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Research and Innovation for Better Health

Towards a more coherent and effective health research and innovation system

Prepared for the HO21 Advisory Board

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The opinions and findings contained in the study are solely those of DAMVAD Analytics.

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Content

Acronyms and abbreviations

AI – artificial intelligence

BIA - User-driven Research based Innovation, The Research Council of Norway

BIOTEK20201 - Biotechnology for innovation, The Research Council of Norway

FHI - Norwegian Institute of Public Health

FME - Centres for Environment-friendly Energy Research, The Research Council of Norway

FRIPRO - Independent projects (Medicine, Health Sciences and Biology), The Research Council of Norway

HO21 - Health&Care21, The Research Council of Norway

HOD – Ministry of Health and Care Services

INNOF - Innovation in the Public Sector

IP - Intellectual Property

IPR - Intellectual Property Rights

KD - Ministry of Education and Research

KMD - Ministry of Local Government and Modernisation

KPI - Key Performance Indicator (tellekanter)

KS - The Norwegian Association of Local and Regional Authorities

KSF – Kommunenes strategiske forskningsorgan

NAERINGSPHD - The Industrial Ph.D. Scheme, The Research Council of Norway

NCE - Centre schemes (Norwegian Centres of Expertise), The Research Council of Norway

NDE - Norwegian Directorate of eHealth

NFD - Ministry of Trade, Industry and Fisheries

NIFU – Nordic Institute for Studies in Innovation, Research and Education

NIHR – National Institute of Health Research, UK

PPI - Public Procurement of Innovative solutions

PSP - Priority Setting Partnerships

RCN – Research Council of Norway

Regional Health Authorities:

- Central Norway Regional Health Authority
- Northern Norway Regional Health Authority
- Southern and Eastern Norway Regional Health Authority
- Western Norway Regional Health Authority

RFFINNL - Regional Research Fund in Norway

RWD - Real-world data

SFF - Norwegian Centres of Excellence

STAMI - National Institute of Occupational Health

TTO - Technology Transfer Office

Executive Summary

This report, commissioned by the Health&Care21 (HO21) Advisory Board and funded by the Research Council of Norway (henceforth RCN), presents the results of an analysis of the Norwegian health research and innovation system, with the aim of identifying its main problems and proposing new solutions. The analysis was carried out by a team of analysts and researchers from DAMVAD Analytics, Cambridge University, Kings College and RAND Europe during 2018. The opinions and findings contained in the study are solely those of DAMVAD Analytics.

The analysis is based on a qualitative and interactive approach with five methodological elements. It includes over 70 interviews in three rounds and two workshops with key stakeholders; allowing participation from a great variety of actors and stakeholders from all parts of the system. The interviews and workshops were complemented by documentary review of relevant academic articles, policy reports, evaluations and websites. Finally, the analysis includes case studies both of concrete impacts in Norway as well as initiatives and reforms from Denmark, Sweden, Finland, UK and Canada for Norwegian inspiration.

The analysis has the following aims formulated by the HO21 Advisory Board:

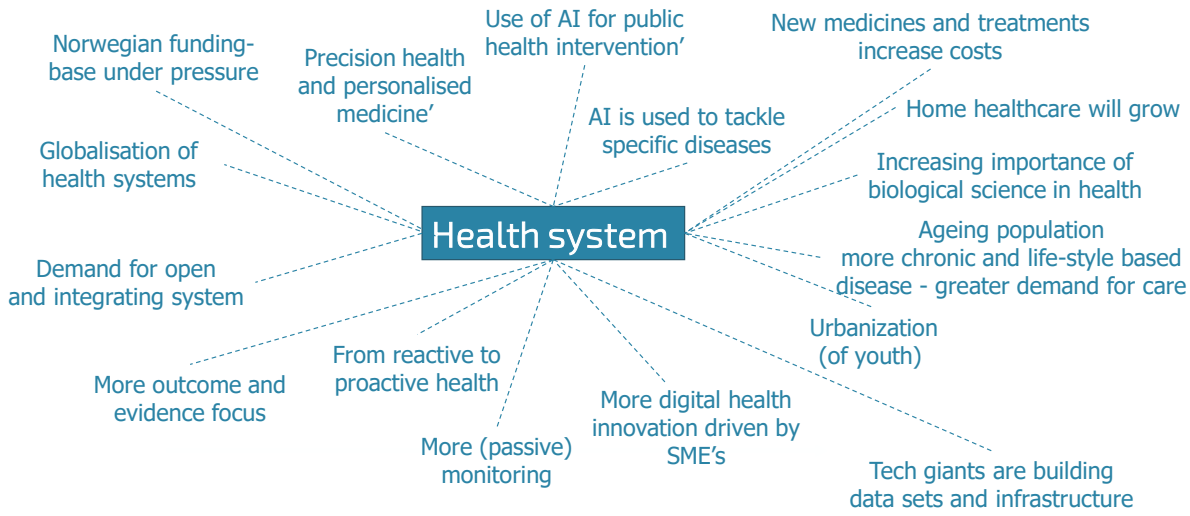
1. Describe today's health research and innovation system.
2. Identify problems and missing links in the health research and innovation chain.
3. Look to international cases and initiatives for inspiration in a Norwegian context.
4. Collect and describe proposals for solutions to the problems identified.
5. Identify trends that can be expected to affect the transformation of the system.
6. Analyse how the digital infrastructure can be part of the solutions.
7. Make recommendations for specific initiatives and support measures.

The analysis builds on the HO21 strategy (HelseOmsorg21-strategien) launched in 2014. The aim of the HO21 strategy process is to promote evidence-based health and care services characterised by high quality, patient safety and efficiency for the 21 Century. The aim of this project is to develop a comprehensive research and innovation system for public health, and health and care that will contribute to high quality research and innovation with a short path to better health. It is also a starting point for this analysis that there are transverse challenges cutting through the health research and innovation system which have to do with both regulations, organization, funding, digitization, competencies and education, leadership, culture and attitudes and not least user involvement.

The HO21 Advisory Board, comprising all relevant stakeholders, points to a future need for tougher priorities and increased productivity in total health services over the next decades. This is due to demographic projections, a dramatic lowering of the income from a smaller oil and gas producing industry, digitization, globalisation and user demand as well as several other major changes affecting the health system and Norwegian society. A large part of the trends evolving now has to do with digital health innovations coming from all parts of the ecosystem, including both public and private, small and large, and local and global actors.

The figure below summarises all the major trends that have been discussed and examined through the project. They have in turned inspired the identification of problems and proposed solutions.

Major trends influencing health R&I system transformation



Basic characteristics of the Norwegian health research and innovation system

The analysis leaves the clear impression of a complex, rather uncoordinated and siloed Norwegian health research and innovation system. There is variation in the types of support measures used across the different actor groups and sectors. The dominant types of support measures are funding for individual basic research and/or innovation projects and/or education whereas little funding goes to building clusters and networks; providing advice or guidance or patient or user involvement. The programmes and support measures have different weight, purpose and target.

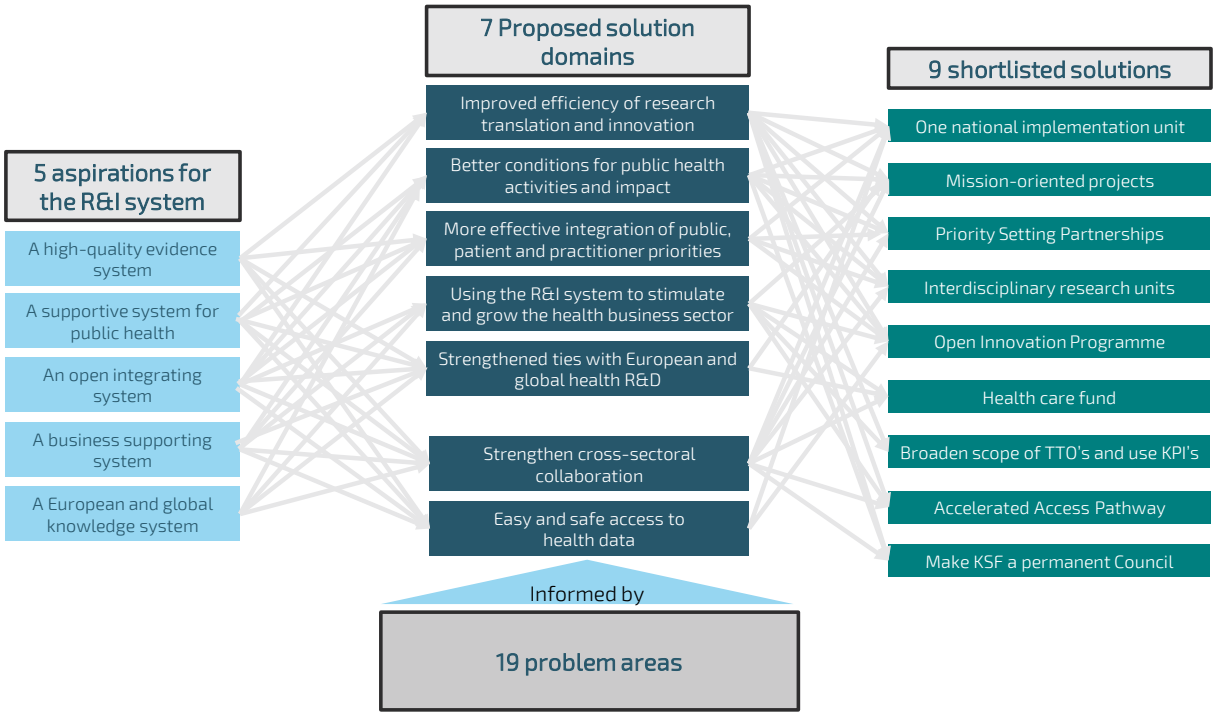
A majority of the funding base is located at the national level and goes to health research and innovation at the universities and in the university hospitals through direct grants. The regional health authorities account for almost half the publicly funded medical and health research in Norway. The Norwegian system is characterised by a low level of private investments compared to most other European countries, especially Denmark and Sweden that both have large health business sectors. Public health research and innovation takes up approximately 15 pct. of total yearly public research and innovation budget for Norway. It is the fastest growing field, over the last two decades.

The Research Council of Norway administers and channels 10-12 pct. of the public funding to health research. This is considerably lower than the 27 pct. of the public funding the Research Council administers on average for all sectors. The other public financiers channel their funds in different ways. The ways research and innovation are funded leaves the impression of a system with weak national coordination and weak competition in Norwegian health research. This arguably has an impact on both the quality and the internationalization of health research since most of the funding

for clinical research is reserved for the hospitals and the regional health authorities. It probably also has an impact on challenges regarding the lack of cross-sectoral cooperation. The analysis leaves the impression of a system characterised by great autonomy to the individual institutions and research areas, and with little room for overall shared documentation, coordination and strategic steering of health research and innovation.

Project structure

The project identified five aspirations for the Norwegian health research system and then developed a list of 19 problem areas identified by respondents, workshops and literature review. These problem areas were combined with the aspirations to identify seven domains for solutions. Forty-six potential solutions were generated from which 9 were selected and developed in the final stage of the project. The structure of the project is shown diagrammatically in the figure below.



Diverging aspirations for the ideal Norwegian health research and innovation system

The rather uncoordinated and siloed Norwegian system is to a large extent reflected in the existence of different, and partly diverging understandings of the system's problems and the changes that are needed. Among the many viewpoints identified through the analysis especially five aspirations for the ideal health research and innovation system dominate in Norway:

1. **A high-quality evidence system** which favours a health research and innovation system based on trustworthy evidence, digitally structured data, a common understanding of methods, available tools, platforms and forums to meet as well as incentives, resources and a common culture for knowledge sharing, cooperation and involvement.

2. A supportive system for public health which is also evidence-based but with a stronger emphasis on population and practice. It favours the factors that affect public health, the causes of social inequalities in health, and the measures that can reduce these inequalities and improve public health by increasing life expectancy and quality of life.

3. An open integrating system which also has a strong focus on practice but is distinct in its blurring of the traditional divisions of labour between different actors in the health system. It is all about facilitating researchers, health personnel, practioners, companies, governments, patients and citizens collaborating.

4. A business supporting system which favours that the research and innovation system shall support the development of a Norwegian health business sector as it is important for the development of the health system and for future growth in Norway. The main argument is that Norway lacks private health businesses and consequently private investments are low.

5. A European and global knowledge system in which the Norwegian health research and innovation system is an integrated – contributing and dependent – part. The argument is that a Norwegian research and innovation system of high quality and relevance must participate and contribute, but also to take in results from the international knowledge system.

The analysis then connects the five aspirations into one collective model, with the aim to illustrate the overall and partly diverging demands made to a Norwegian system that shall deliver health research and innovation of high quality and relevance with a short way to public health and society while also contribute to developing a large and competitive private health business sector in Norway. Followingly, the collective model is used to inspire the identification and understanding of problem areas and proposed solutions in the next parts of the analysis.

19 problem areas identified across the Norwegian health research and innovation system

Through document studies of relevant literature, over 70 interviews with stakeholders and key actors as well as two workshops, the project moved from a broad identification of challenges to a selection and more nuanced description of the 19 most important problem areas confronting the Norwegian health research and innovation system today. The 19 problem areas are grouped into four groups across the health research and innovation system, as shown below.

Norwegian problem areas identified across the health research and innovation system

Resources and productivity in problem and research stage

1) Norway lacks big health businesses and has a low private R&D investment level
2) Leading research environments are not sufficiently engaged in applied research
3) There are few career paths in health research beyond PhD and outside of academia
4) Patients and the public are invited to contribute but without the capacity to do so

Cooperation, financing and involvement in the invention and adoption stages

1) Cross-sectoral cooperation is low
2) Health innovation processes are too slow
3) Support measures do not promote private health business development
4) Low prioritisation of health technology assessment and clinical trials
5) Municipalities lack the capacity and competencies to be involved
6) Not enough public-private cooperation

Implementation and application at the local level

1) Inadequate knowledge of causes and consequences of differences in health and health service utilization
2) Large variations in local knowledge and implementation of treatment guidelines
3) Initiatives at the local level are merely pilots and lacks good documentation
4) Public health interventions are not evaluated or not sufficiently well evaluated
5) Low level of public procurement of innovative solutions
6) New practices, technologies or service models are poorly adopted and diffused

Easy and safe access to health data across the impact chain

1) Researchers and industry experience difficulties getting access to health data
2) Patient journals and health records are spread and not easily accessible
3) Data infrastructure is not made sufficiently available for private and innovation purposes

46 solutions proposed for a more coherent, effective and business contributing system

The analytical process based on document research, interviews, workshops, international case studies and Norwegian impact cases as well as meetings with the HO21 Advisory Board has led to the formulation of 46 solutions for how to improve the Norwegian health research and innovation system. The proposed solutions have been ordered under seven overall headings connected to the aspirations and identified problem areas. The first five headings for solutions are thus linked directly to the aspiration areas. The last two headings for solutions represent cross-cutting problem areas of a more systemic nature and provide central conditions for the whole system to be able to function and transform.

Solutions linked directly to the areas of aspiration

1. Improved efficiency of research translation and innovation
2. Better conditions for public health activities and impact
3. More effective integration of public, patient and practitioner priorities
4. Using the R&I system to stimulate and grow the health business sector
5. Strengthened ties with European and global health R&D

Solutions linked to cross-cutting systemic problem areas

6. Strengthen cross-sectoral collaboration
7. Easy and safe access to health data

Shortlisting and nuancing of 9 solutions with the biggest problem-solving potential

Based on the final policy and recommendation workshop and follow-up interviews, we shortlisted, nuanced and developed the nine solutions identified as having the biggest problem-solving potential

by study participants. It should be noted that all conclusions are solely those of Damvad Analytics. The shortlisted solutions below are merely sketches of policy recommendations which need considerable further development and specification. Where possible we have described how interventions could work in practice, barriers and synergies, alongside who should take lead responsibility, timeframe and estimated costs. We recommend that small operating task forces of 3-5 relevant actors and stakeholders are established to take forward the proposed solutions.

1. Establish one national unit responsible for implementing treatment guidelines and ensuring the commissioning of the same across both specialist and primary health services

The initiative combines the actors' proposal to give the regional health authorities responsibility for both commissioning and implementing new guidelines while at the same time giving Kommunenes Strategiske Forskningsorgan (KSF) the responsibility to promote and share knowledge regarding the implementation of guidelines among Norwegian municipalities.

The initiative would support cooperation between the regional health authorities and the municipalities and should ensure a faster adoption of good solutions. The initiative should also reduce the problematic variation in the availability and quality of treatments by unifying guidelines and help to provide better evidence-based guidance and recommendations on the clinical and cost-effectiveness of treatments, technologies, medicines, diagnostic tools and health activities.

Lead responsibility: Regional health authorities and KSF
Time frame for implementing: 2 years

2. Introduce large-scale mission-oriented projects requiring collaboration from different sectors to solve health challenges

The initiative should work as a network-based process involving all the stakeholders and actors across the health research and innovation chain, including primary care (GPs and community services) and secondary care (hospitals and specialists) as well as universities, patient organisations and health tech providers from the private sector. The initiative also requires cooperation between different ministries to overcome the challenges connected to the sectoral principle. The initiative would probably need a national champion with power to succeed.

The initiative can take inspiration from UK (Mental Health UK) and Denmark (Greater Copenhagen Healthcare Partners) which are described in the international cases studies. The funding should be approximately 100 mio. NOK. Regional projects would have lower costs. The initiative should be financed by funders across sectoral boundaries. The timeframe for projects should be between 2 and 10 years depending on the mission size and complexity. Several other initiatives are synergistic with this initiative, including large national and inter-sectoral health research and innovation announcements, coordinated research infrastructures at the highest strategic and operational level, a joint research administrator support system, mutual governance representation and making health research funding more open to national competition.

Lead responsibility: Ministry for Health and Care (HOD)
Time frame for implementing: 1 year

3. Establish Priority Setting Partnerships (PSPs) as multi-stakeholder collaborations to identify health research areas important to patients, carers and clinicians

The initiative would ensure the societal value of health research by identifying the top ten uncertainties related to the effects of treatments in different areas. Such prioritisation would help raise health research funders' awareness of the issues important to carers, clinicians, patients and society.

The initiative could be realised as a programme in RCN and should involve KSF. Its ambition should be to establish 10 PSP's per year. The central initiative should focus more on methods than themes, e.g. how to best identify priorities and how to ensure those priorities affect what research is carried out. The PSPs should take have a bottom-up approach and be open to different actors and focus on both research and innovation processes, service design thinking and public health. The funding should come from the stakeholders as well as from crowd-sourcing. The initiative is synergistic with the initiative "Make Kommunenes Strategiske Forskningsorgan (KSF) a permanent Council" described below, since KSF could be made responsible for the PSP's.

Lead responsibility: Research Council of Norway and KSF
Time frame for implementing: 2 years

4. Create strong interdisciplinary research units, consisting of clinicians, researchers, educators, university lecturers and university researchers, FHI and KSF with the aim to link basic research and clinical research, and to work for research results to be implemented in clinics and improve the treatment of patients

The research units should include both primary and secondary healthcare as well as industry. A very recent initiative reassembling the same principles are the Mental Health Networks announced by UK Research and Innovation in September 2018.

To ensure that research results can spread across management structures the units should have narrow research areas. The experience is that new actions are easier to handle and implement at management level if they are narrow. The initiative will require a budget of 2,5 mio per unit per year and each unit should be allowed to run up to 10 years. The initiative should include 3-5 units. The leadership of the initiative could be national, regional or joint and individual initiatives should have joint leadership across the research and clinical areas. The initiative is synergistic with other initiatives that focus on producing and implementing evidence and contributing to public health. It can also link to an initiative on PSPs.

Lead responsibility: Norwegian Institute of Public Health (FHI)
Time frame for implementing: 3 years

5. Launch an Open Innovation Programme across health research and innovation to promote experiments with new open innovation measures

The initiative should contain price challenges, partnerships, accelerator fellowships, new innovative procurement initiatives as well as initiatives for online marketplaces, innovators, innovation scouting, etc. It would be important to keep initiatives open to both primary and secondary health care and to ensure private and user involvement. The initiative should focus on removing barriers close to the delivery and implementation or purchase.

A potential lead for the initiative is Innovation Norway. The initiative will need to overcome cultural challenges including organisations and employees who are afraid of failing and sceptical toward private companies and commercial interests being part of the initiative. The initiative is synergistic with other initiatives promoting innovation, open data, cluster programmes, etc.

Lead responsibility: Innovation Norway
Time frame for implementing: 3 years

6. Create a large-scale health care fund to close the capital gap for R&D-intensive health businesses in the translation and market entry stages

The fund should have a management with specialised health knowledge and it should be able to take a lead in investments as well as be a cornerstone in seed and venture financing in the healthcare area. The fund should be based on public and private capital and have a funding base of 500-1.000 mio NOK. It is important that the private sector contributes but also that a fund is prioritised politically.

The proposed initiative is synergistic with other initiatives that promote commercialization and health business development, including proposals to broaden the scope of Innovation Loans and OFU contracts; and give tax incentives for investors investing in health research and innovation projects; as well as initiatives for procurement development and strategic partnerships, and broadening the scope for TTO's to use KPI's for measuring and rewarding contribution to health business development.

Lead responsibility: Ministry of Trade, Industry and Fisheries (NFD)
Time frame for implementing: 5 years

7. Establish an Accelerated Access Pathway to speed route to market for selected, strategically important, transformative innovations

The Pathway should align and coordinate regulatory, reimbursement, evaluation and diffusion processes to bring transformative products to patients more quickly. Products would need to demonstrate the potential for cost savings and improved health. Selected products would benefit from streamlining the processes from market authorisation through to diffusion and receive case management tailored to the individual innovation.

The initiative should bring together a wide range of organisations and actors across the health system to work jointly on the Accelerated Access Pathway in an Accelerated Access Collaborative. The Collaborative's role would be to select the products for the Pathway based on clearly defined selection criteria and increasing strength of evidence of effectiveness as the products moved along the pathway. The Accelerated Access Collaborative is expected to speed of product progression, improve health and quality outcomes, increase the affordability of new technologies and products, create improved value for money and increase for small- and medium-sized enterprises while getting products to patients quick and easily.

Lead responsibility: Regional health authorities
Time frame for implementing: 2 years

8. Make Kommunenes Strategiske Forskningsorgan (KSF) a permanent Council with a budget for research and innovation and a hearing part.

The permanent KSF Council should be funded jointly by RCN, HOD and KMD. Municipalities should fund up to 3 pct. of the money transfers from the government into an accompanying research fund. This would increase the municipalities research budgets. The Council should include the four regions and have local anchorage. Also, KS, The Norwegian Association of Local and Regional Authorities, shall be part of the initiative. The initiative shall adopt the recommendations made by the special KSF working group under the HO21 advisory board.

The initiative is synergistic with initiatives like PraksisNett, which make it possible to recruit patients among GP's for research. The initiative needs to overcome the challenges posed by the organisational silos. It requires that KMF to focus more on health while HOD needs to focus more on primary health care.

Lead responsibility: Research Council of Norway (RCN) and KS
Time frame for implementing: 3 years

9. Broaden the scope of TTO's and use KPI's (tellekanter) measuring and rewarding TTO's for their contribution to innovation and business development in the health sector

The initiative should broaden the mandate of the TTO's to facilitate a stronger push for more investments in areas specifically for the benefit of society, patients or businesses. The broadened scope brings a need for clearer KPI's (tellekanter) that focuses on and reward innovation and contribution to new business development. The TTO's shall shift their focus from passive commercial exploitation, i.e. collecting license fees and royalties from industry to a strategic management of IP by engaging more actively in translational research to explore the potential of discoveries and in business development to drive the creation of new companies, both spin-offs and start-ups.

The TTO's should enter projects at an earlier stage and contribute to fostering an innovation culture in academia. Part of this would include working more with students to develop entrepreneurial talent. The TTOs should be measured by the number of collaborations they have with private health businesses, how much they contribute to new jobs, increased technology flows and increased collaboration between researchers, companies and community actors.

Lead responsibility: Ministry of Education and Research
Time frame for implementing: 2 years

Norsk sammendrag

Rapporten Research and Innovation for Better Health er gjennomført på oppdrag av HelseOmsorg21-rådet og er finansiert av Forskningsrådet. Målet med oppdraget er å analysere dagens forsknings- og innovasjonssystem og foreslå forbedringer. Målet med prosjektet er et helhetlig forsknings- og innovasjonssystem som skal bidra til forskning og innovasjon med kort vei til bedre helse; i folkehelsearbeidet og i helse- og omsorgstjenestene i spesialisthelsetjenesten og primær-helsetjenesten.

Analysen bygger på HelseOmsorg21-strategien fra 2014 som legger til rette for en målrettet, helhetlig og koordinert nasjonal innsats for forskning, utvikling og innovasjon for helse og omsorg i det 21. århundre. Målet med HelseOmsorg21 (HO21) er å bidra til en kunnskapsbasert helse- og omsorgstjeneste kjennetegnet av høy kvalitet, pasientsikkerhet og effektive tjenester.

Analysen skal:

- beskrive dagens forskning- og innovasjonssystem for folkehelsearbeidet og helse- og omsorgssektoren i Norge sett under ett.
- identifisere mangler og barrierer i dagens system.
- beskrive internasjonale reformer og initiativer til inspirasjon for det norske systemet.
- samle og beskrive forslag til løsninger på manglene og barrierene.
- identifiser trender som kan føre til endringer i dagens system.
- beskrive betydningen av en digital infrastruktur for å oppnå målsetning om et helhetlig og effektivt forsknings- og innovasjonssystem.
- utarbeide forslag til konkrete tiltak og støtteforanstaltninger.

Analysen er basert på en kvalitativ og interaktiv tilnærming med fem metodologiske elementer. Analysen inkluderer over 70 intervjuer i tre runder og to workshops med sentrale representanter fra næringsliv, sykehus, universiteter og høyskoler, offentlig forvaltning, kommunesektoren og brukerorganisasjoner. Intervjuene og workshopene er supplert med en gjennomgang av relevante artikler, rapporter, evalueringer og nettsteder. I tillegg inneholder analysen konkrete casestudier i Norge, samt studier av initiativer og reformer fra Danmark, Sverige, Finland, Storbritannia og Canada.

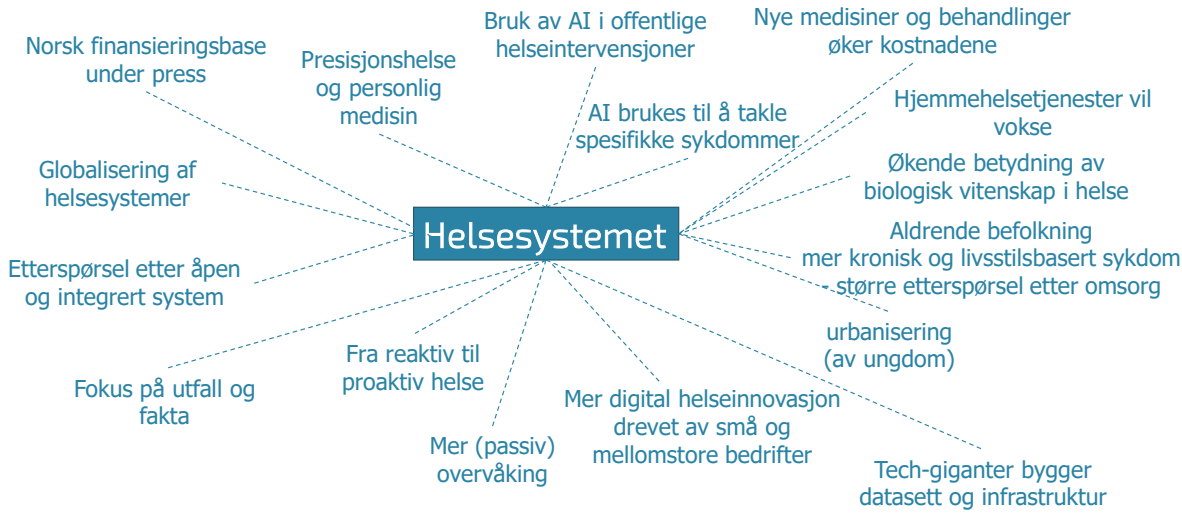
Analysen er utført av et team av analytikere og forskere fra DAMVAD Analytics, Cambridge University, Kings College og RAND Europe i 2018. Damvad Analytics er ene og alene ansvarlig for alle synspunkter og resultater i analysen.

Mens HO21-strategien fra 2014 fokuserte på betydningen av forskning og internasjonalisering av høy kvalitet for hele forsknings- og innovasjonssystemet, ser denne analysen på sammenhengen mellom forsknings- og innovasjonssystemet for folkehelseforskning og innovasjon som en integrert del av forsknings- og innovasjonssystemet for helse- og omsorgstjenesteforskningen. Det eksisterer i dag en rekke hindringer som f.eks. regulerings- og finansieringsmekanismer, organiseringsprinsipper, i tillegg til digitalisering, lav kompetanse og utdanning, brukerinvolvering, lederskap, kultur og holdninger, som forårsaker at Norge i dag ikke har et helhetlig forsknings- og innovasjonssystem for folkehelseforskning og for helse- og omsorgstjenesteforskning sett under ett.

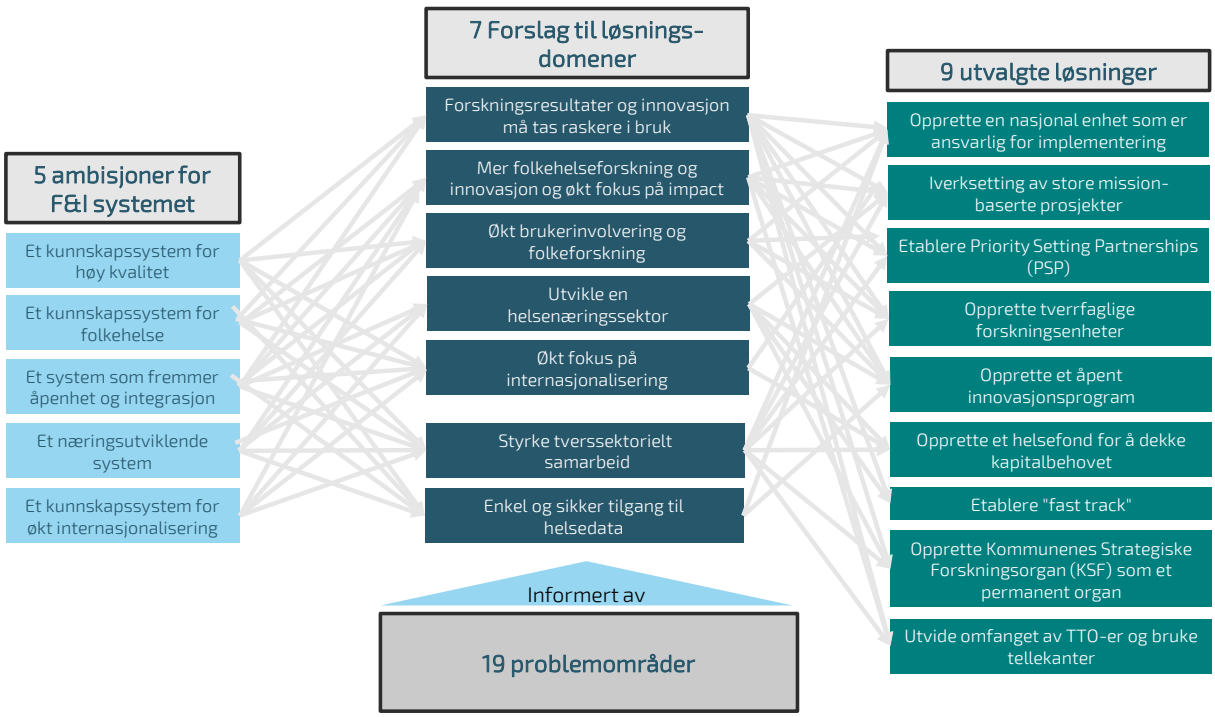
HO21-rådet, som består av 30 sentrale personer fra næringsliv, sykehus, universitetene og høgskolene, offentlig forvaltning, kommunesektoren og brukerorganisasjoner, peker på et fremtidig behov for tøffere prioriteringer og økt produktivitet i helsetjenestene de neste tiårene. Dette skyldes den demografiske utviklingen, en dramatisk nedgang i inntektene fra en mindre olje- og

gassproduksjon, digitalisering, globalisering og brukernes etterspørsel, samt flere andre store endringer som påvirker helsesystemet og det norske samfunnet. En stor del av utviklingen påvirkes av digitale helseinnovasjoner som kommer fra alle deler av økosystemet, inkludert både offentlige og private, små og store og lokale og globale aktører. Figuren nedenfor oppsummerer alle de store trender som har blitt diskutert og undersøkt gjennom prosjektet.

Sterke trender som påvirker helseforsknings- og innovasjonssystemets transformasjon



Analysen har identifisert fem hovedmål for det norske helseforsknings- og innovasjonssystemet og det er utviklet en liste med 19 problemområder. Analysen presenterer syv løsningsområder med total 46 underliggende forslag til spesifikke løsninger inkludert. Herfra er ni forslag til løsninger med størst potensial valgt. Figuren under viser en oversikt over strukturen på prosjektet.



Grunnleggende egenskaper ved det norske forsknings- og innovasjonssystemet for folkehelse-, og helse- og omsorgstjenesten

Analysen gir et klart inntrykk av et komplekst ikke-koordinert og silo-oppdelt system for folkehelseforskning og helse- og omsorgstjenesteforskning og innovasjon i Norge. Det er stor variasjon i hvilke typer støttetiltak som brukes i de ulike sektorene og av de ulike aktørene. De dominerende typene av støttetiltak er finansiering for individuelle grunnforskning og innovasjonsprosjekter og høyere utdanning, mens lite finansiering går til å bygge klynger og nettverk; gi råd eller veiledning eller til pasient- og brukerinvolvering. De ulike støtteprogrammene og virkemidlene vektes ulikt og har forskjellig formål og mål.

Størstedelen av finansieringsgrunnlaget ligger på nasjonalt nivå og går til helseforskning og innovasjon ved universitet- og universitetssykehusene gjennom direkte tilskudd. De regionale helseforetakene står for nesten halvparten av den offentlig finansierte medisin og helseforskningen i Norge. Det norske systemet er preget av et lavt nivå av private investeringer sammenlignet med de fleste andre europeiske land, særlig Danmark og Sverige, som begge har store private helsebransjer. Helseforskning og innovasjon tar ca 15 pst. av det samlede årlige offentlige forsknings- og innovasjonsbudsjettet for Norge. Det er det raskest voksende feltet de siste to tiårene.

Norges forskningsråd administrerer og kanaliserer 10-12 pst. av offentlig finansiering til helseforskning. Dette er betydelig lavere enn de 27 pst. av den offentlige finansieringen som Forskningsrådet administrerer i gjennomsnitt for alle sektorer. De andre offentlige finansiørene kanaliserer sine midler på ulike måter. Måten helseforskning og innovasjon finansieres på gir inntrykk av et system med svak nasjonal koordinering og få konkurranser på tvers av sektorer. Dette har uten tvil en innvirkning på både kvaliteten og internasjonaliseringen av helseforskning, siden det meste av finansieringen til klinisk forskning er reservert for forskning i regi av de regionale helseforetakene. Det har sannsynligvis også innvirkning på utfordringene om lite samarbeid på tvers av sektorer. Analysen gir inntrykk av et system som er preget av stor autonomi til de enkelte institusjonene og forskningsområder og med lite plass til én samlet og felles dokumentasjon, koordinering og strategisk styring av helseforskning og innovasjon.

Et ideelt norsk forsknings- og innovasjonssystem for folkehelse og helse- og omsorgs-tjenesten – fem hovedmål

Det relativt ikke-koordinerte og silo-oppdelte systemet for forskning- og innovasjon gjenspeiler i stor grad de forskjellige og delvis divergerende oppfatninger av hvilke problemer systemet/ene har og hvilke løsninger det er behov for. Blant de mange synspunktene som er identifisert dominerer spesielt fem mål for det ideelle forsknings - og innovasjonssystemet for folkehelse og helse- og omsorgstjenesteni Norge:

1. Et **kunnskapssystem av høy kvalitet** som favoriserer helseforskning og innovasjon og som er basert på sterk evidens, digitalt strukturerte data, en felles forståelse av metoder, tilgjengelige verktøy og plattformer. I tillegg til møtefora, insentiver, ressurser og en felles kultur for kunnskapsdeling, samarbeid og involvering.

2. Et **kunnskapssystem for folkehelse** som er evidensbasert og som har et befolkningsperspektiv. Folkehelsesystemet skal ta innover seg de faktorene som påvirker folkehelsen, årsaker til sosial ulikhet i helse samt utvikle tiltak som kan redusere ulikheter i helse og forbedre folkehelsen i befolkningen.

3. Et **system som fremmer åpenhet og integrasjon** og som har et sterkt fokus på praksis. Systemet skal arbeide for at de tradisjonelle oppdelingene og grensene mellom de ulike aktører i folkehelse, - og helse- og omsorgssystemet nedtones. Hovedfokuset vil være å utvikle samarbeid mellom forskere, helsepersonell, praktikere, bedrifter, myndigheter, pasienter og borgere.

4. Et **næringsutviklende system** som arbeider for å utvikle et norsk helsenæringsliv og som kan bidra til økonomisk vekst i Norge. Hovedargumentet er at private investeringer i Norge er lav sammenlignet med land som det er naturlig for Norge å sammenligne seg med.

5. Et **kunnskapssystem for økt internasjonalisering** av norsk forskning og innovasjon. Norge som forsknings- og innovasjonsnasjon må utvikles til å bli og være en attraktiv partner i det internasjonale forsknings- og innovasjonssystemet. På denne måten vil Norge ha mulighet for å adoptere forsknings- og innovasjonsresultater fra det internasjonale kunnskapssystemet.

19 problemområder og syv løsningsområder

Analysen kobler de fem hovedmålene til én samlet modell med det formål om å illustrere de samlede og delvis divergerende kravene til systemene som skal levere helseforskning og innovasjon av høy kvalitet og relevans med kort vei til bedre helse. De 19 problemområdene som er identifisert er gruppert i fire grupper på tvers av forsknings- og innovasjonssystemet, som vist nedenfor.

Norske problemområder identifisert i forsknings- og innovasjonssystemet

Ressurser og produktivitet i problem- og forskningsfasen

1) Norge mangler store helseforetak og har et lavt privat FoU-investeringsnivå
2) Ledende forskningsmiljøer er ikke tilstrekkelig engasjert i anvendt forskning
3) Det er få karriereveier i helseforskning utover PhD og utenfor akademia
4) Pasienter og offentligheten er invitert til å bidra, men uten kapasitet til å gjøre det.

Samarbeid, finansiering og involvering i oppfinnelses- og adopsjonsfasene

1) Tverssektorielt samarbeid er lavt
2) Helseinnovasjonsprosesser er for sakte
3) Støtteforanstaltninger støtter ikke privat helseutvikling
4) Lav prioritering av helseteknologivurdering og kliniske studier
5) Kommunene mangler kapasitet og kompetanse til å være involvert
6) Ikke nok offentlig-privat samarbeid

Implementering og anvendelse på lokalt nivå

1) Utilstrekkelig kunnskap om årsaker og konsekvenser av forskjeller i bruk av helse og helsetjeneste
2) Store variasjoner i lokal kunnskap og implementering av behandlingsretningslinjer
3) Initiativer på lokalt nivå er bare piloter og mangler god dokumentasjon
4) Helseintervensjoner blir ikke evaluert eller ikke tilstrekkelig evaluert
5) Lavt nivå på offentlige anskaffelser av innovative løsninger
6) Ny praksis, teknologier eller servicemodeller er implemenetres og utbredes dårlig

Enkel og sikker tilgang til helsedata over hele virkningskjeden

1) Forskere og næringsliv opplever vanskeligheter med å få tilgang til helsedata
2) Pasientjournaler og helsjournaler er spredt og ikke lett tilgjengelige
3) Datainfrastruktur er ikke tilstrekkelig tilgjengelig for private og for innovasjon

Rapporten presentere 46 løsninger for å forbedre det norske helseforsknings- og innovasjonssystemet. Syv løsninger er knyttet til de fem hovedmålene og de 19 identifiserte problemområdene. Fem løsninger er direkte koblet til hovedmålene. To løsninger svarer på de tverrgående systemutfordringene.

Fem løsninger knyttet til de fem hovedmålene

1. Forskningsresultater og innovasjon må tas raskere i bruk
2. Mer folkehelseforskning og innovasjon og økt fokus på impact
3. Økt brukerinvolvering og folkeforskning
4. Utvikle en helsenæringssektor
5. Økt fokus på internasjonalisering

To løsninger knyttet til tverrgående utfordringer på systemnivå

6. Styrke tverrsektorielt samarbeid
7. Enklere og sikker tilgang til helsedata

DAMVAD Analytics foreslår

Under følger ni forslag til tiltak som er identifisert til å gi størst effekt hvis de implementeres. De foreslåtte tiltakene er skisser til politiske anbefalinger som krever betydelig videreutvikling og spesifisering. Der hvor det har vært mulig er det gitt en beskrivelse av hvordan tiltaket kan fungere i praksis. I tillegg beskrives evt barrierer og synergier samt estimering av kostnader ved implementering av tiltaket/ene. Damvad Analytics anbefaler at det nedsettes mindre arbeidsgrupper bestående av relevante aktører som utarbeider de foreslåtte tiltakene videre.

1. Opprettelse av én nasjonal enhet som er ansvarlig for implementering av retningslinjer for behandling innen spesialist- og primærhelsetjenesten

Initiativet kombinerer aktørenes forslag om å gi de regionale helseforetakene ansvar for både igangsetting og implementering av nye retningslinjer samtidig som Kommunenes Strategiske Forskningsorgan (KSF) får ansvaret for å fremme og dele kunnskap om gjennomføring av retningslinjer blant norske kommuner.

Initiativet vil støtte samarbeidet mellom de regionale aktørene og kommunene, og kan sikre raskere vedtak av gode løsninger. Initiativet kan bidra til å redusere utfordringene med variasjon i tilgjengelighet og kvalitet på behandlingene ved å gjøre n enhet ansvarlig for å implementere nasjonale retningslinjer.

Hovedansvar: De regionale helseforetakene og KSF
Implementeringstid: 2 år.

2. Iverksettelse av store mission-baserte prosjekter som krever samarbeid fra ulike sektorer for å løse helsemessige samfunnsutfordringer

Initiativet anbefales å fungere som en nettverksbasert prosess som involverer alle relevante aktører på tvers av helseforsknings- og innovasjonskjeden, inkludert primærhelsetjenesten (fastlege og sykepleietjeneste) og spesialisthelsetjenestensamt universiteter, pasientorganisasjoner og helsetech-leverandører fra privat sektor. Initiativet forutsetter samarbeid mellom relevante departementer. Se beskrivelse av eksempler fra Storbritannia (Mental Health UK) og Danmark (Greater Copenhagen Healthcare Partners) i de internasjonale case-studiene. Finansieringen bør være på ca NOK 100 mill. kroner. Regionale prosjekter vil ha en mindre kostnad. Initiativet bør finansieres av aktører på tvers av sektorgrenser. Tidsrammen for prosjektet bør være mellom 2 og 10 år, avhengig av oppdragsstørrelse og kompleksitet.

Hovedansvar: Helse- og omsorgsdepartementet (HOD)
Implementeringstid: 1 år.

3. Etablering av Priority Setting Partnerships (PSP) etter modell fra James Lind Alliance

Initiativet kan realiseres som et program i Forskningsrådet i samarbeid med KSF. Ambisjonen foreslås å etablere 10 PSP per år. Det sentrale initiativet bør fokusere på metoder heller enn temaer, f.eks. hvordan best identifisere de ulike prioriteringene og hvordan sikre at forskningsprosjektene samsvarer med prioriteringene. PSP-ene må ha en bottom-up tilnærming og være åpen for ulike aktører samt fokusere på både forskning og innovasjonsprosesser og servicetenkning. Finansieringen må komme fra aktørene og fra crowd-sourcing. Det foreslås å gjøre Kommunenes Strategiske Forskningsorgan (KSF) til et permanent råd som kan bli ansvarlig for å utvikle PSP-er.

Hovedansvar: Forskningsrådet og KSF
Implementeringstid: 2 år.

4. Opprettelse av tverrfaglige forskningsenheter bestående av klinikere, forskere, undervisere, forskere, FHI og KSF med sikte på å knytte grunnforskning og klinisk forskning sammen. Enhetene vil bidra til økt implementering av forskningsresultater i klinikkene som igjen vil bidra til økt kvalitet på behandlingen av pasienter

Forskningsenhetene bør omfatte både forskere, helsepersonell og næringslivet. Et meget nylig initiativ som har de samme prinsippene er Mental Health Networks initiert av UK Research and Innovation i 2018. For å sikre at forskningsresultater sprer seg over forskjellige ledelsesstrukturer, bør konsentrere seg om avgrensede forskningsområder. Initiativet vil kreve et budsjett på 2,5 millioner kr. per enhet per år, med en varighet opp til 10 år. Initiativet bør omfatte 3-5 enheter. Initiativets ledelse kan være nasjonalt, regionalt eller felles. Individuelle tiltak bør ha felles lederskap på tvers av forskning og kliniske områder. Initiativet har synergier med andre tiltak som fokuserer på å produsere og implementere evidens. Det kan også koble til et initiativ som PSP-ene.

Hovedansvar: Folkehelseinstituttet (FHI)
Implementeringstid: 3 år.

5. Opprettelse av et åpent innovasjonsprogram for folkehelse - og helse -og omsorgs-tjenesteforskning

Initiativet bør inneholde prisutfordringer, partnerskap, akseleratorstipendier, nye innovative anskaffelsesinitiativer samt initiativer for online markedsplasser, innovatører, innovasjonssporing osv. Det vil være viktig å holde tiltakene åpne for det offentlige og det må sikre privat inititativ og brukerengasjement. Initiativet bør fokusere på å fjerne barrierer nær levering, implementering eller kjøp.

En potensiell ledelse for initiativet er Innovasjon Norge. Initiativet må bestå av tiltak som kan bidra til å overvinne kulturelle utfordringer som f.eks. organisasjoner og ansatte som er redd for å mislykkes og er skeptiske mot private selskaper og kommersielle interesser som en del av initiativet. Initiativet har synergier med andre tiltak som fremmer innovasjon, åpne data, klyngeprogrammer etc.

Hovedansvar: Innovasjon Norge
Implementeringstid: 3 år.

6. Opprettelse av et helsefond for å dekke kapitalbehovet for FoU-intensive helsebedrifter i translasjons- og markedsfasen

Fondet bør ha en ledelse med spesialisert helsekunnskap. Fondet skal styre investeringene, samt være en hjørnestein for venturefinansiering i helsesektoren. Fondet bør være basert på offentlig og privat kapital og ha et finansieringsgrunnlag på NOK 500.000 -1.000 000 mill. kroner. Det er viktig at den private sektoren bidrar, men også at fonden prioriteres politisk.

Det foreslåtte initiativet har synergier med andre tiltak som fremmer kommersialisering og helseutvikling, herunder forslag om å utvide omfanget av Innovasjonslån og OFU-kontrakter, og gi skatteincitamenter for investorer som investerer i helseforsknings- og innovasjonsprosjekter; samt initiativer for utvikling av offentlige anskaffelser og strategiske partnerskaper, og utvidelse av muligheten for TTO-er å bruke tellekanter for å måle og belønne bidrag til forretningsutvikling i helsesektoren.

Hovedansvar: Nærings- og fiskeridepartementet (NFD)
Implementeringstid: 5 år.

7. Etablere "fast track" for å øke hastigheten til markedet for utvalgte, strategisk viktige, transformative helseinnovasjoner

"Fast-track" skal tilpasse og koordinere regulerings-, refusjons-, evaluerings- og diffusjonsprosesser for å bringe transformative produkter raskere ut til pasientene. Produktene må vise potensialet for kostnadsbesparelser og bedre helse. Utvalgte produkter vil ha nytte av å slike strømlinjede prosesser fra markedsautorisasjon til diffusjon samt motta saksbehandling tilpasset den enkelte innovasjon.

Initiativet bør samle et bredt spekter av organisasjoner og aktører på tvers av helsesektoren for å arbeide sammen. Rollen til deltakerne vil være å velge produkter på bakgrunn av klart definerte utvalgskriterier og økt styrke av evidens om effektivitet ettersom produktene beveger seg langs stien. Partene forventes å øke hastigheten på produktutviklingen, forbedre helse- og kvalitetsresultatene, gjøre ny teknologi og nye produkter billigere, skape bedre valuta for pengene og øke adgang for små og mellomstore bedrifter samtidig som produktene raskt og enkelt kommer til pasientene.

Hovedansvar: De regionale helseforetakene
Implementeringstid: 2 år.

8. Videreføring av Kommunenes Strategiske Forskningsorgan (KSF) som et permanent organ

KSF bør finansieres i fellesskap av Norges Forskningsråd, HOD og KMD. Kommunene skal finansiere inntil 3 pst. av pengeoverføringene fra regjeringen til et eget forskningsfond for kommunesektoren. Dette vil øke kommunens forskningsbudsjetter. KS må være en del av initiativet. Initiativet har synergier med initiativer som PraksisNett, som gjør det mulig å rekruttere pasienter hos fastleger for forskning. Initiativet må overvinne utfordringene fra organisasjonssiloene. Det krever at KMD skal fokusere mer på helse mens HOD trenger å fokusere mer på primærhelsetjenesten.

Hovedansvar: Forskningsrådet og KS
Implementeringstid: 3 år.

9. Utvide omfanget av TTO-er og bruke tellekanter til å måle og belønne TTO'ene for deres bidrag til innovasjon og bedriftsutvikling i helsesektoren

Mandatet til TTO-ene må gjennomgås. Et nytt og utvidet mandat for TTO-ene bør inneholde tellekanter som fokuserer på og belønner innovasjon og bidrar til ny næringsutvikling. TTO-ene må endre fokus til en mer strategisk styring av IPR ved å engasjere seg mer aktivt i translasjon av forskning for å utforske potensialet for oppfinnelser og næringsutvikling, for å drive etableringen av nye selskaper, både spin-offs og oppstart.

TTO-ene bør gå inn i prosjekter på et tidligere stadium og bidra til å fremme en innovasjonskultur i akademia. En del av dette vil inkludere å arbeide mer med studenter for å utvikle entreprenørskap. TTO-ene bør måles etter antall samarbeid de har med private helseforetak, hvor mye de bidrar til nye arbeidsplasser, økte teknologistrømmer og økt samarbeid mellom forskere, bedrifter og samfunnsaktører.

Hovedansvar: Kunnskapsdepartementet
Implementeringstid: 2 år.

1 Introduction

This report, commissioned by the HO21 Advisory Board under the Research Council of Norway (henceforth RCN), presents the results of an analysis of the Norwegian health research and innovation system, which aimed to identify its main problems and propose new solutions. The analysis was carried out by a team of analysts and researchers from DAMVAD Analytics, Cambridge University, Kings College and RAND Europe during 2018.

Norwegian public health research and development expenditures are estimated to be more than eight billion NOK per year and are approximately 15 pct. of the total budget for publicly funded research and development. Almost 8000 researcher personnel are working with health research and innovation on a daily basis. Health research and development is the fastest growing research field in Norway in terms of public expenditures.

The HO21 Advisory Board, made up of stakeholders from across this sector has identified a need for more focussed priorities and increased productivity in total health services over the next decades. This need stems from demographic projections, a dramatic lowering of the income from a smaller oil and gas producing industry, digitization, globalisation and increased user demand. These changes will require reform of the Norwegian health research and innovation system.

The HO21 Advisory Board, and leading sector stakeholders interviewed in the project, suggest the need to develop the system to ensure that research results are used more effectively by both hospitals and in society, including primary health services and public health. This will require improved infrastructure allowing more effective evidence production and use for both specialist health services, primary health services and public health activities. The Norwegian health research and innovation system also need to develop active roles for patients and the public; including users and practitioners. Last but not least, many actors want a health research and innovation system which can better support the development of the private health business sector in Norway. They feel the private health business potential is enormous, and Norway needs to realise it.

The recent 2017 OECD review of Norwegian Innovation Policy stated that Norway is facing a "triple transition imperative" in which it needs, first, to shift toward a more diversified and robust economy; second, to move to a more competitive, effective and efficient innovation system; and third, to support research and innovation activities that can confront an array of societal challenges, of which several are health related.[1] A major weakness identified by the OECD was that that the Norwegian research and innovation system has an insufficient strategic focus on health as a key field.

The present analysis of the Norwegian health research and innovation system builds on the HO21 strategy (HelseOmsorg21-strategien) launched in 2014. The 2014 strategy delivered nuanced insight on the challenges in the health research system and provided recommendations that were relevant for the entire value chain from ground-breaking basic research to business development and public health work.

[1] OECD Reviews of Innovation Policy: Norway 2017.

It was central to the HO21 strategy that basic research of high quality and international collaboration are essential prerequisites for a high performing research and innovation system. This has been a central priority in Norwegian research policy since the beginning of the 2000s and has led to a large increase in high quality research, publications, citations; and European and broader international cooperation.

However, the 2014-strategy's focus on research and innovation regarding public health – encompassing health promotion, health protection and emergency preparedness, prevention, health services research, cross-sectoral activities, and population health sciences - was limited. In addition, several actors argue that progress regarding optimising innovation and creating business development has been very limited since 2014. Thus, while building on the 2014 strategy and acknowledging the central importance of high-quality basic research and internationalization, this analysis will focus more on the innovation and public health impact issues.

It is clear that there are transverse challenges cutting through the health research and innovation system which involve both regulations, organization, funding, digitization, competencies and education, leadership, culture and attitudes and not least user involvement. It should also be noted that the results of the analysis, have links and implications beyond the healthcare sector.[2]

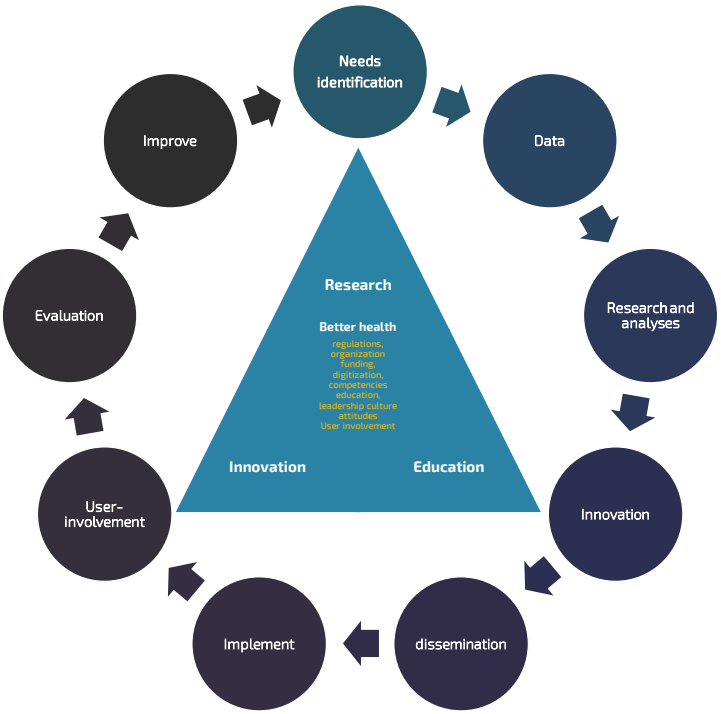
Figure 1 illustrates the conceptual underpinning of HO21. The first part illustrates the focus points of the present strategy work. The second illustration shows the goals of the HO21 – 2014 strategy. On this basis, the project aims as formulated by the HO21 Advisory board for this analysis are:

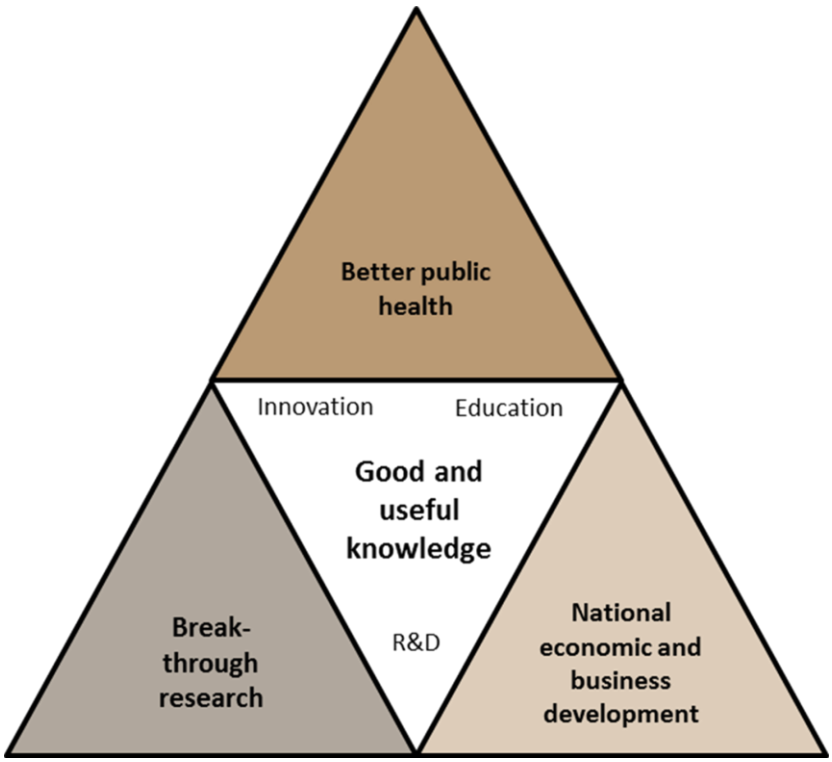
1. Describe today's health research and innovation system.
2. Identify problems and missing links in the health research and innovation chain.
3. Look to international cases and initiatives for inspiration in a Norwegian context.
4. Collect and describe proposals for solutions to the problems identified.
5. Identify trends that can be expected to affect the transformation of the system.
6. Analyse how the digital infrastructure can be part of the solutions.
7. Make recommendations for specific initiatives and support measures.

[2] i.e. Helsenæringsmeldingen (2019), ny folkehelsemelding (2019), St. melding om innovasjon i offentlig sektor (2019), revidert langtidsplan for forskning og høyere utdanning (2018), og ny sykehusplan (2019).

Figure 1. The HO21 strategic focus for the Norwegian health research and innovation system

HO21 strategic focus (2018-2019)
Research and Innovation of high quality and relevance with a short way to public health and society.





Source: HelseOmsorg21 (2014): Nasjonal forsknings- og innovasjonsstrategi for helse og omsorg. Et kunnskapssystem for bedre folkehelse.

2 The ideal health research and innovation system

When seeking to identify the main problems in the Norwegian health research and innovation system and searching for solutions, it quickly became clear that there are different, and partly diverging, aspirations and goals for the Norwegian health research and innovation system and hence views about the changes that are needed.

In numerous interviews and two workshop meetings, we asked a great variety of stakeholders to outline the problems and changes needed in Norwegian health research and innovation system. These discussions were complemented by reviewing a wide range of academic articles and public policy reports. Among the many viewpoints, five particular aspirations for the health research and innovation system could be identified.

1. A high-quality evidence system
2. A supportive system for public health
3. An open integrating system
4. A business supporting system
5. A European and global knowledge system

Figure 2. Five particular aspirations for the ideal health research and innovation system

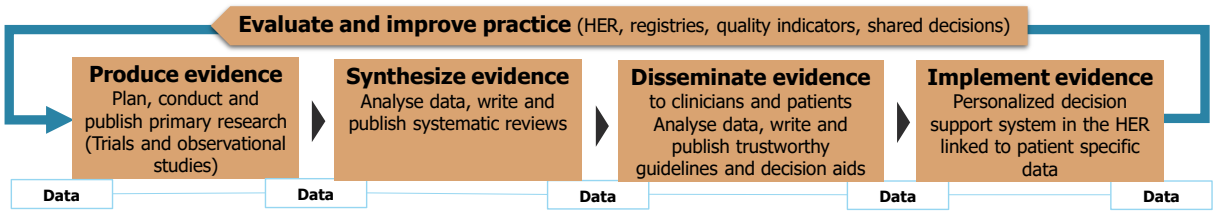
The five aspirations aim to make the health research and innovation system more efficient and effective; to provide better health, but their focus and solutions required to deliver them differ. Because they differ in their emphasis the different aspirations have elements that are complementary

and others that are in tension. The challenge is to maximise the complementarity. Below, we elaborate on each of the aspirations.

1. A high-quality evidence system

This aspiration embodies the idea that policy-makers, clinicians and patients need high-quality research-based evidence to ensure that diagnosis, treatment and follow-up is efficient and effective while allowing well-informed, personalized and shared decision-making at the point of care. To provide this requires trustworthy evidence; digitally structured data; a common understanding of methods, available tools, and forums; as well as appropriate incentives and a common culture of knowledge sharing. The system's evidence chain is illustrated in figure 3.

Figure 3. A high-quality evidence system



The suggestion is that to allow health care systems to function optimally, seamless transfer of the best current evidence is necessary between the communities performing primary research (evidence producers), summarizing research into systematic reviews (evidence synthesizers), creating clinical practice guidelines and decisions aids (evidence processors and disseminators), and those responsible for implementing evidence into improved health care (evidence implementers). The vision in this aspiration is a system that explicitly links innovative eHealth solutions and platforms for digitally structured health data with processes and people to improve health and reduce waste in health care. This aspiration has many supporters. One of the most articulate promoters is Professor Per Vandvik and the Magic project.[3]

The Magic project develops important measures and instruments to effectively share data and help ensure new methods, services and technologies are backed by robust evidence of effectiveness. This approach is an important contribution to solving some of the challenges regarding ensuring effective and consistent clinical trials and technology assessment, which have been debated intensively in Norway in recent years and were highlighted by the Norwegian daily Aftenposten in a series of articles during 2017 and 2018.[4]

[3] The system description has borrowed from interviews and several articles, most notably from Per Vandvik (2016) The Digital and Trustworthy Evidence Ecosystem: Personalised eHealth solutions to increase value and reduce waste in health care. http://magicproject.org/research-and-tools/the-evidence-ecosystem/

[4] Aftenposten has run a series of articles highlighting and discussing the challenges connected to clinical trials and assessments at Norwegian hospitals, e.g. https://www.aftenposten.no/norge/i/4Po76/Helseministeren-

2. A supportive system for public health

The aspiration for a system supporting public health, public health activities and public health knowledge calls for a focus on the factors that affect public health, the causes of social inequalities in health, and the measures that can reduce these inequalities and improve public health by increasing life expectancy and quality of life. For instance, it is a key political objective for Norway to reduce the social inequalities in health. Norway's Public Health Act (Lov om folkehelsearbeid, 2011) sets out five guiding principles for public health activities;

1) Equalizing social health disparities
2) Health in all policies,
3) Sustainable development
4) Prevention of health injury and disease
5) Participation.

Public health activities should, according to Norwegian law, be carried out as a long-term and systematic task. The figure below illustrates the phases that are included in the work.[5]

Figure 4. Phases in systematic public health activities

Source: Norwegian Directorate of Health, translated by Damvad Analytics.

Originally, the public health field developed as a response to threats from devastating epidemics and infectious diseases, but gradually the perspective has broadened to encompass health threats from environmental, societal and other factors. Public health research and innovation hence focuses on prevention of disease and early death; promotion of health; protection against health threats (such as

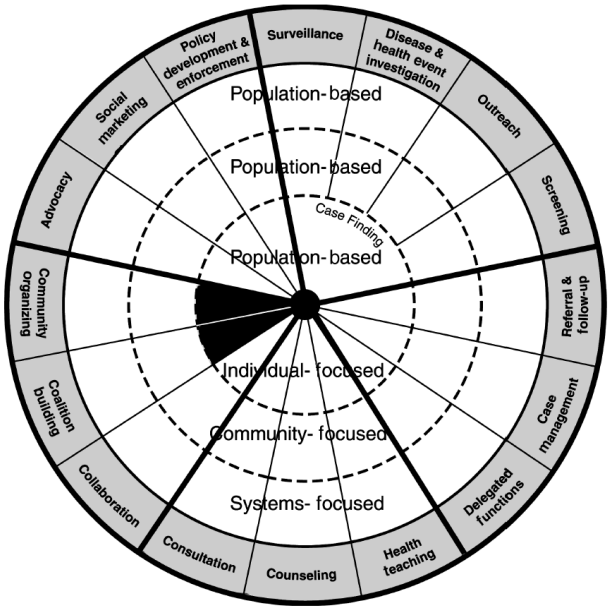
etter-Aftenpostens-avsloring--Vi-er-ikke-gode-nok, see also a response to some the recent articles: https://www.aftenposten.no/meninger/kronikk/i/7lza54/Er-malet-a-skremme_-Aftenposten--Torkel-Steen

[5] https://helsedirektoratet.no/folkehelse/folkehelsearbeid-i-kommunen/veivisere-i-lokale-folkehelsetiltak/hva-er-veivisere-i-lokale-folkehelsetiltak

obesity) and emergency preparedness (for example against pandemic influenza, acute environmental threats such as poisoning of water supplies, bioterrorism etc).

The public health perspective of today takes as its starting point the prevailing needs of society and health policy priorities.[6] Public health is here seen as a synonym for population health. In Norway, public health is broader than just government funded public health system activities. A good example illustrating the diversity of public health approaches is the Intervention Wheel. It is a population-based practice model that encompasses three levels of practice (community, systems, and individual/family) and 17 public health interventions. Each intervention and practice level are seen as contributing to improving population health.[7]

Figur 5. A population-based public health intervention approach



Source: Keller, Linda Olson et al. (2014) Population-Based Public Health Interventions: Practice-Based and Evidence-Supported. Public Health Nursing Vol. 21 No. 5, pp. 453–468.

As public health issues are broad and complex there is a need for research and innovation to take a holistic perspective requiring public health research to be diverse and interdisciplinary. In addition to the research community, target groups for the results of the research are diverse including local and

[6] Research Council of Norway (Work Programme Research Programme on Public Health (FOLKEHELSE). https://www.forskningsradet.no/prognett-folkehelse/Programme_description/1222932153156

[7] The Intervention Wheel, previously known as the Public Health Intervention Model, was originally introduced in 1998 by the Minnesota Department of Health, Section of Public Health Nursing. For a good discussion see: Keller, Linda Olson et al. (2014) Population-Based Public Health Interventions: Practice-Based and Evidence-Supported. Public Health Nursing Vol. 21 No. 5, pp. 453–468.

national politicians, leaders in the public and private sector, administrators, experts in health services and other sectors, and the public-at-large – nationally as well as internationally.[8]

Research on, and innovation in, public health is essential for prevention and treatment of major risk factors and diseases. These include high cholesterol, hypertension, obesity, diabetes, cardiovascular disease, cancer, respiratory diseases such as chronic obstructive pulmonary disease, neurological and rheumatic disorders, depression and other mental health disorders, dementia and addiction, infectious diseases such as hepatitis C and HIV/AIDS, congenital and genetic disorders etc.

3. An open integrating system

This aspiration starts from the premise that in the current system stakeholders can't fully contribute their expertise because they are confined to silos – for example: research is mainly shaped by researchers' priorities and ideas without sufficient reference to patient needs. The aspiration for an open integrating health system is about opening up all stages of the research and innovation process to allow input from everyone with skills or ideas to contribute: researchers, health personnel, practioners, companies, governments, patients and citizens. This applies from the way that problems are identified to how new products and services are created and then adopted by providers of healthcare. The ideal is a system where;

- Evidence and data are generated openly and collaboratively.
- Ideas can come from anywhere, not just health professionals and researchers.
- Innovation is informed by the needs of patients and the knowledge of practitioners.
- International collaboration is encouraged as policymakers realise that health systems around the world can benefit from each other's learning.

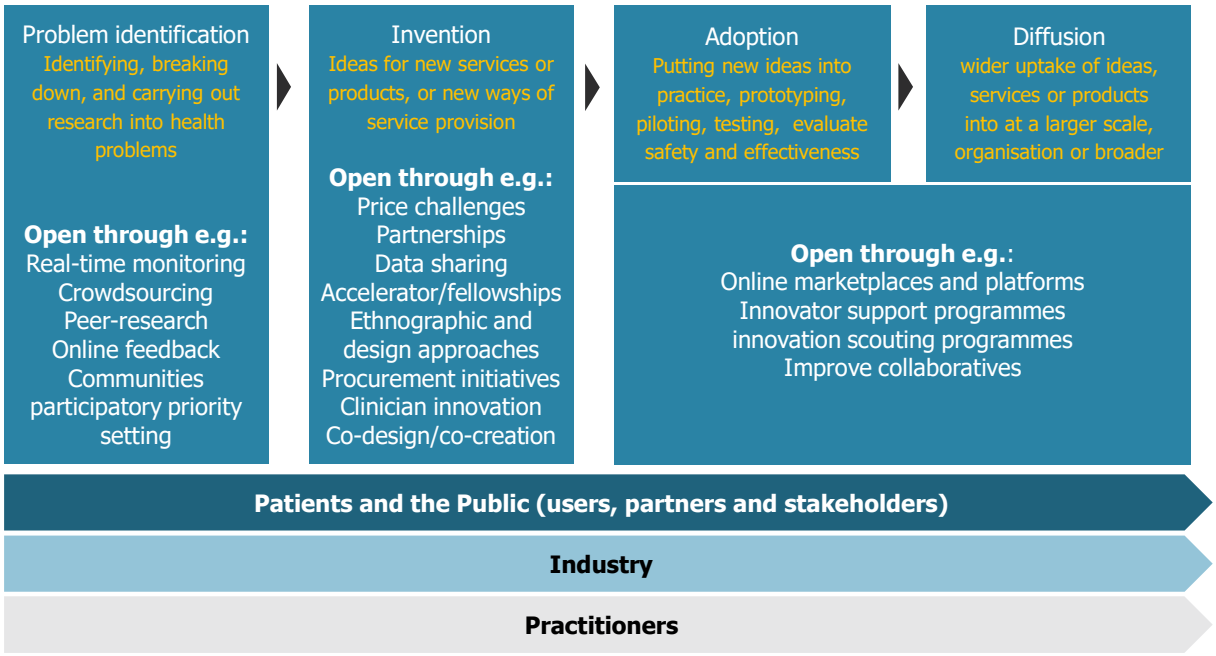
The original promoter of the open innovation perspective is Professor Henry Chesbrough of University of California, Berkeley[9] Taking inspiration from Chesbrough, researchers have been engaged in a recent Nesta project in the UK that developed the idea of an open innovation ecosystem, in which engaged players, intelligent rules and effective articulation of opportunities encourages interactions that support the public interest - in this case, in the health sector.[10] Such a system could be configured as shown in figure 6.

[8] The population health intervention research is a good example of the variety of research disciplines integrated and approaches applied in this field. E.g. Penelope Hawe, and Louise Potvin (2009) What Is Population Health Intervention Research? Can J Public Health 2009;100(1): I8-I14.

[9] Henry Chesbrough (2003); Open Innovation: The new imperative for creating and profiting from technology.

[10] The description of the system aspiration is inspired by many sources, but borrows most notably from Madeleine Gabriel, Isaac Stanley, Tom Saunders (2017); Open innovation in health. A guide to transforming healthcare through collaboration; Nesta, May 2017.

Figure 6. The open integrating system



The stages in the open integrating system are described in more detail below.

Problem identification

The first stage in the process is problem identification: gathering information about experiences and needs; facts about the transmission of diseases and evidence about the efficacy of interventions; both to inform the development of innovations and to help policymakers and funders best target their resources. At this stage, open innovation aims to involve a wider range of actors in collecting and sharing data to more efficiently monitor health issues, for example through data mining and data crowdsourcing. It can also mean giving citizens a role in informing the health innovation agenda, through citizen research and participatory priority setting.

Invention

Open innovation at the invention stage takes the form of collaborating to tackle neglected health issues, for example through challenge prizes and data-sharing initiatives. It can also involve sensitising innovators to health systems and patient needs, for example through pre-commercial procurement programmes, clinician innovation programmes, and ethnographic and design approaches.[11] It can also include opening the invention process to citizens, so that innovation processes reflect their priorities better, using methods such as co-production and co-design.

[11] Ethnography is the use of participant observation entailing prolonged fieldwork. An example of an ethnographic approach in health research is to use mixed methods, including participant observation, to explore complex clinical and organisational issues. There is a long debate about the use of ethnographic methodologies in health care research and for assessing health needs, especially in UK. For example of article discussing the approach, see: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1119117/

Adoption and diffusion

The processes by which new ideas are tested, adapted and ultimately adopted a key aspect of open innovation. Collaborative approaches to promote successful and timely adoption of new ideas include publicising promising innovations, for example through online marketplaces and diffusion support programmes.

4. A business supporting system

The fourth aspiration suggests the research and innovation system should be an effective supporter of the development of a Norwegian health business sector. The concern is that Norway lacks large private health businesses and as a consequence the private investment level in health research and innovation is low compared to other countries and that this can be addressed by reform of the public sector research and innovation.

Those arguing for this aspiration suggest that a culture of public-private cooperation is largely missing in the Norwegian health system. They also note that there is almost no public-private cooperation when it comes to digital health innovation, and there is a general suspicion of private health businesses from public sector researchers. They suggest the Norwegian system is missing appropriate incentives as well as a culture and norms that celebrate and reward new business development, innovation and academic entrepreneurship.

This absence is seen as a problem because of the large potential to develop a globally competitive health business sector in Norway. This is underlined by the 2017 OECD review of Norwegian Innovation Policy which notes that Norway is facing a "triple transition imperative" in which it needs, first, to shift towards a more diversified and robust economy; second, to move to a more competitive, effective and efficient innovation system; and third, to support research and innovation activities that can confront an array of societal challenges, of which several are health related.

In many of the interviews, as well as in the two workshops, the importance of the health business sector was emphasised. There is a general agreement that the development of a private health business sector should be promoted, and the Norwegian Ministry of Trade, Industry and Fisheries is currently preparing a white paper on how to support the development of the Norwegian health business sector. A paper the HO21 board has provided input to.

5. A European and global knowledge system

The fifth aspiration captures the idea that the Norwegian health research system should be an interdependent part of the European and wider research system – contributing to and benefiting from international research and innovation. As measured by citations, around 1 pct. of global knowledge is

https://www.medizinethnologie.net/ethnographic-practice-within-public-health/
https://journals.sagepub.com/doi/abs/10.1177/174498719600100403

produced in Norway, so a Norwegian research and innovation system of high quality and relevance take advantage of the international knowledge system, including through international funding opportunities.

Horizon 2020 and the future Horizon Europe are the most important funding instrument for the internationalization of Norwegian health research and innovation. The European research and innovation cooperation programmes and networks are important for strengthening the quality of Norwegian research and for gaining access to European and international markets. The importance of Norwegian basic research of high quality with a strong emphasis on international research cooperation has been recognised as key to allowing Norwegian research and innovation system to take advantage of the European and global knowledges system. This has been emphasized in Norwegian research policy since the beginning of the 2000s and has resulted in a strong growth in publications, citations and international cooperation.

The Horizon Europe programme's content and missions are not yet finalised, so it is not clear to what extent Norwegian healthcare priorities are included. However, it is clear from the interviews and document studies that Norway's focus was on ensuring Norwegian energy and ICT research and innovation priorites were included rather than pushing Norway's health research and innovation priorities. Norway was not part of the Programme Committee for health in H2020 and it was not involved in suggesting any of the proposals.

On the other hand, many of Horizon Europe's focus areas will be highly relevant to Norway and align well with Norwegian health priorities. Horizon Europe is expected to emphasize sustainability goals and shift the focus towards applied research and public health and society. Identified challenges are likely to include prevention of diseases, health inequality, vulnerable periods in life and vulnerable groups. About 50 pct. of the budget of around EUR 7.7 billion is likely to be used for partnership and mission-oriented research. One important mission is expected to be curing pediatric cancer.[12]

The Norwegian research and innovation system must be better equipped to promote participation in Horizon 2020/Horizon Europe health cooperation networks. Interviewees suggested that the best way to promote Norwegian health research and innovation interests is through European health research networks and innovation clusters. Among those mentioned were ESTHER, an industry-driven initiative and the Innovative Medicines Initiative, which is a big public and private partnership including many of the large pharma companies in Europe. The Human Brain Project and the Active and Assisted Living Programme are also being mentioned as important networks for Norwegian actors.[13]

Interviewees commented that it was often difficult to get access to the European research initiatives, networks and clusters for Norwegian researchers and companies. However, some universities like NTNU have succeeded in doing so in areas outside health, and recent figures show that Norway Health

[12] EUs nye rammeprogram for forskning og innovasjon: Hvordan er helse- og omsorgsperspektiver ivaretatt? Rådsmøte Helse og Omsorg 21. Presentation by Tom -Espen Møller. 29. november 2018

[13] For more information see: https://www.humanbrainproject.eu/en http://www.aal-europe.eu https://www.eithealth.eu and http://www.medtechweek.eu/sites/default/files/PDFS//Healthtech%202030_vision%20by%20MedTech%20Europe%20and%20ESTHER.pdf

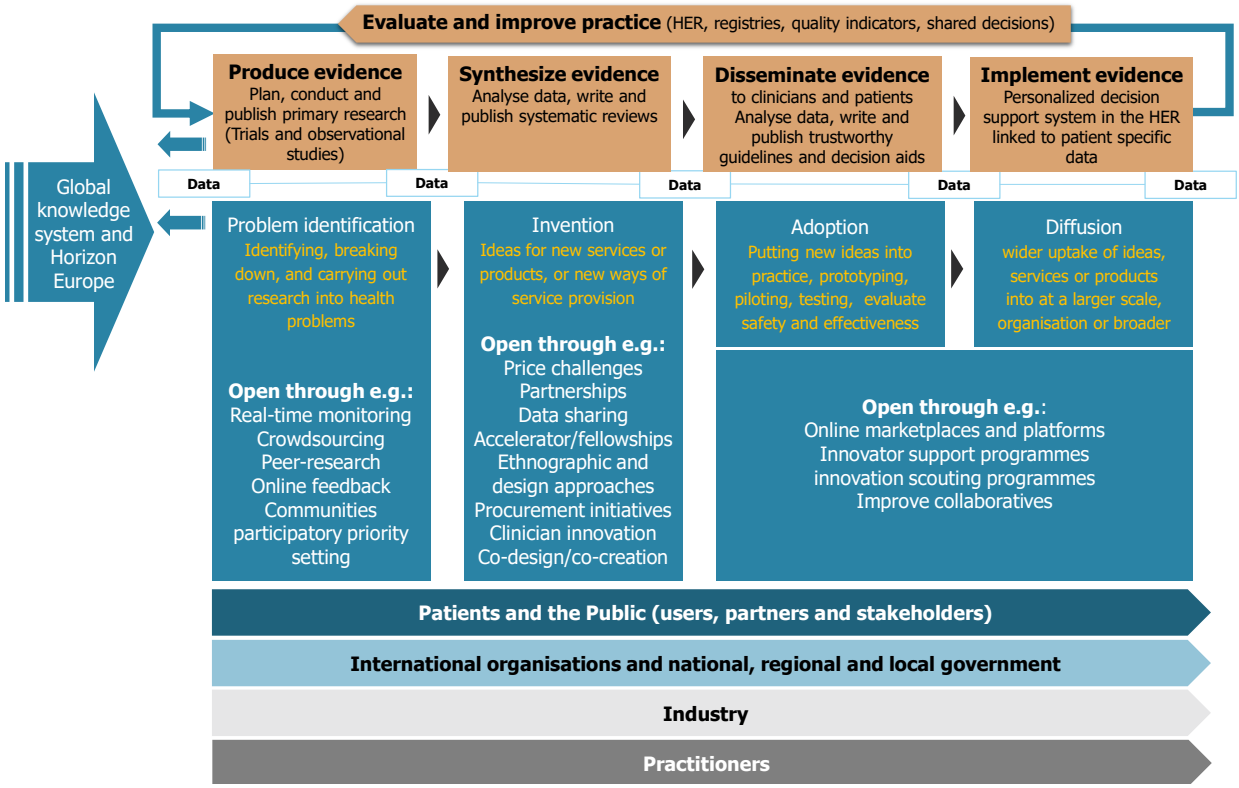
Tech has a rather high success rate of 57 pct. on their EU applications for H2020 financing. However, interviewees suggested that wider success will still require basic research of high quality as well as long-term financing, planning and cooperation between the UH sector and the health industry.

Finally, interviewees argued that Norway needs to establish stronger links to global research and innovation environments to link with the best innovative health start-ups and growth companies. This would allow Norwegian researchers and companies to access talent, skills and investment that are currently only found abroad, primarily in the US.

Integrating the five aspirations

Below we integrate the five aspirations into one model. The idea is to illustrate a system that that can deliver research and innovation of high quality and relevance with a short way to public health and society. A system that is both effective in providing better public health and in developing a dynamic and competitive private health business sector in Norway. The model provides the framework for the analysis and impact cases in the following chapters.

Figure 7. A collective health research and innovation model based on all aspirations

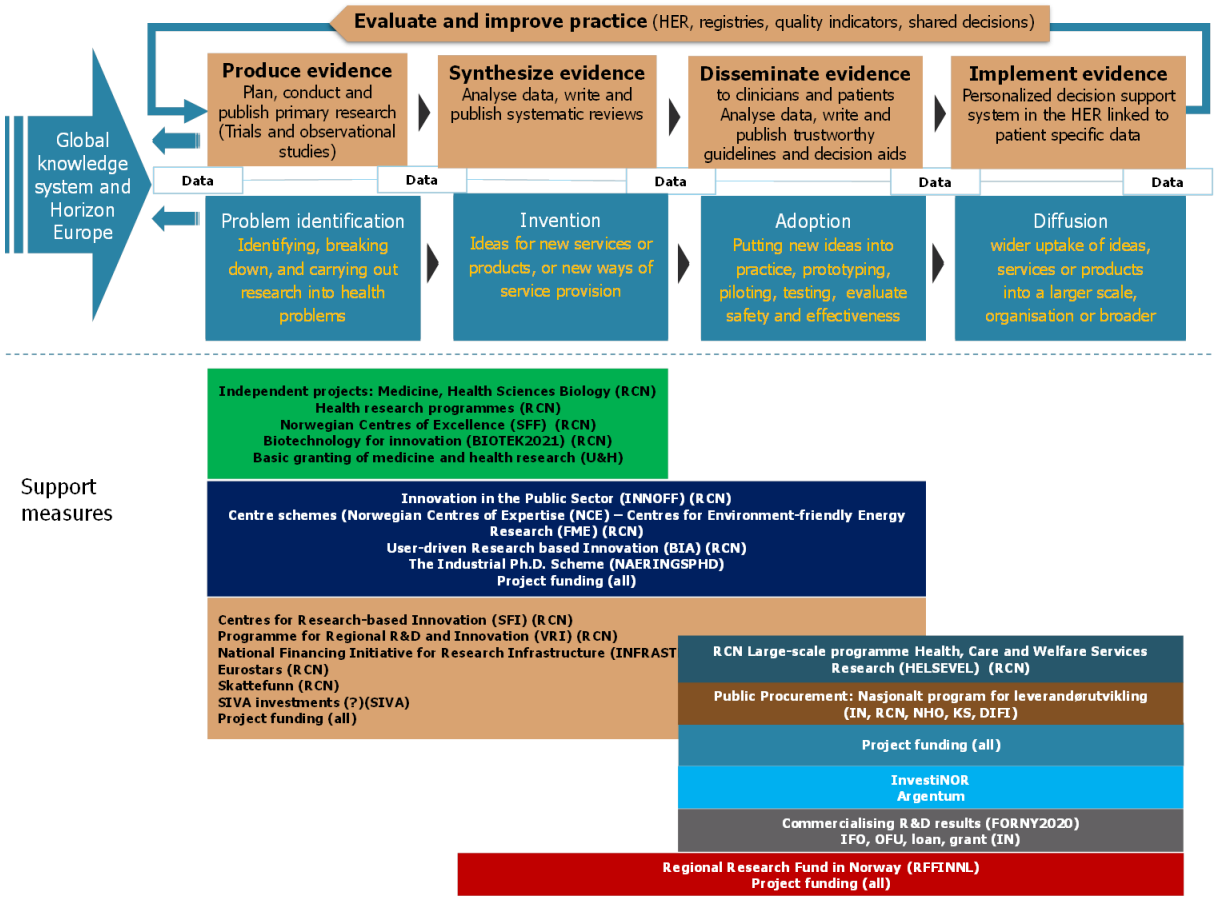


3 Basic characteristics of today's system

This section analyses and describes the basic characteristics of Norway's health research and innovation system today, including: the existing support measures, programmes and initiatives; the responsible actors; the governance and the distribution of resources.

Figure 8 shows the programmes and initiatives that support health research and innovation in Norway. The support system is big, complex and appears relatively uncoordinated with multiple actors operating at different stages and levels through a great variety of support measures and initiatives.

Figure 8: Norwegian support measures for health research and innovation (public and private)



Source: Based on desk research of research and innovation programmes and HelseOmsorg21 - Et kunnskapssystem for bedre folkehelse. Nasjonal forsknings- og innovasjonsstrategi for helse og omsorg, 2014.

It is difficult to draw up one single figure of the whole support system which provides detail on every measure linking its purpose to each part of the health research and innovation system. The support measures listed above are all to a greater or smaller extent relevant for health research and innovation. Some are primarily targeted at health research and innovation, others have a broader purpose but are used by the actors in the health sector.

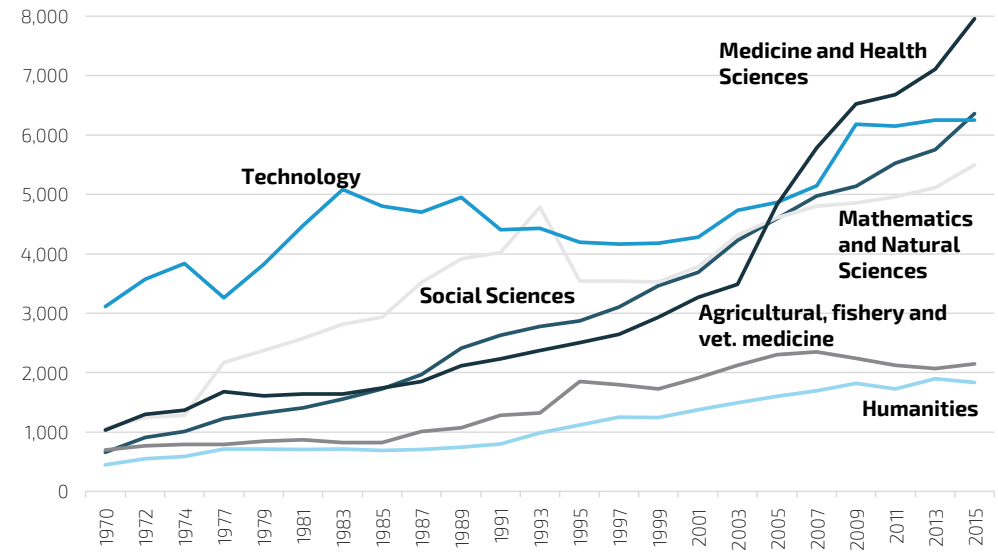
There is a huge diversity of measures. Some of the measures primarily aim to support basic research while others support innovation or higher education. Some are focused on private market entry, other initiatives aim to support other kinds of diffusion: implementation in hospitals, in nursing homes or in society. Some measures support the early pre-design and research phases with user-involvement while others support supplier development and public-private innovation and procurement.

A majority of the funding is allocated at the national level, although most of it is channelled via the regional health authorities. The Ministry of Health and Care Services (HOD) and the Ministry of Education and Research provide the vast majority of the public funding to health research and innovation in the universities and in the university hospitals. Most of health research and innovation in Norway is funded through direct grants, including grants to universities and university colleges (the U&H sector), to the regional health authorities and research institutes.

In addition, it is worth noting that the Norwegian system is characterised by a low level of private investments which makes Norway a so-called "different country", compared to other European countries, especially Denmark and Sweden that both have large health business sectors.

The public health research and innovation budget is approximately 8,4 billion NOK per year which amounts to approximately 15 pct. of the total yearly public research and innovation budget for Norway. As shown in figure 9, Medicine and Health Sciences is the fastest growing field, especially over the last two decades.

Figure 9. R&D expenditures in Norwegian universities, colleges and the institute sector



Source: NIFU
Note: Fixed 2015 prices, NOK million Total: 56.8 billion.

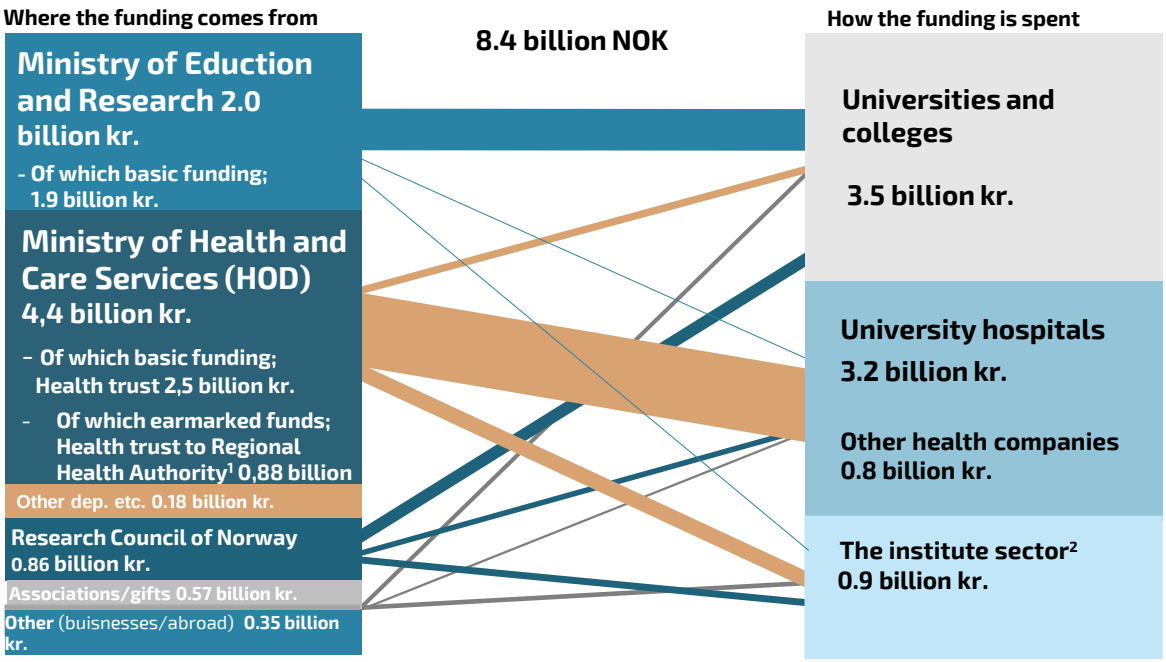
In total, the regional health authorities account for 44 pct. of the publicly funded medical and health research in Norway. The UH sector accounts for 39 pct. while the institutes account for 12 pct.

(primarily Folkehelseinstituttet and Statens arbeidsmiljøinstitutt). The science colleges account for the last 5 pct.

On average, the Research Council of Norway administers and channels about 27 pct. of the public funding for Norwegian research sectors, but only 10-12 pct. of the public funding for health research. The other public financiers channel their funds in different ways. A high share is funded through direct grants, including substantial basic grants, especially to the U&H sector, health authorities and institutes. The Research Council of Norway allocates funds to both the U&H sector and the institutes.

The fact that the Research Council of Norway only administers and channels 10-12 pct. of the public funding of health research leaves the impression of a rather weak national coordination and competition in Norwegian health research. This arguably has an impact on both the quality and the internationalization of health research since most of the funding for clinical research is reserved for hospitals and the regional health authorities. According to some of the interviewees it also explains some of the challenges regarding the lack of cross-sectoral cooperation.

Figure 10. Funding streams in Norwegian health research in 2015



[1] Earmarked funds from Ministry of Health and Care Services to Regional Health Authority supplemented by funds from the framework grant to Regional Health Authority
[2] Only operating expenses (total expenses, including capital expenditures, are not recorded in the institute sector)

Source: NIFU

Note: Total R&D expenses, excl. R&D conducted in business, in the field of medicine and health.

The Research Council of Norway funded approx. 1.3 billion NOK of health linked research in 2016. The biggest funding mechanisms were:[14]

- Free project support (FRIPRO), Norwegian Centres of Excellence (SFF) and National Financing Initiative for Research Infrastructure (INFRASTRUKTUR): 508 mio. NOK
- Health research programmes: 394 mio NOK.
- Generic technology programmes Biotechnology for innovation (BIOTEK2021), ICT and digital innovation (IKTPLUSS), Nanotechnology and Advanced Materials (NANO2021) and User-driven Research based Innovation (BIA) -programme and Centres for Research-based Innovation (SFI)-programme, in total: 391 mio NOK.

The funding streams generally follow 'the sector principle' in the sense that the funders take particular and dominant responsibility for research and innovation in 'their sector'. For instance, the Ministry of Health and Care is the owner of the hospitals and responsible for funding research and innovation in the hospital segment which tends to neglect the needs of public health. This is particularly problematic as the Ministry of Local Government and Modernisation does not have a research budget and therefore cannot fund health research and innovation in the public health sector where it has municipal responsibilities.

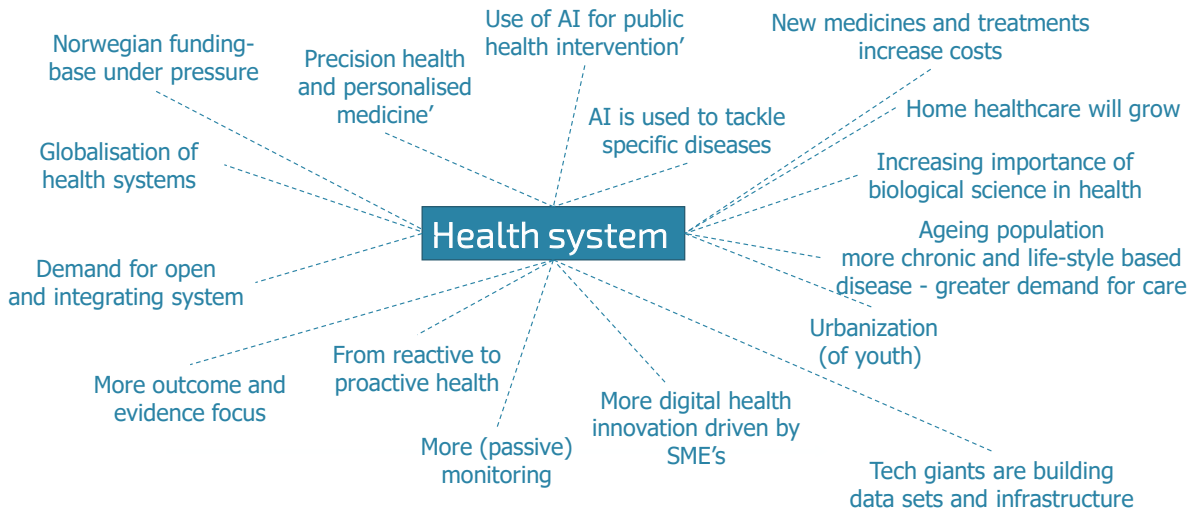
The interviews, document research and analysis leave the impression that similar types of support measures are used across the different actor groups and sectors; mainly funding for individual basic research and/or innovation projects and/or education whereas little funding goes to building clusters and networks; providing advice or guidance; and patient and user involvement. However, these conclusions are tentative as the yearly reports and budgets from the various funders are characterized by a general lack of quantitative measures and limited transparency of what is included under different headings. Different funders use different terms and alternative definitions of the same terms; varying what is reported as health research and innovation in their annual reports and budgets. There is clearly great autonomy for individual institutions and funders, but this comes at the cost of overall clarity, coordination and strategic steering of health research and innovation.

[14] In addition to medical and health research, the funding of approx. 1.3 billion NOK includes technological and social science research that is relevant to health.

4 Major trends influencing the Norwegian health system

There are many important wider trends influencing Norwegian health research and innovation. The trends most likely to affect the transformation of the health and research innovation system were identified through early interviews and the first workshop alongside the literature review. The figure below summarises the major trends discussed and examined in the project and they are discussed in the following paragraphs. The trends have inspired the identification of problems and proposed solutions.

Figure 11. Major trends influencing health R&I system transformation



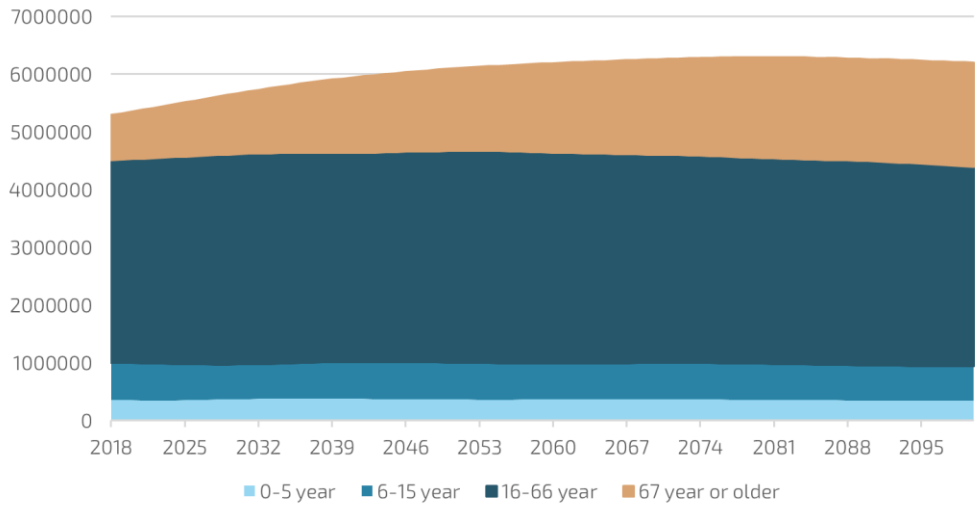
Source: DAMVAD Analytics, 2019

A large wave of the Norwegian population will enter the 67+ age bracket within the next 20 years, see figure 12. This suggests there will be a greater demand for care in Norway to manage increased disease in the population, especially chronic and lifestyle-based diseases. Sedentary lifestyles, changing diets, and rising obesity levels are fuelling an increase in chronic diseases – most prominently, cancer, heart disease, and diabetes.[15]

The rapid urbanization of the youth population while the elderly population remains distributed across Norway, raises questions of whether there will be enough healthcare personnel, e.g. doctors, nurses and social personnel, in rural areas. This problem may be particularly acute for social personnel as they are the most rapidly growing segment of the healthcare labour force (see figure 13).

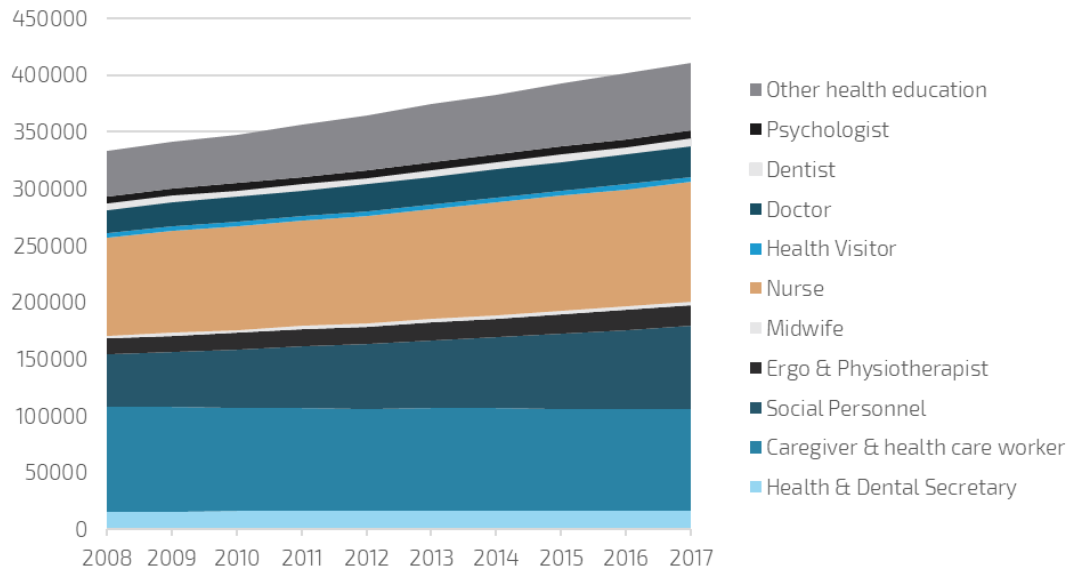
[15] Deloitte (2018), Global health care outlook - The evolution of smart health care.

Figure 12. **The share of the Norwegian population over 67 of age will increase**



Source: SSB (Table 11667)
Note: This population projection is based on medium fertility, life expectancy and domestic relocation and low immigration.

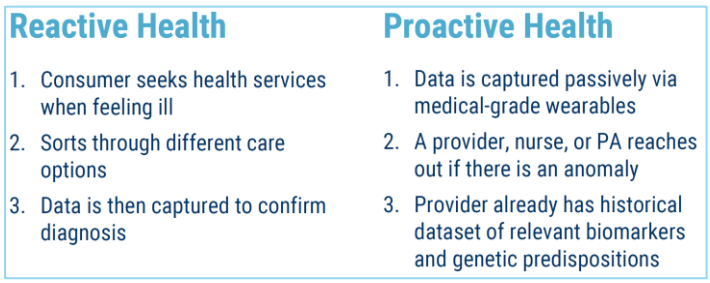
Figure 13. The share of social personnel has seen the biggest increase



Source: SSB (Table 7939)
Note: Social Personnel consists of "Barne- og undgomsarbeidere", "Vernepleier", "Barnevernspedagog" and " Sosionom". Other health education consists of "Annen videregående helseutdanning", "Øvrig helseutdanning på høgskolenivå", "Medisinstudent med lisens" and "Annen helseutdanning på universitetsnivå.

In terms of technologies, the cost of DNA sequencing is expected to continue to fall, as more genomic information becomes available. At the same time, more is being learned about citizens' predispositions to diseases.[16] Understanding detailed cellular mechanisms is becoming increasingly important in areas as wide ranging as the sustainability of life, the environment, ecosystems, food quality, causes of illnesses, and the development of medicines.

Many small health tech companies as well as the tech giants are expected to play a larger role in the health research and innovation system by providing more advanced medical-grade wearables for healthy people (e.g. the Apple Watch), and thus contributing to a more passive health monitoring. As a result, the relationship between doctor and patient could change to a proactive one where the doctor reaches out to the patient if anomalies are identified rather than the patient initiating contact.[17]



Source: CBInsight, 2018.

The algorithms used in machine learning and artificial intelligence are likely to continue to improve as ever larger and more detailed datasets become available. This will drive a major trend toward the use of AI in public health interventions and in tackling specific diseases.[18]

Many of the trends involve digital health innovations from all parts of the ecosystem, including both public and private, small and large, and local and global actors. As illustrated in the figure below, these include: digital health with wearable smartphone and sensor-based technologies; the aggregation of large quantities of structured and unstructured health information and sophisticated analyses with artificial intelligence, machine learning, and natural language processing techniques; and precision-health approaches to identify individual-level risk and the determinants of wellness and pathogenicity.

The new digital innovations provide a plethora of possibilities for health improvement but realising that potential and achieving meaningful transformation will require the right governance and infrastructure provision in Norway. There is a requirement for rapid adoptions of effective interventions. However, there are also risks in early adoption of new innovations that are not evidence-based or that have yet to demonstrate effective integration into patient care. These risks

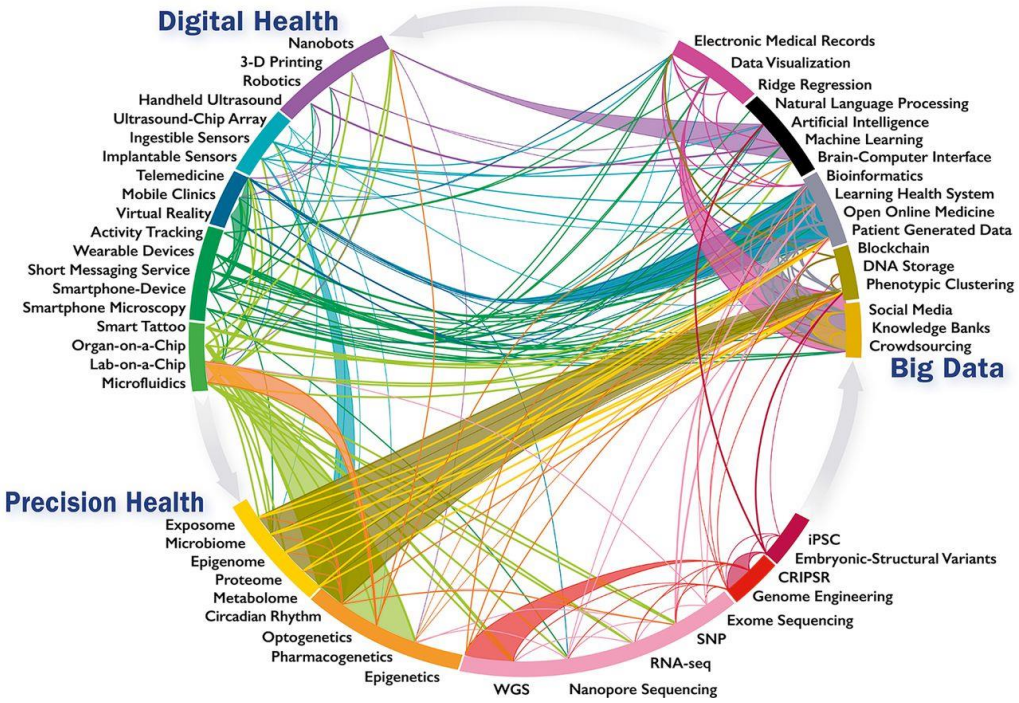
[16] Genomic information is one of several resources that can be mobilised to understand and tackle human health better. Data on population behaviour, diet, education and income, medication, risk factors and diseases are other examples of resources.

[17] CBInsight (2018), Healthcare in 2025, 2035 – What will healthcare look like in the coming decades?

[18] Ibid.

can result in unintended consequences, such as breaches of privacy, patient safety challenges or inadvertently increasing the costs of care. It may also worsen inequalities - if, for example, precision medicine is developed based on certain populations or if some groups do not have access to technologies. There is a need for continuous evaluations of whether and how the innovations actually improve outcomes and the quality of care and the necessary changes will involve major integration challenges across the health system.[19]

Figure 14. New digital innovations in healthcare



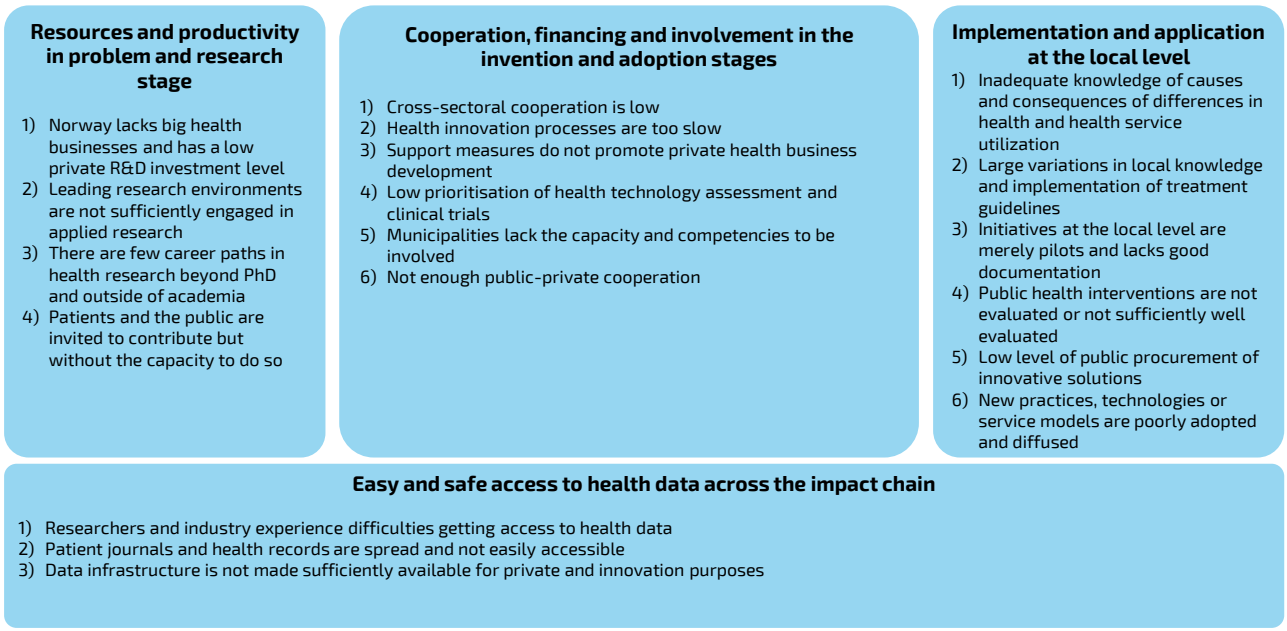
Source: 2017 Roadmap for Innovation—ACC Health Policy Statement on Healthcare Transformation in the Era of Digital Health, Big Data, and Precision Health.

[19] 2017 Roadmap for Innovation—ACC Health Policy Statement on Healthcare Transformation in the Era of Digital Health, Big Data, and Precision Health. Journal of the American College of Cardiology Vol. 70, no. 21, 2017.

5 Norwegian problem areas

Through document studies of relevant literature, more than 70 interviews with stakeholders and key actors, as well as expert workshops; the project moved from a broad identification of challenges to the selection and more nuanced description of the 19 most important problem areas confronting the Norwegian health research and innovation system today. The 19 problem areas are hence placed into four groups across the health research and innovation chain, as described in the figure below.

Figure 15. Norwegian problem areas identified across the health research and innovation chain



Most of the identified problem areas are well-known by the actors in the Norwegian system. In recent years there have been attempts to address several of the problems in different ways. In some cases, problem solutions have been proposed, and for others political initiatives have recently been taken. However, common to all the problems identified: no solution with visible impact has yet been implemented.

Below follows a description of each of the identified problems in the Norwegian health research and innovation system at the overall level. Many are accompanied by examples of concrete impacts arising from the problems. The purpose is to show how the overall issues have concrete impacts.

Resources and productivity in problem and research stage

The first group of problems highlighted in interviews, workshops and document studies concerns resources and productivity at the problem identification and research stage. The problem group comprises of several connected challenges, summarized in the following headlines and detailed below:

1) Norway lacks big health businesses and has a low private R&D investment level.

2) Leading research environments are not sufficiently engaged in applied research.
3) There are few career paths in health research beyond PhD and outside of academia.
4) Patients and the public are invited to contribute but without the capacity to do so.

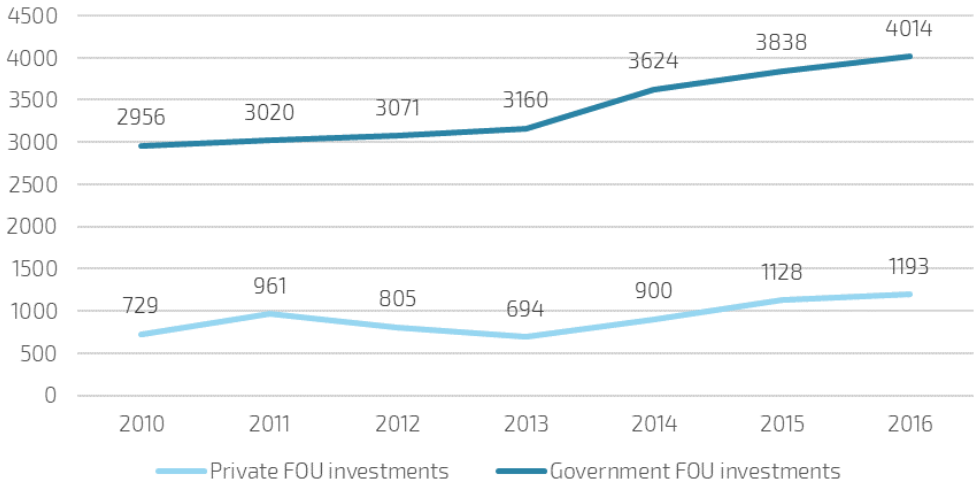
1. Norway lacks big health businesses and has a low private R&D investment level

The limited level of investment by private organisations, foundations and companies, both Norwegian based and international is seen as a clear challenge by the actors in the Norwegian research and innovation system. There is generally a lack of research funding donations from private foundations and a lack of risk-willing capital for research and innovation. The challenge is due to the size, rather than the number of Norwegian health companies. The Norwegian health business sector consists of many small companies including many start-ups and has a yearly growth rate of more than 10 pct. The big health industry players and large health research financing foundations that are present in Norway and Sweden are missing in Norway. This has a clear impact on investment levels, and this is the main Norwegian challenge.

Interviewees argued that although the low private investment level is not a new challenge, it continues to limit the amount of resources available for health research and innovation in the Norwegian system. Furthermore, it forces Norwegian researchers to spend more time than their Nordic colleagues on public research application processes in open competition. The low private investment level in Norwegian research and innovation is well-known and was already identified in the first HO21-strategy from 2014.[20] While Norway's public investment level is comparable to other Nordic countries – Sweden and Denmark – Norway has far less private investment hence overall investment is far lower in Norway. Recent years have not seen a real improvement of the situation, although private investments have increased from a low level since 2013.

[20] HelseOmsorg21 (2014) Nasjonal forsknings- og innovasjonsstrateg for helse og omsorg. Et kunnskapssystem for bedre folkehelse.

Figure 16. Government FoU health investments increase while private investments remain low



Source: OECD and Legemiddel Industrien FOU undersøkelsen 2017.

The interviews as well as the data available give several indications of the challenges associated with the low private investment level in research and innovation in the early research stage. Private actors argue that the Norwegian support system is missing appropriate incentives as well as a common culture and norms that celebrate and reward new business developments in innovation and academic entrepreneurship. This remains the case though several initiatives have been taken in the last two decades to solve these problems.

In 2003, new legislation passed by the Norwegian parliament came into effect, granting universities the right to capitalize upon Intellectual Property (IP) developed by their employees. This shift launched a nationwide initiative to new innovations to market through technology transfer offices (TTO's). Today the TTO's support the initial commercialisation of technology, ideas and patents from universities. However, capital is still lacking for further development and testing of products. Although support is available for prototype development and clinical documentation the products are still too early in development to attract private investors. Interviewees think that although Innovation Norway's instruments are relevant in principle, such as innovation loans and OFU contracts, their scope is too limited and they do not function well for supporting health innovation.[21] In contrast, the Norwegian clean energy sector has Miljøteknologiordningen for simulation, testing and verification of new solutions in clean tech and the oil and gas sector has access to the so called Oljemyggordningen for drawing private investment capital. In 2015, attempts to create a similar instrument for the health sector called Helsemyggordning in the Norwegian Parliament were unsuccessful.[22]

[21] Menon Economics (2017) Helsenæringens verdi, Menon - publikasjon nr. 29/2017.

[22] For more information see https://www.innovasjonnorge.no/miljotek/ and https://data.holderdeord.no/propositions/10605 The proposal was based on a report from Menon Buiness Economics (2013): Helsemyggordningen: Et virkemiddel for å stimulere til helseinnovasjon.

The interviews point to the low private investment level as a particularly challenging problem because the lack of available investment also hold back the growth of the sector itself – preventing the growth of additional investment. As most companies within health tech in Norway are very small, they need Patient Capital investments to grow – investments which are in short supply. This imbalance of public and private investment makes the health sector different from the other sectors and interviewees argue it is not sufficiently recognized. This lead to a lack of research and innovation programmes supporting the development of a private health tech businesses. For example, a recent evaluation of the RCN's BIOTEK2021 programme highlighted a lack of support for commercialisation.[23]

Recently, it has been acknowledged that the small-size of the Norwegian economy is a challenge in itself for attracting international risk-willing capital for start-up and high-growth companies. As this challenge is shared with the other small Nordic economies there are attempts to harmonize regulations and business support measures across the Nordic countries. One concrete proposal is to harmonize tax treatment of stock options and tax incentives for investment.[24]

Several interviewees argue that a key problem is the lack of business competencies and people who can take the ideas developed in research and commercialize them. To solve this Norway would need to focus on developing and attracting a private health business rather than supporting research, innovation and cooperation initiatives that the existing small health business companies are not really equipped to utilize.

According to some of the interviewees, another challenge is that the TTOs in place do not have the mandate and objective to invest in areas specifically for the benefit of society, patients or businesses. They argue that this means that their activity becomes short-sighted and narrow in scope. To change this there needs to be clearer KPI's (tellekanter) that focuses on rewards in innovation and contribution to new business development. The TTO's are evaluated but not on these parameters.

2. Leading research environments are not sufficiently engaged in applied research

Norwegian health research is comparable to that of other Nordic countries when measured by total publications, citations and international collaboration, as shown in the figures below. Since the beginning of the 2000s Norwegian research policy has given central priority to strengthening high-quality basic research and internationalization as it is generally acknowledged that this is an essential prerequisite for the Norwegian research and innovation system to function. This has resulted in a large increase in health publications, citations and international cooperation. However, many of the interviewees felt this has led to a situation where the leading Norwegian research environments are mostly engaged in basic research rather than applied research. One reason for this is the sectoral boundaries built into the Norwegian research funding system that restrict which funds are available to research institutions. As a result, a large share of the funding for applied health research goes directly from the Health and Care Ministry to the regional health authorities without researchers from

[23] Technopolis (2017): Evaluation of the RCN's BIOTEK2021 programme. Final report.

[24] Kreutzer, Idar (2018): An integrated and effective Nordic ecosystem for innovation and green growth. A closer look at access to risk capital in the Nordic countries. Report prepared for Nordic Council of Ministers.

the universities and institutes or other research actors being able to apply for the funding. Hence, their ability to engage in the applied research is restricted.

Figure 17. Norwegian health research is doing well by high Nordic standards

Note: Data covers 2009 to 2016 in the field of biomedicine and health research. The figures apply to the five largest universities in Norway, Denmark and Sweden measured by the number of publications.
Source: DAMVAD Analytics 2018 based on The CWTS Leiden Ranking, 2018.

On the other hand, some of the interviewees argue that the reason why the leading Norwegian research environments are not sufficiently engaged in applied research is not so much due to a siloed funding system but rather a lack of interest in the research questions beyond basic research.

Interviewees also argue that the lack of applied research was due to a lack of incentives for researchers to engage in this type of research. Most researchers are rewarded primarily for their publications and citations – leading to a focus on basic research. To address this, the system needs to provide incentives for researchers to carry out research that will address real world health problems or has the potential to do so. Hence, aspects such as the innovation potential of research proposals and industrial and practitioner collaboration should be rewarded.

Given the strength for Norwegian basic research, the analysis suggests that more effort needs to be made to strengthen applied research focused on identified needs. Basic research is a long-term investment in future applied research. Within the research system, it is crucial to have researchers who have the competence to translate new knowledge from basic research to application. Such translational research requires competence in basic research as much as in applied research.

Collaboration between researchers from different traditions and fields increases the chance that basic research results are translated into practical use. In this context, it is important to ensure that research resources are appropriately distributed in order to safeguard basic research and strengthen applied research most effectively.

3. There are few career paths in health research beyond PhD and outside of academia

Many of the interviewees in academia suggest that the Norwegian health research and innovation system does not provide sufficient career paths outside academia to young researchers that would retain them in research roles beyond their PhD.

Some argue that the main problem is the lack of industry-public research collaboration in the health sector, a consequence of the lack of research-intensive healthcare companies. Interviewees feel that there is a culture of suspicion of private engagement in health research. This is in contrast with the oil and gas sector in Norway where the barriers for public-private cooperation are lower and there is a tradition for both industrial PhDs and traditional PhDs to go from universities to the private sector.

Others mention that an important explanation behind the missing career paths in health research is that many of researchers hold part-time positions besides their main work in hospitals. This creates a lack of full-time permanent research positions in the Norwegian system.

4. Patients and the public are invited to contribute but without the capacity to do so

Our analysis suggests that patient and user involvement is important to properly understand the needs of the health system and to generate appropriate innovation. Those involved in research and the design of innovations are often several steps removed from the healthcare practice. This leads to

the risk that they do not fully understand the needs of clinicians or patients and may not have the information required to best meet them. By the same token, even innovations developed by experienced clinicians may fail to address key patient needs that are obscured from the clinical perspective.

When the health sector is dominated by professionals, other stakeholders such as patients, members of the public or people working in non-health sectors will find it hard to get their priorities addressed by the system.[25] Some stakeholders argue that there is not enough research on prevention, public health and primary healthcare. These are areas in direct contact with the users and therefore benefit from ensuring effective user involvement.

Patient and user involvement in Norwegian health research is increasing and it has become a requirement in most health research projects funded by the Ministry of Health and Care and the Research Council of Norway. The regional health authorities report that the proportion of user involvement in research projects is steadily increasing both overall and within different disciplines. In 2017, almost 60 percent of the research projects reported user involvement.[26]

However, many interviewees indicate that despite the good intentions of the funders, Norwegian patients and the public often do not have the capacity to contribute effectively. The health system's different actors – university researchers, hospitals and municipalities – all work in different ways and have different processes to facilitate the involvement of and communication with patients and citizens. However, there is a need for an overall programme to improve and develop these methods of engagement. Such a programme should allow for wide-spread experimentation with different kinds of user involvement, i.e. real-time monitoring, crowdsourcing, peer-research, online feedback, establishing communities and making participatory priority setting.

Cooperation, financing and private and local involvement

It was evident from the interviews and document studies that the Norwegian health research and innovation system find cross-sectoral cooperation and the involvement of private actors and municipalities difficult. This group of problems is broken down below and each is described in more detail in the following paragraphs.

1) Cross-sectoral cooperation is low
2) Health innovation processes are too slow
3) Support measures do not promote private health business development
4) Low prioritisation of health technology assessment and clinical trials
5) Municipalities lack the capacity and competencies to be involved
6) Not enough public-private cooperation

[25] Madeleine Gabriel, Isaac Stanley, Tom Saunders (2017); Open innovation in health. A guide to transforming healthcare through collaboration; Nesta, May 2017.

[26] Regional helseforetak (2018) Forskning og innovasjon til pasientens beste. |Nasjonal rapport fra spesialisthelsetjenesten 2017.

1. Cross-sectoral cooperation is low

To achieve effective translation of research into health benefit, there is a need for broad cooperation across the whole production chain involving both the UH sector, the research institutes, the hospital sector, the municipal sector as well as private actors, including companies, organisations, foundations and associations.

However, in the interviews as well as in the workshops, many stakeholders suggested that cross-sectoral cooperation is severely hindered by several factors including the Norwegian so-called 'sector principle'. The sector principle runs across the public sector and as enshrined in law, Norwegian ministers have an individual constitutional responsibility towards the Storting (the parliament of Norway). Therefore, each ministry funds only within its own sector. The overall purpose is to ensure accountability of all ministries and the entire Government. However, this causes problems where issues overlap between sectors – for example between health and the regions: where primary health care is under the responsibility of Ministry of Local Government and Modernisation (KMD) but health research funding is held by the Ministry of Health and Care Services (HOD). For this reason, the sector principle has been modified through several measures.

The establishment of the Norwegian Research Council in 1993 is one of these modifying measures. The Research Council considered the challenges with the sector principle in 1998 and argued there was a need to support broad cross-sector initiatives. It recommended using explicit R&D plans as a tool in all ministries. Sector research plans should cover the need for strategic research, R&D related to the development of primary projects in the sectors and research for policy development and management. The council also recommended that a budget plan should be established that combines the submission of research reports and long-term budget once per parliamentary term. The total annual research budget should be submitted jointly by the ministers responsible for coordinating research questions. At government level, sectoral thematic priorities should be used to promote a renewed coordination of sector research efforts.[27]

The Long-term Plan for Research in 2014 and the coordination of research policy between the ministries are the most recent attempts to mitigate the disadvantages with the sector principle. However, these approaches have not been effectively used to address problems in the coordination of health research.

The sector principle separates medical research, funded by the Ministry of Health and Care Services (HOD), from other areas of health provisions, such as public health and primary care, that are the responsibility of the Ministry of Local Government and Modernisation (KMD). This means that the research funded by the the Ministry of Health and Care Services (HOD is not open to competition from researchers in the universities, potentially reducing its quality, and that researchers in public health and primary care find it difficult to obtain funding from a health ministry primarily focused on medical research. This results in a lack of "collaborative action research" (samhandlingsforskning), a lack of

[27] Forskning for framtiden, Forskningsrådets strategi for norsk forskning og for Norges forskningsråd, 1998. See also: Eivind Schmidt: Samordning i statsforvaltningen - "ministerstyre" - et hinder for samordning?

national coordination, that sectors and areas become underfunded, and limited interest and incentives for cooperation between the UoH sector, regional health authorities, institutes, municipalities and the private sector.

Interviewees suggested several solutions, including more national and inter-sectoral announcements, as well as the introduction of larger mission-oriented projects to solve big problems across sectors. There are already initiatives to try and improve cross-sectoral cooperation between universities (UH-sector) and regional health authorities including the Husebekk-committee.[28] The committee identified barriers to collaboration and recommended that research infrastructures be coordinated at strategic and operational level; and that sectors should establish joint research administrators support. The committee also recommended that a formal cooperation forum should be established with high level participation from the ministries, regional health authorities and universities; alongside a system of mutual governance presentation between universities and regional health authorities and between university hospitals and the Faculty of Health.

A second initiative to improve cross-sectoral cooperation was a 2017 expert report delivered to the Norwegian Ministry of Finance and Ministry of Education and Research.[29] The report argues that the sector principle means that long-term and broadly-based research needs are poorly met. In the report it was observed that research spending by several ministries is low, and often not open to national competition. The report recommends an increased focus on the quality of research, through broader competition and urges coordination in research policy across sectors.

The analysis underlines the challenges posed by the sector principle, but the number of initiatives to address it highlights the scale of the challenge involved, suggesting innovative approaches will be needed if the challenges are to be overcome.

2. Health innovation processes are too slow

The interviews and the literature gave a clear impression that the health research and innovation processes are felt to be too slow. While the often-quoted refrain that it takes, on average, 17 years to move from evidence to clinical practice has now been scrutinised and contested, it is widely agreed that the process of research translation is still subject to significant time lags.

An interviewee from a private health business argues: "The pace of digital innovation in hospitals in Norway is excruciatingly slow. The problem is that the strategy gets passed down to the directors responsible for research and innovation at the individual hospitals. Since ICT is a regional matter, the directors at the hospitals are unable to act on it – and if they try, they typically end up with long-

[28] Samordning mellom universiteter og helseforetak. Identifikasjon av utfordringsbilder med forslag til løsninger. Rapport fra nasjonal arbeidsgruppe nedsatt av Kunnskapsdepartementet og Helse- og omsorgsdepartementet, november 2016.

[29] Områdegjennomgang av Norges forskningsråd. Rapport fra ekspertgruppen. Levert til Kunnskapsdepartementet og Finansdepartementet 7. februar 2017.

winded pilots that typically do not scale out of the hospital. We see a lack of authority, a lack of competences and worst of all a lack of incentives to carry on with innovation."

The figures from the regional health authorities show the number of business ideas and signed licence agreements is increasing, but they also acknowledge that there are still relatively few of them. Less than 20 pct. of the research and innovation projects in hospitals report cooperating with either the pharmaceutical industry or the medical-technical equipment industry.[30]

A key challenge is that the key decision-makers who could address the barriers for digital health innovation in hospitals are separated in the research and innovation system. In addition, the directors responsible for research and innovation at the hospitals tend to be researchers. They are generally more concerned with research and they are rewarded for their research published in publications and doctoral theses rather than their contributions to innovation. In sum, there is a mix of three factors setting hindrances for the innovation processes; a lack of direct responsibility, a lack of competences and lack of incentives.

There are no quick-fixes to solve the aforementioned hindrances. However, several stakeholders argue that it is here the Norwegian system could benefit from more open approaches to innovation in health. They argue that there is a need for a program supporting open innovation which promotes experiments with new open innovation measures. It could be price challenges, partnerships accelerator fellowships, ethnographic and design approaches, new innovative procurement initiatives, clinician innovation, co-design and co-creation as well as programmes supporting online marketplaces, innovator support, innovation scouting. It is for instance the aspiration of the industry that hospitals and municipalities more openly post their challenges and needs for companies and research to help solve them.

Another proposal is to establish production-oriented environments for development and testing of digital innovations with synthetic data at the hospitals with the aim to increase hospitals readiness and speed in regard to digital innovation. A variant to the proposal is to have continuous tests of new solutions on limited populations. The tests should provide better skills on all important topics before broader market introductions. The tests should be done in testbeds or as part of the innovation arena in clusters, or it can be done in hospitals and in municipalities.[31]

3. Support measures do not promote private health business development

Several reports from the government and private sector as well as the recent OECD Norwegian Innovation review suggest that Norway needs to establish a more effective health innovation system and promote the development of a private health business sector. Many of the stakeholders interviewed for this project suggest the existing support measures do not work effectively or are

[30] Regionale helseforetak (2018), Forskning og innovasjon til pasientens beste. Nasjonal rapport fra spesialisthelsetjenesten 2017.

[31] Abelia (2018) Norges Posisjon som Velfedfsnasjon i Fremtiden. Innspill fra Abelias Topplederforum for utvikling av helsenæringen.

insufficient to build the scale of private health business development that Norway needs. Among the limitations in the support measures interviewees noted were:

- Overly restrictive requirements for support for strict IP criteria for public support when forming health research and innovation consortia.
- An absence of seed capital for new business development in the health sector.
- Unstable and short-term public financing of health business clusters.
- A general absence of private investment competence in the health sector.
- Lack of initiative shown by Investinor, Norways largest venture investment company funded by the Norwegian government, which focuses on Biotech as one of four sectors with high potential (the others are ICT, Oil and Gas and Aquaculture).
- Lack of large investments in the health business sector by Argentum, another private equity investor managing investments on behalf of the Norwegian government and institutional investors.
- The small size and difficulty of using the general support measures provided by the Research Council of Norway, Innovation Norway as well as several of the other actors in the system in the context of health business development.

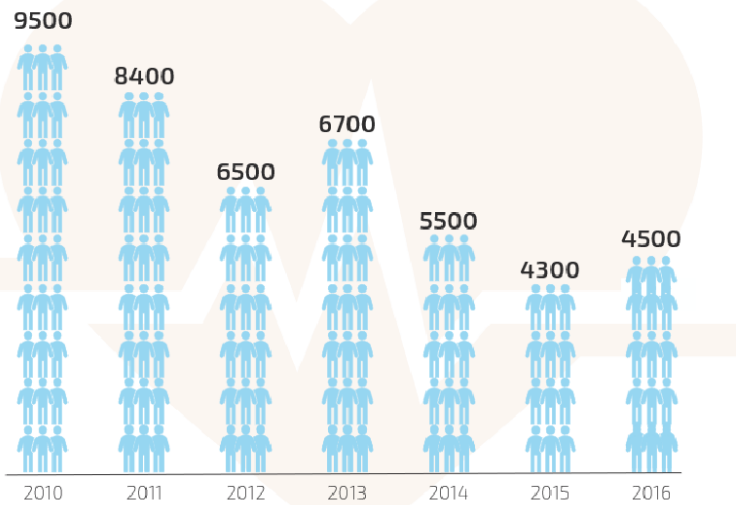
The private actors representing the health businesses suggest more radical solutions to grow a larger health business sector. One proposal is to establish a special fund with the sole purpose of financing health innovation and health business development. Another suggestion is to give investors tax incentives when investing in health research and innovation projects modelled after the Oljemyggordningen.

4. Low prioritisation of health technology assessment and clinical trials

In the workshops, several actors argued that health technology assessments and clinical trials are undervalued in the Norwegian system. This is highlighted by data showing the numbers of Norwegians in clinical trials is falling in comparison to the UK where recruitment is increasing year on year. Over 2017/18, a total of 725,333 people participated in NIHR CRN supported clinical research studies in UK - the highest number since records began and an 8.8 pct. increase since 2016/17.[32]

[32] https://www.nihr.ac.uk/about-us/how-we-are-managed/managing-centres/crn/key-statistics.htm.

Figure 18. The number of people participating in clinical trials has halved since 2010



Source: Legemiddelindustrien, FOU undersøkelsen 2017.

Literature on the challenges faced by the industry when doing clinical trials in Norway suggests there is a lack of capacity for running trials at the hospitals[33] Two key factors identified are firstly that researchers running clinical trials often have to do this in addition to their normal duties, they do not have time set aside for these activities; and secondly that clinical trials are not included in hospital performance measures, and hence there is no incentive for hospitals to participate.

Although industry stakeholders noted that the clinical and ICT departments are positive towards engagement the problems are particularly acute when working with the legal and procurement departments.

Mistrust between healthcare organisations and private industry is compounded by a lack of clear guidelines and regulations on how to collaborate – leading to a lack of clarity about what is appropriate collaboration and what would be inappropriate or illegal. This confusion is particularly problematic when it comes to user involvement. Despite all stakeholders agreeing on the value of user engagement, hospitals are wary of allowing companies access to patients in case this is seen as providing an unfair competitive advantage.

The private actors interviewed argue that there are extremely few success cases in digital innovation at Norwegian hospitals. Sykehuspartner, the regional ICT-organization for about half of Norway's hospitals, reported to Helse Sør-Øst in June 2018 that: "In practical terms, Sykehuspartner's delivery

[33] Menon (2017): Verdien av industrifinansierte kliniske studier i Norge, Publikasjon nr. 59/2017

capabilities within the fields of research and innovation is non-existent (…..)".[34] In other words, the capability to put innovative digital solutions into production is described as non-existent by a large organization in charge of delivering ICT to the health sector.[35]

Part of addressing these challenges is likely to require providing incentives for the hospitals to conduct clinical trials, for instance by rewarding the hospitals for how many patients they have involved in clinical trials or allocating more research funding for the hospital professionals involved in clinical trial work.

Another approach suggested by interviewees would be to change the perspective taken with health technology assessments. To move from viewing a single point of intervention to a broad life cycle view on a new medical technology or process innovation. This would require all partners to be aware of the need for data and evidence throughout the health technology assessment process and to have a mutual understanding of standards for data quality. For this to happen many mindsets must change, especially in the primary health care sector where the necessary competences are missing.

Another change that was suggested to improve the level and quality of health services research is the introduction of a shared knowledge and information platform for all actors in the health care system. The platform would provide services to all, from the basic researchers to the practitioners who wish to implement new processes or technologies. A common evidence and knowledge platform would simultaneously benefit the regulatory agencies and the medical technology firms. The platform would collect and provide data of high quality and could potentially ease the burdens on e.g. the technology firms need to produce data on safety and efficiency for a new medical technology.

5. Municipalities lack the capacity and competencies to be involved

Interviewees generally acknowledge that the Norwegian municipalities lack the capacity and competencies to be involved in research and innovation. Interviewees noted the startling mismatch between care and research resources: Almost an equal amount of money is spent on primary and secondary health care, however far less research resources are committed to primary care.

Interviewees point to a need to increase the research capabilities within municipalities and to increase the research activity of GP's. This would require developing a research culture in public health work in the municipalities and in primary care services. Because research and innovation work are not integrated in the daily work it becomes an additional workload that is difficult to prioritize and is seen as unnecessarily costly and time consuming for the municipalities.

[34] Tjenesteleveranser til forsknings- og innovasjonsaktivitet i Helse Sør-Øst. Utredning av hvordan Sykehuspartner HF kan levere tjenester som understøtter helseforetakene i Helse Sør-Øst sine forsknings - og innovasjonsaktiviteter på IKT-området. HSØ Prosjektveiviser - Foranalyserapport Forskning og innovasjon. 06.06.18.

[35] Translation by Damvad Analytics

The results of a NIFU-survey from 2016 shows that the municipal sector has a relatively marginal role as funder or initiator of research. Few respondents could think of research and innovation projects that were initiated by one or more municipalities.

To address these problems, interviewees suggest establishing cooperation organs to facilitate communication and coordination between universities, municipalities and GPs. An example of such an initiative is the recently launched "Praksisnett" project, which aims to support research in primary care and makes it possible to recruit patients among GP's.

The H021-Advisory Board has also addressed the challenges connected to the lack of research knowledge and competences in the municipality sector, by establishing Kommunenes Strategiske Forskningsorgan (KSF) in 2017.[36] The initiative arose from the strategic ambition of the 2014 H021-strategy. The KSF committee shall deliver its recommendations to the H021 Advisory Board on how to improve the conditions for research and innovation in the municipality sector.

The KSF members agreed that both health personnel, administrative management and politicians need a better knowledge base for the development of the important tasks in the municipalities. KSF discussions have concentrated on where funding for an increased research activity should come from and the best structure for regional structure for research. The members of the committee agree that the municipalities or groups of cooperating municipalities should be central features of the future model, but it is less clear what should be the responsibility of a national agency and what should be a regional responsibility.[37]

6. Not enough public-private cooperation

It is equally evident from the interviews and the workshops as well as from the literature study that the Norwegian research and innovation system is not sufficiently geared towards public-private cooperation and innovation. It is reportedly hard for the private pharma industry to find suitable collaborative research projects with researchers at the universities.

Several interviewees mention that start-ups have big problems with testing and scale-up in Norway. This makes it harder for them to sell their products outside of Norway. There is also a lack of clear guidance on appropriate data. One of the ssolutions proposed is a permanent life science park with a cluster, involving industry, academia and educational partners under same roof. Other proposals include funding to support more start-ups to establish a larger health tech industry, new innovative procurement and innovative partnerships. Some interviewees argue that the continued focus of private investors on the oil, gas and ICT industries is a big problem for the development of more public-private innovation in health. They also noted that the limited funding in healthcare tends to go to

[36] For more information, see: http://www.ks.no/fagomrader/helse-og-velferd/helse-og-omsorg/ksf/ and H021 (2016) Forskning, innovasjon og utdanning i helse- og omsorgstjenestene i kommunene – forslag til organisering.

[37] http://www.ks.no/fagomrader/helse-og-velferd/helse-og-omsorg/ksf/nyheter/hvor-skal-vi-ta-pengene-fra/

primarily pharmaceutical research, while the investors knowledge and focus on MedTech or digital health is very limited.

The Norwegian Ministry of Trade, Industry and Fisheries is currently preparing a white paper on how to better support the development of the Norwegian health business sector, which will be published in 2019.[38]

Implementation and application at the local level

The Norwegian health research and innovation system is faced by several inter-connected challenges regarding the implementation and application of research results at the local level, among the municipalities, GP's, schools and kindergartens, in the local societies and so forth. The challenges are not unique to Norway, but they are more challenging here than in many other countries given that many small Norwegian municipalities are spread out over a very large area. The main challenges being identified in the interviews include:

1) Inadequate knowledge of causes and consequences of differences in health and health service utilization
2) Large variations in local knowledge and implementation of treatment guidelines
3) Initiatives at the local level are merely pilots and lacks good documentation
4) Public health interventions are not evaluated or not sufficiently well evaluated
5) Low level of public procurement of innovative solutions
6) New practices, technologies or service models are poorly adopted and diffused

1. Inadequate knowledge of causes and consequences of differences in health and health service utilization

There is increasing awareness in Norway, as well as in other countries, about consequences of differences in health and health service utilization across different population groups as well as across geographical areas. In Norway the process of assessing these differences has begun and it has become clear that there are major socioeconomic and regional differences in health and use of healthcare. However, the research system has not yet provided enough knowledge of the causes and consequences.

Statistics Norway (SSB) has published a report describing the differences. The report shows that health service utilization is affected more by income than education and that the correlations vary according to type of health service, and according to gender, age, immigrant background and health status. Groups with worse health use health services to a greater extent than groups with good

[38] Innspill fra HelseOmsorg 21-rådet til stortingsmelding om helsenæringen, 29. juni 2018, Medtek Norge: Innspill til stortingsmelding om helsenæringen, 15. mai 2018, and IKT-Norge.

health.[39] Several other studies have shown that for instance immigrants use primary and secondary care less often than the majority population and point to existing barriers for access to care for some immigrant groups that have to be further understood.[40]

Another project led by statistical researchers at SSB is investigating how distance affects health service use.[41] The project has identified major regional differences in health and use of healthcare in Norway; however, causes and consequences of these differences are less clear. Understanding the mechanisms behind regional differences will be essential for establishing effective policies to meet the changing needs of an aging, multicultural and relatively decentralized population.

2. Large variations in local knowledge and implementation of treatment guidelines

The interviews and in the workshops, several actors argue that treatment guidelines are not implemented consistently at the local level.

This may be because there is little research competence present in municipalities, a problem that was highlighted above. With the autonomy of the many small municipalities and the private status of the GPs it is difficult ensure that treatment guidelines are implemented.

Requiring compliance with guidelines might challenge the autonomy of municipalities. Especially if the regional health authorities are to take over the responsibility for commissioning and implementing new guidelines. The establishment of "Kommunenes strategiske forskningsorgan" (KSF) may provide a mechanism for enhanced knowledge creation and sharing among the municipalities. Likewise, the debate related to the forthcoming "Stortingsmelding om helsenæringen" has increased the awareness to the problems in municipal primary care.[42]

3. Initiatives at the local level are merely pilots and lacks good documentation

Another challenge mentioned in many of the interviews as well as in the workshops is that many of the initiatives at the local level are initiated as pilots and never develop beyond this. As a consequence, valuable learning is wasted and opportunities for larger scale improvement are lost.

The individual project-based initiatives are limited in terms of who they reach, how long they last, and how they are institutionalised. There is also great variation in how the projects are carried out and varying quality of execution.

[39] Elin Skretting Lunde, Berit Otnes og Jorun Ramm (2017) Sosial ulikhet i bruk av helsetjenester - En kartlegging. Statistics Norway. Rapporter 2017/16

[40] E.g. Esperanza Diaz et al (2017: Interventions to improve immigrant health. A scoping review. Eur J Public Health. 2017 Jun; 27(3): 433–439.

[41] GeoHealth - Hva betyr avstand til tjenester for bruk, kvalitet og utfall? https://www.ssb.no/forskning/offentlig-okonomi/inntektsfordeling/geohealth(no)

[42] An example is the contribution from Bergen Municipality to the government white paper on policy related to the public and private healthcare sector. https://nettsteder.regjeringen.no/helsenaeringen/innspill/

The individual municipality or institution chooses to initiate the project they find interesting or relevant to their specific situation. The municipalities provide funds that the institutions can apply for to carry out such health-related projects but there are often no requirements for evaluation.

4. Public health interventions are not evaluated or not sufficiently well evaluated

The Norwegian health research and innovation system would benefit from more public health interventions being evaluated. However, as it is demanding to carry out systematic evaluations or controlled experiments, both in public health and in clinical work (e.g. as clinical trials), this is often not done. Many organizations have limited resources and may be tempted to skip evaluation, instead dedicating that money to further intervention activities. The lack of evaluation prevents the system learning and improving and makes it harder for it to demonstrate its benefits. According to the interviewees, this results in a situation where new initiatives are being implemented without sufficient knowledge or follow-up research. [43]

The challenge is how to ensure that more public health interventions and pilots are evaluated. One of the proposed solutions is to establish a funding system which integrates the evaluation as a central part of the health interventions. Ideally this would be linked to a better digital infrastructure with better access for the implementors, researchers and society to a combined data platform across sectors.

5. Low level of public procurement of innovative solutions

Public Procurement of Innovative solutions (PPI) can facilitate a wide diffusion of innovative solutions in the market. The idea behind PPI is to use the public sector's purchasing power to provide a large enough demand to incentivise industry to invest in commercialising innovative solutions. Hence, PPI can help the public health system to modernize its products and services while at the same time provide growth opportunities for companies.

There are clear indications from the interviews that PPI is at a very low level in Norway and that its possibilities are not being fully exploited. Health and care is the second largest expense item in Norwegian public procurement. Although their overall scale is small – around 10 mio. NOK there have been a number of PPI initiatives in Norway including the Nasjonalt program for leverandørutvikling and the development of measures for strengthening public private innovation initiated by Innovation Norway and the Research Council of Norway (ie Innovation Partnerships and support for pre-commercial procurement).[44].[45]

6. New practices, technologies or service models are poorly adopted and diffused

Interviewees noted that even when there is good evidence that new practices, technologies or service models are effective, adoption and diffusion across systems can be limited. For example, while

[43] For a good discussion see Donna Spiegelman (2017): Evaluating Public Health Interventions: 1. Examples, Definitions, and a Personal Note. Am J Public Health. 2016 Jan; 106(1): 70–73.

[44] http://innovativeanskaffelser.no/

[45] Menon Economics (2017) Helsenæringens verdi, Menon - publikasjon nr. 29/2017.

practitioners generate a considerable amount of innovation, these new ideas rarely spread beyond their original settings.

The interviews point to wide variation between municipalities in terms of size, knowledge and implementation capabilities. Examples were given of when municipalities had started an initiative just to try to use new technology without having the skills to measure the effects. There are also variations in treatment between regions, there can be one kind of treatment in Bergen and another kind of treatment in Oslo, suggesting that research on treatment is not being sufficiently implemented.

Easy and safe access to health data

One of the big problem areas mentioned by all actors in interviews and at workshops relates to the digital data infrastructure, and how to ensure easy and safe access to health data for research and innovation purposes. However, this is also an area where several reforms and initiatives have already been proposed in recent years. Some of them are currently being implemented while others are awaiting political decisions or implementation. However, it is clear this is far from being a solved problem. This analysis has attempted to manoeuvre this dynamic and complex field in which there is major uncertainty about the impact of the initiatives already on-going or proposed.

Against this background, the analysis has identified three interrelated challenges:

1) Researchers and industry experience difficulties getting access to health data
2) Patient journals and health records are spread and not easily accessible
3) Data infrastructure is not made sufficiently available for private and innovation purposes

The three challenges are described in further detail below.

1. Researchers and industry experience difficulties getting access to health data

The interviews provided some indications of the problems experienced by Norwegian users (both researchers and industry) when seeking access to health data for research and innovation purposes. It was reported that:

- There are too many small registries and biobanks owned by individual researchers or research groups without any formal coordination or clear rules for access.
- There are too many different health data systems in Norway, it is often hard even for experienced users to find out where the data is located and how to access it.
- It is extremely time consuming to get access to the health data even at large resources such as SSB registries.
- The real-world data (RWD) that can be accessed today are of poor quality according to the users.[46] This is a problem as RWD are used to monitor safety, make regulatory decisions, support coverage

[46] Real-world data (RWD) is an overarching term for data on the effects of health interventions. The data can come from Electronic health records (EHRs), claims and billing activities, product and disease registries, patient-generated data including in home-use settings as well as data gathered from other sources that can inform on health status, such as mobile devices.

decisions and develop guidelines and decision support tools for use in clinical practice. In addition, medical and technical product developers are using RWD to support clinical trial designs and observational studies to generate innovative new treatment approaches.

- Data management is often manual and inefficient.
- Researchers and industry recognise the ambitious and visionary plans for improving the access to health data, but there is a feeling that the situation is uncertain as the plans are not accompanied with the necessary regulations, resources or clear deadlines for implementation by the government.[47]
- The municipalities are not sufficiently open when it comes to granting access to their data.
- Businesses need to work with universities to be able to get access to the data.
- Norway has a strong data-protection agency, but there is a lack of understanding of the rules and regulations regarding data sharing.
- There is not a productive culture for sharing data with the private industry.
- The researchers and industry argue that there is a risk that Norwegian health databases will be left far behind those in US/UK/Asian biobanks/initiatives in the coming years because the data field is progressing extremely slowly in Norway.

The Norwegian Directorate of eHealth (NDE), a sub-ordinate institution of the Ministry of Health and Care Services, has recently established the so-called Helseanalyseplattformen (Health analysis platform) which should facilitate access to health data and facilitate advanced analysis across health records and other sources of health information. The project will investigate and establish a national infrastructure for accessibility and analysis of health data, including the development of organizational solutions and regulations.[48]

Another central initiative is a new site for data access, the so called helsedata.org which was launched in the spring of 2018. The purpose of the website is to make it easier to access health data for researchers and other health data users. In the first version, the website provides a comprehensive overview of key health records, national medical records and socioeconomic data, as well as a description of how to apply for access to data.

2. Patient journals and health records are spread and not easily accessible

The interviewees also point to problems with patient journals and health records being spread between systems. This makes it difficult to use the data because the different journals and/or record systems do not communicate effectively. There are different systems in the different health regions, in the municipalities, and at the level of GP's and primary care. Initiatives to update and improve ICT systems come from the regional health authorities without national coordination so investments made in one region to buy new electronic health record systems do not coordinate with other regions

[47] The challenges connected to accessing health data were addressed by the Norwegian Ministry of Health and Care Services (HOD) in a report which also proposed several initiatives to ensure a more effective access and safe usage of health dataa. Et nytt system for enklere og sikrere tilgang til helsedata. Rapport fra Helsedatautvalget 2016-2017.

[48] Direktoratet for e-helse (2018) Konseptvalgutredning for Helseanalyseplattformen

who have already bought different systems. Because of the lack of an open infrastructure with shared APIs and standards with the different systems it becomes more difficult to share data.

This is not a unique Norwegian problem. A recent survey of nearly 3,000 physicians in the US revealed that 95 pct. have experienced a delay or difficulty delivering medical care because patients' health records were not easily accessible or shared. The survey also revealed that 4 out of 5 doctors believe that a high level of interoperability between different healthcare organizations was critically important.[49]

The challenges have recently been addressed by the Helsedatautvalget (health data committee) in Norway.[50] The Committee noted the need for healthcare professionals to have easier and more secure access to patient information and that municipalities need better tools to enable interaction. The committee concluded that the present solutions do not meet tomorrow's requirements for information security and privacy.

The committee recommends that a common journal and interaction solution is adopted, the goal is for all municipalities, GPs and other private parties to apply the same solution. The recommendation means that health professionals in primary health and care services will get better solutions for administration, performance and documentation of health care in one single joint journal. The resident will hence only have one single record in the municipality, and the journal will also contain necessary health information from the specialist health service. It will facilitate easier and safer digital interaction with other municipals and state services, such as NAV, child welfare and school.

It should be noted that the above proposed solution with one single joint journal is not seen as attractive from the all private suppliers' point of view. Some fear that will close down competition and innovation and lead to a single system, where one big supplier delivers the whole EPJ system. These stakeholders argue that Norway needs instead to build future EPJ systems on a combination of light and heavy IT systems - where open API's and standards make sure that data can flow between the systems.[51]

3. Data infrastructure is not made sufficiently available for private and innovation purposes

According to interviews with representatives of the private health industry the health data solutions that are being planned in Norway are first and foremost being planned for the research community and public actors. Plans are included to allow private actors access to the data, but this is intended primarily for basic research purposes. It is argued that innovation purposes are not at the top of the agenda.

[49] https://www.cleardata.com/blog/surveys-confirm-lack-of-interoperability-continues-to-frustrate-physicians/

[50] Direktoratet for e-helse (2018) Konseptvalgutredning Nasjonal løsning for kommunal helse- og omsorgstjeneste. Hovedrapport juli 2018.

[51] API is the acronym for Application Programming Interface, which is a software intermediary that allows two applications to talk to each other.

Several of the private stakeholders argue that the health data solutions are suggested to implement protections for privacy and safety reasons. However, they feel that the possibilities associated with allowing private actors' access to health data for innovation purposes are neglected. They are concerned that Norway will miss out on innovation possibilities and business development opportunities by adopting health data solutions that are primarily targeted for the research sector.

The health industry is generally positive toward the Norwegian e-health strategy (2017-22) but it is sceptical of how some of it will be implemented, especially the policy of "Felles grunnmur for digitale tjenester" (Common foundation for digital services). Their concern is that the common foundation will be developed by public actors and does not sufficiently take into consideration the need to establish conditions for extensive data sharing, innovation, competition, flexibility and integration of user needs.[52]

Finally, the private health industry is critical of its limited inclusion in the policy processes run by the Directorate of eHealth. The organisations representing the private health industry, Abelia and Norway Health Tech highlight the low participation of business actors or business representatives in a large number of forums that set the premise for ICT initiatives in the health and care sector.[53]

Recent initiatives to improve the digital infrastructure in Norway

Recent years have seen an intense political debate and a lot of policy work in Norway which have resulted in a whole range of proposals and new initiatives. Despite the apparent progress in the digitization and management of health records and journals in Norway our interviewees report that there is still major problems with access and sharing of data. Given the long history of systems failing to deliver on their promises there is skepticism of the current initiatives.

The complications related to accessing health data in Norway has long been known. The cumbersome and time-consuming process of getting access to health data was already acknowledged in a Norwegian Official Report (NOU 1997: 26) from 1997.[54] From the interviews with key actors in the Norwegian health research and innovation system it seems clear that all actors still agree that it is too complicated and time-consuming to get access to health data, whether it is for conducting health analysis, research, improving healthcare or to make evidence-based political decisions. The impact of the Norwegian health data situation is described in the impact cases in chapter 5.

The decentralized organization of the health data systems combined with different actors trying to find their place in the legal framework implies an ineffective data handling process. The interviewees complain about having to fill out the same forms multiple times to finally get access to data and different data handlers making different interpretations of the laws leading to time-consuming processes. The problem with the decentralized system is most present when the client needs data

[52] Letter from Norway Health Tech and Abelia to Statsråd Bent Høie Health and Care Department: e-helse og mulighetsrommet for innovasjon. 09.11.2018.

[53] Ibid. Vedlegg A) Eksempler på manglende næringslivsinvolvering i helse- og omsorgssektoren (ikke uttømmende).

[54] https://www.regjeringen.no/contentassets/1fe9cf37e64344e1a3b3c62f950b100b/170630_helsedatalovutvalget.pdf

from various data systems. Often the data order can be accepted by some of the data handlers but rejected by others. The client must then reformulate the data order and go through all the steps again to finally, after numerous iterations of the process, get access to the data.

In 2010, the Ministry of Health and Care Services initiated the Strategy for modernization and co-ordination of central health registers and medicinal quality registers 2010-2020 (Helseregisterstrategien). The original purpose of the strategy was to improve the utilisation and quality of health data and increase the safety when handling national health registers. During the halfway report in 2015, it was decided to reformulate the strategy as of January 1, 2017. The halfway report concluded that for the rest of the period of the strategy, 2017-2020, the focus should be on developing common technical services with the purpose of enhancing coordination and strengthen the modernization and development of the health registers.[55]

The Ministry of Health and Care established the Directorate of eHealth as a sub-ordinate institution in 2016. The two principal responsibilities for the new Directorate of eHealth was; 1) national steering and coordination of eHealth through close cooperation with regional health authorities, local authorities, technical organisations, and other interested parties, and 2) to develop and administrate digital solutions that will improve and simplify the health and care sector.

The Directorate of eHealth published a report in 2017 called *ICT organization in the health and care sector*, addressing the role of digitalization in the health care sector in the coming years.[56] The report suggested that Norway should mainly focus on three areas regarding digitizing the health and care sector:

1) To create a national service provider,
2) Current and future national products/solutions should be transferred to the service provider,
3) The need to use private vendors should be emphasized in the strategy for the national service.

The report eventually evolved into a new strategy for digitizing the health and care sector in Norway called the National eHealth strategy 2017 – 2022.[57] The strategy is based on the ambition for e-health development that was stated in a white paper from 2012 (Meld. St. 9 (2012-2013)) called 'One Citizen – one journal' (Én innbygger – én journal). It describes strategic areas to emphasize for the period 2017 – 2022.[58] The essential principle in the strategy is that everything that can be solved on a national level should be solved on a national level, including a common solution for connecting journals.

Another offspring from the Helseregisterstrategien 2010-2020 was the establishment of the Health data program (Helsedataprogrammet) in the beginning of 2017. One of the four main projects within the program is called the Health analysis platform (Helseanalyseplattformen). It has frequently been

[55] Ibid.

[56] https://ehelse.no/Lists/Publikasjoner/Attachments/12/Rapport%20-%20IKT-organisering%20i%20helse-%20og%20omsorgssektoren.pdf

[57] https://ehelse.no/Documents/Nasjonal%20e-helsestrategi%20og%20handlingsplan/Nasjonal%20e-helsestrategi%202017-2022%20(PDF).pdf

[58] https://www.regjeringen.no/no/dokumenter/meld-st-9-20122013/id708609/sec1

mentioned in the interviews as an important digital infrastructure project. The essence of the strategies in Norway regarding e-health has for a long time been to establish a national infrastructure for health data, as described above.

Finally, the reports and strategies lead to the Health analysis platform project. The project will examine and establish a national infrastructure that will make it easier to access and analyze health data. The project stretches from 2017 to 2020, including a test of different concepts for the platform between 2017 – 2018. From the different concept platforms, one final concept will be chosen and introduced step-by-step between 2018 – 2020. The platform will make the access to complete health data available for health analysis, governance, administration, research, innovation and business development. Exactly what data sources that will be included in the platform is still under consideration. Among the data sources that is being investigated are national health registers, clinical quality registers, population-based health surveys, biobanks and socioeconomic data.[59]

Beyond the Health Analysis platform, 'Kjernejournal' and 'e-resept' are two initiatives that will lead the health and care sector into a more digital future. The 'Kjernejournal' was rolled out step-by-step in 2016 and was the first national digital solution for sharing patients' health information between all regions and levels within the health care sector. Examples of the kind of information stored in the journal is the patients' medicines, prescriptions, hospital visits, and whatever health related information each patient has added to their respective profile. The 'e-resept' is a national electronic system for pharmaceutical prescriptions and integrated in the 'Kjernejournal' making it easier for health personnel to get necessary information about the patients.

In June 2016, *Stortinget* decided to establish a unified patient and user register for all of Norway's municipalities (Kommunalt pasient- og brukerregister, KPR). KPR is connected to the 'Kjernejournal' and opened up in April 2018 and was made available for everyone. The register consists of individual data about patients and the healthcare activities they have taken part of and the purpose of the register is to give central and local governments easier access to better data. Before KPR was established, the data was stored in different registers and systems and thus making it harder to access and compare municipalities with each other. By storing all the information in one register, the research opportunities will increase and hopefully lead to more research being done to help increase the quality of the healthcare services and public health interventions.

To lessen the bureaucracy, increase the security and encourage innovators to make use of the health data, a centralized solution is needed. 'Centralized' should not be interpreted as one single health data system forced upon everyone, but rather as a common platform where users easily can connect the different datasets. The users should only have to fill out one application to get access to data. This will make the process of data collection more effective.

Many reports and interviewees stress that encouraging innovation and digitalization are the key factors for the future health sector. The global trends highlighted in the previous chapter point to switching from reactive healthcare, treating patients after detecting illness, to preventive healthcare,

[59] https://www.himss.eu/sites/himsseu/files/vestli-directorate-ehealth-national-service-provider.pdf

focusing on collecting data from the patients to prevent illness. For Norway to not fall behind it needs to promote a culture for data sharing to encourage innovative solutions in the healthcare sector.

The interviewees all acknowledge the lack of collaboration between the public and private sector within healthcare, and one of the reasons are the high thresholds created by the limited data access. Interviewees suggest that if businesses are discouraged to enter the sector, innovative solutions are also discouraged. In addition, there is a real risk that the Norwegian ambitions to create a cohesive healthcare data infrastructure will be challenged by the global tech giants, like Google, Apple, Amazon and IBM who are aiming at creating so called data pipes for health giants as well as developing their own healthcare datasets for third parties.

To increase interoperability among hospitals, physicians, and other relevant parties, the industry is slowly shifting to a new technology known as FHIR (Faster Healthcare Interoperability Resources). FHIR creates standards for different data elements so that developers can build application programming interfaces (APIs) that can be used to access datasets from different systems. Google is one of the tech giants that are now building healthcare APIs using FHIR. In addition to plugging into the data streams of the existing health system, Google is also building its own datasets that others could eventually integrate into their own research.[60]

The above sketched development raises a range of policy implications that have received little space in the Norwegian eHealth initiatives or in the debate regarding the data infrastructure for health research and innovation. This is surely a field developing dynamically and national governments are struggling to keep up with regulations and guidelines. Five of the most important implications for Norway to address are listed below:

a) How to reshape national policies to advance the use of international and big data sources for health research and innovation while keeping the data confidential, private and secure?
b) How to ensure a fair distribution of any new benefits that may arise from the collection, combination and analysis of the health relevant data?
c) How to tackle the pressure for the commercialization of the data while at the same time promote the interoperability and use of the data for widespread public and private innovation and for the public good?
d) How to ensure that citizens can act as important stakeholders in the development, evaluation, implementation and monitoring of data initiatives that the technology facilitates?
e) How to govern the relationship and balance of power between the global data-driven platform companies, national governments and international organisations (e.g. EU)?[61]

[60] CBInsights (2018); How Google Plans to Use AI to Reinvent The $3 Trillion US Healthcare Industry.

[61] World Health Organisation (2017): mHealth. Use of appropriate digital technologies for public health. Report by the Director-General. Global diffusion of eHealth: making universal health coverage achievable. The third global survey on eHealth [Internet]. Geneva: World Health Organization; 2016. And Effy Vayena et.al. (2017): Policy implications of big data in the health sector. Bull World Health Organ. 2018 Jan 1; 96(1): 66–68.

6 Norwegian impact cases across the R&I system

It is important to remember that the problem areas described in the previous chapter all have concrete impacts in different parts of the Norwegian health system. Based on expert interviews and the dialogue with members of the HO21 Advisory Board, we have identified seven examples (called impact cases) of problems in the health research and Innovation system. The purpose is to show how the problems have concrete impacts for science, innovation and for the actors involved, not least for the market and the health and well-being of patients and the public.

1. Impact Case: Screening of colorectal cancer

The first case we have selected to describe in further details concerns the 'screening of colorectal cancer'. The Norwegian government has recently announced plans to offer every Norwegian citizen free colorectal cancer screening the year they turn 55.

The government's plans are based on longer process that has evolved since 2010 involving research, international and national data gathering, dialogue and advice from many actors including the Cancer Registry, the hospitals, the patient organisation NORILCO, the Cancer Association and the Universities, as well as a pilot project initiated in 2012 in the two smaller geographical areas of Moss and Bærum (Helse Sør-Øst). On this basis, a report from The Directorate of Health proposing a national screening program was sent to the Ministry of Health and Care Services on 30 June 2017, together with an analysis of budget implications and personnel needs.

Without going into many details about different screening methods, the plan is to send out the first invitations to participate in national cancer screening in 2019, and the offer will then be gradually expanded over a five-year period. It is also a part of the proposal that selected persons called for screening for colorectal cancer can be offered an opportunity to participate in a research project whereby they will be offered additional types of examination.

The proposal hence includes further research, gaining experience with different methods and a gradual implementation. However, it does not tell the public that the effects of the screening program are quite uncertain due to lack of research evidence. Screening is offered equally to men and women, although recent international data indicate that the same methods are less effective when applied to women. None of the screening methods have been shown to reduce the total number of deaths. Also, there is limited evidence concerning negative consequences of screening and one cannot state with certainty which screening methods are the most effective.[62]

The case of screening for colorectal cancer is on the one hand an example of a rather thorough and comprehensive health policy decision making process which has been based on evidence and experience from both Norway and international sources as well as intense dialogue and a pilot since 2012. On the other hand, it is also an interesting case showing that political decisions are made and

[62] Fretheim, A. Liv Merete Reinar, M. Bretthauer (2016) Screening for colorectal cancer: effect on health outcomes, Folkehelseinstituttet. Helsedirektoratet (2017) Nasjonalt screeningprogram mot tarmkreft - Status og anbefalinger. For more information: https://helsedirektoratet.no/kreft/screening-for-kreft#-nasjonal-tarmkreftscreening-i-norge

services are implemented even though the decision makers lack clear evidence about the effects that can be expected from the screening program.

The case of screening for colorectal cancer is an example of a health policy decision process that is based on a thorough and comprehensive process, involving Norwegian and international research-based evidence and experience, that resulted in a political decision. The question here is how to collect and use experience from evaluations and identify and produce evidence (local as well as global) throughout the whole health research and innovation impact chain. This places the screening for colorectal cancer case in all phases in the impact chain as there is to some extent research and evidence available but it is not used to the fullest in the assessment process prior to the wider diffusion of the initiative.

2. Impact case: Health initiatives in schools and kindergartens

The next case we have selected to explore concerns the impact of health initiatives in Norwegian schools and kindergartens. Norway has good schools and kindergartens with competent staff and systems that catch children of all ages who are at risk. However, Norway has a high number of adolescents who fail to complete higher education. Kindergartens and schools are arenas for public health interventions, e.g. for mental health, diet and physical activity. A challenge with making research-based improvements in these areas is that most of the initiatives are project based. They are limited in terms of who they reach, how long they last, and how they are institutionalized. It has been random how the projects are carried out and most have not been scientifically evaluated.

Norway lacks documentation and good criteria of what a successful and high-quality project looks like. It is the individual institution that chooses to start up projects that they find interesting or relevant to their specific case.

There are funds that institutions can apply for to carry out health-related projects. But there is no mechanism that makes sure that these initiatives are evaluated. There are no experimental designs, effect goals, and nothing to compare with. It is not only a Norwegian challenge. It is difficult to find good research on these issues in other countries as well.

How could this situation be improved in Norway? It is clear that Norway needs a new initiative to ensure that projects are evaluated, and learnings can be drawn from these evaluations in a clear and systematic way. A better digital infrastructure could also be a great step in many ways. One example here is access to data. This does not only apply to health data. It is helpful to access other sectors as well, e.g. education, student research, socioeconomic data and so on. But it is very time consuming and expensive. Hence, a digital solution with a combined data platform with anonymous data would be a big leap forward.

An important strategic goal could hence be to have systematic evaluations of health initiatives in schools and kindergartens to collect knowledge and lessons. It is important to be innovative and try out new ideas, but also to collect knowledge about all the initiatives that work well. We need pilot projects and designs with a systematic collection of knowledge. The collected knowledge in turn needs to be shared systematically to all actors across the country.

One recommendation for the HO21 Advisory Board to consider concerns funding. There is a need of better alignment of funding, initiatives and evaluations. As of now, the funding only goes to the implementation of initiatives. If the institution wants to evaluate the initiative, they have to write a separate application in order to get funding for that. And this might take 1-2 years. Thus, Norway needs a better funding system to integrate the evaluation as a central part of the health initiatives in schools and kindergartens. Another recommendation would be better access to data. Norway needs to ensure access to safe solutions with data which can be combined across sectors.

In the case Impact of **health initiatives in schools and kindergartens**, the main challenge is that knowledge generated in the different initiatives are not subject to high quality evaluations, and if evaluations are conducted the results are not institutionalized through knowledge sharing across the sectors. One of the problematic issues is the lack of alignment between funding, initiatives and evaluations. As of now, the funding only goes to the implementation of initiatives. If the institution wants to evaluate the initiative, they must write a separate application to get funding for that. These challenges place the case in both the research problem identification phase and the diffusion and implementation phase.

3. Impact case: Challenges of municipalities and GPs in research

The third case we have selected to describe further regards the role of municipalities and general practitioners (GPs) in research. The overall challenge is that municipalities and GPs lack the capacity and sometimes competencies to be involved in health research and innovation collaborations. There is a mismatch between money used in primary and secondary health care, compared to funded research within the two. There is relatively little research relevant for GPs. One question is then how to establish a system for a better sharing of best practice and how to increase capabilities within municipalities and among GP's for involvement in research.

What are the causes of the problem? In the Norwegian system primary health care is organised under the municipality sector. This is different from many other countries, e.g. Denmark where the primary health services are administered by regional authorities. Because GPs are defined as private enterprises, they have a weak connection to the municipality, especially in the cities. The organisation also challenges the connection of municipalities and GPs to health research institutions and innovation activities. In addition, Norway has a very decentralised structure with many municipalities with varying size and capacities to handle an advanced health service.

Hence the problem is partly caused by the organisation. The authorities share the responsibility but are not engaged and in a sufficient dialogue when it comes to research and innovation relevant for the municipality sector, the GPs and the patients that uses the GPs. The Norwegian Ministry of Local Government and Modernisation has a long range of local responsibilities (e.g housing policy, the Planning and Building Act, public sector reform, etc.). However, in the health service area the Ministry is not engaged and shows very limited interest.

The Ministry of Health and Care Services (HOD), on the other hand, is responsible for providing good and equal health and care services for the population of Norway, but its ownership, engagement and interest stops at the level of the hospitals. It does not own the primary health services.

Regarding education, the hospitals receive substantial resources from the central authorities' budget to take medical students and other health care students into practice as part of their education while this is not the case for the municipalities and GPs. The municipalities receive no direct funding for this purpose. Placement for medical students in primary health care depends on the universities' own financing.

An important part of the problem is the seemingly lack of political will to solve this at the central level between the Ministry of Local Government and Modernisation and The Ministry of Health and Care Services. The engagement by the Research Council, the HO21-process and the establishment of Kommunenes Strategiske Forskningsorgan (KSF) are all steps in the right direction but there has to be a will to engage, coordinate and share resources between the two central Ministries. There seems to be a lack of will, mutual engagement, coordination and the sharing of resources between the two central responsible Ministries which prevents the health research and innovation chain from functioning effectively. Research, innovation and education infrastructure based on KSF should mirror the infrastructure known from the regional hospitals.

There needs to be an organisation that can ensure cooperation and transform the needs, demands and knowledge of the municipalities and the GPs to the research community and vice versa to ensure that research results are known and used in the primary health services. The link is not functioning optimally today. It is not only a problem seen in Norway, still, many other countries have better structural conditions for solving the problem. It should be a goal that all types of health care students be placed in primary health care for a longer time.

There are two recommendations here for the HO21 Advisory Board to consider. First, in regard to the research system, the newly established temporary Kommunenes Strategiske Forskningsorgan (KSF) should be made permanent with sufficient resources and formal authority to fund research, give advice and recommendations. Then in regard to education, the resources should follow the students and not the individual actors in the system. Alternatively, the municipalities need resources, as the hospitals have today, to compensate for the expenses to students' placement in primary health care. Both Ministry of Health and the municipalities should contribute with a small share of the health care budget to research and innovation.

The challenge of **municipalities and GPs participation in research**, originate in the Norwegian system of primary health care as this is placed in the municipal sector. Norway has a very decentralized structure with many municipalities with varying size, hence a large variation in capacities to handle an advanced health and care service through uptake of research-based knowledge. The core of the problem is partly caused by how the regional health authorities, municipalities and GPs are organized. And partly due to the lack of knowledge diffusion in the primary health care sector. This place the challenge in the last part of the health research and innovation chain, the diffusion and implementation stage. The recent establishment of the Kommunenes Strategiske Forskningsorgan (KSF) is an answer to part of the challenges faced by the primary health care system, but as this initiative is temporary, the level of impact is unknown.

4. Impact case: Health technology assessment

In 2011 The Ministry of Health and Care Services (HOD) became aware of the lack of a national systematic way of assessing new medical technologies and processes. Previously the assessments had been conducted by different agencies without a common set of standards for the process.

The initiative Nyemetoder.no (New methods) was then introduced in 2013 with the aim of building a solid system that could provide transparency in the evaluation process. There system was a consequence of an outspoken need for knowledge on what is the evidence for a given acknowledgement of a new technology. The system should provide evidence for the evaluation process, form the basis of systematic review of literature and provided information on the assessment process.

However, the system is challenged because private firms argue that they lack information about how they can use the system for the benefit of their approval process. It is also taken to be a challenge that the system is operated by five different actors; The Ministry of Health and Care Services, The Norwegian Directorate of Health, Norwegian Institute of Public Health, The Norwegian Medicines Agency and the regional health authorities who run the hospitals and other specialist health care services in Norway. This has caused challenges in the organisational setup, challenges in the sharing of knowledge between the different actors and differences in interests as been profound.

Another challenge is that the technology assessment process has been connected to the procurement process which is not seen by all parties as a benefit for the technology assessment process. The entire idea of nyemetoder.no is that it should be a support system for innovation not working against the promotion of innovation.

When nyemetoder.no was established a big need for new rules that could set the boundaries for the system and regulate the area was identified and new rules were hence proposed. However, these have been in hearing among the partners until now, and now the new law is expected to pass and be implemented soon.

Is there a need for new initiatives? It could be relevant to have more help to start-ups and small firms to assist them in providing the right data for the technology assessment process. This could enhance the efficiency of nyemetoder.no system greatly. Today the small firms are assembled in the association MedTech Europe and Norway Health Tech. The two organizations do a lot for the small firms but there is a long way to go.

It is important to say that the problem exists not only in Norway but across the EU. The evaluation of new medical technologies is challenged by the number of entries and the lack of good data provided evidence. Internationally, the biggest challenge is the lack of connections between register data on patients and treatment outcomes as well as data on more “soft” socio-economic factors.

There is hence an urgent need for the development of new methodologies for working with data generated in different settings, e.g. in the primary healthcare sector, hospitals and universities. The main concern is the lack of consensus on quality of the input data and how to exploit even small datasets which normally would be too small to be included in, e.g. an evaluation of a new treatment procedure or a medical technology.

To summarize, the challenge related to the **Health Technology Assessment** of medical equipment and the Norwegian "nyemetoder.no" system has its place of origin in the interface between the regulatory authority and the users and industry. The challenges as they are put forward in the interviews are two faced, innovators and medical equipment firms perceive the system as slow and rigid. On the other hand, the national authorities find that the innovator and the firms behind most medical devises often do not provide the necessary or sufficient research-based evidence of impact, safety and costs to perform a quick, smooth and reliable assessment. This places the health technology assessment challenge firmly in the invention and adoption phases in the health research and innovation impact chain. The cause of the problem is information asymmetry between users (firms and innovators) and the regulatory authorities, a lack of research that provides the evidence needed for technology assessment and a lack of access to patient data in a cost-effective way.

5. Impact Case: Drug Assisted Rehabilitation of pregnant women

The challenge of drug assisted rehabilitation (DAR) of pregnant women became evident when the Norwegian Barneombudet found that the current practice for treatment of pregnancy with opioid addition needed to be revised and updated to a new clinical guideline.[63]

Prior to the development of the new guideline a consensus group was appointed to find and evaluate the current research and evidence on DAR of pregnant women. However, the consensus group was not able to identify research on the current treatment procedure and almost no evidence was available. The consensus group also looked into international literature but found that international evidence and research results were limited. The group therefore recommended some changes in the guidelines based on precautionary principles with focus on the child.

The main problem is probably caused by the fact that the research area is not that prestigious as it deals with a group of patients who in many ways are stigmatized by the society. Even though there is funding for the area little research is done. Only a handful of researchers are involved in the research nationally and internationally.

The prerequisites for proper research are present, in the health register and could be enhanced by only a few additions, e.g. by elaborating the information gathered on the patients. This requires funding which is not available.

It is not just an evidence challenge for the Norwegian system, it is an international challenge. Looking at 40-50 international studies on DAR, the Norwegian consensus group found only a couple of studies using register data and dealing with different treatment effects.

A solution to the lack of research and evidence could be a strengthening of the Health register on pregnant women with drug addictions and with a special focus on the long-term effect of the DAR treatment for children. This could be achieved by linking different registers and data sources and probably by reaching out to national health registers in the other Nordic countries.

[63] Barneombudet is the Norwegian Ombudsman for Children, an advocate for children and young Peoples rights.

To summarize, the **challenge** of **drug assisted rehabilitation of pregnant women is** the lack of available research that address critical issues related to the safety and efficiency of the treatment guidelines. The challenge has to do with the lack of reliable research. Even though funding has been available for the area since 2000 not much research has been done. The lack of research places the challenge firmly in the research stage. The challenge could be avoided by providing high quality data that addresses the main problems. This would promote a change in individual researchers' focus on an otherwise widely neglected research area. The data source should be based on the establishment of a nationwide, or even better a Nordic register, on pregnant woment with opioid addiction which will provide possibilities of life-long follow up of mother and child.

6. Impact Case: A Norwegian Win-Water Situation

In Norway large sections of the pipes for the water-utility system need replacement. Old pipes are leaking, and it creates a two-sided problem. First, 30 pct. of the clean water leaks out before it gets to the end-user. Waste-water is also leaking out. This means a huge loss of natural and financial resources. Most of the time, high pressure inside the clean pipes prevents contamination of the clean water. However, when pressure drops, contamination can get in, often from the waste-water-pipe right beside it. This is a health risk. Already one week after the loss of pressure, the chance of a gastrointestinal infections rises with 58 pct.

The cause of the problem is that while the rest of the water-utility system has been replaced, the pipes have remained mostly unchanged for many years. Old pipes need repair, upgrade or replacement. To do this there is need for a large investment. Norsk Vann estimates an investment of 280 billion NOK is needed before 2040, for the work that needs to be done. This puts a huge financial burden on the municipalities, and in the end, the consumers. The sector is looking for new innovative solutions that reduces the cost of the replacements. This is the only way to ensure that the Norwegian

Preben Aavitsland, a professor at the University of Oslo working on public health, points out that a significant part of the problem is due to small organisational units in the value-chain. This applies at three different stages in the value-chain:

1) The water-utility-system is driven by the municipalities. These very small units do not have the expertise or resources to conduct research or innovation projects. Some municipalities have joined forces to create larger organizational units and detached the water utility-system from the rest of the municipal administration. However, this is still the exception to the rule.
2) On the supply side Norway doesn't have any big companies that can drive the innovation forward. While there are some companies, they do not have the capacity to drive expensive innovation projects.
3) The research environment comes down to two small units at NTNU and MNBU. They cannot meet the demand for new solutions, however excellent they might be.

What is the solution to this challenge? There is arguably a need for an innovation fund that could give out 100-200 million NOK a year. The fund should fund concrete trials for new solutions and infrastructures. An example could be trials in "No-dig"-solutions. Both public and private companies should be eligible to seek the funds. Its fund could be inspired by the Danish VUDP-programme (Joint programme of the water-sector for innovation and trials). The fund could attract companies from

alternative sectors such as the petroleum-business in Norway. The strategic goals should be two-fold according to the expert. In Norway, the goal should be to create cheaper solutions that can be used to decrease the needed investment in replacement of the old pipes. Secondly the goal should be to create a sustainable industry of Norwegian companies that can export solutions and gain an income that can meet the initial investment in the innovation fund.

There are hence mentioned four main recommendations for dealing with this challenge:

1) The municipalities must start to collaborate much more than they do now. Inter-municipal units and water-companies will have a lot better prerequisite for driving innovation. A part of this could be transforming the companies into shareholder-companies as seen in Denmark.
2) Scale up the research in the two units at NTNU and MNBU.
3) Create an innovation fund and start funding trials and demonstration-projects.
4) And the final recommendation is to create more awareness of the problem. A lot of politicians are simply not aware of the size of the investment needed. The same goes for the surrounding industry such as oil companies. If they knew the potentials in this sector, they would probably start to invest in their own R&D projects.

To summarize, in the case A Norwegian **Win-Water Situation** a large part of the pipes in the water-utility system need replacement, old pipes are leaking and could cause health issues due to the contamination of clean drinking water. Repair and replacement are estimated to require an investment of 280 billion NOK over the next 25 years. The volume of the investment calls for the development and implementation of new innovative solutions. This place the impact case in both the invention and adoption phases in the impact chain. As the solution to the challenge could be a development and demonstration program for new innovative technologies or the diffusion of existing technologies into the water-utility sector. The overall goal is the development of cost-efficient solutions.

7. Impact Case: Access to health data

One of the main advantages in Norway is the existence of large amounts of good, structured health data that can be used for generating and testing hypotheses. It is also possible to follow up on new medicine, treatment and medical devices. However, accessing the data is harder, which has led to the data not being widely used.

The problem with few users of the data is not specific to Norway but compared to the other Nordic countries it is harder to get access to the health data in Norway. Another challenge, more specific to Norway, is that large parts of the healthcare service (primærhelsetjenesten) do not have good systems for collecting data (systems for medical records). Further, in Norway we only have a pseudonym prescribed drug register (Reseptregisteret) which makes it difficult to link with other data.

A new digital infrastructure will provide solutions when making previously not accessible data accessible. Easier access to data would also contribute to making Norway a more attractive country for private companies since they then could use the data in their own research. For example, historical patient record data from Norwegian healthcare archives (Norsk helsearkiv) and data obtained directly from population-based health surveys.

The strategic goal for Norway should be to be the best in the world on safe solutions providing access to health data from primary health services, prescribed drug usage, and data from residents in population-based health surveys. There is a need for a new law on health data, or at least that we establish a directly identifiable prescribed drug register containing individual data on all drug usage.

To summarize, easy access to health data is not yet in place in Norway. Despite the existence of large amounts of good, structured health data that should be available for research, follow up studies on new medicine, treatment and medical devices. Accessing the data is not easy, which has led to data not being widely used. The challenges are well-known and investigated in Norway, but there is still a need for policy decisions and regulations that allow for patient safety to be controlled while the access barrier to data is lowered. Easy access to high quality data on, e.g. health records and prescriptive medicine, is required and contribute to the process in all parts of the health research and innovation chain. The strategic goal for Norway should be to be world leading on health data from primary health services, prescribed drug usage, and data from residents in population-based health surveys.

7 From aspirations to future recommendations

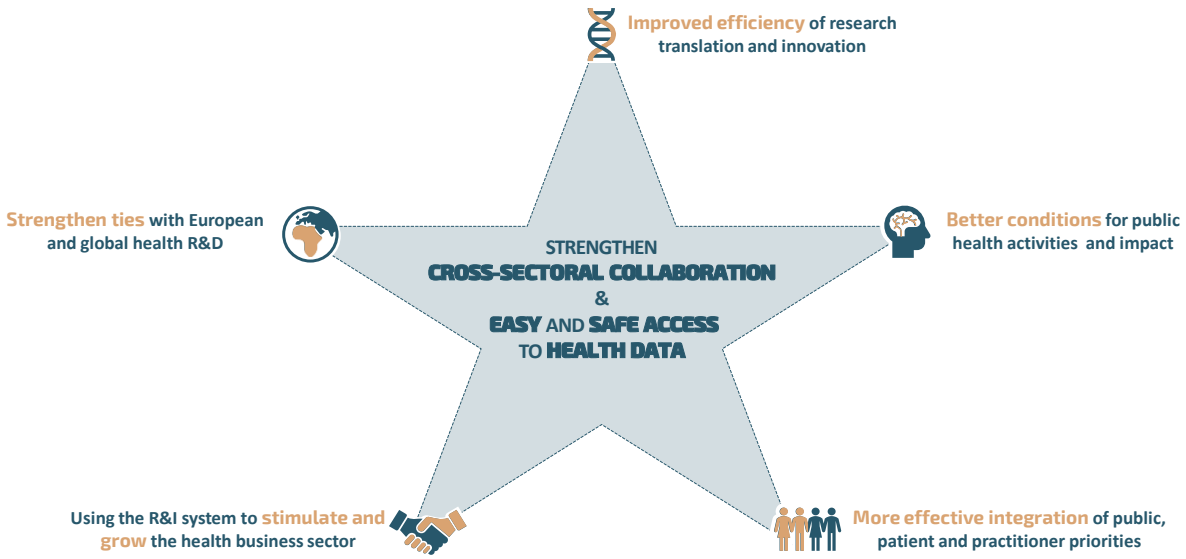
The analysis described so far provided insight into the aspirations of and problems with the Norwegian health research and innovation system. In connection to this a variety of initiatives and suggested actions have been highlighted.

Building on this we used stakeholder consultation and a workshop to develop 46 potential solutions linked to the areas of aspiration and the specific problems identified in the analysis. We then worked with actors in the Norwegian health research and innovation system in a final project workshop to shortlist the ideas with the biggest potential and developed nine potential solutions further. This led to the final development of nine shortlisted solutions. It should be noted that all conclusions are solely those of DAMVAD Analytics.

Proposed solutions

The analytical process based on interviews, workshops and meetings with the HO21 Advisory Board led to the formulation of a large number of solutions for how to improve the Norwegian health research and innovation system. The proposed solutions have been grouped under seven overall aspiration areas and linked to the identified problems. In the figure below, the five headings placed at the tips of the star are linked directly to the aspiration areas, previously described. The two headings placed in the centre of the star, "Strengthen cross-sectoral collaboration" and "Easy and safe access to health data" represent cross-cutting problem areas. They are seen as cross cutting, providing the conditions for the improvement and transformation of the whole system.

Figure 20. Overall areas of aspiration and cross-cutting problem areas for the proposed solutions



A. Proposed solutions linked to main areas of aspiration

The proposed solutions described below are grouped by the five areas of aspiration. It should be noted that some of the solutions answer challenges across more than one problem area.

1. Improved efficiency of research translation and innovation	Proposed solutions
Identified challenges Inefficiency – health research translation and innovation processes are too slow Low prioritization of health technology assessment and clinical trials. There are only few career paths in health research beyond PhD and outside academia.	1. Launch a program supporting open innovation which promotes experiments with new open innovation measures. It could be price challenges, partnerships accelerator fellowships, new innovative procurement initiatives, as well as programmes supporting online marketplaces, innovator support, innovation scouting, etc. 2. Reduce variation in the availability and quality of treatments and provide evidence-based guidance and recommendations on the clinical and cost-effectiveness of treatments, technologies, medicines, diagnostic tools, health activities (Inspiration: UK) 3. Establish production-oriented environments for the development and testing of digital innovations with synthetic data at the hospitals with the aim to increase hospitals readiness and speed regarding digital innovation. 4. Have continuous tests of new medical devices on limited populations. The tests should provide better skills before market introductions. The tests could be done in testbeds or as part of the innovation arena in clusters, in hospitals or in municipalities. 5. Establish fast-track appraisals for products that 'offer exceptional value for money' and ensure that they are made available to patients within 30 days after approval (Inspiration: UK). 6. Speed up the uptake of high-impact and evidence-based innovations through an Innovation Accelerator (Inspiration: UK). 7. Bring organisations across the health system together to work jointly on an Accelerated Access Pathway to speed up the route to market for selected, strategically important, transformative innovations (Inspiration: UK).

2. Better conditions for public health activities and impact	Proposed solutions
Identified challenges Inadequate knowledge of causes and consequences of differences in health and health service utilization Large variations in local knowledge and implementation of treatment guidelines Initiatives at the local level are merely pilots and lack good documentation Public health interventions are not sufficiently evaluated New practices, technologies and service models are poorly adopted and diffused Leading research environments are not sufficiently engaged in applied research	1. Give regional health authorities responsibility for commissioning and implementing new guidelines and ensuring their use. 2. Give "Kommunenes strategiske forskningsorgan" (KSF) a permanent assignment to improve the implementation of guidelines among the municipalities through generating and diffusing new knowledge about implementation. 3. Establish Innovation and Technology Payment schemes to reduce financial impact and procurement barriers related to the uptake of innovations (Inspiration: UK). 4. Introduce KPI's (tellekanter) measuring and rewarding health researchers for collaboration with practitioners and industry where they are contributing to innovation and providing solutions to population health problems. 5. Create strong interdisciplinary research units, "Clinical Academic Groups" (CAGs), linking clinicians and researchers and educators from each region with the aim of linking basic and clinical research to improve the implementation of research results in clinics and improve the treatment of patients (Inspiration: DK). 6. Establish national networks of academic, industry, health service, third sector and local authority stakeholders focusing on particular conditions to spread innovations across the healthcare system as well as generate economic growth (Inspiration: UK). 7. Establish collaborative groupings to bring together service providers, managers, research institutions and local organisations (e.g. councils, charities) etc., modelled on the Collaborations for Leadership in Applied Health Research and Care (Inspiration: UK). Emphasize approaches to reduce the barriers caused by different values, priorities and ways of working. 8. Improve the systematic evaluation of health interventions by ensuring evaluation is integrated into pilot (and other small scale) programmes and that the data infrastructure provides better access for intervention actors, researchers and society across sectors.

3. More effective integration of public, patient and practitioner priorities	Proposed solutions
Identified challenges Patients and the public are invited to contribute but without the capacity to do so Researchers and industry experience difficulties getting access to health data. Low prioritization of health technology assessments and clinical trials Municipalities lack the capacity and competencies to be involved	1. Launch a coordinated government plan to ensure that Norwegian patients can be involved in research priority setting and design and to provide them with the capacities to contribute effectively. The plan should allow for wide-spread experimentation with different kinds of user involvement 2. Formulate a National Strategy for Patient-Oriented Research with a national governance structure and regional support hubs. National contributions to core activities would be matched by regional funding. (Inspiration: Canada) 3. Establish multi-stakeholder Priority Setting Partnerships (PSPs). These would bring together patients, carers and clinicians to identify the health research areas important to them. One approach could be identifying the top ten uncertainties related to treatment in different areas. These priorities should help raise research funders' awareness of issues that are important to patients, carers and clinicians. (Inspiration: UK) 4. Support and expand projects like "PraksisNett", which aim to improve the quality of research in primary care through improved infrastructure and supporting patient recruitment into research.. 5. Reward hospitals for how many patients they have enrolled in clinical trials and technology assessments. 6. Make Kommunenes Strategiske Forskningsorgan (KSF) a permanent Council with a budget for research and innovation and a hearing part, funded jointly by RCN, HOD and KMD. KSF would be funded by 1-3 pct. top slice of the money transfers from the government to the municipalities

4. Using the R&I system to stimulate and grow the health business sector	Proposed solutions
Identified challenges Norway lacks the big health businesses and has a low private R&D investment level. Support measures do not support private health business development in the invention and adoption stages. There is not enough public-private cooperation in the Norwegian system. Low level of public procurement of innovative solutions. New practices, technologies or service models are poorly adopted and diffused	1. Broaden the scope of TTO's and use KPI's (tellekanter) measuring and rewarding TTO's for their contribution to innovation and business development in the health sector. 2. Make large cross-sectoral mission calls focusing on grand challenges requiring large consortia and make it a requirement to include innovative SME's. 3. Include measurable innovation and business-related objectives in the annual letter of assignment from the ministries to the underlying educational and health institutions, so that results are monitored and achievements incentivised. 4. Introduce inspirational short modules of entrepreneurship and IPR training as mandatory modules in the relevant health-related degree courses (medicine, biochemistry, other natural sciences). 5. Establish a Small Business Research Initiative to strengthen research competences, and encourage companies to hire PhDs and find innovative solutions for healthcare problems and increase the growth of innovative health companies (Inspiration: UK) 6. Establish a special fund to build a Norwegian health business sector through increased investment. 7. Improve access to capital through existing instruments, including stronger SkatteFUNN support, stronger measures for research-intensive young enterprises, strengthen health investment competences in Investinor og Argentum and broadening the scope of Innovation Loans and OFU contracts 8. Give tax incentives for investors investing in health research and innovation projects. 9. Launch regional initiatives for Procurement Development & Strategic Partnerships with a focus on the three strategic pillars: business development of corporate procurement; a future pipeline with new innovation projects; and a dedicated consultancy service towards the regional hospitals (Inspiration: Denmark).

5. Strengthen ties with European and global health R&D	Proposed solutions
Identified challenges The Norwegian UH sector and health businesses are not sufficiently part of the European research initiatives, networks and clusters. The environments and actors that could help accelerate the small Norwegian health start-ups and growth companies are not present in Norway.	1. Ensure long-term financing to support planning and cooperation between the UH sector and the health industry to improve the access to leading European research initiatives, networks and clusters and to attract European Horizon financing. 2. Provide public resources to establish stronger links to global research clusters and actors who can help accelerate the most promising Norwegian innovative health start-ups and high-growth companies with expert advice, networks and risk capital.

B. Proposed solutions linked to central cross-cutting problem areas

The proposed solutions below link to the two cross-cutting problem areas, these solutions would help the overall innovation system and support addressing many of the other problem areas.

6. Strengthen cross-sectoral collaboration	Proposed solutions
Identified challenges Cross-sectoral cooperation is low.	1. Develop large national and inter-sectoral health research and innovation programmes. 2. Introduce mission-oriented projects, in which parties from different sectors are required to work together to solve the big health challenges. 3. Establish a formal cooperation forum with high level participation from the ministries, regional health authorities and research institutions to coordinate research infrastructures at the highest strategic and operational level. 4. Establish a joint research administrator support system. 5. Promote mutual governance representation between research institutions and regional health authorities and between university hospitals and the Faculty of Health/ Faculty of Medicine. 6. Award a larger proportion of funding for health research in open national competition available to actors from all sectors.

7. Ensure easy and safe access to health data	Proposed solutions
Identified challenges Users experience difficulties getting access to health data Patient journals and health records are spread and not easily accessible Data infrastructure is not made sufficiently available for private business and innovation purposes	1. Set ambitious goals and aspirations for where Norway should lead the world on health data. These areas could be in primary health services, prescribed drug usage, and data from residents in population-based health surveys. 2. Establish guidelines to address the privacy issues that come with digital development in order to de-risk and encourage investment in effective digital solutions. 3. Ensure medical guidelines and codes are strictly adhered to throughout the health system to achieve better research and higher quality of care. 4. Establish an eHealth standardization forum to work with, and implement, standards for effective information sharing (Inspiration: Sweden) 5. Develop a module-based, standards driven digital environment to ensure compatible systems without requiring a single centralized system. 6. Avoid high charges or unnecessary regulatory restrictions limiting small and private users access to the data platform. 7. Establish a platform where citizens can store their own health data and through which companies and organisations can develop and supply health-related services for citizens (Inspiration: Sweden). 8. Allow competition to encourage different providers to offer innovative digital health solutions to complex problems, and for those solutions to be tested in the market.

Shortlisting and nuancing of 9 proposed solutions

At the final policy and recommendation workshop and through follow-up interviews, nine solutions where identified which the actors believed had the biggest potential. These were then further developed and nuanced by DAMVAD Analytics.

In the workshop, groups were asked to fill out posters detailing how the proposed initiatives would work, what success would look like, what other initiatives were synergistic, associated challenges and solutions and the additional knowledge needed to implement the initiative. Each of the shortlisted solutions serves to address a range of the problems and often speak to more than one of the aspirations. The mapping is shown in the table below which is followed by a more detailed description of each of the nine shortlisted solutions.

Table 3. How the selected solutions are linked to aspirations and problem areas

	1. Improved efficiency of research translation and innovation	2. Better conditions for public health activities and impact	3. More effective integration of public, patient and practitioner priorities	4. Using the R&I system to stimulate and grow the health business sector	5. Strengthen ties with European and global health R&D	6. Strengthen cross-sectoral collaboration	7. Ensure easy and safe access to health data
1. One national implementation unit	■	■	■			■	■
2. Mission-oriented projects	■	■		■	■	■	
3. Priority Setting Partnerships (PSPs)	■	■	■			■	
4. Interdisciplinary research units (CAGs)	■	■	■			■	
5. Open Innovation Programme	■	■	■	■			■
6. Health care fund				■	■	■	
7. Broaden scope of TTO's and use KPI's	■			■			
8. Accelerated Access Pathway	■			■		■	
9. Make KSF a permanent Council	■	■				■	

1. Establish one national unit responsible for implementing treatment guidelines and ensuring the commissioning of the same across both specialist and primary health services

The initiative combines the actors' proposal to give the regional health authorities responsibility for both commissioning and implementing new guidelines while at the same time giving Kommunenes Strategiske Forskningsorgan (KSF) the responsibility to promote and share knowledge regarding the implementation of guidelines among Norwegian municipalities.

The initiative would support cooperation between the regional health authorities and the municipalities and should ensure a faster adoption of good solutions. The initiative should also reduce the problematic variation in the availability and quality of treatments by unifying guidelines and help to provide better evidence-based guidance and recommendations on the clinical and cost-effectiveness of treatments, technologies, medicines, diagnostic tools and health activities.

Lead responsibility: Regional health authorities and KSF
Time frame for implementing: 2 years.

2. Introduce large-scale mission-oriented projects requiring collaboration from different sectors to solve health challenges

The initiative should work as a network-based process involving all the stakeholders and actors across the health research and innovation chain, including primary care (GPs and community services) and secondary care (hospitals and specialists) as well as universities, patient organisations and health tech providers from the private sector. The initiative also requires cooperation between different ministries to overcome the challenges connected to the sectoral principle. The initiative would probably need a national champion with power to succeed.

The initiative can take inspiration from UK (Mental Health UK) and Denmark (Greater Copenhagen Healthcare Partners) which are described in the international cases studies. The funding should be approximately 100 mio. NOK. Regional projects would have lower costs. The initiative should be financed by funders across sectoral boundaries. The timeframe for projects should be between 2 and 10 years depending on the mission size and complexity. Several other initiatives are synergistic with this initiative, including large national and inter-sectoral health research and innovation announcements, coordinated research infrastructures at the highest strategic and operational level, a joint research administrator support system, mutual governance representation and making health research funding more open to national competition.

Lead responsibility: Ministry for Health and Care (HOD)
Time frame for implementing: 1 year.

3. Establish Priority Setting Partnerships (PSPs) as multi-stakeholder collaborations to identify health research areas important to patients, carers and clinicians

The initiative would ensure the societal value of health research by identifying the top ten uncertainties related to the effects of treatments in different areas. Such prioritisation would help raise health research funders' awareness of the issues important to carers, clinicians, patients and society.

The initiative could be realised as a programme in RCN and should involve KSF. Its ambition should be to establish 10 PSP's per year. The central initiative should focus more on methods than themes, e.g. how to best identify priorities and how to ensure those priorities affect what research is carried out. The PSPs should take have a bottom-up approach and be open to different actors and focus on both research and innovation processes, service design thinking and public health. The funding should come from the stakeholders as well as from crowd-sourcing. The initiative is synergistic with the initiative "Make Kommunenes Strategiske Forskningsorgan (KSF) a permanent Council" described below, since KSF could be made responsible for the PSP's.

Lead responsibility: Research Council of Norway and KSF
Time frame for implementing: 2 years.

4. Create strong interdisciplinary research units, consisting of clinicians, researchers, educators, university lecturers and university researchers, FHI and KSF with the aim to link basic research and clinical research, and to work for research results to be implemented in clinics and improve the treatment of patients

The research units should include both primary and secondary healthcare as well as industry. A very recent initiative reassembling the same principles are the Mental Health Networks announced by UK Research and Innovation in September 2018.

To ensure that research results can spread across management structures the units should have narrow research areas. The experience is that new actions are easier to handle and implement at management level if they are narrow. The initiative will require a budget of 2,5 mio per unit per year and each unit should be allowed to run up to 10 years. The initiative should include 3-5 units. The leadership of the initiative could be national, regional or joint and individual initiatives should have joint leadership across the research and clinical areas. The initiative is synergistic with other initiatives that focus on producing and implementing evidence and contributing to public health. It can also link to an initiative on PSPs.

Lead responsibility: Norwegian Institute of Public Health (FHI)
Time frame for implementing: 3 years.

5. Launch an Open Innovation Programme across health research and innovation to promote experiments with new open innovation measures

The initiative should contain price challenges, partnerships, accelerator fellowships, new innovative procurement initiatives as well as initiatives for online marketplaces, innovators, innovation scouting, etc. It would be important to keep initiatives open to both primary and secondary health care and to ensure private and user involvement. The initiative should focus on removing barriers close to the delivery and implementation or purchase.

A potential lead for the initiative is Innovation Norway. The initiative will need to overcome cultural challenges including organisations and employees who are afraid of failing and sceptical toward private companies and commercial interests being part of the initiative. The initiative is synergistic with other initiatives promoting innovation, open data, cluster programmes, etc.

Lead responsibility: Innovation Norway
Time frame for implementing: 3 years.

6. Create a large-scale health care fund to close the capital gap for R&D-intensive health businesses in the translation and market entry stages

The fund should have a management with specialised health knowledge, and it should be able to take a lead in investments as well as be a cornerstone in seed and venture financing in the healthcare area. The fund should be based on public and private capital and have a funding base of 500-1.000 mio NOK. It is important that the private sector contributes but also that a fund is prioritised politically.

The proposed initiative is synergistic with other initiatives that promote commercialization and health business development, including proposals to broaden the scope of Innovation Loans and OFU contracts; and give tax incentives for investors investing in health research and innovation projects; as well as initiatives for procurement development and strategic partnerships, and broadening the scope for TTO's to use KPI's for measuring and rewarding contribution to health business development.

Lead responsibility: Ministry of Trade, Industry and Fisheries (NFD)
Time frame for implementing: 5 years.

7. Establish an Accelerated Access Pathway to speed route to market for selected, strategically important, transformative innovations

The Pathway should align and coordinate regulatory, reimbursement, evaluation and diffusion processes to bring transformative products to patients more quickly. Products would need to demonstrate the potential for cost savings and improved health. Selected products would benefit from streamlining the processes from market authorisation through to diffusion and receive case management tailored to the individual innovation.

The initiative should bring together a wide range of organisations and actors across the health system to work jointly on the Accelerated Access Pathway in an Accelerated Access Collaborative. The Collaborative's role would be to select the products for the Pathway based on clearly defined selection criteria and increasing strength of evidence of effectiveness as the products moved along the pathway. The Accelerated Access Collaborative is expected to speed of product progression, improve health and quality outcomes, increase the affordability of new technologies and products, create improved value for money and increase for small- and medium-sized enterprises while getting products to patients quick and easily.

Lead responsibility: Regional health authorities
Time frame for implementing: 2 years.

8. Make Kommunenes Strategiske Forskningsorgan (KSF) a permanent Council with a budget for research and innovation and a hearing part.

The permanent KSF Council should be funded jointly by RCN, HOD and KMD. Municipalities should fund up to 3 pct. of the money transfers from the government into an accompanying research fund. This would increase the municipalities research budgets. The Council should include the four regions and have local anchorage. Also, KS, The Norwegian Association of Local and Regional Authorities, shall be part of the initiative. The initiative shall adopt the recommendations made by the special KSF working group under the HO21 advisory board.

The initiative is synergistic with initiatives like PraksisNett, which make it possible to recruit patients among GP's for research. The initiative needs to overcome the challenges posed by the organisational silos. It requires that KMF to focus more on health while HOD needs to focus more on primary health care.

Lead responsibility: Research Council of Norway (RCN) and KS
Time frame for implementing: 3 years.

9. Broaden the scope of TTO's and use KPI's (tellekanter) measuring and rewarding TTO's for their contribution to innovation and business development in the health sector

The initiative should broaden the mandate of the TTO's to facilitate a stronger push for more investments in areas specifically for the benefit of society, patients or businesses. The broadened scope brings a need for clearer KPI's (tellekanter) that focuses on and reward innovation and contribution to new business development. The TTO's shall shift their focus from passive commercial exploitation, i.e. collecting license fees and royalties from industry to a strategic management of IP by engaging more actively in translational research to explore the potential of discoveries and in business development to drive the creation of new companies, both spin-offs and start-ups.

The TTO's should enter projects at an earlier stage and contribute to fostering an innovation culture in academia. Part of this would include working more with students to develop entrepreneurial talent. The TTOs should be measured by the number of collaborations they have with private health businesses, how much they contribute to new jobs, increased technology flows and increased collaboration between researchers, companies and community actors.

Lead responsibility: Ministry of Education and Research
Time frame for implementing: 2 years.

Appendix I International case studies

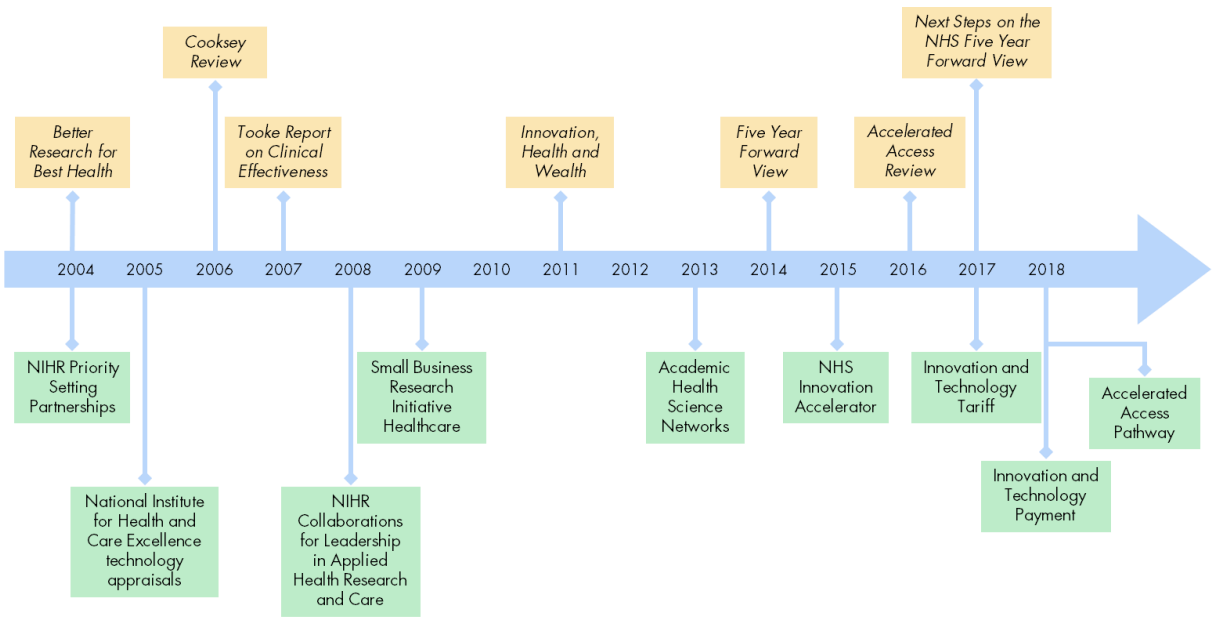
The international case studies provide examples of health research and innovation initiatives or programmes with the aim to support the recommendations for the Norwegian health research and innovation system. We have specifically aimed to cover a variety of schemes across the health research and innovation impact chain, i.e. from the research and problem identification to invention and adoption into practice, to the introduction and spread of innovations. The case studies seek to address how the initiatives or programmes support the health research and innovation landscape. For each initiative/programme, we provide (1) the background of the initiative/programme, including its history, objectives, its structure and placement in the national research and innovation agenda; (2) the funding structure of the initiative/programme and the support it provides; (3) its output and impact, as well as how its success is measured; and (4) any observed challenges related to the initiative/programme and how they are handled.

Health research and innovation cases from England

Background and context

Since the early 2000s, the health research and innovation landscape in England has seen significant changes to address challenges related to the perceived gaps between research, innovation and the adoption of such. Before then, few health policies in the United Kingdom (UK) specifically addressed innovation in health and care, or the relationship of health research and innovation (and how to improve this relationship). The provides an overview of the timeline of the health research and innovation policy documents and related initiatives and programmes discussed in the following.

Timeline of health research and innovation policies in United Kingdom



Source: Rand Europe

One of the first key policy documents to highlight the importance of strengthening the translation of health research into practice was the five-year strategy *Best Research for Best Health* (Department of Health, 2005), which aimed to respond to perceived weaknesses of health and care research in the UK (e.g. perception that funding often resulted in poor-quality research; little research impact on practice) (Morgan Jones et al., 2016, p. 1). This policy led to the establishment of the National Institute for Health Research (NIHR) in 2006, a national funder of health and care research. As of 2018, it is the largest health and care research funder in the UK (annual funding budget of £1bn (ca. NOK 10.7bn[64])) (Morgan Jones et al., 2016, pp. 1–2; NIHR, n.d.-b). The NIHR aims to complement the work of other organisations related to health innovation, evaluation and implementation, including the National Institute for Health and Clinical Excellence (NICE; now National Institute for Health and Care Excellence), England's national institute for evaluating the clinical and cost effectiveness of health and social care technologies and treatments, which was established in 1999 (NICE, 2008, p. 5, n.d.-d); and the now closed National Health Service (NHS) Institute for Innovation and Improvement,[65] a special health authority which aimed to support transforming healthcare by speeding up the development and adoption of innovations and change for improvement (Department of Health, 2005, p. 11).

Only shortly after the establishment of the NIHR, an independent review led by Sir David Cooksey (2006) and a report by a High Level Group on Clinical Effectiveness Group led by Sir John Tooke (2007) laid the foundation for a key NIHR programme to bridge the translation gap in health, Collaborations for Leadership in Applied Health Research and Care (CLAHRCs**Fejl! Henvisningskilde ikke fundet.**). The first CLAHRCs, which are research collaborations between healthcare organisations and academia, were launched in 2008, and a further tranche of funding committed in 2013 (NIHR, 2016a).

In the early 2010s, UK policymakers started to increasingly focus on the introduction and diffusion of innovations in healthcare. A key policy related to this focus is *Innovation, Health and Wealth* (Department of Health, 2011), published in 2011, which aimed to accelerate the adoption and spread of innovations in order to improve the quality of and productivity in healthcare while responding to increasing and changing demands and cost pressures. The policy identified gaps in the translation of health research into practice, and recommended building stronger relationships between academia, industry and healthcare in form of Academic Health Science Networks (AHSNs); the 15 AHSNs across England were launched in 2013 and are delivering a wide range of initiatives supporting innovating in healthcare (The AHSN Network, 2017c). *Innovation, Health and Wealth* also built on and provided additional funding for successful, existing initiatives, for example the Small Business Research Initiative (SBRI) Healthcare programme, a competitive scheme which funds companies to develop and provide innovative solutions to healthcare problems (Lichten, MacLure, Spisak, Marjanovic, & Sussex, 2017, p. 1).

Similarly, the policy *Five Year Forward View* (NHS England, 2014) and its update, the *Next Steps on the Five Year Forward View* (NHS England, 2017b), outlined strategic steps for the NHS in England to overcome the key challenges it faces; both documents included priorities and actions related to

[64] The exchange rate used in this chapter is as of 21 September 2018: £1 = NOK 10.6502.

[65] The NHS Institute for Innovation and Improvement was closed in 2013 and replaced by NHS Improving Quality (GOV.uk, n.d.).

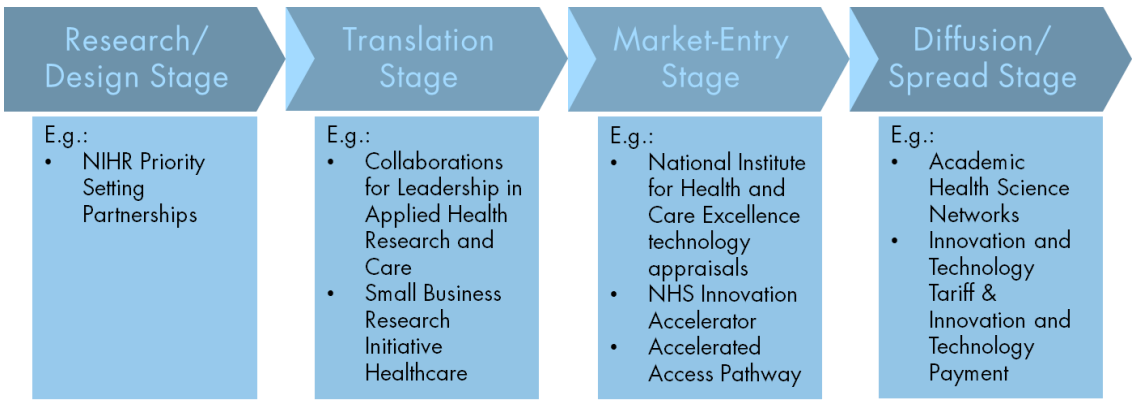
harnessing health innovations and accelerating their introduction and adoption. The NHS Innovation Accelerator (NIA), for instance, was introduced by NHS England and partner organisations in response to the *Five Year Forward View*; the programme supports individuals to introduce their high-impact and evidence-based innovations into the NHS and speed up products' adoption (NHS Innovation Accelerator, 2017a). The Innovation and Technology Payment (ITP), a scheme to reduce financial and procurement barriers by streamlining access to selected cost-saving and clinically effective innovations, is also directly related to needs identified in the policy (NHS England, 2018b).

Most recently, the *Accelerated Access Review* (2016) specifically focused on how to improve clinical and cost efficiency, quality and care for patients by accelerating innovation across the innovation pathway, i.e. from research to translation into practice, to introduction and spread. The review provided detail on the Innovation and Technology Tariff (ITT), a scheme similar to the ITP that aims to simplify procurement for selected cost-saving innovations (NHS England, 2017a, pp. 4, 7). The policy also recommended the introduction of an Accelerated Access Pathway, to speed up the route to market for selected, strategically important, transformative innovations (Accelerated Access Review, 2016, p. 26).

Outline of the case study

The case study in this chapter outlines some key examples of initiatives and programmes in England which aim to further the translation of health research into practice. While the initiatives and programmes described in this case study are not exhaustive, they give insight into some key examples of initiatives along the health innovation pathway. Figure 16 and Table 1 shows where the selected key examples sit on the health innovation pathway and what type of support each initiative/programme offers.

Key examples of initiatives across the health innovation pathway[66]



[66] While some of the initiatives and programmes presented in 16 primarily focus on a specific stage on the health innovation pathway, they sometimes also aim to support efforts on other stages. The Accelerated Access Pathway, for instance, also aims to accelerate and support the spread of innovations.

Table 1. support measures for key examples of health research and innovation initiatives

Stage on the health innovation pathway	Initiative/programme	Main support measures
Research/Design Stage	NIHR Priority Setting Partnerships (PSP)	• Provision of key documents, tools and a guidebook on how to set up a PSP • Support for organisations setting up a PSP in form of Advisors
Translation Stage	Collaborations for Leadership in Applied Health Research and Care (CLAHRCs)	• Average funding of £11.1m (ca. NOK 118.6m) for each CLAHRC over a period of approximately five years
	Small Business Research Initiative (SBRI) Healthcare	• Phase 1: funding for companies for feasibility testing over a period of six months (max. £100,000 (ca. NOK 1.1m)) • Phase 2: funding for companies to continue Phase 1 projects over a period of 12 months (max. £1m (ca. NOK 10.7m)
Market-Entry Stage	National Institute for Health and Care Excellence (NICE) technology appraisals	• Provision of evidence-based recommendations on the clinical and cost-effectiveness of treatments, technologies, medicines, diagnostic tools, health activities, etc.
	NHS Innovation Accelerator (NIA)	• Support to individual NIA fellows, including peer-to-peer support and mentoring, events, networking opportunities, support on developing scaling strategies, learning programmes, etc. • Bursary of up to £20,000 (ca. NOK 213,000)
	Accelerated Access Pathway	• Speeding up the route to market for selected, strategically important, transformative innovations • A £6m Pathway Transformation Fund will support the adoption and diffusion of selected innovations
Diffusion/Spread Stage	Academic Health Science Networks (AHSNs)	• Monetary and non-monetary support to stakeholders across the system (e.g. from industry, academia, charities, health organisations), e.g. delivery of SBRI Healthcare and the ITT and ITP
	Innovation and Technology Tariff (ITT) & Innovation and Technology Payment (ITP)	• Central and direct reimbursement of innovations by NHS England for selected products, which reduces the need for pricing negotiations and reimbursements at individual health organisation or commissioning level

Source: Rand Europe.

The next sections present the ten selected examples and how they support the health research and innovation landscape in England. More specifically, for each initiative/programme, we provide (1) the background of the initiative/programme, including its history, objectives, its structure and placement in the national research and innovation agenda; (2) the funding structure of the initiative/programme and the support it provides; (3) its output and impact, as well as how its success is measured; and (4) any observed challenges related to the initiative/programme and how they are handled. Finally, we show how the different initiatives and programmes link up and provide some cross-initiative/-programme reflections.

Initiatives at the research/design stage

NIHR Priority Setting Partnerships

Overview of the scheme

NIHR Priority Setting Partnerships (PSPs) are multi-stakeholder collaborations to highlight health research areas important to patients, carers and clinicians, which could be explored by research. PSPs are hosted by the James Lind Alliance (JLA), a not-for-profit initiative, which was established in 2004 in response to a UK Medical Research Council (MRC) call for formally bringing together patients, practitioners and researchers to discuss health-related research. The JLA was originally funded by the MRC and the Department of Health (now Department of Health and Social Care). Since 2013, the JLA is funded by the NIHR and managed by the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) (Madden & Morley, 2016, p. 3).

The main objective of the JLA is to bring together patients, carers and clinicians in Priority Setting Partnerships (PSP) to identify the top ten uncertainties related to the effects of treatments. The prioritisation should help raise health research funders' awareness of issues that are important to patients, carers and clinicians (James Lind Alliance, n.d.-b; NIHR, n.d.-c).

PSPs are set up for different health conditions, diseases or specialty areas (e.g. autism, asthma, anaesthesia and perioperative care). Uncertainties related to the health conditions, diseases or speciality areas are usually collected through an online survey (mostly open-ended questions), and in some cases through interviews, focus groups, Delphi techniques, expert panels, nominal group techniques, consensus development conferences, interactive research agenda setting or votings. In addition, existing guidelines and systematic reviews are studied to identify uncertainties. The responses to the survey are systematically managed and processed to a list for prioritisation (e.g. removal out-of-scope submissions, combining similar submissions, summarising submissions to larger categories) (Ball, Harshfield, Carpenter, Bertscher, & Marjanovic, forthcoming; James Lind Alliance, 2018, pp. 26, 32; Madden & Morley, 2016, p. 6). In an interim priority-setting stage, the long list of uncertainties is reduced to a shorter list, which will be used in a final priority-setting workshop where patients, carers and clinicians discuss and select the top ten uncertainties. The top-ten list is published and disseminated using several communication channels, including the JLA website, newsletters, other websites, journals, funding charities, conferences and workshops. Moreover, the PSP's Steering Group are encouraged to reach out to research funders (e.g. the NIHR, the Association for Medical Research Charities (AMRC), the MRC) and disseminate the priority list (James Lind Alliance, 2018, pp. 58–60).

Financing and support model

PSPs are usually funded by one or more of the main organisations (e.g. universities, charities, research funders) involved in the PSP. The JLA Guidebook notes that parties with a commercial interest in the PSP topic must not fund the PSP. Costs for a PSP can vary considerably (depending on e.g. expertise of individuals involved, available infrastructure), and the JLA does not provide information on indicative costs (James Lind Alliance, 2018, pp. 5, 14).

Neither the NIHR nor the JLA provide regular funding for PSPs.[67] The NIHR, however, provides funding for the JLA infrastructure to enable the JLA to oversee PSP processes, to recruit and train JLA Advisors, which are neutral consultants who provide support and guiding for PSPs (NIHR, n.d.-c).[68] The JLA supports PSPs by providing JLA Advisors as well as a publicly available toolbox of key PSP documents and a regularly updated guidebook, which explains how to establish, set up and run a PSP (James Lind Alliance, 2018).

Output and impact

As of September 2018, 95 PSPs have been completed since 2004, delivering a number of research priorities. A success factor for PSPs is the uptake of identified priorities in research. According to the JLA, priorities of a third of all completed PSPs (32 PSPs) have been directly addressed in funded research, e.g. in NIHR-funded studies (e.g. health technology assessments (HTAs)), Cochrane Reviews (systematic literature reviews), projects jointly funded by the NIHR and international funding bodies, projects funded by research charities and foundations, and studies funded by other national public and public research funding bodies (James Lind Alliance, n.d.-a, n.d.-c).

Challenges and how they are handled

According to Ball et al. (forthcoming), key challenges related to PSPs are: accessing specific communities (e.g. involving individuals from vulnerable groups) and costs resulting from reaching out to those communities; sustaining active and ongoing engagement of individuals; ensuring balanced contributions of individuals in PSPs; and sustaining impact after a PSP has completed – there is also no systematic way of collecting evidence on the uptake of priorities as research topics or whether priorities are suitable for research.

Initiatives at the translation stage

NIHR Collaborations for Leadership in Applied Health Research and Care

Overview of the programme

NIHR Collaborations for Leadership in Applied Health Research and Care (CLAHRCs) are UK research collaborations between NHS service providers, NHS commissioners, universities, local organisations (e.g. councils, charities) and AHSNs, which are funded over a period of five years by the NIHR.

The main objectives of CLAHRCs are to (1) 'develop and conduct applied health research relevant across the NHS and translate research findings into improved outcomes for patients'; (2) 'create a distributed model for the conduct and application of applied health research that links those who conduct applied health research with all those who use it in practice across the health community'; (3) 'create and embed approaches to research and its dissemination that are specifically designed to take account of the way that healthcare is delivered across the local Academic Health Science Network'; (4) 'increase the country's capacity to conduct high quality applied health research focused on the needs of patients'; (5) 'improve patient outcomes locally and across the wider NHS'; and (6) to 'contribute to the country's growth by working with the life sciences industry' (NIHR, n.d.-a).

[67] While the NIHR usually does not fund PSPs, it has provided funding for PSPs on two priority areas: alcohol-related liver disease and mesothelioma in the past (NIHR, n.d.-c).

[68] The desk research conducted for this study did not identify any information on the annual budget available to the JLA.

As of 2018, there are 13 CLAHRCs across England. Their main research focus is on targeting chronic disease and public health interventions (NIHR, n.d.-a).

Financing and support model

In 2016/2017,[69] the NIHR spent £1.035bn (ca. NOK 11bn) on health research and infrastructure funding; the 13 CLAHRCs received 2.5 per cent of this budget (£26m, ca. NOK 276.9m) (NIHR, 2017, pp. 40–41). The NIHR provides funding for the CLAHRCs over a period of approximately five years. The current 13 CLAHRCs are contracted to run from 1 January 2014 to 30 September 2019, and have been allocated £144.8m (ca. NOK 1.5bn) for the whole period (between £10.2m (ca. NOK 108.6m) and £11.8m (ca. NOK 125.7m) per CLAHRC).[70] Each CLAHRC is also required to acquire 'matched funding' to the same value as the NIHR funding from their partner organisations (Kislov et al., 2018, p. 2).

Output and impact

In a 2018 systematic review of 26 evaluations of CLAHRCs, Kislov et al. (2018) found that there is a relative lack of systematic data about CLAHRCs' impact on healthcare provision or outcomes (in particular in relation to their objectives described above); the authors noted, however, that such impact may take longer to unfold. Some studies included in the review indicate that some CLAHRC activities had changed the way services were delivered to patients, and helped bring practitioners and researchers closer together (Kislov et al., 2018, p. 6; see also Ling et al., 2011).

In their study on how the NIHR has benefitted the health research landscape in the first ten years of its existence, Morgan Jones et al. (2016) also identified key examples of how CLAHRCs have led to positive changes. They highlighted that, overall, CLAHRCs 'have strengthened local networks and relationships; built capacity in their local academic and NHS communities to undertake and use research […]; developed research and implementation methodologies; and added to the understanding of the complex relation between research and implementation' (Morgan Jones et al., 2016, p. 195; Rycroft-Malone et al., 2011, 2013; Soper et al., 2013). Examples for how CLAHRCs have contributed to the translation of research into practice include: CLAHRC East of England has developed a shortlist of tests for autism in children, which has led to faster diagnoses and quicker access to appropriate care (Morgan Jones et al., 2016, p. 195; NIHR, 2016b); and East Midlands CLAHRC helped develop a tool for early detection of diabetes risk in ethnic minority communities, who are more likely at risk to develop diabetes (Morgan Jones et al., 2016, p. 234).

Challenges and how they are handled

Soper et al. (2013) highlighted that a key challenge of CLAHRCs is having multi-disciplinary and cross-organisational teams working together, which tend to have different working cultures. Similarly, Ling et al. (2011) found that collaborations in CLAHRCs can be challenging due to different values, priorities and ways of working (Ling et al., 2011). Soper et al. (2013) also noted that staff turnover in authority and decision-making positions or NHS policy changes are challenges several of the first CLAHRCs faced (Soper et al., 2013, p. 56). CLAHRCs also require public and patient involvement, which was perceived difficult by some individuals involved in the first round of CLAHRCs. Clear communication and definition of common interests and values were seen as important ways to address these challenges (Ling et al., 2011).

[69] Data for 2017/2018 has not been published yet.

[70] The first nine CLAHRCs received £88m (ca. NOK 937.2m) from 2008 to 2013, i.e. each CLAHRC had funding of on average £9.8m (ca. NOK 104.4m); funding per CLAHRC thus increased for the 2013–2018 funding period (SDO & NIHR, 2009, p. 4).

Small Business Research Initiative Healthcare

Overview of the scheme

The Small Business Research Initiative (SBRI) Healthcare scheme provides competitive funding to companies developing solutions to healthcare problems. The first SBRI Healthcare scheme was launched in 2009. Initially, the scheme was coordinated by the UK's innovation agency, the Technology Strategy Board (now Innovate UK). Since 2012, SBRI Healthcare funding is provided by NHS England and since 2013, the Eastern AHSN based in Cambridge, UK, has been managing the initiative (with support from Health Enterprise East (HEE), a not-for-profit 'innovation hub' providing technology and innovation advice and support to the NHS) (Lichten et al., 2017, p. 2).

The main aim of SBRI Healthcare is to find innovative solutions for healthcare problems as well as to increase the economic growth of innovative companies funded by the scheme (Lichten et al., 2017, p. 1). Healthcare problems and challenges are identified by the SBRI Healthcare team working in close collaboration with clinicians and frontline NHS staff (NHS England & AHSN Network, 2018b, p. 4). Competitive calls for applications for SBRI Healthcare funding are run twice per year, and invite companies to provide ideas and present their innovations which are able to address identified healthcare problems (PA Consulting Group, 2018, p. 16).

SBRI Healthcare is one of several SBRI schemes in the UK, all of which aim to fund innovative ideas responding to government and public sector challenges (e.g. defence and security, agriculture or commerce challenges) (Lichten et al., 2017, p. 1).

Financing and support model

SBRI Healthcare offers two types of competitive funding (Phase 1 and Phase 2 funding). Phase 1 funding is provided for feasibility testing over a period of six months; the maximum funding is £100,000 (ca. NOK 1.1m). Companies which have completed Phase 1 can bid for Phase 2 funding to continue their projects. Phase 2 funding is provided over 12 months, and the maximum funding is £1m (ca. NOK 10.7m). Throughout Phase 2, companies receive support from SBRI Healthcare health economists to build their business model. The health economists also support them through 'light-touch' monitoring, which aims to help businesses to meet their milestones (SBRI Healthcare, 2017). SBRI Healthcare has recently also provided Phase 3 funding to a few companies to enable them to develop real-world evidence to show their products' effectiveness (NHS England & AHSN Network, 2018b, p. 4).

Output and impact

Since NHS England has been providing funding for SBRI Healthcare (2012), in total £81m (ca. NOK 862.7m) has been invested in the scheme, and 164 contracts have been awarded. According to NHS England and the AHSN Network, the scheme has had impact on several areas: £185m (ca. NOK 2bn) of additional funding have been leveraged through grants and venture capital from 2013 to 2018; 60 SBRI Healthcare-funded products are currently available on the market; 21 companies are exporting their SBRI Healthcare-funded products to other countries; 45 intellectual property (IP) patents, copyright and trademarks have been awarded; and 1,050 jobs have been created or safeguarded. Moreover, SBRI Healthcare has led to more than £30m (ca. NOK 319.5m) of savings for the NHS, and approximately 1.2m patients benefit from SBRI Healthcare outcomes (NHS England & AHSN Network, 2018b, pp. 6–7).

A review of the overall SBRI programme described SBRI Healthcare as 'the single best role model for future programmes' among all SBRIs, and recommendations were put forward to further build on the SBRI Healthcare scheme (Connell, 2017, p. 39). However, it should be noted that although the review was described as being

independent, Connell highlighted in the document's foreword that he was a member of the NHS England SBRI [Healthcare] Management Board.

Challenges and how they are handled

Connell (2017), Lichten et al. (2017) and PA Consulting Group (2018) highlighted in their reviews of SBRI Healthcare that while the scheme successfully supports the development of products which are able to respond to healthcare problems, it 'stops' at the adoption and spread stage. Connell (2017) suggested increasing the SBRI Healthcare budget, and improving collaboration with the NIHR to support clinical trials of SBRI Healthcare products, could help overcome adoption and spread challenges (Connell, 2017, p. 91). PA Consulting Group (2018) suggested offering the recently introduced ITP to the most successful innovations to support adoption (PA Consulting Group, 2018, p. 3).

Initiatives at the market-entry stage

National Institute for Health and Care Excellence technology appraisals

Overview of the initiative

The non-departmental public body National Institute for Health and Care Excellence (NICE) was established in 1999[71] in order 'to reduce variation in the availability and quality of NHS treatments and care' for England (NICE, n.d.-d).[72] Its main aim is to provide evidence-based recommendations on the clinical and cost-effectiveness of treatments, technologies, medicines, diagnostic tools, health activities, etc. (NICE, n.d.-d). Since 2005, NICE has been developing four different types of public health guidance: *technology appraisals* assessing health technologies; *clinical guidelines* to provide guidance on treatment and care of specific diseases and conditions; guidance on the safety of *interventional procedures* (i.e. 'any surgery, test or treatment that involves entering the body through skin, muscle, a vein or artery, or body cavity'); and *public health guidance* on activities supporting a healthy life and preventing ill health (NICE, 2008, p. 5). NICE technology appraisals provide guidance and recommendations on the use of medicines, medical devices, diagnostic techniques, surgical procedures as well as health promotion activities that are already used in the NHS or are new to the NHS.[73] An independent technology appraisal committee, which involves members from the NHS, academia, industry and the wider public, develops recommendations based on a review of clinical (i.e. the clinical effectiveness) and economic evidence (i.e. value for money). NICE reviews evidence from several sources, which is mainly provided by the company producing the technology. NICE selects technologies for technology appraisals based on a topic-selection process conducted by the National Institute for Health Research Innovation Observatory (NIHRIO) at the University of Newcastle, which aims to ensure that only topics or products relevant to patients, carers, healthcare professionals and NHS organisations are considered, as well as based on further pre-defined selection criteria (NICE, 2008, 2018a, n.d.-d). The NIHRIO works with VOICE (Valuing Our Intellectual

[71] The institute was originally named National Institute for Clinical Excellence, renamed to the National Institute for Health and Clinical Excellence after merging with the Health Development Agency in 2005, before changing its name to National Institute for Health and Care Excellence in 2013 to reflect its responsibilities set out in the *Health and Social Care Act 2012* (NICE, n.d.-d).

[72] NICE provides guidance for England only, but based on agreements with public health authorities in Northern Ireland, Scotland and Wales some of their guidance is also used in the other three countries (NICE, n.d.-d).

[73] As noted in NICE's guide to technology appraisals, however, the main focus is on new technologies (NICE, 2018a, p. 8).

Capital and Experience) based at the University of Newcastle, an organisation aiming to engage members of the public in research, to ensure that patient and public voices are heard (NIHR, n.d.-d).

Although the Department of Health and Social Care funds NICE, it is operationally independent of the UK Government. It is the only organisation in England that provides structured, evidence-based guidance and recommendations on the use of medical products and treatments in NHS England (NICE, n.d.-d).

Financing and support model

NICE is primarily funded by the Department of Health and Social Care (78 per cent of the overall budget for NICE in 2017/2018), and receives additional funding from NHS England and Health Education England. In addition, it generates income from activities related to the NICE Scientific Advice,[74] its Office for Market Access[75] and research grants. In 2017/2018, NICE received £54.7m (ca. NOK 582.6m) funding by the Department of Health and Social Care, and the total available budget was £70.3m (ca. NOK 748.7m) (NICE, 2018c, p. 28). NICE does not provide funding to companies whose products are assessed for a technology appraisal.

Output and impact

In 2017/2018, NICE published 76 technology appraisals, 70 guidelines and guidance documents, and a wide range of other documents such as medtech innovation and other assessment briefings, bulletins, medicine evidence commentaries, evidence summaries, etc. (NICE, 2018c, p. 27).[76]

On their website, NICE publishes data from national audits and reports, journal papers and local audits which provide insights into how NICE guidance is used and whether it has led to changes in the uptake. In addition, NICE publishes impact reports on priority areas (e.g. cardiovascular disease prevention, maternity, cancer, diabetes, falls and fragility fractures) to show how the health and care system uses NICE guidance as well as how NICE guidance could lead to improvements in the priority areas. Data used for the impact reports include national audits, external reports, surveys and indicator frameworks (NICE, 2018b). For example, the impact report on cancer highlighted that the uptake of new cancer drugs which help the immune system to fight cancer cells rapidly increased after NICE recommended them and showed that they are more effective and have fewer side effects than other treatments (NICE, 2018d). Moreover, the NHS Innovation Scorecard regularly publishes data on the use of products which have received a positive NICE appraisal.

Challenges and how they are handled

A main critique of NICE guidance is that as one of its key criteria for a positive recommendation is cost-effectiveness, it may restrict access to clinically effective products which are not cost-effective, as it is unlikely that commissioners take up treatments that NICE has not recommended (see e.g. Wise, 2016).

Data on the uptake of NICE-appraised products have shown that some products have a high variation in uptake (e.g. uptake of diabetes, Alzheimer's disease and other drugs, see Chaplin, 2014; or uptake of spinal cord stimulation, see Vyawahare, Hallas, Brookes, Taylor, & Eldabe, 2014). Based on a recommendation made in the health policy *Innovation, Health and Wealth* (Department of Health, 2011a), the NHS Innovation Scorecard was

[74] Scientific Advice is a service provided by NICE, which offers fee-based consultation to developers of healthcare technologies and medicinal products (NICE, n.d.-c).

[75] NICE's Office for Market Access provides support to life sciences companies in their efforts to enter into the health system (NICE, n.d.-b).

[76] A detailed list of NICE outputs in 2017/2018 can be found in NICE's annual report (NICE, 2018c, p. 27).

introduced. The Scorecard publishes uptake data on a quarterly basis, which aim to help the NHS identify explanations for variations as well as actions to reduce them (NHS England, 2018c).

A third critique related to NICE's appraisals is the perception that the appraisal process takes too long (single-technology appraisals: min. 61 weeks, multiple technology appraisals: min. 78 weeks; see Cowles, Marsden, Cole, & Devlin, 2017, p. 472). In response to this criticism, NICE introduced fast-track appraisals in 2017: products that 'offer exceptional value for money' are applicable for the faster process, ensuring that they are made available to patients already 30 days after approval (NICE, 2018a, p. 8).

NHS Innovation Accelerator

Overview of the initiative

The NHS Innovation Accelerator (NIA) is a fellowship programme that was introduced in response to the Five Year Forward View (NHS England, 2014), and aims to speed up the uptake of high-impact and evidence-based innovations. The programme is aimed at individuals (who are usually part of businesses, research or health organisations, charities, etc.) and complements other programme focusing on organisations such as SBRI Healthcare (see Section 1.4.2). The programme NIA was launched in 2015 and is delivered in partnership with the 15 AHSNs; it is hosted at the UCLPartners AHSN in London (NHS England, n.d.). More specifically, the programme's key aims are to (1) 'Help create the conditions and cultural change necessary for proven innovations to be adopted faster and more systematically in the NHS; (2) 'Deliver innovation into practice for demonstrable patient and population benefit'; and (3) to 'Learn from Fellows' experiences so that others benefit from knowledge generated' (NHS Innovation Accelerator, 2017a).

Through its fellowship programme, the NIA provides support to individuals from various backgrounds (e.g. industry, academia, clinicians, charities) to scale up the use of their innovations across the NHS and the healthcare system. Individuals can be fellows for up to three years.[77] International calls for fellowship applications are published once per year. Innovations are selected by an expert group of over 100 individuals from a wide range of different health organisations and backgrounds (e.g. NHS England, NHS Digital, AHSNs, NICE, The Health Foundation, clinicians, patients, directors of improvement, commercial directors) (NHS England & AHSN Network, 2018a, p. 4). The NIA offers a wide range of support mechanism to its fellows, including: peer-to-peer support by the programme team and other fellows; events and an online forum to exchange with other fellows; networking through AHSNs; support on developing scaling strategies; mentoring; learning programmes; and a bursary (NHS Innovation Accelerator, 2017c).

Supported innovations are categorised as follows: early intervention and diagnostics; mental health; primary care and urgent care; safety, quality and efficiency within hospitals; self-care and education; and supporting new models of care (NHS England & AHSN Network, 2018a, p. 6).

Financing and support model

The NIA is funded by NHS England and the 15 AHSNs (NHS Innovation Accelerator, 2017b).[78]

The NIA mainly offers non-monetary support mechanisms to NIA fellows. NIA fellows who are successful in the fourth call of the programme (2018) can be granted access to a bursary of up to £20,000 (ca. NOK 213,000).

[77] In the first year, support was only provided for one year, but was then extended to up to three years (Cox et al., 2018, p. 11).

[78] Our desk research did not identify information on the overall budget spent on the scheme.

When applying for an NIA fellowship, applicants have to demonstrate a clear need for the bursary. The funding can be used for e.g. personal development, attendance at events, innovation development and scale-up, and evidence gathering to demonstrate innovations' effectiveness (NHS Innovation Accelerator, 2017b).

Output and impact

According to NHS England and the AHSN Network, as of January 2018, 36 individuals and 37 innovations have been supported by the NIA. The support has resulted in 964 NHS sites using the innovations (in addition to organisations that already used them before), the securing of £40m (ca. NOK 426m) of external funding, the creation of 116 new jobs, 29 prizes awarded to the innovations, and the international selling of 13 of the innovations (NHS England & AHSN Network, 2018a, p. 5).

Challenges and how they are handled

The first cohort of NIA fellows initially received support over a period of 12 months, which was considered to be 'extremely ambitious' given the aim to scale up the innovations across the NHS in that period. All year-one fellows applied for and were granted further support in 2016 (Cox et al., 2018, pp. 11, 71). As of 2018, NIA fellows can receive support for up to three years (NHS Innovation Accelerator, 2017b).

An evaluation of the first round of NIA fellowships (Cox et al., 2018) identified several key challenges related to the NIA; however, most of them are wider challenges of the health innovation landscape in England, and are not necessarily directly related to the NIA, e.g. the identified challenge of delays in up-scaling related to existing commissioning structures and processes. Some fellows interviewed for the evaluation noted that more support for innovators to define the benefits of their innovations to the NHS and how to communicate them would be needed (Cox et al., 2018, pp. 32, 79).

Accelerated Access Pathway

Overview of the initiative

The health policy Accelerated Access Review (2016) concluded that the process from development of a product to the introduction and actual use in the health system tends to take long in England and thus set out the recommendation to create an Accelerated Access Pathway to speed up the route to market for selected, strategically important, transformative innovations. The Pathway, the review stated, 'should align and coordinate regulatory, reimbursement, evaluation and diffusion processes to bring these transformative products to patients more quickly' (Accelerated Access Review, 2016, p. 26). In their response to the review, the UK Government announced that the Pathway will would be launched in April 2018. Five products – ranging from medicines, medical technologies, diagnostic tools to digital products – per year plan to be supported by the Pathway; the products need to demonstrate that they will bring cost savings to the NHS. Selected products should benefit from streamlining of the processes from market authorisation through to diffusion and receive case management tailored to the individual innovation (Department of Health & Department for Business, Energy & Industrial Strategy, 2017, pp. 12–15).

A wide range of organisations and actors across the health system in England are brought together to work jointly on the Accelerated Access Pathway in an Accelerated Access Collaborative. The Collaborative's main role is to select the products for the Pathway based on clearly defined selection criteria. Members of the Collaborative include representatives from NHS England, the Department of Health and Social Care, the Department for Business, Energy & Industrial Strategy, NICE, the UK Medicines and Healthcare products Regulatory Agency, AHSNs, NHS Improvement, industry representatives, patients and clinicians (NICE, n.d.-a).

The Accelerated Access Pathway aims to complement and build on existing schemes, e.g. NICE fast-track appraisals (Department of Health & Department for Business, Energy & Industrial Strategy, 2017, p. 14).

Financing and support model

Our desk research did not identify information on the overall funding of the Accelerated Access Pathway. In the UK Government's response to the *Accelerated Access Review*, the UK Government promised to provide support for adoption and diffusion through the newly introduced £6m (ca. NOK 63.9m) Pathway Transformation Fund (Department of Health & Department for Business, Energy & Industrial Strategy, 2017, p. 14).

Output and impact

Output and impact data is not yet available as the initiative started only recently (2018). The Accelerated Access Collaborative is expected to define success criteria for the Accelerated Access Pathway (e.g. 'level of industry interest in [the Accelerated Access Pathway]; speed of product progression through the [Pathway]; improved health and quality outcomes; increased affordability of new technologies and products; improved value for money; increased impact of AHSNs; and [small- and medium-sized enterprises] getting products to patients quicker and more easily'). This should allow them to identify and analyse any impact of the Pathway (Department of Health & Department for Business, Energy & Industrial Strategy, 2017, p. 16).

Challenges and how they are handled

As the Accelerated Access Pathway was established only recently, challenges related to the initiative have not been identified yet.

Initiatives at the diffusion/spread stage

Academic Health Science Networks

Overview of the initiative

Academic Health Science Networks (AHSNs) are networks of academic, industry, health service, third sector and local authority stakeholders and organisations, which aim to spread innovations across the healthcare system in England as well as generate economic growth (The AHSN Network, 2017a). AHSNs were introduced based on the identified need to improve the translation of research into practice in England, and research showing that stronger relationships between and networks of different actors in the health system could strengthen and accelerate the translation process. The 15 AHSNs, which are located across England, were established in 2013 for an initial five-year licence period. In April 2018, the second five-year licence period started; the contracts for the initial AHSNs were renewed (The AHSN Network, 2017c).

AHSNs' main priorities are promoting and generating economic growth; diffusing innovations across the system; improving patient safety; optimising medicine use; improving quality; reducing variation; supporting the translation of research into practice; and collaborating on national programmes (The AHSN Network, 2017a). Each AHSN works at local level and is responsible for its own projects, programmes and schemes (e.g. SBRI Healthcare, which is managed by the Eastern AHSN).

Financing and support model

AHSNs are primarily funded by NHS England. In the first licence period, they received £50m (ca. NOK 532.5m) per year from NHS England. NHS England funding for the second licence period was reduced to £44.2m (ca. NOK 470.7m) in 2018/2019 and £44.4m (ca. NOK 472.9m) in 2019/2020 due to cost pressures; it will be complemented by £39m (ca. NOK 415.4m) from the UK Government's Office for Life Sciences (Department of Health & Department for Business, Energy & Industrial Strategy, 2017, p. 9; NHS England, 2018d, p. 3). AHSNs are also supposed to generate income from local partners as well as delivering national initiatives and programmes (NHS England, 2017c, p. 5).

AHSNs provide both monetary and non-monetary support to actors across the health innovation landscape. Examples of support initiatives include SBRI Healthcare and the delivery of the ITT and ITP.

Output and impact

There has not yet been a formal, independent evaluation of the AHSNs. In 2017, the AHSN Network published an *Impact Report*, which provides figures on the impact they had had since the start of the first licence period, including: the introduction of over 200 innovations through their influence; benefit brought to over 6 million patients; over £300m (ca. NOK 3.2bn) leveraged by the AHSNs; over 11,000 locations have been developing innovations supported by the AHSNs; and the creation of over 500 jobs (The AHSN Network, 2017b, pp. 4–5).

Challenges and how they are handled

In the first licence period AHSNs were often criticised for working more as individual, local networks than as a national network of 15 AHSNs. In the new licence period, AHSNs are supposed to work closer and more consistently together at national level (NHS England, 2018d, p. 3).

Innovation and Technology Tariff, and Innovation and Technology Payment

Overview of the initiatives

The Innovation and Technology Tariff (ITT) and Innovation and Technology Payment (ITP) are two schemes which aim to reduce financial and procurement barriers related to the uptake of innovations in the NHS in England ; procurement in the NHS in England usually happens at individual trust or clinical commissioning group (CCG) level, meaning that typically each trust or CCG has to individually negotiate pricing with suppliers and use their own budget (i.e. there is no 'central' NHS budget). Both schemes are NHS England initiatives delivered in partnership with the 15 AHSNs (NHS England, 2018b).

The ITT was launched in April 2017 and includes a set of six cost-saving and outcomes-based innovations. Providers and commissioners can order most of these innovations directly from the supplying companies at zero cost; NHS England reimburses the companies directly. The ITT thus aims to reduce the burden for providers and commissioners to negotiate pricing (NHS England, 2017a, pp. 4, 7).

The ITP was introduced in response to needs identified in the Five Year Forward View (NHS England, 2014). It aims to support the adoption of market-ready innovations (e.g. medical devices, diagnostics and digital technologies) which have the potential to improve the quality and efficiency of healthcare. Innovations are selected in a competitive process by a multi-stakeholder panel (including clinicians, providers, commissioners, NICE and AHSN representatives as well as patients), and are on the tariff for a period of one year. The first four

innovations on the ITP were announced in April 2018. Similar to the ITT, NHS England covers the costs when any of the four ITP innovations are ordered by providers and commissioners and does not require price negotiations at individual trust or CCG level (NHS England, 2018b, 2018a, p. 5).

Financing and support model

The desk research conducted for this case study did not identify any information on the overall budget available for the ITT and ITP.

Most innovations on the ITT and ITP are directly reimbursed by NHS England.[79] There are fixed prices for the innovations and there is no need for additional pricing negotiations at local level (NHS England, 2017a, pp. 4, 7).

Output and impact

In order to assess the impact of the ITT and ITP – i.e. an increased uptake of the supported innovations – providers are required to collect and provide data on the uptake and use of ITT and ITP innovations (NHS England, 2017a, p. 6, 2018a, p. 7). In a board paper published in May 2018, NHS England highlighted that as of May 2018 the ITT has been benefitting over 70,000 patients (NHS England, 2018d, p. 2). Information on early impact of the ITP is not yet available.

Challenges and how they are handled

As both the ITT and ITP have only started recently, there have not been any formal evaluations of the schemes, and challenges related to the schemes have not been published yet.

Cross-initiative and programme reflections

As noted above, several of the issues identified in the Norwegian health research and innovation system have also been highlighted in the UK over several decades, including in the development of the recently published Industrial Strategy.[80] The complexity of the challenges and lengthy UK history of trying to optimise the research and innovation system means that a rich landscape of possible interventions exists in the UK. This diversity of initiatives at different points in the research and innovation system provides an opportunity for drawing lessons to inform future policy – including developments in Norway.

It is, however, clearly important to exercise caution in applying or adapting approaches in a new context, in part because such replication is not straightforward, but also because in many cases there is not yet sufficient evidence to conclude whether or not the UK examples are successful. Many of the examples are, nonetheless, underpinned by more general principles which there is evidence to support – for example, the benefits of working with diverse stakeholders and across traditional

[79] One ITT innovation is paid through a National Tariff, and one ITP innovation is only partially reimbursed by NHS England.

[80] HM Government (2017). *Building our Industrial Strategy. Green Paper.*

boundaries, and in learning from implementation and continuing research in practice.[81] Below, we go through some of these general principles.

Different stages on the health innovation pathway need to be linked

The examples of initiatives and programmes supporting the health research and innovation system in England show that significant effort and finance has been invested into improving and strengthening the system across the innovation pathway during the past two decades. Some of the initiatives and programmes try to address bigger-picture challenges and to link different stages of the innovation pathway to each other. The JLA's PSP approach, for instance, was introduced in light of the observed low translation of research into practice and low uptake of innovations, and a key assumption was that if research addresses questions that matter to patients, carers and healthcare professionals, research outcomes would be more likely taken up. Indeed, studies show that involving patients and the public in early stages of research can lead to more public acceptance of research as well as increase later uptake of research findings into practice (Ball et al., forthcoming; Dudley et al., 2015; Esmail, Moore, & Rein, 2015; Forsythe et al., 2017; NIHR, 2015). Similarly, NIHR CLAHRCs aim to link research and practice, and while the Accelerated Access Pathway primarily sits at the market-entry stage, it tries to speed up and better link transformative innovations' introduction into and diffusion in the health system (Department of Health & Department for Business, Energy & Industrial Strategy, 2017; NIHR, n.d.-a).

However, although evaluations – and early assessments of more recent initiatives – indicate that the initiatives and programmes presented in this document have contributed to improving the health innovation pathway in England, and although some of them link different stages on the innovation pathway, they are often seen as detached from each other and unable to address wider system challenges. As noted in a recent RAND Europe report on the health innovation system in England, the health innovation initiative landscape in England is fragmented, and therefore the existing initiatives and programmes are 'often unable to achieve critical mass and scale to support innovations across the pathway' (Marjanovic et al., 2017, p. xiii). Reviews of the initiatives and programmes discussed in this document gave a similar picture: for instance, all three independent reviews of SBRI Healthcare highlighted that the scheme helped bring healthcare and industry closer together, but it is currently unable to overcome adoption and spread challenges on its own (Lichten et al., 2017, p. 30). A similar challenge was found in relation to the NIA: while it generally supports innovators to introduce their products into the health system in England, NHS commissioning structures and processes often delay the up-scale (Cox et al., 2018).

[81] For example, Wooding, S. et al. (2013). *Mental Health Retrosight: Understanding the returns from research (lessons from schizophrenia): Policy Report.* Cambridge, UK: RAND Europe.; Guthrie, S. et al. (2016). *A 'DECISIVE' approach to research funding: Lessons from three Retrosight studies*. Cambridge, UK: RAND Europe.

AHSNs were introduced to close this gap between the translation/market-entry stages and the diffusion/spread stage. However, as noted, while they are considered to have contributed to increasing and accelerating the diffusion of promising innovations, the 15 AHSNs could be better connected to each other as well as to other stakeholders in the system (NHS England, 2018d, p. 3).

Stakeholders across the health system need to be involved and connected more

As highlighted by Marjanovic et al. (2017), a key driver of successful health innovation processes are relationships and networks and related to that actively involving diverse stakeholders in the health (innovation) system in these processes. Indeed some of the initiatives and programmes presented in this document engage several different stakeholders; this engagement is a key element and objective as well as a desired outcome of some of those initiatives and programmes. For instance, CLAHRCs bring together academics, healthcare professionals, commissioners, local organisations and AHSNs, and they also require patient input. Similarly, AHSNs join up stakeholders from academia, industry, the health system, third sector and other organisations; and members of the Accelerated Access Collaborative include e.g. UK Government and other public bodies, health organisations, industry, clinicians and patients. Key of these initiatives and programmes is that stakeholder engagement is not optional and should happen at all stages of the initiative/programme (NICE, n.d.-a; NIHR, n.d.-a; The AHSN Network, 2017a).

A variety of public and governmental organisations as well as key bodies in the health landscape in England are also involved in the delivery and implementation of the presented initiatives and programmes, which shows the importance of the health innovation pathway – and improving it – on the political agenda. The UK Department of Health and Social Care, for instance, funds the NIHR (and subsequently the initiatives it offers), is the main funder of NICE, and is represented on the Accelerated Access Collaborative. Another example is the Office for Life Sciences, a joint office of the Department of Health and Social Care and the Department for Business, Energy & Industrial Strategy, which financially supports the delivery of the *Accelerated Access Review* (2016) and its initiatives (Office for Life Sciences, 2016).

Independent and systematic evaluations as well as a degree of flexibility to adapt to changes are key to health innovation initiatives and programmes

The success – but also challenges and shortcomings – of several of the initiatives and programmes presented above has been captured in evaluations and impact reviews. We consider such continuous evaluations to be key in a functioning and ever-improving health innovation landscape, particularly in light of having a permanently changing health system that needs to adapt to a variety of challenges, from cost pressures to increasing and changing demands. Initiatives and programmes across the health innovation pathway, but also wider health policy approaches, thus need to have a certain degree of flexibility in their approach to adapt to changes in the system as well as to respond to challenges identified in evaluations.

While most of the discussed initiatives and programmes have been subject to evaluations and/or reviews demonstrating their impact, some initiatives/programmes lack independent evaluations and others have not undergone any evaluations at all, although they have been existing for several years. For instance, the AHSN Network has not been formally reviewed yet, and impact data of initiatives/programmes are often self-reported by the organisations delivering them.

Evaluations should not only be independent, but data to support them should also be strategically collected and on an ongoing basis. For instance, Kislov et al. (2018) found that while CLAHRCs have undergone evaluations, there is a relative lack of systematic impact and outcome data, which also hampers making comparisons between different CLAHRCs. Strategic and continuous collection of impact data not only facilitates assessing of the success or shortcomings of an initiative/programme, but may also allow making cross-initiative comparisons, and thus enable better joining up of initiatives and programmes across the innovation pathway.

A set of key drivers could support an innovative health system

Finally, while they are not specific to the initiatives and programmes presented here, there are factors that can positively influence innovating in healthcare and translating research into practice. Marjanovic et al. (2017) found that an innovative health system can be supported by a combination of the right skills, capabilities and leadership; relationships and networks involving stakeholders across the health innovation system; the right information, evidence and resources for innovation; suitable motivations for individuals to innovate and take up innovations as well as defined accountabilities; patient and public engagement and involvement; as well as appropriate funding, commissioning and procurement environments (Marjanovic et al., 2017).

The Canadian Strategy for Patient-Oriented Research

Background and introduction to the initiative

This case study describes the Canadian *Strategy for Patient-Oriented Research* (SPOR), an initiative which aims to engage patients, their carers and families in research processes (Canadian Institutes of Health Research, 2018e). In 2000, the *Canadian Institutes of Health Research Act* created an independent agency responsible for national research investment, the Canadian Institutes of Health Research (CIHR), with the mission 'to create new scientific knowledge and to enable its translation into improved health, more effective health services and products, and a strengthened Canadian healthcare system' ('Canadian Institutes of Health Research Act', 2000). Within the Canadian government, the CIHR is part of the Health Portfolio that supports the Minister of Health and is the federal funding agency for health research. CIHR is responsible for funding research, building research capacity and focusing on knowledge translation that applies the results of research into new policies, practices, procedures, products and services. While CIHR is a federal agency and accountable to the Canadian Parliament, it is independent (Canadian Institutes of Health Research, 2018a). Funding under the CIHR is divided into two categories: investigator-led research and priority-driven research. Priority-driven research addresses pressing health problems of strategic importance to Canada including antimicrobial resistance, aging, substance misuse and HIV/AIDS. SPOR falls within these priority-driven research initiatives (Canadian Institutes of Health Research, 2017a).

SPOR was created after the CIHR published a transformational five-year strategic plan in 2009, which identified four strategic directions that would help the CIHR carry out its mandate. The introduction of this plan resulted from evidence showing that although Canada produces excellent health research, 50 per cent of patients do not receive the most clinically effective care and up to a quarter of patients receive treatments that are not needed or may be harmful (Nova Scotia Health Research Foundation,

n.d.). SPOR was written after a series of consultations with the CIHR's Scientific Council, individuals interested in CIHR's work and key stakeholders from across the health research and university research community. More than 12,000 individuals and organisations were invited to participate in web-based consultations, which were open to all health researchers, interested individuals and stakeholder groups. One of the strategic directions set out in this plan was to address health and health system research priorities, which would guide the priority-driven research that the CIHR funded over the next five years. The first priority identified in the plan was to enhance patient-oriented care and improve clinical results through scientific and technological innovations by creating a flagship strategy for patient-oriented research (Canadian Institutes of Health Research, 2009).

After this five-year plan was published, the CIHR held another series of consultations around patient-oriented research with key stakeholders from universities, academic healthcare organisations, life sciences industries, health charities, and health professional associations, along with another web-based survey filled out primarily by health researchers. One of the central themes of these consultations was the need to better reflect patient perspectives and to respond to regional differences and needs (Canadian Institutes of Health Research, 2011). The result of these meetings and consultations was a specific plan to fulfil the priority identified in the CIHR's five-year plan of creating a flagship programme of patient-oriented research. The plan for SPOR was then developed and unveiled at the annual meeting of the Canadian Medical Association in August 2011.

Objectives and activities

The vision of SPOR is to 'demonstrably improve health outcomes and enhance patients' health care experience through integration of evidence at all levels in the health system' (Canadian Institutes of Health Research, 2011, p. iii). Several goals have been identified to achieve this vision:

- 'To create a collaborative, pan-Canadian process for identifying, establishing and addressing patient-oriented research priorities;
- To establish an integrated, leading-edge pan-Canadian clinical research infrastructure along the full continuum of patient-oriented research;
- To grow Canada's capacity to attract, train and mentor health care professionals and health researchers, as well as to create sustainable career paths in patient-oriented research;
- To strengthen organizational, regulatory and financial support for clinical studies in Canada and enhance patient and clinician engagement in these studies; and
- To improve processes for the early identification of best practices, expedite their development and harmonization into guidelines for patient care and support their adoption by clinicians, caregivers and patients' (Canadian Institutes of Health Research, 2011, p. iii).

In order to advance these goals, CIHR conducts three main SPOR activities: (1) facilitating patient-oriented research; (2) directly funding research; and (3) finding and supporting synergy between patients, partners, researchers, healthcare providers and policymakers (Canadian Institutes of Health Research, 2018e).

Table 2. The activities and initiatives delivered through SPOR

Activity	Initiatives	Description
Facilitating patient-oriented research	SPOR SUPPORT Units	11 provincial/territorial-based organisations that provide access to data and training
	SPOR Evidence Alliances	Coordinating centre where knowledge users can submit health research questions and queries, which will be matched with experts; patients' research queries are reviewed using the UK James Lind Alliance (JLA) Priority Setting Partnership (PSP) approach.
	The Canadian Clinical Trials Coordinating Centre (CCTCC)	Centre that brings together stakeholders to strengthen Canadian clinical trials
Directly funding research	SPOR Networks	Grants to build networks on subject matters that bring together researchers, experts and patients to address important issues in the healthcare system; there are currently seven networks funded under SPOR
	Innovative Clinical Trials (iCTs)	Small grants to build capacity and streamline current start-up process for clinical trials with the goal of increasing Canada's competitiveness
Finding and supporting synergies	SPOR Capacity Development Framework	Framework for a shared vision, key principles and considerations for capacity development in patient-oriented research
	Patient engagement	Tools for patient engagement to include them in governance, event and activity planning, and research

Source: Canadian Institutes of Health Research (2018b, 2018d, 2018c)

Financing model

In terms of funding from the federal government of Canada, the CIHR invests approximately CAD 1bn (ca. NOK 6.3bn) each year to support health research. Overall, 23 per cent of this funding is allocated to priority-driven research initiatives, which includes SPOR and 25 other priority-driven initiatives in areas such as aging, antimicrobial resistance, and other strategic issues (Canadian Institutes of Health Research, 2017a). Between 2010/2011 and 2015/2016 the CIHR spent CAD 356.86m (ca. NOK 2.3bn) on SPOR grants and awards, and the federal Treasury Board allocated an additional CAD 202.83m (ca. NOK 1.3bn) specifically to SPOR (KPMG, 2016).

Although SPOR has a national governance structure and federal funding, finances also come from provincial and territorial funds, as well as other sources. A central principle of SPOR is that core element funding (funding for SUPPORT Units, Networks, patient engagement and the Canadian Clinical Trials Coordinating Centre (CCTCC)) is based on 1:1 matching with non-federal government partners, meaning that provincial and territorial governments must match federal spending. Although most of the regional funding is provided by public funders, several SUPPORT Units have also secured funding from academic institutions and private partnerships. This funding model helps to ensure the initiative's relevance at both a national and regional level (Canadian Institutes of Health Research, 2018e). According to a 2016 evaluation of SPOR, this model also helped to extend federal/provincial partnerships. Together, these funding streams allowed SPOR to spend a total of CAD 76.3m (ca. NOK 482.3m) in 2015/2016 alone (KPMG, 2016).

Output and impact

This section describes key outputs and impacts SPOR has had to date according to a recent evaluation of SPOR (KPMG, 2016). We discuss outputs and impacts along five main elements: SPOR's contribution to stakeholder engagement; the creation of multi-disciplinary research centres, networks and partnerships; contribution to research infrastructure; contribution to capacity building; and publications resulting from SPOR-supported research.

The evaluation of SPOR highlighted that CIHR tended to rely on measuring the amount of activities conducted under SPOR rather than aiming to assess the effectiveness of these activities in advancing patient-oriented research and health outcomes (KPMG, 2016).

Stakeholder engagement

In a 2016 evaluation prepared by KPMG for the CIHR, a central theme that came out of the analysis was that SPOR has made extensive efforts to engage stakeholders across research, clinical and policy communities, and that these stakeholders had the opportunity to learn from one another in a way that would not have been possible without SPOR. From 2013 to 2015, SUPPORT Units engaged over 2,500 stakeholders. Those that engaged with SUPPORT Units were primarily researchers or academics (882), followed by health system and healthcare practitioners/professionals (553), and patient representatives (423) (KPMG, 2016).

Multi-disciplinary research centres, networks and partnerships

SPOR has led to the creation of 11 SUPPORT Units across Canada, as well as seven subject-based SPOR Networks where researchers and other stakeholders interested in common areas of healthcare can work together. Along with facilitating multi-disciplinary research, these centres have led to multi-disciplinary and cross-sectoral partnerships. The total number of partnerships that were reported across SUPPORT Units in 2014/2015 was 37, which were established at the territorial or provincial level in order to align with the regional focus of that particular Unit. In addition to these partnerships, the SPOR funding model of 1:1 federal and non-federal matching for core activities also led to greater federal and provincial/territorial partnerships, as actors at these levels were contributing to a common activity (KPMG, 2016).

Infrastructure

SPOR has contributed to a more robust data platform for the Canadian health system. In the 2016 evaluation, many SUPPORT Units identified that provinces are prioritising data platforms, data access and data linkages due to their work with researchers and policymakers through SPOR. This has especially been important in smaller provinces, where SPOR has allowed them to hire new staff to facilitate data usage and make cross-appointments with universities (KPMG, 2016). Although building a better digital infrastructure is not the main focus of SPOR, it has been included in the *CIHR Health and Health-Related Data Framework and Action Plan* (Canadian Institutes of Health Research, 2017b). Through SUPPORT Units, SPOR contributes to the CIHR's plan to build relevant skills in the analysis of large datasets, data management and biostatistics. SUPPORT Units also contribute to the CIHR plan to enable data access, linkage, use and reuse by funding the creation of data platforms and by identifying opportunities to link health systems data across provincial boundaries (Canadian Institutes of Health Research, 2017b).

SPOR also incorporated the CCTCC as a core function of each SUPPOR Unit. As of the 2016 evaluation, relatively little activity had happened with respect to the CCTCC, but its integration is still developing within SPOR (KPMG, 2016).

Capacity building

In 2015, SPOR published a capacity development framework for patient-oriented research, which can serve as a guide for the health research community (Canadian Institutes of Health Research, 2015a). Additionally, some capacity development work (e.g. capacity building for researchers, patients, healthcare providers, decision makers) has occurred through SUPPORT Units, including through studentships and training related to patient engagement and patient-oriented research. In 2015, Units reported a total of 422 capacity development services.

The most common services were training in research methods and key competencies needed to conduct patient-oriented research (e.g. how to recruit patients, how to deal with vulnerable groups of patients, principles of research ethics) (135) and training in how to translate knowledge into policy and practice (126). Despite this capacity development activity, it was still identified as one of the most under-developed areas of SPOR, especially in terms of training patients how to participate in research (KPMG, 2016).

Publications

In terms of publications, output from the SPOR Network led to the publication of 118 scientific publications, 60 education materials and 25 plain language publications products in five years (KPMG, 2016). Plain-language publications allow for the lay public to access new findings in health research, which is central to SPOR's mission of integrate evidence into the health system. Since SPOR directly funds research, it can be assumed that it will continue to lead to more academic publications and that it will contribute to the wider knowledge base of health researchers years (KPMG, 2016).

Challenges and how they are handled

Despite these outputs, there is still room for improvement in terms of how SPOR measures outcomes and impact. The 2016 evaluation of SPOR recommended that the CIHR could revise the SPOR performance measurement strategy to balance administrative and operational outputs with outcomes and impacts. The need to improve performance measurement was a consistent theme that came out of stakeholder interviews, who expressed that it is not clear if the right outcomes and impacts are being measured. As noted above, the evaluation found that CIHR primarily used the amount of activities to assess their outputs and impacts rather than evaluating the impact of these activities in advancing patient-oriented research and health outcomes (KPMG, 2016).

Along with measuring performance, the 2016 evaluation also identified five other areas where the programme's effectiveness can be improved:

- Communications, including the need to further clarify the mandates for each of SPOR's core elements, the need to better communicate support available through SUPPORT Units, the need to develop consistent and common definitions of patient-oriented research and patient engagement, and more tailored communications with different stakeholders.

- Uncertainty regarding 'what's next', especially around future funding beyond initial five-year commitments.
- Capacity building around patient engagement, including by teaching patients how to participate in research and teaching researchers how to engage patients, and by supporting patient engagement on a national level.
- Low level of understanding and uptake by some sections of the research community who are not convinced that patient-oriented research and patient engagement adds value to research or clinical outcomes.
- Lack of clarity around SPOR's many elements at the national and provincial/territorial level, leading to confusion regarding the integration of capabilities and services, the alignment of priorities and activities, and how all elements of SPOR work together (KPMG, 2016, pp. 2–3).

The evaluation suggested six steps that SPOR could take to improve effectiveness, which are outlined in 3 below. SPOR management agreed with all of these suggestions, and outlined the steps that SPOR would take to address them in their *Management Response Action Plan* (MRAP) (Canadian Institutes of Health Research, 2016).

Table 3. Evaluation recommendations and MRAP responses

Recommendation	Management Response Action Plan
CIHR should increase efforts to strengthen SPOR's role in a common agenda for change to patient-oriented research	• Identify and communicate success within SPOR, as well as best practices for patient engagement and patient-oriented research • Produce a newsletter 3 times per year • Work with partners towards creation of SPOR Patient Engagement Methods Hub • Enhance communication, including by updating Jargon Buster every 18 months • Encourage SUPPORT Units to clearly indicate support they offer and how to access it
CIHR should provide strategic guidance regarding how SPOR elements are to work together toward achieving the Strategy's immediate and long-term outcomes	• Share documents detailing working relationship between SUPPORT Units and Networks • Discuss how SPOR elements work together at meetings and annual summit • Post principle document on website
CIHR should communicate plans for moving beyond the initial five-year funding period to manage sustainability expectations for CIHR investments in SPOR	• Discuss SUPPORT Unit renewal • Develop and communicate clear message
CIHR should strengthen approaches to enable cross-learning, sharing of best practices, and collaboration within and across SPOR elements and between CIHR and Canadian and International organisations	• Re-examine structure, operations and effectiveness of groups to limit duplication of effort and leverage experience and shared learning • Support Patient Engagement Working Group to develop guidelines on patient compensation • Finalise *Foundation Curriculum for Patient-Oriented Research*

Recommendation	Management Response Action Plan
	• Support cross-jurisdictional research through Network on Primary and Integrated Care • Maintain and increase relationships with other patient-oriented research organisations • Refresh membership of SPOR National Steering Committee
CIHR should continue to support effective management and administrative functions within and across SPOR SUPPORT Units and Networks	• Require SUPPORT Units and Networks to be co-lead by CEO-type management and scientific positions • Review funding models, including timing of funding flow
CIHR should revise the existing SPOR performance measurement strategy to balance administrative/operational outputs and outcomes/impact	• Revise performance measurement strategy to demonstrate outcomes and impact • Improve financial monitoring and coding for grants and awards expenditures and for operating and maintenance expenditures

Source: Canadian Institutes of Health Research (2016)

Learnings from the SPOR initiative

Although many lessons from this initiative may be specific to the context within Canada and the CIHR, there are several cross-cutting successes that may inform other research strategies, especially in the health research sector. In particular, SPOR was successful in leveraging national governance mechanisms while still considering provincial/territorial priorities and needs. This was accomplished by its national governance structure accompanied by lateral hubs across provinces and territories, particularly with respect to SPOR SUPPORT Units. This structure was bolstered by an appropriate funding model, with federal contributions to core activities being matched by provincial/territorial government funding. Additionally, SPOR was successful in stakeholder engagement across a broad group of stakeholders in various sectors, which is a key part of the initiative's design (KPMG, 2016).

Research initiatives may also learn from how the CIHR and SPOR responded to suggestions for improvement. Within five months of the evaluation being published, management had identified several concrete steps that the initiative would take, as well as the time frame in which these actions would be put into action. This has helped to ensure SPOR's continued relevance and utility to Canada's wider health research strategy. When the CIHR updated its five-year plan in 2015, SPOR was included as an ongoing priority-driven initiative to achieve their research priority of enhancing patient experiences and outcomes through health innovation, as well as an initiative that helps mobilize health research for transformation and impact (Canadian Institutes of Health Research, 2015). As a result, SPOR is expected to continue to be an important part of Canada's health research strategy.

The longer-term impacts of SPOR are yet to be measured. Evaluation of these outcomes and impacts could be facilitated by new ways to measure impact within SPOR focusing not only on counting activities, but also evaluating the effectiveness of these activities in advancing the missions of SPOR and the CIHR.

British initiatives to increase mental health research impact

This section outlines examples of initiatives which have been implemented in UK mental health research. Mental health is a particularly complex research area for several reasons. First, it is an area in which there remain many unknowns, for example, around the nature of conditions, their causes and effective treatments. It also intersects with a range of other policy areas, including education, welfare and justice among others, meaning that it is useful to think broadly when considering how and where it may be effective to intervene. As a consequence of this, it cuts across departmental remits within government. This has advantages in creating a diversity of policy levers and opportunities for intervening but can also present challenges in assigning responsibility or coordinating policy development. Each of the examples poses questions which it may be useful to consider when thinking about the way we do research and who is involved at each stage.

How should we define research questions?

As discussed earlier in this report, the **James Lind Alliance Priority Setting Partnerships** are collaborations designed to understand the research priorities of clinicians, patients and carers in specific health conditions.

This raises the question of whether by doing research which is more relevant to practice needs – or at least is closer to practice from the start – we are able to apply the findings more quickly. While evaluation of these partnerships has been limited to date, it could be that such questions are more likely to have buy-in from those who will ultimately be important in ensuring uptake in practice, which may make the results easier or quicker to implement in healthcare settings.

Are there different roles for different types of funder in a research and innovation system?

More so than other research disciplines, biomedical and health research benefits from substantial funding from charities and foundations alongside governments and the private sector.[82] Until a few years ago, though, the UK did not have a major mental health research charity that supported research nationally and across all conditions (unlike, for example, Cancer Research UK or the British Heart Foundation).

MQ (www.mqmentalhealth.org) was established to fill that gap, primarily funding research, but also connecting different stakeholder groups in raising awareness and advocating for greater support for mental health research. The organisation is still relatively young, but the progress it is making raises questions about the potential roles of different types of funding organisations. For example, are charities better placed to engage the public (which may be particularly important in an area where stigma is a barrier to people accessing services)? Are charities able to take a longer term view than government funders, due to being less influenced by political cycles? How can charities and public

[82] The UK's Association of Medical Research Charities estimated that its members provided over GBP 1.6bn in funding in 2016, compared with just under GBP 2bn from the two main government funders combined. (https://www.amrc.org.uk/news/charities-funding-contributes-to-uk-medical-research-excellence - accessed November 2018)

funders complement private sector investment? There may be value in taking a wide, cross-sector approach when considering the relative roles of research funders.

Can we work more closely with diverse stakeholders to improve outcomes?

As mentioned elsewhere in this report, **Collaborations for Leadership in Applied Health Research and Care** (CLAHRCs) are structures which have been established by the National Institute for Health Research with the aim of bringing together the healthcare system and universities in conducting more clinically relevant, applied research which results in benefits for patients. In doing this they hope to identify and address problems in clinical practice, to improve the translation of research and to build capacity in the health system to use research findings.

A more recently developed example of working across sectors and stakeholder groups is the **Mental Health Networks** announced by UK Research and Innovation in September 2018. The eight networks bring together researchers from a wide range of disciplines, charities, practitioners and the public to address a variety of research questions – for example, in areas such as student mental health, domestic violence, young people's mental health in a digital society, inequalities and building resilience in individuals and communities.[83]

It is clearly too early at this stage to judge the success of this initiative, but the networks can be considered as reflecting two current trends in UK research. First, the drive to take a more cross-disciplinary approach to research. We have seen this in, for example, the creation of UKRI as an umbrella body for the discipline-specific Research Councils, as well as through the increase in challenge-driven research programmes, which require different disciplines working together to address a complex challenge. Secondly, there is increasing emphasis on the 'co-production' of research.[84] This implies a more active involvement of different stakeholder groups throughout the research process, not merely at the end of a study as passive recipients of findings or in a tokenistic way.

Is continuing research and development in practice an effective way to encourage uptake of research-based interventions?

Over the past few years the UK government has pursued a programme of work aiming to improve employment outcomes for people with mental health conditions. This central government intervention is notable for being a collaboration between two separate departments (the Department of Health and Department of Work and Pensions), something which may be particularly important for making progress in a cross-cutting area like mental health. It is also slightly unusual in that policymakers explicitly tested out several different approaches as pilots and evaluated their success, building an evidence base for what works in the UK context as the service develops.

[83] https://esrc.ukri.org/news-events-and-publications/news/news-items/uk-research-and-innovation-launches-new-mental-health-networks/ (accessed November 2018)

[84] See, for example, recent guidance published by INVOLVE (NIHR-funded initiative to support public involvement in research): Hickey, G., Brearley, S., Coldham, T., Denegri, S., Green, G., Staniszewska, S., Tembo, D., Torok, K., and Turner, K. (2018) *Guidance on co-producing a research project.* Southampton: INVOLVE.

An initial review of interventions to improve outcomes for people with mental health problems identified a number of barriers and challenges in the UK health and employment support systems.[85] The report recommended the piloting of four interventions, some of which were to be implemented in primary care, others in workplaces or through employment services. All four were taken forward and are currently being evaluated or developed further, but one in particular – the provision of embedded vocational support in a psychological therapies programme – has proven promising[86] and has been advanced more quickly. As a result, this intervention is now being scaled up within mental health community services, as well as being adapted for different situations and trialled for physical health conditions. Such trialling in clinical practice would not be appropriate for all types of health interventions but may be a useful approach where there is uncertainty about transferability to new contexts.

Danish health research and innovation cases

The research and problem identification stage

The Copenhagen Bioscience Cluster

The Copenhagen Bioscience Cluster was initiated in 2007 with a donation to the Center for Protein Research at the University of Copenhagen by the Novo Nordisk Foundation. The foundation has since then awarded more than DKK 6.2 billion (€831 million) to research centres, research infrastructures, research programmes and initiatives within the cluster. There are no donations to the cluster as such. NNF finances the centres, infrastructures, programmes and initiatives through grants. The purpose of the cluster is to recruit highly skilled researchers and attract talent to Greater Copenhagen, to stimulate cross-pollination between academia, hospitals and industry and to increase the visibility of research and innovation in the region. For this to succeed, a critical mass is necessary. But the next step is to facilitate the networks that promote collaboration between different related research areas and create world class research within life science.

The cluster has a strict focus on research which means that it only influences the beginning of the research and innovation chain. Focus on commercialization and product development started only recently with the newly initiated BioInnovation Institute complementing the Centers' research focus. This will contribute to the focus of the universities and increase the potential of companies spinning out.

There is no formal organization with a cluster management and members. All centres within the cluster are established as partnerships with public universities and all donations are given directly to the universities. There is no formal expectation for the centres to collaborate. However, the foundation has institutionalised meetings at different levels in the cluster to raise common ideas from a bottom up perspective, promote collaboration and provide contacts and leads between the centres

[85] van Stolk, C., Hofman, J., Hafner, M. and Janta, J. (2014) *Psychological Wellbeing and Work> Improving Service Provision and Outcomes*. Cambridge, UK: RAND Europe.

[86] Steadman, K. and Thomas, R. (2015) *An Evaluation of the 'IPS in IAPT' Psychological Wellbeing and Work Feasibility pilot*. The Work Foundation.

within the cluster. There are regular meetings at director level, at administrator level, at PI level and at junior staff level. Once a year all staff from the centres, infrastructures and other major NNF grant holders are invited for the annual Cluster Days. Cluster initiatives that are successfully implemented are for example the Copenhagen Bioscience Conferences and monthly Copenhagen Bioscience Lectures, but also programmes and infrastructures such as the Copenhagen Bioscience PhD Programme and the Cryoelectron Microscope and network.

This choice of this rather informal cluster management is a direct consequence of the stated intention of a bottom-up approach to cluster building. All initiatives must come from researchers and centres as oppose to the perceived needs as seen from the foundation. This creates a very agile organization that can pick up on the newest trends within the scientific environment and pivot towards the most interesting projects. The Foundation focuses on building lasting collaboration of trust with the researchers. Both between the researchers and the foundation, but also between the different groups. This is to promote and facilitate initiatives of collaborations rather than imposing them top down.

A few challenges

While the bottom-up approach is central to the whole of the organisation of the cluster, it also makes a challenge. Experience shows that when new strategic goals are announced, or new initiatives launched – e.g. new grants for internal collaboration between researchers at cluster entities, researchers sometimes move their research towards pursuing these new opportunities, while abandoning other important strategic aspects, e.g. international collaboration. This is not what is intended. The cluster wants researchers to excel within their own area of expertise and collaborate with other researchers.

Recommendations to a possible Norwegian counterpart

It might be hard to compare the Copenhagen Bioscience Cluster to usual cluster organisations, as it is totally funded by a private foundation. However, its set-up and purpose are similar to the Swedish SciLifeLab-initiative. There are three general recommendations to cluster-building that a Norwegian counterpart can learn from:

1. The most important is to reach critical mass. If everyone is from the same place and working on the same things, it is very hard to create that synergy and collaboration that creates results and scientific breakthroughs.
2. Keep insisting on the bottom up approach and start by getting people excited about the common project instead of imposing an action plan.
3. It can be very hard to motivate researchers to take active part in these sorts of initiatives. For NNF it has worked to set up new research centres or infrastructures that can attract international researchers and initiate new collaborations.

Invention and adoption stage

Copenhagen Health Science Partners

Copenhagen Health Science Partners (CHSP) is a partnership between the University of Copenhagen and the Capital Region for clinical and translational health research, education and innovation. With a common strategic focus on public health initiatives, CHSP promotes and supports selected areas to

create quality and coherence in healthcare. Thus, CHSP works for health research results to be used faster in the treatment of patients. The research academy was established in 2017.

CHSP's position in the national agenda for research and innovation

According to Director Per Jørgensen, there is a trend in Denmark to increasingly move towards research focused on outcomes. The expectation is that health research must result in a product that benefits patients. Per Jørgensen explains that it is precisely the essence of CHSP that fits in this development in the field of health with a cross- and interdisciplinary approach.

Contribution to a more coherent and effective health research and innovation system

The ambition is that university researchers and clinical researchers use CHSP to learn from each other and develop new ideas. In this way, there is a better connection between basic research and clinical research, that together work for the research results to be implemented in clinics and improve the treatment of patients.

This link from research to clinics is central to the project. Since the start of the research academy, it has become clear that organizational cooperation with the clinics is significant. Therefore, the leaders of the research collaborators have both an interest and a collaboration relationship with the individual clinics, ensuring a broad interface and close communication. There is also a focus on allocating time and resources to for example, pass on new procedures and knowledge or relevant results to clinicians through presentations or seminars. This ongoing competence development ensures that health care professionals are more easily implemented and eventually anchored.

In this way, the CHSP supports excellence research coming out to the individual patient in an effective and coherent way. At the same time, experience in educational contexts is used to enable future health professionals to benefit from the value created by CHSP.

Structure and financing model

The cooperation around CHSP is inspired by an English model from King's College in London, which has provided basic research at the university and patient-based research in hospitals closer together. The collaboration model is based, among other things, on the composition of some strong interdisciplinary research units, "Clinical Academic Groups", also called CAGs. A CAG consists of a number of clinicians. researchers and educators from the region as well as university lecturers and researchers.

The presidency of each CAG is represented by professors and doctors from both the University of Copenhagen and the Capital Region. Other CAG members come from partnership organizations as well as other organizations and private companies in the health field. Similarly, Norway's largest university NTNU in Trondheim is now building a similar collaboration inspired by the Danish model.

The 8 CAGs all focus on high-level research collaboration with the potential to create important knowledge and results in key treatment areas and patient groups. In order to ensure that research results can cross management structures without affecting major operating units in hospitals and clinics, all CAGs have a narrow research area of disease. That way, new actions are easier to handle and implement at management level.

CHSP is financed by the Capital Region and the University of Copenhagen, which together have granted DKK 33 million in the period 2017-2020. Of the total funding, DKK 7.2 million is awarded to Ph.D. scholarships. Each CAG receives DKK 0.5 million a year for two years and 450,000 kroner annually for three years to enroll for one new PhD student per year. This means that the CAG itself has to raise funding to cover the remaining expenses for PhD students.

CHSP expects that the CAG structure will subsequently attract additional external funding. CHSP is working strategically to strengthen cooperation with several major funds and the EU as well as to raise awareness of the CAG construction.

Experienced challenges associated with the initiative

Despite of great success in the first year of CHSP, they still faced challenges. In particular, Per Jørgensen emphasizes that new data streams complicate cooperation across players. For example, special security and legislation make it difficult for clinicians and researchers to work on each other's computer system. At the same time, privacy laws make it difficult to transfer clinical data to research contexts. In addition, Per Jørgensen has experienced a need for a more flexible job structure, as it is often difficult to develop formal contracts when the partners must be affiliated with both universities and hospitals. Finally, he points to insurance challenges if researchers attend and conduct attempts at hospitals in relation to insurance for occupational or patient injury.

Adoption and diffusion stage

Public-private innovation in the Danish health system

The Capital Region of Denmark wishes to set new standards for innovative entrances and public-private innovation in the public sector with a new strategic venture. Overall, this should lead to better patient treatment due to faster diagnostics and improved patient pathways. With this initiative, the Corporate Procurement Department in the Capital Region established a new department in 2017: Procurement Development & Strategic Partnerships. The new department is based on three strategic pillars: business development of corporate procurement, a future pipeline with new innovation projects, and a dedicated consultancy service towards the region's hospitals. To guide the initiative Lars Dahl Allerup, New Business Development Manager in the department, has designed seven basic principles to be met in order for the region to invest in a given public-private innovation project.

According to Lars Dahl Allerup the philosophy behind the initiative is that strategic procurement can leverage increased public-private innovation and strengthen research in the healthcare and life science sector.

The project's position in the national agenda for research and innovation

The idea behind the new department derives from a political desire to find new ways to manage quality and healthcare economics, including value-based governance, which is a form of management that puts the patient's needs at the heart of it.

According to Lars Dahl Allerup, both politicians and industry organizations have had a desire to increase public-private partnerships, especially in research and innovation. There have been many good intentions, but Lars Dahl Allerup believes that so far nothing substantial has come to fruition.

This was the starting point for the new department with strategic focus on collaboration with the pharmaceutical and medical industry. With the establishment of Procurement Development & Strategic Partnerships, the Capital Region now acts over recent years' many intentions of increased public-private cooperation and development of public procurement. So far, the initiative has been welcomed both in Denmark and abroad.

A new approach to public procurement in health care

The Capital Region's Corporate Procurement Department is the largest purchasing department in the five Danish regions. They have 30 strategic buyers who buy everything from ambulance operations to software - anything but medicine and separate construction tasks. So far, the department has 7 major public-private innovation projects to be implemented in cooperation with hospitals and private suppliers. The projects must provide increased value for both patient and health professionals through different technologies, new treatment methods and preparatory workflows.

The department has an annual purchasing volume of more than DKK 9 billion and is thus a decisive factor in public procurement for the Danish health service. According to Lars Dahl Allerup, the position of the new department in the Corporate Procurement Department is a new and decisive approach to the traditional approach to public procurement in healthcare. Instead of creating projects through procurement, the new strategic venture must create a new way of purchasing next-generation public procurement.

Prerequisites successful cooperation

The overall prerequisite for collaborators with private suppliers is that the two parties achieve more in common than alone. This implies that both parties are willing to share investments and risks associated with the project, but also share the final results. Just the commercial part and intellectual property rights are often difficult in collaborating with companies because they often do not want to share the results. Even though, the idea behind the strategic venture is that both public and private suppliers must benefit from the work. Lars Dahl Allerup mentions this as the multiple bottom line, which implies using the department's large purchase volume to boost more public-private innovation. For example, in form of value-creating precision medicine, enhanced research, release of clinical time and operating savings for the public sector.

Furthermore, Lars Dahl Allerup emphasizes that it is important to choose both the right private and public partners. The new department, Procurement Development & Strategic Partnerships only collaborates with parties with a progressive and innovative approach to solutions for better patient treatment.

Sweden towards the worlds most advanced eHealth system

The Swedish eHealth Agency (eHälsomyndigheten) is the government agency responsible for leading and coordinating government e-health initiatives. The re-regulation of the Swedish pharmacy market in 2009 resulted in the forming of Apotekens Service AB, which was given the responsibility for handling national registers and databases with sensitive individual pharmacy information. Apotekens Service AB was also responsible for collecting the national pharmaceuticals statistics (nationella

läkemedelsstatistiken). On January 1st, 2014, Apotekens Service AB was converted into a government agency named 'the eHealth Agency' and placed under the Ministry of Health and Social Affairs.[87]

The main mission for the agency is to function as a patient safe pharmaceutical register and an it-function for handing pharmaceuticals for care providers and retailers of pharmaceuticals, for example through electronic prescriptions. The agency also gathers and supplies statistics about pharmaceutical sales from pharmacies, retailers and wholesalers. Anyone selling pharmaceuticals in Sweden is bound by law to report their sales to the eHealth Agency. Further, the agency is responsible for coordinating the government's effort called Vision for eHealth 2025. The goal of Vision for eHealth 2025 is for Sweden to be the best in the world at using the opportunities offered by digitisation and eHealth.

A new focus for the eHealth Agency is to create a tool for the citizens called 'Hälsa för mig' (Health for me).[88] 'Hälsa för mig' is a platform where citizens can store their own health data and companies and organisations can develop and supply health-related services for citizens. By supplying the platform, the eHealth Agency hope that apps helping citizens keep track on their health will be created.

Not a clear role in the national research and innovation agenda

Our interviewee Carl Jarnling does not think the eHealth Agency has a clear role in the national research and innovation agenda. The eHealth Agency is a digital infrastructure and an expert agency. It is the only national initiative registering and supplying statistics about pharmaceutical sales. It collaborates with researchers at a couple of Swedish universities doing research on the sale of pharmaceuticals, but they are not conducting any research themselves or funding research.

Legislation preventing innovation

The two main challenges the eHealth Agency are facing concerns legislation and the general financing system. Recently, the eHealth Agency lost a case in the Administrative courts in Sweden regarding the platform 'Hälsa för mig' to the Swedish Data Protection Authority. Privacy and data protection laws are often in opposition to research and innovation, preventing third parties from using the data. While the laws are there to protect the citizens, it is important to find a balance between privacy and access to date for research and innovation purposes. One way to get around the legislation would be to implement defined 'test zones', for example within specific geographical areas where citizens, researchers and entrepreneurs can operate and test the outcome of altered legislation regarding data protection laws.[89]

Another challenge the interviewee mentioned concerned the general financing system in Sweden. It is not uncommon that data from the eHealth Agency, and other healthcare data sources, is used in interesting pilot experiments trying to make the healthcare sector more effective using technology. However, the healthcare financing system in Sweden is based on the patients physically visiting the

[87] We interviewed Carl Jarnling, head of the unit within the eHealth Agency called Citizen services, for this case.

[88] https://www.halsaformig.se/

[89] https://www.iffs.se/media/22074/bortom-it_low.pdf

care provider. Therefore, innovation aiming to lower the physical visits to care providers, and ultimately lower the cost of the society, rarely leave the laboratory. To encourage innovation in this area the financing system must change from rewarding visits and instead reward cost, time and treatment efficiency.

Measuring success

As stated above, the eHealth Agency is responsible for coordinating the Vision for eHealth 2025. To measure and evaluate the work a monitoring model has been developed and the first test of the model took place in April 2018. The test measure used already existing indicators to try to identify how Sweden performs compared to other countries and presented a list of interesting indicators for future monitoring.[90] Among the mentioned indicators were:

- number of outpatient care bookings online
- available e-services per municipality
- magnitude of structured data in electronic journals
- share of nationally standardized health data
- share of pharmaceuticals purchased online
- share of the population with a Ph.D. within eHealth-related research areas
- and eHealth-related business' market share.

Recommendations for Norway on national standards

From the interviewee's point of view, Norway and Sweden are facing similar legislative problems regarding national standards. A recommendation for Norway is to dare to take bold decisions and create national standards for the sharing of health data. To still allow care providers to choose different ways on how to collect data, but then forcing them to enter the information in a standardized system. National standards would create the best value for everyone involved: patients, the healthcare sector, and the researchers.

Digital health innovation in the Stockholm region

eHealth is top priority in Stockholm County[91]

Digitizing the healthcare sector has long been considered a technical issue in Sweden. Initiatives and funding have historically been directed to improve health technology machines instead of IT systems. The technical focus has resulted in modern machines and obsolete IT systems unable to effectively communicate with each other. In 2014, Stockholm County Council acknowledged that Stockholm and Sweden had fallen behind other countries and highlighted the need for a digital transformation as the most prioritized issue for the county. The two key initiatives focus on improving the work environment

[90] https://ehalsa2025.se/gemensam-organisation-samverkan/arbetsgrupp-for-uppfoljning/

[91] Based on interview with Daniel Forslund, Commissioner for Innovation and eHealth in Stockholm County Council.

for the employees within the healthcare sector and offer a digital healthcare guarantee to the patients and has a budget of 2 bn. SEK over a period of four years.

Sweden was one of the early adopters in the late 1980s to go from paper medical records to electronic medical records (EMR). Those IT systems are now obsolete and do not communicate with each other in many cases and thereby forcing the personnel to enter the same data into various IT systems. In some cases, they still have to print out information and fax it to a third system. The many steps still required to fulfil everyday tasks naturally leads to ineffective use of working hours and increases the costs. To solve this, Stockholm County Council has decided to replace the whole IT environment, including the EMR and thousands of other co-existing systems, with a modern module based standardized information environment. Rather than creating a new mainframe computer system, the standardized environment is meant to function as a platform where new functions can be added as the technology is developed. The main idea is to create openness to innovative ideas. The preparation work for the procurement started in 2014 and the procurement work started in the summer of 2018.

The new platform aims to reduce the stress among the employees in the healthcare sector by decreasing the administrative burden, increase the patient safety by offering convenient and easy access to patients' health records and reduce the waiting time to get treatment caused by obsolete IT systems and inadequate information. Finally, the new platform will provide easier data access and more qualitative data to researchers by automating data flows from treatment methods and medical journals.

Equating digital healthcare with 'normal' healthcare

As mentioned above, Stockholm County was starting to fall behind other countries, and even other counties in Sweden, on digitizing the healthcare sector. The interviewee, Daniel Forslund, now believes Stockholm is one of the top players in Sweden and even in Europe. Daniel Forslund is the commissioner for Innovation and eHealth in Stockholm County Council and acknowledges that around half of the county councils in Sweden are substantially upgrading or replacing their electronic medical record system within the next three years. However, he believes Stockholm has made the furthest strides regarding digital care meetings.

Stockholm County Council has taken a decision which equates a digital care meeting with a 'normal', physical care meeting at a care provider. There are two reasons behind the decision. 1) To create incentives for innovation and 2) to increase access to care. Because of the financing system, before the decision was made care providers only received funding for treating patients who physically visited them. Hence, the financing system was effectively discouraging any type of innovation focusing on reducing the number of physical visits to the care providers. The decision to funding-wise equate a digital visit with a physical visit was thus taken to instead incentivize innovation to reduce the number of physical visits. The decision has been in effect for almost 1,5 years now, and the number of care providers offering video meetings has increased from just a few to 50 out of the 200 health centres in Stockholm County. According to Daniel's calculations, more than half of the health centres in Stockholm County will provide video meetings by the beginning of 2019. A result of the decision and the innovative solutions is that the public's access to care services has increased and made visits to care providers more convenient.

Stockholm is placed high compared to other regions in Europe when measuring innovation and start-ups, specifically when focusing on health tech.[92] Daniel emphasises that the health tech companies have helped the healthcare sector to better understand how health tech can make the healthcare more effective. Unlike many other regions in Europe and counties in Sweden, Stockholm County Council chose not to sign a special agreement with a single provider offering a digital solution to a single problem. Those kinds of contracts tend to create a clear distinction between the digital solution and the rest of the healthcare sector, according to Daniel. The goal in Stockholm is to treat digital healthcare in the same way as the regular healthcare is treated.

Innovation from within

In the coercive regulatory documents for Stockholm County Council it is described that digitalization and technological development must go hand in hand with innovativeness. When signing new agreements or replacing old agreements, innovativeness and involvement of industry, co-workers, and users must always be considered and described. One initiative in Stockholm is called 'SLL Innovation'[93]. SLL Innovation is an innovation organisation within Stockholm County Council and encourages county council workers to be innovative and every year 15 mn. SEK is granted through an innovation fund. The idea for the health sector is that innovation often is created through collaboration between co-workers, researchers, patients and businesses. The innovation organisation was established in 2014 and has resulted in realization of many projects. In 2017, 22 projects were granted funding. Among the realized projects are sensors connecting a pill organiser to a mobile application alerting the user when it is time to take respective pill, a wireless lung function-meter to a mobile application sending information directly to the care provider, and a drone equipped with a defibrillator.

Key takeaways for Norway

According to Daniel, there has for a long time been a generally accepted idea that all problems regarding digitizing healthcare would be solved if only everyone used the same EMR system. It might seem like a great idea, but it is not. A single common EMR system would create a technical monopoly with one single service provider, which without competition would rapidly age. The idea of creating a single common EMR system must be replaced by the idea of standardized system. The standardized system has the same functionality as the single common EMR system but allows competition. Competition will lead to different providers offering innovative solutions to complex problems.

In a similar way that a single common EMR system tend to lead to a monopoly situation and thereby hinder competition, not equating a digital healthcare visit to a physical healthcare visit hinder digital healthcare providers from competing with 'physical' healthcare providers. Equating the two alternatives and thus opening up to innovative solutions might sound easy. However, regulation has slowed down implementation. With today's technology it is important to equate the digital with the physical and not let old regulation hinder innovation

[92] http://ec.europa.eu/growth/industry/innovation/facts-figures/scoreboards_en

[93] http://sllinnovation.se

The Finnish Biobank Act

Introduction to the initiative

The Biobank Act, enforced in September 2013, set the rules for professionally storing and collecting results by creating an infrastructure in which the new biobanks were allowed to operate. The purpose of the act was to support biobank research[94], promote openness in the use of biological samples and secure protection and privacy while processing the samples.

Biobanks can be set up by a private person, corporation or a public institution that has the financial and operational means necessary while also fulfilling the legal and research-related conditions for maintaining a biobank. This means having the personnel, facilities and equipment necessary to carry out the duties of a biobank.[95] Furthermore, a biobank needs to be approved by the National Committee on Medical Research Ethics and work under a license granted by the National Supervisory and Welfare Agency (Valvira). Four biobanks are operating in the whole of Finland and six in the area of hospital districts. By setting biobanks at hospitals, clinical and health data can be easily combined. Moreover, by gathering samples from patients it is more likely that enough samples can be gathered from individuals that are carriers of diseases that are of specific interest.

In addition to the current samples, The National Institute for Health (THL) aims to transfer over 900 000 samples to the THL Biobank to make them more accessible to the research community after making a public announcement and giving donors the possibility to opt-out.[96] In short, the Biobank Act promotes trust by protecting donors' rights and accelerates innovation by granting equal access to data and samples for researchers.

To shed more light on the progressive Biobank Act we interviewed Professor Olli Mikael Carpen. Presently, he is the Professor of Pathology at University of Helsinki, Scientific Director of Helsinki and Senior Consultant of Diagnostic Pathology at Helsinki University Hospital. Olli Carpen was actively involved in establishing the Finnish biobank network and especially in building the first Finnish hospital-integrated biobanks, Auria Biobank and Helsinki Biobank.

The act gives all researchers equal chances to gain access to the biobanks' data and samples. Therefore, the act has promoted research and innovation not only in academics but through public-private relationships. Furthermore, the act requires information from research to be returned to the biobanks. Professor Carpen explains that this was in the beginning feared to be a hindrance for private-public relationships but has resulted in a mutually-benefiting information sharing. By letting

[94] Biobank research entails research that utilizes the samples contained in a biobank or information associated with them for the purposes of promoting health, understanding the mechanisms of disease or developing the products and treatment practices used in health care and medical care

[95] The duties of a biobank include (i) collecting samples and receive information associated with the samples, (ii) store samples and information and provide access to them for research, (iii) analyse, study and process the samples.

[96] http://www.finlandhealth.fi/-/finnish-excellence-in-biobanking

the data accumulate in the biobanks, repetition of certain analyses is avoided and new information is shared.

To balance the freedom to conduct good research, The Biobank Act also formalized donors' rights. This was done through important principles such as the possibility to withdraw consent and the right for donors to know what is being done with their samples. Donors are also notified when they might benefit from the research or when their data has led to progress. Hence, there is a high degree of transparency into the research being done with the samples.

Boost to research

According to Professor Carpen, the Biobank Act has made a whole new level of medical research possible. Company initiated research projects have become more common as well as public-private partnerships. One example comes from the pharmaceutical industry where investments have risen from 220 million euros to 227 million euros from 2015 to 2016. The growth was particularly marked in R&D investments.[97] According to a survey from Pharma Industry Finland (PIF) pharmaceutical brands are especially interested in increasing their register-based research in Europe. An attractive feature to conducting biobank research in Finland is the possibility to link information from longitudinal medical records to a unique id for every person in Finland. Furthermore, the possibility of re-contacting donors, which 90 percent of donors allow, enables researchers to get samples for a specific phenotype.[98] This is especially beneficial for pharma companies that carry out clinical research.

The long-term goal for research that uses information from biobanks is to improve diagnostics and treatment methods. In order to achieve the long-term goals, the digital infrastructure needs to be in place. More specifically, it means that there needs to be a system to catalogue the associative clinical data. Since 2017 the Finbiobank (FINNBB) is one of the key actors in setting up the infrastructure for biobank research. FINNBB is a cooperative owned by the national biobanks that enables researchers to easily access biobank materials through just one actor.

With the necessary infrastructure in place, national scale projects are possible. The FinnGen project is currently the biggest research project in Finland that makes use of biobank data.[99] The project aims to use half a million unique blood samples to create data that can be used for personalized medicine. The FinnGen project is also a testament to the benefits of public-private collaborations. The project involves nine Finnish biobanks, all Finnish University Hospitals and their respective Universities, the Institute of Health and Welfare (THL), the Finnish Red Cross Blood Service and seven large pharmaceutical companies.[100]

[97] http://www.laaketeollisuus.fi

[98] Phenotype is the observable characteristics of an individual that result from the interaction of his genetic inheritance with the environment. E.g. behavior, biochemical properties, shape, and size.

[99] https://www.finngen.fi/en/node/38

[100] Abbvie, AstraZeneca, Biogen, Celgene, Genentech, Merck/MSD and Pfizer

Research for the common good

A prerequisite to conducting good biobank research is to have representative samples. For Finland, this led to the decision to transfer old samples to biobanks from THL. By providing an opt-out policy the assumption is that individuals want to contribute rather than not. This can be seen as a rather controversial decision, but it rests on a strong belief that biobank research has immense potential to improve future health care. The balance between the common good and individual rights in respects to biobank research are widely discussed. For Professor Carpen, the answer lies in structuring the legal framework and having a common national strategy. Biobank research needs to be for the common good and not for serving individual interests. This is the pillar of what biobanks should be used for, Professor Carpen explains. In the short term, research impact is mostly measured by the amount of funding and the number of good quality publications. However, in the long-term the goal should be that it leads to better health care which ultimately benefits the people. Professor Carpen's recommendation for Norway is that the government and hospitals need to be clear in their vision to use biobanks for the common good. To gain the trust of citizens and health care professionals, a common national strategy founded on the belief that biobank research will improve future health care must be established. Therefore, the ultimate success of biobank research lies on a shared vision between all actors: the government, hospitals and the people.[101]

[101] http://www.bbmri.fi/bbmri-network/suomi-biopankkien-osuuskunta-finbiobank/

Appendix II Methodology

The analysis is based on a qualitative and interactive approach with the five methodological elements described below.

1. Document Studies

The analysis has first been based on document studies, including the collection and analysis of all written material relevant for describing today's health research and innovation system, perspectives on problems and solutions as well as digital and data issues. The document studies have actively related to the previous work as well as the conclusions of the HO21 Advisory Board. The document studies have included a large number of relevant documents, evaluations, statistics, program documents and action plans, annual reports and final reports, as well as analyses, including international analyses. The document study has especially focused on the public and academic debates connected to the problem areas identified. In many of the topic areas there have been a lot of articles and publications to possibly include, of which many have been proposed by members of the HO21 Advisory Board, the interview persons and the Research Council.

2. Country studies of selected initiatives

To put the Norwegian health research and innovation system in an international perspective we have conducted case studies of specific reforms and initiatives in Denmark, Sweden, Finland, UK and Canada. The purpose of the international case studies has been to increase the understanding of the problem areas and to inspire the proposed solutions. We have specifically aimed to cover a variety of initiatives and schemes across the entire health research and innovation system. Each of the international case studies seek to address how the initiatives or programmes support the health research and innovation landscape. For each initiative/programme, we have as far as possible studied: (1) The background of the initiative/programme, including its history, objectives, its structure and placement in the national research and innovation agenda; (2) the funding structure of the initiative/ programme and the support it provides; (3) its output and impact, as well as how its success is measured; and (4) any observed challenges related to the initiative/programme and how they are handled. The International case studies are based on a review of relevant documents and personal interviews with stakeholders or people with special knowledge in each country.

3. Norwegian impact case studies

To illustrate how the identified problems in the Norwegian health research and innovation system have concrete impacts for science, for innovation, for the actors involved and not least for the market and the health and well-being of patients and the public in different parts of the Norwegian health system. The case studies have been selected based on proposals in interviews and in the dialogue with members of the HO21 Advisory Board. Each impact case study has been based on interviews with experts or actors connected to the case as well as follow up document studies. In each case study we have asked about the challenge/situation making the case relevant, the causes of the problem, if there are gaps in the support measures, supporting health research and innovation, if the challenges identified are unique to Norway and whether Norway needs a new initiative or the solution to the problem can be found elsewhere.

4. Interviews with stakeholders in three rounds

The interview element plays a central role, and as such contributes to answering the majority of the questions set for analysis. Furthermore, the interviews help to test and validate results that are found through other sources. A large number of interviews have been conducted with key actors and stakeholders connected to health research and innovation and with knowledge and insight on the research and innovation policy agenda. This involves interviews with actors from academia, hospitals, policy actors at both national, regional and local level, interest organisations, user organisations, companies and experts. The interview persons have been selected on the basis of the document studies as well as proposals from the members of the HO21 Advisory Board, the Research Council and other interview persons.

We have planned and conducted the interviews in three rounds. In the first round, initial exploratory interviews have been conducted to determine assumptions / hypotheses which then could be tested in the second round of interviews. The second round was also building on and testing the insight and hypotheses that came from document studies and the first stakeholder workshop as well as from discussions with the HO21 Advisory Board. The results of the second round of interviews were analysed, presented and discussed with key stakeholders at a second workshop with the specific purpose to test problem understanding and identify solutions. Finally, we have carried out follow-up interviews to clarify questions or issues that were raised in the last workshop as well as in meetings with the HO21 Advisory Board.

5. Workshops

Two workshops have been held throughout the process. The first workshop took place on the 19th of June 2018 in Oslo. The workshop was planned and facilitated by leading staff from the consultant team consisting of DAMVAD Analytics and University Cambridge (CSaP). A total of 15 participants from research, enterprises, academia, policy and government institutions as well as the Research Council of Norway offered their insight in the workshop. The purpose of the workshop was to get the participants views on the key factors influencing the ability of the Norwegian health research and innovation system to develop high quality, cost-effective, fast and sound results. In addition, the workshop should give suggestions on what steps can be taken to increase the performance of the health research and innovation system. The workshop should hence help the consultant team to focus its research in the following months of the project period.

The second workshop took place on 6 November 2018 in Oslo. It was again hosted by The Norwegian Research Council. 25 participants offered their insight in this workshop. The workshop was organized by Steven Wooding, Cambridge University and Torben Vad, DAMVAD Analytics. In addition to this, Alexandra Pollitt from Kings College and Catriona Manville from RAND Europe contributed with international insights and inspiration to the discussions. Prior to the workshop the participants were sent five themes indicating major challenges in the Norwegian health research and innovation system. Under each theme of challenges up to eight proposed solutions were highlighted. The participants worked with the proposed solutions in two rounds during the workshop. In the first round they were asked to work on their first priority and in the second round they were able to shuffle to another table.

The purpose of the workshop was to get the participants views and comments on the tentative key results and recommendations. Hence, it should contribute to the analysis by providing insight on how to interpret and use the results of the analysis. The insights from the workshop provided numerous perspectives on the key results that have been included in the final report in regard to proposed solutions.

The detailed perspectives, results and pictures from each of the workshops are summarised in two separate workshop reports that have been shared with the participants, the members of the H021 Advisory Board and the Research Council.

Appendix III Interview persons

Ann Kristin Hageløkken	Senior Adviser	SIVA
Anne Lise Ryel	Secretary General	Norwegian Cancer Society
Arild Kristensen	Managing director	Norwegian Smart Care Cluster
Arnfinn Sundsfjord	Dean	University of Tromsø (former member of the HO21 Advisory Board)
Asbjørn Lilletun	CEO	Norinnova Technology Transfer
Bjørn Gustafsson	Dean	NTNU
Brita Solveig	Vice-dean	NTNU
Camilla Stoltenberg	Director General	Norwegian Institute of Public Health (FHI)
Carl Jarnling	Head of the unit Citizen services	The Swedish eHealth Agency
Clara Gram Gjesdal	Co-director	Western Norway Regional Health Authority
Dag Rune Olsen	Rector	University of Bergen
Daniel Forslund	County Council with responsibility for innovation, digitization, eHealth and patient-related services	Stockholms County Landsting
Eirik Melandsø	Health Sector Expert.	Innovation Norway
Eirik Næss-Ulseth	Founder and investor	Novelda
Erlend Smeland	Director of Research, Innovation and Education	Oslo University Hospital HF
Frode Vartdal	Dean	University of Oslo
Gro Jarmtvedt	Dean	OsloMet
Guri Rørtveit	Head of Department/professor	Global Public Health and Primary Care, Universitet i Bergen
Hans Christian Westlye	Director of knowledge and technology	Virke
Ingvild Eide Graff	Research Director	Uni Helse

Jacob C Hølen	Director	National Committee for Medical and Health Research Ethics
Jan Akselsen	Leader Scientific guidance	Norwegian Medicines Agency
Jarle Grumstad	Ass. Chief Adviser	Norwegian Nurses Organisation
Jo Cranner	Senior Adviser	Norwegian Nurses Organisation
Jesper Allerup	Policy Advisor	Danish Medical Association
Jesper W. Simonsen	Executive Director	Research Council of Norway
John-Arne Røttingen	Director General	Research Council of Norway
Jon Anders Drøpping	Senior R&D Afviser	KS
Jørg Gustav Mørland	Professor emeritus	Norwegian Centre for Addiction Research
Kathrine Myhre	CEO	Norway Health Tech
Knut Inge-Klepp	Executive Director	Norwegian Institute of Public Health
Kristian Kise Haugland	Chairman	Mental helse
Lars Dahl Allerup	Business Development Manager	The Capital Region of Denmark, Corporate Procurement
Lasse Frantzen	Senior Adviser	Norwegian Directorate of Health
Leif Rune Skymoen	CEO	Takeda
Lena Lundgren	Director	Microsoft Norge
Lillian Elvestad	Secretary General	FFO
Livar Frøyland	Director Research	NIFES
Marit Leegard	Senior Adviser	Norwegian Nurses Organisation
Marta Ebbing	Director of Management and Staff for Health Data and Digitalisation	Norwegian Institute of Public Health
Mathias Aguirre Havgar	Representative	Innovation Norway
Mette Kalager	Associate professor	University of Oslo
Mona Skaret	Director	Innovasjon Norge

Monica Larsen	Senior Advisor	Legemiddelforeningen
Nina Mevold	Director General Health and care	Bergen Kommune
Ole Alexander Opdalshei	Ass. Director General	Norwegian Cancer Society
Olli Mikael Carpen	Professor	Helsinki University Hospital
Ottar Mæstad	Director General	Chr. Mikkelsensinstitutt
Per Jørgensen	Director	Copenhagen Health Science Partners (CHSP)
Petter Risøe	CEO	Diffia
Preben Aavitsland	Professor	University of Oslo
Randi Reinertsen	Director Research	SINTEF
Siv Cathrine Høymork	Director Quality and Research	Northern Norway Regional Health Authority
Sophie Labrosse	Cluster Officer	Novo Nordisk Foundation
Stig Arild Slørdahl	Director Genereal	Central Norway Regional Health Authority
Tarje Bjørgum	Director	Abelia
Tom Pike	Chairman	Vaccibody AS
Toril Hernes	Vice-dean	NTNU
Trude Andresen	County Chief Executive	Eiker Kommune
Øystein Kruger	Director research and innovation forskning og innovasjon	South-Eastern Norway Regional Health Authority
Øyvind Melien	Senior Advisor	Norwegian Directorate of Health and FHI

Appendix IV Workshop Participants

Workshop 19 June 2018

1. Bjørn Gustafsson	Dean	Norwegian University of Science & Technology
2. Alexander Opdahlshei	Ass. Director General	Norwegian Cancer Society
3. Kari Hengebøl	Chief Operating Officer	C3 Centre for Connected Care
4. Kristin Skogeng	Senior Advisor	Norwegian Directorate of Health
5. Jutta Heix	Head of International Affairs	Oslo Cancer Cluster
6. Roar Samuelsen	Senior Advisor	Norwegian Institute of Public Health
7. Ninia Margrethe Johnsen	Director	Norwegian Institute of Public Health
8. Ingvild Eide Graff	Director Research	Uni Research, NORCE
9. Agnes Landstad,	Managing director	FFA, Abelia
10. Ingvild Graff	Executive Vice President - Health	NORCE
11. Jon Magnussen	Vice-dean	Norwegian University of Science & Technology
12. Cathrin Carlyle	User representative	Northern Norway Regional Health Authority
13. Kristian Kise Haugland	Country manager	Mental helse
14. Robert Hvad Straumann,	Director	Virke
15. Jan Petter Akselsen,	Leader Scientific guidance	Norwegian Medicines Agency
16. Irene Olaussen,	Senior Advisor	Norwegian Directorate of eHealth
17. Hilde D.G. Nielsen	Leader HO21-secreatariat	HO21-secreatariat
18. Steven Wooding	Senior Research Fellow	Cambridge University
19. Torben Bundgaard Vad,	Partner, Project Lead	DAMVAD Analytics

Workshop 6 November 2018

1. Bjørn Gustafsson	Dean	Norwegian University of Science & Technology
2. Guri Rørtveit	Director/Professor	University of Bergen
3. Kjetil Tasken	Director	Institute of Cancer Research
4. Nina Langeland	Professor	University of Bergen
5. Randi Stokke	PHD Fellow	Norwegian University of Science & Technology
6. Sameline Grimsgaard	Professor, Director Tromsøundersøkelsen	University of Tromsø
7. Esperanza Diaz	Associate Professer	University of Bergen
8. Gro Jamtvedt	Dean	Oslo Metropolitan University
9. Cathrin Carlyle	User representative	Northern Norway Regional Health Authority
10. Hilde Lurås	Director	HØKH, Ahus
11. Bjørn Tore Gjertsen	Director Research	Western Norway Regional Health Authority
12. Ole Alexander Opdalshei	Ass. Director General	Norwegian Cancer Society
13. Randi Reinertsen	Director Research	SINTEF
14. Jon Anders Drøpping	Director	KS
15. Sigrid Askum	Director	KS
16. Anne Gamme	Director	KS
17. Asbjørn Lilletun	Adm. Direktør	Norinnova Technology Transfer
18. Monica Kjeken	Seniorrådgiver	Legemiddelindustrien
19. Tarje Bjørgum	Fagleder	Klima og Helse Abelia
20. Tom Pike	Chairman	Vaccibody AS
21. Torbjørn Furulund	Director	NHO Service og Handel
22. Hilde D.G. Nielsen	Leader HO21-secreatariat	HO21-secreatariat
23. Ina Kathrine Dahlsveen	Senior Adviser	Research Council of Norway
24. Jesper W. Simonsen	Executive Director	Research Council of Norway
25. Torben Bundgaard Vad	Partner, Project Lead	DAMVAD Analytics
26. Sofie Lohmann	Research Assistant,	DAMVAD Analytics
27. Steven Wooding	Senior Research Fellow	University of Cambridge
28. Catriona Manville	Research Leader	RAND Europe
29. Marlene Altenhofer	Analyst	RAND Europe
30. Alexandra Pollitt	Research Fellow	King's College London

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Short summary: The analysis of today's health research and innovation system is made on behalf of the HO21 Advisory Board. The purpose is to identify problems and propose solutions for a system of high quality and relevance with a short way to public health and society.

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