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Health Data Activism

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Master in Health Services Management

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Human Resources and Organizational Behaviour Department

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Abstract

Patients need to be made aware of their right to access their own health data, as this is something that belongs to them. The role of associations is fundamental in transmitting this information to patients. Thus, health data activism comes to promote the safety of users, showing them this very right, in the formation of this new concept. Thus, the focus of the thesis is the promotion of health data and the creation of an (ambitious) model of how patient organisations can innovate and promote the rights associated with the use and access to health data (health data activism).

In this research, the methodology to be followed will be questionnaires and interviews to the Organisations/Associations, and it can be defined as a thematic content analysis. In this way, we can classify that in this project we will have both a qualitative and quantitative analysis, but mainly qualitative. The data of the study was collected using qualitative methods such as questionnaires and interviews. The data analysis process of the study involved descriptive statistical analysis for the questionnaires, while in-depth content analysis was done for the interviews.

The results obtained were collected through the 229 associations contacted, 27 replied to the questionnaire, in which 13 of them agreed to do an interview.

After collecting all the inputs from the results, one can define the concept "Health Data Activism" as a movement that captures an action and efforts of a person or an organization/association can be taken in promoting the rights of access and better use of health data, how to use it and the value that can be extracted from their health data.

Identify who are the key actors in the health system that relate to health data (e.g., digital health agency, research agencies, etc.) to engage them in the priorities of health data activism: easy access to health data and that the exploitation of the value of the data is promoted and the value generated is returned to patients.

Keywords: health, data, activism, patient, associations, digital

Classification JEL: Health, Education, and Welfare

Resumo

Os pacientes precisam de ser sensibilizados para o direito de acederem aos seus próprios dados de saúde, pois trata-se de algo que lhes pertence. O papel das associações é fundamental na transmissão desta informação aos doentes. Assim, o ativismo dos dados de saúde vem promover a segurança dos utilizadores, mostrando-lhes este mesmo direito, na formação deste novo conceito. Assim, o foco da tese é a promoção dos dados de saúde e a criação de um modelo (ambicioso) de como as associações de doentes podem inovar e promover os direitos associados à utilização e acesso aos dados de saúde (ativismo de dados de saúde).

Nesta investigação, a metodologia a seguir será a de questionários e entrevistas às Organizações/Associações, sendo que se pode definir como uma análise de conteúdo temática. Desta forma, podemos classificar que neste projeto teremos uma análise tanto qualitativa como quantitativa, mas sobretudo qualitativa. Os dados do estudo foram recolhidos utilizando métodos qualitativos, tais como questionários e entrevistas. O processo de análise de dados do estudo envolveu uma análise estatística descritiva para os questionários, enquanto a análise aprofundada do conteúdo foi feita para as entrevistas.

Os resultados obtidos foram recolhidos através das 229 associações contactadas, 27 responderam ao questionário, em que 13 delas aceitaram fazer uma entrevista.

Depois de se recolher todos os contributos dos resultados, pode-se definir o conceito "Ativismo de Dados de Saúde" como um movimento que capta uma ação e os esforços de uma pessoa ou uma organização/associação podem ser levados na promoção dos direitos de acesso e melhor utilização dos dados de saúde, como utilizá-los e o valor que pode ser extraído dos seus dados de saúde.

Identificar quem são os atores chave no sistema de saúde que se relacionam com os dados de saúde (por exemplo, agência de saúde digital, agências de investigação, etc.) para os envolver nas prioridades do ativismo dos dados de saúde: fácil acesso aos dados de saúde e que a exploração do valor dos dados seja promovida e o valor gerado seja devolvido aos pacientes.

Palavras-chave: saúde, dados, ativismo, paciente, associações, digital

Classificação JEL: Saúde, Educação e Bem-Estar

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Glossary of Acronyms

EU- European Union

IT- Information Technology

EPF- European Patients' Forum

EC- European Commission

EHDS- European Health Data Space

GDPR- General Data Protection Regulation

OHC- Online Health Communities

DHE- Digital Health Europe

WHO- World Health Organisation

HSM - Health Social Movement

NHS - National Health Service

CDC - Centers for Disease Control and Prevention

DH- Digital Health

GP – General Practitioner

EPW - European Programme of Work

EHS - Environment, Health, and Safety

UK – United Kingdom

US – United States

AIDS - Acquired Immunodeficiency Syndrome

1. Introduction

The European Health Data Space (EHDS) is the first proposal for domain-specific common European data spaces. It will address the specific health challenges to electronic access and sharing of health data and is one of the European Commission's priorities in health and will be an integral part of building a European Health Union (European Commission, 2022c). The EHDS will create a common space where individuals can easily control their electronic health data. It will also allow researchers, innovators, and policy makers to use this electronic health data in a secure and trusted privacy-preserving way. Currently, individuals have difficulties exercising their rights over their electronic health data, including accessing and transmitting their electronic health data nationally and cross-border. (European Commission, 2022b).This is despite the provisions of Regulation (EU) 2016/679 [here after the General Data Protection Regulation (GDPR)], where individuals' rights over their data, including health data, are safeguarded. As demonstrated by the study assessing EU Member States' rules on health data considering the GDPR, the uneven application and interpretation of the GDPR by Member States creates considerable legal uncertainties, resulting in barriers to the secondary use of electronic health data. Thus, it creates certain situations where individuals cannot benefit from innovative treatments and policymakers cannot react effectively to a health crisis due to barriers preventing researchers, innovators, regulators, and policymakers from accessing the necessary electronic health data (European Commission, 2022b) In addition, due to different standards and limited interoperability, digital health product manufacturers and digital health service providers operating in one Member State face additional barriers and costs when entering another Member State (European Commission, 2022a).

In September 2022, health ministers and delegates from 53 World Health Organisation (WHO)/Europe Member States adopted the Region's first digital health action plan - an ambitious agenda that will drive digital transformation in Europe and Central Asia, with the aim of improving people's health and well-being (World Health Organisation, 2022).

The new action plan is a concrete step towards making the European Programme of Work (EPW) a reality by leveraging digital tools to advance universal health coverage, protect people from health emergencies, and promote health and well-being in the Region. This plan encourages countries to prioritize advancing digital health literacy to help achieve

national health goals, improve health system performance, and guide future digital health investments and transformation. It proposes that they do so by recognizing the needs of citizens and health professionals, while promoting an integrated care approach that institutionalizes digital health in the Region (World Health Organization, 2022).

Dr Hans Henri P. Kluge, WHO Regional Director for Europe, explains that "*To be meaningful and really promote better health, digital tools need good governance, appropriate legislation, and policies that promote the healthy use of these tools, while providing the people who use them - health workers and patients - with the training and support they need to make the best use of them.*" (World Health Organization, 2022).

It considers countries' priorities in the telemedicine, health data and health information systems, artificial intelligence and big data and countering the online infomedic, as well as their needs and challenges, including issues with access to digital health services among vulnerable groups. Putting patients at the centre of digital solutions for digital solutions to be truly successful, the people using them need to receive the right training and knowledge (European Commission, 2022a).

"*WHO/Europe is here to support countries as they leverage the use of digital tools in an inclusive and transparent way, while protecting people's privacy and specific needs,*" said Dr Natasha Azzopardi-Muscat, Director of the Division of Health Policy and Systems, WHO/Europe. (World Health Organization, 2022). "*Digital literacy of all users should be a key component of any successful digital health strategy. Together with the governments of our Region, we will work on solutions that put the needs of patients and health professionals at the centre.", continued* Dr. Natasha Azzopardi-Muscat, as seen in the WHO Regional Digital Health Action Plan. (World Health Organization, 2022).

There has never been so many data about us, and about us as patients.

Nowadays, the digital transfer is not yet a widespread business as usual activity because public bodies are still in the transitional period for transferring their digital records.(Özdemir, 2019).

Moreover, we have Environment, Health, and Safety (EHS) Regulations from EHS Compliance which is an industry regulation that refers to the rules, policies, programs, and protocols surrounding workplaces and aims to ensure that all company activities do

not put the workers' health and safety at risk or cause any excessive environmental damage (Safety Culture, 2022).

Benefit-cost analysis can play an important role in legislative and regulatory policy debates on protecting and improving health, safety, and the natural environment. Although formal benefit-cost analysis should not be viewed as either necessary or sufficient for designing sensible public policy, it can provide an exceptionally useful framework for consistently organizing disparate information, and in this way, it can greatly improve the process and, hence, the outcome of policy analysis. If properly done, benefit-cost analysis can be of great help to agencies participating in the development of environmental, health, and safety regulations, and it can likewise he useful in evaluating agency decision-making and in shaping statutes (Arrow et al., 1996).

The Data Act will make more data available for use. It will set up rules on who can use and access what data for which purposes across all economic sectors in the EU (European Commission, 2022c).

However, we cannot talk about data or health data without talking about the cern of the matter- the patient. So, we must pay attention that the patient must keep up with the speed of digital, of data, of legislations. And for that you must make sure that the patient is included, that the patient is safe and, above all, is interactive.

User safety is an unquestioned target in the health care system. Health system error significantly reduces the value that health and care systems should provide to citizens. Thus, lack of safety in patient care is not only the result of proactive errors by healthcare professionals, however much it may be related to lack of proactive protective measures or harmful side effects (Kalra et al.,2020).

Patient safety is significantly affected by the lack of adequate information exchange via verbal communication between teams and written communication. However, currently most "written" communication happens via what each professional document/writes about a particular patient at a particular time in a particular application/information technology (IT) support. There is an inherent expectation that, ideally, this information will be "made available" to others caring for the patient who may need it for their actions and decisions. Such perfect "communication," although electronic record keeping, does not exist (Silva et al., 2021).

The current lack of interoperability can be summarized as a lack of coordination between the different actors in the health system (individual perspective) as they make choices about information system or a market failure (collective perspective) (Schulz et al., 2021).

They have the right to know the benefits of giving their own data and for what purpose, how it is used, how it is handled. But for this there needs to be promotion of this information, there needs to be more inclusion and more activism. So there needs to be more proactive positioning of patients.

Patient outcomes could be better if accessibility and full reuse of data was a reality. (Schulz et al., 2021). If there was greater interoperability between this health data so that there would be better access and use of it.

Thus, it is imperative that there is a great deal of interoperability between countries so that the exchange of user health data is done securely to avoid the patient safety issues described earlier.

Thus, through data activism, it is possible for users suffering from serious diseases to contribute their health data to improve medical research, and/or alternatively, to share information about themselves online for all to see (Lehtiniemi & Ruckenstein, 2019).

You can even devise a concept of Health Data Activism for the use or secondary use of patient and patient organisation data, but if this term is not co-created with those, we see promoting it, and pushing and developing it, we have failed from the start. Beyond that, it needs to be pointed out that other things have been designed into patients - patient centricity without working with patients and families on what is the centre of health for them, or integration of care movements, again not often asking patients and cares what has fallen (un)integrated in the first place. One wishes to avoid that an original conceptualisation is put first, but after being discussed and articulated with the associations, a Joint Position on Inclusive Digital Health with the aim of promoting inclusive and participatory digital health and then again reworked into a conceptualisation (Martins et al., 2022).

1.1.   Relevance of the Study

Empowerment is not a linear process. Even the most empowered patient may become vulnerable and need more support when faced with a life-changing diagnosis; a patient's healthcare needs may change throughout their life. While access to information is helping some patients to advocate for themselves at certain points in their lives, empowerment is further away for others (Vahdat et al., 2014). For example, people who cannot read, those who do not have access to the internet, and those who lack the understanding or time to search for health-related information are likely to rely more on the knowledge and expertise of clinicians. Health literacy is also highly variable.(Kruk et al., 2018). Health literacy - "personal characteristics and social resources necessary for people to access, understand and use information to make decisions about their health" - is significantly associated with engagement in medical decision-making (Krist et al., 2017). In other words, the more health literacy a patient has, the more they can participate in their own health care. According to the Centers for Disease Control and Prevention (CDC), people who live in the most health literate areas have 31% more flu shots, 26% fewer preventable hospitalizations and 18% fewer emergency department visit (Cairney et al., 2021).

There is significant crossover between those groups who are digitally excluded and those are risk of poor health, for example there is a clear correlation between the socioeconomic status of a ward and both the levels of basic digital skills of its inhabitants and their average life expectancy, with people in deprived areas tending to be more digitally excluded and in worse health. The shift towards digital by default and digital first means that those who are digitally included can more easily access services that will have positive impacts on their health; be it employment and benefits or health information and services.

According to the study (Good Things Foundation, 2021) 41% feel less confident in using online health information, 58% feel lonely or isolated, 79% have visits to their general practitioner (GP) for minor illnesses, 79% have visits to their GP for minor illnesses, 78% have progressed to booking in their own healthcare organization and the cost, and 80% still have paper prescriptions, 61% still invest time in paying for face-to-face appointments.

Problems that exist from non-health data activism: lower self-management of conditions, lower uptake of digital health tools and services, time invested in booking face-to-face

appointments and all travel costs, loneliness, and isolation (exclusion). In addition, this non-participation and exclusion also interferes for the health and care system, namely higher cost of providing services in person, less appropriate use of services, including primary care and urgent care, and lower patient adherence to medication and treatment.

Patient outcomes could be better if accessibility and full reuse of data were a reality. Many projects, funded by the European Commission (EC), have shown the value of interoperability, how to achieve it both nationally and cross-border (Schulz et al., 2021). The consolidated knowledge on standards and support for a set of eHealth Network, adopted recommendations on the use of standards and broader interoperability frameworks. Finally, the GDPR clarified the nature of personal data as the property of each citizen, the right to its portability and its visibility which undoubtedly helped but did not significantly change the landscape of health data interoperability. This issue is still quite fragmented, with most citizens having no way to see all their health data online, or even parts of it (such as data held by a hospital/clinic), much less file a request for data portability between organizations or for other data processing rights (Ruckenstein et al., 2017).

Therefore, it seems that having eHealth standards, while fundamental, is not stimulating enough for organizations and national health systems to adopt and adapt to a fully interoperable ecosystem (Dobrev, 2010).

Thus, the best examples of organizations/associations that have this promotion of health data at the European, National, and International level should be verified, so that Portuguese Patient Associations can be raised to the same level and thus achieve greater interoperability of health data.

1.2. Objective of the study

In this research the focus of the thesis is the promotion of health data and the creation of an (ambitious) model for how patient associations can innovate, "take the leap" and promote rights associated with using and accessing health data (health data activism).

The object of investigation is 27 organizations/associations at the European, International and National levels, in which 6 was Portuguese associations, out of a total of 229 associations contacted.

In this way, the precision of this major project is achieved, the need for a great deal of interoperability between the countries of the European Union (EU) to make the exchange of user data easier, safer, and simpler.

1.3.   Research questions and their context

Health Data Activism is a movement for everyone to join in making every effort for maximum sharing and secondary use of health data. Efforts that lead to the maximum use of health data - which belongs to each one to the extent that it can be used, safely and with privacy, for the benefit of the owners of that data - the citizens.

In order to explore this topic, three important research questions have been identified that will help guide the study, namely:

1) **Is its useful to have a concept (Health Data Activism) that captures the efforts patients and citizens need to do to truly benefit from the value that can be extracted from their health data?**

Nowadays, the quantification and identification of patients always depends on the access they give to their health data. This access is fundamental for the identification of users in the various areas of the disease, so that studies and research on the disease can be carried out. Furthermore, when we talk about better use of data, we are also talking about greater interoperability between the different health entities, so that health data is not lost during the connection between them.

But, as health is special good, and ethical standards are especially high in this field, a careful and sensitive, though innovation-friendly approach is necessary. It is also crucial to involve patient groups in ongoing processes, as many patients and citizens have concerns regarding the privacy and security of their own health data. Only by their involvement, the chances for shifting the public mind set towards Big Data in Health can

be ensured. The most important lesson learned in this process is therefore that awareness raising regarding the added value of Big Data in Health is needed quite urgently, a communication strategy to encourage a positive public mind set towards Big Data in Health is needed. The aim of this should be to stimulate a continuous, open dialogue with all stakeholders and patient groups, which could be supported by setting up a European platform to exchange experiences and discuss how to best address current and future challenges. (Habl et al., 2016).

2) How can Health Activism Data be conceptualized? - Preliminary Concept

The concept of *"Health Data Activism"* is the junction of two strands: *"Health Activism"* and *"Data Activism",* thus originating "Health Data Activism", and they are fundamental to the importance of the objectives for a better understanding.

Conceptualizing health data activism - which is part of a larger dimension - digital activism - has to do with having free access to the Internet, having a digital cell phone, digital identification / digital skills, being part of student education in schools.

Therefore, a brief conceptualization is through data activism, personal health can be redefined as a collective and political issue; people suffering from serious illnesses can contribute their health data to improve medical research, or alternatively share information about themselves online for all to access (Lehtiniemi, T., & Ruckenstein, M., 2019). This has several components, namely protection, quality, security, privacy, and value extraction.

As a result, data activism is defined as a concept that has been proposed as a heuristic tool to think about how people engage politically with the data infrastructure, the datafication process, and the massive data collection by businesses and government (Thomas & Fliert Elske, 2019). This concept aims to promote new forms of civic and political engagement. It thus emerged as a response to problematic aspects of datafication that include tensions between openness and ownership of data, and asymmetries in terms of data use and distribution (Ruckenstein et al., 2017).

Thus, data activism is seen as successful for its ability to intervene in the public sphere and communities (Arias-Zapata, 2019). Consequently, through data activism, it is possible for users suffering from serious diseases to contribute their health data to

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improve medical research, and/or alternatively, to share information about themselves online for all to see.

Health data flows, on the other hand, can become part of a multiplicity of different agendas, each wanting to assert a particular writing to codify, protect, and modify health. Questions and contestations may arise about who defines "health" and based on what kind of data processing. Examining the case of personal genomics, Gregory & Bowker (2016) emphasize how the political, economic, and social affects the possibilities of data collection and creation. These are determined by the plethora of decisions and transformations involved in designing their platforms. In a study of clinical data, Neff (2013) emphasizes the need to translate data across the social world of patients and healthcare providers, advocating the "social interoperability" of "health data" (Lehtiniemi, T., & Ruckenstein, M., 2019).

On the other hand, when we talk about "Health Data," we mean prescriptions hospital, discharge letters, laboratory results, pathology results, imaging, basic health data, namely ethnicity, reproductive health, sexually transmitted infections, genetically based diseases, and disease risk exposures, these can be misused, thus leading to lack of user security, as any electronic database can be hacked (Tabassum et al, 2013).

As a result, health data activism is a collective action and initiative that emerges in Online Health Communities (OHCs), aimed at challenging and changing the status of health during capacity building, knowledge, sharing and dissemination (Chamakiotis et al., 2021). Thus, through data activism, personal health can be redefined as a collective and political matter. The current lack of interoperability can be summarized as a lack of coordination between the different actors in the health system (individual perspective) as they make choices about information system or a market failure (collective perspective) (Schulz et al., 2021).

For that, it is imperative that there is a great deal of interoperability between countries so that the exchange of user health data is done securely to avoid the patient safety issues described earlier.

3) How do European/International/National patient organizations promote health data activism?

To answer this question a questionnaire will be constructed and sent to the organizations/associations by email. A final question will be included in this e-mail: a proposal for an interview where the subject will be discussed in depth, with the aim of answering questions that the organizations have about the topic. In these interviews it will be asked whether they have a website, what kind of website they make, for those who are info excluded, and if there is something/someone in the headquarters to teach people how to work with digital.

2. Thesis structure

This dissertation is divided into several parts, each representing a different chapter. Firstly, we have the introduction where the relevance of the study, the aim of the study and the main research questions that led to this study are analysed. In addition, one of the main points of this dissertation is the presentation and the rationale for why there is the movement of health data activism" where it is inserted in the background.

Next, the methodology is presented, describing the research method used, the sample and the type of population covered, data collection, data analysis and ethical aspects and other problems that one could have in this research.

The next chapter is the chapter on results, where the results of the research can be analysed very carefully. This will be followed by a discussion of the results evaluated above, how this health data activism could have a bigger and better impact on these results (suggestion of this new concept) and finally the implications for future work, for example the involvement of associations.

Finally, the chapter on conclusions and recommendations that follows will describe the main findings and recommendations for future work in three areas, which are for patient organisations, policy makers and academics.

3. Background

The importance of accurate data in healthcare can mean the difference between life and death to that specific patient and to the larger collective of patients. Today, doctors at every moment of the care process need instant access to the most up to date and accurate patient information possible (Gottlieb, 2021).

To enhance, facilitate and promote secure data sharing and open use of data policy actions are needed both at national and at international level. Openness and transparency of government data (including health data) as well as non-proprietary private data should be promoted and the safe access to public-sector data as well as its re-use should be improved. Data sharing between health care providers (e.g., clinician practices, hospitals, imaging centres) and other settings in which care and services are delivered should be supported through public and private sector incentives and resources, which will enable key data holders to participate in data sharing. Health data of various sources need to be linked to provide a comprehensive picture of patients' entire care pathway and care history and statistical methods to use these new sources of data need to be developed. (Habl et al., 2016).

Overall, at EU level, eight out of ten respondents (80%) have used the internet for private purposes within the last 12 months. Most respondents (59%) say that they have used the Internet to search for health-related information within the last 12 months. Amongst these, over half of the respondents (55%) say that they looked for general information on health-related topics or ways to improve their health. A similar proportion (54%) looked for information on a specific injury, disease, illness, or condition. Just under a quarter of people (23%) looked for specific information on a medical treatment or procedure, while a tenth of respondents (10%) used the Internet to look for information to get a second opinion after visiting their doctor (European Commission, 2022).

Considering the Eurobarometer analysis, we can see that in Europe 80% of people are health literate, they are capable. However, they need to ask for more. Health Data Activism notoriously supports activism themes for digital health literacy. But it's not just about that. It's about letting patients know that it is demanding to use and exploit their data. It's not enough for patients to know they have a right to their data and see it on a user portal or in an app. It is imperative that they know that they can and should use it,

handle it, show them the discoveries and research that has been done with their data or that they might do (European Commission, 2022).

Health data is increasingly recognized as an intangible assets of health systems and looked upon with hope for new medical discoveries as well as a source of health systems sustainability (Bravo et al., 2015). Lack of safe patient care is not only the result of proactive errors by healthcare professionals, but it may be related to lack of proactive protective measures or harmful side effects (Kalra et al., 2020) many of which imply better and more innovative usage of health data.

Patient safety is clearly an attribute of health care systems that minimizes the incidence and impact of adverse events and maximizes recovery from such events. The National Patient Safety Foundation identifies the key property of safety as emerging from the proper interaction of components of the health care system, thereby leading the way to a renewed focus patient safety, as a systemic property. Its goal has been defined as: "*the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of care.*" (Emanuel et al, 2009).

Patient empowerment is one of the key elements of patient-centred healthcare. It can be seen as both a pre-requisite for and an outcome of patient-centred healthcare – a goal as well as a process. There has been some work done in the field of patient safety to investigate strategies for empowering psychiatric patients (Samuel et al., 2021). The results suggest that healthcare providers consider patients as crucial partners in risk management and expect them to play a key role in actively enhancing safety. Policy makers should be aware that risk management in mental health settings particularly relies on the therapeutic relationship between health professionals and patients. For citizens to be able to access and share their health data in a conscientious and fully informed way, their empowerment in terms of skills and competences is an important approach (Samuel et al., 2021). The World Health Organization defines citizen empowerment as *"a process through which people gain greater control over decisions and actions affecting their health"* (Samuel et al., 2021). Most citizen engagement projects focusing on personal health data should take note in the design of the data platform of the intensely diverse backgrounds of participating citizens. Target groups should be actively supported by means of training and a very user-friendly design (of both the appearance and functionality of any tool) (Samuel et al., 2021).

In this study we will talk about a new concept "Health Data Activism". Thus, we will present the new legislation on "Data Act" that came out in February 2022 contextualize and connect the data activism. We will address the patient empowerment and legislation for patient data autonomy and self-determination from United Kingdom (UK) and in the United States (US) or the General Data Protection Regulation (GDPR) in the EU. We will look at how patient organisations and health data are interconnected and the concept of this connection later. Finally, some considerations on the concept of "Health Data Activism" to promote digital health as well as a refined conceptual proposal are presented.

When we talk about health data activism it is important to talk about patient empowerment and legislation about data protection but also about data usage (secondary use for example, such as legislation in Finland or France, on the recently proposed Regulation on the European Health Data Space in the EU) for patient data autonomy and self-determination (European Commission, 2022b). VaÈlimaÈki & Leino-Kilpi, define self-determination as an important concept within healthcare as well as an important right for the patient regardless of age, gender, culture, or social background. Furthermore, self-determination depends on a person's interest in making decisions regarding their own care (Nordgren & Fridlund, 2001). Respect for patient self-determination means that patients have the right to make decisions according to their own personal values and wishes if the rights of others are not violated (Nordgren & Fridlund, 2001). Patient empowerment it is a topic that has a lot of relevant to health data activism, because "Big Data are getting bigger: the volume of data created, captured, copied and consumed globallyis expected to reach 181 zettabytes in 2025" considering the Report of 2022 "Clinician of the Future", and that`s because we have to talk about data activism before and the new legislation first (Herzhof, 2022).

3.1. Data Activism- New legislation (Context)

This concept, self-determination, originates from the liberal idea of free and independent individuals with the capacity to make rational decisions (Mill, 1974). From an international perspective, demands for individual patient rights in healthcare have increased and resulted in changes to patient legislation around the world at the same time (Nordgren & Fridlund, 2001).

The way data is handled and how patients have this autonomy over their health data is different around the world, making it important to understand how this autonomy and self-determination are legislated.

In Europe, patient empowerment is supported by the EU legislation and advocated by through the European Patients' Forum which aims to "promote the development and implementation of policies, strategies and health services that empower patients to participate in decision-making and the management of their condition" (Bravo et al., 2015).

In many European countries, the role of the patient within healthcare, this view has changed in the last 20 years, from considering the patient only as a passive recipient of care but accepting him/her as an active participant and resource. Rodwell and Cahill have shown that informed consent, participation, and empowerment are the factors considered important to strengthen the role of the patient (Nordgren & Fridlund, 2001).

Already in the UK, "High quality care for all", the National Health Service (NHS) has committed to giving patients more choice and control over their healthcare (2) by making hospital funding dependent on performance against a range of quality measures, including Patient-Reported Outcome Measures (PROMs) (3) implementing the use of personalised care plans and personal health budgets. In October 2014, NHS England's Five Year Forward View reiterated a commitment to patient empowerment, to be enacted through shared decision making and new mechanisms such as "integrated personal commissioning", a new approach involving mixed funding of health and social care for people with complex needs (Bravo et al., 2015)

Analysis of published definitions of patient empowerment, and analysis of UK stakeholder interviews suggested that the level of patient empowerment is modifiable through healthcare interventions that can be implemented by healthcare providers or health systems to promote patient empowerment. Examples of healthcare provider-level interventions include patient-centred training interventions, shared decision-making, motivational interviewing, counselling, health coaching, and signposting to support services (Bravo et al., 2015).

Recently in the United States, several health systems offering patient access to health coaching services to support health behavior change, chronic disease self-management, and various other patient care processes. Although evidence is already emerging to

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support the use of health coaching to improve health outcomes such as psychological well-being, quality of life, and disease-specific metrics, the field has been hampered by a lack of role clarity (Denneson et al., 2020).

In the early 1960s, major social changes were once again occurring in the United States. Distrust of authority and emphasis on self-determination were key concerns among the population and were expressed by many people through their participation in the consumer, civil rights, and/or women's movements (Nordgren & Fridlund, 2001).

In health care, changes occurred during the 1960s and 1970s that increased patients' rights. Following the Nuremberg trials, the doctrine of "informed consent", which ensured patients receive adequate information about their treatment options, was drafted in the 1960s. In the 1970s, the American Hospital Association issued a "Patients' Bill of Rights" which set out the rights patients had when they were hospitalised. The "Living Will", a legal document by which individuals could express their wishes regarding medical intervention, was also invented in the 1970s (Roberts, 1999; Nordgren & Fridlund, 2001).

During the last three decades, the "asymmetrical distribution of power between the doctor" and the patient has become more "symmetrical" and a new view of how individuals behave in matters concerning their health has emerged (Roberts, 1999). This new view is diametrically opposed to other theoretical conceptualisations of illness behavior, such as Talcott Parsons' "sick role" (Varul, 2010). In the new view of patient roles, the distribution of power between patient and health care provider is altered such that patients are more in control of their health and their encounters with health professionals (Roberts, 1999).

In 1990, the Ottawa Charter for Health Promotion made empowerment a key issue in health promotion which served to draw attention to the importance of patient involvement and activation in health care (Nordgren & Fridlund, 2001).

Many of authors highlight the fact that "feeling empowered" is easier for some people than others in the United States of America. Thus, while empowerment at the individual level is important, and should not be ignored, it is also crucial to investigate the larger structural context in which the individual the empowerment may or may not develop for individuals at times in history. The organisation and community levels of analysis assist in this task. The concepts of empowerment at the organizational level are largely derived from management theory (Roberts, 1999). As Wallerstein maintained: in an

"empowering" organisation, individuals assume real decision-making roles and therefore become empowered through their work (Wallerstein, 1991). Empowered organisations develop and exert influence in the larger community to promote system-level change (Gibson, 1991; Roberts, 1999).

What these conceptualisations of empowerment lack is a recognition that the source of patient empowerment may not be professional healthcare. While health professionals can facilitate patient empowerment, there are also other ways that people can take charge of their health. Similarly, many individuals currently participate in support groups, read health awareness books, research the internet for medical information, and more. People who do these things are empowering themselves (Nordgren & Fridlund, 2001). If and when individuals take the knowledge and/or skills they have gained from these various sources back into the health care setting, they can then facilitate an egalitarian relationship with their doctors (Roberts, 1999).

 In short, patient empowerment is a multi-level construct that has manifestations at the micro, meso, and macro levels of society. To better understand this concept, one must study all these levels and recognize that each level can influence the others. Patient empowerment is a characterisation of a type of patient role in which one or more individuals "take charge" of their health and their interactions with health professionals. What difference does it make if patients are active participants in their healthcare? And which patients want to "take charge"? (Roberts, 1999). This concept and its usefulness is not exclusive to the United States, and one might want to consider cross-cultural understandings of the concept. For example, Saltman (1994) showed that patients in Britain, Denmark and Sweden have varying degrees of control over which doctor and hospital they use when they are ill (choice of doctor/hospital was one aspect of Saltman's view patient empowerment (Saltman, 1994; Roberts, 1999). Specifically, people in Britain and Denmark have more control over their choice of doctor than over their choice of doctor people in Sweden. This suggests that there may be important cross-cultural differences in the enactment of patient empowerment. Thus, it is inevitable to see how comparison and political conditions affect people's understanding and embodiments of patient empowerment (Roberts, 1999).

In the United States, clinical interventions and regulatory health institutions promote patient engagement and empowerment as a novel transformation in healthcare delivery,

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with the promise of eliciting increased patient participation in their own health care. The concept of patient empowerment, however, obscures how closely related this discourse is to established doctrines of patient compliance/adherence. Empowerment reconstitutes the fundamentally authoritarian ideology of adherence and compliance into a neoliberal ideology of self-actualization and self-management. This example explores how communities of people living with type 1 diabetes have designed their own diabetes management tools, exemplifying empowered and self-managing patients. Their efforts are a patient-led response to significant gaps in diabetes care in current commercial devices and regulatory restrictions. These self-designed diabetes systems expose the limits of regulatory and commercial commitments to patient empowerment. Moreover, the institutional demands on the individual to achieve empowerment neglect the social, economic, and political obstacles for many to manage their chronic health conditions (Gottlieb, 2021).

As we know, consumers and businesses generate data using products and services. As stated in the new Data Act, The European Data Strategy at a Glance Benefits of the Data Act, they will benefit in 3 aspects, namely (European Commission, 2022a):

1) Cheaper prices for aftermarket services and reparation of their connected objects.
2) New opportunities to use services relying on access to this data.
3) Better access to data collected or produced by a device.

Citizen data activism can be about surveilling the corporate surveilles themselves. Citizen data activism should be in close collaboration with citizen science movements which capitalize on crowdsourcing for scientific purposes. We need to develop alternatives to surveilles by collecting and interpreting our own data –to break *"the monopoly of interpretation"* as stated previously. (Gezgin, 2019) Data is the basis for many new digital products and services. The use of connected objects (Internet of Things) increasingly generates data. (Gezgin, 2019).

3.2. Health Activism- Context: Patient Associations

In the late 1960s, the women's health movement began challenging patriarchal norms embedded in medical stereotypes, framing those norms as detrimental for women's health. Twenty years later, acquired immunodeficiency syndrome (AIDS) patients

advocated for clinical research that could lead to the discovery of a treatment for their disease and mental health activists marched for the rights of mentally disabled patients. In the 1990s, for the first time, breast cancer activists drew public attention to the environmental causes of breast cancer (Brown et al., 2004; Vicari & Cappai, 2016).

 These and many other Health Social Movements (HSMs) share a common element: in one way or another, they challenge traditional conceptions of medical authority. HSMs advocate for the inclusion of non-scientific and non-governmental views in the management of public health, as the 'scientization of decision-making can exclude the public from important policy debates and diminish public capacity to participate in the production of scientific knowledge itself' (Brown & Zavestoski, 2004). Brown and Zavestoski (2004) advance that contemporary 'societal rationalisation' – or the assumption according to which policymaking must be primarily informed by scientific evidence – foregrounds the role of scientific expertise by simultaneously downplaying that of public knowledge. The target of HSMs' critiques is then often the absent-to limited power of patients in the management of public health that is common in traditional forms of patients' exclusion from health consultations and in paternalist approaches to patient involvement (Vicari & Cappai, 2016).

Hence, HSMs hold a twofold relationship with medicine, on one hand they do depend on medical expertise in the development of scientific research with diagnostic and prognostic objectives but on the other hand they challenge social, cultural, economic and often politicised dominance of medical authority in health decision-making (Vicari & Cappai, 2016) Drawing upon the American tradition of social movement theory, Brown and colleagues provide a typology of HSMs that describes three ideal types: health access movements – that 'seek equitable access to healthcare and improved provision of healthcare services' –, constituency-based health movements – that 'address health inequality and health inequity' across social groups –, and embodied health movements – that 'address disease, disability or illness experience by challenging science on aetiology, diagnosis, treatment and prevention' (Vicari & Cappai, 2016). Now, while other HSMs categorisations have perhaps provided more comprehensive explanations of HSMs' mobilising potentials and political orientation, Brown and colleagues' issue-based taxonomy directly focuses both on specific areas of action and on the institutional outcomes HSMs try to achieve (Vicari & Cappai, 2016). In particular, Embodied Health Movements (EHMs) are characterised by three elements that make them the most

contemporary instances of health activism: they introduce the embodied experience of a disease in activist performances, they directly challenge medical science's success in solving health problems that are often 'socially and economically mediated' (Brown et al., 2004), and they ease collaborations between patients, patients' families, health professionals and lay people via what we may call instances of fluid interaction. Given that EHMs move the boundaries 'between what are considered to be patient skills and initiatives and what remains the responsibility of the doctor' (Barbot, 2006), they have also been given the attribute of 'boundary movements' (Vicari & Cappai, 2016).

EHMs, as boundary movements, blur traditional distinctions between lay people and professionals and 'A central vehicle for blurring these boundaries is the use of what we term the "citizen/science alliance," a lay-professional collaboration in which citizens and scientists work together on issues identified by laypeople' (Vicari & Cappai, 2016).. In the emergence of these alliances between patients and health professionals, patient organisations obviously play a pivotal role (Vicari & Cappai, 2016).

Patient organisations: from auxiliaries to scientific partners in EHMs, Embodied Health Movements, the traditional division of skills between health professionals and patients – with the former holding power over medical knowledge and policy access and the latter dealing with the psychosocial aspects of illness – was overturned when patient organisations 'joined established actors in the production of medical and scientific knowledge' (Barbot, 2006). According to this new model, not only did 'active patients' (Barbot, 2006) share relevant information on their illness and generated resources for self-support, they also engaged in the production of scientific knowledge. In fact, Landzelius introduces yet another label for HSMs that directly challenges traditional boundaries between health professionals and patients, that of "patient organisation movements": a label that clearly calls attention to the figure of the patient, the phenomenon of organisation, and the dynamics of movements. Landzelius' work – together with that of several scholars primarily from the field of medical sociology– focuses on the role of patient organisations in bridging the gap between patients, health professionals and health policymakers and in providing the grounds for successful interactions. While different patient organisations may hold alternative views on patients' role in the production of scientific knowledge (Vicari & Cappai, 2016). instances of patient organisations' engagement in biomedical research may be categorised under three models: auxiliary, emancipatory and partnership (Vicari & Cappai, 2016). The auxiliary model covers a

wide range of organisations that, to different degrees, delegate research decisions to scientific councils, and limit their ability to decide which research to finance. In the most advanced instances of patient organisations' engagement within this model, patient organisations work to acquire scientific knowledge and be able to confront scientific experts (Vicari & Cappai, 2016).The role of patient organisations here is of central importance as '(1) the patient organisation is master of its research policy; and (2) patients are specialists' partners in their own right' (Vicari & Cappai, 2016). In sum, at the very least, EHM patient organisations work towards the expansion of discursive space around specific illnesses and ease interactions among different actors involved in biomedical research and policy-making relevant to those illnesses. It should, however, be noted that these communication processes do not happen in a media vacuum; media ecologies certainly shape discourse dynamics and influence interaction processes among different institutional and non-institutional actors (Vicari & Cappai, 2016).

3.3. Data Activism- New legislation (Concept)

Through data activism, it is possible for patients suffering from all diseases to contribute their health data to improve medical research, and/or alternatively, to share information about themselves online for all to see.

According to George and Leidner (Gezgin, 2019) data activism "is triggered when closed governments refuse to share data or when open government is threatened by the removal of open data"; "it examines, manipulates, leverages and takes advantage of existing data, but also resists and meddles data creation and use—and these tactics can be seen as antiprograms to pre-set hegemonic uses of data and software" (Milan, 2016). Somewhat converging with George and Leidner (2018), Milan & Van Der Velden (2016) identify 2 kinds of data activism which are on a continuum rather than discrete categories: Pro-active data activism ("ways of affirmative engagement with data", "data-based advocacy") and reactive data activism ("tactics of resistance to massive data collection", "encryption practices") (Gezgin, 2019). According to Milan and Gutiérrez (2015): Re-active data activism comprises the practices of resistance to the threats to civil and human rights that derive from corporate and government privacy intrusion. Pro-active data activism embraces those individuals and civil society organizations that take advantage of the possibility for social change and civic engagement offered by big data. (Gezgin, 2019)

New legislation: The Data Act is a proposed Regulation harmonising rules on fair access to and use of data. It will play a key role in the digital decade, helping to shape the rules for the digital economy and society, like it can see in the link https://digital-strategy.ec.europa.eu/en/library/data-act-factsheet. The European Commission refers the Data Act is part of the overall European strategy for data, and complements the Data Governance Regulation of November 2020 by clarifying who can create value from data and under which conditions. It will also introduce rules concerning the use of data generated by devices connected to the Internet of Things and it will make more data available for use. It will set up rules on who can use and access what data for which purposes across all economic sectors in the EU (European Commission, 2022).

3.4.   Health Data Activism- Concept

Health activism involves a challenge to the existing order whenever it is perceived to lead to a social injustice or health inequality and uses a range of tactics that vary according to the function, structure, and purpose of those trying to redress the imbalance of power that has created the situation in the first place. (Laverack, 2012). Historically, there are examples of how health activism has helped people who are low on the social gradient and whose social conditions are shaped by having less economic or social protection from social injustice and inequality. The role of health activism has been to challenge the perpetrators of social injustice by using, if necessary, action that goes beyond the conventional or routine. Health activism has been a successful strategy for pressure groups, focusing on a specific, sometimes localized and often short-term issues. Health activism provides a way for public health professionals to enact the social justice perspective of "valuing others" and utilise the significant power and privilege they possess to effect change. In a recently published guide to health activism, Glen Laverack presents health activism as a way to overcome a political environment in which "politicians and corporations are unwilling to share power with the marginalised in society" (Llewellyn, 2015).

3.5.   Need for a movement concept for the promotion of data use

The main motivation of this dissertation was to study how access to and better use of health data could be promoted. Thus, it was first necessary to verify who was able to do

so, despite illiteracy in health. Thus, several aspects were analysed, namely patient empowerment, whether they had the perception that they had the right to their own data, as we were their owners, whether they knew how to use them, how to handle them and what was done with them and what benefits they would bring. Thus, we asked patients' organisations, which are the voice of the patients, to help us in this study so that they could help patients in some way, and that they could also benefit. In this discovery a concept "Health Data Activism" is growing, trying to capture attitudes and actions that a person or organisation may have in promoting health data and the best way to use it.

4. Methodology

The following methodology was used that included questionnaires and semi-structured interviews based on revised theory and previous literature.

(a) Questionnaires – sent to patient associations for collection their perspective about their ativism, what they do to be activated, how they do it and how they use the health data.

b) Interviews – to understand in depth the responses from the questionnaire.

c) Refining the concept of Health Data Activism based on results from the questionnaire and the interviews.

A questionnaire was sent to several patient organisations to try to understand how each organisation deals with the topic, how prepared they feel and what they think about this topic. After this questionnaire, representatives of the organisations responded whether or not they would be willing to do a short interview on why and what was not clear from the questionnaire - any doubts they might have and some topics they would like to discuss and develop.

In this research, the methodology to be followed was the application of questionnaires and interviews to the Organisations/Associations. In this way, we could classify that in this project we had a qualitative and quantitative analysis, but mainly qualitative. Qualitative data collects information that does not only seek to measure a theme, but to describe it, using impressions, opinions, and points of view.

Qualitative research is less structured and seeks to dig deeper into a topic to gain information about people's motivations, ideas, and attitudes. While this approach provides a more detailed understanding of the research questions, it makes the analysis of the results more difficult. Whereas quantitative data aims to collect hard facts: numbers. Quantitative data is structured and statistical. They form the basis for drawing general conclusions from your research (Castleberry & Nolen, 2018).

Thus, the quantitative data was demonstrated through the scoring of the questionnaires carried out and then proceeded to the interviews. The qualitative analysis can be seen through the answers to the questionnaires and the interviews.

In this type of research, the literature review was one of the major bases that gave the structure and knowledge necessary for us to understand the general concept that was being analyzed. After achieving this goal, with an intense literature review, with several analyses performed on the importance and advantages of interoperability of patient health data between the various countries of the European Union, the knowledge achieved allowed us to create a questionnaire and several interviews that will lead to the final goal.

Thus, this segment of this research was developed through the following phases: (1) Preparation of the questionnaire which included a brief general description of the theme "Health Data Activism" and the practices that were carried out throughout this research. (2) After having completed the previous point, the body of a well-structured e-mail had to be written, so that we could send it to the organizations/associations. In this e-mail, the written work on the theme, the questionnaire, and the link to the site where the work is published were attached. (3) The organisations/associations that accepted, interviews were carried out with them. (4) Finally, we wanted to verify which are the best examples of organisations/associations that have a distinctive level of sophistication, to take Portuguese Patients' Associations to that level.

Inclusive Digital Health must cover on the one hand empowerment and participation - digital if possible - of individuals and patients so that they are not excluded from this change, but also the development of open, flexible, secure and interoperable systems that allow an efficient exchange of health information and data enabling health and economic benefits for the owners of these data - all citizens. The lack of adequate information sharing through verbal or written communication between teams jeopardises the security of health data, but also the quality of healthcare for patients. It is thus called Health Data

Activism, the movement for each one to make every effort for maximum sharing and secondary use of health data. Thus, this Joint Position aims to be a step towards promoting Inclusive Digital Health, leading to empowerment, literacy, and advocacy for the maximum use of health data to the extent that it can be used, safely and with privacy, for the benefit of the owners of that data - the citizens and those with chronic diseases. In this way, the importance of citizens' understanding that it is safe to share their health data and the awareness that they themselves have a right to their own health data is highlighted. This is a topic that deserves the concern and attention of the Signatory Organisations, Entities and Personalities.

Patient organisations work towards expanding the discursive space around specific diseases and facilitating interactions between the different actors involved in biomedical research and policy-making relevant to these diseases. Digital empowerment and the exploitation of health data are seen as ways to promote the health and well-being of individuals with disease.

The associations, entities and personalities listed in Annex B jointly commit their efforts within their areas of influence, their knowledge and their remit and competence to the promotion of Inclusive Digital Health. On the 24th of November this Joint Position was presented at the III Conference on Societal Health, at ISCTE, where the 15 patient organisations that signed this Position, from the 44 organisations that were contacted, were made known, as it can see in annex B. Please note that this document will remain open and editable so that we can reach as many signatures as possible.

4.1. Population and Sample

The sample of the research was quite large, since the aim is to interoperate as many European countries as possible. Thus, ensuring a greater consistency and quality of data.

Thus, we had as sample 27 organizations/associations at the European, International and National levels, in which 6 was Portuguese associations, out of a total of 229 associations contacted. Over this sample were contacted through the European Patients' Forum (EPF). The European Patients' Forum (EPF) is an independent, non-profit, non-governmental

organization that groups patient organizations across Europe and in all disease areas. Their 77 members include specific patient groups, active at the EU level, and national patient coalitions (European Patients´ Forum, 2021.) This forum emphasizes the importance of a Europe where patient organizations are valued partners in creating equitable, person-centered, accessible, and sustainable healthcare systems based on patients' unique knowledge (European Patients´ Forum, 2021). Moreover, Diabetes Associations that belong to the IDF, International Diabetes Associations and other associations that were communicated that the associations that had already responded were asked to send it to others that they knew could help us in this study.

4.2. Data Collection

The data for the study were collected through qualitative methods such as interviews, direct observation, and analysis of documents such as questionnaires and organisational documents (Bryman & Bell, 2011).

Given the current pandemic situation and the organisations/associations being of European, international, and national scope, preference was given to conducting interviews via zoom. However, it was much more beneficial and enriching to have been conducted face-to-face, as Radcliffe (2013) cited by Robert et al, indicated that face-to-face interviews provide greater flexibility to control the questionnaire topics and the interview process (Robert et al., 2011).

For these interviews to have taken place it was necessary to obtain consent from the Organisation and a commitment to data protection and confidentiality. The interview process included planning and preparation, note-taking and recording of the interview. Recording the interview allowed the data to be preserved for future analysis and reduced variation in questions (Bryman & Bell, 2011; Pathiranage et al., 2020).

Firstly, a questionnaire was conducted where there was a brief description of the concept and the practices that were developed. After this questionnaire was sent to the associations/organisations, they responded whether or not they accepted to have an interview. Once they had accepted, an interview protocol was emailed to them which again included an abbreviated overview of the topic, date and time of the meeting,

participant instructions, participant consent form and the semi-structured questions to be asked.

Once the Associations/Organisations had accepted, we moved on to the interview. The duration of each interview was approximately 30 minutes, as there was the verbalisation of the acceptance of the recording of the interview, followed by a thank you for the acceptance, the questions to be asked and some relevant notes that arose during the conversation. If the representative of the association/organisation was unable to do the interview, he/she was asked to do it to someone else. If this was not possible, they were asked to answer the interview questions by email.

The researcher also took field notes based on his observations. These notes allowed him to specify the key dimensions of everything he observed or heard in a summarised and detailed way (Bryman & Bell, 2011). Subsequently, the data collected was organised to facilitate its follow-up and access in the future. To allow for greater organisation, the data in this study were electronically archived by computer folders and transcribed into Microsoft Excel 2016 and Microsoft Word 2016. Study participants were identified by the acronyms of the Organisation/Association and the date of the interview, such as ECL13/01, Association of European Leagues Against Cancer, 13 January, to maintain data confidentiality and to facilitate the analysis of the responses to each question, making the process simpler, more efficient, and organised.

The data used throughout the research was totally real, being collected through the questionnaires and interviews carried out to the Associations/Organisations.

4.3. Data Analysis

The data analysis process of the study involved an in-depth evaluation of the data, verification of the credibility of the evidence collected and interpretation of the results.

The general method that was used to analyse the data collected was thematic content analysis.

Thus, a critical analysis of the questionnaires sent to the Organisations/Associations was carried out and, if they accepted, an interview was subsequently conducted with their

representative. So that it was possible to carry out the data analysis of this research, the interviews were transcribed, categorised by similar concepts, and analysed by themes (Pathiranage et al., 2020).

This type of analysis categorised in this case by the Organisation/Association levels of focus (European level, international level and national level) emphasised the role of language as a power resource that is related to ideology and sociocultural change (Bryman & Bell, 2011). Discourse was therefore conceived as a 'generating mechanism' that not only provides an account of what happens in organisations, but also a process by which meaning is created.

The analysis of the organisational documents consisted of the analysis of the annual reports and the analysis of the mission, vision and values of the Organisation/Association. In addition, the websites of each organisation were analysed, to already have a basis of what they understand, namely, how many countries the organisation involves, whether it has any European projects, how many members the organisation has involved, among others. According to Sinkovics and Alfoldi (2012) cited by Pathiranage et al, indicated that research can be supported by computer programs to analyze data and store searchable information (Pathiranage et al., 2020). Thus, the data were analysed with the help of Microsoft Word 2016 and Microsoft Excel 2016 spreadsheets to organise, analyse and document the collected data.

In this way, the questionnaires were analysed using a descriptive statistical analysis, which from my sample, from my data set, a summary extracted from the graphs made was generated. The analysis of the interviews was performed qualitatively, in table form, to make it easier to organise all the information obtained, as shown below.

Table 1. Summarizes the main themes from answers to all the questions asked in the interview.

Questions asked in the interview	Replies by the Associations
1) *Did you already hear about this concept?*	- This is one of the subjects where we all gain from working as a team, it is a transversal subject for all users and all the associations that represent them. - Quite interesting topic, data topic is a super important topic. -Theme already discussed in some movements. - Our level is still not very advanced. our activism is a little bit about who we are, what we are, and where we are, we are very little active.
2) *Do you think that the access of health data is a problem?*	- It is a problem as a situation to improve. -An urgent need. -Improvements with RGPD - Hospitals/ organizations don't have things set up to be quick and practical for the hospital. Clinical process- send a cd and send to the person. -A lot of the data is not standardised, and records are missing.
3) *Is the issue of access one that the association has already discussed?*	-Topic that has been discussed internally. -In smaller and more specific associations it is not a priority. - Yes. We are handling them nationally, as well as internationally. How to handle them, but it is a time-consuming process. - I have felt a positive evolution in this aspect, I think so. The associations have been gaining a lot of maturity.

4) *Do patients in any country have more access more than others? And do they talk about it?*	- Yes, Anglo-Saxons and Nordics yes, Mozambique no longer. -Portugal is in the tail of the rich countries, according to the Economist, 10th place in quality. -Very large discrepancies between countries. -Germany is top 1 in Health Digitalization. - Data interoperability is essential, especially in chronic disease.
5) *Have you ever done a questionnaire to systematically collect information about the access your patients have or don't have to information?*	-No, but it would be quite interesting to have that feedback. -No, because we don't have quantified users. **-**Yes, and the results were surprisingly satisfactory (just 1 association said yes).
6) *How is patient health data used?*	-Service Provider Institutions- clinical part, studies, research, regulation. -Non-Provider Institutions- do not do clinical health research.
7) *Have you ever done an event on health data?*	-No, but it is very interesting idea. -Yes, it was a success event (2 associations said yes)
8) *Do you consider that patients already have substantial autonomy over their health data? If not, do you agree with that?*	-Average: 10%-40% are aware -Most do not know that they have the right to access their data (if they do, they do not know where to look for it) - They have very little, the younger and qualified generation has it, the rest of the population doesn't have it - no training or literacy.

9) From 1 to 5 how strong is the promotion of access and better use of health data in your association?	- The average of the responses from all the associations is 3. -Comparison between the value attributed to the association and general, the value attributed to national access is always higher.

After listening to the interviews and after a thorough transcription, an analysis of the interviews was carried out (content analysis). The purpose of this analysis was to identify information based on questions asked in the interviews. As mentioned by Guerra (2006: 62), "content analysis has a descriptive dimension which aims at reporting what was told to us and an interpretative dimension which results from the analyst's questions about an object of study".

4.4. Ethical Aspects and other Problems

The biggest limitation in this type of research is always the amount of sample we can have, in the sense that after contacting the Organizations/Associations, the biggest concern is even if we will get a response from them. This way, it is always a little unpredictable if we will have all the answers from these Organizations/Associations, and even if we do, in this research the ideal will be that all Organizations/Associations answer both the questionnaire and the interview. In order to have a larger sample of organizations/associations sign and accept the declaration of data activism.

In addition, the Code of Conduct advocates that the researcher should take every precaution to ensure that the interviewees are in no way harmed directly or adversely affected by the outcome of their participation in the research, i.e., that the study participants do not experience any harm due to their participation in the project. According to the guidelines, researchers should examine results by subgroups only in situations where there are ten or more respondents involved, which is the case. (Bryman & Bell, 2011).

In this sense, this project will have some ethical issues associated with maintaining the confidentiality of participants and their privacy. However, the issue of confidentiality in relation to qualitative analysis (both questionnaires and interviews) will be difficult to

maintain since field notes and transcription of interviews may allow Associations or Organizations to be easily identified. Thus, extra care must be taken in publishing responses unless permission is granted by the Organizations/Associations.

Thus, all participants will be informed of all stages of the research honestly and truthfully. Participants will sign an informed consent form, where all Organizations/Associations will receive information to make an informed decision about whether to participate in this project. Thus, they will have the chance to accept to answer the questionnaire and/or the interview, the authorization form for the recording of the interviews, the form that will guarantee data protection and the protection of the identity of the interviewees.

On the other hand, the privacy of the Organization/Association must also be considered. Thus, participants can withdraw at any time, as well as refuse to answer certain questions that might compromise the invasion of privacy. This easiness should be clear to have a good fluency during the interview, thus having a good relationship between the Organization/Association and the interviewer.

5. Results

In this study results are analyzed by two means, questionnaires with 11 short questions in which 4 of them have a scale from 1 to 5, where 1 corresponds to "Not Being Important", while 5 is "Very Important".

In addition, we have the analysis of the interviews in which 9 open-ended questions are evaluated. The interviews had a minimum duration of 30 minutes, all of them zoomed in, except three, which was done in person.

In the end, 27 answers were obtained from the questionnaire, while only 13 were obtained from the interviews.

5.1. Results from questionnaire

Thus, by analysing the **questionnaire** we can see, through image 1, after a brief introduction to the concept of "Health Data Activism", the associations were asked how important this topic was in the organisation. As can be seen in image 1, 59.3% of the associations agree that it is quite important, while 29.6% think it is only important and there are other priorities to be discussed, 3.7% of the associations state that it is a moderately important topic and 7.4% is somewhat important.
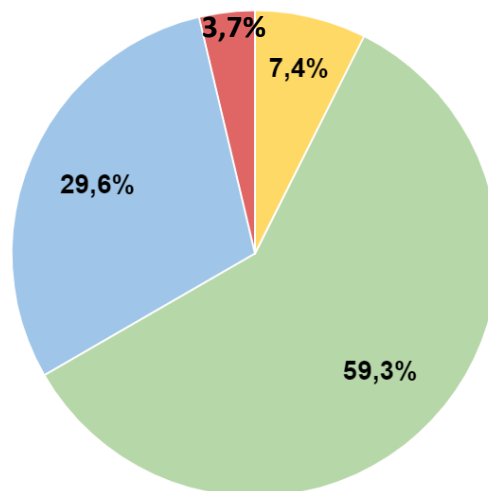

Image 1. Answers of "How this concept "Health Data Activism" is important for your association?"

In the image 2, we asked how useful this topic was in their associations, and the answers were more varied, with 33.3% saying it is very useful, which shows that it is a topic that has been discussed and shows the associations' concern for this topic. The most frequent response is that 37% of the associations state that this concept is useful in their organisation, while 14.8% consider it of moderate relevance and the remaining 14.8% state that it is substantially important.

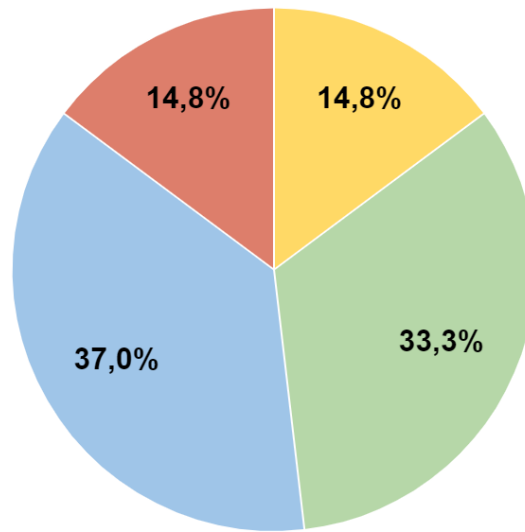## 2. How usefull this concept is in your association?

Image 2. Answers of "How useful this concept is in your association?"

However, despite being, for the majority, a very important and valued theme, we wanted to know, at this point, how strong they thought they were in promoting access and better usefulness in health data.

3. From 1 to 5 how strong is the promotion of access and better use of health data in your association?
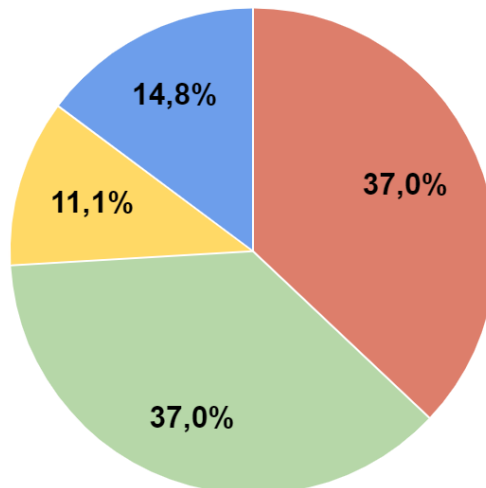

Image 3. Answers of "From 1 to 5 how strong is the promotion of access and better use of health data in your association?"

In image 3, it can be seen that 37% of the associations contacted consider that they are very strong in terms of promoting access and better use of access to health data, 14.8% state that they are strong, 37% believe that they can still improve in this area of access, since they are still at a moderate level and, finally, 11.1% of the associations reveal that they are still at level 2, and are therefore aware that they can do much more in this respect.
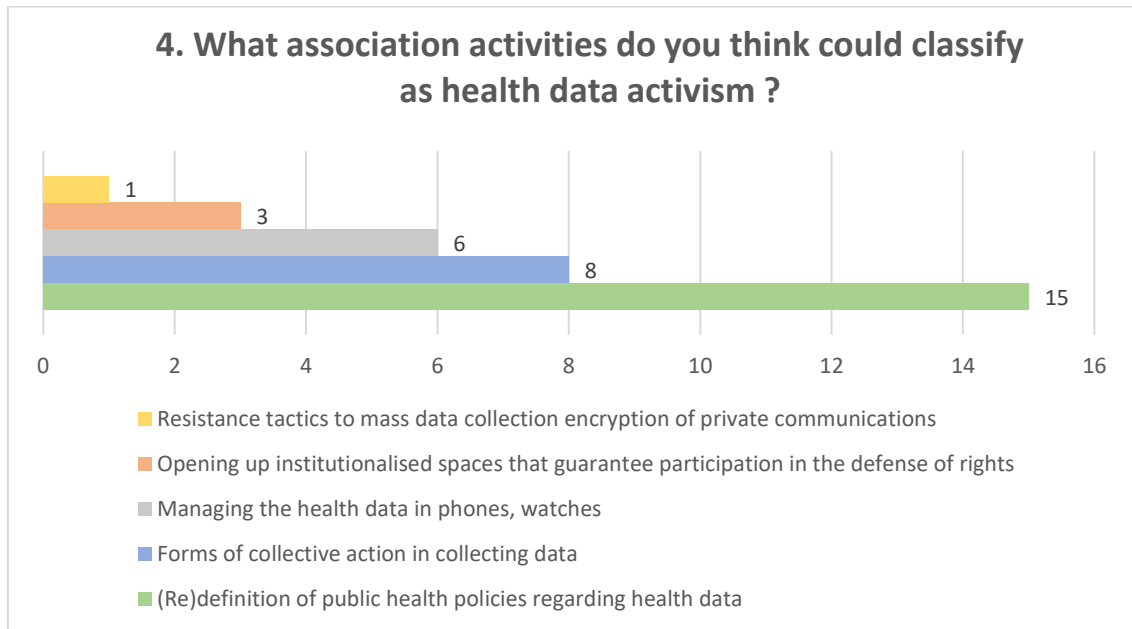

Image 4. Answers of "What association activities do you think could classify as health data activism?"

Furthermore, we asked the associations which activities they classified as health data activism, and most of the associations (15 replies) consider that (Re)definition of public health policies regarding health data was the activity with the most potential. Besides that, forms of collective action in collecting data (8 answers) and managing the health data in phones and/or watches (6 replies) were the most chosen. The opening up institutionalised spaces that guarantee participation in the defense of rights (3 replies) and the resistance tactics to mass data collection encryption of private communications (1 answer) were the least selected.

For the question 5, they were asked to choose two of the activities they thought most relevant from those they had selected in the previous question and to explain why they had chosen them.

Table 2. Answers of "Regarding the previous question, question number 4, choose 2 activities that you consider that are the most important and explain why."

Question 5. Activities that the associations consider that are the most important.	**Why?**
(Re)definition of public health policies regarding health data (8 answers)	This should be carried out at EU level as equal standards on this topic need to be implemented in all EU countries to ensure equal rights to patients in different countries; Advocacy with Policy Makers on patient data and creation on data tools where patients can control their data; Re definition PHP; redefinition of public health policies is the most important, as it helps to create a systemic change; Collecting clinical data from a large number of patients allows them to be analyzed with innovative IT tools and better understand various clinical aspects, then implementing strategies to improve outcomes; (Re)definition of public health policies regarding health data: because the importance of regulating the utilization public health data; Definition of policies as regards health data, since technology is constantly evolving, and the current infrastructure is not able to guarantee that the patient is getting the most out of it.
Forms of collective action in collecting data (9 answers)	Patient access to their own data to improve transparency and security; Forms of collective action in collection is crucial for Real World Data to be used to improve decisions; Ability for as many people as possible to participate in data collection with guaranteed security and privacy - especially those who cannot participate in online forms that can guarantee it (access to data from the elderly or people in parts of the world that have wifi and access challenges - these voices are essential in data activism). And how to use and update public policy around the world to enable access and use of this data; Continuous monitoring is very important because we are able in real time to correct hypo and hyperglycemic situations; Those who collect the data are not always interested in improving patients' condition but may have commercial

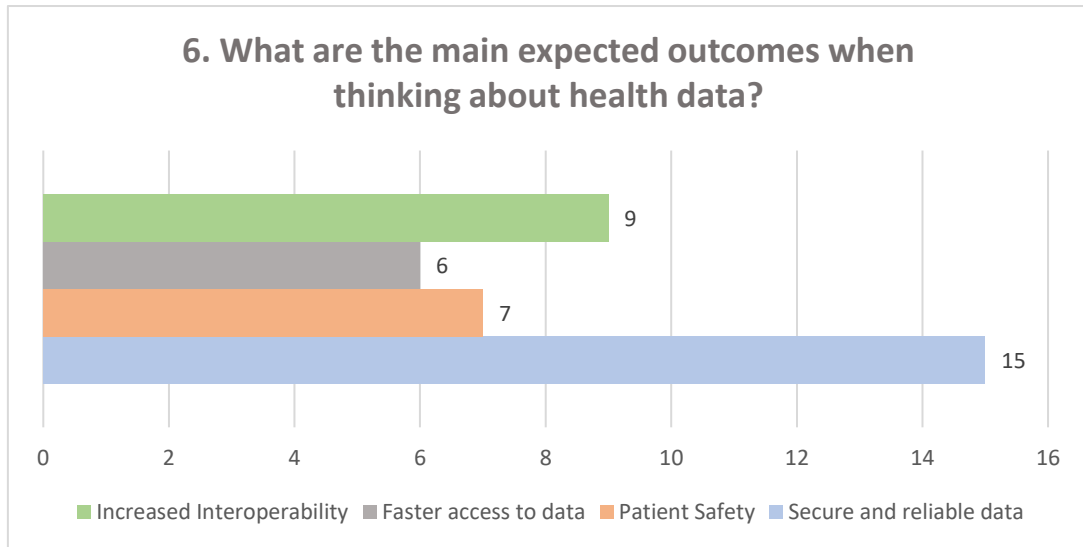|	
	interests as a priority; Engagement in registry of centres of expertise and engagement in patient driven registries
Managing the health data in phones, watches (2 answers)	Managing the health data in all devices must be guaranteed in secured and optimized environments; Health Data in watches/phones are currently underestimated from a clinical perspective
Opening up institutionalised spaces that guarantee participation in the defense of rights (6 answers)	Include this issue in our conferences and webinars; include this issue when approaching the policy decision makers; Opening of specialized spaces; patients to benefit from their *own* data (and for that, to access it first). value extraction at the expense of patients; Overseeing own health data, having a right not to share, having meaningful contribution to policy; We (patient organisations and patients) have an important contribution to make with shaping the European Health Data Space so that data works for the patient. Data should be owned by the patient, and they should be empowered to use the data to improve their own health as well as share the data to who they wish to improve medical research and clinical care; Create knowledge on data property, sharing, security. Give training on your rights of data management (self-health data).
Resistance tactics to mass data collection encryption of private communications (3 answers)	More articulated Health Data access, by public and private medical institutions, to give a more effective service and treatments to our patients.

Image 5. Answers of "What are the main expected outcomes when thinking about health data?"

The next question asked what the main expected outcomes were when thinking about health data. Thus, there was one answer that stood out, with 15 answers, in which they stated that secure and reliable data. The next one was interoperability, with 9 answers, and patient safety, with 7 answers, followed by faster access to data, with 6 answers.

Table 3. Answers of "Regarding the previous question, question number 6, choose 2 outcomes that you consider that are the most important and explain why."

Question 7. Outcomes that the associations consider that are the most important.	Why?
Patient Safety (8 answers)	Patient Safety must be the core of the European Health Data Space; patient safety is the key - if this aspect is jeopardized, a technical set up no longer matters as the end-user will simply avoid using the system; better outcomes and better care for patients; For the patient to be able to partner with their healthcare team to improve their own care is the primary objective; due to the clinical aspect that health data plays in treatment scenarios; FAIR data with data protection for the patient (by using the successor of the EUPID numbers)
Increased interoperability (6 answers)	it may mean better and faster response to the health problem; Interoperability is imperative to have valuable data for research

	and better results; being able to access secure data and above all coming from different databases allows to broaden the perspective of analysis; To avoid repeating unnecessary medical exams; especially thinking of the rare disease community, which I work with and know best, I would have to highlight the importance of having increased data interoperability: this is fundamental, especially in the context of disease registries.
Secure and reliable data (11 answers)	will be necessary to properly inform healthcare policies and intervention campaigns, and to disseminate correct information to patients; Implementation of FAIR data for Patient Data; will be necessary to properly inform healthcare policies and intervention campaigns, and to disseminate correct information to patients; being able to access secure data and above all coming from different databases allows to broaden the perspective of analysis; Reliability of data is fundamental in order to use data itself; Large, viable and relevant data sets. proper use by the right people of the data; Creating more robust data sets would increase overall quality enabling better data analysis. These would increase the quality of individual or group reporting tools; due to the clinical aspect that health data plays in treatment scenarios; will develop AI for the benefit of health care.
Faster access to data (5 answers)	Easy access to data; Fast Access to patient data both to promote R&D and Care; it may mean better and faster response to the health problem; will assist in innovation, research, and precision health.

8. How important do you think is health data?
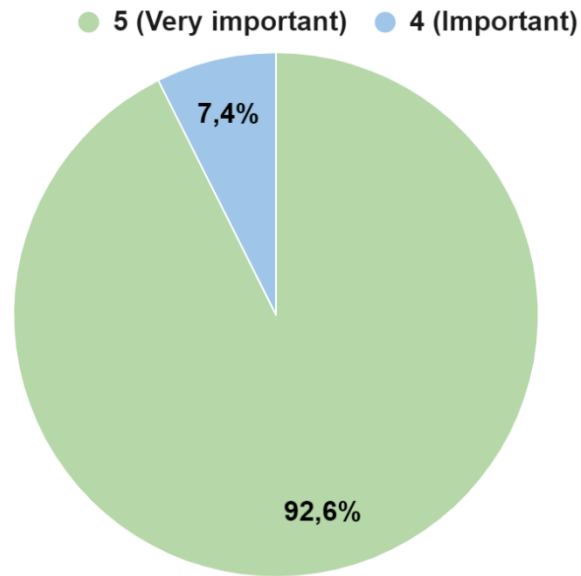
Image 6. Answers of "How important do you think is health data?"

As can be seen from image 6, many associations, around 92.6%, responded that the health data theme was quite important in the associations' own principles, and that around 88.5% of these associations, image 7, stated that they could be even more activist on this health data topic.

9. Do you think your association could become more health activated?
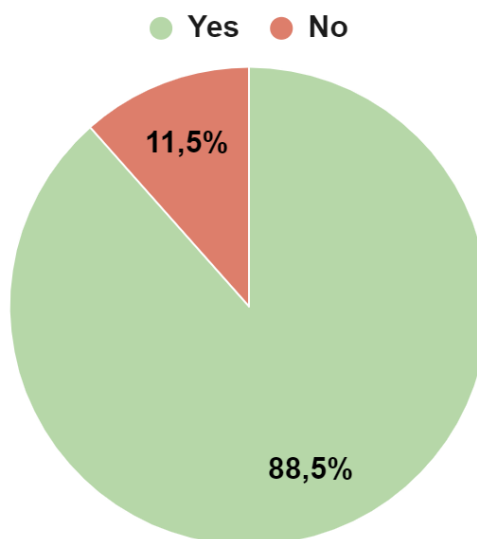
Image 7. Answers of "Do you think your association could become more health activated?"

Bearing in mind that 88.5% of the associations consider that they can be even more health activated, the big question is to understand how these associations manage to innovate and become more activist, as we can see in Table 4.

Table 4. Answer of "How association could be more health active?"

| *Question 10.*	**Replies by the associations**
If yes, how do you think you can do it?	-Promote meetings with patient associations, individual patients, National authority for data in health, Ministry of Health, doctors, nurses. -Develops tools and services for patient data. -Access to reliable data for research and epidemiology. -Put health data as a priority and make our associates aware of its importance in the quality of life. -Actively participating in all phases of a major initiative. by increasing knowledge among the patient community on their rights. -Encourage members to place greater emphasis on accurate data collection. -Improving research in Artificial Intelligence. -Having more resources to activate member organizations, raise awareness, training. -To spread best practice in this area and support other patient organisations. The rights of our patients would be more respected if the information in data health services were more reliable. -Having a specific area on this topic. -By learning more about the topic and increasing awareness.

5.2. Results from Interviews

In the final question of the questionnaire participants were asked if they would be available for an in-depth interview. 85.2% of associations agreed to do an interview, however not all responded to the email for the interview invitation. A total of 13 interviews were conducted out of 23 that had initially accepted, while 14.8% did not accept from the outset. The results of the interviews are shown in Table 1, where they will be discussed in the following section.

6. Discussion- Health Data Activism

6.1. Analysing Results

The associations agree on the importance of health data as a priority, agree that they can be more active about health data. The Health Data Research UK shows how this importance of health data can be with some examples of the improvement of their knowledge of health and care has helped solve challenging health problems, such as diagnosing rare diseases, improving the performance of health systems, identifying diseases early, studying effects of immunisation, better understanding why certain populations are affected by the same disease, assessing the safety of medical interventions and making connections between disease and lifestyle choices. (Health Data Research UK, 2022).

They were consistent in agreeing to be interviewed, showing interest, curiosity to this topic.

However, they disagreed on how important the concept is for the organisation, as well as on the usefulness of this topic. Patient organisations, as well as other organisations, tend to think that they don't need a concept. Their priority is wellbeing and patient care, which is correct, but to understand the direction and needs of users, it is fundamental to name the topics, the concepts, so that we can all understand them and have a better communication between organisations, ministries, entities.

In addition, they also disagreed on the activities that they would classify as health data activists and, finally, on the main expected outcomes when thinking about health data. In

addition, they also disagreed on the activities they would classify as health data activists and, finally, on the main results expected when thinking about health data, as verified in the results of table 1 and 2. These disagreements depend on the level of digitisation, the capacity of each association and, depending on that level, the priority given to the needs. If it is a smaller association, logically the priority is the wellbeing and care of the user, while a larger and more developed association will have more room to innovate. However, this perspective depends a lot on who supervises the association or organisation. The person's vision influences the entire organisational structure and the way in which it is possible to innovate and improve (Brown et al., 2020).

In question 10 of the questionnaire the associations were asked how they thought there could be more activities at the level of their patients' health data, so the answers were quite similar and direct. Through network with other associations, they should provide more resources to activate users and various entities to change their perceptions and raise awareness about the value of health data; development of tools and services for patient data; access to reliable data for research and epidemiology; health data being seen as a priority and raising awareness of its importance in quality of life; participate actively in all phases of a major initiative, increasing awareness among the patient community of their rights; to encourage members to place greater emphasis on accurate data collection; improve research in Artificial Intelligence; disseminate best practice in this area and support other patient organisations and providing a specific area on this topic.

In which concerns to the interviews, the associations agree that they had already heard about the topic, that the topic was quite interesting and that they had already heard about it in some movements in which some associations are involved. They also agree that access to health data is a problem and an urgent need, which has been improving with the GDPR. In addition, there is a uniform opinion that access to health data is not homogeneous and equal for all. There are countries, namely Germany, the Anglo-Saxon and Nordic countries that have a much easier access, unlike Mozambique. Portugal is currently among the rich countries, and is in 10th place in terms of quality, according to the Economist. It was unanimous that a questionnaire had not been carried out to collect information on whether users have autonomy over their own rights to have access to their health data, as well as an event on health data to promote this knowledge, this awareness.

On the opposite, the answers regarding whether the problem of access to health data had already been discussed in the associations received rather disparate answers, as for

smaller, more specific associations, it is not a priority for them now. How the users' health data is used also drew quite different answers, since the associations that do not provide medical services do not do clinical research, while those that do carry out trials, regulations, research, and clinical part. Next, it was noted that there were quite different answers as to the percentage of users who had substantial autonomy over their health data, with some associations stating that they did indeed know that they had this right but did not know where this data was, whilst other associations qualified the percentage of people who were aware that they had this right as quite low, together with the percentage of the age range of users that the association covers. Lastly, on the question of how strong they were in promoting access to and better use of health data, the answers vary greatly and there is no equity. These disagreements in the answers show that one should invest in better professionalism in the associations. If the priority of these entities is the empowerment of the user, the safety of the user, there must be a much deeper investment in this sense. Furthermore, as mentioned in the Methodology section, there was the presentation of the Joint Position on Participatory Societal Health on the 24th of November, with only 15 signatures from the 44 associations that were contacted. These 34% of associations that accepted to be part of this Joint Position (Martins et al., 2022) demonstrate interest, care, knowing more, innovating for the user, who believe that there can be better participation and inclusion of the user. The remaining associations show that they do not want the commitment, they do not accept it. This non-commitment is a childish attitude and is a consequence for them. (Martins et al., 2022).

A curiosity that I highlight is that the same question was asked "From 1 to 5 how strong is the promotion of access and better use of health data in your association?", both in the questionnaire and in the interview, and the answers vary after a short introduction of the theme and the clarification of questions asked throughout the interview. Furthermore, this question was asked in the interview with the aim of qualifying in a value both the association and the general level. And, surprisingly, the general values are always higher than in the association, for the simple fact that they think they can do and be better, they think they can be more activist than they already are.

It would be essential for patients' organisations to be incorporated into political power, as they are the voice of patients. As in Britain, in the absence of the State, civil society moves forward, the strong associations are the great driving force. In England, it was the associations that alerted the National Health Service (NHS) on the issue of data sharing,

in high school with the universities. The Coalition will work to provide insights and influence the policymaking process to progress this agenda by identifying gaps in the evidence and conducting research to offer novel insights on patient priorities in digital health; developing policy recommendations; and engaging with Government stakeholders and other policymakers to advocate and campaign for system improvements. (Patient Coalition, 2022). The European Patients' Forum called on policymakers to make patient empowerment a priority in health policy, starting with the development of an EU-wide strategy and action plan (European Patients´ Forum, 2021).

DECO Proteste is an example of consumer activism, it is the largest consumer protection organisation in Portugal. Their activity aims to contribute to more informed, participative, and demanding consumers, raising awareness of their rights. Their mission is to respond to consumers' needs, considering the differences and specificities of each region. It is this awareness that all associations should have so that there is the promotion of health data in a safe, credible way, exemplifying this activism for health data and the rights they have for these (DecoProteste, 2022).

It is important, as mentioned, that users have the awareness and initiative to have access to their health data, how to use it and how to handle it. However, health professionals also have a fundamental role in this education of their promotion. There was a study that took place in the United States of America in 2020, in which the evolution of the user's motivation in sharing their data and educating them with the help of health professionals was notable (Ivanova et al., 2020). It was discussed that some of the patients consented to sharing their data, however health professionals emphasised that there was a greater motivation to do so when they were looking for something in return (for example a prescription) *"Health professionals' views on data sharing are integral to the redesign of health data sharing and informed consent. In addition, they seek clarity on the impact of patient-controlled sharing on the role and scope of practice of healthcare professionals."*(Ivanova et al., 2020).

Studies show that trust and communication between health professional and patient affects positive data sharing and can be used to reduce fear of disclosure. It was thus found that the educations health professionals made in motivating patients, an increase in patient sharing was reflected with greater trust (Ivanova et al., 2020). Thus, for there to be a better understanding about the importance of data sharing by patients, an intervention

of health professionals is needed so that there is this promotion and education (Data Saves Life, 2022).

6.2. Suggesting a new concept- Health Data Activism matured concept

In the European area, and increasingly in the rest of the world, the law is clear, health data belongs to the patient, and he has control over it. This legal right, legally established, cannot be exercised if it is not known.

There are more and more elderly people, and this leads to more chronic diseases, which shows that there must be a greater integration of care. And that's why Health Data Activism is important, this term inexistent until now, is the junction of two concepts: Health Activism + Data Activism, this need for health data usage is also related to demography.

And who is close to the patients? Who interacts with these chronically ill patients? It could be patient organisations. Patient organisations are often bodies that fight for patients' rights (accurate therapy, diagnosis, and use of patients' health data). So, what is needed is to create awareness for this right so that it is more fully exercised. But this means activism by patients themselves in relation to their own data.

The question is: How can this activism be conceptualised, can it be thought of?

The impact of this study is health data activism, a wakeup call to the organisations themselves to get moving, it is a mobilisation tool for organisations.

Studies show that trust and communication between the health professional and the patient affects the positive sharing of data and can be used to reduce the fear of disclosure. Thus, it was found that education of health professionals did to motivate patients, an increase in patient sharing was reflected with greater trust. Thus, for there to be to be a better understanding about the importance of data sharing by patients, an intervention of health professionals is needed to have this promotion and education (Data Saves Life, 2022).

Health data activism can encourage citizens or patients with rarer diseases to contribute their data to improve medical research and/or share information about them so that they can use it for their own benefit. However, this requires them to develop awareness and understanding that it is safe to share health data.

Researchers must be sensitised to not only research on more serious/rare diseases, but those with higher prevalence. Have equal right and access to research.

After to collect all the inputs from the results, it can be **defining the term "Health Data Activism" as a movement that captures an action and the efforts from a person or an organization/association can take in promoting the rights to seamless access to and best use of health data, how to use it and the value that can be extracted from their health data.**

6.2.1. Patient Empowerment Movement vs Health Data Activism Movement

As noted earlier, patient empowerment is one of the key elements of patient-centred healthcare. It can be seen as a prerequisite and an outcome of patient-centred healthcare - a goal as well as a process. This empowerment is allied to patient empowerment, which has been analysed earlier, as well. Thus, the EPF defines it as a "process that helps people gain control over their own lives and increases their capacity to act on issues they themselves define as important" (European Patients' Forum, 2021). In addition, it demonstrates the critical role that the patient plays. Aspects of empowerment include health literacy, shared decision-making and self-management. (European Commission, 2022). Although better quality patient-centred care is now being demonstrated, patients with chronic conditions are often referred to as the most underutilised resource in the healthcare system. Too many patients are struggling to get the support they need to become equal partners in care (Bravo et al., 2015).

In the other hand, when we talk about health data activism, we are talking about promoting access to health data, as well as better use of it. We also stress that patients must be made aware that they have a right to their own data (Samuel et al., 2021). However, the data belongs to the patient, there is already a new legislation on this topic, but we have to understand how patients see this, if they have the perception, if they agree, if they think it, is the easiest way. And we can't talk about patients without talking about

the largest entity that represents them - the patient organisations. It's fundamental that we have their opinion on how this is possible. And that's where the health data activism movement comes in, the inclusion of the user as the centre of healthcare. This is a humble contribution to this abroad discussion.

6.3. Future work

The XpanDH is devoted to facilitating the extensive adoption of the EEHRxF through the maturation of a pan-European Ecosystem of Early Adopters of new/adapted digital solutions that implement EEHRxF specifications, within a specific socio-technical ethos of support for trusted, sustainable and resilient solutions.

Therefore, an ecosystem of users, developers and adopters is needed in Europe to foster Digital Health innovation that nurtures interoperability (in the form of the EEHRxF) at its core. This is the spirit with which the XpanDH consortium was formed to serve Europe by Expanding Digital Health through a pan-european EHRxF-based ecosystem.

XpanDH is an ambitious project aimed at preparing and building capacity in individuals and organisations to be ready to use the European Electronic Health Records Exchange format (EEHRxF), by establishing a pan-European effort through a Network of Networks approach, that will ensure that the involved and multiple digital health actors are motivated, inspired and supported to advance to concrete adoption of the EEHRxF by guidance and real examples organised as an aggregation of interoperability assets - the X-bundle -, around the EEHRxF. The XpanDH project pursues the main goal of maturing and accelerating a sustainable and scalable interoperability environment in Europe for digital health innovations based on the EEHRxF, involving both the supply and demand sides of healthcare provision.

XpanDH will involve different stakeholders not just as opinion-providers but as active partners engaged in finding resources and with the will to create joint services based on the EEHRxF. This challenge will be addressed by the project through the XpanDH networks - X-Nets - networks of organisations directly or indirectly related to health and digital health and that will be involved or need to be involved in an expanding European Digital Health Ecosystem as it matures its use of the European EHRxF, mainly Patient Associations. To establish the X-Bundle Readiness model, develop its evaluation

processes, and build educational materials (ICT toolkit) for the relevant parties (HCP, ISP and Patient Organisations) on the steps to take to reach their next level in the EEHRxF readiness model. XPanDH will encourage a common understanding of the benefits of EEHRxF, of data interoperability, data access, control and sharing for better health among the general public and patients, promoting Health Data Activism. They will be engaged through the Policy and external Advisory Boards (WP1), but specially via the X-Nets to become informal EEHRxF ambassadors. This task will create stakeholder networks around the adoption domains and beyond. Firstly, it will create networks to exchange knowledge and experiences specific to the adoption domains, focused on two main stakeholders: patients/citizens and healthcare providers. Supported by the Patient association and the Citizens and Society X-Nets the task will focus on access to data from healthcare professionals - specifically mobile access to hospital information (by engaging with the mHealthHub community), telemonitoring and teleconsultation. The healthcare provider network will focus on continuity of care and clinical workflows through streamlining primary use of data across health systems, as well as hospital reporting.

7. Conclusions and Recommendations
7.1. Conclusions

Health data activism can stimulate and environment where it becomes possible for citizens in general and patients suffering from serious diseases to contribute their health data to improve medical research (Herzhof, 2022) and/or alternatively share information about themselves to whom they think benefit from that access to better care for them. However, researchers should be sensitised not only to research about the most serious diseases the rarest but rather also the more 'normal' ones. Focusing on, a much broader panoply of diseases. We should all have the right to the same research, and to this end, researchers should be sensitised to make this happen, the inclusion of society, of patients.

Citizens should have and be made to develop awareness and understanding that it is safe to share their health data and that it can improve and help others or even themselves in an indirect manner (Samuel et al., 2021). For example, if a citizen is going to travel or work in another country, it is essential and advantageous for health institutions to have access to the patient's full history and health data, which will bring many benefits. On the level

of secondary use of health data this means participating, benefiting and, access to research.

Through questionnaires and interviews it is possible now to conclude *"How do European/International/National patient organisations promote health data activism?"*. Most patient organisations are activists without knowing it. However, the response was almost unanimous on how they could be more and what resources they needed, as shown in table 3 of the results.

Taking this into account, we must ally and contact the associations, which are the activists, the voice of the patients, and they are the ones who can show patients and train people for this new concept and all that it encompasses - capacity building, literacy, empowerment, inclusion, and participation of the patient. It has imperative put health data as a priority and make the associates aware of its importance in the quality of life and it is fundamental to have an action framework to defense the rights of the patients.

Since the Alma-Ata conference in 1978, participation in health, understood as a right and a duty, has been systematically reiterated in various official documents as a priority that should be implemented (WHO, 1981; 1998; 2002). The social collectives, the social movements in health, as Brown and Zavestoski (2005) define them, which have been fighting for the promotion and defense of rights in health. Within the scope of this action, we highlight the struggle and pressure exerted by these collectives, particularly the associations of people with a disease or affected by the disease, for the opening of institutionalised spaces that ensure participation in the defence of rights and the redefinition of public health policies (Filipe et al., 2014). These can play a central role in the exercise of democracy, by framing the right to participate in decision-making, especially in contexts where the governance structure still fails to provide mechanisms and create sustained spaces for regular and systematic citizen participation (Crisóstomo et al., 2017).

To conclude I highlight, once more, the importance of the movement health data activism. This movement has a lot of to different actors. Health systems will benefit from this activism as they develop vital health improvements that are needed, including identifying risk factors and accelerating diagnosis, identifying disease transmission routes, thereby preventing diseases or conditions, predicting outcomes and increasing the effectiveness of treatments, improving the quality and safety of treatments, disseminating knowledge

and improving public health strategy (Kruk et al., 2018). Healthcare providers-individual health and care professionals and provider organisations can use health data to: Redesign better care pathways, improve patient care, gain insights for strategic planning and organisational quality improvement, use healthcare resources more efficiently and engage in more clinical research (Crisóstomo et al., 2017)

Already in the medical research sector health data can support research organisations and scientific associations to develop new treatments and devices, such as: a new drug to help fight a difficult-to-treat cancer, developed by a pharmaceutical company; an infusion pump that continuously delivers a controlled dose of medication to someone while they are at work or home, developed by a medical device manufacturer; a smart monitoring system that gives patients an alert on their mobile phone when a blood measurement needs urgent attention, developed by a healthcare software company; a better way to support patients with advanced dementia in their home, pioneered by a social services organization (Data Saves Life, 2022; Health Data Research UK, 2022)

However, these benefits will only be possible with the provision of patient data. Patients will know that when they look at their own health data, they gain insight into how their health is evolving over time. They will be more health literate and empowered, allowing them to adapt their lifestyle more easily, which has a positive impact on their care outcomes and quality of life. In addition, they will interact better with their health and care professionals. In addition, knowing that their health data can be provided to scientific research that will accelerate the development of new medical products and treatments for individuals who need them, there will certainly be more patient participation and inclusion.

7.2. Recommendations

7.2.1. For Patient Associations

Organisations are to invest in promoting of patient participation. Patient participation means involvement of the patient in decision making or expressing opinions about different treatment methods, which includes sharing information, feelings and signs and accepting health team instructions (Vahdat et al., 2014). Given that patient participation causes improved health outcomes, enhanced quality of life, and delivery of more appropriate and cost-effective services, if patients are regarded as equal partners in

healthcare, they would actively participate in their own health care process, and more carefully monitor their own care (Davis et al., 2007). Therefore, health professionals generally have a positive attitude toward patient participation and consider this concept as a special privilege for themselves and the patients. Planning and providing patient-oriented healthcare, based on opinions, needs, and preferences of patients are recommended (Vahdat et al., 2014).

So that they can act as the voice of the patients about health data, patient associations should do a questionnaire to systematically collect information about the access that their patients have about their health data and/or do an event of the importance of the activism of their health data.

Identify who are the key actors in the health system that relate to the health data (e.g., digital health agency, research agencies, etc.) to engage them in health data activism priorities: easy access to health data and that exploration of value from data is promoted and value generated is returned back to patients.

7.2.2. For policymakers

Ministries of health should promote or make mandatory that patients are engaged in the design or co-creation of any solutions/tools that will relate or process health data.

Health and Research legal documents and policies need to incorporate principles promoted by health data activism, such as access to and the capacity to use a person's own health data, or that research using health data reverts to value for patient and is as equitable and participated as possible.

The government has three main priorities: a reduction of poverty, inequality, and social exclusion; the consolidation of public finances; and enhancement of sustainable economic growth, employment, and competitiveness (Guglielmin et al., 2018). At a time of austerity, and with an ageing population structure, achievement of these goals is challenging and requires an input from all of us. Health is a human right and a central element of well-being. Health is also an essential prerequisite for the achievement of our governmental goals. (Guglielmin et al., 2018).

"Health in All Policies" (HiAP) describes the pursuit of health equity. It has five main elements: treat health as a human right; identify evidence of the 'social determinants' of health inequalities, recognise that most powers to affect health are not held by health departments, promote intersectoral policymaking and collaboration inside and outside of government, and generate political will (Cairney et al., 2021). Studies describe its potential but bemoan a major implementation gap. Some HiAP scholars learn from policymaking research how to understand this gap, but the use of policy theories is patchy. In that context, our guiding research question is: How does HiAP research use policy theory to understand policymaking? It allows us to zoom-out to survey the field and zoom-in to identify: the assumed and actual causes of policy change, and transferable lessons to HiAP scholars and advocates. Municipalities can promote adequate support and training for staff involved with HiAP and can place greater emphasis on identifying locally based health and health equity indicators and tracking their progress (Cairney et al., 2021).

7.2.3. For academics

In future research it will be interesting if we have 3 different perspectives, namely Organisations/Associations, Doctors/Health Professionals and Government. This way, it will be possible to analyse the perspective of each one of the entities and personalities and, in a more efficient way, to draw practical lines so that there is this awareness and so that each one of the parties has the perception of how important the promotion of health data is and, above all, the conscious use of these same data. Thus, bringing together these three large entities will certainly be more advantageous than can be done with the main focus being the wellbeing and health of the user.

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9. Annexes

Annex A. Questionnaire sent to the Patient Associations

1. How this concept "Health Data Activism" is important for your association?

◯ 1 (Not important)

◯ 2 (A little important)

◯ 3 (Moderate)

◯ 4 (Important)

◯ 5 (Very important)

2. How usefull this concept is in your association?

◯ 1 (Not usefull)

◯ 2 (A little usefull)

◯ 3 (Moderate)

◯ 4 (Usefull)

◯ 5 (Very usefull)

3.   From 1 to 5 how strong is the promotion of access and better use of health data in your association?

◯ 1 (Weak)

◯ 2 (Low)

◯ 3 (Moderate)

◯ 4 (Strong)

◯ 5 (Very strong)

4. What association activities do you think could classify as health data activism ? (no more than 3)

○ Forms of collective action in collecting data

○ (Re)definition of public health policies regarding health data

○ Opening up institutionalised spaces that guarantee participation in the defense of rights

○ Resistance tactics to mass data collection encryption of private communications

○ Managing the health data in phones, watches

5. Regarding the previous question, question number 4, choose 2 activities that you consider that are the most important and explain why.

Texto de resposta longa

6. What are the main expected outcomes when thinking about health data?

○ Faster access to data

○ Patient Safety

○ Secure and reliable data

○ Increased interoperability

7. Regarding the previous question, question number 6, choose 2 outcomes that you consider that are the most important and explain why.

Texto de resposta longa

8. How important do you think is health data?

○ 1 (Not important)

○ 2 (A little important)

○ 3 (Moderate)

○ 4 (Important)

○ 5 (Very important)

9. Do you think your association could become more health activated?

◯ Yes

◯ No

10. If yes, how do you think you can do it?

Texto de resposta curta

11. Are you available to do an interview?

◯ Yes

◯ No

Annex B. Joint Position on Participatory Digital Health: signatures

Nome da Organização	Representante	Assinatura
Associação de Apoio a Portadores de Alterações nos Genes relacionados com Cancro Hereditário (EVITA)	Dra. Tamara Milagre	Aceitou
Associação de doentes com LUPUS (ADL)	Dra. Filipa Branco	Aceitou
Associação de Insuficientes Respiratórios Crónicos - AIRC	Dr. José dos Reis	Aceitou
Associação Nacional contra a Fibromialgia e Síndrome de Fadiga Crónica	Dr. Ricardo Fonseca	Aceitou
Associação Nacional de Esclerose Múltipla	Dr. Higino Tavares	Aceitou
Associação Nacional para a Saúde Mental (AlertaMente)		Aceitou
Associação Portuguesa de Apoio a Mulheres com Endometriose (MulherEndo)	Dra. Susana Fonseca	Aceitou
Associação Portuguesa de Celíacos- APC	Dra. Susana Tavares	Aceitou
Associação Portuguesa de Doentes com Enxaqueca e Cefaleias (Migra)	Dra. Madalena Plácido	Aceitou
Associação Portuguesa de Doentes da Próstata - APDP	Joaquim Domingos	
Associação Portuguesa de Esclerose Lateral Amiotrófica (ELA)	Dr. Pedro Ramos	Aceitou
Associação Portuguesa de Insuficientes Renais (APIR)	Dr. José Miguel Correia	Aceitou
Associação Portuguesa de Fibromialgia	Dra. Joana Vicente	Aceitou
Associação Protetora dos Diabéticos De Portugal - APDP	Dr. José Boavida	Aceitou
Sociedade Portuguesa de Diabetologia	Dr. João Raposo	Aceitou