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Establishing Adaptive Governance in NFDI Consortia:

Lessons Learned from Deliberative Forums with Patients on their Role in the Governance of the German Human Genome-Phenome Archive (GHGA)

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1. Introduction

There is widespread support for patient and public involvement (PPI) as an ethical requirement in biomedical research and policy development [1, 2], including research using personal health data, such as genomic data [3]. Sharing genomic and other personal health data is important for progress in health research [4], but poses ethical, legal and societal challenges for the governance of research and the institutions that conduct and support it. These challenges arise in part from the varied interests of the stakeholders involved, including patients, researchers, and funders [5]. In recent years, there has been a rise in collaborations between research institutions that conduct joint research programs. In these research consortia, the objectives and stakeholders in research are multiplied and more varied, making governance even more complex [6]. There has been debate about strengths and weaknesses of different forms of governance of research, with proponents of adaptive governance highlighting its responsiveness and flexibility to evolving goals and needs of stakeholders [5, 7]. However, there are no set standards for involving patients in the governance of health research. Moreover, as it is a highly context-specific process, cultural, legal and social contexts of the individual institutions or consortia must be considered.

Within the German National Research Data Infrastructure (NFDI), there are consortia supporting research with personal health data, one of which is the German Human Genome-Phenome Archive (GHGA) [8]. We describe GHGA's PaGODA Project (Patient Involvement in the Governance of an Omics Data Archive), whose goals are to gather patients' views for their involvement in the governance of GHGA by conducting deliberative forums, and to implement these views. We focus here on the process of translating the findings from the forums into the GHGA governance policy, and identify procedural factors that were important for the process.

2. The deliberative Forums

In this participatory project, we have collaborated with two patient communities (cancer and rare diseases), represented by patient experts as co-researchers in study design, writing the study protocol, developing discussion guides, recruitment, and writing results.

In July 2022, we conducted two one-day long, online, live deliberative forums with 26 members of the cancer and rare diseases communities in Germany (Table 1) on ethical issues related to the operations and governance of GHGA. Deliberative forums are a qualitative research method in which participants are educated about a complex issue, which they then discuss with a focus on dialogue and understanding varied points of view [9]. The quality of the deliberative forums was assessed using a participant questionnaire, as well as a pre- and post-survey instrument to measure knowledge gain and opinion shift.

3. Translation of the participants‘ recommendations into GHGA policy

The question arises: How can the preferences expressed by the patients be concretely implemented in GHGA’s governance structure? The first step of the translation process was qualitative analysis of the forums, which was done using the framework approach [10, 11]. The results were summarized in a draft document in plain German, which was reviewed by GHGA members. The focus of this step was an assessment of the feasibility of participants’ recommendations as well as their potential impact on other stakeholders, especially data controllers, researchers, and funders. The document was adjusted to include this assessment, then sent to the forum participants to make sure that the report reflected what was said in the forums. We invited the forum participants to a consensus-building dialogue event with GHGA members in March 2023 to discuss issues from the forums where there was a divergence of opinion. 17 participants attended. The resolutions from the dialogue event were included in the document, which, after a second round of feedback from GHGA members, became the final white paper on patient involvement in the governance of GHGA.

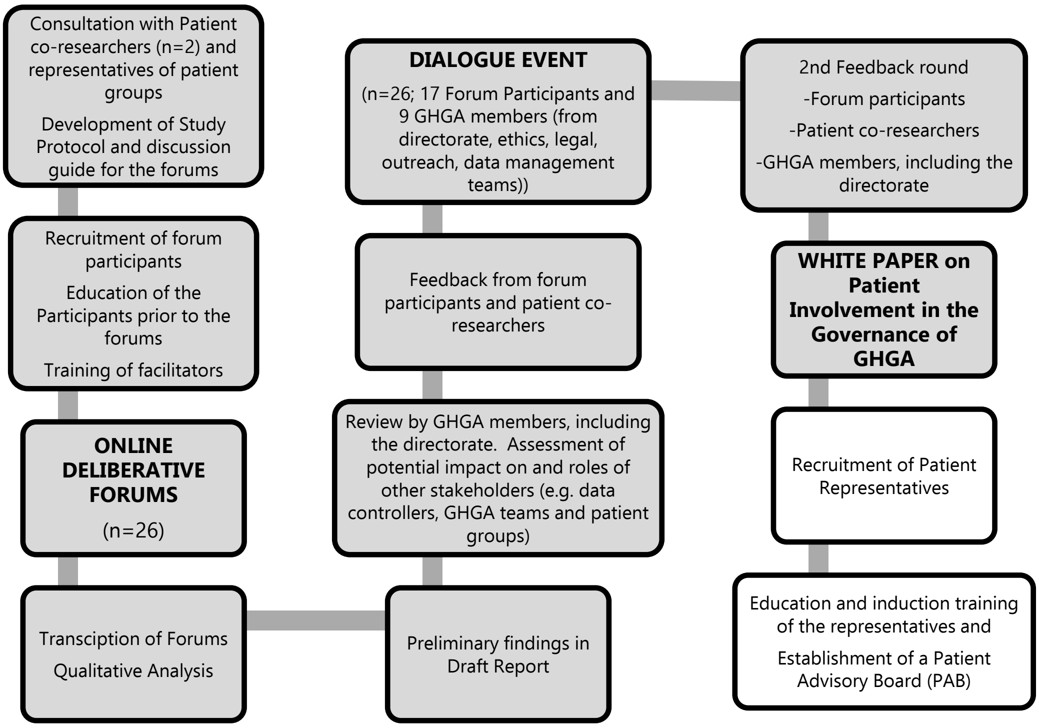

Figure 1. The steps of the PaGODA Participatory Project. The grey boxes indicate completed steps.

Table 1. Characteristics of participants of the dialogue forums.

Total number recruited	29
Did not participate due to illness	3
Forum participants	26
Male	8
Female	18
Disease category (more than one possible)	
Rare disease (RD)	10
Genetic predisposition for an RD	2
Cancer	7
Genetic predisposition for cancer	7
Relative of individual with RD	1
Representative of an RD Patient group	1
Age	
18-29	1
30-39	1
40-49	5
50-59	11
60-69	6
70-79	2
Level of Education	
Secondary school	6
Highschool diploma	6
College diploma	11
Doctorate	3

4. Results of the Translation Process

All topics on which there was a divergence of opinion among the participants were resolved during the dialogue event. Moreover, nearly all the overarching recommendations that were made by the forum participants were reflected or directly mentioned in the white paper. During the dialogue event, it was broadly agreed that a patient advisory board (PAB) consisting of patient representatives should be formed. A consensus was reached on the number of representatives, how they should be recruited, their roles, and whether they should be financially compensated. Concerning a recommendation pertaining to the GHGA data access procedures, potential impacts on data controllers were identified in the first feedback round. Possible roles of the data controllers in implementing the participants' recommendations were discussed and agreed upon in the dialogue event. Recommendations that were not reflected in the white paper were transparently discussed during the dialogue event to the satisfaction of all present.

5. Discussion and lessons learned: Key procedural factors that were necessary for implementation of participants' recommendations

Almost all the recommendations made by the patients in the deliberative forums will be reflected in the actual GHGA policy on governance. This is encouraging, as it has been previously observed that recommendations from deliberative exercises are rarely taken up into policy [12, 13]. Factors that contributed to this policy uptake [12] of the participants' recommendations into the white paper included: (i) Collaboration with patient co-researchers during the entire life-cycle of the project; (ii) Interdisciplinarity of the study team, which included expertise from ethics, medicine, philosophy, social sciences, and communications (iii) Attention to the framing of the goals of the project and of deliberation topics, taking into account legal and procedural constraints, and communicating these clearly to the participants; and (iv) Support of GHGA members and the leadership in feedback rounds and impact assessment. These factors should be considered by personal health data infrastructures and consortia aiming to implement adaptive governance frameworks that are responsive to the needs and perspectives of their stakeholders.

Competing interests

The authors have no conflicts of interest to declare.

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