



Fact sheet

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Personalised medicine:

Initial situation

There have never been so many opportunities to collect, store and (thanks to the increasing capability of information technology) to connect health data more quickly and cost-effectively, and to gain insights from these data. In addition, great progress has been made in the field of genetics since the whole human genome was decoded in 2003. The determination of more and more genetic characteristics and the storage of genetic data continues at constantly decreasing prices.

These developments are changing medical research and medical practice gradually but profoundly. In the area of research, new experimental approaches, especially in genetic research, are providing new insights into the molecular mechanisms that underlie the development of diseases. We can look forward to a better understanding of the mechanism of action of medications, the discover of new approaches to therapy and the development of new active substances.

Incorporation of these research findings into medical practice is referred to as "personalised medicine". By optimizing the use of health data, we can expect that medical practice will become more predictive, preventive and personalised, as well as more precise and participative.

Definitions

Personalised medicine (also called precision medicine or individualized medicine) generally includes diagnostic, preventive and therapeutic measures that are optimally tailored to an individual. A person is examined, in particular to determine genetic characteristics. The results of these examinations are then incorporated into the decision-making process for therapeutic and preventive measures for the treatment of that person. It is hoped that such tailor-made treatments will provide more effective therapy with fewer side effects. In the long term, they should also have a positive effect on cost development.

The concept of **personalised health** goes beyond personalised medicine; for example, it plays an important role in prevention. personalised health focuses not only on patients but also on people who are healthy. In addition to information about a person's 'biology', other health-related data from various sources are taken into account (see next section).

Health data, big data

The term 'health data' means data collected from various sources that may in some way either describe or influence a person's state of health. It is information on health conditions (e.g. symptoms, allergies, visual or hearing impairment), on health care (e.g. medications, surgical procedures), data

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from conventional investigations (e.g. blood pressure, laboratory values, electrocardiography, radiography), and results from genetic tests. Socio-economic data (e.g. education, occupation, migration background), information on lifestyle (e.g. nutrition, alcohol and drug use, smoking, exercise) and data on environmental factors (e.g. air and water quality, passive smoking, occupational exposure to noxious agents) are also included in health data.

Health data can come from numerous sources. For example, information about a patient's state of health can be derived not only from the health record (on paper or in electronic form), but also from health insurers or mobile devices. Information on people's eating habits can be obtained from loyalty cards from the supermarket, data on their sporting activities can be derived from fitness trackers, and general information on air and water quality is available from environmental data.

The term *big data* is often used in connection with health data. *Big data* refers to very large quantities of data that are derived from very different sources and can only be evaluated with high-performance technologies.

Opportunities and risks

As the approaches of personalised medicine are gradually being established, representatives of research, clinical practice, insurance companies, law and ethics are starting to address the opportunities and risks of these developments.

The prospect of gradually being able to provide healthcare that is more efficient and more patient-centred is an outstanding opportunity. This would mean that therapies with the best chance of success would be used, while ineffective or harmful treatments would be avoided. Prevention and health promotion could also be improved, because individually tailored measures would be recommended.

For private companies, personalised medicine offers opportunities for research and innovation in diagnostic tests and pharmaceutical manufacturing as well as information and communication technologies.

However, there are risks in the area of protecting data and personal information: The greater the amount of personal information that is stored, the more difficult it is to ensure that the data are permanently anonymised. There is also a risk of discrimination against people who cannot or do not wish to participate in the trend towards digitisation, and against those whose health record might be unfavourable.

The impact on healthcare costs is difficult to estimate. The increased use of diagnostic tests prior to treatment results in increased costs, especially for genetic investigations. Medications that are designed specifically for a small group of patients are also very expensive, since the development costs can only be covered by a few cases. However, costs can be saved by using medications in a more specific manner, refraining from ineffective treatments and thus avoiding the costs of follow-up treatment of any serious side effects. The extent to which the different factors will change the overall costs is difficult to predict.

Projects in Switzerland

In Switzerland, various private and public initiatives in the field of personalised medicine and health have been launched in recent years. Most of these initiatives are focused on research. Only in a small proportion of the projects are health data used primarily in favour of patients or consumers (e.g. to support treatment processes, for creation of individual fitness or nutrition plans, etc.). It is worth mentioning the Swiss eHealth strategy, a comprehensive strategy associated with digital transformation of the health system that includes introduction of electronic health records at national level.

The most comprehensive publicly funded initiative to date is the Swiss personalised Health Network (SPHN) initiative (see also www.sphn.ch). This laid the foundation for a data organisation coordinated

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throughout Switzerland. The development of a nationally coordinated, interoperable data infrastructure should enable nationwide accessibility and the exchange of health-related data, especially for research. Instead of a centralised database, the SPHN will build a dynamic network of existing data sources and finance the work needed to make the data internationally accessible for research and linkable to other types of data. The FOPH-BAG, together with the State Secretariat for Education, Research and Innovation SERI-SBFI, is the responsible authority for this initiative.

Personalised Medicine and the FOPH-BAG

The FOPH is responsible for the health of the population in Switzerland and as such is responsible for more than twenty acts and numerous ordinances. These range from the regulation of human research through healthcare to health insurance.

The interfaces to personalised medicine are therefore numerous and can be subdivided into the following six categories: research, approval of medicinal products and market surveillance, diagnostic tests, prevention and treatment, social insurance compensation, education of professionals and information regarding the population.

The responsible units in the FOPH check regularly to see whether action needs to be taken or legislation needs to be modified in view of recent developments in personalised medicine, be it in research or in the application of these developments to healthy or ill persons.

This leaflet is a very condensed version of the evolving working paper "Current Developments in Data-Driven Medicine and the Challenges and Tasks for the FOPH" of June 2017.

<https://www.bag.admin.ch/bag/en/home/themen/mensch-gesundheit/biomedizin-forschung/biomedizinische-forschung-und-technologie/masterplan-zur-staerkung-der-biomedizinischen-forschung-und-technologie/personalisierte-medizin.html>

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