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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-018896
Article Type:	Research
Date Submitted by the Author:	28-Jul-2017
Complete List of Authors:	Souliotis, Kyriakos; University of Peloponnese, Faculty of Social Sciences; Agapidaki, Eirini; Faculty of Social and Political Sciences, University of Peloponnese Peppou, Lilly; University Mental Health Research Institute Tzavara, Chara; Centre for Health Services Research, Department of Hygiene, Epidemiology and Medical Statistics, Medical School, National & Kapodistrian University of Athens Varvaras, Dimitrios; Universita degli Studi di Roma Tor Vergata Facolta di Medicina e Chirurgia Buonomo, Oreste; Universita degli Studi di Roma Tor Vergata Facolta di Medicina e Chirurgia Debiais, Dominique; Europa Donna, Forum France Hasurdjiev, Stanimir; Bulgarian National Patients' Organization Sarkozy, Francois; FSNB Health & Care
Keywords:	Patient participation, health policy decision making, cancer patient organizations

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3 **1 Cancer Patients' Organization participation in health policy**
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5 **2 decision making: a snapshot/cluster analysis of the EU-28**
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7 **3 countries.**

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9 4 Kyriakos Souliotis^{1,2*}, Eirini Agapidaki¹, Lily-Evangelia Peppou³, Chara
10
11 5 Tzavara¹, Dimitrios Varvaras⁴, Oreste Buonomo⁴, Dominique Debiais⁵,
12
13 6 Stanimir Hasurdjiev⁶, Francois Sarkozy⁷.

14
15
16
17
18 8 ¹ Faculty of Social and Political Sciences, University of Peloponnese, Corinth,
19
20 9 Greece;

21
22 10 ² Centre for Health Services Research, Department of Hygiene, Epidemiology
23
24 11 and Medical Statistics, Medical School, University of Athens, Athens, Greece

25
26 12 ³ University Mental Health Research Institute, Athens, Greece

27
28 13 ⁴ Department of Surgery, University of Rome Tor Vergata, Rome, Italy

29
30 14 ⁵ Europa Donna, Paris, France

31
32 15 ⁶ Bulgarian National Patients' Organization, Sofia, Bulgaria

33
34 16 ⁷ FSNB Health & Care, Paris, France

35
36 17 *** Corresponding author:**

37
38 18 Kyriakos Souliotis

39
40
41 University of Peloponnese, Faculty of Social and Political Sciences,
42
43 Department of Social and Education Policy, Corinth, Greece; Damaskinou &
44
45 Kolokotroni Str., 20100, Corinth, Greece; soulioti@hol.gr; tel : + 302741074991
46
47 fax: +302741074990.

48
49
50 19 **Keywords:** Patient Participation, Health Policy Decision Making, Cancer
51
52 Patient Organizations.

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54 21 **Word count:** 2604

22 **Abstract**

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

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

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

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

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

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

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

50 51 **Strengths and Limitations of the Study**

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

61 **Introduction**

62 Cancer is a most common and severe non-communicable diseases, impinging
63 on both health and healthcare ¹. Cancer patients have to cope not only with the
64 stress and the dramatic changes in their lifestyle and quality of life, but also
65 with the medical interventions, procedures and bureaucracy (e.g.
66 reimbursement processes) involved in the treatment of the illness ². Although
67 public spending on health and long-term care has increased in the majority of
68 European countries (EU), the needs of cancer patients remain largely unmet ³.
69 An illustration of this point is waiting times in cancer care in Sweden, which in
70 2014 were found to be higher than those in Albania ⁴. Increased public
71 spending is a necessary but not sufficient condition to ensure effectiveness
72 and sustainability of the healthcare system ⁵. This led to the engagement of

1
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3 73 patients in the development of protocols and procedures and shifted the
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5 74 health policy agenda from the treatment of the disease to the management of
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7 75 patient⁶.

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9 76 In an effort to provide more effective and appropriate services, the healthcare
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11 77 systems' philosophy has been shifted from a biomedical (which is doctor-
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13 78 focused) to a more holistic and self-managed approach ⁶. A lot of programs,
14
15 79 tools and models have been implemented to empower cancer patients and
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17 80 facilitate their participation in the delivery of health care services⁷. The
18
19 81 physicians is no longer considered to be the "expert" or the providers and the
20
21 82 patient only the receiver, instead there is clinical shared decision making. No
22
23 83 one knows better the nature of a disease and the needs deriving from it but the
24
25 84 patients themselves⁸. This is the fundamental principle underlining patient
26
27 85 participation in a whole spectrum of healthcare activities, including health
28
29 86 policy decision making⁹. Researchers suggest that apart from health-related
30
31 87 incentives¹⁰, the drivers for public participation in health policy stem from the
32
33 88 personal interest to promote and disseminate the democratic principles of
34
35 89 legitimacy, transparency and accountability¹¹. In line with this, fifteen years
36
37 90 ago the Council of Europe established the right of the European citizens to be
38
39 91 engaged in health policy decision making processes as an essential right of
40
41 92 individuals living in a democratic society¹².

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45 93 The initiatives undertaken by most EU countries to establish and increase
46
47 94 patient participation in health policy decision making are summarized on
48
49 95 legislation level⁹. Only a handful of countries have developed informational,
50
51 96 educational and other interventions to empower patients to take part in such
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53 97 processes¹³. As a result, even though the legislation is almost similar among
54
55 98 the countries with a legal framework for patient participation in health policy

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3 99 decision making; the degree and impact of such involvement varies
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5 100 significantly¹⁴. The evidence suggests that patient participation greatly affects
6
7 101 the performance of the health care system⁸. In other words, patients with the
8
9 102 same type of cancer and at the same stage of the disease will receive different
10
11 103 treatments in different countries. Therefore, it is crucial to assess the degree
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13 104 of patient participation in health policy decision making across Europe, as it
14
15 105 may result in health inequalities between countries. This need becomes even
16
17 106 more pronounced in the case of cancer, as the disease has a multivariate
18
19 107 impact and can be a chronic or a fatal disease depending on the quality of
20
21 108 treatment. In a response to this research call, the present study aimed to
22
23 109 provide a snapshot of Cancer Patients' Organization (CPOs) participation in
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25 110 health policy processes in EU-28 countries.
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30 112 **Methods**

31
32 113 The instrument of the study:

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34 114 For the purpose of the study a self-reported questionnaire was developed,
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36 115 entailing questions on participants' socio-demographic characteristics, their
37
38 116 involvement in the CPO (e.g. position in the CPO, years of membership) and
39
40 117 the CPO's level of representation (e.g. whether the CPO is a member of a
41
42 118 national or international federation), among others.

43
44 119 Moreover, the questionnaire encompassed the Patient Participation and
45
46 120 Health Democracy Index (HDI), an original scale measuring the degree of
47
48 121 CPOs participation and its impact on shaping health policy. The Health
49
50 122 Democracy Index consists of 17 questions: 8 items investigate CPOs level and
51
52 123 of participation (***Degree of Participation***) in processes such as: reforms,
53
54 124 panels at the Ministry of Health, hospital boards, Ethics Committees in
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3 125 clinical trials, Health Technology Assessment procedures (2 items: one for the
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5 126 scientific evaluation of new treatments and methods and one for the economic
6
7 127 evaluation) and the national parliament. Each question may have one of the
8
9 128 following answers: (i) it is not a legal requirement and it never happens, (ii))
10
11 129 it is not a legal requirement and it rarely happens, (iii) it is not a legal
12
13 130 requirement but it often happens, (iv) it is a legal requirement and it never
14
15 131 happens, (v) it is a legal requirement and it often happens, (vi) it is a legal
16
17 132 requirement and it happens very often, and (vii) it is a legal requirement and
18
19 133 it always happens. Concomitantly, the HDI entails 9 items tapping the impact
20
21 134 of PO participation on the aforementioned 8 realms (reforms, ministry of
22
23 135 health, other health-related organizations, hospital boards, ethics committee,
24
25 136 HTA and national parliament), which are rated on a 6-point scale ranging
26
27 137 from absent to very high. In addition, ***the Impact of Participation*** sub-
28
29 138 scale entails a 9th item enquiring about the frequency by which a substantial
30
31 139 change is observed in the content of a health policy decision as a result of the
32
33 140 involvement of the PO. The particular item is rated on a 6-point scale ranging
34
35 141 from never to very often.

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38
39 142 Higher composite scores on the sub-scales denote higher degree and impact of
40
41 143 participation. Both sub-scales displayed good internal consistency (Cronbach
42
43 144 $\alpha = 0,879$ and Cronbach $\alpha = 0,874$ respectively). Converging evidence has
44
45 145 substantiated the psychometric properties of the Health Democracy Index¹⁵ .

146 Participants and Procedures:

147 Potential participants were identified through various channels (e.g. internet
148 search, on line databases of European cancer patients' associations, registries
149 of the ministry of health etc). As CPO was considered any non-profit
150 organization with a legal entity. In addition, the CPO should have been

1
2
3 151 cancer-specific, be primarily composed of patients and their caregivers and
4
5 152 representing and/or supporting their needs. To be recruited for the study, a
6
7 153 CPO should have had an active representation of cancer patients at a national
8
9 154 level and a valid and accessible website. CPOs from EU-28 member states
10
11 155 were included in the study. In order to be eligible for participation, an
12
13 156 individual should have been a member of a CPO and older than 18. The final
14
15 157 sample consisted of 1.266 members of CPOs from EU-28 countries.
16
17 158 An email was sent to the CPO board members informing them about the study
18
19 159 and inviting them to participate. Following the acceptance, the Institutional
20
21 160 Review Board of each organization approved the study protocol and then
22
23 161 forwarded the invitation for participation to all of its members. All
24
25 162 respondents filled a written informed consent form. Data were collected
26
27 163 online (via web-link and email). The questionnaire was translated
28
29 164 appropriately for each participant to complete it in their native language.

165 **Results**

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

173 **Table 1. Number of Countries in each HDI cluster**

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

174

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

176 follows:

177 a) High Degree – High Impact: “Health Democratic environment”. The

178 environment fosters patient empowerment and participation.

179 b) High Degree – Low Impact: ostensible participation. The system enables

180 participation and thus organizations do participate; however, they cannot

181 effectively claim their rights. It is also possible that the health policy decision

182 making processes are fragmented and/or not open enough to take CPOs into

183 consideration.

184 c) Low Degree – High Impact: limited but impactful participation. The health

185 policy shaping system does not give enough room for participation; however,

186 it takes patient organizations into consideration. It seems that quality

187 outweighs quantity. One may suggest that either the health policy decision

188 making system takes highly into consideration the claims of CPOs or that they

189 are very effective in advocating their interests.

190 d) Low Degree – Low impact: Window of opportunity. The decision making

191 system does not facilitate participation and CPOs are not effective in

192 advocating their claims.

193 **Good and Promising Practices Across the EU.**

1
2
3 194 There is a number of good and promising practices for enhancing patients'
4
5 195 involvement in shaping health policy across the EU. Some countries have only
6
7 196 introduced pertinent legislation; while others have achieved patients'
8
9 197 participation in health planning (at a local and a national level) and in Health
10
11 198 Technology Assessment procedures, among others. In an effort to shed light
12
13 199 on the four clusters that emerged from the data, one case example per cluster
14
15 200 will be briefly discussed.

17 201 *High Degree – High Impact*

20 202 United Kingdom was found to be in the group of countries with high degree of
21
22 203 participation and high impact. To accomplish high patient involvement the
23
24 204 Research Governance Framework for Health and Social Care underlines
25
26 205 “Research [should be] pursued with the active involvement of service users
27
28 206 and carers including where appropriate, those from hard to reach groups
29
30 207 such as the homeless.”¹⁶ To support the public involvement in health research,
31
32 208 the United Kingdom has introduced INVOLVE, a national advisory group
33
34 209 affiliated to the National Institute for Health Research. This initiative
35
36 210 demonstrates substantial activity in terms of consultation, collaboration and
37
38 211 user control research^{14 17}. Another example of institutionalized public
39
40 212 involvement is the National Institute for Health and Care Excellence (NICE).
41
42 213 NICE has incorporated a step-wise and comprehensive approach to engage
43
44 214 patients in decisions regarding treatments and services, health technologies,
45
46 215 clinical practice and public health programs¹⁸.

49 216 *High Degree – Low Impact*

51
52 217 The decentralization of the healthcare system in 2001 in Finland has led to an
53
54 218 increased public participation in health policy decision making, although
55
56 219 there is still much to be done. In 1999, the government set the foundations for

1
2
3 220 the patients' participation in all levels and sectors pertaining to health policy.
4
5 221 A network of agencies at local and national level was developed. Agencies were
6
7 222 affiliated to the Ministry of Health with the task to facilitate, increase and
8
9 223 sustain public involvement in each step of health policy decision making
10
11 224 processes by carrying out local health needs assessments, priority setting
12
13 225 surveys and informal evaluations¹⁹.

14
15
16 226 *Low Degree - High Impact*

17
18 227 Cyprus was found to be in the cluster of countries characterized by low degree
19
20 228 of participation and high impact. In 2016, the Pancyprian Federation of
21
22 229 Patient Associations and Friends conducted a national study in order to assess
23
24 230 patients' organizations participation in health policy decision making and
25
26 231 identify unmet needs. The study results were disseminated to the community,
27
28 232 local press and other key-stakeholders. A few months later, the systematic
29
30 233 advocating and lobbying activities ended successfully. New legislation
31
32 234 providing for patients' participation in health policy decision making at
33
34 235 national level was established by the Cyprus Parliament based on the
35
36 236 Declaration for Patients Participation in Health Policy Decision Making²⁰.

37
38
39 237 *Low Degree – Low Impact*

40
41 238 Year 1999 was a landmark for patients' participation in shaping health policy
42
43 239 in Italy. Many cancer patients claimed for a new treatment. The public
44
45 240 pressure was so high that the Ministry of Health decided to conduct a clinical
46
47 241 trial to examine its effectiveness. The clinical trial was designed and
48
49 242 implemented with the aid of patients' representatives. Finally, the therapy was
50
51 243 found to have no effect on the course of the disease; however the citizens
52
53 244 gained access to health policy decision making. A year later, the government

1
2
3 245 introduced legislation providing for patients' participation and established
4
5 246 new institutional agencies²¹.

247 **Ethics Approval**

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

254 **Contributions**

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

260 **Funding statement**

261 Research was funded by Novartis Pharma, Basel under the AGORA initiative-
262 i.e. a European Think Tank which aims to optimize patient access to
263 innovative treatments. Nonetheless, the company was not involved in any way
264 in the design, implementation and interpretation of research findings. Final
265 publication is fully owned by the authors.

266 **Conflict of interest statement**

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

269 **Patient consent statement**

270 Not Applicable

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15 277 **Data sharing statement**

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17 278 The datasets used and/or analyzed during the current study are available from
18
19 279 the corresponding author on reasonable request.

20
21 280 **References:**

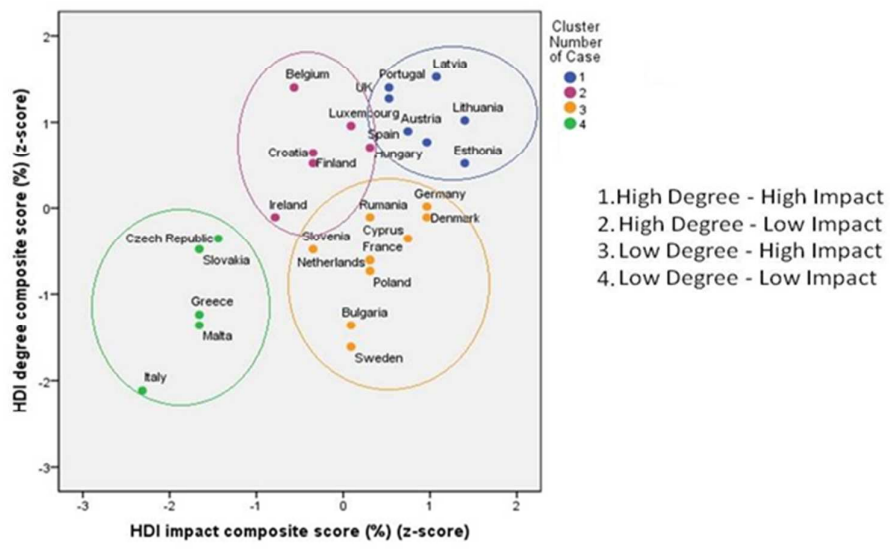
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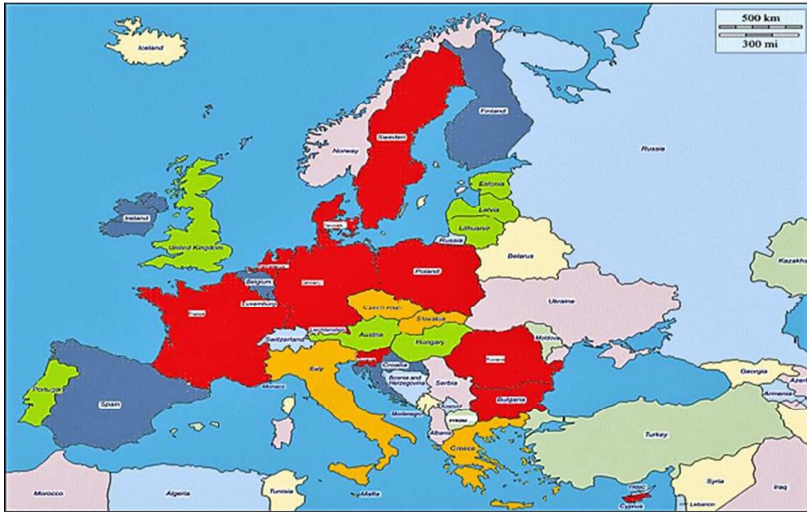
Picture 1. HDI Cluster Analysis of EU-28 Countries



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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

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-018896.R1
Article Type:	Research
Date Submitted by the Author:	01-Feb-2018
Complete List of Authors:	Souliotis, Kyriakos; University of Peloponnese, Faculty of Social Sciences; Peppou, Lilly; University Mental Health Research Institute Tzavara, Chara; Centre for Health Services Research, Department of Hygiene, Epidemiology and Medical Statistics, Medical School, National & Kapodistrian University of Athens Agapidaki, Eirini; Faculty of Social and Political Sciences, University of Peloponnese Varvaras, Dimitrios; Universita degli Studi di Roma Tor Vergata Facolta di Medicina e Chirurgia Buonomo, Oreste; Universita degli Studi di Roma Tor Vergata Facolta di Medicina e Chirurgia Debiais, Dominique; Europa Donna, Forum France Hasurdjiev, Stanimir; Bulgarian National Patients' Organization Sarkozy, Francois; FSNB Health & Care
Primary Subject Heading:	Health policy
Secondary Subject Heading:	Oncology, Patient-centred medicine
Keywords:	Patient participation, health policy decision making, cancer patient organizations

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3 **1 Cancer Patients' Organization participation in health policy**
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5 **2 decision making: a snapshot/cluster analysis of the EU-28**
6
7 **3 countries.**
8

9 4 Kyriakos Souliotis^{1,2*}, Lily-Evangelia Peppou³, Chara Tzavara², Eirini
10
11 5 Agapidaki¹, Dimitrios Varvaras⁴, Oreste Buonomo⁴, Dominique Debiais⁵,
12
13 6 Stanimir Hasurdjiev⁶, Francois Sarkozy⁷.
14

15
16
17
18 8 ¹ Faculty of Social and Political Sciences, University of Peloponnese, Corinth,
19
20 9 Greece;

21
22 10 ² Centre for Health Services Research, Department of Hygiene, Epidemiology
23
24 11 and Medical Statistics, Medical School, University of Athens, Athens, Greece

25
26 12 ³ University Mental Health Research Institute, Athens, Greece

27
28 13 ⁴ Department of Surgery, University of Rome Tor Vergata, Rome, Italy

29
30 14 ⁵ Europa Donna, Paris, France

31
32 15 ⁶ Bulgarian National Patients' Organization, Sofia, Bulgaria

33
34 16 ⁷ FSNB Health & Care, Paris, France

35
36 17 *** Corresponding author:**

37
38 18 Kyriakos Souliotis

39
40
41 University of Peloponnese, Faculty of Social and Political Sciences,
42
43 Department of Social and Education Policy, Corinth, Greece; Damaskinou &
44
45 Kolokotroni Str., 20100, Corinth, Greece; soulioti@hol.gr; tel : + 302741074991
46
47 fax: +302741074990.
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49

50
51 19 **Keywords:** Patient Participation, Health Policy Decision Making, Cancer
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53 20 Patient Organizations.

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55 21 **Word count:** 2604
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22 **Abstract**

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

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

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

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

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

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

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

50 51 **Strengths and Limitations of the Study**

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

61 **Introduction**

62 Cancer is the most common and severe non-communicable diseases,
63 impinging on both health and healthcare ¹. Cancer patients have to cope not
64 only with the stress and the dramatic changes in their lifestyle and quality of
65 life, but also with the medical interventions, procedures and bureaucracy (e.g.
66 reimbursement processes) involved in the treatment of the illness ². Although
67 public spending on health and long-term care has increased in the majority of
68 European countries (EU), the needs of cancer patients remain largely unmet ³.
69 An illustration of this point is waiting times in cancer care in Sweden, which in
70 2014 were found to be higher than those in Albania ⁴. Increased public
71 spending is a necessary but not sufficient condition to ensure effectiveness
72 and sustainability of the healthcare system ⁵. As a result of this, alternative

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3 73 routes have been sought in an endeavour to advance its effectiveness. This led
4
5 74 to the engagement of patients in the development of treatment protocols and
6
7 75 procedures; while it shifted the health policy agenda from the treatment of the
8
9 76 disease to the management of patient⁶.

10
11 77 In an effort to provide more effective and appropriate services, the healthcare
12
13 78 systems' philosophy has been shifted from a biomedical (which is doctor-
14
15 79 focused) to a more holistic and self-managed approach ⁶. A lot of programs,
16
17 80 tools and models have been implemented to empower cancer patients and
18
19 81 facilitate their participation in the delivery of health care services⁷. The
20
21 82 physician is no longer considered to be the "expert" or simply the provider;
22
23 83 while the patient is only the receiver. Instead, there is clinical shared decision
24
25 84 making. No one knows better the nature of a disease and the needs deriving
26
27 85 from it but the patients themselves⁸.

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29
30 86 This is not limited to the physician-patient relationship, as patients may
31
32 87 collectively participate in decision making in various realms, including
33
34 88 guideline development, government policy and research agenda setting,
35
36 89 among others⁹⁻¹¹. Patient participation at the collective level is primarily
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38 90 justified on the grounds of democratic values. Patients are affected by the
39
40 91 consequences of certain decisions, and therefore, they should have a say in the
41
42 92 process. Concomitantly, their subjective knowledge of a disease and its
43
44 93 treatment may enhance the quality of health care decision making¹²,
45
46 94 upgrading the overall effectiveness and efficiency of the healthcare system.

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52 96 While patients' collective action is increasingly recognized as an important
53
54 97 driver of health policy and service provision, there is paucity of research on
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56 98 their association. The De Montfort study in the UK has substantiated

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3 99 increased contact between patient groups and policymakers the past years,
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5 100 while professional bodies and pharmaceutical companies were shown to have
6
7 101 increasingly involved patient groups in discussions on policy proposals¹³.
8
9 102 Nonetheless, according to the researchers, their findings do not shed light on
10
11 103 the powers exerted by patient groups, as their heightened participation is not
12
13 104 necessarily translated into high political effectiveness. In a similar vein, while
14
15 105 the Dutch model in Netherlands allows to some extent patient organizations
16
17 106 to be an equal party in health policy processes, this is not met in practice¹⁴.
18
19 107 Moreover, evidence from Mixed Advisory Committees in Italy highlight the
20
21 108 limited influence of users' voice on decision making by health authorities¹⁵. In
22
23 109 2006, a workshop with 22 academic researchers and two representatives of
24
25 110 patient organizations documented high involvement of patient groups with
26
27 111 policymakers and political institutions. Nonetheless, a noteworthy diversity
28
29 112 among European countries was stressed ¹⁶.
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35 114 The initiatives undertaken by most EU countries to establish and increase
36
37 115 patient participation in health policy decision making are summarized on
38
39 116 legislation level¹⁷. Nonetheless, based on information provided by the
40
41 117 European Health Consumer Index¹⁸, countries display marked diversity in
42
43 118 terms of the degree to which their healthcare law is based on patients' rights.
44
45 119 Additionally, variability is also documented in the degree to which patient
46
47 120 organizations are involved in decision-making¹⁸. This in turn may create
48
49 121 health inequalities between countries. As a corollary of this, there is
50
51 122 imperative need to investigate the degree and impact of patient organization
52
53 123 participation in health policy decision making in the European Union. This
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55 124 need becomes even more pronounced in the case of cancer, as the disease has

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3 125 a multivariate impact and can be a chronic or a fatal disease depending on the
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5 126 quality of treatment¹⁹. In response to this research call, the present study
6
7 127 aimed to provide a snapshot of Cancer Patients' Organization (CPOs)
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9 128 participation in health policy decision making in EU-28 countries.
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11 12 13 130 **Methods**

14 15 131 **Instrument**

16
17 132 For the purpose of the study a self-reported questionnaire was developed,
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19 133 entailing the following sections:

20 21 134 *Respondents' characteristics*

22
23 135 Data were collected on participants' socio-demographic characteristics
24
25 136 (gender, age, educational attainment, self-reported economic status) and their
26
27 137 involvement in the CPO. In particular, participants had to rate their degree of
28
29 138 familiarity with cancer and their knowledge about its treatment/ their
30
31 139 country's healthcare system/ their country's reimbursement process (rating
32
33 140 options: very low-low-moderate-high-very high). Moreover, they had to rate
34
35 141 their degree of involvement in the organization (rating options: absent-very
36
37 142 low-low-moderate-high-very high). Data were also gleaned with regard to
38
39 143 their position in the organization (president/or other board member –
40
41 144 employed by the organization-voting member-nonvoting but active member-
42
43 145 non-active member) and the duration of their membership.
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47 146 *Organizational characteristics*

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49 147 Information was also collected concerning the cancer patient organization.
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51 148 Specifically, participants had to indicate whether the organization provided
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53 149 information material to its members (yes-no) and training (yes-no).
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3 150 Furthermore, they were asked whether their organization was a member of a
4
5 151 national cancer federation (yes-no).
6
7 152 *Health Democracy Index*
8
9 153 Moreover, the questionnaire encompassed the Patient Participation and
10
11 154 Health Democracy Index (HDI), an original scale measuring the degree of
12
13 155 patient organization participation and its impact on shaping health policy. The
14
15 156 Health Democracy Index consists of 17 questions: 8 items investigate CPOs
16
17 157 level and of participation (***Degree of Participation***) in processes such as:
18
19 158 reforms, panels at the Ministry of Health, hospital boards, Ethics Committees
20
21 159 in clinical trials, Health Technology Assessment procedures (2 items: one for
22
23 160 the scientific evaluation of new treatments and methods and one for the
24
25 161 economic evaluation) and the national parliament. Each question may have
26
27 162 one of the following answers: (i) it is not a legal requirement and it never
28
29 163 happens, (ii)) it is not a legal requirement and it rarely happens, (iii) it is not
30
31 164 a legal requirement but it often happens, (iv) it is a legal requirement and it
32
33 165 never happens, (v) it is a legal requirement and it often happens, (vi) it is a
34
35 166 legal requirement and it happens very often, and (vii) it is a legal requirement
36
37 167 and it always happens. Concomitantly, the HDI entails 9 items tapping the
38
39 168 impact of PO participation on the aforementioned 8 realms (reforms, ministry
40
41 169 of health, other health-related organizations, hospital boards, ethics
42
43 170 committee, HTA and national parliament), which are rated on a 6-point scale
44
45 171 ranging from absent to very high. In addition, ***the Impact of Participation***
46
47 172 sub-scale entails a 9th item enquiring about the frequency by which a
48
49 173 substantial change is observed in the content of a health policy decision as a
50
51 174 result of the involvement of the PO. The particular item is rated on a 6-point
52
53 175 scale ranging from never to very often.
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3 176 Higher composite scores on the sub-scales denote higher degree and impact of
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5 177 participation. Both sub-scales displayed good internal consistency (Cronbach
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7 178 $\alpha = 0,879$ and Cronbach $\alpha = 0,874$ respectively). Converging evidence has
8
9 179 substantiated the psychometric properties of the Health Democracy Index²⁰ .
10
11 180 Specifically, the development of the index has followed the subsequent steps:
12
13 181 (i) definition of the construct (i.e. patient organization participation in health
14
15 182 policy decision making), (ii) review of the construct definition, (iii) item
16
17 183 drafting, (iv) item review) and (v) pilot testing of its psychometric properties
18
19 184 (internal consistency , test-retest reliability, construct validity ad convergent
20
21 185 validity). As the index was originally developed in Greece²¹, an international
22
23 186 working group consisting of European stakeholders (policy-makers, members
24
25 187 of patient organizations and researchers with background on patient
26
27 188 empowerment held various meetings to discuss the adaptation of the index to
28
29 189 European standards.²⁰

32 190 Participants and Procedures:

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34 191 Potential participants were identified through various channels (e.g. internet
35
36 192 search, on line databases of European cancer patients' associations, registries
37
38 193 of the ministry of health etc). As CPO was considered any non-profit
39
40 194 organization with a legal entity. In addition, the CPO should have been
41
42 195 cancer-specific, be primarily composed of patients and their caregivers and
43
44 196 representing and/or supporting their needs. To be recruited for the study, a
45
46 197 CPO should have had an active representation of cancer patients at a national
47
48 198 level and a valid and accessible website. CPOs from EU-28 member states
49
50 199 were included in the study. In order to be eligible for participation, an
51
52 200 individual should have been a member of a CPO and older than 18. The final
53
54 201 sample consisted of 1.266 members of CPOs from EU-28 countries and the

202 mean number of respondents per country was 45 (Table 1). Demographics of
 203 the sample are shown in table 2.

204

205 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

206

207 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

208

209

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

217 Statistical analysis

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

220 Ward's method was used to compute distance patterns and determine the
 221 appropriate number of clusters for the K-means clustering procedure. K-
 222 means clustering was performed for the classification of cluster subgroups and
 223 was based on Euclidian distance. We changed all variables to z-scores to yield
 224 equal metrics and equal weighting. For the consistency and validity of the
 225 hypothesized groups of countries in the total sample; the total sample was
 226 divided into a split-half random sample. K-means clustering was used then for

227 the two subsamples to determine the presence of similar cluster subgroups
 228 from the previous analyses. Additionally, analysis of variance ANOVA was
 229 used to compare Degree of Participation and Impact of Participation scores
 230 between the four groups defined by cluster analysis. Statistical analyses were
 231 performed using the SPSS for Windows Version 19.0 statistical package (SSPS
 232 Inc., Chicago, IL).

233 **Results**

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

242 Table 3. Median scores of Degree of Participation and Impact of Participation
 243 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

244 *median of the percent score (i.e. ((score-possible minimum score)/(maximum-
 245 minimum possible score))*100)
 246

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

249 **Table 4. Number of Countries in each HDI cluster**

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

250
 251 The total sample was afterwards divided into a split-half random sample and
 252 K-means clustering was repeated for the two subsamples. Clustering results
 253 indicated that the four-cluster solution similar to the previous analyses was

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3 254 the most homogeneous solution in each subsample. Furthermore, Degree of
4
5 255 Participation and Impact of Participation scores were compared between the
6
7 256 four country groups as defined by cluster analysis. All pair wise comparisons
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9 257 were significant ($p < 0.001$) confirming more evidence of the cluster solution.
10

11 258

12 259 **Discussion**

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14
15 260 In modern health care systems, patients not only participate in decisions
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17 261 concerning their own health and healthcare (i.e. the micro-level), but in
18
19 262 decision making processes on the meso- and macro-level, that is in local
20
21 263 health authorities, organizations, health technology assessment procedures or
22
23 264 at the parliament, to name few²². Their influence in these processes is greatly
24
25 265 enhanced if they are grouped together. For this reason, patient organizations
26
27 266 emerge as an indispensable vehicle for facilitating democracy, promoting
28
29 267 patient interests and influencing health policy decision making²².

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32 268 Nonetheless, existing evidence suggests wide diversity in the European Union
33
34 269 with regard to patient organization participation in health policy decision
35
36 270 making^{16,18}. At the same time, converging evidence indicates that a greater
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38 271 degree of participation on the part of patient organizations does not guarantee
39
40 272 the effectiveness of this participation^{13-15,22}. In other words, patient
41
42 273 organizations may be given opportunities to have a say in health policy-
43
44 274 decision making, but are they being heard?

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46
47 275 The findings from the present study reveal four groups of countries:

48
49 276 a) High Degree – High Impact: “Health Democratic environment”. The
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51 277 environment fosters patient organization participation and patient groups
52
53 278 contribute substantially to health policy decision-making
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3 279 b) High Degree – Low Impact: ostensible participation. The system provides
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5 280 ample opportunity for patient organization participation; however, this does
6
7 281 not exert a significant impact.

8
9 282 c) Low Degree – High Impact: limited but impactful participation. The health
10
11 283 policy shaping system does not give enough room for participation; however,
12
13 284 it takes patient organizations into consideration. It seems that quality
14
15 285 outweighs quantity. One may suggest that either the health policy decision
16
17 286 making system takes highly into consideration the claims of CPOs or that they
18
19 287 are very effective in advocating their interests.

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21
22 288 d) Low Degree – Low impact: Window of opportunity. The decision making
23
24 289 system does not facilitate participation and CPOs are not effective in
25
26 290 advocating their claims.

27
28 291 Interpretations

29
30 292 The findings of the present study corroborate the wide diversity among
31
32 293 European countries with respect to the degree and impact of cancer patient
33
34 294 organization participation in health policy decision making. These findings are
35
36 295 to a large extent consonant with findings from the European Health Consumer
37
38 296 Index¹⁸. Interestingly, both Bulgaria and Sweden rank very low in the Degree
39
40 297 subscale (median=12.5 and median= 8.33 respectively); however, they rank
41
42 298 high in the Impact subscale (median = 35.65 and median = 35.40
43
44 299 respectively). At first glance, this appears in sharp contrast to the findings
45
46 300 from the European Health Consumer Index, where Bulgaria was found to
47
48 301 score good in the indicator “patient organizations involved in decision
49
50 302 making” and Sweden intermediary. Nonetheless, the low scores documented
51
52 303 in the Degree subscale of the present study are probably explained by both
53
54 304 countries’ low performance in the indicator “healthcare law based on patients
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3 305 rights". As a result of this, these countries score very low in the Degree
4
5 306 subscale (enquiring about the opportunities of CPOs to participate in health
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7 307 decision-making); however, they do well in the Impact subscale (enquiring
8
9 308 about the impact of this participation). In other words, while the healthcare
10
11 309 system may not provide CPOs with ample opportunity to participate, CPOs
12
13 310 appear to manage well into capitalizing on the scarce opportunities given. This
14
15 311 is perhaps the explanation why in this group of countries in spite of low degree
16
17 312 of participation, there is high impact of participation. It is highly likely that
18
19 313 CPOs in these countries have better advocacy and lobbying skills.
20
21 314 Alternatively, it may be the case that CPOs form stronger coalitions in these
22
23 315 countries. A study by Wood on patient groups in UK and USA has indicated
24
25 316 that in both countries there is a proliferation of patient organizations;
26
27 317 however their political effectiveness is disproportionately low due to their
28
29 318 autonomous activity and their reluctance to collaborate²³. A similar concern
30
31 319 was raised by the Vienna workshop, where heightened competition and
32
33 320 tensions among patient organizations was suggested to hinder their political
34
35 321 effectiveness ¹⁶. Therefore, CPOs in countries with high impact may be more
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37 322 politicized and more united.
38
39 323 This may also explain why in certain countries there is high degree of
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41 324 participation but low impact. Members of CPOs in these countries may not be
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43 325 trained enough in lobbying and advocacy skills and do not engage into joint
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45 326 campaigning. Alternatively, the system may ostensibly involve patient
46
47 327 organizations in health policy decision making. This is congruent with the
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49 328 concern raised in UK¹³ that the involvement of patient associations in health
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51 329 policy decision making may solely serve the purpose of adding legitimacy to
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3 330 governments, while the latter advance their own interests. Therefore, one
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5 331 should investigate further what happens in these countries.

6
7 332 It merits noting that the Health Democracy Index entails items tapping
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9 333 patient organization participation in health policy decision making on various
10
11 334 realms: hospital boards, health technology assessment, ethics committees in
12
13 335 clinical trials, national parliament, ministry of health, to name few. It is highly
14
15 336 likely that an item-per-item analysis may reveal a different pattern of results
16
17 337 with regard to country ranking. Our research team is currently working on this
18
19 338 direction .

20
21
22 339 Good Examples

23
24 340 *A good example of a country with High Degree of Participation*

25
26 341 The decentralization of the healthcare system in 2001 in Finland has led to an
27
28 342 increased public participation in health policy decision making. In 1999, the
29
30 343 government set the foundations for the patients' participation in all levels and
31
32 344 sectors pertaining to health policy. A network of agencies at local and national
33
34 345 level was developed. Agencies were affiliated to the Ministry of Health with
35
36 346 the task to facilitate, increase and sustain public involvement in each step of
37
38 347 health policy decision making processes by carrying out local health needs
39
40 348 assessments, priority setting surveys and informal evaluations²⁴.

41
42
43 349 *A good example of a country with High Impact of Participation*

44
45 350 Cyprus was found to be in the cluster of countries characterized by low degree
46
47 351 of participation and high impact. In 2016, the Pancyprian Federation of
48
49 352 Patient Associations and Friends conducted a national study in order to assess
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51 353 patients' organizations participation in health policy decision making and
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53 354 identify unmet needs. The study results were disseminated to the community,
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3 355 local press and other key-stakeholders. A few months later, the systematic
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5 356 advocating and lobbying activities ended successfully. New legislation
6
7 357 providing for patients' participation in health policy decision making at
8
9 358 national level was established by the Cyprus Parliament based on the
10
11 359 Declaration for Patients Participation in Health Policy Decision Making²⁵.

12 360 Limitations

13
14
15 361 The study was not without its limitations. As there is no sampling frame for
16
17 362 CPOs in Europe, the representativeness of the sample is contested. In spite of
18
19 363 systematic efforts to recruit participants through various pathways one may
20
21 364 not exclude the possibility that the most active and motivated CPO members
22
23 365 agreed to participate. In this reasoning, sampling bias may have emerged if
24
25 366 responders differed systematically from non-responders in terms of their
26
27 367 views about their CPOs participation in health policy decision making. Finally,
28
29 368 as the present study addressed cancer patient organizations, findings cannot
30
31 369 extrapolated to other disease groups.

32 370 Conclusion

33
34
35 371 There is substantial diversity in EU-28 with regard to CPO participation in
36
37 372 health policy decision making. Study findings indicate that a high degree of
38
39 373 participation is not synonymous to high impact. As a result of this, there is
40
41 374 still a ways to go in order to ensure that both the healthcare system will create
42
43 375 ample opportunity for CPOs to participate in health decision making and that
44
45 376 CPOs will be capable of capitalizing on them.

46 377 **Ethics Approval**

47
48
49 378 The study was approved by the Research and Ethics Committee of the
50
51 379 University of Peloponnese, Corinth, Greece in accordance with the ethical
52
53 380 standards delineated in the 1964 Declaration of Helsinki. Furthermore, the

1
2
3 381 Institutional Review Board of the participating patients associations reviewed
4
5 382 and approved the study. Informed consent for participation was obtained
6
7 383 from all participants.
8

9 384 **Contributions**

10
11 385 The study was designed by KS, EA, LP, CT, DV, OB, DD, SH and FS. EA, LP,
12
13 386 CT, DV, OB and DD were responsible for the data collection. CT, KS and FS
14
15 387 performed the statistical analysis. KS, EA, LP, CT, DV, OB, DD, SH and FS
16
17 388 contributed to the interpretation of the results and draft the manuscript. All
18
19 389 authors have read and approved the final manuscript.
20

21
22 390 **Funding statement**

23
24 391 Research was funded by Novartis Pharma, Basel under the AGORA initiative-
25
26 392 i.e. a European Think Tank which aims to optimize patient access to
27
28 393 innovative treatments. Nonetheless, the company was not involved in any way
29
30 394 in the design, implementation and interpretation of research findings. Final
31
32 395 publication is fully owned by the authors.
33

34
35 396 **Conflict of interest statement**

36
37 397 We have read and understood BMJ Open policy on declaration of interests
38
39 398 and declare that we have no competing interests.
40

41 399 **Patient consent statement**

42
43 400 Not Applicable
44

45 401 **Licence**

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3 407 **Data sharing statement**

4
5 408 The datasets used and/or analyzed during the current study are available from
6
7 409 the corresponding author on reasonable request.

8
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Figure 1. Cluster analysis results
Figure 2. Patient organization participation in EU-28 by country cluster

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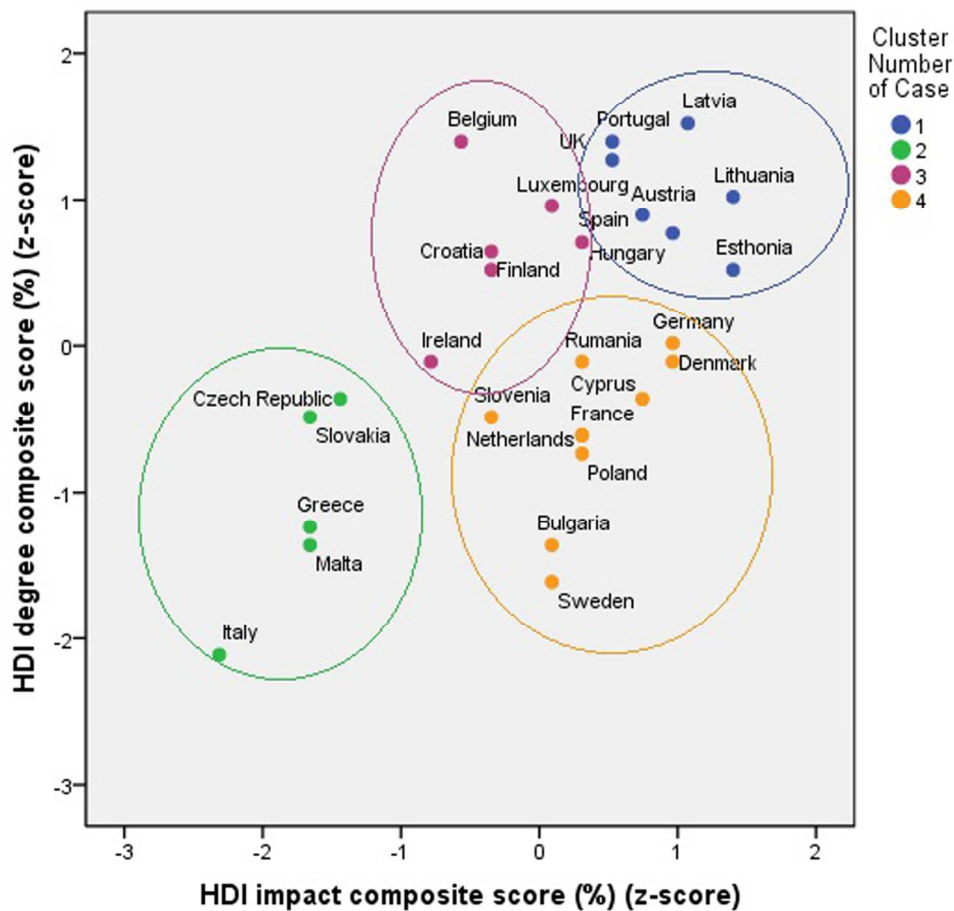
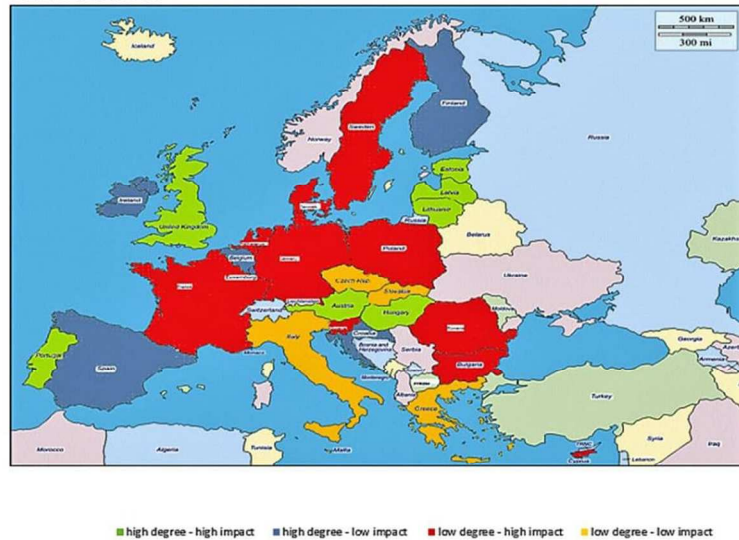


Figure 1. Cluster analysis results

133x124mm (300 x 300 DPI)

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



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

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30 279x181mm (300 x 300 DPI)

BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-018896.R2
Article Type:	Research
Date Submitted by the Author:	04-Apr-2018
Complete List of Authors:	Souliotis, Kyriakos; University of Peloponnese, Faculty of Social Sciences; Peppou, Lilly; University Mental Health Research Institute Tzavara, Chara; Centre for Health Services Research, Department of Hygiene, Epidemiology and Medical Statistics, Medical School, National & Kapodistrian University of Athens Agapidaki, Eirini; Faculty of Social and Political Sciences, University of Peloponnese Varvaras, Dimitrios; Università degli Studi di Roma Tor Vergata Facoltà di Medicina e Chirurgia Buonomo, Oreste; Università degli Studi di Roma Tor Vergata Facoltà di Medicina e Chirurgia Debiais, Dominique; Europa Donna, Forum France Hasurdjiev, Stanimir; Bulgarian National Patients' Organization Sarkozy, Francois; FSNB Health & Care
Primary Subject Heading:	Health policy
Secondary Subject Heading:	Oncology, Patient-centred medicine
Keywords:	Patient participation, health policy decision making, cancer patient organizations

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3 **1 Cancer Patients' Organization participation in health policy**
4
5 **2 decision making: a snapshot/cluster analysis of the EU-28**
6
7 **3 countries.**
8

9 4 Kyriakos Souliotis^{1,2*}, Lily-Evangelia Peppou³, Chara Tzavara², Eirini
10
11 5 Agapidaki¹, Dimitrios Varvaras⁴, Oreste Buonomo⁴, Dominique Debiais⁵,
12
13 6 Stanimir Hasurdjiev⁶, Francois Sarkozy⁷.
14

15
16
17
18 8 ¹ Faculty of Social and Political Sciences, University of Peloponnese, Corinth,
19
20 9 Greece;

21
22 10 ² Centre for Health Services Research, Department of Hygiene, Epidemiology
23
24 11 and Medical Statistics, Medical School, University of Athens, Athens, Greece

25
26 12 ³ University Mental Health Research Institute, Athens, Greece

27
28 13 ⁴ Department of Surgery, University of Rome Tor Vergata, Rome, Italy

29
30 14 ⁵ Europa Donna, Paris, France

31
32 15 ⁶ Bulgarian National Patients' Organization, Sofia, Bulgaria

33
34 16 ⁷ FSNB Health & Care, Paris, France

35
36 17 *** Corresponding author:**

37
38 18 Kyriakos Souliotis

39
40
41 University of Peloponnese, Faculty of Social and Political Sciences,
42
43 Department of Social and Education Policy, Corinth, Greece; Damaskinou &
44
45 Kolokotroni Str., 20100, Corinth, Greece; soulioti@hol.gr; tel : + 302741074991
46
47 fax: +302741074990.
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49

50
51 19 **Keywords:** Patient Participation, Health Policy Decision Making, Cancer
52
53 20 Patient Organizations.

54
55 21 **Word count:** 2604
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22 **Abstract**

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

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

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

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

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

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

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

50 51 **Strengths and Limitations of the Study**

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

61 **Introduction**

62 Cancer is the most common and severe non-communicable diseases,
63 impinging substantially on both health and healthcare ¹. Cancer patients have
64 to cope with the stress and the dramatic changes in their lifestyle and quality
65 of life as well as the procedures and bureaucracy (e.g. reimbursement
66 processes) often involved in the treatment of the illness ². Although public
67 spending on health and long-term care has increased in the majority of
68 European countries (EU), cancer patients' needs remain largely unmet ³. An
69 illustration of this point is waiting times in cancer care in Ireland, which in
70 2015 were found to be higher than their counterparts in Albania ⁴. Increased
71 public spending is a necessary but not sufficient condition to ensure
72 effectiveness and sustainability of the healthcare system ⁵.

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3 73 In an effort to provide more effective and appropriate services, the healthcare
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5 74 system philosophy has shifted from a biomedical approach (which is doctor-
6
7 75 focused) to a more holistic and self-managed one ⁶. Many programs, tools and
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9 76 models have been implemented in order to empower cancer patients and
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11 77 facilitate their participation in the delivery of health care services⁷. In this
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13 78 frame, the physician is no longer considered to be the “expert” or just the
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15 79 provider and the patient only the receiver. Rather, there is clinical shared
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17 80 decision making. No one knows better the nature of a disease and the needs
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19 81 deriving from it but the patients themselves⁸.

22 82 This is not limited to the individual physician-patient relationship, as patients
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24 83 may collectively participate in decision making in various realms, including
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26 84 guideline development, government policy and research agenda setting,
27
28 85 among others⁹⁻¹¹. Patient participation at the collective level is primarily
29
30 86 justified on the grounds of democratic values. Patients are affected by the
31
32 87 consequences of certain decisions, and therefore, they should have a say in the
33
34 88 process. Concomitantly, their subjective knowledge of a disease and its
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36 89 treatment may enhance the quality of health care decision making¹²,
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38 90 upgrading the overall effectiveness and efficiency of the healthcare system.

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43 92 While patients’ collective action is increasingly recognized as an important
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45 93 driver of health policy and service provision, there is paucity of research on
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47 94 their association. The De Montfort study in the UK substantiated increased
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49 95 contact between patient groups and policymakers during the past years, while
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51 96 professional bodies and pharmaceutical companies were found to involve
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53 97 patient groups in discussions on policy proposals to a larger extent than in the
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55 98 past¹³. Nonetheless, according to the researchers, the available evidence does

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3 99 not shed enough light on the influence exerted by patient groups, as their
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5 100 heightened participation is not necessarily translated into high political
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7 101 effectiveness. In a similar vein, while the Dutch model in Netherlands allows
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9 102 patient organizations to be an equal party in health policy processes to some
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11 103 extent, this is not met in practice¹⁴. Moreover, evidence from Mixed Advisory
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13 104 Committees in Italy highlight the limited influence of users' voice on decision
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15 105 making by health authorities¹⁵. In 2006, a workshop with 22 academic
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17 106 researchers and two representatives of patient organizations documented high
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19 107 involvement of patient groups with policymakers and political institutions;
20
21 108 however, marked diversity among European countries was stressed ¹⁶.
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26 110 The initiatives undertaken by most EU countries to establish and increase
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28 111 patient participation in health policy decision making are reflected on
29
30 112 legislation level¹⁷. Nonetheless, based on information provided by the
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32 113 European Health Consumer Index¹⁸, countries display important differences
33
34 114 in terms of the degree to which their healthcare law is based on patient rights.
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36 115 Additionally, noteworthy variation is also observed in the degree to which
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38 116 patient organizations are involved in decision-making¹⁸. This in turn may
39
40 117 create health inequalities between countries. As a corollary of this, there is an
41
42 118 imperative need to investigate the degree and impact of patient organization
43
44 119 participation in health policy decision making in the European Union. This
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46 120 need becomes even more pronounced in the case of cancer, as the disease has
47
48 121 a multifaceted impact and can be a chronic or a fatal disease depending on the
49
50 122 quality of treatment¹⁹. In response to this research call, the present study
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52 123 aimed to provide a snapshot of cancer patients' organization (CPOs)
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54 124 participation in health policy decision making in EU-28 countries.
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5 126 **Methods**

6
7 127 Instrument

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9 128 For the purpose of the study a self-reported questionnaire was developed,
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11 129 entailing the following sections:

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13 130 *Respondents' characteristics*

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15 131 Data were collected on participants' socio-demographic characteristics
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17 132 (gender, age, educational attainment, self-reported economic status) and their
18
19 133 involvement in the CPO. In particular, participants had to rate their degree of
20
21 134 familiarity with cancer and their knowledge about its treatment/ their
22
23 135 country's healthcare system/ their country's reimbursement process (rating
24
25 136 options: very low-low-moderate-high-very high). Moreover, they had to rate
26
27 137 their degree of involvement in the organization (rating options: absent-very
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29 138 low-low-moderate-high-very high). Data were also gleaned with regard to
30
31 139 their position in the organization (president/or other board member –
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33 140 employed by the organization-voting member-nonvoting but active member-
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35 141 non-active member) and the duration of their membership.

36
37 142 *Organizational characteristics*

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39 143 Information was also collected concerning the cancer patient organization.

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41 144 Specifically, participants had to indicate whether the organization provided
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43 145 information material to its members (yes-no) and training (yes-no).

44
45 146 Furthermore, they were asked whether their organization was a member of a
46
47 147 national cancer federation (yes-no).

48
49 148 *Health Democracy Index*

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51 149 Moreover, the questionnaire encompassed the Patient Participation and
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53 150 Health Democracy Index (HDI), an original scale measuring the degree of

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3 151 patient organization participation and its impact on shaping health policy. The
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5 152 Health Democracy Index consists of 17 questions: 8 items investigate CPOs
6
7 153 level and of participation (***Degree of Participation***) in processes such as:
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9 154 reforms, panels at the Ministry of Health, hospital boards, Ethics Committees
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11 155 in clinical trials, Health Technology Assessment procedures (2 items: one for
12
13 156 the scientific evaluation of new treatments and methods and one for the
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15 157 economic evaluation) and the national parliament. Each question may have
16
17 158 one of the following answers: (i) it is not a legal requirement and it never
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19 159 happens, (ii)) it is not a legal requirement and it rarely happens, (iii) it is not
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21 160 a legal requirement but it often happens, (iv) it is a legal requirement and it
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23 161 never happens, (v) it is a legal requirement and it often happens, (vi) it is a
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25 162 legal requirement and it happens very often, and (vii) it is a legal requirement
26
27 163 and it always happens. Concomitantly, the HDI entails 9 items tapping the
28
29 164 impact of PO participation on the aforementioned 8 realms (reforms, ministry
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31 165 of health, other health-related organizations, hospital boards, ethics
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33 166 committee, HTA and national parliament), which are rated on a 6-point scale
34
35 167 ranging from absent to very high. In addition, ***the Impact of Participation***
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37 168 sub-scale entails a 9th item enquiring about the frequency by which a
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39 169 substantial change is observed in the content of a health policy decision as a
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41 170 result of the involvement of the PO. The particular item is rated on a 6-point
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43 171 scale ranging from never to very often.
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47 172 Higher composite scores on the sub-scales denote higher degree and impact of
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49 173 participation. Both sub-scales displayed good internal consistency (Cronbach
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51 174 a = 0,879 and Cronbach a = 0,874 respectively). Converging evidence has
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54 175 substantiated the psychometric properties of the Health Democracy Index²⁰ .
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3 176 Specifically, the development of the index has followed the subsequent steps:
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5 177 (i) definition of the construct (i.e. patient organization participation in health
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7 178 policy decision making), (ii) review of the construct definition, (iii) item
8
9 179 drafting, (iv) item review) and (v) pilot testing of its psychometric properties
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11 180 (internal consistency, test-retest reliability, construct validity and convergent
12
13 181 validity). As the index was originally developed in Greece²¹, an international
14
15 182 working group consisting of European stakeholders (policy-makers, members
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17 183 of patient organizations and researchers with background on patient
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19 184 empowerment held various meetings to discuss the adaptation of the index to
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21 185 European standards.²⁰

22 186 Participants and Procedures:

23
24 187 Potential participants were identified through various channels (e.g. internet
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26 188 search, on line databases of European cancer patients' associations, registries
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28 189 of the ministry of health etc). As CPO was regarded any non-profit
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30 190 organization with a legal entity. In addition, the CPO should have been
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32 191 cancer-specific, be primarily composed of patients and their caregivers and
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34 192 representing and/or supporting their needs. To be recruited for the study, a
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36 193 CPO should have had an active representation of cancer patients at a national
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38 194 level and a valid and accessible website. CPOs from EU-28 member states
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40 195 were included in the study. In order to be eligible for participation, an
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42 196 individual should have been a member of a CPO and older than 18.
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50 198 An email was sent to CPO board members informing them about the study
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52 199 and inviting them to participate. Following their acceptance, the Institutional
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54 200 Review Board of each organization approved the study protocol and
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56 201 forwarded the invitation for participation to all of its members. All
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3 202 respondents filled a written informed consent form. Data were collected
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5 203 online (via web-link and email). The questionnaire was translated to each
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7 204 country's official language.

9 205 Patient and Public Involvement

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11 206 Patients play an integral role in this project and thus they have participated in
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13 207 various stages of the research process. The development of the HDI, which has
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15 208 been utilized to assess CPO participation in health policy decision making, has
16
17 209 involved both patients-members of patient organizations and patient
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19 210 representatives during the phases of (i) reviewing the construct definition, (ii)
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21 211 item drafting, (iii) item review and (iv) adaptation of the index to pan-
22
23 212 European standards (20,21). Moreover, patient representatives have
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25 213 participated in the formulation of research objectives, the design of the study
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27 214 and the interpretation of its findings; while members of patient organizations
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29 215 have constituted the study sample of this research work. It deserves
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31 216 mentioning that results will be disseminated to all identified CPOs,
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33 217 irrespectively of whether they participated or not.

36 218 Statistical analysis

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39 219 Descriptive statistics such as means, medians, standard deviations, absolute
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41 220 and relative frequencies were computed, where appropriate.
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43 221 Ward's method was used to compute distance patterns and determine the
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45 222 appropriate number of clusters for the K-means clustering procedure. K-
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47 223 means clustering was performed for the classification of cluster subgroups and
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49 224 was based on Euclidian distance. We changed all variables to z-scores to yield
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51 225 equal metrics and equal weighting. For the consistency and validity of the
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53 226 hypothesized groups of countries in the total sample; the total sample was
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55 227 divided into a split-half random sample. K-means clustering was used then for

228 the two subsamples to determine the presence of similar cluster subgroups
 229 from the previous analyses. Additionally, analysis of variance ANOVA was
 230 used to compare Degree of Participation and Impact of Participation scores
 231 between the four groups defined by cluster analysis. Statistical analyses were
 232 performed using the SPSS for Windows Version 19.0 statistical package (SSPS
 233 Inc., Chicago, IL).

234 **Results**

235 Sample Characteristics

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

238 Demographics of the sample are shown in table 2.

239

240 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

241

242 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

243

244 *Degree and Impact of CPO Participation*

245 Composite scores of the HDI sub-scales (**Degree of Participation** and
246 **Impact of Participation**) were used for clustering analysis (Figure 1).

247 The findings revealed four groups of countries according to their score: a) high
248 degree - high impact, b) high degree – low impact, c) low degree - high impact,
249 d) low degree –low impact. Table 3 presents median scores of Degree of
250 Participation and Impact of Participation per country. The median score for
251 all countries was 33.3 for Degree of Participation and 34.69 for Impact of
252 Participation .

253 Table 3. Median scores of Degree of Participation and Impact of Participation
254 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

255 *median of the percent score (i.e. ((score-possible minimum score)/(maximum-
256 minimum possible score))*100)
257

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

260 **Table 4. Number of Countries in each HDI cluster**

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

261
262 The total sample was afterwards divided into a split-half random sample and
263 K-means clustering was repeated for the two subsamples. Clustering results
264 indicated that the four-cluster solution recorded in the previous analyses was
265 the most homogeneous solution in each subsample. Furthermore, the Degree
266 of Participation and Impact of Participation scores were compared between
267 the four country groups as defined by cluster analysis. All pair wise
268 comparisons were significant ($p < 0.001$) providing additional evidence for the
269 cluster solution.

270

271 Discussion

272 In contemporary health care systems, patients not only participate in
273 decisions concerning their own health and healthcare (i.e. the micro-level),
274 but in decision making processes on the meso- and macro-level (i.e. in local
275 health authorities, organizations, health technology assessment procedures or
276 at the parliament, to name few)²². Their influence in these processes is greatly
277 enhanced if they are grouped together. For this reason, patient organizations
278 emerge as an indispensable vehicle for facilitating democracy, promoting
279 patient interests and influencing health policy decision making²².

1
2
3 280 Nonetheless, existing evidence suggests wide diversity in the European Union
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5 281 with regard to patient organization participation in health policy decision
6
7 282 making^{16,18}. At the same time, converging evidence indicates that a greater
8
9 283 degree of participation on the part of patient organizations does not guarantee
10
11 284 the effectiveness of this participation ^{13-15,22}. In other words, patient
12
13 285 organizations may be given opportunities to have a say in health policy-
14
15 286 decision making, but are they being heard?

17 287 The findings from the present study revealed four groups of countries:

20 288 a) High Degree – High Impact: “Health Democratic environment”. The
21
22 289 environment fosters patient organization participation and patient groups
23
24 290 contribute substantially to health policy decision-making

26 291 b) High Degree – Low Impact: ostensible participation. The system provides
27
28 292 ample opportunity for patient organization participation; however, this does
29
30 293 not exert a significant impact.

32 294 c) Low Degree – High Impact: limited but impactful participation. The health
33
34 295 policy shaping system does not give enough room for participation; however,
35
36 296 it takes patient organizations into consideration. It seems that quality
37
38 297 outweighs quantity. One may suggest that either the health policy decision
39
40 298 making system takes highly into consideration the claims of CPOs or that they
41
42 299 are very effective in advocating their interests.

45 300 d) Low Degree – Low impact: Window of opportunity. The decision making
46
47 301 system does not facilitate participation and CPOs are not effective in
48
49 302 advocating their claims.

51 303 Interpretations

54 304 The findings of the present study corroborate the wide diversity among
55
56 305 European countries with respect to the degree and impact of cancer patient

1
2
3 306 organization participation in health policy decision making. These findings are
4
5 307 to a large extent consonant with findings from the European Health Consumer
6
7 308 Index¹⁸. Interestingly, both Bulgaria and Sweden rank very low in the Degree
8
9 309 subscale (median=12.5 and median= 8.33 respectively); however, they rank
10
11 310 high in the Impact subscale (median = 35.65 and median = 35.40
12
13 311 respectively). At first glance, this appears in sharp contrast to the findings
14
15 312 from the European Health Consumer Index, where Bulgaria was found to
16
17 313 score good in the indicator “patient organizations involved in decision
18
19 314 making” and Sweden intermediary. Nonetheless, the low scores documented
20
21 315 in the Degree subscale of the present study are probably explained by both
22
23 316 countries’ low performance in the indicator “healthcare law based on patients
24
25 317 rights”. As a result of this, these countries score very low in the Degree
26
27 318 subscale (enquiring about the opportunities of CPOs to participate in health
28
29 319 decision-making); however, they do well in the Impact subscale (enquiring
30
31 320 about the impact of this participation). In other words, while the healthcare
32
33 321 system may not provide CPOs with ample opportunity to participate, CPOs
34
35 322 appear to manage well into capitalizing on the scarce opportunities given. This
36
37 323 is perhaps the explanation why in this group of countries in spite of low degree
38
39 324 of participation, there is high impact of participation. It is highly likely that
40
41 325 CPOs in these countries have better advocacy and lobbying skills.
42
43 326 Alternatively, it may be the case that CPOs form stronger coalitions in these
44
45 327 countries. A study by Wood on patient groups in UK and USA has indicated
46
47 328 that in both countries there is a proliferation of patient organizations;
48
49 329 however their political effectiveness is disproportionately low due to their
50
51 330 autonomous activity and their reluctance to collaborate²³. A similar concern
52
53 331 was raised by the Vienna workshop, where heightened competition and
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3 332 tensions among patient organizations was suggested to hinder their political
4
5 333 effectiveness¹⁶. Therefore, CPOs in countries with high impact may be more
6
7 334 politicized and more united.

8
9 335 This may also explain why in certain countries there is high degree of
10
11 336 participation but low impact. Members of CPOs in these countries may not be
12
13 337 trained enough in lobbying and advocacy skills and do not engage into joint
14
15 338 campaigning. Alternatively, the system may ostensibly involve patient
16
17 339 organizations in health policy decision making. This is congruent with the
18
19 340 concern raised in UK¹³ that the involvement of patient organizations in health
20
21 341 policy decision making may solely serve the purpose of adding legitimacy to
22
23 342 governments, while the latter advance their own interests. Therefore, one
24
25 343 should investigate further what happens in these countries.

26
27 344 It merits noting that the Health Democracy Index entails items tapping
28
29 345 perceived patient organization participation in health policy decision making
30
31 346 on various realms: hospital boards, health technology assessment, ethics
32
33 347 committees in clinical trials, national parliament, ministry of health, to name
34
35 348 few. It is highly likely that an item-per-item analysis may reveal a different
36
37 349 pattern of results with regard to country ranking. Our research team is
38
39 350 currently working along this direction .

40
41 351 Good Examples

42
43 352 *A good example of a country with High Degree of Participation*

44
45 353 The decentralization of the healthcare system in 2001 in Finland has led to an
46
47 354 increased public participation in health policy decision making. In 1999, the
48
49 355 government set the foundations for the patients' participation in all levels and
50
51 356 sectors pertaining to health policy. A network of agencies at local and national
52
53 357 level was developed. Agencies were affiliated with the Ministry of Health, so as

1
2
3 358 to facilitate, increase and sustain public involvement in each step of health
4
5 359 policy decision making processes by conducting local health needs
6
7 360 assessments, priority setting surveys and informal evaluations²⁴.
8

9
10 361 *A good example of a country with High Impact of Participation*

11 362 Cyprus was found to be in the cluster of countries characterized by low degree
12
13 363 of participation and high impact. In 2016, the Pancyprian Federation of
14
15 364 Patient Associations and Friends conducted a national study in order to assess
16
17 365 patients' organizations participation in health policy decision making and
18
19 366 identify unmet needs. The study results were disseminated to the community,
20
21 367 local press and other key-stakeholders. A few months later, the systematic
22
23 368 advocating and lobbying activities ended successfully. New legislation
24
25 369 providing for patients' participation in health policy decision making at
26
27 370 national level was established by the Cyprus Parliament based on the
28
29 371 Declaration for Patients Participation in Health Policy Decision Making²⁵.
30

31
32
33 372 Limitations

34
35 373 The study was not without its limitations. As there is no sampling frame for
36
37 374 CPOs in Europe, the representativeness of the sample is contested. In spite of
38
39 375 systematic efforts to recruit participants through various pathways one may
40
41 376 not exclude the possibility that the most active and motivated CPO members
42
43 377 agreed to participate. In this reasoning, sampling bias may have emerged if
44
45 378 respondents differed systematically from non-respondents in terms of their
46
47 379 views about their CPOs participation in health policy decision making.

48
49 380 Moreover, the HDI taps the patient perspective on the degree of and impact of
50
51 381 patient organization participation and thus findings deriving from its use
52
53 382 should be considered complementary to other perspectives (e.g. policy
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3 383 makers' perspective or more objective indices, such as data emanating from
4
5 384 the parliament minutes). Finally, as the present study addressed cancer
6
7 385 patient organizations, findings cannot extrapolated to other disease groups.
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9 386

10
11 387 It is noteworthy that since the aim of the present report was to provide a
12
13 388 snapshot of CPO participation in health policy decision making in EU-28 from
14
15 389 patients' perspective, we could not have explored potential links between our
16
17 390 data and other system performance indices, such as cancer survival rates and
18
19 391 percentage of total health expenditures spent on cancer care across countries.
20
21 392 Nonetheless, we are currently designing an ecological study that would enable
22
23 393 us to go into greater depth on the topic.
24
25

26 394 Conclusion

27
28 395 There is substantial diversity in EU-28 with regard to perceived CPO
29
30 396 participation in health policy decision making. Study findings indicate that a
31
32 397 high degree of participation is not synonymous to high impact. As a result of
33
34 398 this, there is still a ways to go in order to ensure that both the healthcare
35
36 399 system will create ample opportunity for CPOs to participate in health
37
38 400 decision making and that CPOs will be capable of capitalizing on them.

41 401 Acknowledgments

42
43 402 Authors would like to express their gratitude to all cancer patient
44
45 403 organizations who responded to our research call and particularly to their
46
47 404 members who shared their perspective and experience with us.

49 405 Ethics Approval

50
51 406 The study was approved by the Research and Ethics Committee of the
52
53 407 University of Peloponnese, Corinth, Greece in accordance with the ethical
54
55 408 standards delineated in the 1964 Declaration of Helsinki. Furthermore, the
56
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1
2
3 409 Institutional Review Board of the participating patients associations reviewed
4
5 410 and approved the study. Informed consent for participation was obtained
6
7 411 from all participants.
8

9
10
11 412 **Contributions**

12 413 The study was designed by KS, EA, LP, CT, DV, OB, DD, SH and FS. EA, LP,
13 414 CT, DV, OB and DD were responsible for the data collection. CT, KS and FS
14 415 performed the statistical analysis. KS, EA, LP, CT, DV, OB, DD, SH and FS
15 416 contributed to the interpretation of the results and draft the manuscript. All
16 417 authors have read and approved the final manuscript.
17
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21
22 418 **Funding statement**

23 419 Research was funded by Novartis Pharma, Basel under the AGORA initiative-
24 420 i.e. a European Think Tank which aims to optimize patient access to
25 421 innovative treatments. Nonetheless, the company was not involved in any way
26 422 in the design, implementation and interpretation of research findings. Final
27 423 publication is fully owned by the authors.
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34 424 **Conflict of interest statement**

35 425 We have read and understood BMJ Open policy on declaration of interests
36 426 and declare that we have no competing interests.
37
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41 427 **Patient consent statement**

42 428 Not Applicable
43
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3 435 **Data sharing statement**

4
5 436 The datasets used and/or analyzed during the current study are available from
6
7 437 the corresponding author on reasonable request.

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4 517 *Figure 1.* Cluster analysis results

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6 518 *Figure 2.* Patient organization participation in EU-28 by country cluster

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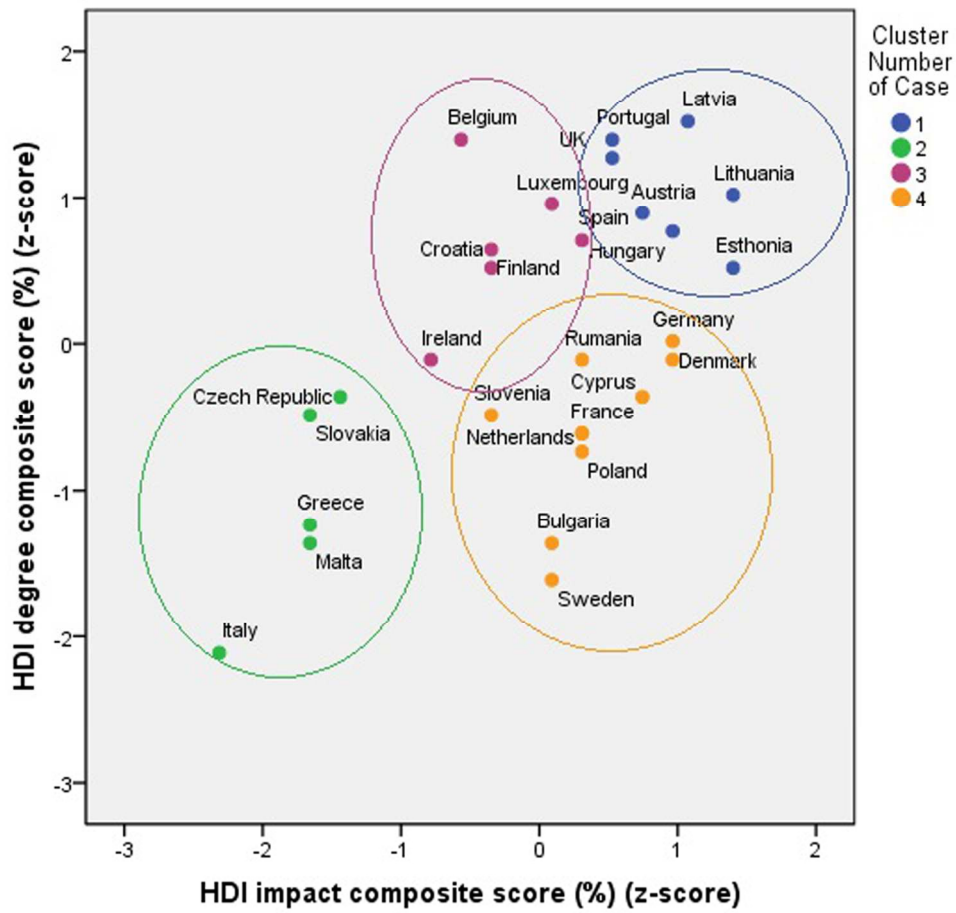


Figure 1. Cluster analysis results

133x124mm (300 x 300 DPI)

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

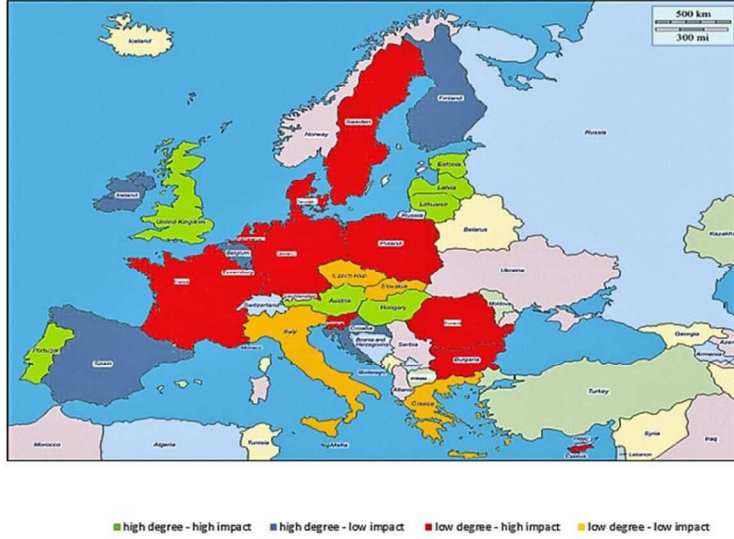


Figure 2. Patient organization participation in EU-28 by country cluster

279x181mm (300 x 300 DPI)

BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-018896.R3
Article Type:	Research
Date Submitted by the Author:	20-May-2018
Complete List of Authors:	Souliotis, Kyriakos; University of Peloponnese, Faculty of Social Sciences; Peppou, Lilly; University Mental Health Research Institute Tzavara, Chara; Centre for Health Services Research, Department of Hygiene, Epidemiology and Medical Statistics, Medical School, National & Kapodistrian University of Athens Agapidaki, Eirini; Faculty of Social and Political Sciences, University of Peloponnese Varvaras, Dimitrios; Università degli Studi di Roma Tor Vergata Facoltà di Medicina e Chirurgia Buonomo, Oreste; Università degli Studi di Roma Tor Vergata Facoltà di Medicina e Chirurgia Debiais, Dominique; Europa Donna, Forum France Hasurdjiev, Stanimir; Bulgarian National Patients' Organization Sarkozy, Francois; FSNB Health & Care
Primary Subject Heading:	Health policy
Secondary Subject Heading:	Oncology, Patient-centred medicine
Keywords:	Patient participation, health policy decision making, cancer patient organizations

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3 **1 Cancer Patients' Organization participation in health policy**
4
5 **2 decision making: a snapshot/cluster analysis of the EU-28**
6
7 **3 countries.**
8

9 4 Kyriakos Souliotis^{1,2*}, Lily-Evangelia Peppou³, Chara Tzavara², Eirini
10
11 5 Agapidaki¹, Dimitrios Varvaras⁴, Oreste Buonomo⁴, Dominique Debiais⁵,
12
13 6 Stanimir Hasurdjiev⁶, Francois Sarkozy⁷.
14

15
16
17
18 8 ¹ Faculty of Social and Political Sciences, University of Peloponnese, Corinth,
19
20 9 Greece;

21
22 10 ² Centre for Health Services Research, Department of Hygiene, Epidemiology
23
24 11 and Medical Statistics, Medical School, University of Athens, Athens, Greece

25
26 12 ³ University Mental Health Research Institute, Athens, Greece

27
28 13 ⁴ Department of Surgery, University of Rome Tor Vergata, Rome, Italy

29
30 14 ⁵ Europa Donna, Paris, France

31
32 15 ⁶ Bulgarian National Patients' Organization, Sofia, Bulgaria

33
34 16 ⁷ FSNB Health & Care, Paris, France

35
36 17 *** Corresponding author:**

37
38 18 Kyriakos Souliotis

39
40
41 University of Peloponnese, Faculty of Social and Political Sciences,
42
43 Department of Social and Education Policy, Corinth, Greece; Damaskinou &
44
45 Kolokotroni Str., 20100, Corinth, Greece; soulioti@hol.gr; tel : + 302741074991
46
47 fax: +302741074990.
48
49

50
51 19 **Keywords:** Patient Participation, Health Policy Decision Making, Cancer
52
53 20 Patient Organizations.

54
55 21 **Word count:** 2604
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22 **Abstract**

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

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

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

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

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

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

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3 48 necessitated in order to address inequalities in health policy decision making
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5 49 in EU-28.
6

7 50
8 **51 Strengths and Limitations of the Study**
9

- 10
11 • The study included a large sample from the 28 member states of the
12 European Union.
13
14
15 • An innovative and validated tool was employed in order to assess the
16 level of cancer patients' organizations participation in health policy
17 decision making
18
19 • The cross-sectional design of the study does not allow making causal
20 inferences.
21
22 • The convenience sample of the study might have limited the
23 generalizability of the results.
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30
31 **61 Introduction**
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33 62 Cancer is the most common and severe non-communicable diseases,
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35 63 impinging substantially on both health and healthcare ¹. Cancer patients have
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37 64 to cope with the stress and the dramatic changes in their lifestyle and quality
38
39 65 of life as well as the procedures and bureaucracy (e.g. reimbursement
40
41 66 processes) often involved in the treatment of the illness ². Although public
42
43 67 spending on health and long-term care has increased in the majority of
44
45 68 European countries (EU), cancer patients' needs remain largely unmet ³. An
46
47 69 illustration of this point is waiting times in cancer care in Ireland, which in
48
49 70 2015 were found to be higher than their counterparts in Albania ⁴. Increased
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51 71 public spending is a necessary but not sufficient condition to ensure
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53 72 effectiveness and sustainability of the healthcare system ⁵.
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3 73 In an effort to provide more effective and appropriate services, the healthcare
4
5 74 system philosophy has shifted from a biomedical approach (which is doctor-
6
7 75 focused) to a more holistic and self-managed one ⁶. Many programs, tools and
8
9 76 models have been implemented in order to empower cancer patients and
10
11 77 facilitate their participation in the delivery of health care services⁷. In this
12
13 78 frame, the physician is no longer considered to be the “expert” or just the
14
15 79 provider and the patient only the receiver. Rather, there is shared decision
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17 80 making in clinical practice. No one knows better the nature of a disease and
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19 81 the needs deriving from it but the patients themselves⁸.

22 82 This is not limited to the individual physician-patient relationship, as patients
23
24 83 may collectively participate in decision making in various realms, including
25
26 84 guideline development, government policy and research agenda setting,
27
28 85 among others⁹⁻¹¹. Patient participation at the collective level is primarily
29
30 86 justified on the grounds of democratic values. Patients are affected by the
31
32 87 consequences of certain decisions, and therefore they should have a say in the
33
34 88 process. Concomitantly, their subjective knowledge of a disease and its
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36 89 treatment may enhance the quality of health care decision making¹²,
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38 90 upgrading the overall effectiveness and efficiency of the healthcare system.

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43 92 While patients’ collective action is increasingly recognized as an important
44
45 93 driver of health policy and service provision, there is paucity of research on
46
47 94 their association. The De Montfort study in the UK has substantiated
48
49 95 increased contact between patient groups and policymakers during the past
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51 96 years, while professional bodies and pharmaceutical companies were found to
52
53 97 have involved patient groups in discussions on policy proposals to a larger
54
55 98 extent than in the past¹³. Nonetheless, according to the researchers, the

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3 99 available evidence could not shed enough light on the influence exerted by
4
5 100 patient groups, as their heightened participation is not necessarily translated
6
7 101 into high political effectiveness. In a similar vein, while the Dutch model in
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9 102 Netherlands allows patient organizations to be an equal party in health policy
10
11 103 processes to a large extent; this is not met in practice¹⁴. Moreover, evidence
12
13 104 from Mixed Advisory Committees in Italy highlight the limited influence of
14
15 105 users' voice on decision making by health authorities¹⁵. In 2006, a workshop
16
17 106 with 22 academic researchers and two representatives of patient organizations
18
19 107 documented high involvement of patient groups with policymakers and
20
21 108 political institutions; however, marked diversity among European countries
22
23 109 was stressed ¹⁶.

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26 110
27
28 111 The initiatives undertaken by most EU countries to establish and increase
29
30 112 patient participation in health policy decision making are reflected on
31
32 113 legislation level¹⁷. Nonetheless, based on information provided by the
33
34 114 European Health Consumer Index¹⁸, countries display important differences
35
36 115 in terms of the degree to which their healthcare law is based on patient rights.
37
38 116 Additionally, noteworthy variation is also observed in the degree to which
39
40 117 patient organizations are involved in decision-making¹⁸. This in turn may
41
42 118 create health inequalities across countries. As a corollary of this, there is an
43
44 119 imperative need to investigate the degree and impact of patient organization
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46 120 participation in health policy decision making in the European Union. This
47
48 121 need becomes even more pronounced in the case of cancer, as the disease has
49
50 122 a multifaceted impact and can be a chronic and fatal disease depending on the
51
52 123 quality of treatment¹⁹. In response to this research call, the present study
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3 124 aimed to provide a snapshot of cancer patients' organization (CPOs)
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5 125 participation in health policy decision making in EU-28 countries.
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7 126

9 127 **Methods**

11 128 Instrument

13 129 For the purpose of the study a self-reported questionnaire was developed,
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15 130 entailing the following sections:

17 131 *Respondents' characteristics*

19 132 Data were collected on participants' socio-demographic characteristics
20
21 133 (gender, age, educational attainment, self-reported economic status) and their
22
23 134 involvement in the CPO. In particular, participants had to rate their degree of
24
25 135 familiarity with cancer and their knowledge about its treatment/ their
26
27 136 country's healthcare system/ their country's reimbursement process (rating
28
29 137 options: very low-low-moderate-high-very high). Moreover, they had to rate
30
31 138 their degree of involvement in the organization (rating options: absent-very
32
33 139 low-low-moderate-high-very high). Data were also gleaned with regard to
34
35 140 their position in the organization (president/or other board member –
36
37 141 employed by the organization-voting member-nonvoting but active member-
38
39 142 non-active member) and the duration of their membership.
40
41

43 143 *Organizational characteristics*

45 144 Information was also collected concerning their CPO. Specifically, participants
46
47 145 had to indicate whether their organization provided information material to
48
49 146 its members (yes-no) and training (yes-no). Furthermore, they were asked
50
51 147 whether their organization was a member of a national cancer federation (yes-
52
53 148 no).

55 149 *Health Democracy Index*

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3 150 Moreover, the questionnaire encompassed the Patient Participation and
4
5 151 Health Democracy Index (HDI), an original scale measuring the degree of
6
7 152 patient organization participation and its impact on shaping health policy. The
8
9 153 Health Democracy Index consists of 17 questions: 8 items investigate CPOs
10
11 154 level of participation (***Degree of Participation***) in processes such as:
12
13 155 reforms, panels at the Ministry of Health, hospital boards, Ethics Committees
14
15 156 in clinical trials, Health Technology Assessment procedures (2 items: one for
16
17 157 the scientific evaluation of new treatments and methods and one for the
18
19 158 economic evaluation) and the national parliament. Each question may have
20
21 159 one of the following answers: (i) it is not a legal requirement and it never
22
23 160 happens, (ii)) it is not a legal requirement and it rarely happens, (iii) it is not
24
25 161 a legal requirement but it often happens, (iv) it is a legal requirement and it
26
27 162 never happens, (v) it is a legal requirement and it often happens, (vi) it is a
28
29 163 legal requirement and it happens very often, and (vii) it is a legal requirement
30
31 164 and it always happens. Concomitantly, the HDI entails 9 items tapping the
32
33 165 impact of CPOs participation on the aforementioned 8 realms (reforms,
34
35 166 ministry of health, other health-related organizations, hospital boards, ethics
36
37 167 committee, HTA and national parliament), which are rated on a 6-point scale
38
39 168 ranging from absent to very high. In addition, ***the Impact of Participation***
40
41 169 sub-scale entails a 9th item enquiring about the frequency by which a
42
43 170 substantial change is observed in the content of a health policy decision as a
44
45 171 result of the involvement of the patient organization. The particular item is
46
47 172 rated on a 6-point scale ranging from never to very often.
48
49 173 Higher composite scores on the sub-scales denote higher degree and impact of
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51 174 participation. Both sub-scales displayed good internal consistency (Cronbach
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3 175 $\alpha = 0.879$ and Cronbach $\alpha = 0.874$ respectively). Converging evidence has
4
5 176 substantiated the psychometric properties of the Health Democracy Index²⁰ .
6
7 177 Specifically, the development of the index has followed the subsequent steps:
8
9 178 (i) definition of the construct (i.e. patient organization participation in health
10
11 179 policy decision making), (ii) review of the construct definition, (iii) item
12
13 180 drafting, (iv) item review) and (v) pilot testing of its psychometric properties
14
15 181 (internal consistency , test-retest reliability, construct validity ad convergent
16
17 182 validity). As the index was originally developed in Greece²¹, an international
18
19 183 working group consisting of European stakeholders (policy-makers, members
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21 184 of patient organizations and researchers with background on patient
22
23 185 empowerment) held various meetings to discuss the adaptation of the index to
24
25 186 European standards.²⁰

26 187 Participants and Procedures:

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29
30 188 Potential participants were identified through various channels (e.g. internet
31
32 189 search, on line databases of European cancer patients' associations, registries
33
34 190 of the ministry of health etc). CPO was considered any non-profit organization
35
36 191 with a legal entity. In addition, the CPO should have been cancer-specific, be
37
38 192 primarily composed of patients and their caregivers and representing and/or
39
40 193 supporting their needs. To be recruited for the study, a CPO should have had
41
42 194 an active representation of cancer patients at a national level and a valid and
43
44 195 accessible website. CPOs from EU-28 member states were included in the
45
46 196 study. In order to be eligible for participation, an individual should have been
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48 197 a member of a CPO and older than 18.

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54 199 An email was sent to CPO board members informing them about the study
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56 200 and inviting them to participate. Following their acceptance, the Institutional

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3 201 Review Board of each organization approved the study protocol and
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5 202 forwarded the invitation for participation to all of its members. All
6
7 203 respondents filled a written informed consent form. Data were collected
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9 204 online (via web-link and email). The questionnaire was translated to each
10
11 205 country's official language.

13 206 Patient and Public Involvement

15 207 Patients play an integral role in this project and thus they have participated in
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17 208 various stages of the research process. The development of the HDI, which has
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19 209 been utilized to assess CPO participation in health policy decision making, has
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21 210 involved both patients-members of patient organizations and patient
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23 211 representatives during the phases of (i) reviewing the construct definition, (ii)
24
25 212 item drafting, (iii) item review and (iv) adaptation of the index to pan-
26
27 213 European standards^{20,21}. Moreover, patient representatives have participated
28
29 214 in the formulation of research objectives, the design of the study and the
30
31 215 interpretation of its findings; while members of patient organizations have
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33 216 constituted the study sample of this research work. It deserves mentioning
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35 217 that results will be disseminated to all identified CPOs, irrespectively of
36
37 218 whether they participated or not.

41 219 Statistical analysis

43 220 Descriptive statistics such as means, medians, standard deviations, absolute
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45 221 and relative frequencies were computed, where appropriate.
46
47 222 Ward's method was used to compute distance patterns and determine the
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49 223 appropriate number of clusters for the K-means clustering procedure. K-
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51 224 means clustering was performed for the classification of cluster subgroups and
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53 225 was based on Euclidian distance. We changed all variables to z-scores to yield
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55 226 equal metrics and equal weighting. For the consistency and validity of the

227 hypothesized groups of countries in the total sample; the total sample was
 228 divided into a split-half random sample. K-means clustering was used then for
 229 the two subsamples to determine the presence of similar cluster subgroups
 230 from the previous analyses. Additionally, analysis of variance ANOVA was
 231 used to compare Degree of Participation and Impact of Participation scores
 232 between the four groups defined by cluster analysis. Statistical analyses were
 233 performed using the SPSS for Windows Version 19.0 statistical package (SSPS
 234 Inc., Chicago, IL).

235 **Results**

236 Sample Characteristics

237 The final sample consisted of 1,266 members of CPOs from EU-28 countries
 238 and the mean number of respondents per country was 45 (Table 1).

239 Demographics of the sample are shown in table 2.

241 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
Estonia	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

242

243 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

244

245 *Degree and Impact of CPO Participation*246 Composite scores of the HDI sub-scales (**Degree of Participation** and247 **Impact of Participation**) were used for clustering analysis (Figure 1).

248 The findings revealed four groups of countries according to their score: a) high

249 degree - high impact, b) high degree – low impact, c) low degree - high impact,

250 d) low degree –low impact. Table 3 presents median scores of Degree of

251 Participation and Impact of Participation per country. The median score for

252 all countries was 33.3 for Degree of Participation and 34.69 for Impact of
 253 Participation .

254 Table 3. Median scores of Degree of Participation and Impact of Participation
 255 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

256 *median of the percent score (i.e. ((score-possible minimum score)/(maximum-
 257 minimum possible score))*100)
 258

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

261 **Table 4. Number of Countries in each HDI cluster**

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

262
 263 The total sample was afterwards divided into a split-half random sample and
 264 K-means clustering was repeated for the two subsamples. Clustering results
 265 indicated that the four-cluster solution recorded in the previous analyses was
 266 the most homogeneous solution in each subsample. Furthermore, the Degree
 267 of Participation and Impact of Participation scores were compared between
 268 the four country groups as defined by cluster analysis. All pair wise
 269 comparisons were significant ($p < 0.001$) providing additional evidence for the
 270 cluster solution.

271

272 Discussion

273 In contemporary health care systems, patients not only participate in
 274 decisions concerning their own health and healthcare (i.e. the micro-level),
 275 but in decision making processes on the meso- and macro-level (i.e. in local
 276 health authorities, organizations, health technology assessment procedures or
 277 at the parliament, to name few)²². Their influence in these processes is greatly
 278 enhanced if they are grouped together. For this reason, patient organizations

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2
3 279 emerge as an indispensable vehicle for facilitating democracy, promoting
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5 280 patient interests and influencing health policy decision making²².
6
7 281 Nonetheless, existing evidence suggests wide diversity in the European Union
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9 282 with regard to patient organization participation in health policy decision
10
11 283 making^{16,18}. At the same time, converging evidence indicates that a greater
12
13 284 degree of participation on the part of patient organizations does not guarantee
14
15 285 the effectiveness of this participation ^{13-15,22}. In other words, patient
16
17 286 organizations may be given opportunities to have a say in health policy-
18
19 287 decision making, but are they being heard?
20
21
22 288 The findings from the present study revealed four groups of countries:
23
24 289 a) High Degree – High Impact: “Health Democratic environment”. The
25
26 290 environment fosters patient organization participation and patient groups
27
28 291 contribute substantially to health policy decision-making
29
30 292 b) High Degree – Low Impact: ostensible participation. The system provides
31
32 293 ample opportunity for patient organization participation; however, this does
33
34 294 not exert a significant impact.
35
36 295 c) Low Degree – High Impact: limited but impactful participation. The health
37
38 296 policy shaping system does not give enough room for participation; however,
39
40 297 it takes patient organizations into consideration. It seems that quality
41
42 298 outweighs quantity. One may suggest that either the health policy decision
43
44 299 making system takes highly into consideration the claims of CPOs or that the
45
46 300 latter are very effective in advocating their interests.
47
48 301 d) Low Degree – Low impact: Window of opportunity. The decision making
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50 302 system does not facilitate participation and CPOs are not effective in
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52 303 advocating their claims.
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56 304 Interpretations
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3 305 The findings of the present study corroborate the wide diversity among
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5 306 European countries with respect to the degree and impact of CPOs
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7 307 participation in health policy decision making. These findings are to a large
8
9 308 extent consonant with findings from the European Health Consumer Index¹⁸.
10
11 309 Interestingly, both Bulgaria and Sweden rank very low in the Degree subscale
12
13 310 (median=12.5 and median= 8.33 respectively); however, they rank high in the
14
15 311 Impact subscale (median = 35.65 and median = 35.40 respectively). At first
16
17 312 glance, this appears in sharp contrast to the findings from the European
18
19 313 Health Consumer Index, where Bulgaria was found to score good in the
20
21 314 indicator “patient organizations involved in decision making” and Sweden
22
23 315 intermediary. Nonetheless, the low scores documented in the Degree subscale
24
25 316 of the present study are probably explained by both countries’ low
26
27 317 performance in the indicator “healthcare law based on patients rights”. As a
28
29 318 result of this, these countries score very low in the Degree subscale (enquiring
30
31 319 about the opportunities of CPOs to participate in health decision-making);
32
33 320 however, they do well in the Impact subscale (enquiring about the impact of
34
35 321 this participation). In other words, while the healthcare system may not
36
37 322 provide CPOs with ample opportunity to participate, CPOs appear to manage
38
39 323 well into capitalizing on the scarce opportunities given. This is perhaps the
40
41 324 explanation why in this group of countries in spite of low degree of
42
43 325 participation, there is high impact of participation. It is highly likely that CPOs
44
45 326 in these countries have better advocacy and lobbying skills. Alternatively, it
46
47 327 may be the case that CPOs form stronger coalitions in these countries. A study
48
49 328 by Wood on patient groups in UK and USA has indicated that in both
50
51 329 countries there is a proliferation of patient organizations; however their
52
53 330 political effectiveness is disproportionately low due to their autonomous
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3 331 activity and their reluctance to collaborate²³. A similar concern was raised by
4
5 332 the Vienna workshop, where heightened competition and tensions among
6
7 333 patient organizations was suggested to hinder their political effectiveness¹⁶.
8
9 334 Therefore, CPOs in countries with high impact may be more politicized and
10
11 335 more united.

12
13 336 This may also explain why in certain countries there is high degree of
14
15 337 participation but low impact. Members of CPOs in these countries may not be
16
17 338 trained enough in lobbying and advocacy skills and may not engage into joint
18
19 339 campaigning. Alternatively, the system may ostensibly involve patient
20
21 340 organizations in health policy decision making. This is congruent with the
22
23 341 concern raised in UK¹³ that the involvement of patient organizations in health
24
25 342 policy decision making may solely serve the purpose of adding legitimacy to
26
27 343 governments, while the latter advance their own interests. Therefore, one
28
29 344 should investigate further what happens in these countries and endeavour to
30
31 345 identify the determinants of impactful participation overall²⁴

32
33
34 346 It merits noting that the Health Democracy Index entails items tapping
35
36 347 perceived patient organization participation in health policy decision making
37
38 348 on various realms: hospital boards, health technology assessment, ethics
39
40 349 committees in clinical trials, national parliament, ministry of health, to name
41
42 350 few. It is highly likely that an item-per-item analysis may reveal a different
43
44 351 pattern of results with regard to country ranking. Our research team is
45
46 352 currently working along this direction.

47
48
49 353 Good Examples

50
51 354 *A good example of a country with High Degree of Participation*

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54 355 The decentralization of the healthcare system in 2001 in Finland has led to an
55
56 356 increased public participation in health policy decision making. In 1999, the

1
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3 357 government set the foundations for the patients' participation in all levels and
4
5 358 sectors pertaining to health policy. A network of agencies at local and national
6
7 359 level was developed. Agencies were affiliated with the Ministry of Health, so as
8
9 360 to facilitate, increase and sustain public involvement in each step of health
10
11 361 policy decision making processes by conducting local health needs
12
13 362 assessments, priority setting surveys and informal evaluations²⁵.

15
16 363 *A good example of a country with High Impact of Participation*

17
18 364 Cyprus was found to be in the cluster of countries characterized by low degree
19
20 365 of participation and high impact. In 2016, the Pancyprian Federation of
21
22 366 Patient Associations and Friends conducted a national study in order to assess
23
24 367 patients' organizations participation in health policy decision making and
25
26 368 identify unmet needs. The study results were disseminated to the community,
27
28 369 local press and other key-stakeholders. A few months later, the systematic
29
30 370 advocating and lobbying activities ended successfully. New legislation
31
32 371 providing for patients' participation in health policy decision making at
33
34 372 national level was established by the Cyprus Parliament based on the
35
36 373 Declaration for Patients Participation in Health Policy Decision Making²⁶.

37
38
39 374 Limitations

40
41 375 The study was not without its limitations. As there is no sampling frame for
42
43 376 CPOs in Europe, the representativeness of the sample is contested. In spite of
44
45 377 systematic efforts to recruit participants through various pathways one may
46
47 378 not exclude the possibility that the most active and motivated CPO members
48
49 379 agreed to participate. In this reasoning, sampling bias may have emerged if
50
51 380 respondents differed systematically from non-respondents in terms of their
52
53 381 views about their CPOs participation in health policy decision making.

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3 382 Moreover, the HDI taps the patient perspective on the degree of and impact of
4
5 383 patient organization participation and thus findings deriving from its use
6
7 384 should be considered complementary to other perspectives (e.g. policy
8
9 385 makers' perspective or more objective indices, such as data emanating from
10
11 386 the parliament minutes). Finally, as the present study addressed CPOs,
12
13 387 findings cannot extrapolated to other disease groups.
14

15
16 388

17
18 389 It is noteworthy that since the aim of the present report was to provide a
19
20 390 snapshot of CPO participation in health policy decision making in EU-28 from
21
22 391 the patients' perspective, we could not have explored potential links between
23
24 392 our data and other system performance indices, such as cancer survival rates
25
26 393 and percentage of total health expenditures spent on cancer care across
27
28 394 countries. Nonetheless, we are currently designing an ecological study that
29
30 395 would enable us to go into greater depth on the topic.
31

32 396 Conclusion

33
34 397 There is substantial diversity in EU-28 with regard to perceived CPO
35
36 398 participation in health policy decision making. Study findings indicate that a
37
38 399 high degree of participation is not synonymous to high impact. As a result of
39
40 400 this, there is still a long way to go in order to ensure that both the healthcare
41
42 401 system will create many opportunities for CPOs to participate in health
43
44 402 decision making and that CPOs will be capable of capitalizing on them.
45

46 403 Acknowledgments

47
48 404 Authors would like to express their gratitude to all cancer patient
49
50 405 organizations who responded to our research call and particularly to their
51
52 406 members who shared their perspective and experience with us.
53

54 407 Ethics Approval

1
2
3 408 The study was approved by the Research and Ethics Committee of the
4
5 409 University of Peloponnese, Corinth, Greece in accordance with the ethical
6
7 410 standards delineated in the 1964 Declaration of Helsinki. Furthermore, the
8
9 411 Institutional Review Board of the participating patients associations reviewed
10
11 412 and approved the study. Informed consent for participation was obtained
12
13 413 from all participants.

14 15 414 **Contributions**

16
17 415 The study was designed by KS, EA, LP, CT, DV, OB, DD, SH and FS. EA, LP,
18
19 416 CT, DV, OB and DD were responsible for the data collection. CT, KS and FS
20
21 417 performed the statistical analysis. KS, EA, LP, CT, DV, OB, DD, SH and FS
22
23 418 contributed to the interpretation of the results and draft the manuscript. All
24
25 419 authors have read and approved the final manuscript.

26 27 420 **Funding statement**

28
29 421 Research was funded by Novartis Pharma, Basel under the AGORA initiative-
30
31 422 i.e. a European Think Tank which aims to optimize patient access to
32
33 423 innovative treatments. Nonetheless, the company was not involved in any way
34
35 424 in the design, implementation and interpretation of research findings. Final
36
37 425 publication is fully owned by the authors.

38 39 426 **Conflict of interest statement**

40
41 427 We have read and understood BMJ Open policy on declaration of interests
42
43 428 and declare that we have no competing interests.

44 45 429 **Patient consent statement**

46
47 430 Not Applicable

48 49 431 **Licence**

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437 **Data sharing statement**

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

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11 521
12 522 *Figure 1.* Cluster analysis results

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14 523 *Figure 2.* Patient organization participation in EU-28 by country cluster

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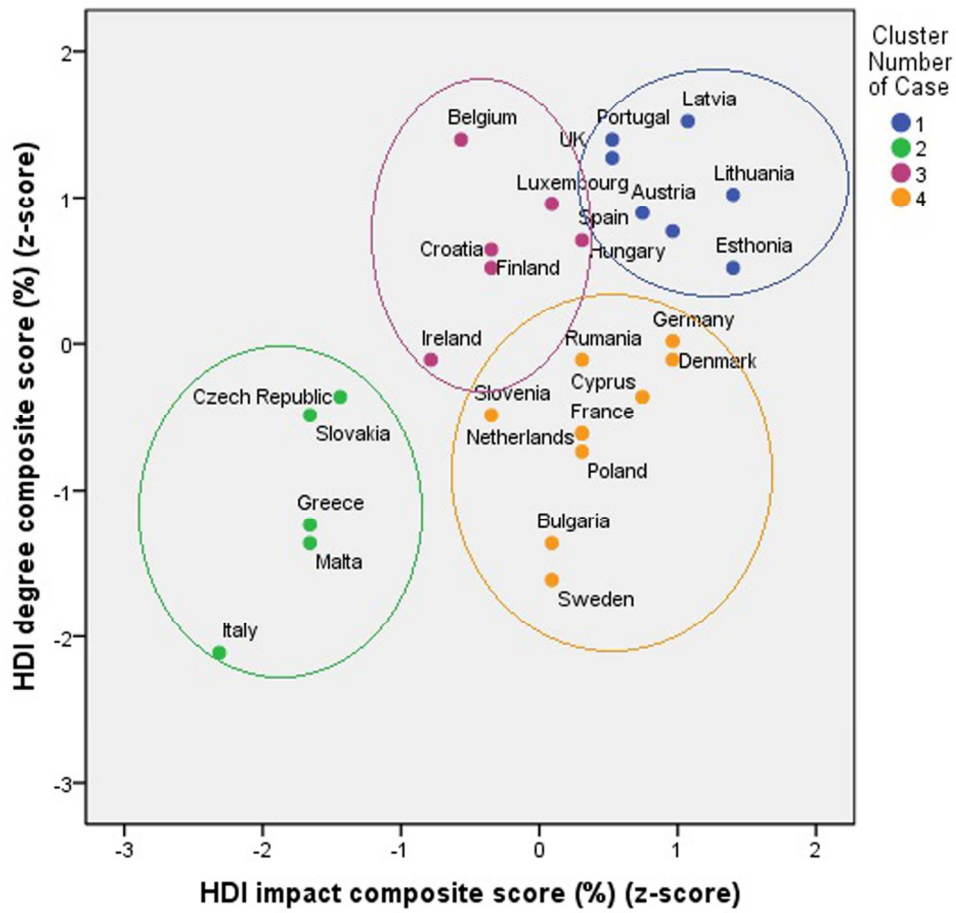


Figure 1. Cluster analysis results

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

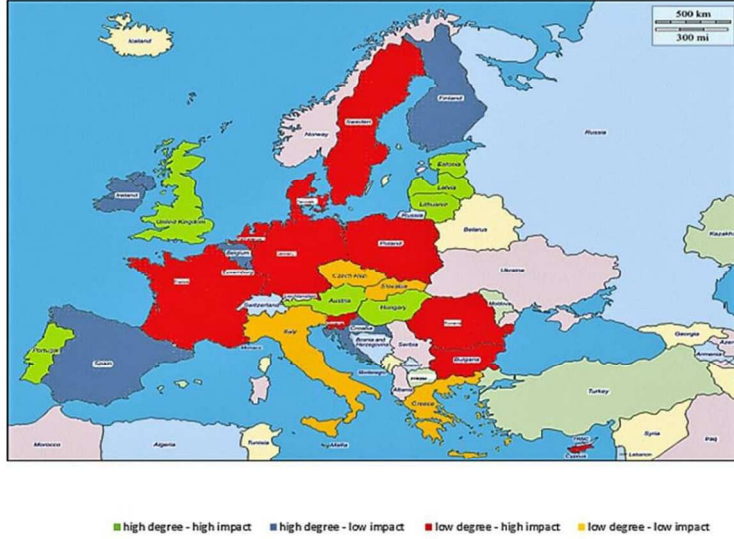


Figure 2. Patient organization participation in EU-28 by country cluster

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