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# Executive Summary of the Council Report 2021 „Digitalisation for Health – Aims and Framework Conditions for a dynamically learning Health System“

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## Introduction

1. Germany lags way behind other countries when it comes to digitalising healthcare. Improvements in its healthcare structure, information technology, organisation and legislation are urgently needed to ensure healthcare is error-free, efficient and effective, and that medical advancements are implemented across the board – including with regard to processing of information and cross-sectoral communication.

2. The Health System Advisory Council thus recommends devising a strategy for the digitalisation of the healthcare system. The aim of digital advancement is to facilitate a dynamically learning health system. However, digitalisation is not an end in itself, but a means to an end. The purpose behind healthcare policy and healthcare provision is ensuring patients' wellbeing – seen in this instance as the wellbeing of all current and all future patients. This sets the benchmark against which digitalisation of the healthcare system is both measured and evaluated. The idea is to shape digitalisation in a way that healthcare provision is improved with patients' wellbeing in mind. Thus, where research – ranging from basic research to healthcare research – contributes to patients' wellbeing, its facilitation and targeted promotion is equally important via suitable digitalisation means.

3. Because the conditions for digital healthcare in Germany are primarily set by the public sector, standards regarding data protection and data security can be prescribed; effective monitoring programmes and controls can be enforced, as can sanctions against violations. In this way, *greater* (informational) self-determination is ensured than if people are left to take their concerns regarding their lives and their health to purely commercial providers of online consultation and healthcare services, many of which are in other legal and economic systems.

4. Similarly, a digital healthcare system with a public policy framework enables scientifically accepted standards of evidence-based medicine and quality assurance to be defined for the healthcare

measures on offer along with policy provisions to ensure that the findings benefit *all* – both in terms of the medical care of individuals (e.g. drug safety) and the targeted further development of the healthcare system as a whole (e.g. hospital planning).

## Digitalisation framework

5. To ensure optimal use of healthcare digitalisation for the benefit of patients, the debate in Germany must be conducted in a new and different way than has been the case so far. Be it in policymaking, in society, in the sciences and in the healthcare system itself, the debate must consider *all* norms affected by digitalisation of the healthcare system and balance them in a way that is both value and practice-oriented. The coronavirus pandemic has shown that informational self-determination of the individual is not only a matter of their own life and health and the life and health of others, but is also reliant, for example, on education and training as well as cultural and working life as the conceptual and substantive foundations of human coexistence.

6. Data protection must be rethought along the lines of holistic patient protection. First and foremost, it must be weighed against and constructively reconciled with the protection of life and health. Data protection policymakers and data protection officers must also face up to this responsibility – the former in legislation, the latter in implementation. In the healthcare sector, data protection must be made *integral* to protecting life and health, not *in opposition* to it. Above all, data protection must enable the secure *use* of health-related data to aid better care and research so that individual patients can be helped in a more targeted way. This involves the evaluation of large amounts of data. The age-old maxim of as little data as possible and its strictly purpose-related use has been superseded by reality. And most importantly, it no longer does justice to the right of each and every individual to optimal processing of their data in protecting their lives and their health. Data *security* must become the overriding norm – in conjunction with severe criminal sanctions for those who attempt to cross or actually cross the boundaries drawn by the legal and social community.

7. Digitalisation that is widely accepted by both service providers and patients includes adequate and transparent measures as well as information to ensure data and information security. The risk of malfunctions in the information technology needed in caring for patients must be prevented wherever possible. In addition to state-of-the-art security measures, this includes organisational measures such as the provision of crisis and emergency plans that enable an appropriate response should an IT security incident occur.

8. The increased generation and storage of data necessary for effective digitalisation of healthcare can make it more difficult to achieve environmental and social sustainability goals. In policymaking, energy efficiency standards, recycling targets, robustness incentives, decent work standards along the supply chain and other appropriate measures can help in attaining environmental sustainability. And in all of this, the risk of higher costs may have to be accepted. To achieve social sustainability, ensuring across-the-board access to high-speed broadband networks is just as important as providing both general and target group-specific information, and empowering people to be able to deal with digitalised healthcare provision.

9. One of the challenges in digitalisation involves securing efficient, target-oriented finance. For example, investment in digitalisation in the inpatient sector must be promoted, but not in a way that preserves inefficient hospital structures. In the short term, discretionary financing of digitalisation

should be linked to performance-oriented structural changes, while in the longer term, the investment costs of digitalisation should be incorporated into regular funding – ideally in conjunction with a transition to a monistic finance system. In the medium term, investment in digitalisation should be suitably integrated into the remuneration of outpatient services.

**10.** To make full use of the benefits that digitalisation brings, further expansion of high-performance, nationwide internet access is indispensable. This applies especially to fibre-optic coverage. In addition, as an information, communication and security infrastructure, the telematics infrastructure (TI) must be kept at a technically appropriate, sustainable level. As part of that effort, attention must also be paid to the durability of products and components, to the long-term usability of health-related data stored and to energy use.

## Electronic health record

**11.** The electronic health record (EHR) can facilitate needs-based, coordinated care by providing timely access to structured, consistent information. The Council thus recommends the use of a structured, user-friendly EHR whose content is uploaded from primary documentation in compliance with standardised provisions. As a general rule and on the basis of an opt-out process (e.g. the right to object to data being stored), an EHR should be set up for each individual (at birth or when taking up residence in Germany) and – for the purposes of viewing, storage and processing of information – give treating healthcare providers access to the data it contains.

**12.** The insured person should also be able to object to access by service providers (concealing certain EHR content). The success or failure of the EHR in Germany depends on the number of active users: Only with adequate take-up can service providers work with the EHR as a matter of routine and the necessary investment in the respective infrastructure be justified. The multiple opt-in process to be implemented in 2021 or from 2022 (separate and repeated consent required for file creation, for file access to add or view content, and for renewed access and use of the data for research purposes; opt-out for specific content types) bears the risk – among other things due to the effort involved – that such a fundamental service in healthcare provision, with its vast potential and opportunities, will be used by too few people. In terms of healthcare and research, the Council believes in data sharing to improve care.

**13.** In communications about opportunities for improved healthcare from the use of health-related data, the specific benefits to be had from improved data resources should be explained in a well-founded, easy-to-understand way. Information should focus on patients' questions and concerns. The personal benefit for patients will lie above all in the fact that detailed information about their health is readily available, can be compared and considered, and thus makes it easier to arrive at an early diagnosis or align treatment to their specific needs.

**14.** To achieve widespread use of an EHR that is useful for both patients and service providers, it is necessary to inform insured persons in a way that is appropriate for the target group. Communicating the benefits and risks of the EHR should be seen as a collective responsibility, even if the bulk of the burden falls to the health insurance funds (as the institutions issuing the EHR) and in some cases to the service providers. And in their public relations work, institutions such as the Federal Centre for Health Education (BZgA) should also promote the use of an EHR.

**15.** It will also be to patients' benefit if data related to their own treatment as well as the treatment of all others can be used for healthcare research. A close link between healthcare and research increases the chances of differentiated diagnostics and targeted treatment at the current state of science. To facilitate this individual and collective benefit, a check should be made as to whether a statutory authorisation standard for data processing without the need for consent can be created for health-related data on the basis of Article 9 (2) of the General Data Protection Regulation (GDPR). There is already corresponding provision for the use of statutory health insurance funds' billing data under Sections 303a to f of Book V of the German Social Code (SGB V). The treatment data that is already collected and documented under the provisions of collectively financed healthcare should be forwarded via the EHR in pseudonymised form to a central 'collection point' (Research Data Centre), which manages and secures that data in trust and makes it available for research in curated form.

## Digital health apps

**16.** Despite their potential benefits, digital health apps have yet to be widely implemented in healthcare provision. Evaluation of an app's effectiveness and benefits is considered key in tapping this unused potential. However, the short cycles in developing health apps combined with the partially long periods of established study designs pose a challenge. The risk-benefit assessment and the reimbursement process must both be designed to ensure only the safest possible, quality apps with proven benefit can enter the healthcare system, while also providing an incentive for providers to invest in developing those health apps.

**17.** Initial specifications for the risk-benefit assessment and reimbursement for low-risk health apps were set out in the Digital Healthcare Act (DVG). This is to be welcomed in principle, as it provides greater transparency as to which apps meet the requirements for safety, functional capability, quality and data protection, and have a positive healthcare effect. For risk-benefit assessment of apps in higher risk classes, the Council recommends devising a risk-benefit assessment procedure once the respective apps have entered the market and basing it on the model used for medicinal products and medical devices. With a view to the short innovation cycles involved with health apps, flexible (adaptive) study designs are proposed. To aid decision makers, health economics assessments can provide supporting information.

**18.** The amount of remuneration for an app should be based in particular on the extent of the positive effects on health and should also be set in relation to the cost-benefit ratio of the app and the prices for existing services. Even after market entry and inclusion in the SHI catalogue of services, quality, safety, functional capability and benefit should all be evaluated, as not only the app itself but also the prevailing conditions are all subject to constant change. Accordingly, the opinions and experiences of users should also be regularly documented and this knowledge should be taken into account when developing and enhancing a health app.

**19.** It is important to ensure competition for efficient solutions in digital hardware and digital health products. This also includes the many and diverse facets in ensuring interoperability, for example within and between operating systems. It is conceivable to be able to download health apps that are secure in terms of technical quality from an online platform, such as the German National Health Portal, in order, among other things, to limit the gatekeeper and rule-setting functions of the big internet platforms. For apps and services which are part of the telematics infrastructure (such as

the EHR app), care should be taken to increase freedom of choice for both patients and service providers.

## Research data

**20.** The aim of an efficient research data infrastructure for health-related data is to facilitate a dynamically learning health system which provides patients with the best individual treatment while serving efficient allocation of resources within the system itself. Responsible handling of health-related data includes an integrated understanding of data protection: Not only as defensive data protection law, but as an integral part of patient protection. In quality healthcare provision, this should see adequate processing of health-related data as a fundamental entitlement for all. It explicitly includes the promotion of scientific knowledge for use in improving health promotion and patient care.

**21.** In the interest of patient welfare, when developing new data resources, it is important to minimise the risks from data use and, most importantly, to maximise the potential benefits to be had from medical research. In doing so, the potential harms caused from not using data must be appropriately assessed and considered. Data protection should serve in protecting the patient, their life and their health.

**22.** A patient's informational self-determination should no longer be seen solely in relation to the protection of personal data. Data protection must not stand in the way of the right of each and every insured person to adequate processing of their health-related data for the purpose of providing the best possible treatment and improving the healthcare system, and also for the purpose of research to improve prevention, diagnosis and treatment. Data protection must take this basic entitlement of all individuals into account and ensure it is honoured. It should be noted that for the majority of research questions, pseudonymised data is required, in which direct reference to the person is removed; it could, however, be restored under strict conditions via trusted third parties (TTFs). Anonymisation or aggregation, by way of contrast, results in a great loss of information and prevents additional information from other data sources being added. There would also be no way to contact patients via re-personalisation on the part of the TTF if, as a result of research using their data, findings were obtained that would be of vital importance for their lives and health. For efficient and effective use of resources, care must be taken to ensure that data resources which are generally accessible for research and often financed by public funds can actually be used as widely as possible. Currently, scientific research with potential added value for society is all too often prevented due to legal, administrative or technical hurdles. In international competition, this significantly weakens Germany's standing as a science and innovation location.

**23.** Consent procedures must be further developed in such a way that in the interest of patient wellbeing, secondary use of treatment data is regulated in a low-threshold, straightforward way and, to the extent possible, not tied to the specific treatment situation. Priority should be given to examining whether the possibility of data processing on a legal basis without the need for consent or opt-out can be provided on the basis of Article 9 (2) of the GDPR for health-related data considered particularly relevant for healthcare research. As the scientific, systematic and comprehensive evaluation of treatment data is highly important in ensuring quality care for every patient, but that data is also particularly sensitive and in need of protection, the possibility should be looked into of sector-specific

legislation on the use of health-related data. In addition, the countless research clauses spread across federal, state and ecclesiastical law (in relation to Church-run hospitals) along with the heterogeneous processing conditions in place should be replaced by easily-applicable, uniform rules on research using health-related data (under the provisions of the possible legislation on using health-related data). Finally, it should be legally and technically possible for health-related data collected in EU member states to be available for cross-border secondary use in healthcare research.

**24.** In addition to EHR data, data from high-quality registries form an important basis for healthcare research. A systematic, permanent funding structure should thus be created which facilitates the establishment and expansion of medical registers, which are of great benefit in research, care, quality assurance and patient information. To this end, an independent body should be created to document and evaluate existing registers and identify the kinds of registers that do not exist but could potentially be of use.

## Digital health literacy

**25.** There is a considerable need for education and action with regard to digital health literacy among the general public and health professionals. Health literacy should thus be promoted, especially with regard to media literacy and critical judgement. Individuals remain to be empowered with formal and non-formal or informal learning opportunities and educators with digital and health literacy, but the underlying conditions must also be improved by providing low-threshold access to electronic tools, target group-specific programmes, target group participation in technical development and the provision of access to evidence-based, easy-to-understand information supply. By promoting digital health literacy, the aim is to reduce rather than increase health-related and social inequality. In turn, good digital health literacy can promote digitalisation by enabling health professionals to actively use digital services, such as the EHR, use them purposefully in joint decision-making and be involved in their further development.

**26.** The Council recommends transfer of the German National Health Portal to a politically independent body. The portal must be rapidly developed into the best-quality, centrally managed knowledge platform for all issues concerning health and disease management, and decisions relating to healthcare services. The health information prepared for the portal must be quality-assured and evidence-based. Provision and application of scientifically sound, easy-to-follow health information that meets the standard of evidence-based health information criteria is the prerequisite for informed decisions and for successful participation in decision-making processes. Here, content from different providers, whose content quality is guided by a methodological manual and regular evaluation, are to be made available to the general public free of advertising and in user-friendly formats. The long-term goal is to improve overall health literacy and patient sovereignty.

## Strategy for a dynamically learning health system

**27.** If a dynamically learning health system is to make a sustainable contribution to patient wellbeing, digitalisation must be driven in that direction by means of strategic steps. The necessary infrastructural conditions must thus be created – notably, fibre-optic network expansion, rapid implementation of the telematics infrastructure, creation and expansion of a research data infrastructure, timely, binding and internationally-connectable interoperability, and standardisation (for example, in documentation and filling the EHR).

**28.** To implement the strictest requirements for data and information security for all digital technologies in the healthcare sector, decisive, far-reaching strategies are needed. The Council calls for transparency in the handling of data and the provision of data security to protect informational self-determination and ensure people’s privacy rights. These are key prerequisites in fostering people’s confidence and trust in the EHR and in fostering people’s willingness to make their data available for research use.

**29.** The Council believes that improvements in research conditions with regard to clear, uniform regulations on secondary use, general use, linking and simplification of data at practitioner level when requesting and handling data resources are essential in developing new research approaches. This can facilitate more far-reaching innovations with the aim of translating new findings and therapy approaches as quickly as possible into clinical treatment/standard care.

**30.** Digitalisation can improve healthcare provision by making treatment information available across sectors in a timely way, thus increasing patient safety. For current and future generations to benefit from digitalisation, health-related and social inequalities must be reduced through the (targeted) promotion of digital health literacy, and as many people as possible should be involved and contribute on a collective basis by agreeing to make their data available for use. Finally, the Council believes that digitalisation must be embedded in an overarching sustainability strategy.