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Summary of The Norwegian Strategy for Personalised Medicine in Healthcare

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PREFACE

In the field of personalised medicine, prevention, diagnostics, treatment, and follow-up are adapted to the biological characteristics of the individual. The use of personalised medicine is set to transform the health service. The aim is to offer patients more precise and targeted diagnostics and treatment, while treatment without effect is avoided. There are already examples where this approach is used, e.g. within rare diagnoses and cancer. Technological advances present new opportunities in diagnostics and treatment, and personalised medicine is thus a field where clinical practice and research are closely linked. Personalised medicine is an important area for innovation and commercial development.

Personalised medicine requires advanced equi**pm**ent, a multidisciplinary approach and a high level of expertise. Through the strategy, we aim to build firm foundations for the future of the public health service. The primary healthcare service should be involved in this development. The strategy will contribute to consistent, high-quality services. The key recommendations include: development of expertise, a coordinated national development of the field, development of ICT systems and registries. Health care providers, patient organisations, industry and commerce will play important roles in the follow-up of the strategy.

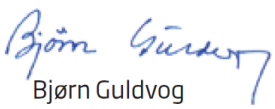
Large-scale genetic analyses, which has recently been introduced in clinical practice, is one of the main issues of the strategy. Such analyses generate large quantities of sensitive medical information and data. Genome analyses may provide major opportunities for patients, but will also raise a number of challenges that are particularly linked to the fact that genetic data is extremely sensitive. Therefore, developments must take place within a robust and ethically sound framework that ensures data security and protection of privacy.

The strategy must be viewed as an initial step, which will be followed up with concrete action plans. There is no specific funding for this strategy. Thus, funding for the initiatives must be proposed through ordinary budget processes.

The established principles for priority setting in healthcare will apply to personalised medicine.

The strategy was developed in close collaboration with patient organisations and the healthcare sector. The Directorate of Health would like to thank all contributors, including participants of the various working groups as well as those responding during the public consultation process.

We are looking forward to working with the different stakeholders to implement this strategy in the healthcare services.



Bjørn Guldvog

Director General of Health

TABLE OF CONTENTS

1. BACKGROUND

1.1 About the strategy

January 2015, the Ministry of Health and Care Services asked the Directorate of Health to develop a national strategy for implementation of personalised medicine in public healthcare. The strategy is meant to support and form a basis for the healthcare service in the development and implementation of personalised medicine. Development of a national strategy for personalised medicine was one of the key recommendations in a report published by the Regional Health Authorities in 2013-2014 .

The strategy is relatively brief . It is based on the documents from working groups where expert from relevant fields of medicine, technology and law have participated.

Different stakeholders and experts have contributed through participation in steering groups, project groups, reference groups and working groups. Patient and user organisations, the health services as well as The Association of the Pharmaceutical Industry in Norway have provided considerable input. During spring 2016, a draft strategy was submitted for public consultation, and relevant comments were incorporated.

Personalised medicine and related areas are characterised by rapid development. The recommendations in the strategy thus have a five-year perspective, from 2017 to 2021, and both the strategy and the coming action plans will be revised during the latter part of this period. The implementation and follow-up of the strategy must adapt to the forthcoming discussion of the Reports to the Storting (Parliament) on prioritisation in healthcare and on the evaluation of our Act on medical use of Biotechnology.

1.2 Scope

The strategy focuses on development and implementation of personalised medicine in the healthcare services. It is based on the previous report1, input from working groups and project groups, and comments submitted during the consultation process, and aims to be in harmony with European recommendations.

Our main focus is on areas of medicine where personalised medicine has already been introduced in the healthcare service, and where the introduction of new technology

represents not only opportunities but also challenges. For this reason, we give considerable attention to genetic/genome analyses using next generation or high-throughput DNA sequencing technologies. Newborn screening is briefly discussed - but not screening in general, and we do not have in-depth discussions on direct-to-consumer genetic testing or "mobile health".

participate in such processes. Competent authorities as well as the healthcare services should provide relevant information and guidance of high quality. The information must be tailored to meet the needs of patients and their relatives, as well as decision makers and the public. Expertise and knowledge must be shared throughout the healthcare system, including both primary and specialist healthcare; and between different

2. VISION, AIMS AND PRINCIPLES

The strategy's vision is:
More targeted and personalised healthcare

2.1 Strategic aims

The strategy is a tool for realisation of the overall vision. It's overall aim is to ensure coordinated building of expertise and coordinated knowledge based developments in the field of personalised medicine, and to pave the way for further research and innovation.

Aim 1: Our healthcare service provide high-quality and relevant information and guidance on personalised medicine

Active participation of the patients in decision making processes concerning their treatment is a crucial principle in our healthcare services, and likewise, the citizen involvement in developing the healthcare services. Personalised medicine may appear complex, and knowledge is required in order to

disciplines, professions and professionals.

Follow-up on the recommendations under A; Expertise and information, will provide tools for satisfying these requirements.

Aim 2: Our healthcare service will implement personalised medicine as part of its services, and organisation of services and building of infrastructure will take place in nationally coordinated processes

Healthcare should be secure, equitable and of high quality. Personalised medicine uses emergent technology-based approaches and is highly specialised. The implementation of personalised medicine requires an approach that can ensure that these interventions are equitable and available for patients in all regions of the country. A considerable amount of public funding has been allocated to

investment in high-technology and high-capacity equipment. The capacity of this equipment should be utilised in a way that facilitates equitable services. To achieve this goal, we need to establish systems for collaboration, standardisation, sharing of expertise and knowledge, and supportive ICT systems such as EPR (electronic patient records), decisions support systems (DSS) and health registries.

Follow-up on the recommendations under B; Quality and academic and clinical development C; Health registries, and D; information and communication technologies (ICT) will contribute to satisfy these aims.

Aim 3: Our healthcare service will contribute to research and development as well as innovation in the field of personalised medicine, both nationally and internationally.

Research and development is an important driver in the emerging field of personalised medicine. Research and innovation are expected to provide new diagnostic tools and novel treatments for our patients. The development of diagnostic tools, drugs and ICT- /decisions support systems requires collaborative efforts involving different sectors and stakeholders, e.g. the healthcare sector, universities and colleges, and industry and enterprises.

Follow-up on the recommendations under C; Health registries, and D; Information and communication technologies (ICT) will contribute to satisfy these aims.

2.2 Guiding principles

Development and implementation of personalised medicine should contribute to strengthen quality and patient security, and to establish robust research groups and networks. Important guiding principles for this strategy are:

- Equal access to adequate diagnostics and treatment for all patients
- Implementation of personalised medicine should take place in a framework that protect the integrity and autonomy of the patient; in particular in relation to information derived from their biological material
- Implementation of personalised medicine should be based on established criteria for priority setting in healthcare and should be socio-economically sustainable

3. STRATEGIC AREAS AND SUMMARY OF RECOMMENDATIONS

The strategy's recommendations cover five tightly linked areas. The systems that are developed to implement the strategy in clinical practice must be in compliance with national norms and standards, and harmonised to international recommendations.

A. Expertise and information

National development and implementation of personalised medicine requires building, strengthening and dissemination of expertise and knowledge. Personalised medicine will gradually be introduced in various areas of clinical practice, both in specialist and in primary healthcare. Healthcare providers and patients need guidance. Adequate expertise and knowledge about personalised medicine must be available throughout the healthcare system, and arenas for collaboration to achieve this goal must be established. This will require contributions, collaboration and promotion of personalised medicine from the healthcare sector, the education, and teaching sector as well as the industry and corporate sector. Personalised medicine is complex and currently, the general public has limited knowledge about this concept. Therefore, high-quality information on personalised medicine must be made available also to the general public. Information is a key factor for the active participation of patients and relatives in decision making processes that concern their healthcare.

Recommendations:
A1: Include personalised medicine as a topic in relevant educations
A2: Establish a national network of regional resource centres for personalised medicine
A3: Develop national competence standards for genetic counselling
A4: Information for the public

B. Quality and academic and clinical development

Expertise and knowledge of the "state of the art" of technological solutions for personalised medicine varies considerably from one region to another. The interventions offered to the patients vary correspondingly. In order to reduce undesirable variation (differences) and offer patients equitable healthcare service, it is necessary to establish standardised routines. Personalised medicine encompasses a number of areas, and the degree of development and implementation of perosnalised medicine varies from one area to another. Each area of medicine has its own specific needs for standardisation and development. Acting to standardise nationally is an important responsibility for the Directorate of Health, and issuing of guidelines and other normative documents is an essential tool to ensure the implementation of such standards.

Recommendations:
B1: Develop action plans
B2: Issue normative documents and standards for the clinical use of high-throughput technologies and genome-wide analyses
B3: Analyse the need for and eventually develop quality standards

C. Health registries

Development of personalised medicine and the increased use of large-scale analyses demand collection of large quantities of data, as well as a need to store and process new types of medical information. Safe and secure storage and processing of medical information is a prerequisite for protecting privacy and for maintaining the population's trust in the healthcare as well as research. Health registries in this field must be developed in compliance with the National Health Registry project, for which the Ministry of Health and Care Services is responsible.

Recommendations:
C1: Establish a national and anonymous genetic variant database
C2: Further develop the Norwegian Cancer Registry to include more information on cancer genome variants
C3: Consider whether there is a need to include genome tests in the National registry on communicable diseases, and thus, the need for further developments on this registry
C4: Further investigations of the possibilities to establish a national system for storage and processing of raw data/medical information from clinical genome tests and analyses, both for healthcare purposes and for research.

D. Information and communication technology (ICT)

National systems for secure and appropriate storage of large quantities of data must be developed. Standardised systems are required to build up registries and to allow for effective analysis and sharing of data both nationally and internationally. The Electronic Health Record (EHR) is an important ICT-based tool for healthcare providers. Development of appropriate architecture and functionality for handling of genomic data in the EHR will be pivotal for successful implementation of

personalised medicine. Such developments have to be coordinated with other national initiatives in eHealth, and should facilitate the contribution from public as well as private industry and enterprises.

Recommendations:
D1: Further investigations of the possibilities to establish a national system for storage and processing of raw data/medical information from clinical genome tests and analyses, both for healthcare purposes and for research.
D2: To develop functionalities for handling of "personalised medicine"/large-scale data through the Electronic Patient Record (EPR).

E. Research and innovation

Norway has strong research communities working in the field of personalised medicine. It is crucial to maintain and further develop this research to continually improve clinical services. Increased coordination of the research, innovation efforts and initiatives concerning personalised medicine is required. Efforts should be made to facilitate contributions from the healthcare services, the higher education sector as well as private enterprises. Research and clinical practice are closely integrated in the development of personalised medicine based diagnostics and treatment the healthcaremust facilitate this integration.

Recommendations:
E1: Establish an action plan for PM-based research and innovation
E2: Develop clinical pathways that integrate clinical treatment and research

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