed at filling this gap.

Collaboration

Notable collaborations within the region include encouragement for researchers in the "caring sciences" to work together. This involves nursing and therapist staff. Funding is available for joint projects between University and hospitals across the region. Senior managers from the region confirmed that they provided ALF funding to support collaborations with other regions.

International collaborations between Orebro University and Aston and Glasgow Universities in the UK to facilitate exchange of students and teaching staff were raised at the hearing, but not detailed in the self-evaluation.

The population local to the Örebro region is approximately 350,000 although inter-regional collaborations are used to access a wider section of Sweden's population, for example in highly specialised care.

The response from the region regarding collaboration with patient organisations was not well developed. The region recognized that it needs to do more to involve patients in decisions to prioritise and allocate funding, in the design and conduct of studies, and needs to make effort to feedback research results to patients. There is no explicit strategy for this in place, yet.

57 Data from Statistics Sweden.

Implementation of research results in clinical practice

Annual results from quality registers are used to evaluate changes in clinical practice and each department head is responsible for examining this data and identifying areas for improvement. The panel agreed that this approach was not as strong as that outlined in other regions, where it was mandatory to refer to appropriate registry data on a regular basis to modify practice.

It was noted that there was an active collaboration with Uppsala to use registers for randomised clinical trials. This is a powerful and cost effective approach. The first application of this was in cardiology, and it is now being used in other areas.

Örebro has its own well regarded health technology assessment unit – CAMTÖ (Centre for Assessment of Medical Technology in Örebro) which provides local and regional HTA-reports and reports on HTAs done by other organizations within Sweden or the SBU (Swedish Agency for Health Technology Assessment and Assessment of Social Services) to RMK.

The attendees from the Örebro region highlighted Enhanced Recovery After Surgery (ERAS) programmes as an additional example of work from the region with relevance to implementation and clinical impact. ERAS programmes have been shown to have a positive impact on clinical outcomes[58]. The ERAS care system includes an evidence-based guideline, an implementation programme, and an interactive audit system to support practice change. ERAS has been used by 26 hospitals leading to a reduction in complications by 30 %. Örebro initiated this approach, translated it to several disease areas and secured European Commission funding to continue to extend it. ERAS USA includes Harvard and others. The panel agreed that this might be a good quality example of impact, but could not assess it in detail since it was not included in the self-evaluation response.

Örebro's research priorities emphasize broader "every day" health issues, such as chronic diseases, important to the health of a wide proportion of Sweden's population, in recognition that the region cannot compete with established specialisms in other regions.

Impact beyond academia of the clinical research

The region submitted a single impact case study (the Scandinavian Prostate Cancer Group Trial Number 4), although it was open to them to submit up to three. The case was included to highlight that the research infrastructure in Örebro has the capability for high quality clinical research with impact.

The panel agreed that this is a high quality long-term follow up study with impact on international policies for the treatment and management of prostate cancer. In 2010 the Cochrane Review showed that at that time the evidence this study produced was considered the only good quality evidence in the world. Since that time follow up has strengthened the importance of the results, although new treatments and management regimens have become increasingly important for treatment of prostate cancer.

It was also noted that further case studies could have been included. While one additional promising example was highlighted in discussion (the ERAS programme), the panel was not able to assess this impact without a fully evidenced case study.

[58] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5438526/

EVALUATION OF THE PREREQUISITES FOR CLINICAL RESEARCH – REPORT FROM ALF PANEL 3

The starting point for the evaluation of the prerequisites for clinical research have been formulated by the National ALF Steering Committee. In accordance with these, the evaluation will be conducted by a panel of international experts and based on assessment of various data, including self-evaluations and hearings.

The overall aim is to increase the quality of clinical research. The panel's mission is to make a balanced assessment of the quality of the prerequisites for clinical research in the ALF regions and group them into one of three categories according to the resource allocation model (poor quality, good–high quality or very high quality).

According to the starting points formulated by the National ALF Steering Committee, the prerequisites for clinical research should be evaluated with regard to critical success factors in order to strengthen clinical research. Based on the instructions of the National ALF Steering Committee, the Swedish Research Council has focused on the following critical success factors, called "components" in the evaluation, to evaluate the quality of clinical research:

- Research infrastructure
- Time for research
- Next generation of researchers
- Career models for clinical researchers

There was initially an ambition that funding for clinical research also should be included as an evaluation component. Since there are no good methods for obtaining comparable financial statistics from county councils and universities in the ALF regions today, financial information was only provided as background information in this evaluation.

The rubrics for the assessment, the self-evaluation form, the PI survey and the instructions to the panel's pre-evaluation, as well as the schedule for site visits and hearings can be found under the following links:

- rubrics
- self-evaluation form
- PI survey
- instruction for the pre-evaluation
- site visit schedule.

The composition of the expert panel

A panel of international experts appointed by the Swedish Research Council carried out the evaluation. The appointments were based on proposals from the ALF regions and from scientific councils and committees within the Swedish Research Council.[59] In addition, the project group made nominations based on contacts made during a study trip to England and the Netherlands.

The panel consists of twelve members (see table 16), with many years of experience in managing and organising clinical research, and of postgraduate education. Profile areas of the members are knowledge of organisation, leadership, funding of research, prioritisation of research, merit systems, postgraduate education and internship, mentoring, research infrastructures and quality assurance structures. In addition to these profile areas, all members have expertise in different disciplines.

[59] The Committee for Clinical Therapy Research (KKBF), the Committee for Clinical Studies (KKS), the Scientific Council for Medicine and Health (MH), the National Steering Group for ALF, regional boards at the Swedish university hospitals.

During the recruitment, the Swedish Research Council's policy on conflict of interest was followed. All members of the international panel were informed about the Swedish Research Council's policy on conflicts of interest, and they declared that no conflict of interest existed. When assembling the panel, an even gender and geographical distribution was taken into account as far as possible. The desired gender distribution of 40-60 per cent from each gender was achieved.

Table 16. Expert panel for the evaluation of the prerequisites for clinical research (ALF 3)

Name	Organisation	Country
Stig Arild Slørdahl (chair)	Helse Midt- Norway	Norway
Inger Thune	University of Oslo	Norway
Rien de Vos	Academic Medical Center	The Netherlands
Ian Hall	Nottingham University	United Kingdom
Erik Fosse	Oslo University Hospital, University of Oslo	Norway
Nina Langeland	University of Bergen	Norway
Björn Gustavsson	Norwegian University of Science and Technology	Norway
Marite Rygg	Norwegian University of Science and Technology	Norway
Marja-Riitta Taskinen	University of Helsinki	Finland
Jaap Bonjer	VU University Medical Center Amsterdam	The Netherlands
Lars Bo Svendsen	Rigshospitalet, University of Copenhagen	Denmark
Janna Saarela	FIMM, Institute for Molecular Medicine Finland, University of Helsinki	Finland

Assessment criteria

The evaluation of the prerequisites for clinical research was based on four components:

1. Research infrastructures relate to the accessibility of the research infrastructures in the ALF region, financing, maintenance and upgrade strategies, technical maintenance and support staff, infrastructure prioritisation, etc.
2. Time for research refers to how the ALF regions ensure that enough time is allocated to research in the daily life of the clinic, how best to combine clinical employment and clinical research, etc.
3. Next Generation Researcher (Education) is about how the ALF region works to make clinical research an attractive option in in the ALF region, and how cross-disciplinary and interdisciplinary research areas are stimulated, etc.
4. Career models for clinical research concern how ALF regions develop career paths for clinical researchers that enable clinical research and clinical work in parallel, as well as how clinical research is encouraged in the career, etc.

The components were assessed as to how they were implemented in the seven ALF regions, in terms of creating good prerequisites for clinical research. In order to guide the assessment on how these components have been implemented and developed, an assessment matrix (rubric) was developed. The focus for the assessment is on how each ALF region has developed the respective component of the organisation in the operations, and with regard to structures, processes and results. The assessment matrix has also provided the basis for the data collection, partly via self-assessment carried out by the managements of the seven ALF regions, and also via a questionnaire sent to research leaders in the respective ALF regions.

The evaluation process

The evaluation was carried out by the panel in three steps:

1. a pre-evaluation of the prerequisites for clinical research in the ALF regions based on the regions' self-assessments and a survey directed to research group leaders in the ALF regions (instructions)

2. local site visits and hearings about the activities of the seven ALF regions (schedule)
3. final discussions and assessments, where the panel categorised the ALF regions into one of the three categories according to the resource allocation model.

The evaluation was done using the following information:
- self-assessment from the respective ALF region
- the results of the survey sent to the research team leaders
- site visits including hearings.

In addition, the panel received background information compiled by the Swedish Research Council on the scope of the ALF funding, the approximate population size and geographical scope of the ALF regions.

Self-evaluation

A self-evaluation template was sent along with instructions to the ALF regions on 6 September 2017 (self-evaluation form). The deadline for submission of the completed self-evaluation was 18 October 2017. In the self-assessment, the management bodies of each ALF region was asked to report how they worked to implement and develop the four different components that were included in the assessment, in terms of structures, processes and results.

Survey to Principal Investigators (PI)

A survey was sent to the PIs identified by the ALF regions, on 6 September 2017 (questionnaire). The deadline for submission of the answers was 27 September 2017. The survey contained questions about the PI's background as a researcher, if and what medical profession they have, mobility, time to research as well as a number of assessment questions based on the assessment matrix used for questions in the self-evaluations. The following table sets the response rate for the survey for each region.

Table 17. Response rate from the PI survey for the various ALF regions

ALF region	Invited PIs	Number of completed answers	Response rate
Stockholm	775	482	62%
Västra Götaland	265	218	82%
Skåne	681	330	48%
Uppsala	185	129	70%
Västerbotten	296	188	64%
Östergötland	237	176	74%
Örebro	148	117	79%

Site visits

As there were organisational components to be assessed, and to enable the panel to get a local picture of the respective ALF region and to meet as many representatives of the regions as possible, site visits with hearings were made to each region. The panel was divided up into three groups that met the various ALF regions during the period 15–17 January 2018, as shown in Table 18.

Table 18. The division of the panel into three groups for the site visits

Group 1	Group 2	Group 3
ALF regions Östergötland and Stockholm	**ALF regions Umeå, Uppsala and Örebro**	**ALF regions Skåne and Västra Götaland**
Stig Slørdal	Nina Langeland	Lars Boo Svendsen
Marite Rygg	Erik Fosse	Inger Thune
Jaap Bonjer	Ian Hall	Rien de Voos
Marja-Riitta Taskinen	Janna Saarela	Björn Gustafsson

Assessment

In order to carry out the assessment, the panel initially used a four-point rating scale for each component and aspect. The purpose of using a four-point scale as a first step was to ensure that the assessment of the prerequisites for clinical research in the seven different ALF regions was based on shared notion of what good quality consists of in this respect. The scale initially used by the panel has the following ratings:

1. Beginner (beginning)
2. Under development (development)
3. Established (accomplished)
4. Exemplary.

The assessment was carried out according to the following structure, and according to the three steps reported above.

Step 1

Before the panel met in Stockholm, a pre-evaluation of each ALF region was performed by the individual panel members, based on the self-evaluations and the answers to the survey to the research group leaders. Using the four-point scale above, panel members made individual assessments of how well each ALF region had implemented the structures, processes and results for each component. The panelists were instructed to use the scale, so that each point corresponds to the same breadth and depth through all assessments, and to provide rating, rate reasoning and complementary questions for the site visits to each ALF region.

When the panel met in Stockholm prior to the site visits, the individual pre-evaluations were calibrated to ensure that the assessment scale was used in the same way and with the same meaning by all panel members. The supplementary questions for the hearings were compiled by the panel prior to the site visits.

Step 2

In the next step, site visits were made and hearings held, where the panel had the opportunity to ask supplementary questions to the management, business managers and researchers and doctoral students in clinical research of the ALF region. The hearings focused on discussing the four components, with the intention of supplementing and clarifying the evidence submitted in the self-evaluations. In conjunction with the site visits and hearings, an overall assessment was made for each component, and in addition a preliminary assessment for the entire ALF region regarding the prerequisites for clinical research present. When the panel's three groups met again after the site visits and hearings, the results were discussed in order to calibrate and jointly agree on a balanced assessment of all ALF regions.

Step 3

In the final step, the results of the panel, according to the four-scale assessment scale, were converted to the three graded evaluation categories developed by the National Steering Group (poor quality, good–high quality or very high quality). Each ALF region was to be grouped into one of the three ca-

tegories. In addition, the panel agreed on a summary assessment that justifies the categorisation. The panel also summarised its general reflections on the prerequisites for clinical research in Sweden in the seven ALF regions.

The purpose of the above process was to create a clear and transparent evaluation of the prerequisites for clinical research in the seven ALF regions, so that each region is assessed based on its prerequisites on an equivalent scale.

Panel meetings

The panel met in Stockholm in connection with the site visit during 14–19 January 2018. Members of the panel are jointly responsible for the final assessments and the panel's report. Discussions to calibrate and jointly agree on a balanced assessment of all ALF regions were carried out after the site visits. All panel members noted all the evidence for the assessment of the seven ALF regions and participated actively in hearings with representatives of the ALF regions in the three groups reported above.

Project organisation

The project team at the Swedish Research Council consisted of Maria Bergström (project manager), Maria Starborg (assistant project manager), Gustav Hansson, Richard Andersson, Ulrica Horwath, Magnus Lagerholm and Carl Sundström.

Reflections and general comments

Regionalization of health care in Sweden integrating primary, secondary and tertiary care provides an excellent basis for collaboration between health care professionals, providing coordinated care to the patient throughout the health care system. A joint strategy between county councils and the universities to engage all health care professionals in education and research is the basis of high quality of care.

Sweden has established an important system for securing clinical research in the regions through the ALF funding mechanism. ALF funding forms the background, financing resources and time for clinical research. These are very important prerequisites and foundations to promote clinical research regardless of the scope of the research. Clinical research requires easy and open access to relevant available infrastructure and resources, including core facilities, registries, technical platforms, biobanks etc. The evaluation panel recognizes the importance of how core funding is used to support such platforms and the relevance of this funding to help improve health care in the country. The panel reflections should be considered alongside those made by the other two international panels for further developing the system.

The present panel has evaluated the prerequisites for clinical research in the seven regions that obtain ALF funding and the overall impression is that the money is well spent, and that the investment made provides excellent value for the Swedish population.

One potential challenge for excellent collaborations in clinical research is that the health care systems and universities are separate entities. The ALF money is intended to solve some of this challenge, but this depends upon very good leadership from the top to the bottom of the key partners to promote a shared vision and strategy. The regions have very different resources, and there seemed to be variable ways of allocating resource, with some regions predominantly devolving the funding to areas of existing strength and other regions concentrating more on investing to intentionally uplift some less resourced areas of activity which were thought to be strategically important.

The regional system seems to function well, but the panel felt there was a need for joint national strategies and discussions between the regions to deal with some issues. Sweden has several extensive health registries which create excellent possibilities for clinical and translational research, in particular if combined with biobank data. The present system with several hundred "private" biobanks is a hurdle, and further developing an integrated National biobank system should be encouraged. This will further strengthen Sweden as an excellent contributor to international clinical epidemiological research and provide a platform to help with the development of new therapeutic strategies to benefit patients.

In general, mechanisms to allocate time for research and structures to support career development are well organized, but the variation between the counties is too large and optimal solutions can still be harmonized. A special challenge is the need to increase research in primary health care throughout Sweden to strengthen the focus on the whole health care chain, rather than just concentrating on the secondary care sector. Ideally this would result in a fully integrated research strategy across disciplines: this will be needed to drive improvements in health care.

The PI survey in all regions showed that very few clinical researchers go abroad, either as postdoctoral fellows or on sabbaticals. The panel thinks this is a neglected area that is important for the future of Swedish medical research, and that providing some incentives to support international collaboration would be beneficial.

Whilst the panel has identified some areas for attention, overall the panel was impressed with the general level of support for clinical research in Sweden, and no region was considered to fall into the category of having inferior quality prerequisites for research. Three regions were considered to meet the criteria for very high quality performance. It is important to note that this is not an assessment of the extent of the physical infrastructure itself, but rather how the ALF funding available to the region is used to support research. These regions all showed evidence of strong partnership working between the county council and the university at all levels. In addition, there was a shared strategy for clinical research that was evident at all levels in the organizations, with clinical research being a priority for both organizations. Finally, there were robust and strategic approaches to allocate time for research and to foster the next generation researchers.

Assessment results

ALF-region Stockholm

Overall assessment

Good-high quality

Clinical researchers in the Stockholm region have the possibility of accessing world-leading infrastructure. The region seems to be in a strong financial position with joint strategies, including joint representation in strategic boards, and with formal agreements in place between key partners. At the top level, they are continuously trying to improve the environment for clinical research, and one of the important tools for doing this is through the research schools.

However, the two main institutions seem to be insufficiently united from a bottom-up perspective. The strategic agreement at the top level was not reflected at the departmental level. There are variations between departments, clinical areas and institutions in enhancing the clinical research environment which were reflected in differing approaches to allocating time for research and optimizing access to infrastructure. The county leadership could more clearly emphasize that clinical research with collaboration between health institutions and university is an important priority for all health deliverers (i.e. both public and private) in the region. Furthermore, as the pre-eminent research region in the country, there is also an opportunity to take a more active role in coordinating and maximizing use of research infrastructure throughout the country, and for the region to collaborate more extensively on a national basis. Career paths could be more flexible, also encouraging medical specialists to start a PhD in a later career stage. The new organizational structure at the university hospital is an opportunity for enhanced collaboration in a long-term perspective, but may also represent a challenge as it may be energy-consuming during the implementation phase.

Whilst significant strengths existed in terms of the nature of the arrangements to access research infrastructure, the overall strategy to support researchers at all stages of their career and secure time for research, some weaknesses were identified regarding implementation of the strategies further down in the system, securing the best use of the available resources and co-ordinating the use of allocated research time. Hence the ALF-region Stockholm was assessed as being of good to high quality.

Access to Research Infrastructure

The amount and quality of the research infrastructure for clinical research in Karolinska Institutet (KI) and Stockholm County Council (SCC) are very well suited for the delivery of clinical research. The university and county are jointly committed to a major investment plan for infrastructure to develop modern laboratories and state of the art methodologies with a jointly generated priority process to support research infrastructure and several specialized advisory committees to promote adoption of new technologies in clinical research. Infrastrukturrådet (IR) evaluates and monitors the organization of facilities. A core facility group reports to Infrastrukturrådet on research needs through a bottom-up process.

Recent large investments include translational research laboratories – Bioclinicum and the build-up of Biomedicum that will provide space for about 100 research groups. An overarching principle has been to concentrate the different infrastructures in close connection to the Karolinska University Hospital to promote interaction and collaboration.

Karolinska Institutet and the county council have identified six important areas in need of further development of research infrastructure. Among these, the animal facilities have been reorganized to provide "modern housing" with experimental facilities. KI Biobank is integrated with SMB to become a service organization allowing collection of biobank samples. SciLife Lab started in 2009, and is a joint activity between four partners (Karolinska Institutet, Royal Institute of Technology, Stockholm University and Uppsala University) representing a successful example of a long-term strategic invest-

ment at national level. The Karolinska Cell Therapy Center is a special resource to guarantee Advanced Therapy Medicinal Products (ATMP) and cell therapy products for unmet clinical needs. A specific unit, The Karolinska Trial Alliance (KTA) exists to facilitate clinical trials set-up and performance, and this support seems to be well appreciated among clinical researchers.

The county council has three major foundations: Center for Molecular Medicine (CCM), Center for Cancer Research (CCK) and Center for Innovative Medicine (CIMED) to support clinical research. These host unique long-term core-facilities that are open to all scientists. Annual funds are generated for core facilities with commitments for 3-year support cycles. The reimbursement system for researchers is based on performance and support of research facilities.

The information channel for access of infrastructures are joint websites at the ALF-region, and users are further guided to more detailed homepages. Facility Expo was organized in 2017. A transparent user-fee model of services is developed. However, the feedback from clinical researchers in the region revealed that there was still some lack of knowledge of the available facilities and thus variable access, and therefore these may be underused, especially by clinical researchers.

Overall, the infrastructure for clinical research at the region is close to exemplary and forms a foundation for excellent research. However, the dissemination of the knowledge about and the access to the research infrastructure in the departments can be improved to fulfill the potential.

Time for Research

Time for research for clinicians can be funded in three ways; either by external funding outside the ALF/County Council (CC) model, through application to one of the different positions in the ALF/CC funding model, or through applications to the more competitively funded ALF/CC projects. Altogether, 75 percent of the 157 competitively funded ALF/CC projects were used to support salaries in 2016.Time for research is secured in contracts signed by the research director, the employee and his/her clinical director. Research conditions, including time for research, are reported in annual reports. A recent survey has indicated that 98% of the research time has been used, which is an extremely good result.

In reality, leaders at the hospital departmental level, the students and postdoctoral fellows regarded accessing protected time for research as a challenge. Even if many of the students confirmed that they were allowed to use their contracted research time, the possibilities to use the time varied between departments depending on the research area, the size of the department/section and also depending on the position of the researcher. In general, it seemed to be easier to take out research time as a resident and more difficult as a specialist due to a lack of clinical specialists/sub-specialists within the departments. Also, as the ALF funding is provided as a defined amount of money, using it to support research time is more expensive for the department if the researcher is a specialist than a resident.

In the new hospital management plan, time for research is intended to be reported monthly in each department, which may further secure the intention of ensuring that time allocated to research is actually used for that purpose. This will allow better monitoring, follow-up and evaluation, and give a better possibility to create solutions for the areas that struggle.

Next Generation Researchers

Stockholm County Council and Karolinska Institutet (KI) strive to expose students at an early stage to research through clinical science training programs. These programs finance PhD studies for undergraduates in medicine (MD/PhD), psychology, dentistry and speech therapy. The programs also finance 'Forskar-AT' for PhD students and medical post-doctoral fellows; and 'Forskar-ST' for residents who combine their PhD studies with training in a medical specialty. The calls for PhD grants are widely communicated.

The number of PhD students who undertake PhD studies in parallel to clinical work has increased. There is also support for the education of some of the existing PhD students in research schools, giving the students a comprehensive educational offer customized to the different clinical disciplines (in Epidemiology, Molecular Medicine, Psychiatry and Family Medicine). Currently, only 40 percent of all clinical PhD students at KI are part of such a research school. The 2018 Karolinska Institute

strategy is to increase the number of PhD students in research schools by 25 percent through lowering the number of courses in each research school. Since the research schools are highly regarded both by the students and the university and may be particularly important for PhD students undertaking their studies as part-time students and part-times clinicians, it would be sensible to consider a further increase in availability of such schools for clinical PhD students.

As a high-quality institution Karolinska Insitutet has a focus on competition. However, such a focus can be a threat and create stress for young students and researchers at the start of their career, with the risk of losing potentially good researchers due to the competitive environment. A highly competitive environment might also oppose open and interdisciplinary collaboration across institutions. Another concern is that the higher economical costs of medical specialist PhD students form a hurdle for starting a PhD in a later career stage.

Career Models

The region has a comprehensive career model in five stages for clinical researchers with economic incentives in place. It is also a goal that all managers at the university hospital should have a PhD and for the top positions to be held by clinical researchers at professorial level. The competition to get combined positions is very high and the number seems limited. The impression is that it is difficult to do clinical research without having these combined positions even though the variations between the departments seem to be significant. There is clearly very high competition to obtain research positions in the region, but more could be done to the career model to secure the importance of collaboration. Many clinical researchers seem to undertake research mainly within their own departments and research groups, and a strategy to promote collaboration between departments, Karolinska Institutet and other institutions is warranted.

Evaluation of the PhD program is based on exit polls. A continuous improvement cycle would potentially be beneficial including collecting anonymous comprehensive feedback periodically.

The region could facilitate more mobility both by formal agreements with other regions and also by more open and collaborative attitudes to promote research experts to work in other parts of Sweden. This would also bring benefits in other regions.

ALF-region Västra Götaland

Overall assessment

Very high quality

The collaboration between University of Gothenburg and the Västra Götaland health region works excellently. HälsoSam is a joint, credible, non-political steering committee. HälsoSam makes decisions on overall strategy, budget and the final acceptance of R&D projects. The overall governance structure is transparent and well supported throughout the organisations.

The aim to create a critical mass of high quality clinical research leading to improved health is clear. Research applications and projects are set up in agreement between the researchers and heads of departments, often focusing on problems identified in the clinic. The leadership creates and spreads confidence and enthusiasm. Younger and senior researchers state that their leaders are supportive and provide good conditions to pursue research.

The region has highly relevant, easy available, well-functioning infrastructure and preconditions for clinical research in place. There is considerable focus on gender balance, multi-disciplinary research and internationalisation. Together, this has paved the way for high quality research resulting in health care improvements. The majority of the ALF grants are allocated 'bottom up' and announced in open competition, but there are clear coordinated processes at all levels to ensure funds are allocated in line with the overarching strategy.

There has been a considerable shift from a purely financially orientated focus to recognizing the value of high quality clinical research in the clinical departments. Support spanning all stages on the

career ladder from students to professors in combined positions is excellent and securing research time is working well. Most heads of clinical departments have academic backgrounds, securing a focus on research.

Given the comprehensive nature of the arrangements to access research infrastructure, the strength of the overall strategy to support researchers at all stages of their career, and the co-ordination of the use of allocated research time ALF-region Västra Götaland was assessed as being of very high quality.

Access to Research Infrastructure

The goal in the region is to pursue the creation of knowledge within the health science sector in order to provide the best possible environment to facilitate prevention, alleviation and treatment of disease. There is a joint strategy between the county council and the university on how to secure, finance and maintain research infrastructures. There are good examples of the success of this approach, exemplified in areas including gynaecology, management of leukaemia and psychiatry. A wide range of highly relevant, high quality clinical research facilities and core facilities is available to support clinical research in the region. These infrastructures are established, evaluated and run in close collaboration between the university and region. Knowledge about these infrastructures is well distributed and a supportive website is in place. Additionally, introductory courses presenting the different core facilities are offered, and there seems to be a general awareness of the availability of the different research infrastructures among researchers.

The facilities are open to all researchers regardless of their employment and the fees for using the facilities are transparent and reasonable. Clinical core facilities especially emphasized include the Gothia Forum which provides help in completing research applications; the genomics core facility; the innovation core facility; the health metric unit and the regional biobank which collects together previously widely spread "private" biobanks. One point of minor concern is a relative lack of more basic administrative support for running clinical trials in the departments for busy clinicians. This would include for example help with sending out invitations to research subjects, and collecting and processing data.

In summary, there is an excellent environment in place with established and well-functioning clinical research infrastructure. In order to reach this level, ALF funds have been instrumental, and continue to be allocated strategically.

Time for Research

The regional health care system has gone through considerable changes in recent years. This includes a paradigm shift from a production-orientated system to a system focusing on the value of clinical research and the need to develop a healthcare system based upon a quality-based concept. An ALF supported system enables recruitment of researchers in an effective manner. This makes clinical research possibilities readily available for employees and young researchers in the region.

Clinical research is now highly prioritized throughout the health care system, decisions supporting this focus are followed up in the departments, and time allocated for research for PhD's, postdoctoral positions and assistant professors is incorporated into the system and works well in practice. Additionally, research active consultants are allocated time for research by their departments in order to facilitate clinical research. In practice, if an application is sent six months in advance, time to do research is usually secured if the application is granted. Most leaders in the departments have an academic background, and because of this, the system seems to function effectively to reduce potential conflict. A reporting system with individual accounts and monthly reports is used. Whilst securing clinical operation has to be prioritised, if time for research needs to be postponed, it is compensated at a later stage.

Next Generation Researchers

An effective and highly appreciated career ladder including seven steps with financial support during the career makes research possible in combination with clinical work. In addition, approximately 64

percent of the ALF money in the region is available through project grants applied for in open competition. About 16 percent of the funds are distributed to persons with combined positions between the university and healthcare (professors and lecturers). In order to recruit the next generation researchers, a program containing MD-PhD, AT-PhD, ST-PhD is in place. Furthermore, there is an economic incentive to carry on with research, including a salary rise when reaching a higher academic level. Support from the Wallenberg institution is also important for recruiting top national and international researchers.

In order to have a suitable recruitment basis, the research education is set up in a coherent system, starting with an MD-PhD or PhD and progressing to postdoctoral positions, associate professor and full professorship. There is a wish both from the university and from the hospital departmental heads to send young researchers abroad to get international experience. The system thus has a special focus on young investigators, aiming to stimulate independency so that young investigators can establish their own research groups. The competition to get a position within the system is significant, but is perceived as fair as it supports quality and the most talented and ambitious researchers. The PhD period is often very long when performed in combined positions, and consideration should be given to the idea that publications published before enrolment in the PhD program could be able to be included in the PhD thesis.

The existing system works very well to support good clinical researchers. There is however, a concern that too few young doctors are involved in basic research, this may reduce the ability to deliver high quality translational research. Similarly, the opportunity to perform basic research in later stages of the career also needs attention.

Career Models

As discussed above, the career model in place in general works effectively and supports career development across all stages of the career.

A minor concern was that an uneven gender distribution for receiving larger grants seems to exist, but this is probably due to socio-historic circumstances and not on how the current system for clinical research is set up, and this issue is not unique to this region. There seems to be an active attitude to support women at all organizational levels and change is underway to help achieve a better gender balance in number of professors and leaders. The fact that female researchers still receive less funding must though have a continuous focus.

A general hurdle throughout Sweden is to become independent and establish your own research group. After successful PhD and postdoctoral periods, the possibilities for funding are often sparse when you reach an associate professor position. In this situation ALF funding should be used strategically to make it possible to establish your own research group. It is a particularly positive step that the region has paid special attention to this problem by establishing a new category position, the universitetssjukhusöverläkare (University Hospital Senior Clinician). This has proven very successful in order to secure the possibility of performing long-term clinical research.

In conclusion, the prerequisites for a clinical research career are well structured and are working well.

ALF-region Skåne

Overall assessment

Very high quality

The collaboration between Lund University and the Skåne health region is long-standing and works excellently. The strategies and decisions made by the ALF steering group are supported at all levels in the organisations. The way in which ALF resources are allocated is transparent, functional and credible.

The overall strategy is to provide the best environment possible for high quality clinical research and to foster the next generation of clinical researchers for improved diagnostics, prevention, and tre-

atment of disease. Clinically relevant research is stimulated through bottom-up open calls but there are also calls with a focus on specific clinical areas deemed to be important. The leadership creates and spreads confidence and enthusiasm. Younger and senior researchers state that their leaders are supportive and provide good conditions to pursue research. Researchers in both organisations have equal and easy access to relevant, high quality research infrastructure.

The seven-step career ladder that has served as a role model for health regions in Sweden works well. Recruitment into career track research active positions is highly competitive but fair. There is considerable focus on gender equality, multi-disciplinary research and internationalization. Most heads of clinical departments have academic backgrounds and have a focus on research, and the mechanisms in place to secure time for research in the clinic are working well. Together, this has secured high quality research resulting in considerable health care improvements.

Given the shared strategic vision of the partners, the comprehensive nature of the arrangements to access research infrastructure, the strength of the overall strategy to support researchers at all stages of their career, and the co-ordination of the use of allocated research time ALF-region Skåne was assessed as being of very high quality.

Access to Research Infrastructure

The overall aim in the region is to provide the best environment possible for high quality clinical research and to foster the next generation of clinical researchers for improved diagnostics, prevention, and treatment of disease. This aim is translated in the region in a way that is efficient, transparent and credible by a strategy that ensures easy access to infrastructure.

The board of directors is well interconnected and reflective. They present strategies on how to ensure easy access and to set up necessary clinical research infrastructures, including regional and national registers, biostatistics support, biobanks and other core facilities. There is an infrastructure group with representation from both organisations and with a clear aim to constantly develop and improve clinical facilities. There are several good examples of this effective joint working, one being Forum South, a dedicated clinical trials and competence centre. This centre provides expertise and support for researchers on study design, statistics, ethics and more. There are a large number of high quality registries available for both the university and region. These registries cover a wide range of areas with cross-referencing possible which helps ensure maximum value from the use of these resources. Lund University Bioimaging Center offers a range of modalities including MRI, PET/SPECT/CT, electron microscopy and a national 7T MRI facility. The Center of Excellence in Biological and Medical Mass Spectrometry for biological and clinical research is highly interdisciplinary.

Thus, the infrastructure is well developed, with state of the art facilities that are managed in an effective way to promote access by researchers. The promotion of the facilities includes a website, a monthly calendar, and outreach activities. Access is in general very good, and young investigators in particular have easy access often assisted by the supervisor or other more senior figures acting as an intermediary. The infrastructure fees are subsidised and hence generally affordable for users. Introductory courses for PhD students are available, but due to the many advanced features of the steadily expanding and advanced infrastructure already established refresher courses for researchers and supervisors might be of benefit.

Time for Research

As discussed above, the overall strategy is to provide the best environment possible for high quality clinical research, and this extends to ensuring adequate time is allocated for research. To secure a structured and reliable system for allocation of research time, all decisions relating to time for research in the clinic are made with full involvement and consent from the heads of clinical departments.

Whilst a system to secure adequate allocation of time for research has been in place for a long period, many modifications have been made over the years, and it is clear this process is actively managed.

The management has established a number of specific programs so that clinically active researchers can combine research with their clinical work. The ALF research committee plays a key role in this process by the development of specific strategies and various support structures to encourage this activity.

In order to secure research time for clinicians with pressure from clinical commitments, a process for defining, allocating, monitoring and managing research time has been developed. This system works very well and appropriate clinical work time and research time is usually granted. A large group of researchers spend equal time in the clinic and research (50–50%), but other distributions of time allocated have also proven valuable. A salary incentive system is in place to avoid loss of money if a clinician pursues a combined research position. The same salary is given to those working 100 percent as residents as those combining clinical activity with research support by ALF funding.

Overall, this system is working excellently. The system for allocating time for research is respected at all levels in the organization, and the researchers acknowledge that the contracted time for research is available for them.

Next Generation Researchers

Skåne developed 20 years ago a unique programme aiming to recruit clinical researchers. A seven step "young researcher's programme" was established starting with medical students taking a PhD, followed by AT-PhD, ST-PhD and so on. This is now the role model for several similar programs in other Swedish regions. Young researchers describe that they were satisfied with their PhD period, including education, guidance and support.

The system is regarded as being highly competitive, but fair. If you are dedicated and ambitious, you have a good chance of obtaining grant funding to support research. Thus, students and young doctors in general find it possible to do clinical research, and when they chose to do so they are well taken care of. The systems seem to work best for those who run through the programme from the start. However, for consultants with no research experience that have already finished their residency, finding grant support for PhD positions and research is somewhat more difficult, as they do not fit into the career ladder.

The ALF system works well in conjunction with the funding of the Wallenberg foundation where Skåne region has made special arrangements to attract international young researchers and pairing these with upcoming national investigators with potential for becoming future research leaders. This is highly successful and has led to an increase in the numbers of awards of young investigator ERC grants.

Career Models

In general, the environment for developing a clinical research career was well structured and works well. This was particularly the case for the earlier stages of the research career where the career model is working excellently from medical student to PhD student. Also post doctoral positions are handled well in the present system. When climbing further up in the academic career ladder the positions are more competitive, but the system is still considered fair and on a high international level. For many, as noted elsewhere in Sweden, a PhD is regarded the final ticket to a consultant (överläkare) position in the university hospital. In this situation ALF funding could be used more strategically to help make it possible to establish new research groups. As an example, there is a salary incentive scheme in place for those choosing an academic path in parallel with specialist training. Additionally, the region has a considerable focus and supports both ingoing and outgoing exchange of academic clinicians to promote a higher degree of internationalisation.

Although there is a majority of women in PhD and post doc positions, only 24 percent of full professors are women. An uneven gender distribution of larger grants also exists. Encouragingly however, there is an active attitude to support women at all organizational levels and change is underway to address gender balance in the number of professors and leaders. Similarly, the fact that female researchers currently receive less funding has a continuous focus.

ALF-region Uppsala

Overall assessment

Good-high quality

The Uppsala ALF-region has several strong research areas, including cardiology, oncology, Women's health, antibiotic resistance, and radiation therapy. At the highest level there seems to be rather variable relations and communication between the University and the Region. 25 percent of the ALF budget is kept at this strategic level to jointly fund more expensive infrastructure and the Gullstrand research positions. However, most of the funding decisions are made in 23 Councils for Research, Education and Development, to which the remaining 75 percent of ALF funding is distributed. There appears to be a lack of joint strategy on prioritization and long-term goals. While some of the infrastructure is world-class and also of national importance, access to infrastructure is rather variable. The need to set up additional local infrastructure in parallel to centrally funded infrastructure reflects the less than optimal functioning of some of the core infrastructure. There is also variation between departments regarding the emphasis on research which in turn leads to variability in the allocation of time available for research. There is some support for early stage clinical researchers, postdoctoral and early stage independent researchers, but again coordination is mainly at department level and less at the university/hospital level. There is also ear-marked ALF-funding for PhDs in allied health professions such as nurses and physiotherapists. The Gullstrand positions are filling some of the gaps between the postdoc positions and permanent positions.

Thus, whilst some of the research environment in Uppsala is excellent, there is a clear potential for further improvement through a more coordinated approach by the university and county council. In addition, whilst some aspects of the processes to access research infrastructure work well, in other areas improvements could be made to facilitate access. Similarly, whilst some areas of strength were identified in support for researchers at all stages of their career, and the co-ordination of the use of allocated research time, some weaknesses also exist in making the best use of the available resources. Hence, ALF-region Uppsala was assessed as being of good to high quality.

Access to Research Infrastructure

Uppsala has well developed physical research infrastructure, with some nationally important facilities such as the Uppsala Biobank (including the UCAN project), a PET/MR unit and a new proton therapy unit. The large infrastructures are providing professional research services, and many of them were in a process of further developing their services and have a lot of potential. The SciLife national infrastructures seemed highly valued and well-functioning. Major infrastructure was partly funded from several different sources, including the county council, university, ALF committee, and from national funding. These all make their own decisions, but there is some coordination through joint committee members. Funding decision are made for 3 years at a time enabling longer term development and maintenance.

New focused research centers of excellence were established recently (MedTech Science and Innovation Centre, Uppsala antibiotic center) to provide opportunities for multidisciplinary collaborations.

Overall, however, there seems to be a lack of overarching infrastructure strategy despite the representation of both the university and hospital in various committees deciding on financial support. Despite some of the infrastructure being world-class it remained unclear if there was access for research patients to the clinically used infrastructures during normal working hours, and how projects were prioritized when there was excess demand. Hence some local units had been set up in parallel to the major, hospital/university/ALF supported units which suggests there is less than optimal functioning (or possibly high pricing) of the available jointly funded infrastructure, such as the clinical trial unit.

Access to some of the infrastructures, such as the clinical trial unit and tissue biobank seemed variable and at times dependent on the area of the research or on knowing the right person to faci-

litate access. This had led to delay in some projects, particularly those involving young investigators. The user fee structure of some infrastructure did not facilitate usage by the less well funded areas of research.

New developments in infrastructure, such as the new proton therapy unit, will provide opportunities for strategic recruitments and the strengthening of certain research areas.

Time for Research

There is a reasonable critical mass of researchers and strong university departments with which researchers can collaborate so research time should be well spent. In general, time allocated for research could be used for research. The Gullstrand funding scheme seemed to be valuable and provided protected research time. This was appreciated by trainees although there seems to be insufficient number of positions available.

There was a major weakness in that the institution lacked a clear overall strategy to maximize the way in which research time could be used to underpin research strengths and infrastructure. This was reflected in the way in which research time was allocated and the way in which researchers currently utilized their allocated research time. Use of dedicated research time appeared to be almost entirely at the individual researcher's discretion, and whilst some researchers were clearly successful, others were potentially lacking strategic direction as a consequence of the lack of overall vision and associated strategy. The current devolved nature of research resource allocation made it difficult to use resource strategically to address this issue. Any difficulties with ensuring that contracted research time was protected, were dealt with locally within hospital departments, and it was unclear what if any mechanism existed to resolve disputes where they arose. Perhaps in part because of these issues recruitment was a problem to key clinical academic positions as they became available. Particular problems also existed in ensuring that PhD students that were not ALF funded were allocated sufficient research time.

Whilst the ALF –region Uppsala has a strong academic tradition there is a significant risk that recruitment and retention of clinical researchers will be problematic in the future if the issues identified above are not addressed.

Next Generation Researchers

As discussed above there are a number of strong research groups within the hospital and university, including cardiology, oncology, women's health and research into antibiotic resistance. Uppsala also has a very strong university outside the medical faculty. Thus, the environment to train the next generation of researchers should in theory be excellent, and there are widespread opportunities for cross-disciplinary research. However, the lack of coordination between the university and hospital above the department level, and the decentralized model where the allocation of 75 percent of ALF money is at the department level, means that overall strategies to support the next generation of researchers are often missing.

25 percent of the ALF money is put centrally into the Gullstrand positions, which were seen as a successful program.

The lack of coordination between hospital and university may kill talent and in the end reduce the quality of research. It is also a problem that very good infrastructure may not be utilized maximally to support the next generation of researchers. This threatens the recruitment of next generation researchers at Uppsala. The slight decline in PhDs over the last few years may be a consequence of this.

Career Models

The goal is to ensure a high number of research-educated health care professionals in all disciplines in the region. In addition to medically qualified individuals there is ear-marked ALF-funding for PhDs in health categories such as nurses and physiotherapists. Also, financial incentives are in place to compensate for potentially slower salary increases for active researchers needing to complete specialist training and also to complete a PhD. A PhD is required for senior consultant positions. International

postdoctoral positions and sabbaticals are encouraged and supported, although take-up remains fairly low. Gender balance in recruitments is actively considered. Specific post-postdoctoral positions are available through the highly competitive Gullstrand positions where candidates get combined clinical and research positions for 3–5 years, although the number of these positions remains small

Despite these positive aspects, there seems to be little coordination between the hospital and university regarding support for early stage clinical researchers, and coordination is mainly at department level and less at the university/hospital level. In particular, postdoctoral and early stage independent researchers seem to be less well supported and were not generally being encouraged to apply for international grants.

The Gullstrand positions are popular and seem to be good tools which can be expanded, the same goes for other postdoctoral positions which could be increased.

Although the dialogue between the hospital and university organizations at the more strategic level has improved somewhat during the past 2–3 years, it would certainly benefit from even closer dialogue. There are obviously many talented clinical researchers who will benefit from such coordinated leadership support.

A lack of encouragement and support from the ALF-region will result in retention problems of talented young clinical scientists. Increasing financial constraints on the clinical departments may pose a threat to the funding of research time for young researchers, since the departments fund a large part of the candidates research time at present.

ALF-region Västerbotten

Overall assessment

Very high quality

The size, geographical location and the demography of this region pose unique challenges, but also some opportunities for research that ALF-region Västerbotten are systematically addressing. They have access to a population of approximately 1 million and work closely with Östersund, Sunderby (Luleå) and Sundsvall local hospitals. These hospitals are integrated in the overall research strategy by the allocation of academic staff and research resident positions.

There is excellent regional research infrastructure such as the Wallenberg Centre for molecular medicine, The Molecular infection Medicine Sweden institute, The Centre for Medical Technology and Radiation Physics, Chemical Biology Centre, the SciLife Laboratory, the 6M building for translational research along with an established structure for primary health care research. These are readily available for researchers.

Västerbotten has a strong and coherent strategy for securing capacity for clinical researchers to spend time undertaking research. In addition, the two tier tenure track for researchers, with parallel and flexible interconnected academic clinician-scientist track at the university and clinical researcher track at the hospital, which is unique for Västerbotten, and an excellent strategic move, encouraging young researchers to choose an academic career at an early stage. The agreements between hospital and university are made at a strategic level, thereby facilitating the young researchers' access to resources.

A clear strategy in establishing and supporting excellent infrastructure and well-organized career tracks compensates for possible recruitment issues, although retention of good clinical researchers will be a critical factor during the next few years. By continuing their current strategies to support career pathways, further strengthening their infrastructure and expanding the collaboration across the faculties of the university they should overcome these challenges.

Given the comprehensive nature of the arrangements to access research infrastructure, the strength of the overall strategy and collaboration between the county and university to support researchers at all stages of their career, and the co-ordination of the use of allocated research time ALF-region Västerbotten was assessed as being of very high quality

Access to Research Infrastructure

There is a jointly owned, well thought out strategy of setting up, maintaining and evaluating major infrastructure by the ALF-region. A number of impressive nationally recognized facilities exist, with expert staff, which is efficiently shared between the research and clinical use based on contracts between the county council and the hospital and available for clinical researchers of both employers. Joint research laboratory facilities for basic and clinical researchers enable and enhance collaborations.

The ALF- region has a broad range of high quality infrastructure for pre-clinical and clinical research. The state of the art imaging facility providing 3T MRI and also PET MRI is efficiently shared between research and clinical use, and supported by expert radiochemists and the cyclotron currently providing an impressive amount of 14 different tracers for research and clinical use. There is equal access to the infrastructure by university and hospital researcher.

Umeå University has made high-quality translational research available through the nationally supported infrastructure of the SciLifeLab which in Umeå includes the Swedish Metabolomics center, the Swedish NMR Centre, Cryo-EM and Chemical Biology Consortium Sweden.

The 6M building owned by the county council harbors clinicians, scientists and health care laboratory operations researchers and functions effectively to enable novel collaborations and sharing of expertise.

The university campus with several excellent additional institutes within the natural and social sciences is located in close vicinity to the Hospital, facilitating cross-disciplinary research.

A set of clinical trial units in Umeå and the other county hospitals, enables recruitment of out-patients, and collaborations with relevant hospital departments work well when an overnight stay is needed. Researchers have access to samples from the unique regional biobank cohort and registry which covers an impressive proportion of the population, and expert assistance in dealing with the regulatory requirements, ethical permits, project design, are easily available. However, access to the follow-up, registry and clinical data for phenotyping is under development, and is at the moment not up and running. Modern biobanking facilities for sample types other than blood are also at the moment missing and this is an area which requires addressing.

There are unique opportunities to undertake research which is specific to this northern region (examples include primary care research in remote areas, telemedicine to support research, climate change related projects).

Joint decision-making, coordination and strategic resourcing by the hospital and university, combined with research excellence in focused areas, enables setting up national infrastructures that will further strengthen the research and help with strategic recruitments.

Time for Research

Västerbotten has developed a clear strategy for securing capacity for clinical researchers to spend time undertaking research. There is good capacity in terms of the numbers of research-active clinicians. The devolved model could potentially lead to clinical researchers based outside of Umeå having less time for research, but it seems that significant time was available for research in other centers as well. They have established good working relationships between the county council and university staff to ensure no barriers or unnecessary delays for accessing core facilities. In addition, there appears to be a reasonably robust process to ensure that job-planning is reviewed and to ensure that clinical researchers with protected research time are actually able to use that time for research. There are clear strengths in the processes allowing access to imaging, nuclear medicine and biobanking infrastructure, and the charging structures appear transparent, and researchers reported no significant delays in accessing infrastructure.

The large geographical spread of the region and the devolved nature of the medical school could have led to researchers working in centers where they are relatively isolated, and inefficiencies in time utilization, but the ALF-region has evidently put in place mechanisms to address this issue, and has turned these challenges into benefits.

The majority of active clinical researchers in this region are 'home grown', and are thus hopefully well placed to take advantage of the ability to access infrastructure which can support their research. Focusing projects on areas of research strength and ensuring continued access e.g. to nuclear medicine capabilities will be important.

The major threat is that the best researchers currently active in Västerbotten might relocate to other centers, thus reducing critical mass and placing additional time pressure on researchers who remain. The age profile of the faculty is such that a significant number of senior positions will become vacant in the next 5 years which could also create time pressures on remaining researchers due to the additional service demands a reduced workforce would create on clinicians.

Next Generation Researchers

Given the challenges posed by the imminent retirement of some senior academic staff, the building up of new scientific staff is important. The close coordination between hospital and university has made it possible to create a two-tier career program where the young doctors after finalizing an initial period of research can choose either an academic clinician-scientist track or a clinical researcher track. In both tracks they will potentially have 33-50 percent time for research.

The university and the hospital are very closely aligned, facilitating cross-disciplinary research projects also outside the medical field. For example there are already joint projects with the physics department and informatics department at the university, and there is scope to broaden such collaborations in large cross-disciplinary projects.

The decentralized model where about 10 per cent of the faculty is placed at three other hospitals, has made recruitment of researchers from the local hospitals possible, and has led to several high-quality papers from the local hospitals.

The program involving general practitioners in research combined with the National school in General practice has led to several primary care doctors undertaking PhDs and continued collaboration with the university.

ALF money is used for a salary incentive program that works effectively.

The region has established several international postdoctoral programs and this also facilitates recruitment.

Since this region occasionally has challenges in recruiting health professionals in certain areas, there is a risk that there will be a limited number of candidates for positions. The region has tried to compensate for this by instituting the tenure track incentives and facilitating access to advanced infrastructure.

The success rate for female applicants for attracting ALF grants could be higher. This may require more attention unless success rates increase in the near future.

The close geographical vicinity between centers of excellence in natural sciences and the hospital and the faculty of medicine in Umea facilitates cross-disciplinary research.

In addition, the location of an advanced university in a relatively scarcely populated area provides opportunities for dedicated research in telemedicine, infectious diseases and other topics where these conditions are an issue.

Career Models

The County Council and University jointly have a clear and comprehensive career model with two arms in place; one being the clinical researcher track and the other being the academic clinician scientist track. This reflects a strategy to support careers across all stages. This commences at the student level (for all health care professions) where there are possibilities to get research experience. It is also possible to undertake international sabbaticals. There is a salary incentive scheme in place for those choosing a clinical research path in parallel with specialist training. The tenure track model is unique in Sweden.

The career program for clinician-scientists aims to bridge the 'gaps' – especially regarding mid-level tenure-track/meriting positions – in the clinician-scientist career path. There are two arms, to which

both the university and the county are committed. The program was expanded in 2016 with ALF- and County Council-funded career/mid-level postdoctoral positions which are also available for other health care professionals. The departments are enthusiastic about this tenure-track scheme, and talented applicants have already been successful in achieving national competitive grants.

This program has not yet been fully evaluated, and so far the first candidates are still only midway in their tenure tracks. In the future the program will be evaluated, and both retention rates and success factors need to be assessed.

Recently career support from ALF funding was opened to other health professions. It will be interesting to observe how successful this approach is and a further example of why evaluation will be needed. However, it seems likely that the program will lead to better retention of talented clinical scientists. The research school in general practice is also a good starting point for strengthening medicine in a very large geographic area where there is a need for high quality medicine in remote areas.

Even with good and innovative incentives in place there is a risk of losing very competent clinicians and researchers to larger institutions in Sweden, particularly since there is a general shortage of specialists all over Sweden in many disciplines. Recruitment internationally works well in preclinical disciplines, but less so for clinical positions. Retention of good clinicians will be a critical factor during the next few years, and this challenge comes in parallel with a wave of retirements in important positions. By continuing their current strategies for career pathways, strengthening their infrastructures and expanding the collaboration across the faculties of the university they should succeed in overcoming these challenges.

ALF-region Östergötland

Overall assessment

Good-high quality

The Faculties of Medicine and Science & Technology have a long tradition of fruitful interaction. There is a collegial and transparent environment in Region Östergötland (RO) and Linköping University (LiU) with accessible leadership. A joint multidisciplinary research strategy, including allied health care professionals, is a cornerstone in the clinical research profile and is supported by the entire region.

Following a Research Evaluation in 2014, the infrastructure and research support services have been expanded to facilitate clinical trials. Active recruitment of international top scientists has helped to build some world-leading centers to be included in the clinical research infrastructure in the region.

The university and region have revitalized the 'Student to Docent' program paving a path from medical school to associate professorship, including research in primary health care. In addition, opportunities exist for other health care professionals. However, few clinical researchers go abroad, and this reduces the possibilities for international collaboration.

The joint research strategy is fully and harmoniously endorsed by both partners. The organizational structure is convoluted which may pose a threat. The decentralized system for allocating time for research also poses a threat, especially in smaller departments with less focus on research. Thus, accessibility of time for research varies highly between departments, and is strongly dependent on the department heads.

Whilst significant strengths existed in terms of the nature of the arrangements to access research infrastructure, the overall strategy to support researchers at all stages of their career, and the co-ordination of the use of allocated research time, some weaknesses in making the best use of the available resources were identified. Hence, Östergötland County was assessed as being of good to high quality.

Access to Research Infrastructure

There is a longstanding collaboration between the region of Östergötland and the university with a number of joint infrastructures and joint investments. After an external evaluation of medical and health-related research in 2014, the overall infrastructure for clinical research was strengthened

through collaboration with the two other counties in the South-East Healthcare Regions (SEHR). This has led to the county council and the university being proactive in supporting and prioritizing new and important infrastructure to increase the amount of clinical research.

There is a long tradition of interdisciplinary collaboration and it seems easy to get access to and start new collaborations taking advantage of the research infrastructure. The region has a clear policy regarding subsidizing the use of infrastructure and charging all users the same infrastructure access fees. An important structure for clinical studies is the Forum Östergötland with a Clinical Research Unit and the biobank/core facilities. The activity at Forum Östergötland has grown considerably over the past years, but some researchers felt that more statistical and bio-informatics support was required to adequately support clinical research. The region has established and developed excellent infrastructures like The Centre of Medical Imaging and Visualization (CMVI)/ Centre for social and affective neuroscience (CSAN) and employed excellent academic and technical staff by an active recruitment policy.

Time for Research

The long-term collaboration between the Region Östergötland and the University of Linköping should also facilitate access to allocated research time. The first mutual policy to ensure time for clinical research was signed in 1997, but the evaluation in 2014 showed that this policy did not seem to produce the results intended. Several changes were therefore made in the model for allocation of time for clinical research. The research funding is now aimed to increase and be directed to more competitive research groups in order to improve the research quality. While it previously was too easy to get funding for small research grants, the new policy has lowered the grant success rate from 95 to 60%. The decentralized structure has persisted, and as a consequence the responsibility for time to research is thus devolved to the Production units (PU) and heads of department. To better ensure the research focus in the departments, since 2015 each PU (which may consist of several departments) should have a Head of Research. There are annual audits and annual planning meetings to demonstrate and plan the use of research time in the departments; and this is controlled by the Research Support Unit. To enhance the management's focus on research, there are now mandatory research courses for clinical Heads (as of 2017).

Currently, the accessibility of time for research seems to vary highly from hospital department to hospital department, and is strongly dependent on the clinical department heads. For example, some hospital departments have hired extra doctors to ensure that the contracted time for research could be secured while in other hospital departments the researchers struggled to get their allocated research time.

The formal structures are very complicated and unclear, and it was therefore difficult to see who really had responsibility and power to decide upon allocations of time for research in the departments, and how the control systems worked. This may in part be because of the decentralized system which is in place and it seemed to be a particular issue in smaller departments with less focus on research. An interesting compensatory mechanism has been established involving retrospective funding to ensure that time for research is actually used as planned. The processes needed to promote equal access to contracted research time require harmonization across departments.

Next Generation Researchers

Overall, the environment to support next generation researchers appears good. The contracts of new Strategic Research Arenas (SRA) (2015) include a responsibility for research training and clinical collaboration. Decisions on ALF and clinical research are the responsibilities of the University Hospital Clinics committee and there are two formal documents that state the incentives for combining clinical work and research.

The career development program is described in the document "From student to docent". A number of formal structures have been set up to foster future researchers. Applications for support are peer-reviewed by internal and external reviewers. A combined MD/PhD training program for 3–5 students per term started 2017. This program aims to increase the number of future research leaders.

Region Östergötland finances at least 20 percent of research-protected time for clinicians who are PhD students at Linköping University, including general practitioners. Funding for additional research time can be applied for from ALF. The joint Research Council of Southeastern Sweden (FORSS) also provides funding for clinical PhD-students. Researchers and students stressed that the research schools are important. The Center for Medical Imaging and Visualisation (CMIV) has 40 PhD students in its research school. A separate strategic program aimed at MDs in primary care was launched in 2016 allowing GPs to apply for 20 percent research time. Evidence of success is that currently about 50 percent of the PhD students at Linköping University are clinically active MDs. There is also a joint policy document about incentives to support recruitments. If the specialization time for physicians is prolonged due to combination with PhD studies, the salaries are raised to specialist level after 5 years.

The three centers, Center for Medical Imaging and Visualisation (CMIV), Center for Social and Affective Neuroscience (CSAN), The Linköping Wallenberg Center for Molecular Medicine (WCCM), and the five strategic areas are attractive research environments and thus important tools to raise interest among the next generation researchers.

Career Models

In 2008 Region Östergötland together with Linköping University started a program from "Student to Docent" to facilitate each step of an academic career. This program is expected to attract young researchers to combine research with clinical careers. The evaluation in 2014 criticized the lack of sufficient research time to support younger researchers' career development. Consequently, the program is going through a revitalization process and several actions have been taken to strengthen the program at various steps. The overall aim of the strategy is to foster research-trained healthcare personnel and promote development of a sufficient number of research leaders. Information on the homepage is the platform for guidance about the career model.

Region Östergötland started its policy on research competence evaluation in 2017. In the career-model, students and health care personnel can apply for funds for research-protected time. Research opportunities for medical students, AT- and ST-forskar positions provide secured time for research. There is a special career track for "young talents" and the Wallenberg Centre for Molecular Medicine (WCMM) provides additional positions for young talented individuals. Senior clinical researchers with combined LiU/RÖ positions will have more allocated research time in their tenures starting 2018.

Academic recruitment has also been revitalized and is reviewed annually with a special focus on good employment conditions and maintaining a strong infrastructure. A special task force is responsible for high profile clinical recruitments, and the needs for various clinical specialists are acknowledged. However, recruitment still remains a challenge.

In summary, there are a number of initiatives in place to improve the possibilities to do clinical research at the different steps in the career of a health professional. Preliminary evidence of the success of these approaches is an increase in the number of clinicians that reach the level of associated professors ("docent"). It is also important to encourage young clinical researchers to spend some time in research positions abroad.

ALF-region Örebro

Overall assessment

Good to high quality

Whilst there has been some clinical research in Örebro for many years, the medical school has only recently come into existence. Örebro receives the best student feedback of all of Sweden's medical schools, but the need to develop and deliver a new curriculum has meant that initially the majority of attention in this center was aimed at ensuring the quality and delivery of medical education. Over the last few years however, Örebro has developed a strategy and made infrastructure investments to build a research profile. There are excellent and coherent links between the region and the university. Ine-

vitably, given this context, and with a lower level of external funding than other regions, the environment for clinical research is at a much earlier stage of development than in the other more established centers. There is however a newly established clinical research center which functions effectively, and some internationally recognized research groups. The co-ordination of support for research careers and research time allocation is in general good. Despite the relatively early stage of developments in Örebro, significant momentum has been achieved and the environment should continue to improve over future years as long as investment in research capacity funding is maintained.

Whilst significant strengths existed in terms of the nature of the arrangements to access research infrastructure, the overall strategy to support researchers at all stages of their career, and the co-ordination of the use of allocated research time, the region is still in an early stage of the development. Hence ALF-region Örebro was assessed as being of good to high quality.

Access to Research Infrastructure

The existing infrastructure (Biobank, unit for clinical trials, grants office, imaging, joint research laboratories with expert staff) are operating well and researchers from both the hospital and university have equal access with the same subsidized user fees. There is a formal structure for collaboration between the county council and the university: the Joint Executive Committee acts at a strategic level and decides on yearly budgets. Short-term strategy and operational issues are handled at the level of the ALF committee and the Health Science Committee. An evaluation committee and an infrastructure group with representatives from both parties also operate. Infrastructure is funded by a combination of hospital, university and ALF funding, and the council clearly sees the development of research as a priority.

The joint strategy and funding for local infrastructure, appears to function well and facilities and resources were equally accessible to researchers from the hospital and university. There are also relatively extensive new joint basic research laboratory facilities for clinical researchers with expert staff available, and this facility also appears to function effectively.

The relative lack of overall physical infrastructure is an obvious weakness. There are plans to acquire a second MRI system for research needs, but there is no obvious mid-to-long term strategy for further development of infrastructure. Without continued investment, the lack of critical mass and limited amount of senior researchers will potentially prevent development of modern infrastructure limiting the opportunities for expansion of clinical research in the future.

There are some areas of strength within the university outside of the clinical area (see below), and there are significant opportunities to develop multidisciplinary research. Close collaboration between the hospital and university should enable strategic decision-making and investment in large infrastructure as the center moves forward.

Time for Research

Örebro has a recently established medical school and hence should be well placed to build up research priorities in a strategic manner. The need to protect research time for clinical researchers was clearly appreciated at all levels, and in practice this appears to work well. Feedback from the PI survey was strong in this respect. The overall collegial atmosphere meant that if there were pressures on using designated research time these were solved effectively and clinical researchers did not think there were significant problems in keeping research time protected.

The lack of locally accessible major nationally recognized infrastructure is a potential weakness which might impact on the efficient use of researchers' time. In addition, whilst access to research time did not appear to be a large problem there did appear to be some issues with accessing hospital clinical facilities, for example for MR imaging studies, during normal working hours which could also impact on the efficient use of researchers' time. Initially clinical researchers had spent a lot of time and effort on building a strong reputation for the new medical faculty and in this start-up period for the medical school concentrating on education issues had hindered research development due to time pressures. However, this was now much improved and in general was not considered to be an ongoing

problem, although some postdoctoral researchers still felt additional pressure on time allocations because of the need to deliver teaching.

There are some areas of particular strength in the medical school and also outside the clinical areas within the university (for example in computer science and artificial intelligence), but there did not appear to be a clear strategy to prioritize areas for collaboration or a strategy to allocate research time to support interdisciplinary research. As 75% of the current ALF allocation goes to support research time, a review of how best to invest this strategically over the next 5 years would be a worthwhile exercise.

The possible threat in Örebro is that key academic staff leaves or retire: As the critical mass is low and recruitment challenging this could reduce the critical mass of clinical researchers further. This could impact on the time available for remaining researchers to conduct research.

Next Generation Researchers

There are structured plans for the research residency, but few positions available. Residents outside the ALF funding are employed under the same conditions and hence do not seem to be disadvantaged. There seems to be good coordination between hospital and university on researcher recruitment and career development. Research residents also seem to get time for research, and the PhD students appear well motivated. Although there are physically separate hospitals which contribute to both teaching and research, overall co-ordination seemed to be good. Similarly, researchers funded from both from the university and the county council side seem to have equal opportunities.

One issue which needs to be addressed is the relative lack of research ambition, which probably in part stems from the less competitive atmosphere which seems to exist in ALF- region Örebro compared with the other ALF-regions. This could be addressed by setting goals to identify and develop areas where the university and hospital aim at becoming the best in Sweden.

As mentioned above, there are a number of good research groups outside the medical faculty in the university with collaboration opportunities for the clinical researchers. These opportunities should be utilized and will help in the development of researchers with cross-disciplinary expertise. Encouragingly, establishing collaboration between the health care professions seems to be easy and should be utilized further.

A major threat for young researchers building their research careers is vulnerability if senior academic mentors leave or retire and recruitment fails. Building a clear strategy defining the region's uniqueness, identifying 1 or 2 areas where they could be best in Sweden and making an action plan to deliver this would be beneficial and might also help with recruitment.

Career Models

The formal structure for collaboration between the county council and university which are in place and which allocate the yearly budget allows funds to be used strategically to support careers.

About 20 percent of all internships are combined with a research period. A number of new positions as professors or senior lecturer combined with clinical work were created within the ALF framework. Recruitment has in general been successful for new positions in biomedicine and clinical medicine and there had apparently been a five-fold increase in research positions since 2015. This means that there are very good opportunities for medical doctors and also other health care professionals interested in research to get research positions. Doctors who have finished their PhD have relatively easy access to 2-year 50% postdoc positions, which can be renewed once.

The relative ease to get a research position locally does however create some weaknesses. There is little or no pressure on postdoctoral fellows to spend a period abroad. Although there is a grants office, there seems to be little encouragement for young researchers to apply for competitive national or international grants. It seems that the main focus since establishing the medical school in 2011 has been to secure the training of medical students, which has been done successfully, and there has been less focus on developing research careers until recently. The hospital and the university could jointly establish a clear strategy on developing high ambitions for the next generation researchers.

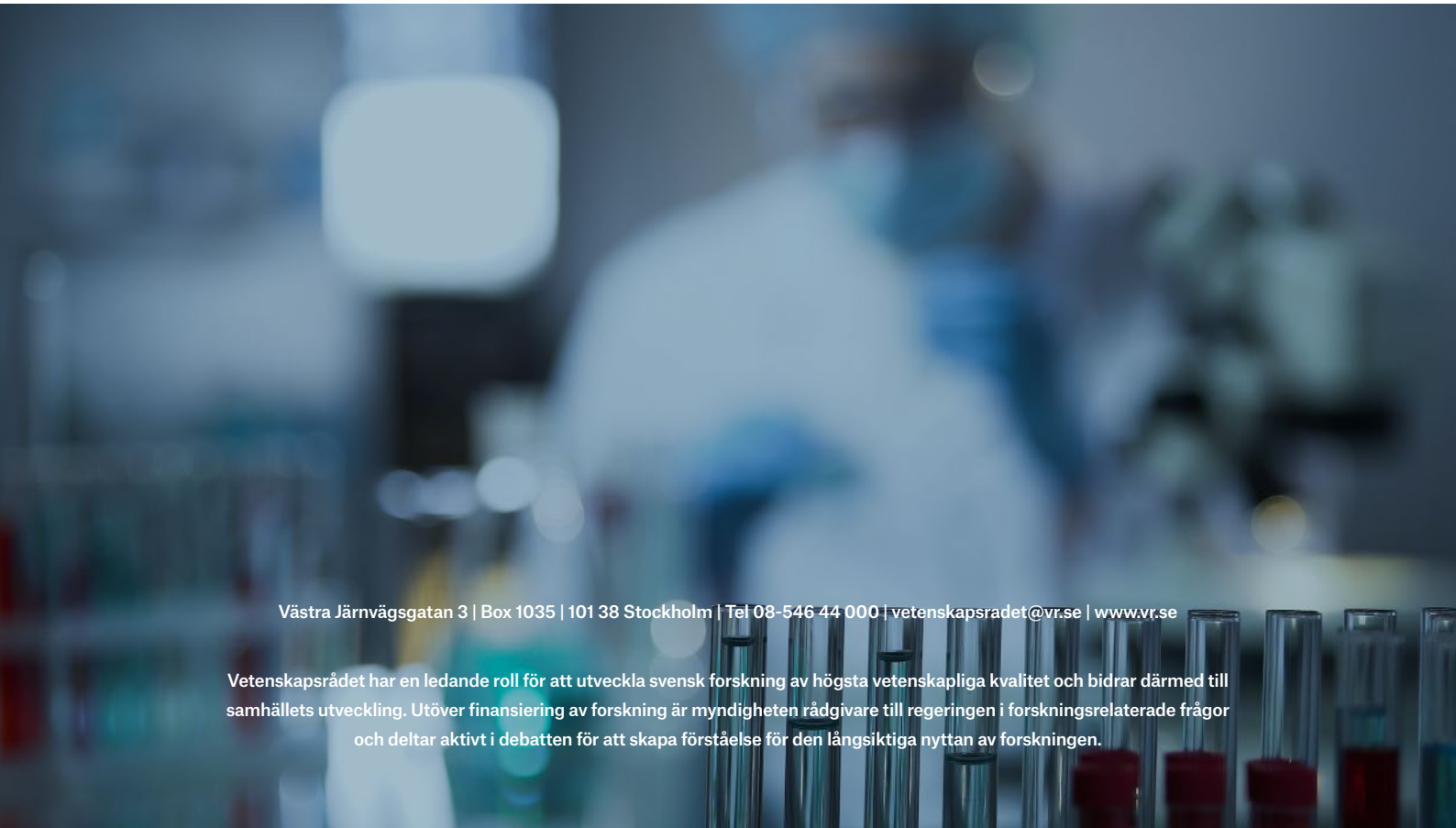
Rapidly increasing funds both at the university and hospital through the new medical school and the recent allocation of ALF funding has created an opportunity to establish nationally or even internationally excellent research groups. Even though the initial work has been done to establish a complete and broad medical school, at present there are relatively few excellent research groups. Perhaps due to the stage of development of the medical school, currently there are no tenure track positions, and creating stability by providing longer duration research positions was seen as a priority among the young independent researchers. Without a clear, common strategy between the university and hospital to identify research strengths and support research talents and encourage these young researchers towards internationalization and excellence, the chance to build an internationally recognized center may be missed.

Rapporten utgör en redovisning av två regeringsuppdrag (U2016/02935/F och U2016/04203/F) till Vetenskapsrådet att utvärdera den kliniska forskningens kvalitet vid de landsting som omfattas av ALF-avtalet.

Utvärderingarna omfattar tre huvudområden och har genomförts av tre externa och oberoende expertpaneler:

1. den vetenskapliga produktionens kvalitet (panel 1)
2. forskningens kliniska betydelse och samhällsnytta (panel 2)
3. forskningens förutsättningar (panel 3).

Panelernas bedömningar ligger till grund för Vetenskapsrådets beslut om den kliniska forskningens kvalitet i respektive landsting.



Västra Järnvägsgatan 3 | Box 1035 | 101 38 Stockholm | Tel 08-546 44 000 | vetenskapsradet@vr.se | www.vr.se