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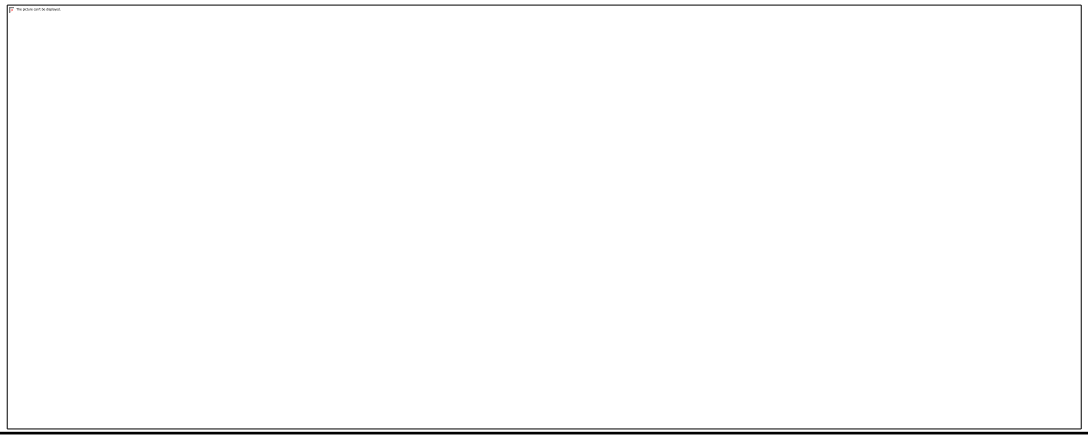
Patient Participation in Health Policy Making, Governance and Health Research: A Scoping Review



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Abstract

Introduction: At the end of the last millennium, patient movements started to demand to be involved in political decision making procedures affecting general healthcare service provision on the basis of representing patients' 'lived' experiences with the decisions. However, uncertainty prevails regarding how to achieve participatory best practices. Subsequently, this study examines what kind of activities and practices governmental institutions at the EU and German level have introduced to address patient participation, and what the current level of patient participation at these institutions is.

Methods: This study is based on a governmental document analysis paired with complementary expert interviews.

Results: Various activities were found at the examined institutions, though in general, the sector of health policy making and governance offers more participatory opportunities than the health research sector. The European Commission has recently adopted guidelines to improve stakeholder consultations and introduced the EU health policy platform. EMA has a longstanding history of extensive patient consultation through a standing working party. The German government mostly informally consults patient organizations during legislative procedures, but the corporative federal joint committee established a unit for patient representation and patients join all committee meetings on a strongly consultative basis. The German health research sector offers quite limited opportunities for patients to influence strategic of operational decisions.

Discussion: To improve the current status of patient participation, governmental bodies are encouraged to ensure active patient participation, broadly introduce public hearings, establish standing patient representations at central governmental institutions, and provide sufficient financial and structural support to patient organizations.

Key Words

Patient Participation – Health Policy Making – Health Research – Health Democracy – European Union – Germany

Word Count: 11,546

1. Introduction

During the pre-millennial decades, professional demarcation and low levels of health literacy in the broad population continued to prevent patients from participating in healthcare, irrespective of whether decisions concerned their own treatment, or health policy making and health research (Duffett, 2017). Societal groups operating in health-related fields have existed for multiple decades (Akrich, Nunes, Paterson & Rabeharisoa, 2008). Organizations such as self-help and empowerment groups, e.g. Alcoholics Anonymous, emerged in the 1940s, or, societal advocacy groups for individuals that were stigmatized or expelled from the community due to a medical condition emerged in the 1960s. Patient organizations flourishing in the 1980s and 1990s were characterized by their medical and experimental activism and motivated by a lack of therapeutic, societal and political attention to certain diseases. This covered, in particular, diseases such as rare conditions that were often not recognized as diseases, or HIV and malignant forms of cancer for which no satisfactory treatment was available, thus going beyond the scope of contemporary medicine. Patient activism generally follows three different objectives including the support of affected individuals, as well as raising awareness and exposing the "lived" experience with the disease among the population and in politics (Akrich et al., 2008).

Many groups felt the need to get involved in political discussions because care provision as well as the structural planning of care constituted a highly professionalized discipline influenced by a paternalistic political culture for most of modern medicine (Akrich et al., 2008). While the underlying democratic structures of European countries advanced enormously after World War II, it was not until the turn of the millennium that societal actors solicited the democratization of healthcare (Souliotis, Peppou et al., 2017; Moreira, 2014). The term democratization of healthcare refers to the formation of structures that let societal actors, e.g. patient representatives, sit at the table of political discussions and decision making, thereby affecting political development and programs through more than only general elections. International declarations applying to the European Union (EU), such as the Ljubljana Charter on Reforming Healthcare affirmed by the World Health Organization (WHO Europe, 1996), the Recommendation on Patient Participation adopted by the Council of Europe (2000), or the European Charter of Patients' Rights (Active Citizenship Network, 2002), acknowledge the voice of patients and endorse active citizen and patient participation in healthcare and health policy making.

1.1. Patient Participation, a Mean of Health Democracy?

Anchoring patient participation in the formal structures of healthcare serves several goals. The idea that patient participation is 'a positive thing' in itself, because it fulfills a democratic function, is often used as the moral basis of discussions about its consolidation in the healthcare sector (Conklin, Morris & Nolte, 2010; Souliotis, Agapidaki et al., 2017). Other proponents argue that patient participation legitimizes healthcare decisions (Abelson et al., 2003), fosters trust and confidence (Wiseman, Mooney, Berry & Tang, 2003) and opens a pathway for the inclusion of societal interests and values in healthcare decision making (Cleemput et al., 2015). Further, authors have found patient participation to enhance a healthcare system's responsiveness to the medical needs of the population (Moreira, 2014). Appropriate and responsive healthcare governance has been linked to improved healthcare service quality as well as augmented healthcare system effectiveness and efficiency (Hibbard & Greene, 2013). This is because patient participation assists the development of more purposeful healthcare arrangements and is likely to reduce misjudgment which contributes to cost containment while providing better care (Conklin, Morris & Nolte, 2010; Souliotis, Peppou et al., 2017). In addition, patient participation facilitates a valuable dialogue with experts that widens their understanding of patients' experiences and provides a platform for sharing constructive ideas (Cleemput et al., 2015). Patient participation also stimulates patients' understanding of the functioning of the national healthcare system, the complexity of reimbursement systems as well as other structural and provisional challenges (Souliotis, Agapidaki et al., 2017; Conklin, Morris & Nolte, 2010). All these factors are essential to establish what is commonly known as a 'patient-centered' healthcare system (Souliotis, Peppou et al., 2017). Several authors have argued that the provision of healthcare information and the subsequent empowerment of patients is crucial to enable effective patient participation, and only healthcare systems that involve patients can be deemed to provide 'patient-centered care' (Richards, Montori, Godlee, Lapsley & Paul, 2013; Constand, MacDermid, Dal Bello-Haas & Law, 2014).

1.2. Defining Patient Participation in Healthcare

Patient participation has been used synonymously with terms such as 'involvement', 'engagement', 'empowerment' or 'representation' (Conklin, Morris & Nolte, 2015). In general terms, patient participation in healthcare refers to patients contributing, in some degree, to decision making in settings directly or indirectly affecting healthcare service provision. Challenges of facilitating patient participation are the complexities of determining

a proper definition regarding its structural level, intensity and scope of application, as well as overcoming discrepancies in the understanding and interpretation of patient participation (Longtin et al., 2010). For instance, the Eurobarometer qualitative study on patient involvement demonstrates that often both the patients' side and the treatment providing side simply associated the concept of patient participation with medical compliance (European Commission, 2012a).

Commonly, there are three structural levels of a healthcare system. First, the micro levels at which patients and practitioners interact directly to discuss the patient's treatment. Second, the meso level at which patient participation can span from involvement in the governance of a healthcare institution, e.g. in form of a hospital's patients' committee, to patient engagement in regional politics, e.g. in the context of a regional health promotion campaign. Third, patient participation at macro level mostly refers to involvement in state, national or EU policy making. At the macro level in particular, the need for another distinction becomes apparent: differentiating between individual patient participation and collective patient participation. The latter further comprises two forms of participation, first, the cumulative involvement of a group of patients and, second, the representation of patients and their interest through an individual who may, but does not necessarily have to, be a patient him- or herself. Another difficulty relates to criteria of selecting patients or patient representatives for the duty of expressing the collective interests of the patients.

Intensity and scope of application describe two interconnected dimensions of patient participation which are subject to substantial interpretation in both theoretical academia and practical implementation (Ocloo & Matthews, 2016). In the context of this study, intensity refers to the level of participation in a decision making process and can be depicted as a spectrum, whereas the scope of application refers to the different tasks and types of decisions within an institution at any structural level that patients are involved in. Merely allowing patients to have access to information, e.g. about different treatment options at micro level or about the outcomes of committee meeting at macro level, defines the weakest level of participatory intensity; however, access to information is a prerequisite for active patient participation. The next steps on the intensity spectrum are consultation with patients regarding their opinion and concerns, e.g. in written or verbal form and as a one-time or repeated procedure, and cooperation with patients, e.g. in form of a continuous dialogue between patients and policy officers in the effort of drafting a new legislation. The highest level of

intensity is usually defined by shared decision making power and responsibility in strategic or operational decisions, though the power is rarely evenly distributed. The scope of application for engaging patients may include a variety of different matters. At the macro level, for instance, decision making procedures do not only address the development of new policies but also political agenda setting, fund allocation, program evaluation, or determining which entity sets the rules of procedure for patient participation in the course of different affairs or issues.

In this study, a broad and outcome-oriented definition is used declaring patient participation to be inherent in decision-making activities and practices when they are carried out 'with' or 'by' patients rather than 'to', 'about' or 'for' them (Caress et al., 2012). No restrictions regarding the individuals representing patients are provided, therefore, the terms 'patient' and 'patient representative are used interchangeably.

1.3. Filling the Gap

Despite the various endpoints described in the literature, gaps remain regarding how to achieve effective, evidence-based patient participation and what level of participation is appropriate in the variety of decision making settings (Cleemput et al., 2015; Conklin, Morris & Nolte, 2015; Ocloo & Matthews, 2016). On the basis of existing uncertainty about best practices, the aim of this study is to identify, and describe the current state of macro level activities (legislations, policies, strategies) at the German state and national level as well as at the EU level that promote, permit and facilitate patient participation in healthcare. This analysis is of an exploratory nature and intends to give a general overview of how, and the degree to which, state, national and EU politics address patient participation in the operating processes of healthcare policies, governance and heath research. The primary research objective is to compose a brief scoping review of the political and legal framework influencing patient participation in healthcare policy making, governance and health research in Germany and at EU level. The following research questions will guide the study:

- How do government-affiliated decision-making activities and practices at EU level and the German national and state level address patient participation in the fields of health policy making, governance and health research?
- What is the inherent level of patient participation in these decision-making activities and practices in the fields of health policy, governance and health research?

1.4. Context of this Study

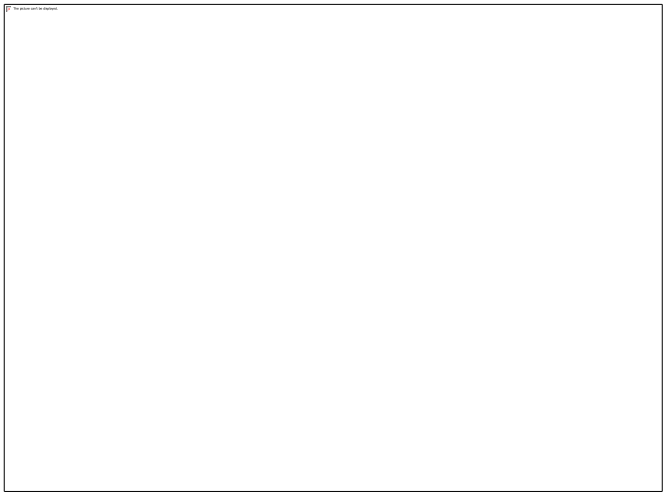

Figure 1: APPS Project Region.

This study is part of the multi-national research project 'Approche Patient Partenaire de Soins' (transl.: patient as a partner approach, hereafter 'APPS project') which aims to explore different ways of advancing the current paradigm shift regarding patients' role in healthcare. The APPS project is funded by EU Interreg VA of the Grande Region, and carried out in the border region of Lorraine (France), the Grand Duchy of Luxembourg, Wallonia (Belgium) and Rhineland-Palatinate and Saarland (Germany; see Figure 1). Although the APPS project mainly focuses on participation at lower levels, exploring patient participation at the macro level is justified by the interconnectedness of the levels. Participatory circumstances at the macro level may interact with developments at lower levels of the healthcare sector, and may influence the presence (and degree of implementation) or absence of patient participation at lower levels. While this study intends to examine the top-down activities supporting patient participation at all levels, it is recognized that patient participation might also have reached the macro level through bottom-up demands of patients and citizens and is therefore not a one-way street.

2. Theoretical Framework

A theoretical framework, named Health Ecosystem Patient Participation Continuum (hereafter 'HEPP Continuum') was composed in order to answer the research question about the level of patient participation found in existing government-affiliated activities and practices (see Figure 2). The framework is based on similar theoretical approaches, including Carman et al.'s Continuum of Engagement (2013) and Pomey et al.'s Advance Patient Engagement Continuum (2015). The previous frameworks were modified by adding a neutral participatory baseline, the horizontal level 'non-participation'. Unlike its predecessors, this framework differentiates the macro level into multiple sectors that influence health service provision to the patient. In Figure 2, the sectors 'health policy and governance', 'health research' and 'medical education' are listed, because they constitute the focus sectors of the APPS project, however, this study will only consider the sectors 'health policy and governance' and 'health research'. Carman et al. and Pomey et al. determined 'partnership' to be the highest level of patient participation. This framework employs a more tangible highest level, namely 'co-decision making'. While co-decision making can be determined by law, the framework's predecessors used the term 'partnership' which has an emotional component that cannot be dictated by the government. Several factors can influence the application of patient participation, such as the variety of decision-making domains ('decisive areas'), the way in which patient participation is enforced ('implementation') and other influencing factors addressing the characteristics of patient representatives and the hosting institution. These modifications were made to establish a framework that relies only on concrete indications of structural patient participation.

For this analysis of current activities and practices in the patient participation sphere, a focus was put particularly on any indications of government-affiliated procedures or regulations that allow for patient participation at the macro level. Therefore, an emphasis was laid on patient participation in institutional work procedures, e.g. through a standing patient committee that has to be consulted in predetermined circumstances, instead of a national strategic framework vaguely mentioning that practitioners should involve patients in their treatment. As this is a brief scoping review, attention is given to any field shaped by governmental decisions that affects patients. This includes areas, inter alia, agenda setting for politics and research, drafting of legislation, fund allocation, the existence of standing patients' committees or lack thereof, the development of health programs and campaigns, the evaluation of new treatment

options, the provision of publicly accessible information platforms, or the structural support of patient participation through e.g. financial compensation for patients working on macro level and other facilitators. Finally, multiple forms of implementation of patient participation were considered relevant for the investigation of current activities and practices in governmental structures.

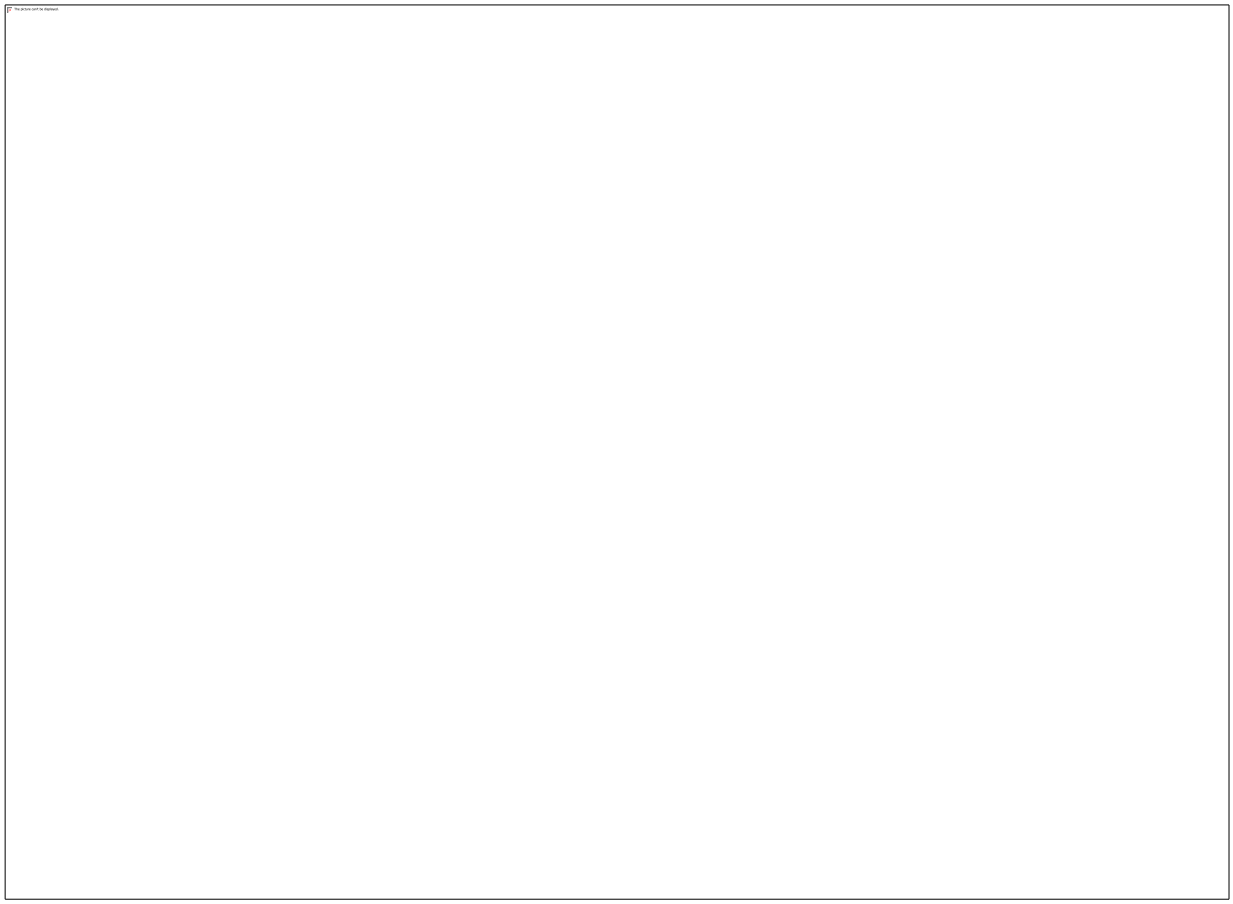

Figure 2: The Healthcare Ecosystem* Patient Participation (HEPP) Continuum.

** The framework's title includes the term 'healthcare ecosystem' because it emphasizes the larger systemic context in which healthcare services are delivered to patients. It is not claimed that the displayed sectors represent all components of a complex healthcare ecosystem.*

3. Methods

3.1. Study Design

In order to answer the main research question about existing governmental activities and practices that enhance patient participation at the macro level, this study consists of a document analysis and complementary, exploratory, semi-structured interviews with experts. This form of data triangulation was chosen to avoid examining government-affiliated activities and practices on patient participation that are only described in governmental sources. Instead, expert interviews are used as an additional source of realistic assessment and verification of the identified activities and practices.

3.2. Document Analysis

Investigations into the level of patient participation at German and EU level started out with an internet-based document search.

3.2.1. Document Search Strategy

Due to the fact that patient participation can appear in different forms and thematic areas as well as in underlying procedural structures of an institution, the search strategy was defined in a rather flexible and result-oriented manner. First, the following government-affiliated institutions were identified as relevant with respect to their influence on decision making in the fields of health policy, governance and health research at German and EU level.

- EU level: Commission (DG Santé, CHAFEA, DG RTD), Council of the EU, Council of Europe, European Medicines Agency
- German level: National Government, National Ministry of Health and subordinate institutes, Federal Joint Committee, National Ministry of Education and Research and subordinate institutes
- Federal level: Federal Government of Rhineland-Palatinate and Saarland and respective State Ministry of Health

Second, the websites of these institutions were systematically searched for essential documents. Due to the study's emphasis on governmental activities and practices regarding patient participation, the main but not exclusive focus of the internet-based search were types of documents such as hard policies (regulations and directives), soft policies (recommendations and conclusions), strategic frameworks, action plans, organizational

principles, position papers, rules of procedures, the existence or absence of institutional units for patient and citizen participation, governmental requirements (e.g. for funding), as well as campaigns and other initiatives. In addition, a snowball search strategy was used if a document referred to another relevant source. In order to ensure a systematic inspection, a form of log book was kept documenting the search through the multiple categories and subcategories of the institutions' websites to record the exact origin of each document.

Third, the collected relevant documents on EU level websites were examined for the terms '(patient) participation', '(patient) representation', '(patient) involvement', '(patient) empowerment', '(patient) engagement', '(patient) sovereignty', '(patient) consultation', '(patient) organization' as well as variations of the respective underlying word stem. Documents identified on the websites of German institutions were searched for the terms 'Patientenpartizipation', 'Patientenbeteiligung', 'Patientensoveränität', 'Patientenvertretung', 'Patientenorganisation' and 'Patientenfürsprecher', again considering variations of the respective word stem.

Finally, documents were selected if they either contained information on any level of patient participation, or constituted an important structural cornerstone that would be essential to frame and organize patient participation. Inclusion criteria therefore stretched to any document containing details about the current level and scope of patient participation in different forms of institutional activities in decisive areas of the domains health policy making, governance and health research at the macro level. Even the absence of structures providing for patient participation in decisive areas was seen as a value-adding indication. Exclusion criteria were any other domains, such as quality of care assessment, or regulations and procedures of committees exercising institutional task that specifically exclude the need for input on patient interests, such as purely scientific committees. The internet-based document search was carried out in March and April 2018. Figure 3 shows an overview of the document search and selection in form of a PRISMA scheme.

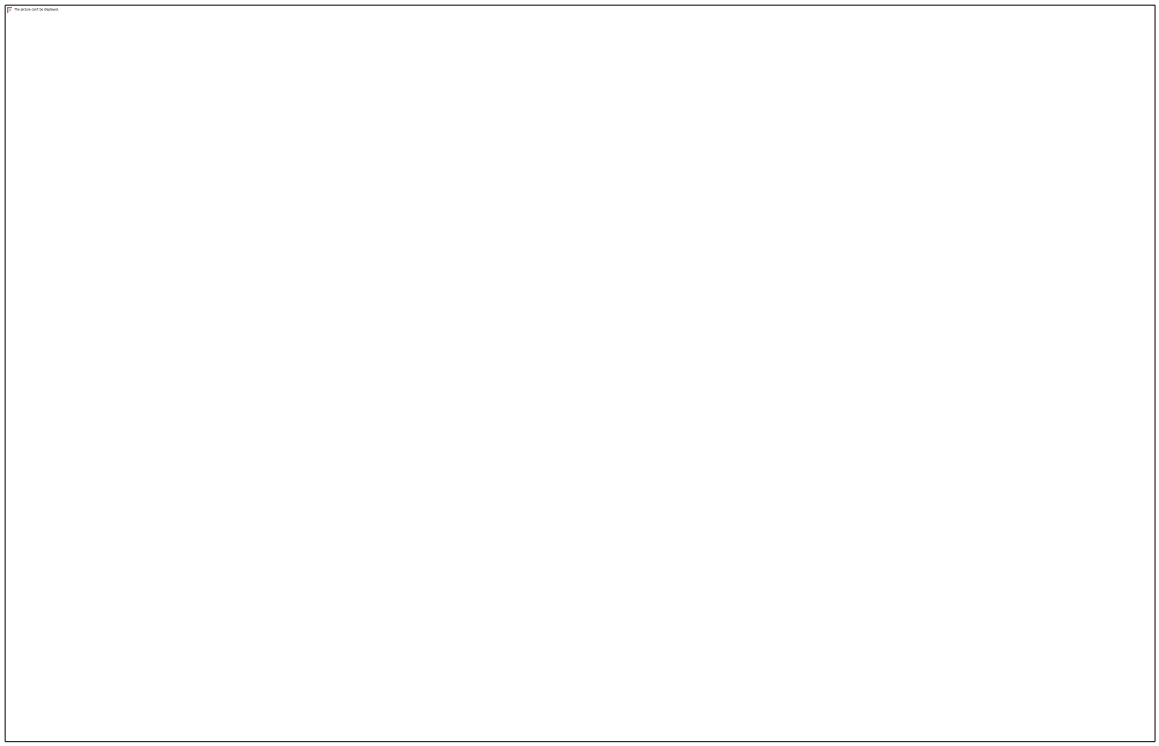

Figure 3: PRISMA Scheme.

3.2.2. Document Analysis Strategy

An overview of the collected documents was established and for each document, the following information was gathered: title, date of publication, publishing author or organization, type of document, classification hard or soft policy, internet link of the source, healthcare domain (health policy, governance, research, other), mentioning of patient participation – yes or no, estimation of the preliminary position on theoretical framework continuum, explanation for preliminary position, and finally, connected documents. The document overview assisted the clustering and the selection of all relevant documents based on their content, significance and respective implications for government-affiliated participatory activities and practices in health policy making, governance and research at the macro level. Further, the overview served as a brief preliminary assessment of the level of patient participation entailed in the respective governmental activities and practices. In order to classify the state of current affairs regarding patient participation in the examined institutions on German and EU level, the HEPP Continuum was used as a theoretical framework based on the framework approach described by Pope, Ziebland and Mays (2000).

3.3. Expert Interviews

Complementary, exploratory semi-structured interviews were conducted via the telephone during the course of this study. The reason for conducting complementary interviews was to

use data triangulation for the purpose of obtaining a more realistic assessment of current governmental activities and practices for patient participation as well as general results' validation.

3.3.1. Selection of Interview Partners

In line with Patton (2002) and Suri (2011), a purposeful sampling method was used to identify individuals that work in the examined governmental institutions on German and EU level as either patient representatives themselves or employees of an organizational unit dealing with patient participation in the respective institution. Potential interview partners were determined with the help of organizational charts and through contact information publicly published in reports as well as thematically related committee meetings or conference. All interview partners were given an information letter about this study to decide on their participation. Eight interviews with nine experts were conducted, thereby gaining insights from six institutions; an overview of the interview partners can be found in Appendix 1. Interviewees were asked to share their views and experience of the current implementation and level of patient participation at EU and German level.

3.3.2. Interview Guide and Informed Consent

A standardized, semi-structured interview guide was constructed on the basis of the predefined topics (Alshenqeeti, 2014), namely, 'development of patient participation', 'current level of patient participation' and 'barriers, facilitators and room for improvement'. For each topic, one or two standardized main questions were asked, and additional questions for a specific institution were formulated. To counteract sources of bias, extra effort was taken to ensure that questions were formulated in a clear, open-ended and non-suggestive manner (Alshenqueeti, 2014). For German speaking interviewees, the interview guide was translated into German using the forward-backward translation method, carried out by a German native speaker with proficient knowledge of the English language (Guillemin, Bombardier & Beaton, 1993). Consent was sought verbally at the beginning of the telephone interview. The interview partners were given sufficient time and information in advance as well as at the beginning of the telephone interview to make an informed decision about participating in this study. Provided information included clearly stating the study context, its purpose, aim, and the procedure of the interview. Also, measures of confidentiality and anonymity as well as the study's voluntary and financially uncompensated nature were discussed. Participants' questions were solicited, they were provided with contact information and obtaining their

verbal consent was documented (Salkind, 2010). The interview guide including the telephone script for obtaining the interviewees' verbal consent can be found in Appendix 2. The telephone interviews took place in May and June of 2018, approximately 30 minutes, and were recorded to ensure data accuracy.

After each interview, an interview report was composed including general notes and entire quotes from the interview. For the purpose member checking, the interview report was sent to the respective interviewee to ensure that the obtained information was correct and in line with the statement intention (Birt, Scott, Cavers, Campbell & Walter, 2016). In the post-interview exchange, interview partners were again asked about the level of anonymity they would want to be applied to their information. All nine interviewed experts returned the interview report with additional remarks; therefore, complete respondent validation can be claimed.

3.3.3. Interview Analysis Strategy

The content of the interviews was compared to findings of the document analysis and used to round up the scoping review of patient participation in health policy making, governance and health research at the macro level. The HEPP Continuum was used to classify the level of patient participation at the different institutions analyzed.

4. Results

In order to answer the research question on how and what kind of government-affiliated activities and practices address patient participation, Section 4.1. provides an introductory brief sketch of the analyzed institutions on EU level and in Germany. Section 4.2 addresses the opportunities for patients to participate in health policy making and governance at the EU level, and Section 4.3. concerns patient participation in German health policy making and governance. Finally, Section 4.4. elaborates on the extent to which patients are involved in core activities of research, again, at the EU and German level. The analysis of existing participatory activities and practices in the domains health policy making and governance as well as health research was carried out in accordance with the HEPP Continuum as the underlying theoretical framework.

4.1. Institutions

Though they vary in their scope of application and intensity, participatory opportunities for patients are in place in the procedures of decision making in healthcare policy making, governance and health research at the EU level as well as at the German national and state level. Figure 4 gives an overview of the analyzed institutions divided by sector.

Figure 4 is not a comprehensive schematic illustration of all interacting institutions that play a role in decision making procedures in the sectors of health policy, governance and research at EU and German level. At the EU level, the EU institutional triangle comprises the European Parliament, the Council of the EU and the European Commission; the first two being the legislative organs of the EU, based on the Ordinary Legislative Procedure (Greer et al., 2014). The European Commission has the right to initiate policy proposals and to draft them within the respective thematic Directorate General (DG), depending on the subject matter of the policy. With regard to patient participation in health policy, governance and research, this study focuses on the DG for health and food safety (DG Santé) and the DG for research and innovation (DG RTD). Additionally, the Commission and its DG's enforce the implementation of EU policies and other activities. For this purpose, DG's are assisted by executive agencies, such as the Executive Agency for Consumers, Health, Agriculture and Food (CHAFEA). The final relevant EU institution is the European Medicines Agency (EMA), which coordinates the authorization of pharmaceutical products. EMA also operates in the general field of medicinal research and collaborates with patient organizations –

historically, in the context of medicines for rare diseases, though the participatory scope has been broadened (Greer et al., 2014).

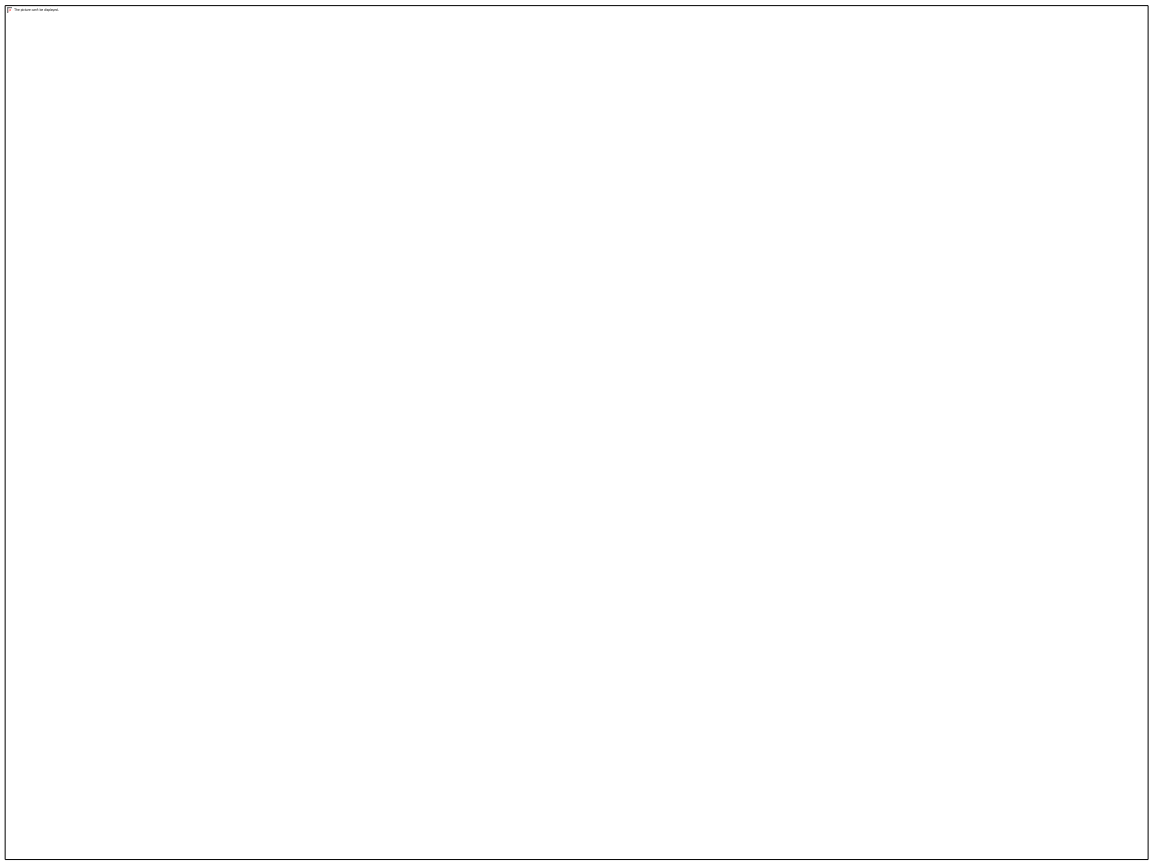

Figure 4: A brief overview of the analyzed institutions that influence decisions in the sectors of health policy making, governance and health research at the EU level, German national and German state level.

** at EU level: The European Commission's DG Santé (Directorate General for Health and Food Safety), DG RTD (Directorate General for Research and Innovation) and CHAFEA (Consumers, Health, Agriculture and Food Executive Agency); EMA (European Medicines Agency).*

*** at German national level: BMG ('Bundesministerium für Gesundheit', transl.: national ministry of health); GBA ('Gemeinsamer Bundesausschuss', transl.: federal joint committee); associated institutes include PEI ('Paul Ehrlich Institut'), BfArM ('Bundesinstitut für Arzneimittel und Medizinprodukte', transl.: national institute for medicinal products and medical devices), IQWiG ('Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen', transl.: institute for quality and cost-efficiency in healthcare), IQTiG ('Institut für Qualitätssicherung und Transparenz im Gesundheitswesen', transl.: institute for quality assurance and transparency in healthcare), and the agency of the commissioner for patients' affairs of the national government ('Geschäftsstelle des Patientenbeauftragten der*

Bundesregierung'); BMBF ('Bundesministerium für Bildung und Forschung', transl.: national ministry of education and research).
**** at German state level: the governments of the states Rhineland-Palatinate and Saarland, with their respective state ministry of health, namely, the 'Ministerium für Soziales, Arbeit, Gesundheit und Demographie' (transl.: state ministry of social matters, employment, health and demography) in Rhineland-Palatinate and the 'Ministerium für Soziales, Gesundheit, Frauen und Familie' (transl.: state ministry of social matters, health, women and family) in Saarland.*

In Germany, decisions in health policy, governance and health research are influenced by the composition and political focus of the current national government, which is organized into different ministries, inter alia, the national ministry of health (BMG) and the national ministry of education and research (BMBF). The latter structures the financing of health research, thereby exercising power on the focus and design of health research. Germany is a federal republic, therefore legislative authority is individually granted to the governments of the sixteen federal states, unless overruled by national regulation (Busse & Blümel, 2014). Matters regarding the administration and organization of the healthcare system are bound to multiple national requirements; however, the states are involved in the national legislative procedures through the federal council ('Bundesrat'), the other legislative body being the German parliament ('Bundestag'). While the German government sets general regulations, the national healthcare system is substantially shaped by the self-governed federal joint committee (GBA). This corporative committee is composed of the coalitions of medical practitioners, dentists, hospitals and health insurances (Busse & Blümel, 2014) which collectively decide on the organization, requirements and benefit coverage of social health insurance schemes. Further, the committee establishes provisions for medical, dental, ambulatory and palliative care, hospital care and planning, medicinal and treatment prescriptions, and other matters of healthcare such as quality assurance or immunization (Busse & Blümel, 2014).

4.2. Patient Participation in EU Health Policy Making and Governance

Within the EU, healthcare is a matter of Member State competence based on the subsidiarity principle (European Union, 2012), meaning the EU cannot legally require Member States to establish any national framework for patient participation in health policy making or governance. However, following Article 168 of the Treaty of the Functioning of the European

Union, the EU may implement supportive and complementary activities to ensure "a high level of human health protection" for European citizens (European Union, 2007, p. 122). With its origin being of rather economic nature, the Union is still predominantly shaped by international trade and industrial goals that echo in its current strategic framework, namely Europe 2020 strategy (European Commission, 2010). Despite the economic emphasis, the Commission interweaved some preoccupation with health matters as an indirect EU duty, based on the argument that health and human well-being is a prerequisite for a strong European workforce and a society capable of attaining economic growth and prosperity.

Even though the Commission does not have the competence to demand patient participation in national healthcare matters, the institution itself has taken measures to ensure patient and stakeholder participation during "in-house" operations. For the purpose of attaining better policy outcomes, the Commission introduced the Better Regulation Guidelines, a scheme assisting the development and appraisal of EU policies and initiatives (European Commission, 2015a). One of the six guidelines foresees extensive and frequent stakeholder consultations for all legislative activities and program assessments (European Commission 2015b). Therein, stakeholders are described as entities who are either directly influenced by the policy, responsible for its implementation, or showed interest in the initiative otherwise. Minimal requirements for stakeholder consultations in respective activities of the Commission include the development of a stakeholder consultation strategy and program assessment plan a priori of the implementation of the activity or initiative. In addition, the consultation strategy is expected to already provide stakeholders with an opportunity to submit feedback on the consultation strategy proposal. Consultation with relevant stakeholders must be completed in at least English, French and German, and, in addition to the consultation of selected relevant stakeholders, the public needs to be consulted for a minimum period of 12 weeks on an internet-based platform. The consultation strategy of each activity or initiative requires approval of a Commission-affiliated work unit (European Commission, 2015b). Based on the HEPP Continuum, internal policy making and program evaluation procedures with the Commission and thus with DG Santé involve patients and patient organizations in a strong consultative manner, though not in form of a standing representation.

In accordance with these guidelines, the Strategic Plan 2016-2020 of DG Santé demonstrates the Commission's ambition to broaden stakeholder consultation. For the purpose of structuring consultation procedures in the field of health, the EU Health Policy Platform was

established specifically to enhance "the dialogue with health stakeholders" (European Commission, 2016a, p.8) and to facilitate "regular meetings with health stakeholders" (p.8). The digital platform allows health stakeholders, e.g. patient organizations, to collaborate with like-minded organizations on the preparation of joint statements, create thematic networks and start discussions or polls that will be submitted to the Commission (European Commission, 2016b; European Commission, n.d.). In addition to this written form of consultation, which is not financially compensated by the Commission, DG Santé hosts bi-annual round table discussions with key stakeholders (European Commission, 2016b). Considering the theoretical framework, DG Santé offers patient organizations the opportunity to consult in policy making and structurally supports their work and exchange by providing a digital platform which constitutes a fair approach to continuous patient consultation despite the thematic diversity and geographic dispersion of the different stakeholders in the project-like nature of Commission activities. While the platform improved collaboration and information-sharing among patient groups (European Commission, n.d.), it remains unclear how much impact the input of stakeholders has on EU policies and if and when the Commission is obligated to act upon such kind of bottom-up requests of health stakeholders. The lack of financial compensation on the platform is deemed unfavorable.

In line with the overall EU strategy (European Commission, 2010), the Commission has implemented a series of supportive framework programs in the field of health, namely the first health program 2003-2008 (European Parliament & Council, 2002), the second health program, also called the EU health strategy 2008-2013 (European Parliament & Council, 2007), and currently, the third health program 2014-2020 (European Parliament & Council, 2014). In short, it is a financing instrument with a budget of nearly €450 million to co-finance projects aiming to improve citizen health, enhance health systems, widen access to healthcare, or protect the Union from transnational health threats (European Parliament & Council, 2014). One objective of the series is to advance the dissemination of health information among the public and the involvement of patients in healthcare. Patients are not fundamentally involved in all projects, but projects in the field of health promotion and participation, which receive funds from the health program, have to ensure that project partners inform and consult with, inter alia, patient organizations at the community level (European Parliament & Council, 2002). In addition, the second health program pushed for participatory advancement by explicitly calling for projects investigating best practices of

sharing information with health stakeholders and establishing consultation mechanisms and other engagement procedures in healthcare (European Parliament & Council, 2007).

The policy framework of the health program is drafted by DG Santé in a lengthy process during which many different stakeholders, including patients and patient organizations, are formally or informally consulted by the Commission with regard to priority setting (Interview 2). An interview partner states that "for all [health-related] topics, it is very important to get at least the opinion of patients, [this is] the reason why it is important to support patient organizations". For this reason, the funding mechanism 'operating grant' was introduced during the second health program to specifically support activities of patient organizations (Interview 2). Once the framework is adopted, it is the duty of CHAFEA to achieve the propositions of the Commission. CHAFEA issues calls for project proposals and manages the fund allocation and implementation and the projects. This agency is more involved in the governance of the health program and is not in the focus of this analysis of patient participation in decision making procedures as the agenda for the health program is set by the Commission. However, CHAFEA could still improve their participatory activities by consulting with thematically relevant patient organizations on a case-to-case basis in the context of drafting calls for proposals for projects that directly affect patients in healthcare.

The consultation of patients in the context of the third health program has been broadened by a mandatory mid-term evaluation including an open public consultation program (European Commission, 2017a; European Commission, 2017b). In accordance with the Better Regulation Guidelines, DG Santé carried out a mid-term evaluation of the third health program between November 2016 and February 2017, giving citizens, patients and healthcare professionals the opportunity to express their views on the state of implementation, the thematic focus and resource allocation of the third health program. 11% of 133 respondents were patients and health service users who expressed general satisfaction with the program and wished to expand the involvement of the EU in healthcare matters. Theoretically, every EU citizen could have participated in this open public consultation, but fifteen patients and health service users do not precisely represent the collective body of European patients. In the full mid-term evaluation report, the Commission uses the positive feedback of the public consultation as a mean of legitimacy for continued EU activities in the field of health. Even though this is in the interest of patients, the inference is weak and further action should be taken to reach more patients.

A further multinational activity taken on by DG Santé is guiding EU wide assessment programs in the fields of health system performance (HSPA) and health technology (HTA) which are procedures benefitting from cross-border collaboration, thus falling under EU competence. The expert group on HSPA established by the Commission in 2014 aims to issue recommendations for Member States regarding activities that enhance the performance of national healthcare systems. Following the group's rules of procedure, patient representatives and other stakeholders might only join the meeting as invited observers (European Commission, 2017c). Similar practices are in place at the network for the national HTA authorities called EUnetHTA (European Commission, 2013a). The rules of procedure of EUnetHTA state that stakeholders, including patient representatives, may join meetings strictly as observers with no voting right. Public consultations may be requested by the network in "duly justified circumstances […] such as in decision's impact on public health" (European Commission, 2016c, p.4). Overall, the network aims to establish reliable and transferable knowledge for health technologies through Member State cooperation, so to have a common EU-wide standard and reduced assessment duplication. The purpose of assessments is therefore rather scientific and technological, hence, the HTA network strategy describes involved stakeholders as having to be "associated with both the strategic and the scientific-technical level" (European Commission, 2014a, p. 15). However, the benefit of patient participation is characterized by patient experiences with e.g. medical procedures, which is a relevant applicatory factor. As a patient advocate on European level puts it: "I can add to [the discussion] with what I have available, and that's my experience with the healthcare system and what it means for my life and what I think is acceptable" (Interview 5).

Reports published by the HSPA expert group even refer to the importance of patient engagement in order to successfully implement governmental programs (European Commission, 2016d; European Commission, 2017d). In practice, patients have no active opportunities to add their views to the discussion, which contradicts the Commission's general position on patient participation during "in-house" activities. Patient organizations solely participate on a meager informative basis in the HSPA and HTA network meetings, as determined on the basis of the HEPP Continuum. However, at the beginning of 2018, the Commission issued a proposal for an EU regulation on HTA that foresees the establishment of procedural rules including the consultation of patients and patient organizations for joint clinical and joint scientific assessments (European Commission, 2018). The coordination group of the HTA network shall further consult with patient organizations before formulating

the priorities of the annual work program. While not yet adopted, the Commission's proposal indicates the growing importance of patient participation in EU health activities in line with the Better Regulation Guidelines (European Commission, 2015b).

In addition to macro level policy making activities that influence patient participation at the macro level, there are also macro level activities that affect patient participation at lower levels. The EU Directive 2011/24 on the Application of Patients' Rights in Cross Border Healthcare is one of the few legislative acts on EU level directly addressing the role of patients in healthcare (European Parliament & Council, 2011). The directive requires, inter alia, healthcare service providers, e.g. insurance companies, hospitals, and healthcare professionals, to disclose relevant information to patients regarding their diagnosis, treatment options or reimbursement arrangements in a cross-border context. Adopting the EU Directive at the national level had the effect that international patients would have had more rights by law than national patients which induced national governments to expand patients' rights in general, including the right to information (European Commission, 2016e). Regarding patient participation, on the HEPP Continuum the Directive theoretically achieved the universal implementation of the first, but passive, level of patient participation in healthcare: access to information.

Due to the lack of direct competence in the field of healthcare, the EU uses soft policies to steer national approaches to operationalize, in this instance, patient participation. The Council Recommendation on Patient Safety advises Member States to engage patient organizations in policy making procedures and in the outlining of programs for patient safety (Council of the EU, 2009). Patients' interest in and perception of the issue is crucial to adopting efficient provisions and cannot be elicited otherwise but through some form of dialogue. Similarly, the Commission Communication on Effective, Accessible and Resilient Health Systems encourages Member States to use patient input, e.g. experience and interests, as a valuable factor for continuous governmental efforts to improve the national healthcare system (European Commission, 2014b). Therein, patients may propose constructive ideas for a legislative emphasis as well as practical matters. The Council Conclusions towards Modern, Responsive and Sustainable Health Systems represent an interesting case of soft EU policies. The original document published in 2011 did not mention patient participation as a beneficial approach for healthcare system improvement (Council of the EU, 2011), whereas the revised version published in 2013 encourages Member States to involve patient organizations in the

process of policy making and program planning for integrated care (Council of the EU, 2013a). Lastly, the eHealth Action Plan 2012-2020 aims to empower patients through digital solutions and patients were consulted during the development of the action plan (European Commission 2012b). Although these soft policies are not binding to Member States, they indicate the EU's preoccupation with patient participation and its benefits for healthcare around Europe.

Ever since its first activities in the 1990s, the European Medicines Agency (EMA) has put an emphasis on active participation of patients (Interview1). EMA's core task is the enforcement of a centralized market authorization procedure for medicinal products within the EU single market (EMA, n.d.). For the purpose of a standardized, high-quality procedure, EMA also encourages pharmaceutical innovation and exercises supporting tasks during the primary testing of medicine in clinical trials as well as during post-evaluation procedures. The legal basis of the agency, EU Regulation 726/2004, foresees that not only the management board of EMA but also all committees working with human medicinal products to "establish contacts, on an advisory basis, with parties concerned with the use of medicinal products, in particular patient organizations" (European Parliament & Council, 2004, p.64). To do justice to their advisory role, EMA adopted a Framework for Interaction between EMA and Patients and Consumers and their Organizations in 2005, which has been revised in 2009 and 2014 indicating the consistent preoccupation with patient participation (EMA, 2014). Further, in 2006, EMA established the standing Patients' and Consumers' Working Party (PCWP) that delegates patient representatives to be engaged in "all matters of direct or indirect interest to patients in relation to medicinal products" (EMA, 2016, p. 2), which effectively covers all areas of EMA. The agency receives high praise from their patient representatives for the Interaction Framework which has been co-developed by patients, calling EMA "an excellent model for patient engagement" (Interview 1).

A crucial factor of patient participation at EMA is that all patient representatives are patients themselves, therefore immensely able to speak for patients and their experiences with healthcare (Interview 3). One patient representative points out: "[Patients] have the tendency to look at 'what does this medicine mean for my daily life', while we see that for instance for regulators mortality is often the most important factor. But patients say 'I accept the risk of early mortality if I have a lot of benefits from the medicine'" (Interview 5). All three interviewed patient representatives agree that EMA has managed to not only built

participatory structures but also a culture that values patient input with regard to the assessment of medicinal products. The delegation of patients to participate in committee meetings is possible due to the PCWP's patient database that registers patients – individually or as affiliated with an organization – which are eager to represent patients' experiences with medicinal products in front of a committee (Interview 3). A patient advocate explains that "every time there is a request for a scientific advice [in my field], EMA sends the confidential document to one of my colleague, she reads it and if she thinks there should be a patient in the discussion, we can propose patients from out database to go to the meetings" and "often, when we cannot find a patient, the first thing that the EMA experts say at the beginning [of the meeting is] 'it's really a pity we don't have a patient [here]'" (Interview 1). This indicates that EMA is not only concerned with creating formal opportunities for patient participation but also want patients to have a real impact during decisions, therefore positioning the level of inherent patient participation between consultation and co-development on the HEPP Continuum. When asked about current shortcomings of the overall progressive participatory system, patient representatives endorsed public hearings in all areas to at least provide information on the occurring scientific discussions as only a couple of patient representatives are allowed per meeting (Interview 1). Further, the importance of strengthening patient participation in core research activities was mentioned (Interview 3).

4.3. Patient Participation in German Health Policy Making and Governance

With respect to the national government's focus on patient (or civil) participation, the current coalition agreement (2017-2020) declares "patient well-being is a crucial factor for health political decisions, and patient-centered care is the guiding principle of our healthcare system" (German Government, 2018, p. 95). Experts in the field see this as an announcement by the government wanting to apply patient-oriented procedures throughout health policy making, though they recognize the vagueness of the statement (Interview 6). National provisions mainly address patient participation at the individual level and predominantly involve information availability for patients as information and knowledge are needed to empower individual patients during their encounter with the healthcare system. This is why the current government foresees the establishment of a National Health Portal (Nationales Gesundheitsportal) in order to widen the digital accessibility of healthcare system information for citizens and patients. Regarding patient – or even just civil society – participation in policy making, the government has announced the formation of an expert committee in charge of developing approaches to endorse democratic structures by means of public participation in

policy making processes (German Government, 2018). It remains unclear who the members of this expert committee will be; nevertheless, the initiative demonstrates the government's interest in widening participatory processes for policy making of all fields. Several interview partners mentioned that a lot of unofficial patient consultations take place in German health policy making procedures which are only anchored in informal practices (Interview 6; Interview 8).

Even though the BMG does not operate its own unit of patient representation or some other platform for patients' input, it works closely with the independent agency of the commissioner for patients' affairs of the national government (Patientenbeauftragte der Bundesregierung). Founded in 2003, the main function of the commissioner is to advocate patients' interest to the government and to protect patients' rights to care and information (German Government, 2003). One expert from the agency explains: "The commissioner needs to be involved by all federal ministries in the drafting procedures of laws and regulations and all activities that affect patients. Simultaneously, patients can reach out to the commissioner and point out shortcomings in the healthcare system, which we then try to find a solution for" (Interview 6). This could entail a suggestion for a legislative change, but often an official letter to the institution in question can set the record straight. The experts disclose that patient participation at the BMG and at the agency of the commissioner for patients' affairs is mainly carried out by continuous but informal consultations with patient organizations when it comes to the preparation of legislative activities (Interview 6). Due to the informal nature of patient participation it is difficult to evaluate the exact level, or rather, intensity of the consultations on the HEPP Continuum. The interview partners all agreed that the acknowledgement of including patient representatives as experts for patient experiences in political discussions has positively developed since its first introduction in 2003 (Interview 6; Interview 7; Interview 8).

In addition to the BMG, the Federal Joint Committee (Gemeinsamer Bundesausschuss, hereafter 'GBA') substantially shapes the German healthcare system (BMG, n.d.), hence often called the "small healthcare legislator" (Interview 6). The GBA is organized into nine subcommittees each focusing on a different thematic focus of healthcare service provision and reimbursement (GBA, n.d.). By law, patient representation is mandatory during the all meetings of all subcommittees of the GBA, and legislative regulations are in place specifically defining the characteristics of patient organizations eligible to participate, which

e.g. prohibits a healthcare professional from acting as a patient representative, or determines that at least 50% of patient representatives should have a medical condition themselves (BMJV, 2003; Interview 8). At the GBA, patient representatives are given the right to co-develop proposals (Mitberatungsrecht) and the right to propose changes regarding the service inclusion into the benefits catalogue (Antragsrecht); however, patient representatives do not have the right to vote in decisions of the subcommittees (GBA, 2018a; GBA, 2018b). Whether or not patient representatives should be granted the right to vote is continuously being discussed, but one expert explains that the right to co-development and proposal right are much more important from the patient representatives side "because we are able to force the decision makers (representatives of healthcare professionals, healthcare service providers and insurance companies) to address our arguments. Fortunately, all meetings are public which puts the decision makers under pressure because they cannot simply say 'not interested in your opinion' or 'we do not care what you think' but instead have to address our concerns" (Inteview 8).

This classifies the GBA as an institution facilitating patient participation to the extent of co-development on the theoretical Continuum. In order to support and structure the work of patient representatives, an independent unit for patient representation (Stabstelle Patientenvertretung) with its own coordination board (Koordinierungsausschuss) was established at the GBA in 2008 (German Government, 2007). Four patient organizations are permanently represented in the board and legislative requirements are in place to regulate the criteria for eligible organizations (BMJV, 2003). Approximately 220 patient representatives from several patient organizations – many of them voluntarily – represent patients' interests in the meetings of the GBA's subcommittees. Further governmental activities to support and facilitate patient participation at the national level include financial compensation for their work and travel expenses, as well as a budget for trainings which is carried out by the unit of patient participation. However, experts raise concerns about the sufficiency of these activities, because most organizations finance themselves through donations and membership contributions and may be inclined to accept funds from the industry, thereby reducing their independence (Interview 6). They argue that in order for patient organizations to perform the growing tasks and responsibilities at the national and state level, it is worth considering to introduce some form of basic funding for patient organizations. A patient representative argues: "Regarding the federal support, we would appreciate if especially patient organizations that nominate and coach new patient representatives received more federal

support. When looking at the enormous amount of resources made available to the coalitions of healthcare professionals or insurance companies, it becomes apparent that some form of adjustment is needed" (Interview 8). This critique needs to be considered in the context of the growing expectations and responsibilities of patient representatives who are supposed to speak for patients but also need to be able to follow technical, medical or legal discussions, hence, need additional qualifications (Interview 8).

National institutes support the decision making procedures of the BMG and GBA with their thematic assessments making them a relevant platform for patient input. The Paul-Ehrlich-Institute for vaccines and bio-medicinal products and the National Institute for Medicinal Products and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, hereafter 'BfArM') for pharmaceutical market authorization, two rather scientific institutes working in close cooperation with EMA, organized a meeting with patient representatives to discuss opportunities of future cooperation, according to a press release in 2015 (BfArM, 2015). In mid 2018, when this study was conducted, the websites of the two institutions did not give any further indication for the intended collaboration with patient representatives. Hence, without any inside knowledge about the participatory practices of the two institutes, their given level of patient participation remains at a merely informative state on the HEPP Continuum. In contrast, the National Institute for Quality and Cost Efficiency in Healthcare (Institute für Qualität und Wirtschaftlichkeit im Gesundheitswesen, hereafter 'IQWiG') and the National Institute for Quality Assurance and Transparency in Healthcare (Institut für Qualitätssicherung und Transparenz im Gesundheitswesen, hereafter 'IQTiG') have introduced procedures to involve patients. Though IQWiG and IQTiG work in slightly different ways, in general, they consult patients through the use of written questionnaires or verbal consultation to elicit patients' perspectives on the medical procedure or product in question (IQTiG, 2017; IQTiG, 2018; IQWiG, 2016; IQWiG, 2017). Relevant patient organizations are identified through the unit of patient participation at the GBA. Further, the institutes' consulting board of trustees (Kuratorium) which may issue an opinion on the scientific recommendations of the respective institute also involves several patient representatives (IQTiG, n.d.; IQWiG, n.d.).

Based on EU Directive 2011/24/EU on Patients' Rights in Cross-Border Healthcare, in 2013, the German Patients' Rights Act was adopted. The act consolidated the right of individual patients to information about healthcare services, their own diagnosis and insurance tariffs, as

well as to being involved in their treatment (German Government, 2013). Self-evidently, the latter statement is vaguely formulated, because national policy cannot regulate the exact manner of care provision by healthcare professionals. With regard to macro level participatory opportunities in the preparation procedures of policies, a draft version of the policy considered to expand the competences of patient representatives at the GBA by giving them the right to vote (German Government, 2012). However, the proposal was eventually rejected by the government on the basis that, first, the existing structures have already led to more patient engagement and patient-centered decision making at the GBA. Second, the unit of patient representation cannot obtain a voting right because individuals working for the unit have not been democratically elected to exercise this advocating task (German Government, 2012). In the end, the Patients' Rights Act theoretically introduced an omnipresent informative level of patient participation at lower levels, based on the HEPP Continuum.

The Patients' Rights Act grants patient representatives at the state level the right to consult on recommendations for healthcare demand planning in the State Committee (Landesgremium; German Government, 2013). This board is composed of representatives of insurance companies, healthcare institutions and professionals that issues non-binding recommendations for healthcare planning – a decision ultimately made by the state government. Minor differences exist between the states, e.g. in Rhineland-Palatinate two patient representatives join the meetings on a consultative basis (Rhineland-Palatinate Government, 2013) whereas in Saarland it is only one patient representative (Saarland Government, 2012). Patient representatives should also be consulted by the statewide admission committee and appeal committee (Zulassungsausschuss and Berufungsaussschuss; German Government, 2013) that coordinate the licensing procedures for healthcare professionals. A patient representative from Rhineland-Palatinate also mentions five other committees in the domains of healthcare demand planning, quality assurance and related to the medical service of health funds (medizinischer Dienst der Krankenkassen, 'MDK'). In all committees, patient representatives join on a consultative basis (Interview 7). According to the respective state law of Rhineland-Palatinate for hospital care (Krankenhausgesetz) regulating healthcare service planning, patient organizations are part of the consortium that composes recommendations for the state government (Rhineland-Palatinate Government, 2016; Saarland Government, 2015). The patient representative further lists a state law of healthcare profession (Heilberufsgesetz) which determines patient participation to be part of the ethical commission and mediation committees of Rhineland-Palatinate (Interview 7).

In the committees at state level, patients are continuously given the opportunity to consult (HEPP Continuum). Similar to the participatory developments at national level, the interviewed patient representative of Rhineland-Palatinate expresses great changes with regard to the number of committees that involve patients and with regard to the perception of patients' inputs in these meetings (Interview7). "I can remember the first meeting that included patient representatives [in 2004], and when it was time to vote they wanted us to leave the room because we had no voting right". While general acknowledgement of patient representatives is not a large problem anymore, a lack of sufficient structural and financial support – for organizational, educational and counseling functions – prevails at state level even to a stronger degree than at the national level. In particular for committees regulated by state law, no form of financial support is offered for coordinative tasks at state level and needs to be covered voluntarily by available patient organizations (Interview 7). Lastly, the patient representative petitions to introduce the same standards for patient-representing organizations at state level as the existing ones at national level (BMJV, 2003), so to ensure patient-oriented and adequate consultation of the committees.

4.4. Patient Participation in EU and German Health Research

Patients and civil stakeholders in general are not offered as many participatory opportunities in the field of health research as they are in health policy making and governance. At the EU level, DG RTD is in charge of coordinating research activities. In 2016, DG RTD adopted its current strategic framework which follows the overall mission statement 'open innovation, open science, open to the world' (European Commission, 2016f).Therein, among other objectives, the DG aims to intensify the involvement of relevant stakeholder, also including actors of the civil society such as patient organizations with regard to health-related research. In the early 2000s, the Commission saw the need for society to understand scientific procedures and started to enhance the transparency and inclusiveness of its activities. Over the last decade, the Commission's approach to counteract these deficits grew into the current inclusive approach of bringing science and society closer together and acknowledging mutual opportunities (Interview 4). For this reason, DG RTD's sector for responsible research and innovation seeks to reform operating procedures within the DG in order to move in an increasingly participatory direction by e.g. removing barriers for and maximizing the impact of stakeholder participation. An interview partner adds: "For us, it's an important policy priority to involve citizens and other groups in research and innovation", which in the field of healthcare would also refer to patient organizations (Interview 4). Civil society organizations

(CSOs) are involved in research agenda setting procedures at the Commission; however, participation in coordination and implementation of research projects is still limited. A report on CSO involvement in EU funded research projects concluded that CSOs have a low level of involvement, received relatively small funds and mostly do not carry out core activities but peripheral roles in research (European Commission, 2017e). One expert particularly emphasized the importance of collaboration with patients in research (Interview 3).

Horizon 2020, the EU's current research and innovation framework, is also a funding instrument that holds a budget of €80 billion (Council of the EU, 2013b; European Parliament & Council, 2013a). Over the course of seven years, Horizon 2020 supports research projects of societal value also including health-related research. In the three work programs of Horizon 2020, few of the health-related calls for proposals mention a preference for research projects involving civil society or patient organizations (European Commission, 2013b; European Commission, 2015c; European Commission, 2017f). The evaluation of research proposals and final fund allocation is carried out by independent experts of the research topic in question; however, the EU regulation laying down the rules of participation does not foresee external stakeholder involvement in the research project as a criterion for selection for an award (European Parliament & Council, 2013b). Likewise, the interim evaluation report of Horizon 2020 concludes "the involvement of citizens and/or civil society in Horizon 2020 can be further improved [and] CSOs that do participate generally take on non-core roles in project consortia and rarely coordinate" (European Commission, 2017g, p. 16). So, when looking to broaden participatory opportunities, one interview partner points out that "there can also be what might be seen as fake public engagement, where you have engagement processes put in place but where by design or unforeseen circumstances they have very little impact on the R&I outcomes, and that's something we would definitely recommend against because it reduces the trust in science" (Interview 4). DG RTD actively uses their current strategy to indicate openness and societal orientation to counteract such mistrust. Horizon 2020 also co-funds the Innovative Medicine Initiative (IMI) which has supported the establishment of the European Patient Academy on Therapeutic Innovation (EUPATI) a project aiming to provide information for patients and to train (future) patient representatives for pharmaceutical-related discussions, such as carried out at EMA (EUPATI, 2017). In summary, DG RTD itself consults societal groups, such as patient organizations, during agenda setting procedures, but it could reinforce active participation of patient organizations during the conduction of

research projects. These results position DG RTD at different level of patient participation on the HEPP Continuum for different decisive areas.

The BMBF is the central institution of the analysis of the level of patient participation in government-affiliated activities for health research in Germany. Only two soft policies of health research were found. First, in its health research framework program the BMBF writes that health-related research results should be communicated with, inter alia, patient organizations (BMBF, 2010). Second, an action plan for care research implies that patients should be involved at all stages of the process from research planning and project coordination to the evaluation of the results (BMBF, 2014), but no further information about such practices could be found on the ministry's website. The same lack of information about participatory practices exists for any pro-participatory statements made on the EU research framework following (Horizon 2020; German Government, 2017). In general position papers, the BMBF affirms that public participation is of high importance to the national government and describes participation as a valuable way of increasing the legitimacy and transparency of research-related decisions and the acceptance of science in the broader public (BMBF, 2017). However, the ministry also expresses that participation does not constitute a political goal in itself (BMBF, 2016). With regard to the ministry's structural organization, it does not operate a unit for civil inclusion, such as DG RTD's sector for responsible research and innovation.

Due to the scarcity of available information it remains unclear whether the BMBF provides other internal procedures to include societal groups, such as patient organizations. Therefore, the BMBF's participatory activities are limited to initiatives, such as 'Future Forum' (Zukunftsforum) and 'Citizen Dialogue' (Bürgerdialog) aiming to elicit the views of the population on societal questions in general, not necessarily addressing the health research agenda (BMBF, 2016). The Citizens Science initiative aims to actively engage citizens in the gathering of data for research, and the initiative Years of Science (Wissenschaftsjahre) is a tool for communicating research development and results with the public (BMBF, 2016). Considering that on its website the BMBF presents these four campaigns as opportunities for citizens to actively shape research in Germany (BMBF, n.d.), the scope of participatory activities in research agenda setting or core-activities in research conduction are at best informative (HEPP Continuum). Overall, the BMBF presents itself as an institution open for public participation; but, there are no standing processes that engage the public or patients

continuously in activities directly affecting any decision making procedures in German health research.

5. Discussion

Over the last fifteen years, political effort has substantially advanced the scope of participatory opportunities in decision making procedures in the fields of health policy, governance and research. Considering the prevailing uncertainty regarding the organization of patient participation, this study tried to establish a scoping overview of patient participatory activities and practices at EU and German national and state level. Subsequently, the research question addressed what kind of activities and practices are currently carried out to permit and facilitate macro level patient participation and how these activities can be structured with regard to their corresponding level of patient participation as determined by the Healthcare Ecosystem Patient Participation Continuum. For this purpose an internet-based document analysis was conducted on the websites of governmental institutions at the EU level and at German national and state level. Further, complementary semi-structured expert interviews were undertaken to obtain a more realistic assessment by experts working in the field of the activities and practices by experts working in the field.

At the EU level, the Commission has implemented guidelines to ensure extensive stakeholder consultation for the purpose of better policy making. DG Santé has introduced the EU health policy platform to gather the opinion of and consult with a wide spectrum of health stakeholders, including patient organizations. In the field of research, participatory activities are much more limited; however DG RTD operates a unit focusing on stakeholder and civil society involvement in research. Overall, the Commission and analyzed affiliated institutions are collectively considered to engage in patient consultation and they advanced patient participation in recent years. EMA promotes by far the most participatory environment among EU institutions, as patients and consumers form a standing working party and patient representatives, who are patients themselves, are members of all EMA committees that address human health. At the German national level, the government and ministry of health consult patient groups for legislative acts on a rather informal basis, but the independent federal commissioner of patient affairs provides a doorway for patients' remarks. The self-regulated GBA has established an independent unit for patient participation and delegates representatives to join every meeting of the nine subcommittees on the participatory basis of consultation to co-development. The exemplary states Rhineland-Palatinate and Saarland follow a similar consultative level of patient participation, but the structural basis for participation is not as developed as at the national level. Matters of research at German level

can only be deemed passively informative because participatory events do not seem to have an impact on the research agenda.

5.1. Recommendations for Patient Participation at Macro Level

This overview study on the participatory activities and practices at several levels and in multiple institutions brings out essential core factors that play an important role in the facilitation of active patient participation. Thus the four following recommendations for patient participation at the macro level were formulated.

- Passive participation in form of access to information does not constitute a sufficient level of active patient participation. Hence, the first recommendation is that institutions in decision making positions should always provide opportunities for active participation, in other words introducing procedures for consultation during which patients can express their opinions and ideas. When referring to matters of decision making, a particular focus should lay on agenda setting, legislative processes and program evaluations. Whether with regard to their own treatment at the micro level or the benefit-risk assessment of a new medicinal therapy at the macro level, informing patients and patient organizations enables patients to actively participate and is in itself an important patient right. Nevertheless, providing patients with information cannot and should not be considered equivalent to providing opportunities for active participation.

- The EU as well as the German government is making an effort to open up policy making and research to the public by advancing information accessibility, a fundamental patients' right. Most of the shared information, however, refers to micro level material on e.g. treatment and benefit options. In order to achieve information disclosure at the macro level, in other words, information about political or evaluative discussions at the macro level, the second recommendation is to widely introduce public hearings as a standard practice for the majority of committee meetings; unless there are urgent reasons for concealment. Public hearings promote procedural transparency and societal understanding of decisions. Further, public hearings seem to produce the effect that other members of the meeting are compelled to address the arguments and views of the participating patient representatives. While different actors are still trying to overcome uncertainty about the most effective way of implementing

participatory structures for patients' input, an entirely different approach to participation is describes by Scharpf (1999). He distinguishes between input and output democracy, in other words the impact that participation is having on the final decision. Governmental institutions need to arrive at output patient participation through one way or another, and public hearings seem to increase the impact of patients during the meetings. Considering the HEPP continuum, increasing the level of participation to the extent of a voting right – which has previously raised legal concerns – is not necessary, if practices are in place that facilitate continuous patient consultation which is thoroughly accounted for by the other parties is in place. This could be enhanced through the broad introduction of public hearings.

- Patient participation does not have to be organized in a standardized manner, different levels of participatory intensity are deemed appropriate in different governmental institutions. The third recommendation is that central decision making institutions, such as the federal government or DG Santé, should have structures in place to enable continuous face-to-face consultation, or even co-development procedures, which allow for patients to have a stronger impact on the decisions. In supportive institutions, such as CHAFEA at the EU level or IQWiG and IQTiG at the German level, patient consultation on a case-to-case basis is deemed sufficient by this analysis. Due to the ever-growing scope of responsibilities given to patient organizations and their representatives, their resources should for now be invested in procedures of decision making.

- Almost all patient organizations were established on a voluntary basis and usually finance themselves through donations and membership fees. As patient organizations are being asked to join more meeting and consult more institution the scope of their tasks and responsibilities grew drastically over the last fifteen years. The EU and German government have started to financially compensate their work hours and travel expenses as well as introduced structural support such as the EU health policy platform or the unit for patient representation at the GBA. However, the fourth recommendation is to provide involved patient organizations with basic funding in order to facilitate them to take on the growing body of activities, to train and qualify patient representatives, to protect organizations from having to fall back on financial support of e.g. the pharmaceutical industry, and to give patient organizations the

capacity to still look after patients that reach out to them for help. Basic funding would also help patient organizations exercise their consultative tasks at state level, where, in the example of Rhineland-Palatinate, only patient participation regulated by national law is sufficiently compensated.

5.2. Strengths and Limitations

The overall approach of this study benefitted from the broad variety of examined institutions and interviewed experts. However, several remarks need to be acknowledged with regard to the findings and subsequent classification of government-affiliated participatory activities and practices on the HEPP Continuum. The internet-based search was restricted to publicly available documents, which is not an infallible indicator of the activities and practices in place. In particular at the German national and state level, information was quite limited which might have caused the arrival at wrong conclusions. Several participatory procedures are of informal nature, making the respective interviews with experts from Germany not only complementary but essential to the findings. Due to time constraints, this analysis was limited to government-affiliated participatory activities and practices, even though patient organizations exercise many more tasks. Lastly, a certain level of social desirability in the experts' answers cannot be ruled out.

5.3. Conclusion

Over the course of the last fifteen years, various governmental activities and practices advanced the application and level of patient participation in health policy, governance and health research at the EU and German national and state level. In essence, current efforts to improve patient participation should address the facilitation of participatory activities, e.g. through basic funding of involved patient organizations, as well as focus on ensuring that patients' views are thoroughly taken into account in the decision making process. Against the background of ongoing EU discussions about a central HTA coordination, national patient organizations would increasingly enter the EU level and would need to frequently collaborate with patient organizations from different Member States of the EU. This would mean that a substantial expansion of participatory tasks for patient organizations is ahead of patient organizations. To facilitate adequate patient participation and input in the widening scope of responsibilities, patient organizations need to be sufficiently supplied with financial and structural support.

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Appendix

Appendix 1: Overview of Interview Partners

Interview	Date	Institution/ Unit/ Position	Member Check
1	28.05.18	EMA Patients' and Consumers' Working Party, patient representative	29.05.18
2	04.06.18	CHAFEA, Unit of Health and Food Safety	05.06.18
3	04.06.18	EMA Patients' and Consumers' Working Party, patient representative	23.06.18
4	04.06.18	DG RTD, Unit Science with and for Society	06.06.18
5	06.06.18	EMA, Pharmacovigilance Risk Assessment Committee, patient representative	08.06.18
6	20.06.18	Agency of Federal Commissioner for Patients' Affairs	25.06.18
7	27.06.18	Rhineland-Palatinate, patient representative	27.06.18
8	28.06.18	GBA, patient representative	02.07.18

Appendix 2: Interview Guide and Telephone Transcript for Informed Consent

Code for Interviewee	Institution	Name of Interviewer	Date

Introduction

Thank you for participating in this study. We are exploring the current activities and practices at the EU and German levels that promote, permit and facilitate patient participation in health policy making, governance and research. The purpose of this study is to compose a scoping report on patient participation at the macro level. Interviews with people working in this field – like you – serve as a source of realistic assessment of the current situation.

This study is part of a multinational research project on patient partnerships in healthcare (APPS). It is led by the University of Liège, Belgium, and funded by EU Interreg Grande Region.

The interview will take approximately 30 minutes, and includes 3-4 main questions, covering generic and specific questions about your views on the current state of patient participation.

Participation in this study is completely voluntary, this means you can refuse to answer any question and you can withdraw at any point without penalty or reason. Participation will not be compensated financially.

We will treat all data with a high level of confidentiality, store all files appropriately on our server and only use them for our research purpose. We want you to determine the level of anonymity applied to your persona or position in the final report. Please select one of the following modes:

[ ] Entirely concealed: "… an expert in this field states …"

[ ] Largely concealed: "… an expert from institution X states …"

I have noted down your instruction, and you will also have the chance to revise them when receiving a summary of the interview in form of an interview report.

The content of this interview will be analyzed and used to write a report on the current activities and practices with regard to patient participation.

Do you have any questions about the background of the study, the interview procedure or any other matter? [ ] No [ ] Yes, regarding …

Before I ask for your consent to participate in this study and for the interview to be recorded, do you feel that you have been given enough time, as well as enough information on the character and scope of the study, to make an informed decision on your participation in this study?
[ ] Yes [ ] No, because …

Do you agree to be interviewed and to the recording of this phone call?
[ ] Yes [ ] No, because …

start audiotape

Individual Obtaining Consent
I have read this form to the subject. An explanation of the study was given to the subject in advance in form of an information letter as well as prior to the interview. Questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the provided information. The subject has provided verbal consent to participate in this study.

_____ _____
Signature of Person Obtaining Consent Date

Guiding Theme	Questions	Notes
Opening Question	What is your role in patient representation? How are you/your organization affected by patient participation?	
Development of Patient Participation	- Tell me about your views on the development of patient participation/ representation over the last years. - What were important "turning points" that caused movement in this field and why did these changes occur?	
Current Level of Patient Participation	- How are patients/ patient organizations/ patient representatives currently involved at your organization? - Tell me about your views on the current level of patient participation. Are you satisfied?	
Barriers, Facilitators and Room for Improvement	- What are barriers to patient participation? Why? - What are facilitators of patient participation? Why? - Is there room for improvement?	
Other	- When do you perceive patient participation/ representation to be (most) value-adding (if at all)? - Is patient participation a goal in itself or should it only be part of a process if there is evidence for it producing better healthcare (better quality, lower costs, etc.)?	

Closing

Thank you for taking time to be interviewed. We appreciate your participation. Do you have any further questions?

Discuss ways of future contact and wrap up interview