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Keywords:	Patient participation, health policy decision making, cancer patient organizations

Cancer Patients' Organization participation in heath policy decision making: a snapshot/cluster analysis of the EU-28 countries.

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Abstract

Objectives: Even though the patient involvement in health policy decision making is well documented however the studies evaluating the level of this participation and impact are scarce. This need becomes even more pronounced in the case of cancer. It is evident that patients with the same type of cancer and at the same stage of the disease will receive different treatments in different countries. Therefore, it is crucial to assess the degree of patient participation in health policy decision making across Europe, as it may result in health inequalities between countries. In a response to this research call, the present study aimed to provide a snapshot of Cancer Patients' Organization participation in health policy processes in EU-28 countries.

Setting: Cancer Patient' Organizations from the 28 EU-countries.

Participants: 1.266 members of Cancer Patient Organizations from the 28 EU countries.

Primary and secondary outcome measures: we collected socio-demographic data, data about individual's involvement in the cancer patient' organization and levels of representation. A 9-item index containing questions about the type and impact of participation in various facets of health policy decision making was used to assess the level of cancer patient' organizations participation in health policy decision making processes and its impact.

Results: The findings revealed four groups of countries according to their score: a) high degree of participation - high impact, b) high degree – low impact, c) low degree - high impact, d) low degree –low impact.

Conclusion: Cancer patient' participation in health policy decision making processes varies significantly among EU-28 countries. Although progress has been made in upgrading the patients role in terms of legislation, however

more need to be done in order to adress inequalities in health policy decision making between EU-countries and ensure that patient' voice is heard.

Strengths and Limitations of the Study

- The study included a large sample from the 28 member stated of the European Union.
- An innovative and validated tool was employed in order to assess the level of cancer patient' organizations participation in health policy decision making
- The cross-sectional design of the study does not allow deducing causal relationships.
- The convenience sample of the study might have limited the generalizability of the results.

Introduction

Cancer is a most common and severe non-communicable diseases, impinging on both health and healthcare [1]. Cancer patients have to cope not only with the stress and the dramatic changes in their lifestyle and quality of life, but also with the medical interventions, procedures and bureaucracy (e.g. reimbursement processes) involved in the treatment of the illness [2]. Although public spending on health and long-term care has increased in the majority of European countries (EU), the needs of cancer patients remain largely unmet [3]. An illustration of this point is waiting times in cancer care in Sweden, which in 2014 were found to be higher than those in Albania [4]. Increased public spending is a necessary but not sufficient condition to ensure effectiveness and sustainability of the healthcare system [5]. This led to the engagement of patients in the development of protocols and procedures and shifted the health policy agenda from the treatment of the disease to the management of patient[6].

In an effort to provide more effective and appropriate services, the healthcare systems' philosophy has been shifted from a biomedical (which is doctor-focused) to a more holistic and self-managed approach [6]. A lot of programs, tools and models have been implemented to empower cancer patients and facilitate their participation in the delivery of health care services[7]. The physicians is no longer considered to be the "expert" or the providers and the patient only the receiver, instead there is clinical shared decision making. No one knows better the nature of a disease and the needs deriving from it but the patients themselves[8]. This is the fundamental principle underlining patient participation in a whole spectrum of healthcare activities, including health policy decision making[9]. Researchers suggest that apart from health-related incentives[10], the drivers for public participation in health policy stem from the personal interest to promote and disseminate the democratic principles of legitimacy, transparency and accountability[11]. In line with this, fifteen years ago the Council of Europe established the right of the European citizens to be engaged in health policy decision making processes as an essential right of individuals living in a democratic society[12].

The initiatives undertaken by most EU countries to establish and increase patient participation in health policy decision making are summarized on legislation level[9]. Only a handful of countries have developed informational, educational and other interventions to empower patients to take part in such processes[13]. As a result, even though the legislation is almost similar among the countries with a legal framework for patient participation in health policy decision making; the degree and impact of such involvement varies significantly[14]. The evidence suggests that patient participation greatly affects the performance of the health care system[8]. In other words, patients with the same type of cancer and at the same stage of the disease will receive different treatments in different countries. Therefore, it is crucial to assess the degree of patient participation in health policy decision making across Europe, as it may result in health inequalities between countries. This need becomes even more pronounced in the case of cancer, as the disease has a multivariate impact and can be a chronic or a fatal disease depending on the quality of treatment. In a response to this research call, the present study aimed to provide a snapshot of Cancer Patients' Organization (CPOs) participation in health policy processes in EU-28 countries.

Methods

The instrument of the study:

For the purpose of the study a self-reported questionnaire was developed, entailing questions on participants' socio-demographic characteristics, their involvement in the CPO (e.g. position in the CPO, years of membership) and the CPO's level of representation (e.g. whether the CPO is a member of a national of international federation), among others.

Moreover, the questionnaire encompassed the Patient Participation and Health Democracy Index (HDI), an original scale measuring the degree of CPOs participation and its impact on shaping health policy. The Health Democracy Index consists of 17 questions: 8 items investigate CPOs level and of participation (***Degree of Participation***) in processes such as: reforms, panels at the Ministry of Health, hospital boards, Ethics Committees in clinical trials, Health Technology Assessment procedures (2 items: one for the scientific evaluation of new treatments and methods and one for the economic evaluation) and the national parliament. Each question may have one of the following answers: (i) it is not a legal requirement and it never happens, (ii)) it is not a legal requirement and it rarely happens, (iii) it is not a legal requirement but it often happens, (iv) it is a legal requirement and it never happens, (v) it is a legal requirement and it often happens, (vi) it is a legal requirement and it happens very often, and (vii) it is a legal requirement and it always happens. Concomitantly, the HDI entails 9 items tapping the impact of PO participation on the aforementioned 8 realms (reforms, ministry of health, other health-related organizations, hospital boards, ethics committee, HTA and national parliament), which are rated on a 6-point scale ranging from absent to very high. In addition, ***the Impact of Participation*** sub-scale entails a 9th item enquiring about the frequency by which a substantial change is observed in the content of a health policy decision as a result of the involvement of the PO. The particular item is rated on a 6-point scale ranging from never to very often.

Higher composite scores on the sub-scales denote higher degree and impact of participation. Both sub-scales displayed good internal consistency (Cronbach a = 0,879 and Cronbach a = 0,874 respectively). Converging evidence has substantiated the psychometric properties of the Health Democracy Index[15] .

Participants and Procedures:

Potential participants were identified through various channels (e.g. internet search, on line databases of European cancer patients' associations, registries of the ministry of health etc). As CPO was considered any non-profit organization with a legal entity. In addition, the CPO should have been cancer-specific, be primarily composed of patients and their caregivers and representing and/or supporting their needs. To be recruited for the study, a CPO should have had an active representation of cancer patients at a national level and a valid and accessible website. CPOs from EU-28 member states were included in the study. In order to be eligible for participation, an individual should have been a member of a CPO and older than 18. The final sample consisted of 1.266 members of CPOs from EU-28 countries.

An email was sent to the CPO board members informing them about the study and inviting them to participate. Following the acceptance, the Institutional Review Board of each organization approved the study protocol and then forwarded the invitation for participation to all of its members. All respondents filled a written informed consent form. Data were collected online (via web-link and email). The questionnaire was translated appropriately for each participant to complete it in their native language.

Results

Composite scores of the HDI sub-scales (**Degree of Participation** and **Impact of Participation**) were used for clustering analysis (Picture 1). The findings revealed four groups of countries according to their score: a) high degree - high impact, b) high degree – low impact, c) low degree - high impact, d) low degree –low impact. The number of countries in each cluster can be seen in Table 1 and a snapshot of the European countries clustering can be found in Picture 2.

Table 1. Number of Countries in each HDI cluster

Cluster	1.High degree and high impact: *Health Democratic Environment*	**7 countries**: Latvia, Portugal, UK, Lithuania, Austria, Hungary, Estonia.

	2. High degree and low impact: *Ostensible Participation*	**6 countries**: Belgium, Luxembourg, Spain, Finland, Croatia, Ireland.
	3. Low degree and high impact: *Limited but impactful participation*	**10 countries**: Germany, Denmark, Romania, Cyprus, Slovenia, Netherlands, France, Poland, Bulgaria, Sweden.
	4. Low degree and low impact: *Opportunities to develop*	**5 countries**: Czech Republic, Slovakia, Greece, Malta, Italy

According to the conceptual framework of the HDI, each category is defined as follows:

a) High Degree – High Impact: “Health Democratic environment”. The environment fosters patient empowerment and participation.

b) High Degree – Low Impact: ostensible participation. The system enables participation and thus organizations do participate; however, they cannot effectively claim their rights. It is also possible that the health policy decision making processes are fragmented and/or not open enough to take CPOs into consideration.

c) Low Degree – High Impact: limited but impactful participation. The health policy shaping system does not give enough room for participation; however, it takes patient organizations into consideration. It seems that quality outweighs quantity. One may suggest that either the health policy decision making system takes highly into consideration the claims of CPOs or that they are very effective in advocating their interests.

d) Low Degree – Low impact: Window of opportunity. The decision making system does not facilitate participation and CPOs are not effective in advocating their claims.

Good and Promising Practices Across the EU.

There is a number of good and promising practices for enhancing patients' involvement in shaping health policy across the EU. Some countries have only introduced pertinent legislation; while others have achieved patients' participation in health planning (at a local and a national level) and in Health Technology Assessment procedures, among others. In an effort to shed light on the four clusters that emerged from the data, one case example per cluster will be briefly discussed.

High Degree – High Impact

United Kingdom was found to be in the group of countries with high degree of participation and high impact. To accomplish high patient involvement the Research Governance Framework for Health and Social Care underlines "*Research [should be] pursued with the active involvement of service users and carers including where appropriate, those from hard to reach groups such as the homeless.*"[16] To support the public involvement in health research, the United Kingdom has introduced INVOLVE, a national advisory group affiliated to the National Institute for Health Research. This initiative demonstrates substantial activity in terms of consultation, collaboration and user control research [14 17]. Another example of institutionalized public involvement is the National Institute for Health and Care Excellence (NICE). NICE has incorporated a step-wise and comprehensive approach to engage patients in decisions regarding treatments and services, health technologies, clinical practice and public health programs[18].

High Degree – Low Impact

The decentralization of the healthcare system in 2001 in Finland has led to an increased public participation in health policy decision making, although there is still much to be done. In 1999, the government set the foundations for the patients' participation in all levels and sectors pertaining to health policy. A network of agencies at local and national level was developed. Agencies were affiliated to the Ministry of Health with the task to facilitate, increase and sustain public involvement in each step of health policy decision making processes by carrying out local health needs assessments, priority setting surveys and informal evaluations[19].

Low Degree - High Impact

Cyprus was found to be in the cluster of countries characterized by low degree of participation and high impact. In 2016, the Pancyprian Federation of Patient Associations and Friends conducted a national study in order to assess patients' organizations participation in health policy decision making and identify unmet needs. The study results were disseminated to the community, local press and other key-stakeholders. A few months later, the systematic advocating and lobbying activities ended successfully. New legislation providing for patients' participation in health policy decision making at national level was established by the Cyprus Parliament based on the Declaration for Patients Participation in Health Policy Decision Making[20].

Low Degree – Low Impact

Year 1999 was a landmark for patients' participation in shaping health policy in Italy. Many cancer patients claimed for a new treatment. The public pressure was so high that the Ministry of Health decided to conduct a clinical trial to examine its effectiveness. The clinical trial was designed and implemented with the aid of patients' representatives. Finally, the therapy was found to have no effect on the course of the disease; however the citizens gained access to health policy decision making. A year later, the government introduced legislation providing for patients' participation and established new institutional agencies[21].

Ethics Approval

The study was approved by the Research and Ethics Committee of the University of Peloponnese, Corinth, Greece in accordance with the ethical standards delineated in the 1964 Declaration of Helsinki. Furthermore, the Institutional Review Board of the participating patients associations reviewed and approved the study. Informed consent for participation was obtained from all participants.

Contributions

The study was designed by KS, EA, LP, CT, DV, OB, DD, SH and FS. EA, LP, CT, DV, OB and DD were responsible for the data collection. CT, KS and FS performed the statistical analysis. KS, EA, LP, CT, DV, OB, DD, SH and FS contributed to the interpretation of the results and draft the manuscript. All authors have read and approved the final manuscript.

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Conflict of interest statement

We have read and understood BMJ Open policy on declaration of interests and declare that we have no competing interests.

Patient consent statement

Not Applicable

Licence

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Data sharing statement

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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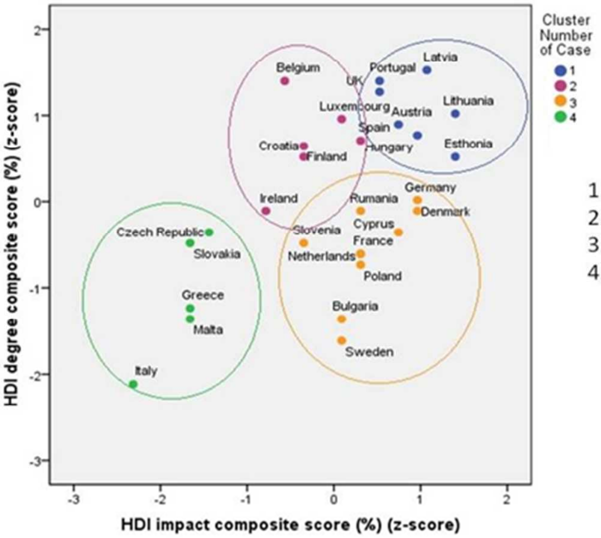
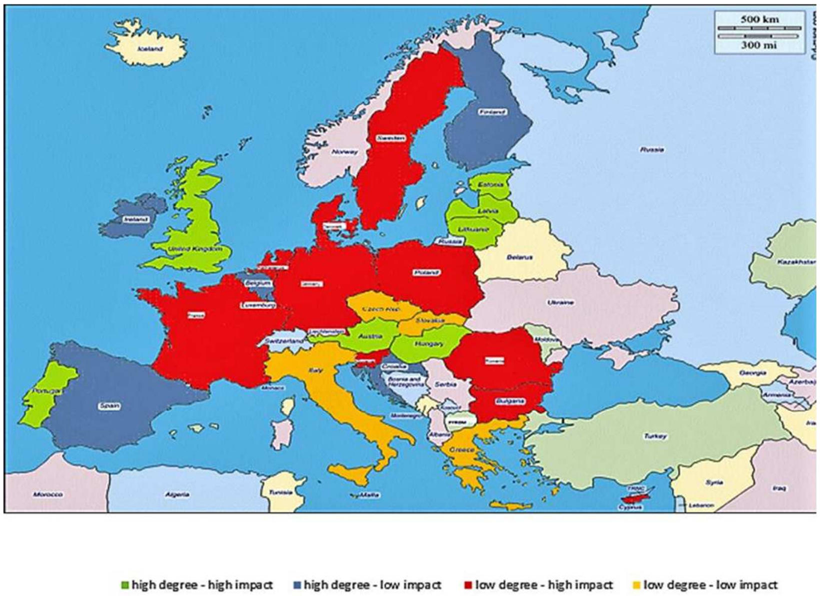
Picture 1. HDI Cluster Analysis of EU-28 Countries



1. High Degree - High Impact
2. High Degree - Low Impact
3. Low Degree - High Impact
4. Low Degree - Low Impact

Picture 2. Snapshot of European countries clustering according to HDI score.



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Results: The findings revealed four groups of countries according to their score: a) high degree of participation - high impact, b) high degree – low impact, c) low degree - high impact, d) low degree –low impact.

Conclusion: Cancer patient' participation in health policy decision making processes varies significantly among EU-28 countries. Although progress has been made in upgrading the patients role in terms of legislation, however

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Strengths and Limitations of the Study

- The study included a large sample from the 28 member stated of the European Union.
- An innovative and validated tool was employed in order to assess the level of cancer patient' organizations participation in health policy decision making
- The cross-sectional design of the study does not allow deducing causal relationships.
- The convenience sample of the study might have limited the generalizability of the results.

Introduction

Cancer is the most common and severe non-communicable diseases, impinging on both health and healthcare [1]. Cancer patients have to cope not only with the stress and the dramatic changes in their lifestyle and quality of life, but also with the medical interventions, procedures and bureaucracy (e.g. reimbursement processes) involved in the treatment of the illness [2]. Although public spending on health and long-term care has increased in the majority of European countries (EU), the needs of cancer patients remain largely unmet [3]. An illustration of this point is waiting times in cancer care in Sweden, which in 2014 were found to be higher than those in Albania [4]. Increased public spending is a necessary but not sufficient condition to ensure effectiveness and sustainability of the healthcare system [5]. As a result of this, alternative routes have been sought in an endeavour to advance its effectiveness. This led to the engagement of patients in the development of treatment protocols and procedures; while it shifted the health policy agenda from the treatment of the disease to the management of patient[6].

In an effort to provide more effective and appropriate services, the healthcare systems' philosophy has been shifted from a biomedical (which is doctor-focused) to a more holistic and self-managed approach [6]. A lot of programs, tools and models have been implemented to empower cancer patients and facilitate their participation in the delivery of health care services[7]. The physician is no longer considered to be the "expert" or simply the provider; while the patient is only the receiver. Instead, there is clinical shared decision making. No one knows better the nature of a disease and the needs deriving from it but the patients themselves[8].

This is not limited to the physician-patient relationship, as patients may collectively participate in decision making in various realms, including guideline development, government policy and research agenda setting, among others[9-11]. Patient participation at the collective level is primarily justified on the grounds of democratic values. Patients are affected by the consequences of certain decisions, and therefore, they should have a say in the process. Concomitantly, their subjective knowledge of a disease and its treatment may enhance the quality of health care decision making[12], upgrading the overall effectiveness and efficiency of the healthcare system.

While patients' collective action is increasingly recognized as an important driver of health policy and service provision, there is paucity of research on their association. The De Montfort study in the UK has substantiated increased contact between patient groups and policymakers the past years, while professional bodies and pharmaceutical companies were shown to have increasingly involved patient groups in discussions on policy proposals[13]. Nonetheless, according to the researchers, their findings do not shed light on the powers exerted by patient groups, as their heightened participation is not necessarily translated into high political effectiveness. In a similar vein, while the Dutch model in Netherlands allows to some extent patient organizations to be an equal party in health policy processes, this is not met in practice[14]. Moreover, evidence from Mixed Advisory Committees in Italy highlight the limited influence of users' voice on decision making by health authorities[15]. In 2006, a workshop with 22 academic researchers and two representatives of patient organizations documented high involvement of patient groups with policymakers and political institutions. Nonetheless, a noteworthy diversity among European countries was stressed [16].

The initiatives undertaken by most EU countries to establish and increase patient participation in health policy decision making are summarized on legislation level[17]. Nonetheless, based on information provided by the European Health Consumer Index[18], countries display marked diversity in terms of the degree to which their healthcare law is based on patients' rights. Additionally, variability is also documented in the degree to which patient organizations are involved in decision-making[18]. This in turn may create health inequalities between countries. As a corollary of this, there is imperative need to investigate the degree and impact of patient organization participation in health policy decision making in the European Union. This need becomes even more pronounced in the case of cancer, as the disease has a multivariate impact and can be a chronic or a fatal disease depending on the quality of treatment[19]. In response to this research call, the present study aimed to provide a snapshot of Cancer Patients' Organization (CPOs) participation in health policy decision making in EU-28 countries.

Methods

Instrument

For the purpose of the study a self-reported questionnaire was developed, entailing the following sections:

Respondents' characteristics

Data were collected on participants' socio-demographic characteristics (gender, age, educational attainment, self-reported economic status) and their involvement in the CPO. In particular, participants had to rate their degree of familiarity with cancer and their knowledge about its treatment/ their country's healthcare system/ their country's reimbursement process (rating options: very low-low-moderate-high-very high). Moreover, they had to rate their degree of involvement in the organization (rating options: absent-very low-low-moderate-high-very high). Data were also gleaned with regard to their position in the organization (president/or other board member – employed by the organization-voting member-nonvoting but active member-non-active member) and the duration of their membership.

Organizational characteristics

Information was also collected concerning the cancer patient organization. Specifically, participants had to indicate whether the organization provided information material to its members (yes-no) and training (yes-no).

Furthermore, they were asked whether their organization was a member of a national cancer federation (yes-no).

Health Democracy Index

Moreover, the questionnaire encompassed the Patient Participation and Health Democracy Index (HDI), an original scale measuring the degree of patient organization participation and its impact on shaping health policy. The Health Democracy Index consists of 17 questions: 8 items investigate CPOs level and of participation (***Degree of Participation***) in processes such as: reforms, panels at the Ministry of Health, hospital boards, Ethics Committees in clinical trials, Health Technology Assessment procedures (2 items: one for the scientific evaluation of new treatments and methods and one for the economic evaluation) and the national parliament. Each question may have one of the following answers: (i) it is not a legal requirement and it never happens, (ii)) it is not a legal requirement and it rarely happens, (iii) it is not a legal requirement but it often happens, (iv) it is a legal requirement and it never happens, (v) it is a legal requirement and it often happens, (vi) it is a legal requirement and it happens very often, and (vii) it is a legal requirement and it always happens. Concomitantly, the HDI entails 9 items tapping the impact of PO participation on the aforementioned 8 realms (reforms, ministry of health, other health-related organizations, hospital boards, ethics committee, HTA and national parliament), which are rated on a 6-point scale ranging from absent to very high. In addition, ***the Impact of Participation*** sub-scale entails a 9th item enquiring about the frequency by which a substantial change is observed in the content of a health policy decision as a result of the involvement of the PO. The particular item is rated on a 6-point scale ranging from never to very often.

Higher composite scores on the sub-scales denote higher degree and impact of participation. Both sub-scales displayed good internal consistency (Cronbach a = 0,879 and Cronbach a = 0,874 respectively). Converging evidence has substantiated the psychometric properties of the Health Democracy Index[20] . Specifically, the development of the index has followed the subsequent steps: (i) definition of the construct (i.e. patient organization participation in health policy decision making), (ii) review of the construct definition, (iii)item drafting, (iv) item review) and (v) pilot testing of its psychometric properties (internal consistency , test-retest reliability, construct validity ad convergent validity). As the index was originally developed in Greece[21], an international working group consisting of European stakeholders (policy-makers, members of patient organizations and researchers with background on patient empowerment held various meetings to discuss the adaptation of the index to European standards.[20]

Participants and Procedures:

Potential participants were identified through various channels (e.g. internet search, on line databases of European cancer patients' associations, registries of the ministry of health etc). As CPO was considered any non-profit organization with a legal entity. In addition, the CPO should have been cancer-specific, be primarily composed of patients and their caregivers and representing and/or supporting their needs. To be recruited for the study, a CPO should have had an active representation of cancer patients at a national level and a valid and accessible website. CPOs from EU-28 member states were included in the study. In order to be eligible for participation, an individual should have been a member of a CPO and older than 18. The final sample consisted of 1.266 members of CPOs from EU-28 countries and the mean number of respondents per country was 45 (Table 1). Demographics of the sample are shown in table 2.

Table 1. Number of respondents per country

	N	%
Country		
UK	49	3.9
Austria	47	3.7
Belgium	34	2.7
Bulgaria	31	2.4
Germany	44	3.5
Denmark	44	3.5
Esthonia	35	2.8
Ireland	51	4
Spain	42	3.3
Croatia	46	3.6
Cyprus	37	2.9
Latvia	32	2.5
Lithuania	38	3
Luxembourg	30	2.4
Malta	32	2.5
Netherlands	42	3.3
Hungary	33	2.6
Poland	44	3.5
Portugal	47	3.7
Rumania	45	3.6
Slovakia	38	3
Slovenia	41	3.2
Sweden	43	3.4
Czech Republic	45	3.6
Finland	45	3.6
Greece	63	5
France	93	7.3
Italy	95	7.5

Table 2. Sample demographics

	N	%
Age, mean (SD)	54.6(14.8)	
Sex		
Men	534	42.2
Women	732	57.8

Education level		
No formal qualification	9	0.7
Primary School Education	7	0.6
Secondary School Education	378	29.8
University Degree	520	41.1
Postgraduate Degree	352	27.8
Self-report economic status		
Low	13	1.0
Medium to Low	238	18.8
Medium	529	41.8
Medium to High	387	30.6
High	98	7.7

An email was sent to the CPO board members informing them about the study and inviting them to participate. Following the acceptance, the Institutional Review Board of each organization approved the study protocol and then forwarded the invitation for participation to all of its members. All respondents filled a written informed consent form. Data were collected online (via web-link and email). The questionnaire was translated appropriately for each participant to complete it in their native language.

Statistical analysis

Descriptive statistics such as means, medians, standard deviations, absolute and relative frequencies were calculated were appropriate.

Ward's method was used to compute distance patterns and determine the appropriate number of clusters for the K-means clustering procedure. K-means clustering was performed for the classification of cluster subgroups and was based on Euclidian distance. We changed all variables to z-scores to yield equal metrics and equal weighting. For the consistency and validity of the hypothesized groups of countries in the total sample; the total sample was divided into a split-half random sample. K-means clustering was used then for the two subsamples to determine the presence of similar cluster subgroups from the previous analyses. Additionally, analysis of variance ANOVA was used to compare Degree of Participation and Impact of Participation scores between the four groups defined by cluster analysis. Statistical analyses were performed using the SPSS for Windows Version 19.0 statistical package (SSPS Inc., Chicago, IL).

Results

Composite scores of the HDI sub-scales (**Degree of Participation** and **Impact of Participation**) were used for clustering analysis (Figure 1). The findings revealed four groups of countries according to their score: a) high degree - high impact, b) high degree – low impact, c) low degree - high impact, d) low degree –low impact. Table 3 presents median scores of Degree of Participation and Impact of Participation per country. The median score from all countries was 33.3 for Degree of Participation and 34.69 for Impact of Participation .

Table 3. Median scores of Degree of Participation and Impact of Participation per country

	Median for degree of participation*	Median for impact of participation*
Latvia	60.42	41.84
Portugal	58.33	36.73
Belgium	58.33	26.53
UK	56.25	36.73
Lithuania	52.08	44.90
Luxembourg	51.04	32.65
Austria	50.00	38.78
Hungary	47.92	40.82
Spain	46.88	34.69
Finland	45.83	28.57
Estonia	43.75	44.90

Croatia	43.75	28.57
Germany	35.42	40.82
Denmark	33.33	40.82
Rumania	33.33	37.69
Ireland	33.33	24.49
Cyprus	29.17	38.78
Czech Republic	29.17	18.37
Slovenia	27.08	38.57
Slovakia	27.08	16.33
Netherlands	25.00	36.69
France	25.00	36.69
Poland	22.92	35.69
Greece	14.58	16.33
Bulgaria	12.50	35.65
Malta	12.50	16.33
Sweden	8.33	35.40
Italy	5.60	10.20

*median of the percent score (i.e. ((score-possible minimum score)/(maximum-minimum possible score))*100)

The number of countries in each cluster can be seen in Table 4 and a snapshot of the European countries clustering can be found in Figure 2.

Table 4. Number of Countries in each HDI cluster

Cluster	1.High degree and high impact: *Health Democratic Environment*	**7 countries**: Latvia, Portugal, UK, Lithuania, Austria, Hungary, Estonia.
	2. High degree and low impact: *Ostensible Participation*	**6 countries**: Belgium, Luxembourg, Spain, Finland, Croatia, Ireland.
	3. Low degree and high impact: *Limited but impactful participation*	**10 countries**: Germany, Denmark, Romania, Cyprus, Slovenia, Netherlands, France, Poland, Bulgaria, Sweden.
	4. Low degree and low impact: *Opportunities to develop*	**5 countries**: Czech Republic, Slovakia, Greece, Malta, Italy

The total sample was afterwards divided into a split-half random sample and K-means clustering was repeated for the two subsamples. Clustering results indicated that the four-cluster solution similar to the previous analyses was the most homogeneous solution in each subsample. Furthermore, Degree of Participation and Impact of Participation scores were compared between the four country groups as defined by cluster analysis. All pair wise comparisons were significant ($p<0.001$) confirming more evidence of the cluster solution.

Discussion

In modern health care systems, patients not only participate in decisions concerning their own health and healthcare (i.e. the micro-level), but in decision making processes on the meso- and macro-level, that is in local health authorities, organizations, health technology assessment procedures or at the parliament, to name few[22]. Their influence in these processes is greatly enhanced if they are grouped together. For this reason, patient organizations emerge as an indispensable vehicle for facilitating democracy, promoting patient interests and influencing health policy decision making[22]. Nonetheless, existing evidence suggests wide diversity in the European Union with regard to patient organization participation in health policy decision making[16,18]. At the same time, converging evidence indicates that a greater degree of participation on the part of patient organizations does not guarantee the effectiveness of this participation [13-15,22]. In other words, patient organizations may be given opportunities to have a say in health policy-decision making, but are they being heard?

The findings from the present study reveal four groups of countries:

a) High Degree – High Impact: “Health Democratic environment”. The environment fosters patient organization participation and patient groups contribute substantially to health policy decision-making

b) High Degree – Low Impact: ostensible participation. The system provides ample opportunity for patient organization participation; however, this does not exert a significant impact.

c) Low Degree – High Impact: limited but impactful participation. The health policy shaping system does not give enough room for participation; however, it takes patient organizations into consideration. It seems that quality outweighs quantity. One may suggest that either the health policy decision making system takes highly into consideration the claims of CPOs or that they are very effective in advocating their interests.

d) Low Degree – Low impact: Window of opportunity. The decision making system does not facilitate participation and CPOs are not effective in advocating their claims.

Interpretations

The findings of the present study corroborate the wide diversity among European countries with respect to the degree and impact of cancer patient organization participation in health policy decision making. These findings are to a large extent consonant with findings from the European Health Consumer Index[18]. Interestingly, both Bulgaria and Sweden rank very low in the Degree subscale (median=12.5 and median= 8.33 respectively); however, they rank high in the Impact subscale (median = 35.65 and median = 35.40 respectively). At first glance, this appears in sharp contrast to the findings from the European Health Consumer Index, where Bulgaria was found to score good in the indicator “patient organizations involved in decision making” and Sweden intermediary. Nonetheless, the low scores documented in the Degree subscale of the present study are probably explained by both countries’ low performance in the indicator “healthcare law based on patients rights". As a result of this, these countries score very low in the Degree subscale (enquiring about the opportunities of CPOs to participate in health decision-making); however, they do well in the Impact subscale (enquiring about the impact of this participation). In other words, while the healthcare system may not provide CPOs with ample opportunity to participate, CPOs appear to manage well into capitalizing on the scare opportunities given. This is perhaps the explanation why in this group of countries in spite of low degree of participation, there is high impact of participation. It is highly likely that CPOs in these countries have better advocacy and lobbying skills. Alternatively, it may be the case that CPOs form stronger coalitions in these countries. A study by Wood on patient groups in UK and USA has indicated that in both countries there is a proliferation of patient organizations; however their political effectiveness is disproportionally low due to their autonomous activity and their reluctance to collaborate[23]. A similar concern was raised by the Vienna workshop, where heightened competition and tensions among patient organizations was suggested to hinder their political effectiveness [16]. Therefore, CPOs in countries with high impact may be more politicized and more united.

This may also explain why in certain countries there is high degree of participation but low impact. Members of CPOs in these countries may not be trained enough in lobbying and advocacy skills and do not engage into joint campaigning. Alternatively, the system may ostensibly involve patient organizations in health policy decision making. This is congruent with the concern raised in UK[13] that the involvement of patient associations in health policy decision making may solely serve the purpose of adding legitimacy to governments, while the latter advance their own interests. Therefore, one should investigate further what happens in these countries.

It merits noting that the Health Democracy Index entails items tapping patient organization participation in health policy decision making on various realms: hospital boards, health technology assessment, ethics committees in clinical trials, national parliament, ministry of health, to name few. It is highly likely that an item-per-item analysis may reveal a different pattern of results with regard to country ranking. Our research team is currently working on this direction .

Good Examples

A good example of a country with High Degree of Participation

The decentralization of the healthcare system in 2001 in Finland has led to an increased public participation in health policy decision making. In 1999, the government set the foundations for the patients' participation in all levels and sectors pertaining to health policy. A network of agencies at local and national level was developed. Agencies were affiliated to the Ministry of Health with the task to facilitate, increase and sustain public involvement in each step of health policy decision making processes by carrying out local health needs assessments, priority setting surveys and informal evaluations[24].

A good example of a country with High Impact of Participation

Cyprus was found to be in the cluster of countries characterized by low degree of participation and high impact. In 2016, the Pancyprian Federation of Patient Associations and Friends conducted a national study in order to assess patients' organizations participation in health policy decision making and identify unmet needs. The study results were disseminated to the community, local press and other key-stakeholders. A few months later, the systematic advocating and lobbying activities ended successfully. New legislation providing for patients' participation in health policy decision making at national level was established by the Cyprus Parliament based on the Declaration for Patients Participation in Health Policy Decision Making[25].

Limitations

The study was not without its limitations. As there is no sampling frame for CPOs in Europe, the representativeness of the sample is contested. In spite of systematic efforts to recruit participants through various pathways one may not exclude the possibility that the most active and motivated CPO members agreed to participate. In this reasoning, sampling bias may have emerged if responders differed systematically from non-responders in terms of their views about their CPOs participation in health policy decision making. Finally, as the present study addressed cancer patient organizations, findings cannot extrapolated to other disease groups.

Conclusion

There is substantial diversity in EU-28 with regard to CPO participation in health policy decision making. Study findings indicate that a high degree of participation is not synonymous to high impact. As a result of this, there is still a ways to go in order to ensure that both the healthcare system will create ample opportunity for CPOs to participate in health decision making and that CPOs will be capable of capitalizing on them.

Ethics Approval

The study was approved by the Research and Ethics Committee of the University of Peloponnese, Corinth, Greece in accordance with the ethical standards delineated in the 1964 Declaration of Helsinki. Furthermore, the

Institutional Review Board of the participating patients associations reviewed and approved the study. Informed consent for participation was obtained from all participants.

Contributions

The study was designed by KS, EA, LP, CT, DV, OB, DD, SH and FS. EA, LP, CT, DV, OB and DD were responsible for the data collection. CT, KS and FS performed the statistical analysis. KS, EA, LP, CT, DV, OB, DD, SH and FS contributed to the interpretation of the results and draft the manuscript. All authors have read and approved the final manuscript.

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Conflict of interest statement

We have read and understood BMJ Open policy on declaration of interests and declare that we have no competing interests.

Patient consent statement

Not Applicable

Licence

Data sharing statement

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Figure 1. Cluster analysis results

Figure 2. Patient organization participation in EU-28 by country cluster

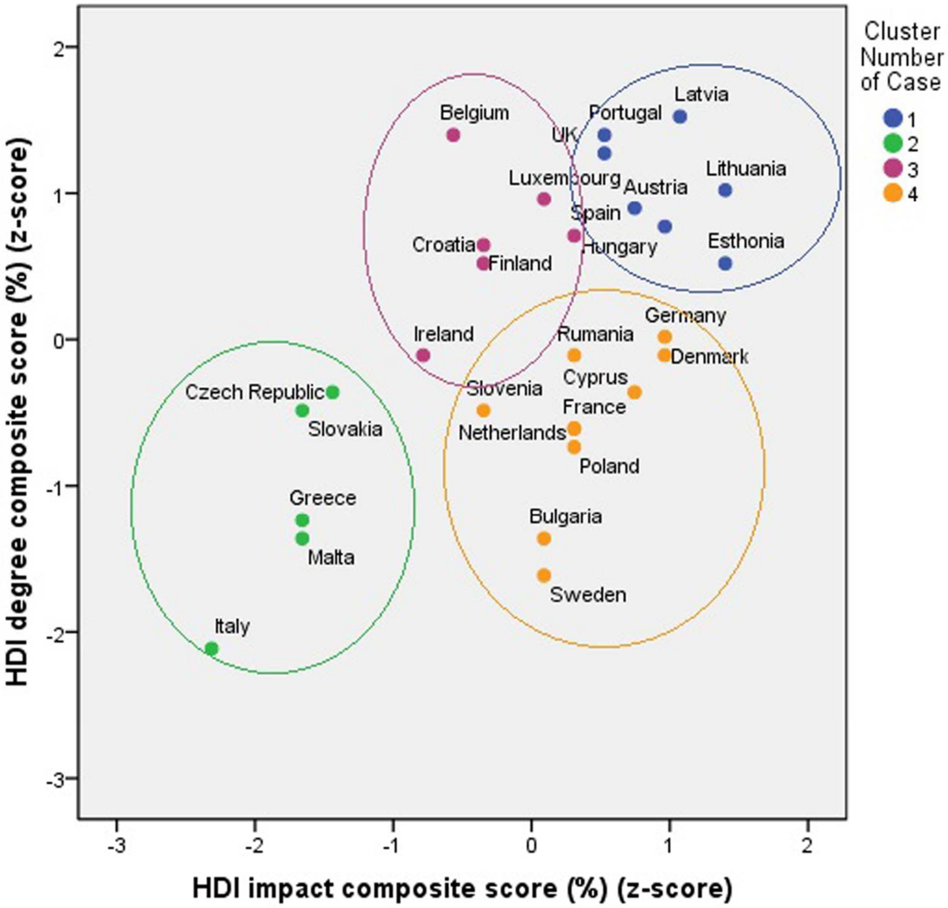
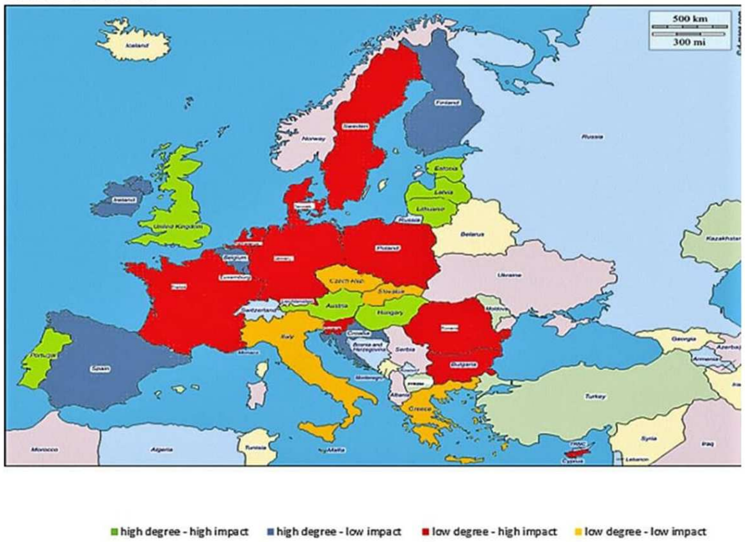


Figure 1. Cluster analysis results

133x124mm (300 x 300 DPI)

Picture 2. Snapshot of European countries clustering according to HDI score.



🟩 high degree - high impact 🟦 high degree - low impact 🟥 low degree - high impact 🟨 low degree - low impact

Figure 2. Patient organization participation in EU-28 by country cluster

279x181mm (300 x 300 DPI)

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Cancer Patients' Organization participation in heath policy decision making: a snapshot/cluster analysis of the EU-28 countries.

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Cancer Patients' Organization participation in heath policy decision making: a snapshot/cluster analysis of the EU-28 countries.

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Abstract

Objectives: Even though patient involvement in health policy decision making is well documented, studies evaluating the degree and impact of this participation are scarce. This is even more conspicuous in the case of cancer. There is evidence showing that patients with the same type of cancer and at the same stage of the disease will receive different treatments in different countries. Therefore, it is crucial to assess the degree of patient participation in health policy decision making across Europe, as it may result in health inequalities between countries. In a response to this research call, the present study aimed to provide a snapshot of cancer patients' organization (CPO) participation in health policy processes in EU-28 countries.

Setting: Cancer Patient' Organizations from the 28 EU-countries.

Participants: 1.266 members of Cancer Patient Organizations from the 28 EU countries.

Primary and secondary outcome measures: information about participants' socio-demographic characteristics and their involvement in their CPO was collected as well as data about the CPO. A 17-item index containing questions about the type and impact of participation in various facets of health policy decision making was used to assess the level of CPOs participation in health policy decision making processes and its impact.

Results: The findings revealed four groups of countries according to their score: a) high degree of participation - high impact, b) high degree – low impact, c) low degree - high impact, d) low degree –low impact.

Conclusion: Cancer patient' participation in health policy decision making processes varies significantly among EU-28 countries. Although progress has been made in upgrading the patients role in terms of legislation, however

more need to be done in order to address inequalities in health policy decision making between EU-countries and ensure that patient' voice is heard.

Strengths and Limitations of the Study

- The study included a large sample from the 28 member stated of the European Union.
- An innovative and validated tool was employed in order to assess the level of cancer patient' organizations participation in health policy decision making
- The cross-sectional design of the study does not allow deducing causal relationships.
- The convenience sample of the study might have limited the generalizability of the results.

Introduction

Cancer is the most common and severe non-communicable diseases, impinging substantially on both health and healthcare [1]. Cancer patients have to cope with the stress and the dramatic changes in their lifestyle and quality of life as well as the procedures and bureaucracy (e.g. reimbursement processes) often involved in the treatment of the illness [2]. Although public spending on health and long-term care has increased in the majority of European countries (EU), cancer patients' needs remain largely unmet [3]. An illustration of this point is waiting times in cancer care in Ireland, which in 2015 were found to be higher than their counterparts in Albania [4]. Increased public spending is a necessary but not sufficient condition to ensure effectiveness and sustainability of the healthcare system [5].

In an effort to provide more effective and appropriate services, the healthcare system philosophy has shifted from a biomedical approach (which is doctor-focused) to a more holistic and self-managed one [6]. Many programs, tools and models have been implemented in order to empower cancer patients and facilitate their participation in the delivery of health care services[7]. In this frame, the physician is no longer considered to be the "expert" or just the provider and the patient only the receiver. Rather, there is clinical shared decision making. No one knows better the nature of a disease and the needs deriving from it but the patients themselves[8].

This is not limited to the individual physician-patient relationship, as patients may collectively participate in decision making in various realms, including guideline development, government policy and research agenda setting, among others[9-11]. Patient participation at the collective level is primarily justified on the grounds of democratic values. Patients are affected by the consequences of certain decisions, and therefore, they should have a say in the process. Concomitantly, their subjective knowledge of a disease and its treatment may enhance the quality of health care decision making[12], upgrading the overall effectiveness and efficiency of the healthcare system.

While patients' collective action is increasingly recognized as an important driver of health policy and service provision, there is paucity of research on their association. The De Montfort study in the UK substantiated increased contact between patient groups and policymakers during the past years, while professional bodies and pharmaceutical companies were found to involve patient groups in discussions on policy proposals to a larger extent than in the past[13]. Nonetheless, according to the researchers, the available evidence does not shed enough light on the influence exerted by patient groups, as their heightened participation is not necessarily translated into high political effectiveness. In a similar vein, while the Dutch model in Netherlands allows patient organizations to be an equal party in health policy processes to some extent, this is not met in practice[14]. Moreover, evidence from Mixed Advisory Committees in Italy highlight the limited influence of users' voice on decision making by health authorities[15]. In 2006, a workshop with 22 academic researchers and two representatives of patient organizations documented high involvement of patient groups with policymakers and political institutions; however, marked diversity among European countries was stressed [16].

The initiatives undertaken by most EU countries to establish and increase patient participation in health policy decision making are reflected on legislation level[17]. Nonetheless, based on information provided by the European Health Consumer Index[18], countries display important differences in terms of the degree to which their healthcare law is based on patient rights. Additionally, noteworthy variation is also observed in the degree to which patient organizations are involved in decision-making[18]. This in turn may create health inequalities between countries. As a corollary of this, there is an imperative need to investigate the degree and impact of patient organization participation in health policy decision making in the European Union. This need becomes even more pronounced in the case of cancer, as the disease has a multifaceted impact and can be a chronic or a fatal disease depending on the quality of treatment[19]. In response to this research call, the present study aimed to provide a snapshot of cancer patients' organization (CPOs) participation in health policy decision making in EU-28 countries.

Methods

Instrument

For the purpose of the study a self-reported questionnaire was developed, entailing the following sections:

Respondents' characteristics

Data were collected on participants' socio-demographic characteristics (gender, age, educational attainment, self-reported economic status) and their involvement in the CPO. In particular, participants had to rate their degree of familiarity with cancer and their knowledge about its treatment/ their country's healthcare system/ their country's reimbursement process (rating options: very low-low-moderate-high-very high). Moreover, they had to rate their degree of involvement in the organization (rating options: absent-very low-low-moderate-high-very high). Data were also gleaned with regard to their position in the organization (president/or other board member – employed by the organization-voting member-nonvoting but active member-non-active member) and the duration of their membership.

Organizational characteristics

Information was also collected concerning the cancer patient organization. Specifically, participants had to indicate whether the organization provided information material to its members (yes-no) and training (yes-no). Furthermore, they were asked whether their organization was a member of a national cancer federation (yes-no).

Health Democracy Index

Moreover, the questionnaire encompassed the Patient Participation and Health Democracy Index (HDI), an original scale measuring the degree of patient organization participation and its impact on shaping health policy. The Health Democracy Index consists of 17 questions: 8 items investigate CPOs level and of participation (***Degree of Participation***) in processes such as: reforms, panels at the Ministry of Health, hospital boards, Ethics Committees in clinical trials, Health Technology Assessment procedures (2 items: one for the scientific evaluation of new treatments and methods and one for the economic evaluation) and the national parliament. Each question may have one of the following answers: (i) it is not a legal requirement and it never happens, (ii)) it is not a legal requirement and it rarely happens, (iii) it is not a legal requirement but it often happens, (iv) it is a legal requirement and it never happens, (v) it is a legal requirement and it often happens, (vi) it is a legal requirement and it happens very often, and (vii) it is a legal requirement and it always happens. Concomitantly, the HDI entails 9 items tapping the impact of PO participation on the aforementioned 8 realms (reforms, ministry of health, other health-related organizations, hospital boards, ethics committee, HTA and national parliament), which are rated on a 6-point scale ranging from absent to very high. In addition, ***the Impact of Participation*** sub-scale entails a 9th item enquiring about the frequency by which a substantial change is observed in the content of a health policy decision as a result of the involvement of the PO. The particular item is rated on a 6-point scale ranging from never to very often.

Higher composite scores on the sub-scales denote higher degree and impact of participation. Both sub-scales displayed good internal consistency (Cronbach a = 0,879 and Cronbach a = 0,874 respectively). Converging evidence has substantiated the psychometric properties of the Health Democracy Index[20] .

Specifically, the development of the index has followed the subsequent steps: (i) definition of the construct (i.e. patient organization participation in health policy decision making), (ii) review of the construct definition, (iii)item drafting, (iv) item review) and (v) pilot testing of its psychometric properties (internal consistency , test-retest reliability, construct validity ad convergent validity). As the index was originally developed in Greece[21], an international working group consisting of European stakeholders (policy-makers, members of patient organizations and researchers with background on patient empowerment held various meetings to discuss the adaptation of the index to European standards.[20]

Participants and Procedures:

Potential participants were identified through various channels (e.g. internet search, on line databases of European cancer patients' associations, registries of the ministry of health etc). As CPO was regarded any non-profit organization with a legal entity. In addition, the CPO should have been cancer-specific, be primarily composed of patients and their caregivers and representing and/or supporting their needs. To be recruited for the study, a CPO should have had an active representation of cancer patients at a national level and a valid and accessible website. CPOs from EU-28 member states were included in the study. In order to be eligible for participation, an individual should have been a member of a CPO and older than 18.

An email was sent to CPO board members informing them about the study and inviting them to participate. Following their acceptance, the Institutional Review Board of each organization approved the study protocol and forwarded the invitation for participation to all of its members. All respondents filled a written informed consent form. Data were collected online (via web-link and email). The questionnaire was translated to each country's official language.

Patient and Public Involvement

Patients play an integral role in this project and thus they have participated in various stages of the research process. The development of the HDI, which has been utilized to assess CPO participation in health policy decision making, has involved both patients-members of patient organizations and patient representatives during the phases of (i) reviewing the construct definition, (ii) item drafting, (iii) item review and (iv) adaptation of the index to pan-European standards (20,21). Moreover, patient representatives have participated in the formulation of research objectives, the design of the study and the interpretation of its findings; while members of patient organizations have constituted the study sample of this research work. It deserves mentioning that results will be disseminated to all identified CPOs, irrespectively of whether they participated or not.

Statistical analysis

Descriptive statistics such as means, medians, standard deviations, absolute and relative frequencies were computed, where appropriate.

Ward's method was used to compute distance patterns and determine the appropriate number of clusters for the K-means clustering procedure. K-means clustering was performed for the classification of cluster subgroups and was based on Euclidian distance. We changed all variables to z-scores to yield equal metrics and equal weighting. For the consistency and validity of the hypothesized groups of countries in the total sample; the total sample was divided into a split-half random sample. K-means clustering was used then for the two subsamples to determine the presence of similar cluster subgroups from the previous analyses. Additionally, analysis of variance ANOVA was used to compare Degree of Participation and Impact of Participation scores between the four groups defined by cluster analysis. Statistical analyses were performed using the SPSS for Windows Version 19.0 statistical package (SSPS Inc., Chicago, IL).

Results

Sample Characteristics

The final sample consisted of 1.266 members of CPOs from EU-28 countries and the mean number of respondents per country was 45 (Table 1).

Demographics of the sample are shown in table 2.

Table 1. Number of respondents per country

	N	%
Country		
Austria	47	3.7
Belgium	34	2.7
Bulgaria	31	2.4
Croatia	46	3.6
Cyprus	37	2.9
Czech Republic	45	3.6
Denmark	44	3.5
Esthonia	35	2.8
France	93	7.3
Germany	44	3.5
Greece	63	5
Hungary	33	2.6
Ireland	51	4
Italy	95	7.5
Latvia	32	2.5
Lithuania	38	3
Luxembourg	30	2.4
Malta	32	2.5
Netherlands	42	3.3
Poland	44	3.5

Portugal	47	3.7
Rumania	45	3.6
Slovakia	38	3
Slovenia	41	3.2
Spain	42	3.3
Sweden	43	3.4
UK	49	3.9

Table 2. Sample demographics

	N	%
Age, mean (SD)	54.6(14.8)	
Sex		
Men	534	42.2
Women	732	57.8
Education level		
No formal qualification	9	0.7
Primary School Education	7	0.6
Secondary School Education	378	29.8
University Degree	520	41.1
Postgraduate Degree	352	27.8
Self-report economic status		
Low	13	1.0
Medium to Low	238	18.8
Medium	529	41.8
Medium to High	387	30.6
High	98	7.7

Degree and Impact of CPO Participation

Composite scores of the HDI sub-scales (**Degree of Participation** and **Impact of Participation**) were used for clustering analysis (Figure 1). The findings revealed four groups of countries according to their score: a) high degree - high impact, b) high degree – low impact, c) low degree - high impact, d) low degree –low impact. Table 3 presents median scores of Degree of Participation and Impact of Participation per country. The median score for all countries was 33.3 for Degree of Participation and 34.69 for Impact of Participation .

Table 3. Median scores of Degree of Participation and Impact of Participation per country

	Median for degree of participation*	Median for impact of participation*
Austria	50.00	38.78
Belgium	58.33	26.53
Bulgaria	12.50	35.65
Croatia	43.75	28.57
Cyprus	29.17	38.78
Czech Republic	29.17	18.37
Denmark	33.33	40.82
Estonia	43.75	44.90
Finland	45.83	28.57
France	25.00	36.69
Germany	35.42	40.82
Greece	14.58	16.33
Hungary	47.92	40.82
Ireland	33.33	24.49
Italy	5.60	10.20
Latvia	60.42	41.84
Lithuania	52.08	44.90
Luxembourg	51.04	32.65
Malta	12.50	16.33
Netherlands	25.00	36.69
Poland	22.92	35.69
Portugal	58.33	36.73
Rumania	33.33	37.69
Slovakia	27.08	16.33
Slovenia	27.08	38.57
Spain	46.88	34.69
Sweden	8.33	35.40
UK	56.25	36.73

*median of the percent score (i.e. ((score-possible minimum score)/(maximum-minimum possible score))*100)

The number of countries in each cluster can be seen in Table 4 and a snapshot of the European countries clustering can be found in Figure 2.

Table 4. Number of Countries in each HDI cluster

Cluster	1.High degree and high impact: *Health Democratic Environment*	**7 countries**: Latvia, Portugal, UK, Lithuania, Austria, Hungary, Estonia.
	2. High degree and low impact: *Ostensible Participation*	**6 countries**: Belgium, Luxembourg, Spain, Finland, Croatia, Ireland.
	3. Low degree and high impact: *Limited but impactful participation*	**10 countries**: Germany, Denmark, Romania, Cyprus, Slovenia, Netherlands, France, Poland, Bulgaria, Sweden.
	4. Low degree and low impact: *Opportunities to develop*	**5 countries**: Czech Republic, Slovakia, Greece, Malta, Italy

The total sample was afterwards divided into a split-half random sample and K-means clustering was repeated for the two subsamples. Clustering results indicated that the four-cluster solution recorded in the previous analyses was the most homogeneous solution in each subsample. Furthermore, the Degree of Participation and Impact of Participation scores were compared between the four country groups as defined by cluster analysis. All pair wise comparisons were significant ($p<0.001$) providing additional evidence for the cluster solution.

Discussion

In contemporary health care systems, patients not only participate in decisions concerning their own health and healthcare (i.e. the micro-level), but in decision making processes on the meso- and macro-level (i.e. in local health authorities, organizations, health technology assessment procedures or at the parliament, to name few)[22]. Their influence in these processes is greatly enhanced if they are grouped together. For this reason, patient organizations emerge as an indispensable vehicle for facilitating democracy, promoting patient interests and influencing health policy decision making[22].

Nonetheless, existing evidence suggests wide diversity in the European Union with regard to patient organization participation in health policy decision making[16,18]. At the same time, converging evidence indicates that a greater degree of participation on the part of patient organizations does not guarantee the effectiveness of this participation [13-15,22]. In other words, patient organizations may be given opportunities to have a say in health policy-decision making, but are they being heard?

The findings from the present study revealed four groups of countries:

a) High Degree – High Impact: "Health Democratic environment". The environment fosters patient organization participation and patient groups contribute substantially to health policy decision-making

b) High Degree – Low Impact: ostensible participation. The system provides ample opportunity for patient organization participation; however, this does not exert a significant impact.

c) Low Degree – High Impact: limited but impactful participation. The health policy shaping system does not give enough room for participation; however, it takes patient organizations into consideration. It seems that quality outweighs quantity. One may suggest that either the health policy decision making system takes highly into consideration the claims of CPOs or that they are very effective in advocating their interests.

d) Low Degree – Low impact: Window of opportunity. The decision making system does not facilitate participation and CPOs are not effective in advocating their claims.

Interpretations

The findings of the present study corroborate the wide diversity among European countries with respect to the degree and impact of cancer patient organization participation in health policy decision making. These findings are to a large extent consonant with findings from the European Health Consumer Index[18]. Interestingly, both Bulgaria and Sweden rank very low in the Degree subscale (median=12.5 and median= 8.33 respectively); however, they rank high in the Impact subscale (median = 35.65 and median = 35.40 respectively). At first glance, this appears in sharp contrast to the findings from the European Health Consumer Index, where Bulgaria was found to score good in the indicator "patient organizations involved in decision making" and Sweden intermediary. Nonetheless, the low scores documented in the Degree subscale of the present study are probably explained by both countries' low performance in the indicator "healthcare law based on patients rights". As a result of this, these countries score very low in the Degree subscale (enquiring about the opportunities of CPOs to participate in health decision-making); however, they do well in the Impact subscale (enquiring about the impact of this participation). In other words, while the healthcare system may not provide CPOs with ample opportunity to participate, CPOs appear to manage well into capitalizing on the scarce opportunities given. This is perhaps the explanation why in this group of countries in spite of low degree of participation, there is high impact of participation. It is highly likely that CPOs in these countries have better advocacy and lobbying skills.

Alternatively, it may be the case that CPOs form stronger coalitions in these countries. A study by Wood on patient groups in UK and USA has indicated that in both countries there is a proliferation of patient organizations; however their political effectiveness is disproportionally low due to their autonomous activity and their reluctance to collaborate[23]. A similar concern was raised by the Vienna workshop, where heightened competition and tensions among patient organizations was suggested to hinder their political effectiveness [16]. Therefore, CPOs in countries with high impact may be more politicized and more united.

This may also explain why in certain countries there is high degree of participation but low impact. Members of CPOs in these countries may not be trained enough in lobbying and advocacy skills and do not engage into joint campaigning. Alternatively, the system may ostensibly involve patient organizations in health policy decision making. This is congruent with the concern raised in UK[13] that the involvement of patient organizations in health policy decision making may solely serve the purpose of adding legitimacy to governments, while the latter advance their own interests. Therefore, one should investigate further what happens in these countries.

It merits noting that the Health Democracy Index entails items tapping perceived patient organization participation in health policy decision making on various realms: hospital boards, health technology assessment, ethics committees in clinical trials, national parliament, ministry of health, to name few. It is highly likely that an item-per-item analysis may reveal a different pattern of results with regard to country ranking. Our research team is currently working along this direction .

Good Examples

A good example of a country with High Degree of Participation

The decentralization of the healthcare system in 2001 in Finland has led to an increased public participation in health policy decision making. In 1999, the government set the foundations for the patients' participation in all levels and sectors pertaining to health policy. A network of agencies at local and national level was developed. Agencies were affiliated with the Ministry of Health, so as to facilitate, increase and sustain public involvement in each step of health policy decision making processes by conducting local health needs assessments, priority setting surveys and informal evaluations[24].

A good example of a country with High Impact of Participation

Cyprus was found to be in the cluster of countries characterized by low degree of participation and high impact. In 2016, the Pancyprian Federation of Patient Associations and Friends conducted a national study in order to assess patients' organizations participation in health policy decision making and identify unmet needs. The study results were disseminated to the community, local press and other key-stakeholders. A few months later, the systematic advocating and lobbying activities ended successfully. New legislation providing for patients' participation in health policy decision making at national level was established by the Cyprus Parliament based on the Declaration for Patients Participation in Health Policy Decision Making[25].

Limitations

The study was not without its limitations. As there is no sampling frame for CPOs in Europe, the representativeness of the sample is contested. In spite of systematic efforts to recruit participants through various pathways one may not exclude the possibility that the most active and motivated CPO members agreed to participate. In this reasoning, sampling bias may have emerged if respondents differed systematically from non-respondents in terms of their views about their CPOs participation in health policy decision making.

Moreover, the HDI taps the patient perspective on the degree of and impact of patient organization participation and thus findings deriving from its use should be considered complementary to other perspectives (e.g. policy makers' perspective or more objective indices, such as data emanating from the parliament minutes). Finally, as the present study addressed cancer patient organizations, findings cannot extrapolated to other disease groups.

It is noteworthy that since the aim of the present report was to provide a snapshot of CPO participation in health policy decision making in EU-28 from patients' perspective, we could not have explored potential links between our data and other system performance indices, such as cancer survival rates and percentage of total health expenditures spent on cancer care across countries. Nonetheless, we are currently designing an ecological study that would enable us to go into greater depth on the topic.

Conclusion

There is substantial diversity in EU-28 with regard to perceived CPO participation in health policy decision making. Study findings indicate that a high degree of participation is not synonymous to high impact. As a result of this, there is still a ways to go in order to ensure that both the healthcare system will create ample opportunity for CPOs to participate in health decision making and that CPOs will be capable of capitalizing on them.

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Ethics Approval

The study was approved by the Research and Ethics Committee of the University of Peloponnese, Corinth, Greece in accordance with the ethical standards delineated in the 1964 Declaration of Helsinki. Furthermore, the

Institutional Review Board of the participating patients associations reviewed and approved the study. Informed consent for participation was obtained from all participants.

Contributions

The study was designed by KS, EA, LP, CT, DV, OB, DD, SH and FS. EA, LP, CT, DV, OB and DD were responsible for the data collection. CT, KS and FS performed the statistical analysis. KS, EA, LP, CT, DV, OB, DD, SH and FS contributed to the interpretation of the results and draft the manuscript. All authors have read and approved the final manuscript.

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Conflict of interest statement

We have read and understood BMJ Open policy on declaration of interests and declare that we have no competing interests.

Patient consent statement

Not Applicable

Licence

Data sharing statement

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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516

517 *Figure 1*. Cluster analysis results

518 *Figure 2*. Patient organization participation in EU-28 by country cluster

519

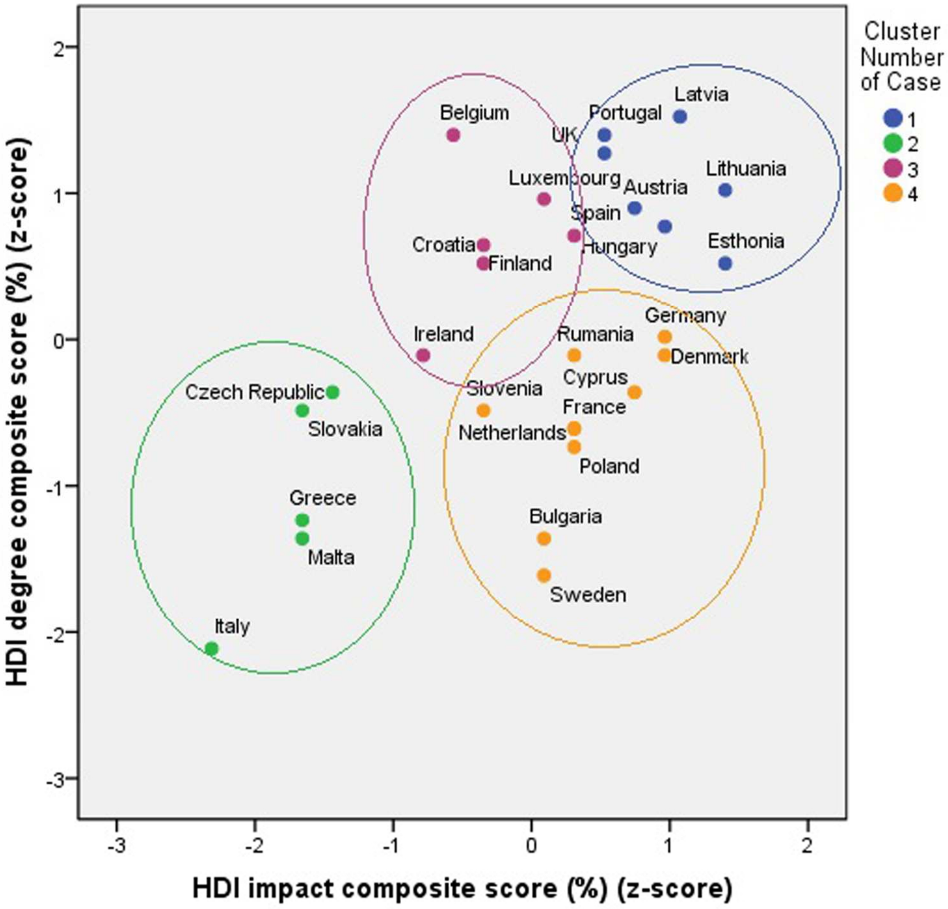

Figure 1. Cluster analysis results

133x124mm (300 x 300 DPI)

Picture 2. Snapshot of European countries clustering according to HDI score.

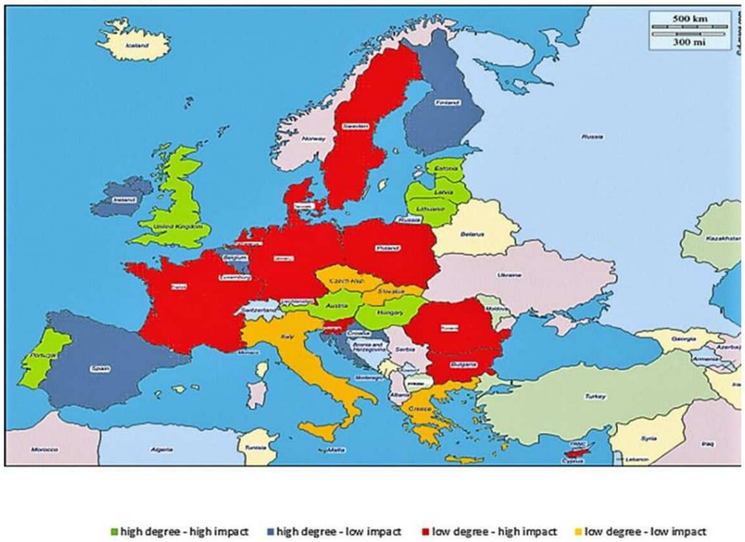

Figure 2. Patient organization participation in EU-28 by country cluster

279x181mm (300 x 300 DPI)

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Cancer Patients' Organization participation in heath policy decision making: a snapshot/cluster analysis of the EU-28 countries.

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Keywords: Patient Participation, Health Policy Decision Making, Cancer Patient Organizations.

Word count: 2604

Abstract

Objectives: Even though patient involvement in health policy decision making is well documented, studies evaluating the degree and impact of this participation are scarce. This is even more conspicuous in the case of cancer. There is evidence showing that patients with the same type of cancer and at the same stage of the disease will receive different treatments in different countries. Therefore, it is crucial to assess the degree of patient participation in health policy decision making across Europe, as it may result in health inequalities across countries. In a response to this research call, the present study aimed to provide a snapshot of cancer patients' organization (CPO) participation in health policy processes in EU-28 countries.

Setting: Cancer Patients' Organizations from the 28 EU-countries.

Participants: 1,266 members of Cancer Patients' Organizations from the 28 EU countries.

Primary and secondary outcome measures: information about participants' socio-demographic characteristics and their involvement in their CPO was collected as well as data about the CPO. A 17-item index containing questions about the type and impact of participation in various facets of health policy decision making was used to assess the degree of CPOs participation in health policy decision making processes and its impact.

Results: The findings revealed four groups of countries according to their score: a) high degree of participation - high impact, b) high degree – low impact, c) low degree - high impact, d) low degree –low impact.

Conclusion: Cancer patient participation in health policy decision making processes varies significantly across EU-28 countries. Although progress has been made in upgrading patients' role in terms of legislation, more effort is

necessitated in order to address inequalities in health policy decision making in EU-28.

Strengths and Limitations of the Study

- The study included a large sample from the 28 member stated of the European Union.
- An innovative and validated tool was employed in order to assess the level of cancer patients' organizations participation in health policy decision making
- The cross-sectional design of the study does not allow making causal inferences.
- The convenience sample of the study might have limited the generalizability of the results.

Introduction

Cancer is the most common and severe non-communicable diseases, impinging substantially on both health and healthcare [1]. Cancer patients have to cope with the stress and the dramatic changes in their lifestyle and quality of life as well as the procedures and bureaucracy (e.g. reimbursement processes) often involved in the treatment of the illness [2]. Although public spending on health and long-term care has increased in the majority of European countries (EU), cancer patients' needs remain largely unmet [3]. An illustration of this point is waiting times in cancer care in Ireland, which in 2015 were found to be higher than their counterparts in Albania [4]. Increased public spending is a necessary but not sufficient condition to ensure effectiveness and sustainability of the healthcare system [5].

In an effort to provide more effective and appropriate services, the healthcare system philosophy has shifted from a biomedical approach (which is doctor-focused) to a more holistic and self-managed one [6]. Many programs, tools and models have been implemented in order to empower cancer patients and facilitate their participation in the delivery of health care services[7]. In this frame, the physician is no longer considered to be the “expert” or just the provider and the patient only the receiver. Rather, there is shared decision making in clinical practice. No one knows better the nature of a disease and the needs deriving from it but the patients themselves[8].

This is not limited to the individual physician-patient relationship, as patients may collectively participate in decision making in various realms, including guideline development, government policy and research agenda setting, among others[9-11]. Patient participation at the collective level is primarily justified on the grounds of democratic values. Patients are affected by the consequences of certain decisions, and therefore they should have a say in the process. Concomitantly, their subjective knowledge of a disease and its treatment may enhance the quality of health care decision making[12], upgrading the overall effectiveness and efficiency of the healthcare system.

While patients’ collective action is increasingly recognized as an important driver of health policy and service provision, there is paucity of research on their association. The De Montfort study in the UK has substantiated increased contact between patient groups and policymakers during the past years, while professional bodies and pharmaceutical companies were found to have involved patient groups in discussions on policy proposals to a larger extent than in the past[13]. Nonetheless, according to the researchers, the available evidence could not shed enough light on the influence exerted by patient groups, as their heightened participation is not necessarily translated into high political effectiveness. In a similar vein, while the Dutch model in Netherlands allows patient organizations to be an equal party in health policy processes to a large extent; this is not met in practice[14]. Moreover, evidence from Mixed Advisory Committees in Italy highlight the limited influence of users' voice on decision making by health authorities[15]. In 2006, a workshop with 22 academic researchers and two representatives of patient organizations documented high involvement of patient groups with policymakers and political institutions; however, marked diversity among European countries was stressed [16].

The initiatives undertaken by most EU countries to establish and increase patient participation in health policy decision making are reflected on legislation level[17]. Nonetheless, based on information provided by the European Health Consumer Index[18], countries display important differences in terms of the degree to which their healthcare law is based on patient rights. Additionally, noteworthy variation is also observed in the degree to which patient organizations are involved in decision-making[18]. This in turn may create health inequalities across countries. As a corollary of this, there is an imperative need to investigate the degree and impact of patient organization participation in health policy decision making in the European Union. This need becomes even more pronounced in the case of cancer, as the disease has a multifaceted impact and can be a chronic and fatal disease depending on the quality of treatment[19]. In response to this research call, the present study aimed to provide a snapshot of cancer patients' organization (CPOs) participation in health policy decision making in EU-28 countries.

Methods

Instrument

For the purpose of the study a self-reported questionnaire was developed, entailing the following sections:

Respondents' characteristics

Data were collected on participants' socio-demographic characteristics (gender, age, educational attainment, self-reported economic status) and their involvement in the CPO. In particular, participants had to rate their degree of familiarity with cancer and their knowledge about its treatment/ their country's healthcare system/ their country's reimbursement process (rating options: very low-low-moderate-high-very high). Moreover, they had to rate their degree of involvement in the organization (rating options: absent-very low-low-moderate-high-very high). Data were also gleaned with regard to their position in the organization (president/or other board member – employed by the organization-voting member-nonvoting but active member-non-active member) and the duration of their membership.

Organizational characteristics

Information was also collected concerning their CPO. Specifically, participants had to indicate whether their organization provided information material to its members (yes-no) and training (yes-no). Furthermore, they were asked whether their organization was a member of a national cancer federation (yes-no).

Health Democracy Index

Moreover, the questionnaire encompassed the Patient Participation and Health Democracy Index (HDI), an original scale measuring the degree of patient organization participation and its impact on shaping health policy. The Health Democracy Index consists of 17 questions: 8 items investigate CPOs level of participation (***Degree of Participation***) in processes such as: reforms, panels at the Ministry of Health, hospital boards, Ethics Committees in clinical trials, Health Technology Assessment procedures (2 items: one for the scientific evaluation of new treatments and methods and one for the economic evaluation) and the national parliament. Each question may have one of the following answers: (i) it is not a legal requirement and it never happens, (ii)) it is not a legal requirement and it rarely happens, (iii) it is not a legal requirement but it often happens, (iv) it is a legal requirement and it never happens, (v) it is a legal requirement and it often happens, (vi) it is a legal requirement and it happens very often, and (vii) it is a legal requirement and it always happens. Concomitantly, the HDI entails 9 items tapping the impact of CPOs participation on the aforementioned 8 realms (reforms, ministry of health, other health-related organizations, hospital boards, ethics committee, HTA and national parliament), which are rated on a 6-point scale ranging from absent to very high. In addition, ***the Impact of Participation*** sub-scale entails a 9th item enquiring about the frequency by which a substantial change is observed in the content of a health policy decision as a result of the involvement of the patient organization. The particular item is rated on a 6-point scale ranging from never to very often.

Higher composite scores on the sub-scales denote higher degree and impact of participation. Both sub-scales displayed good internal consistency (Cronbach α = 0.879 and Cronbach α = 0.874 respectively). Converging evidence has substantiated the psychometric properties of the Health Democracy Index[20] . Specifically, the development of the index has followed the subsequent steps: (i) definition of the construct (i.e. patient organization participation in health policy decision making), (ii) review of the construct definition, (iii)item drafting, (iv) item review) and (v) pilot testing of its psychometric properties (internal consistency , test-retest reliability, construct validity ad convergent validity). As the index was originally developed in Greece[21], an international working group consisting of European stakeholders (policy-makers, members of patient organizations and researchers with background on patient empowerment) held various meetings to discuss the adaptation of the index to European standards.[20]

Participants and Procedures:

Potential participants were identified through various channels (e.g. internet search, on line databases of European cancer patients' associations, registries of the ministry of health etc). CPO was considered any non-profit organization with a legal entity. In addition, the CPO should have been cancer-specific, be primarily composed of patients and their caregivers and representing and/or supporting their needs. To be recruited for the study, a CPO should have had an active representation of cancer patients at a national level and a valid and accessible website. CPOs from EU-28 member states were included in the study. In order to be eligible for participation, an individual should have been a member of a CPO and older than 18.

An email was sent to CPO board members informing them about the study and inviting them to participate. Following their acceptance, the Institutional

Review Board of each organization approved the study protocol and forwarded the invitation for participation to all of its members. All respondents filled a written informed consent form. Data were collected online (via web-link and email). The questionnaire was translated to each country's official language.

Patient and Public Involvement

Patients play an integral role in this project and thus they have participated in various stages of the research process. The development of the HDI, which has been utilized to assess CPO participation in health policy decision making, has involved both patients-members of patient organizations and patient representatives during the phases of (i) reviewing the construct definition, (ii) item drafting, (iii) item review and (iv) adaptation of the index to pan-European standards[20,21]. Moreover, patient representatives have participated in the formulation of research objectives, the design of the study and the interpretation of its findings; while members of patient organizations have constituted the study sample of this research work. It deserves mentioning that results will be disseminated to all identified CPOs, irrespectively of whether they participated or not.

Statistical analysis

Descriptive statistics such as means, medians, standard deviations, absolute and relative frequencies were computed, where appropriate.

Ward's method was used to compute distance patterns and determine the appropriate number of clusters for the K-means clustering procedure. K-means clustering was performed for the classification of cluster subgroups and was based on Euclidian distance. We changed all variables to z-scores to yield equal metrics and equal weighting. For the consistency and validity of the hypothesized groups of countries in the total sample; the total sample was divided into a split-half random sample. K-means clustering was used then for the two subsamples to determine the presence of similar cluster subgroups from the previous analyses. Additionally, analysis of variance ANOVA was used to compare Degree of Participation and Impact of Participation scores between the four groups defined by cluster analysis. Statistical analyses were performed using the SPSS for Windows Version 19.0 statistical package (SSPS Inc., Chicago, IL).

Results

Sample Characteristics

The final sample consisted of 1,266 members of CPOs from EU-28 countries and the mean number of respondents per country was 45 (Table 1). Demographics of the sample are shown in table 2.

Table 1. Number of respondents per country

	N	%
Country		
Austria	47	3.7
Belgium	34	2.7
Bulgaria	31	2.4
Croatia	46	3.6
Cyprus	37	2.9
Czech Republic	45	3.6
Denmark	44	3.5
Esthonia	35	2.8
Finland	45	3.6
France	93	7.3
Germany	44	3.5
Greece	63	5
Hungary	33	2.6
Ireland	51	4
Italy	95	7.5
Latvia	32	2.5

Lithuania	38	3
Luxembourg	30	2.4
Malta	32	2.5
Netherlands	42	3.3
Poland	44	3.5
Portugal	47	3.7
Rumania	45	3.6
Slovakia	38	3
Slovenia	41	3.2
Spain	42	3.3
Sweden	43	3.4
UK	49	3.9

Table 2. Sample demographics

	N	%
Age, mean (SD)	54.6(14.8)	
Sex		
Men	534	42.2
Women	732	57.8
Education level		
No formal qualification	9	0.7
Primary School Education	7	0.6
Secondary School Education	378	29.8
University Degree	520	41.1
Postgraduate Degree	352	27.8
Self-report economic status		
Low	13	1.0
Medium to Low	238	18.8
Medium	529	41.8
Medium to High	387	30.6
High	98	7.7

Degree and Impact of CPO Participation

Composite scores of the HDI sub-scales (**Degree of Participation** and **Impact of Participation**) were used for clustering analysis (Figure 1). The findings revealed four groups of countries according to their score: a) high degree - high impact, b) high degree – low impact, c) low degree - high impact, d) low degree –low impact. Table 3 presents median scores of Degree of Participation and Impact of Participation per country. The median score for all countries was 33.3 for Degree of Participation and 34.69 for Impact of Participation .

Table 3. Median scores of Degree of Participation and Impact of Participation per country

	Median for degree of participation*	Median for impact of participation*
Austria	50.00	38.78
Belgium	58.33	26.53
Bulgaria	12.50	35.65
Croatia	43.75	28.57
Cyprus	29.17	38.78
Czech Republic	29.17	18.37
Denmark	33.33	40.82
Estonia	43.75	44.90
Finland	45.83	28.57
France	25.00	36.69
Germany	35.42	40.82
Greece	14.58	16.33
Hungary	47.92	40.82
Ireland	33.33	24.49
Italy	5.60	10.20
Latvia	60.42	41.84
Lithuania	52.08	44.90
Luxembourg	51.04	32.65
Malta	12.50	16.33
Netherlands	25.00	36.69
Poland	22.92	35.69
Portugal	58.33	36.73
Rumania	33.33	37.69
Slovakia	27.08	16.33
Slovenia	27.08	38.57
Spain	46.88	34.69
Sweden	8.33	35.40
UK	56.25	36.73

*median of the percent score (i.e. ((score-possible minimum score)/(maximum-minimum possible score))*100)

The number of countries in each cluster can be seen in Table 4 and a snapshot of the European countries clustering can be found in Figure 2.

Table 4. Number of Countries in each HDI cluster

Cluster		
	1.High degree and high impact: *Health Democratic Environment*	**7 countries**: Latvia, Portugal, UK, Lithuania, Austria, Hungary, Estonia.
	2. High degree and low impact: *Ostensible Participation*	**6 countries**: Belgium, Luxembourg, Spain, Finland, Croatia, Ireland.
	3. Low degree and high impact: *Limited but impactful participation*	**10 countries**: Germany, Denmark, Romania, Cyprus, Slovenia, Netherlands, France, Poland, Bulgaria, Sweden.
	4. Low degree and low impact: *Opportunities to develop*	**5 countries**: Czech Republic, Slovakia, Greece, Malta, Italy

The total sample was afterwards divided into a split-half random sample and K-means clustering was repeated for the two subsamples. Clustering results indicated that the four-cluster solution recorded in the previous analyses was the most homogeneous solution in each subsample. Furthermore, the Degree of Participation and Impact of Participation scores were compared between the four country groups as defined by cluster analysis. All pair wise comparisons were significant ($p<0.001$) providing additional evidence for the cluster solution.

Discussion

In contemporary health care systems, patients not only participate in decisions concerning their own health and healthcare (i.e. the micro-level), but in decision making processes on the meso- and macro-level (i.e. in local health authorities, organizations, health technology assessment procedures or at the parliament, to name few)[22]. Their influence in these processes is greatly enhanced if they are grouped together. For this reason, patient organizations emerge as an indispensable vehicle for facilitating democracy, promoting patient interests and influencing health policy decision making[22]. Nonetheless, existing evidence suggests wide diversity in the European Union with regard to patient organization participation in health policy decision making[16,18]. At the same time, converging evidence indicates that a greater degree of participation on the part of patient organizations does not guarantee the effectiveness of this participation [13-15,22]. In other words, patient organizations may be given opportunities to have a say in health policy-decision making, but are they being heard?

The findings from the present study revealed four groups of countries:

a) High Degree – High Impact: “Health Democratic environment”. The environment fosters patient organization participation and patient groups contribute substantially to health policy decision-making

b) High Degree – Low Impact: ostensible participation. The system provides ample opportunity for patient organization participation; however, this does not exert a significant impact.

c) Low Degree – High Impact: limited but impactful participation. The health policy shaping system does not give enough room for participation; however, it takes patient organizations into consideration. It seems that quality outweighs quantity. One may suggest that either the health policy decision making system takes highly into consideration the claims of CPOs or that the latter are very effective in advocating their interests.

d) Low Degree – Low impact: Window of opportunity. The decision making system does not facilitate participation and CPOs are not effective in advocating their claims.

Interpretations

The findings of the present study corroborate the wide diversity among European countries with respect to the degree and impact of CPOs participation in health policy decision making. These findings are to a large extent consonant with findings from the European Health Consumer Index[18]. Interestingly, both Bulgaria and Sweden rank very low in the Degree subscale (median=12.5 and median= 8.33 respectively); however, they rank high in the Impact subscale (median = 35.65 and median = 35.40 respectively). At first glance, this appears in sharp contrast to the findings from the European Health Consumer Index, where Bulgaria was found to score good in the indicator “patient organizations involved in decision making” and Sweden intermediary. Nonetheless, the low scores documented in the Degree subscale of the present study are probably explained by both countries’ low performance in the indicator “healthcare law based on patients rights”. As a result of this, these countries score very low in the Degree subscale (enquiring about the opportunities of CPOs to participate in health decision-making); however, they do well in the Impact subscale (enquiring about the impact of this participation). In other words, while the healthcare system may not provide CPOs with ample opportunity to participate, CPOs appear to manage well into capitalizing on the scarce opportunities given. This is perhaps the explanation why in this group of countries in spite of low degree of participation, there is high impact of participation. It is highly likely that CPOs in these countries have better advocacy and lobbying skills. Alternatively, it may be the case that CPOs form stronger coalitions in these countries. A study by Wood on patient groups in UK and USA has indicated that in both countries there is a proliferation of patient organizations; however their political effectiveness is disproportionally low due to their autonomous activity and their reluctance to collaborate[23]. A similar concern was raised by the Vienna workshop, where heightened competition and tensions among patient organizations was suggested to hinder their political effectiveness [16]. Therefore, CPOs in countries with high impact may be more politicized and more united.

This may also explain why in certain countries there is high degree of participation but low impact. Members of CPOs in these countries may not be trained enough in lobbying and advocacy skills and may not engage into joint campaigning. Alternatively, the system may ostensibly involve patient organizations in health policy decision making. This is congruent with the concern raised in UK[13] that the involvement of patient organizations in health policy decision making may solely serve the purpose of adding legitimacy to governments, while the latter advance their own interests. Therefore, one should investigate further what happens in these countries and endeavour to identify the determinants of impactful participation overall[24]

It merits noting that the Health Democracy Index entails items tapping perceived patient organization participation in health policy decision making on various realms: hospital boards, health technology assessment, ethics committees in clinical trials, national parliament, ministry of health, to name few. It is highly likely that an item-per-item analysis may reveal a different pattern of results with regard to country ranking. Our research team is currently working along this direction.

Good Examples

A good example of a country with High Degree of Participation

The decentralization of the healthcare system in 2001 in Finland has led to an increased public participation in health policy decision making. In 1999, the government set the foundations for the patients' participation in all levels and sectors pertaining to health policy. A network of agencies at local and national level was developed. Agencies were affiliated with the Ministry of Health, so as to facilitate, increase and sustain public involvement in each step of health policy decision making processes by conducting local health needs assessments, priority setting surveys and informal evaluations[25].

A good example of a country with High Impact of Participation

Cyprus was found to be in the cluster of countries characterized by low degree of participation and high impact. In 2016, the Pancyprian Federation of Patient Associations and Friends conducted a national study in order to assess patients' organizations participation in health policy decision making and identify unmet needs. The study results were disseminated to the community, local press and other key-stakeholders. A few months later, the systematic advocating and lobbying activities ended successfully. New legislation providing for patients' participation in health policy decision making at national level was established by the Cyprus Parliament based on the Declaration for Patients Participation in Health Policy Decision Making[26].

Limitations

The study was not without its limitations. As there is no sampling frame for CPOs in Europe, the representativeness of the sample is contested. In spite of systematic efforts to recruit participants through various pathways one may not exclude the possibility that the most active and motivated CPO members agreed to participate. In this reasoning, sampling bias may have emerged if respondents differed systematically from non-respondents in terms of their views about their CPOs participation in health policy decision making.

Moreover, the HDI taps the patient perspective on the degree of and impact of patient organization participation and thus findings deriving from its use should be considered complementary to other perspectives (e.g. policy makers' perspective or more objective indices, such as data emanating from the parliament minutes). Finally, as the present study addressed CPOs, findings cannot extrapolated to other disease groups.

It is noteworthy that since the aim of the present report was to provide a snapshot of CPO participation in health policy decision making in EU-28 from the patients' perspective, we could not have explored potential links between our data and other system performance indices, such as cancer survival rates and percentage of total health expenditures spent on cancer care across countries. Nonetheless, we are currently designing an ecological study that would enable us to go into greater depth on the topic.

Conclusion

There is substantial diversity in EU-28 with regard to perceived CPO participation in health policy decision making. Study findings indicate that a high degree of participation is not synonymous to high impact. As a result of this, there is still a long way to go in order to ensure that both the healthcare system will create many opportunities for CPOs to participate in health decision making and that CPOs will be capable of capitalizing on them.

Acknowledgments

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Ethics Approval

The study was approved by the Research and Ethics Committee of the University of Peloponnese, Corinth, Greece in accordance with the ethical standards delineated in the 1964 Declaration of Helsinki. Furthermore, the Institutional Review Board of the participating patients associations reviewed and approved the study. Informed consent for participation was obtained from all participants.

Contributions

The study was designed by KS, EA, LP, CT, DV, OB, DD, SH and FS. EA, LP, CT, DV, OB and DD were responsible for the data collection. CT, KS and FS performed the statistical analysis. KS, EA, LP, CT, DV, OB, DD, SH and FS contributed to the interpretation of the results and draft the manuscript. All authors have read and approved the final manuscript.

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Conflict of interest statement

We have read and understood BMJ Open policy on declaration of interests and declare that we have no competing interests.

Patient consent statement

Not Applicable

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Data sharing statement

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Figure 1. Cluster analysis results

Figure 2. Patient organization participation in EU-28 by country cluster

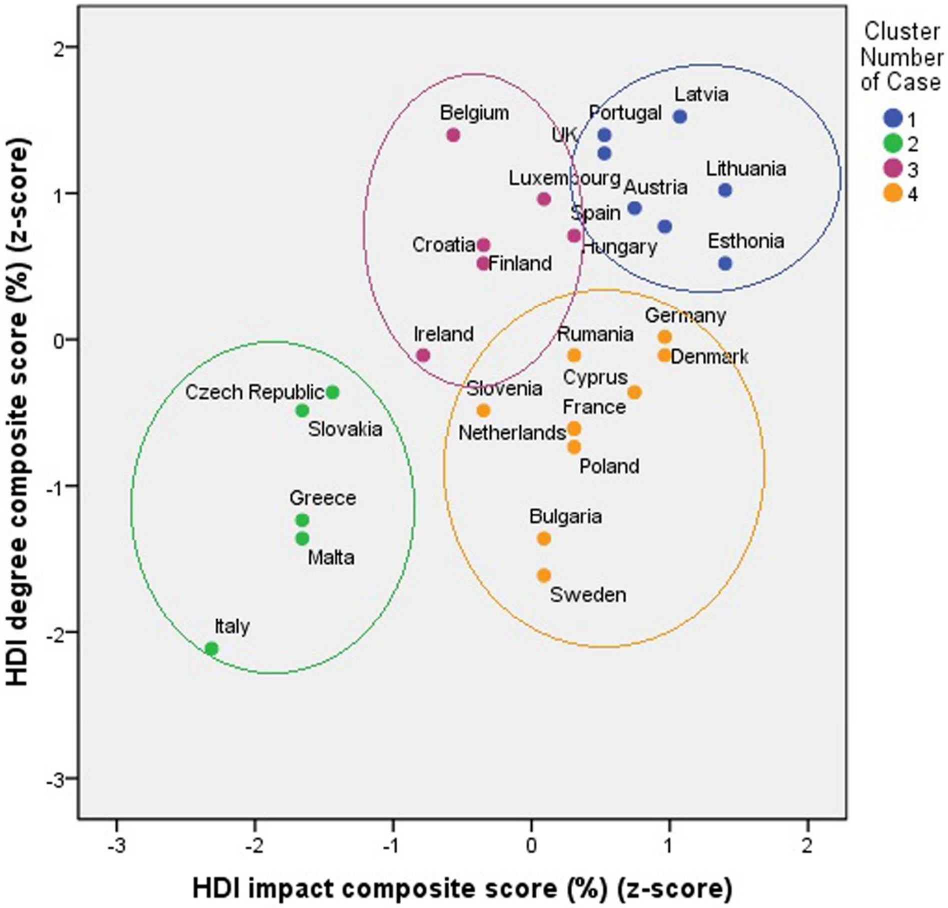

Figure 1. Cluster analysis results

133x124mm (300 x 300 DPI)

Picture 2. Snapshot of European countries clustering according to HDI score.

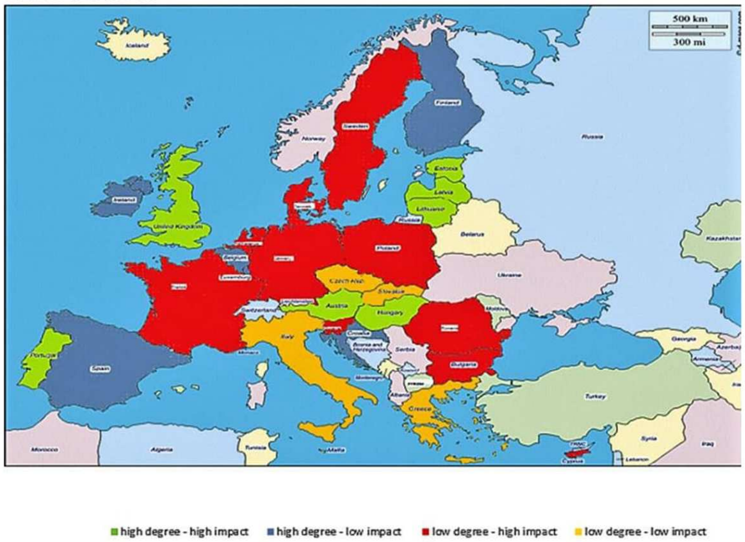

Figure 2. Patient organization participation in EU-28 by country cluster

279x181mm (300 x 300 DPI)