

Work programme

2017 –

Programme
High-quality and Reliable Diagnostics, Treatment and Rehabilitation – BEHANDLING





The Research Council
of Norway

Work Programme 2017-

High-quality and Reliable Diagnostics, Treatment and Rehabilitation

BEHANDLING

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Summary

This research programme will support clinical research¹ to promote high-quality and reliable diagnostics, treatment and rehabilitation that improve clinical practice throughout disease trajectory. Projects awarded funding by the programme must have patient and service-relevant endpoints and incorporate user involvement.

Diseases that pose major societal challenges will comprise a key area of focus. The thematic priorities of the programme will be targeted towards areas in which there is a high disease burden, such as mental health disorders, musculoskeletal disorders, alcohol and drug addiction, cancer, cardiovascular disease and diseases affecting the brain and nervous system, as well as areas in which knowledge is lacking, such as chronic pain disorders and fatigue syndromes. The programme will work to enhance research expertise and research capacity in areas of relevance to its objectives. The programme will strive to meet the need for research in and for the municipal health and care services, including the dental services, and in the specialist health care services. The programme is based on the needs, challenges and proposed measures described in relevant political documents as well as other government reports.

The research questions will determine the choice of methodology. The programme will therefore have a broad-based methodological approach. Controlled clinical studies² and prospective observational studies will play a central role, but the programme will also fund studies with other methodological approaches and encourages the use of new methodology. The programme encourages the use of data from various registries and biobanks, including population cohorts and health surveys, to generate new clinical knowledge. Enhancing multidisciplinary cooperation and translational research are vital to achieving ground-breaking results and expanding knowledge in areas in which effective treatment does not exist and in personalised medicine. The programme will promote high-quality research of benefit to end-users/patients.

¹ Clinical research is research that provides a basis for improving diagnostics, treatment, rehabilitation and patient care.

² Clinical studies are studies on patients in which various interventions are assessed by investigators according to a research protocol. There are two main types of clinical studies: clinical trials and observational studies (ref. <https://clinicaltrials.gov/ct2/about-studies/learn#WhatIs>).

Background

Strategic perspectives

The Research Programme on High-quality and Reliable Diagnostics, Treatment and Rehabilitation (BEHANDLING) is a new programme launched in the wake of the conclusion of several smaller health research programmes. The BEHANDLING programme has a long-term perspective and a 10-year programme period, with a broad mandate designed to meet the knowledge needs of several levels within the health services: the municipal health and care services, the dental health services, and the specialist health care services. The programme is an instrument for realising national health-policy and research-policy objectives and priorities in the field of clinical research.

The BEHANDLING programme is part of the Research Council of Norway's new programme structure. Four broad-based health research programmes have been launched to generate knowledge targeted towards dealing with critical health and societal challenges and to benefit the development of Norwegian health research and innovation in the health care sector. The three other health research programmes are: the Research Programme on Better Health and Quality of Life (BEDREHELSE), the Large-scale Programme on Health, Care and Welfare Services Research (HELSEVEL) and the Programme for Global Health and Vaccination Research (GLOBVAC).

The health research programmes will give priority to research areas within an integrated framework to realise or enable new scientific synergies and encourage cross-sectoral efforts. The relationship of the BEHANDLING programme to the other health research programmes and other relevant Research Council programmes is described in the chapter "Interfaces and cooperation with other activities within and outside the Research Council".

Identification of needs. The programme will work to generate new knowledge based on documented knowledge gaps and will develop processes to enable researchers and end-users of the research – i.e. patients, health care personnel, decision-makers in the health and care services, and the health authorities – to provide input on the research questions they view as most relevant and beneficial. Identification of needs also entails that the programme will, when relevant, take the initiative to draw up systematic knowledge summaries prior to selecting the research questions to be addressed in the calls for proposals. Research activities are to build on and supplement previous research.

User involvement in individual projects. User representatives are to be involved in the research process and can contribute to devising more relevant research questions and achieving better, more useful outcome measures in clinical research. User representatives can also identify factors that may encourage or discourage patient participation in projects, bring new perspectives to the analysis and interpretation of results, provide input on the type of language used, method of presentation and dissemination channels, as well as enhance understanding of what is needed to ensure that the research is implemented and applied. In this context the term "users" refers to patients and their family members.

Benefit and implementation of new knowledge. The knowledge acquired is considered beneficial if it is applicable and can be used in clinical practice. This may take the form of development of new treatment methods or improvement of existing ones, design of new work processes, or application of new products or technologies in diagnostics, treatment and rehabilitation. Documented changes in clinical practice, or revision or consolidation of clinical guidelines, are indicators of the benefit of research. Innovation in both the private and the public

sector is essential to solving health-related challenges facing society. The extensive public investment in research within the health care sector represents an underexploited resource for commercial development.

Interdisciplinary and cross-sectoral collaboration.

The development of high-quality and reliable diagnostics, treatment and rehabilitation depends upon high-quality research conducted across service levels and involving an array of actors in the health services. Multiregional participation in clinical treatment studies and participation in international collaborative projects under and outside of EU programmes are vital to enhancing the quality and benefit of the health services. Achieving this will require national and interdisciplinary competence development and network-building both within and between the municipal health and care services, the dental services, the university hospitals and the specialist health care services in general. Collaboration across disciplines and sectors is important for ensuring more rapid implementation, and can also help to promote the commercialisation of research outcomes, for example through cooperation with technology transfer environments, commercial partners, end-users/patient groups, etc.

Utilisation of national advantages. In Norway, the use of national identity numbers makes it possible to follow an individual's health and disease development throughout his or her entire life. There are a number of health and quality registries in Norway that make it possible to conduct longitudinal analyses that would be difficult to carry out in other countries. The planned patient registry for the municipal health and care services (Norwegian acronym: KPR) is an important component of ongoing efforts. Registry data, alone or in combination with biobank material, are a unique resource that provides a basis for translational research and clinical research, including comparative effectiveness research and innovation activities. Collection of biological samples takes place in connection with large-scale, population-based health surveys, research projects (research biobanks), and diagnostics and treatment (clinical biobanks).

Use of research networks and research support units. Various competency centres, clinical research support units, technological core facilities and other types of support units help to enhance the quality and effectiveness of clinical research. The municipalities lack both basic infrastructure for R&D activities and personnel with research expertise. It is essential to develop good infrastructure for research on municipal health challenges, such as routines and procedures for systematic collection and storage of data, including necessary IT systems. Research networks must be established for groups of health care personnel in the municipal health and care services, as well as between the research community and the municipal health and care services, preferably across the professions.

Conducting large-scale national and international multicentre studies in accordance with good clinical practice (GCP) and high quality standards requires administrative personnel and others who can assist researchers in planning, designing, implementing and reporting from the study. It is important to make use of existing research support units.

Background documentation. This work programme is based on a number of official reports and guiding documents. These are listed in the attachment.

Scientific perspectives

The scientific perspectives are based on the knowledge that is needed to provide patients with high-quality, reliable diagnostics, treatment and rehabilitation throughout the course of their illness or the trajectory of disease.

Diagnostics refers to procedures and assessments used to determine a diagnosis. Treatment encompasses interventions to cure or alleviate disease, health problems, injuries or disability. The definition also includes secondary preventive interventions. Rehabilitation refers to time-limited planned processes with clearly defined objectives and means, in which several actors cooperate on providing necessary assistance to patients and users in their efforts to achieve optimal functional level, coping skills, independence and social participation. While treatment may be provided by one or more professions, rehabilitation is understood to be cooperation between a minimum of three actors in addition to the user and his or her family members.

Trends such as rising life expectancy, greater social inequality, wider ethnic and cultural diversity, and increased immigration and travel are leading to changes in health and illness patterns among the population and knowledge needs. Antimicrobial resistance is a global challenge that requires special attention and research activity.

Health challenges affecting many people. There is a need for more research-based knowledge about diagnostics, treatment and rehabilitation of large and growing patient groups, such as those suffering from cardiovascular disease, diabetes, COPD³ and cancer (non-communicable diseases (NCD)), musculoskeletal disorders, and diseases affecting the brain and nervous system that lead to dementia. Research is also needed on chronic pain disorders, fatigue syndromes and as-yet unexplained illnesses. There is also great need for research on mental health disorders and alcohol and drug addiction and on the relationship between these and combinations of these and somatic diseases.

An ageing population and extended life expectancy for the chronically ill are leading to more multimorbidity, or a larger number of patients with more than one chronic disease. While research on these patient groups is difficult, it is all the more important to gain a deeper understanding of how to treat their individual diseases and to determine the best treatment in light of the fact that they have multiple diseases which may be interacting.

Knowledge is also lacking about patients suffering from rare diseases.⁴ Although each patient group is small, taken together, rare diseases affect a large number of people.

Knowledge about specific groups. A wider degree of inclusion of patients from the primary health care services in clinical studies conducted by the primary health care services alone or in collaboration with the specialist health care services is called for. Furthermore, it is vital that participants in clinical studies are representative of the patient population from which they have been recruited. Greater diversity among the population necessitates research on specific population groups. Factors such as age, gender, ethnicity and socio-demographic status are important in health research, and subgroup analysis should be encouraged when this is relevant.

Personalised medicine. Personalised medicine involves the use of molecular methods to tailor diagnostics and treatment to specific biological characteristics of the individual patient. This is linked to the patient's history of disease, clinical findings and relevant endpoints, lifestyle factors and environmental factors, at either the individual or patient group level. Diagnostics and treatment tailored to the individual can reduce human costs by avoiding useless treatments and may potentially reduce costs for the health services. The development of personalised medicine challenges the traditional division of clinical studies into phases and creates a need for new

³ Chronic obstructive pulmonary disease (COPD).

⁴ Rare diseases are diseases which affect a small number of people compared to the general population. A disease or disorder is defined as rare in Europe when it affects less than 1 in 2 000.

methodology, including the linkage of data from clinical studies to genetic data and large-scale data analyses.

Non-pharmacological clinical studies. Clinical studies of technical medical equipment, non-pharmacological interventions and eHealth are currently not subject to the same requirements and systematic approach as clinical trials of pharmaceuticals. There is, however, a great need for knowledge related to the introduction and use of such methods and equipment for examination, diagnostics, treatment and follow-up of procedures. Thus, more clinical studies and implementation research related to the introduction and use of technical medical equipment and non-pharmacological interventions are called for.

The municipal health and care services. The municipalities have a statutory responsibility to take part in and facilitate research activity. However, the volume of clinical research conducted in the municipal health and care services is small and not adequately proportional to the responsibilities, tasks and scope of these services. Strengthening patient- and practice-based research that takes clinical reality and patients' experienced needs as its point of departure is a key aim. The municipalities' tasks have changed as a result of the Coordination Reform. The large patient pool is an under-used resource in research. At the same time, there is little data collection in the municipal health and care services targeted towards research, and the data collected are to some degree insufficient and of varying quality. Research activity must be intensified, which will require effective solutions for research infrastructure and collaboration with the university and university college sector and with the regional health authorities to avoid research groups that are too small and fragmented.

The dental services. It is essential to strengthen clinical research in odontology. Although research of this type is largely carried out at university faculties of odontology, most clinical activity takes place in the public and private dental services. There is little in the way of organisational framework conditions to facilitate research activity and research expertise is limited. There is a need for research on diagnostic and treatment-related aspects of oral health, and the public authorities need better insight into what comprises suitable treatment in light of the individual patient's general illness and life situation. There is great potential to be found in exploring topics in the interface between odontology and medicine and enhancing understanding of oral health as an element of general health.

The specialist health care services. The specialist health care services have a statutory responsibility to carry out research. Hospitals conduct patient-oriented research, including experimental treatments and clinical trials. It is essential to conduct randomised clinical trials and comparative effectiveness research as well in order to safeguard quality and patient safety. Translational research plays an important role in developing new treatment interventions. Pursuant to national principles, experimental treatments, i.e. all treatments whose efficacy, risks and side-effects have not been sufficiently documented to include them in ordinary treatment programmes, are as a rule to be provided solely through clinical studies. It is also important to strengthen implementation research and research on the quality, efficacy and cost-efficiency of established treatment and rehabilitation methods. While there is extensive research activity at university hospitals, health trusts that are not affiliated with universities or rehabilitation institutions do not have the same degree of corresponding resources and expertise. Thus, these must establish research collaboration with health trusts affiliated with universities and other research actors.

Research ethics. Translational research and clinical research are strictly regulated by national and international legislation, regulations and conventions. Research projects designed to produce new knowledge about health and disease must be assessed and approved by the Regional Committees

for Medical and Health Research Ethic (REC) to ensure that scientific and medical progress is not achieved at the expense of the rights and integrity of the individual and to regulate the obligations of researchers. Other bodies authorised to approve research projects may also be relevant.

There is a major need for clinical studies in children. Children are often treated with pharmaceuticals whose efficacy and side-effects have not been tested separately in minors. Furthermore, a number of diseases afflict only children. Increased research on this patient group is accompanied by medical, ethical and communication-related challenges. Research that may cause damage, research in emergency medicine or palliative treatment, or research on patients who are incompetent or have reduced competence to give informed consent must be subject to thorough ethical reflection. On the other hand, a lack of research on these patient groups may result in treatment interventions that are inadequately documented. It is critical that knowledge development for high-quality, reliable diagnostics, treatment and rehabilitation takes place within a sound framework for social responsibility and ethical considerations.

Objectives of the programme

Primary objective

The BEHANDLING programme will support clinical research activities to help to ensure that patients receive high-quality and reliable diagnostics, treatment and rehabilitation throughout their disease trajectory.

Secondary objectives

The programme will:

- Increase the amount of beneficial, high-quality clinical research on patient groups and research questions that are underrepresented in clinical research;
- Increase the number of clinical studies with multiregional participation;
- Increase the amount of beneficial, high-quality clinical research in environments where little research is being conducted;
- Foster beneficial, high-quality clinical research in, for and about the field of rehabilitation, the municipal health and care services, the dental services and the specialist health care services;
- Enhance knowledge about illness in and treatment of patients in the municipal health and care services;
- Promote clinical research on research questions of relevance across service levels and disciplines;
- Encourage methodological development, also in personalised medicine, enhance analytical capacity and improve the evidence base;
- Develop and strengthen user involvement and communication and dissemination activities;
- Boost innovation and commercial development by developing new products, technical medical equipment, diagnostics, treatments and rehabilitation methods;
- Encourage the increased use of health and quality registries, biobanks and data sharing in clinical studies;
- Foster translational research in areas in which knowledge-based treatment is lacking;
- Promote better, more personalised medicine, including stem cell treatments;
- Strengthen national and Nordic cooperation and increase participation in the European Research Area (ERA), the EU framework programme and other international research cooperation;

- Advance knowledge-based clinical practice.

The programme's performance targets will be described in its action plans.

Priority research tasks

Thematic priority areas

Researchers and users may have very different opinions about the areas on which research should be focused. The programme attaches importance to pursuing patient-based, clinically oriented research questions with endpoints that are considered relevant and capture diverse aspects of health, functionality and quality of life. This increases the likelihood that the results will be applied in the near future. Research projects must be based in the health services to help to ensure that the results are put to use later on. The programme emphasises the importance of including considerations relating to gender and ethnic perspectives in diagnostics, treatment and rehabilitation as well as of addressing health economics issues, when this is relevant.

Clinical research

The programme will promote clinical research:

- on diseases that pose major societal challenges in terms of prevalence, cost and/or complexity, among other things;
- on research questions and patient groups that, for different reasons, are not given priority by commercial interests, including development and evaluation of non-pharmacological interventions and studies on new areas of use for non-patented drugs;
- to develop effective, relevant studies of children, the elderly, patients with unexplained medical conditions, patients with multimorbidity and other groups that historically speaking have rarely been included in clinical trials and clinical research;
- that integrates research questions across service levels or encompasses multiple regions;
- that views mental health, oral health, other somatic health problems, and alcohol and drug addiction together in the same context;
- on established treatment methods with uncertain effect and safety.

Translational research

Translational research is important for patient groups and conditions for which effective diagnostics and treatment do not exist. The programme may award funding to translational and clinical projects based in basic research environments, provided that the description of the path to clinical application clearly highlights the relevance of the project to the end-users of the research and the project lies within the scope of the programme's objectives.

Innovation

The programme will provide funding for research that promotes clinical and commercial innovation within priority areas, including development and testing of advanced technical medical equipment.

Research methods

Both qualitative and quantitative studies are eligible for funding under the programme. The research questions will determine the choice of methodology. Relevant types of studies include:

- Comparative intervention studies with controls;
- Prospective observational studies with a control group;
- Clinical studies that combine data and material from existing biobanks, research and quality registries, and other health registries;

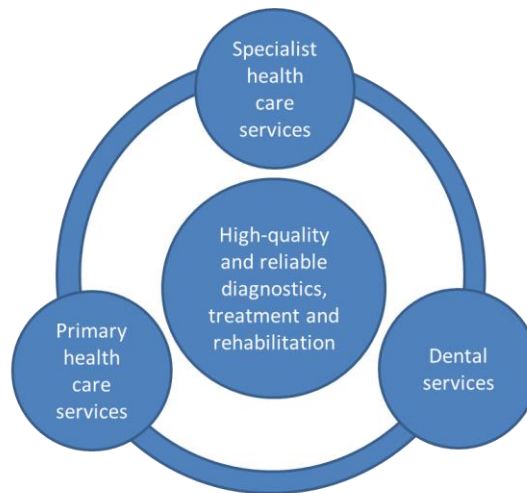
- Exploratory studies on illnesses for which no effective diagnostics, treatment and/or rehabilitation exists;
- Development of methodology for and implementation of studies on personalised medicine, new advanced therapies and complex interventions;⁵
- Studies with a methodological approach that is well-suited to exploring areas in which knowledge is lacking.

Strategic priorities

The programme will:

- Encourage clinical environments that represent prioritised patient groups and major clinical research tasks but lack necessary infrastructure and expertise, e.g. the municipal health and care services, to enter into research cooperation with established research environments in order to safeguard project quality and patient safety.
- Encourage the formation of core groups and larger consortia in which collaboration across professions and services leads to clear synergies and facilitates internationalisation.
- Facilitate long-term funding.
- Support the use of research support units that can help to implement clinical trials and satisfy more stringent requirements relating to study design and choice of method, data collection, statistical analysis and model development.
- Promote the use of the Norwegian Clinical Research Infrastructures Network (NorCRIN), a network of research support units. NorCRIN develops, coordinates and facilitates research support services for large clinical trials, provides advice and training, and can take on operative tasks in connection with the launch of multiregional and national multicentre trials.
- Promote and provide incentives for national, Nordic and other international collaboration on clinical studies, including participation in and use of the European Strategy Forum on Research Infrastructures (ESFRI) network.
- Encourage data sharing and reuse of data from registries, linkages between registries, health surveys, biobanks and experimental research within the regulatory framework and duty of confidentiality.
- Establish meeting places and networks across subject areas and sectors to promote unity, boost recruitment and develop sustainable research and innovation activities.

⁵ Complex interventions are comprised of complicated/multimodal interventions involving multiple professions and a heterogeneous patient population. Complex interventions often have an extended duration and treatment takes place in various settings, including the patient's own home.



High-quality and reliable diagnostics, treatment and rehabilitation

Relevant forms of support

Various types of funding instruments and forms of support will be used to achieve the programme's objectives and support the programme's strategic priorities. Funding instruments and support will be adapted to the programme's needs. Forms of support/application types that may be used include:

- Researcher projects;
- Personal post-doctoral research fellowships;
- Targeted funding;
- Pre-projects;
- Support for research networks;
- Innovation projects for the public sector;
- National graduate-level researcher schools;
- Support for events;
- Personal overseas research grants;
- Other support.

The BEHANDLING programme will work together with the other health research programmes and other Research Council activities to address the interfaces between the relevant programmes, e.g. through joint calls for proposals. Tools for identifying the need for research must be developed in cooperation with the other programmes. These tools may, for example, be based on defining and prioritising research needs through documented knowledge gaps (systematic knowledge summaries, the Health Research Classification System,⁶ health technology assessments, etc.), input from users via various schemes, and use of one or more panels comprising broad representation of researchers and end-users of the research, e.g. patients, health care personnel, decision-makers in the health and care services and the health authorities. This will make it easier to give priority to research targeted towards user needs.

⁶ The Health Research Classification System (HRCS) is a tool for analysing research activity in the area of health by generating profiles of research portfolios with regard to relevance for health and disease and type of research (www.hrcsonline.net). All projects are classified along two dimensions: type of research activity and health category.

International cooperation

International cooperation is vital for improving quality and enhancing capacity in Norwegian research. At the same time, Norway has the same major health challenges as many other countries. The programme will therefore encourage international research cooperation and knowledge sharing across national borders.

EU cooperation

The largest, most important cooperative arena for the programme is the EU framework programme, Horizon 2020 (2014–2020) (the Societal Challenge: Health, Demographic Change and Wellbeing), and any future framework programmes. This primarily encompasses participation in thematic programmes related to health under Horizon 2020, the ERA-NET scheme (networking of national research programmes in the European Research Area), Joint Programming Initiatives (JPI) and research infrastructure within the programme's thematic priority areas (e.g. the European Clinical Research Infrastructure Network (ECRIN)), as well as any other priority areas in the area of health. Health-related calls for proposals (individual calls, ERA-NETs and JPIs) within other thematic programmes under Horizon 2020 may also be of relevance.

Nordic cooperation

Nordic cooperation must be further developed in areas where this will provide particular advantages. The strategy document [Nordic Potential in Medical Research – Cooperation for Success](#) (2014) from the Joint Committee of the Nordic Medical Research Councils (NOS-M), for example, has identified biobanks and registries and personalised medicine as areas within medical research where the Nordic countries have an exceptionally solid basis for success provided they collaborate. The 25 million inhabitants of the Nordic region should be viewed more widely as a shared population base, and research should build on Nordic cooperation on clinical trials established under the Nordic Trial Alliance (a three-year pilot project). NordForsk – an organisation under the Nordic Council of Ministers that funds and facilitates Nordic cooperation on research and research infrastructure – is also a relevant partner for the programme.

Other international cooperation

Norwegian researchers should be encouraged to increase their collaborative activities with US researchers on the basis of the Memorandum of Understanding between the Research Council and the National Institutes of Health (NIH). Bilateral cooperation with selected countries outside Europe is relevant as well, as described in the various [roadmaps for bilateral research cooperation](#).

The Government's [Strategy for Research and Innovation Cooperation with the EU](#) from June 2014 states that the Research Council is to use national funding to encourage researchers to apply for EU funding, participate in joint European activities and take primary responsibility for support and mobilisation schemes targeting the EU.

An important aspect of the programme's activity is to assess which international programmes, activities and bilateral cooperation both within and outside of the EU will be given priority and to what extent. The programme will continually consider the use of relevant instruments such as funding for positioning activities, mobility schemes and institutional collaboration as a means of promoting more international cooperation.

Communication and dissemination activities

Research under the programme must have a cumulative perspective and provide a basis for new knowledge development for other researchers in the field and for clinical practice. Results from the programme must have an impact and be significant for patients and family members of patients, for politicians and the health and welfare administration at all levels, for service providers and the professions, and for the business sector and the public at large. A wide array of communication and dissemination activities is needed.

Project results under the programme will be disseminated in various ways, via:

- national and international scientific publication and other scientific channels;
- popular science channels, including social media;
- knowledge transfer between research, the field of practice and users within the framework of the project;
- knowledge transfer to and implementation of project results in the field of practice/the health services outside the framework of the project;
- knowledge transfer between the research community and trade and industry;
- mandatory registration of clinical studies in databases such as kliniskestudier/helsenorge.no, ClinicalTrials.gov and the Current Research Information System in Norway (CRISTin)
- other appropriate channels;
- conferences, seminars and publications targeted towards patients, family members of patients, service providers and politicians.

The programme will establish different types of meeting places for researchers and users, both nationally and internationally. Dissemination activities will be tailored to the various programme arenas, and will be designed to promote an integrated research, education and innovation system (R&D&I system) in the programme's thematic priority areas. Dissemination will be a key aspect of the action plans to be prepared throughout the programme period. Importance will also be attached to more long-term implementation of new knowledge. The programme will help to compile data about how this follow-up takes place.

Funding

The programme is primarily funded by the Ministry of Health and Care Services. Certain types of projects that the programme is seeking to fund are cost-intensive, e.g. national multicentre studies. The programme will make an effort to ensure that the projects awarded funding receive realistic allocations and thus benefit from satisfactory working conditions with a view to achieving high-quality results. The size of the budget will determine which activities may be launched and the degree to which the programme's objectives are achieved. Three-year action plans will be drawn up and will describe the thematic priority areas for the period in question in greater detail.

Interfaces and cooperation with other activities within and outside the Research Council

The BEHANDLING programme will cooperate with closely related activities when appropriate, such as on calls for proposals and scientific activities. In particular, the programme will work together with the three other health programmes: the Large-scale Programme on Health, Care and

Welfare Services Research (HELSEVEL), the Research Programme on Better Health and Quality of Life (BEDREHELSE) and the Programme for Global Health and Vaccination Research (GLOBVAC).

The BEDREHELSE programme is targeted towards health-promotion, prevention and research on interventions to advance national public health-policy objectives.

The HELSEVEL programme focuses on services research, which can provide insight into coherent patient pathways and the knowledge needed for cooperation and coordination in and between the specialist health care services and the municipal health and care sector, and services within the welfare sector.

The GLOBVAC programme addresses long-term improvements in the health status of individuals and the reduction of health inequalities for poor people in low- and middle-income countries.

The BEHANDLING programme also shares an interface with other Research Council activities and initiatives at the Research Council, including the funding scheme for independent projects (FRIPRO), the large-scale programme on Biotechnology for Innovation (BIOTEK2021), the Programme on Commercialising R&D Results (FORNY2020), the IKTPLUSS initiative on information technology and digital innovation (IKTPLUSS) and the National Financing Initiative for Research Infrastructure (INFRASTRUKTUR) which aims to expand national infrastructure and make it available to a wide array of research groups.

The BEHANDLING programme shares an interface with research activities funded by actors outside the Research Council as well, such as the regional health authorities and the Norwegian Cancer Society. In 2016 the regional health authorities will be launching a joint programme on clinical treatment research in the specialist health care services. The BEHANDLING programme will provide funding for clinical research in, for and about the municipal health and care services and the specialist health care services, including the dental health services. The programmes must cooperate to achieve a productive distribution of research tasks.

Monitoring and evaluation

The programme seeks to generate knowledge that addresses critical challenges to society. The objectives developed for the programme have their starting point in the challenges facing the health care sector, which are broadly described in key public documents in the area of health and research policy.

Constant follow-up and monitoring will be needed to ensure that the programme is developing in the right direction. The follow-up measures will be set out in the programme's action plans and in the planning of calls for proposals and further development of the programme. The programme will be monitored mainly through portfolio analyses and summary reports from the projects and in summaries from the programme's various focus areas during the programme period. The portfolio analyses will provide various types of knowledge overviews and may be focused on different target groups. The programme's action plans may also be revised on the basis of these analyses.

After five years, the need for a state-of-the-art review or external evaluation of the programme will be considered. An evaluation may look at the programme's scientific content, achievement of objectives, results and impact (an impact assessment) or assess whether the programme is organised in a manner that is suitable for achieving the programme's objectives.

The programme has high aspirations regarding user involvement in the research projects and the benefit of the research. This will be followed up, and the programme's annual report will address the extent to which these objectives have been achieved.

The Health Research Classification System (HRCS) will be used in analyses of the portfolio. The HRCS is a tool developed in the UK (www.hrcsonline.net) to analyse research activity of relevance for health and disease. The HRCS classifies all research in the area of health within all fields and disciplines along two dimensions: the type of research activity and the type of health or disease being studied.

The programme will also actively incorporate the Health&Care21 monitor being established. This monitor will compile knowledge about resource use, the results and the impact of research and innovation in the health and care field, and will include indicators for all of the focus areas in the Health&Care21 strategy. The monitor will be an important management tool for the various actors in their efforts to follow up the Health&Care21 strategy.

Attachment and references

This work programme is based on the following documents (with links):

- [The Health&Care21 strategy](#) (2014) and the [Government's action plan for follow-up of the Health&Care21 strategy](#) (2015–2018) (in Norwegian)
- Meld. St. 7 (2014–2015) [Long-term plan for research and higher education](#), white paper from the Ministry of Education and Research
- Meld. St. 26 (2014–2015) [The primary health and care services of tomorrow – localised and integrated](#), white paper from the Ministry of Health and Care Services
- Meld. St. 28 (2014–2015) [Legemiddelmeldingen – Riktig bruk – bedre helse](#), white paper on the proper use of pharmaceuticals and health, Ministry of Health and Care Services
- [The research and innovation strategy to improve coordination](#) (2012–2015), Ministry of Health and Care Services (in Norwegian)
- Meld. St. 10 (2012–2013) [High Quality – Safe Services](#), white paper from the Ministry of Health and Care Services
- Meld. St. 29 (2012–2013), [Future Care](#), white paper from the Ministry of Health and Care Services
- [Strategy for Research and Innovation Cooperation with the EU](#), Ministry of Education and Research, 2014
- Meld. St. 11 (2015–2016) [Nasjonal helse- og sykehusplan \(2016–2019\)](#), white paper on the national health and hospital plan (2016–2019), Ministry of Health and Care Services
- [Research for Innovation and Sustainability](#): Strategy for the Research Council of Norway 2015–2020
- [The Research Council of Norway's Strategy on International Cooperation 2010–2020](#)
- [NCD-Strategy](#) (2013–2017), Ministry of Health and Care Services
- [The Future Nordic Co-operation on Health](#), Bo Könberg – Nordic Council of Ministers, 2014
- [Nordic Potential in Medical Research – Cooperation for Success](#), Joint Committee of the Nordic Medical Research Councils (NOS-M), 2014



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