Involvement of patient organisations in digital health research

A position paper on the current status with demands for the future

Finalised version

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Abstract

As part of a discourse process, patient organisations/self-help groups in Germany (see Section D) have drawn up a position paper on the involvement (participation) of patient organisations/self-help groups in digital health research. The following points were identified based on the current situation:

- Participation and compensation in research
- Information and consent processes in the context of digital health research
- Research management and data sharing

With this position paper, the patient organisations/self-help groups formulate important demands for health policy decision-makers. These are the key points summarised:

- To ensure success and bring about a minimum level of cooperation between patients and researchers, patients and their representatives must be actively involved in digital transformation processes from the beginning.
- All parties involved must realistically design the participation of patient organisations, patients, and relatives in the application of digital research processes. In particular, this requires:
    - a clear definition of the scope and design of participation, transparent involvement of patient organisations from start to finish, from planning to application to research results,
    - empowerment of patient organisations to participate in the research process,
    - an understanding of the specific nature and variability of voluntary structures and
    - target group-oriented, barrier-free preparation and communication of research results.
- Professional, monetary, personnel, structural, and technical equipment is the basic prerequisite for the involvement of patient organisations.
- More attention needs to be paid to vulnerable groups. Stigmatisation and discrimination must be prevented.

Essentially, and in contrast to the current legal situation, patients should be the owners of their health data. Only the patients themselves should be able to decide on the further use of their data.

Introduction

Advancing digitalisation affects many areas of social life and the economy and has already changed them significantly. The Federal Ministry of Health (BMG) has addressed this issue with the aim of improving healthcare and passed two laws to this end in 2024.[2]

The aim of the Digital Act (DigiG) is to improve everyday healthcare in Germany with digital solutions. For this purpose, better access to health data for research and development, which is regulated in the Health Data Utilisation Act (GDNG), should contribute to this.
In our view, an important goal is for those affected to have an influence on what and how research is carried out and for researchers to be able to orientate themselves more closely to actual needs. The involvement of patient organisations in shaping this participatory approach is regulated in the GDNG.

As part of the PANDORA research project (see appendix), representatives of patient organisations met in June 2024 to name key ethical, social, and legal problem areas, identify the most urgent need for action and formulate recommendations for political decision-makers.

There was broad agreement that people must be at the centre of the digital transformation. Patients' (health) goals are, for example, prevention, a valid diagnosis, therapy, a cure, and coping with/managing the illness are central. The social and familial embedding of patients should also be taken into account.

This results in challenges in the following areas

- Participation, e.g. type, scope and form of patient involvement
- Handling of data, e.g. data collection, protection against misuse and discrimination
- Digital transformation processes, e.g. future potential applications of artificial intelligence (AI)

Criteria such as age and physical and mental limitations should be taken into consideration based on the individual needs of patients. The integration of vulnerable groups, such as children, presents a challenge. Analogue alternatives are needed to integrate people who are unable to participate in the digitalisation process for health reasons, for example, or who do

[2] See also list of abbreviations and glossary.

not want to for other reasons. To better understand and support future digital change processes, patients need:

- On the one hand, general awareness and general education. This should be prepared on a topic-specific basis and by a neutral organisation, supported with public resources and disseminated in a practical manner via the media and educational institutions.
- On the other hand, individualised education. This should be tailored to the needs of the individual patients.

The aforementioned prerequisites are essential to be able to make self-determined decisions in digital health research. To overcome these challenges, this position paper describes the current situation and derives demands from it.
These are divided into the following topics:

- Participation in research
- Information and consent processes in the context of digital health research
- Research management and data sharing

A. Participation in Research

Current Situation:
It is known that the stakeholders involved in this position paper have been insufficiently included in previous legislative projects by means of consultation, etc. This also applies to the digital transformation of healthcare systems.
The participation of patients, their relatives and patient organisations currently includes neither the right to initiate new measures nor involvement in the prioritisation of measures that have already been agreed.

There are currently many projects in the field of digital healthcare in which patient involvement is being considered. Many of these projects have short durations and, like innovative projects, are not integrated into the existing structure of the healthcare system. Systematic cooperation with patient organisations is generally not planned, which means that the full potential of possible patient participation is not exploited. Patient organisations are regularly consulted in the context of legislative and regulatory procedures. They regularly make use of the opportunity to comment, but it remains unclear whether these positions are read or taken

into account.

The Health Data Utilisation Act (GDNG) even provides for patient organisations to be able to conduct research with health data. However, the necessary resources are not made available to patient organisations to an appropriate extent.

The participation of patient organisations in digital health research and the associated challenges have increased significantly in recent years. This is reflected in many current research projects. As a rule, the participation of patient organisations is even made a condition of third-party-funded research.

However, the participants at the stakeholder conference recognise the problem that the forms of participation vary greatly. They range from preliminary stages of participation, such as a letter of intent without further involvement, to the role of the patient organisations as ‘test persons and data providers’, to comprehensive participation through co-determination, such as co-research. The reasons for a lack of participation include inadequate communication about the research objectives and conditions, a lack of clarity about the resources required for participation, and a lack of knowledge on the part of the patient organisations. In addition, limited voluntary resources and financial means are obstacles to successful participation in studies and research projects.

Demands:
To establish the necessary participation competence on all sides, barrier-free communication formats, concrete information exchanges and training measures are required between researchers and patient organisations. In this exchange, the specific problems of the patient organisation and the requirements placed on them by the research must be addressed. On the other hand, this also applies to the demands placed on them from a research perspective. Only a respectful and appreciative collaboration will enable the promising involvement of patient organisations for both sides.

Voluntary involvement in patient organisations must be understood in its specificity and variability (e.g. with regard to the competence of those affected, fluctuation, and illness-related restrictions). These results, among other things, show the need for additional specialist staff for patient organisations to participate in patient-centred research.

Real participation is only possible by consciously looking at compensating for the inequalities between research and patients and patient organisations.

For example, patient organisations are insufficiently (or not at all) involved in the evaluation of the results of studies and research projects. In the interests of the desired participation, this needs to be improved. The provision of target group-specific information on project modalities and expectations is also essential so that patient organisations can successfully make their contribution.

Participation in digital health research must be guaranteed barrier-free at all levels in accordance with the UN Convention on the Rights of Persons with Disabilities and the Disability Equality Act. In addition, in individual cases, there are people affected who do not have access to digital communication or for whom access is only possible to a limited extent for health reasons. Here, it is important to create appropriate, individualised and equal opportunities to overcome these obstacles.

Ideally, the scope of participation of patient organisations, patients and relatives should be clearly defined in advance. In addition, the framework conditions for all parties involved are fully discussed and mutually agreed upon. The possibilities of those involved are assessed individually and financial and organisational support from the researchers is included. This ensures that patient organisations, patients and their relatives are involved in all phases of the process. This also includes the co-determination of patient organisations regarding the subject of the research and the research question. Participation in partnership on an equal footing conveys mutual appreciation. Such participation is reflected, for example, in the involvement of patient organisations in decision-making bodies and advisory boards. The potential of patient organisations as co-researchers should be recognised and actively integrated into research concepts. Subjective knowledge ensures that the needs of patients are taken into consideration and supports the transfer of results into practice.

Guidelines and standards that regulate the participation of patient organisations, patients and relatives are desirable. Monitoring can ensure compliance with these rules.

Motivating and successful patient participation also requires target group-orientated preparation and communication of research results. Research projects that are supported by public

funds should also publish their findings in a way that is comprehensible to the general public. In summary, this means the desired research participation of patient organisations, patients and their relatives:

- Participation needs transparency and involvement from start to finish. The transparency required and to be established should permeate the entire process right through to the research results. It is important to involve patient organisations as early as the planning and formulation of the research question and application stage.
- Participation competence must be established on both sides. Appropriate resources, in terms of time, funding and personnel, must be ensured. This requires the empowerment of patient organisations and researchers.
- Access to research content must be guaranteed without barriers. The processing and research output must be comprehensible for all participants.

There is also a need for a support centre for patient organisations to provide advice on participation and to evaluate and further develop standards. This should be independent and permanently funded. Communication with patient organisations should always take place on an equal footing.

B. Information and consent processes in the context of digital health research

Current situation:
Patient sovereignty and informational self-determination are at risk.

Communication barriers in the healthcare system are very high for many patients, as a lot of written information is unstructured and not tailored to the target group. This applies in particular to the provision of information in clarification and consent processes. Many people currently find it considerably difficult to access and understand this information for various reasons (sensory impairments such as sight or hearing, cognitive and linguistic limitations and lack of digital skills). Patient organisations therefore play a crucial role as knowledge brokers. They support patients in making informed decisions.

However, patient organisations cannot address all the challenges faced by patients. Although the GDPR is intended to ensure the protection of personal rights, in particular health data, its

implementation poses an additional challenge in the digital transformation. Handling and legal instructions are very long and formulated in a very complex way. The focus is on legal protection, while insufficient attention is paid to the comprehensibility for patients. There is usually a significant information gap: in practice, this means that researchers and healthcare professionals have detailed knowledge, while patients often have to make decisions based on insufficient or incomprehensible information.

There are fears that the use and disclosure of the data collected are difficult to understand, that professionals involved (researchers, healthcare professionals) exchange information about patients' data without their consent and that patients' wishes are ignored in the process. Some patients feel that their needs are not taken seriously. Time pressure and cost aspects in research institutions (e.g. hospitals and university clinics) exacerbate this. There is therefore a risk that communication between those involved will be inhibited.

Demands:
The right to informational self-determination of patients derived from Article 1, Paragraph 1 of the German Basic Law also applies in the context of consent and clarification. The relationship between informational self-determination and the use of health data for scientific or research purposes should be balanced. Patients should remain the sole owners of their health data. This contradicts the newly introduced Health Data Utilisation Act (GDNG), which may still have to stand up to scrutiny by the Federal Constitutional Court.

Information and clarification must be prepared in a way that is understandable to laypeople, accessible at a low threshold, non-discriminatory and barrier-free. This should be achieved, for example, by using plain language. The information should be clearly structured and focussed on key facts. To ensure this, patient organisations should already be consulted during the creation, dissemination and communication phases.

From the patients' point of view, there are very heterogeneous needs with regard to the provision of their health data. An opt-out approach in the sense of broad consent is particularly difficult for people without prior knowledge. Others even demand an opt-in approach with regard to the respective purpose of use.

When the data is collected, patients must be provided with information about the type of

data, its intended use, data storage, data protection and data security.

Patients should be given sufficient time and support to familiarise themselves with the information. Clarification and consent should, if desired, be separated in time. It must be possible for everyone to object at any time without experiencing any disadvantages.

Responsibilities should be clearly defined in order to promote understanding and a relationship of trust between all those involved in the research process.

C. Research Management and Data Sharing

Current Situation:
The involvement of patient organisations in digital health research covers a broad spectrum. Data expertise is very heterogeneous in the many different patient organisations. There is often a lack of target group-orientated information. Some patient organisations have set up their own digital registers and promote their own research projects. Monitoring apps are also widespread, are sometimes co-initiated by patient organisations and could be put to good use for research. Potential misuse of data is a risk that must always be considered. The resources of non-profit organisations such as patient organisations that are based on voluntary work are limited and are generally not sufficient to develop the necessary digital skills independently.

Overall, from the perspective of patient organisations, there is a justified interest in a broader collection and consolidation of health data for research and patients. There is also a desire to promote participatory research with the aim to achieve patient-relevant and high-quality results more quickly.
There is a large number of heterogeneous, digital data collection and too few disease-specific registers. Cross-disease aspects and comorbidities are not sufficiently taken into account.

One problem with quantitative data, however, is that they tend to neglect aspects of patients' lives (such as living conditions and quality of life) and experiential knowledge. Patient Reported Outcomes as subjectively perceived and measurably documented health conditions are still too rarely collected as a quality indicator. Feedback on results from data-based

research, whether to patient organisations or individual patients, is often not provided.

AI is increasingly being used in data research projects. Despite its potential, the participants at the stakeholder conference recognise the risk that the derivation of results generated with AI may not be transparent.

In general, patients are often unable to understand how their data is used.

Demands:
Patient organisations should be systematically and substantially involved in data collection and research projects based on them from the outset. The involvement of patient organisations can significantly improve the quality of processes and results with regard to patient-oriented research (see also Section A). The prerequisite for the involvement of patient organisations is that they are supported professionally and in terms of money, personnel, structure and technology in accordance with their role. Only well-equipped patient organisations can play an independent and patient-empowering role. Patient organisations also need a legally protected right to external advice for their members on data-based research, IT security and data protection.

Trust in data-based digital research must be strengthened in a targeted manner. Patient organisations can make a valuable contribution here in particular.

Patient organisations must be involved at an early stage in the planning of data collection and surveys and in the further course of the project.

Data collection must be carried out according to internationally recognised interoperable standards (so-called FAIR criteria: findable, accessible, interoperable, and reusable). The international compatibility of registries is of great importance for patients, especially in the area of rare diseases.

To reduce potential risks, we specifically call for:
Overall, vulnerable groups must be given more attention than before. The dangers of stigmatisation and discrimination must be taken into consideration. They must be counteracted in a targeted manner.

As patients have very heterogeneous needs with regard to data donation, differentiated consent options are required. For example, there should be both ‘broad’ consent and targeted, problem-specific or sponsor-specific consent.

The willingness to donate data presupposes that the data is secure. Digital data collection must be aligned with the GDPR. Compliance with these security standards must be intensively monitored by an independent organisation in a transparent and comprehensible manner. The requirements of the GDPR regarding the possibility of inspecting stored data, recalling or deleting data and correcting data must be in compliance.

The social impact and ethical implications of the use of AI must be continuously evaluated with the systematic involvement of patient organisations.
From the outset, it must be explained to the patient organisations involved whether the intended research project is public welfare-oriented research or research with primarily commercial interests. This can be important for the patient organisations’ decision to participate in the research.

If companies use health data with a commercial interest, patients who donate their data or cooperating patient organisations should be able to benefit from this in the interests of the common good, for example through access to projects and results, patent freedom and open access.

D. Participating Patient Organisations

ACHSE e.V., ADHS Deutschland e.V., Adipositas Verband Deutschland e.V., Alopecia Areata Deutschland e.V., Arbeitsgemeinschaft Allergiekrankes Kind (AAK) e.V., Arbeitsgemeinschaft Spina Bifida und Hydrocephalus e.V., ARVC Selbsthilfe e.V., Borderline-Netzwerk / Lebenskünstler e.V., Bundesverband Osteoporose Deutschland e.V., Bundesverband Schädel-Hirnpatienten in Not e.V., Bundesverband Selbsthilfe Körperbehinderter e.V., CoganSyndrom e.V., Deutsche Alzheimer Gesellschaft e.V., DASH - Deutsche Angst-Hilfe e.V., Deutsche Gesellschaft für Muskelkranke e.V. (DGM), Deutsche Tinnitus-Liga e.V. (DTL), Deutscher Psoriasis-Bund e.V. (DPB), Deutscher Vitiligo-Bund e.V., Familienbund der Katholiken in der Diözese Würzburg e.V. – intakt.info, Frauenselbsthilfe Krebs Bundesverband e.V., Förderverein für Knochenmarktransplantation in Hamburg e.V. (KMT),

Haus der KrebsSelbsthilfe – Bundesverband e.V., K.I.M.M. e.V., Landesvereinigung Selbsthilfe Berlin e.V., Kopf-Hals-M.U.N.D.-Krebs e.V, Lymphselbsthilfe e.V., MigräneLiga e.V. Deutschland, Morbus Fabry Selbsthilfegruppe e.V., Morbus Osler Selbsthilfe e.V. – Morbus Osler Stiftung, Morbus Wilson e.V., Mukoviszidose e.V., Myelom Deutschland e.V., Narkolepsie Netzwerk e.V., PoTS Deutschland e.V. – Selbsthilfe für Dysautonomien, Pro Retina Deutschland e.V., Sarkoidose Selbsthilfe Schleswig-Holstein e.V., Selbsthilfeverein für Umweltgeschädigte e.V., Selbsthilfeorganisation Dystonie-und-Du e.V., TEB e.V. Selbsthilfe

E. List of Abbreviations and Glossary

GDPR	General Data Protection Regulation
AI	Artificial Intelligence

Definitions:

People affected	Anyone who has a chronic/hereditary disease, regardless of age, gender, or other criteria, as well as their family members and carers.

Definitions (continued)

Broad consent	General agreement to use health data for future research projects without having to obtain consent for each individual project, as opposed to informed consent, which is required for each specific study. Your YES can be withdrawn at any time.
Digital Transformation processes	Use of data and algorithmic systems for new or improved processes.
Digitalisation	Digital connection and networking of the real world as well as the sharing and processing of data. These can be used by several people at the same time and are highly scalable.
Letter of intent	Agreement in principle.
Open Access	Free access to scientific literature and other materials on the Internet.
Opt-in	Declaration of consent to receive data or to be contacted by a company/ organisation. The procedure is voluntary and must be actively confirmed by each person.
Opt-out	Refers to a procedure in which existing data records of customers or similar are automatically included in a list, service or data collection unless they actively object.
Participation	Active involvement of various interest groups in research projects to enrich purely scientific research with the perspective of patients, for example. This leads to the active involvement of all participants.
Patient Reported Outcomes	Evaluation of an intervention by the patient's subjective assessment.
Patient organisation	Patient representatives and self-help organisations. Self-organised associations of people with the same or similar illnesses with the purpose to jointly advocate for them.

Appendix

Appendix A: Information on the stakeholder conference of the PANDORA project

The stakeholder conference **'Shaping digital health research together'** was held in Hamburg on 3 and 4 June 2024 as part of the PANDORA project. Over 30 representatives of patient and self-help organisations from all over Germany took part both on site and digitally to develop a position paper on digital health research. The conference aimed to make digital health research patient-centred and to strengthen the voice of patients (www.pandora-forscht.de/stakeholder-conference).

Background:
The joint project 'PANDORA - Patient-oriented digitalisation' in health research and care is a cooperation between the Hamburg University of Applied Sciences (Prof. Sabine Wöhlke), the University Medical Center Göttingen (Prof. Claudia Wiesemann & Prof. Silke Schicktanz) and the Hannover Medical School (Prof. Marie-Luise Dierks) (www.pandora-forscht.de). A patient advisory board is actively involved. The research network focuses on research and care initiatives in which patient organisations are involved in a participatory manner. Funded by the Federal Ministry of Education and Research (BMBF), PANDORA is investigating the ethical and social implications of e-health and other digital research and care initiatives in the healthcare sector. Based on interviews, focus groups, a national survey and a stakeholder conference, relevant ethical issues relating to autonomy, trust and transparency are analysed from the perspective of patient organisations. The PANDORA project also aims to develop information formats, e.g. brochures or podcasts, to raise awareness of the ethical competence of patient organisations in the process of digitalising the healthcare system.

Stakeholder conference:
The PANDORA project offered the opportunity to hold a stakeholder conference in which patient organisations from Germany developed a position paper. A stakeholder conference is a discourse procedure that can be used to develop political positions with citizen participation (see www.praediadem.de).
More than 300 representatives of patient organisations were invited nationwide, of which more than 40 took part in the discourse process. To participate in the stakeholder conference, the patient organisations submitted a non-binding statement on the topics of secondary

data use, broad consent and participation in research projects. More than 30 patient organisations took part in the stakeholder conference in June 2024 to discuss various topics. In five working groups, the participants developed central core topics and derived demands as well as recommendations for digital health research. At the end of the conference, a draft position paper was produced containing the main concerns of the patient organisations.
During the conference, an editorial team was formed for the further development of the position paper, consisting of four representatives from different patient organisations. The team took over the further development of the position paper by formally revising the draft, taking great care to ensure that no new aspects were added.
The editorial team consisted of the following members (in alphabetical order):

- Thomas M. Duda, PRO Retina Foundation for the Prevention of Blindness Germany
- Hartmut Gartzke, ADHS Deutschland e.V.
- Wiebke Papenthin, Morbus Wilson e.V.
- Verena Winter, Lymphselbsthilfe e.V.

In September 2024, the revised position paper was sent to the participating patient organisations for a two-week comment and consolidation phase. The changes made by the editorial team were communicated transparently (all revisions were visible to the patient organisations). The editorial team then processed the feedback from this comment phase. The final position paper was signed and published by the participating patient organisations and presented to the public at a press conference in Berlin in November 2024.

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Prof. Dr. Silke Schicktanz
Institute of Ethics and History of Medicine, University Medical Center Göttingen

Federal Ministry of Education and Research

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