



theta

Toronto Health Economics and
Technology Assessment Collaborative

Picturing Elsi+ in Health Technology Assessment



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Health Technology Assessment

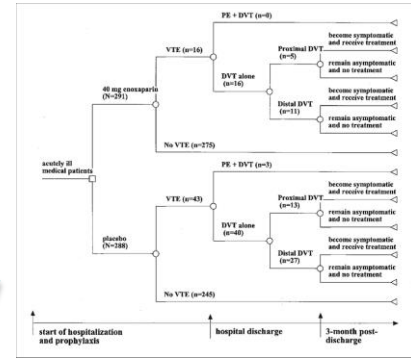
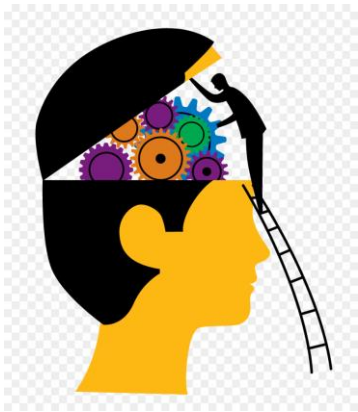
- Decisions about health technologies (adoption, optimal use, disinvestment) are not only scientific questions, but are heavily **value-laden**.



ELSI in HTA

- HTA agencies, public decision makers are exploring methods to better integrate the consideration of ethical, legal, and social issues (ELSI) into HTA
- Also recognize the importance of patient and public perspectives in the decision-making process (+)





Satisfaction

Experienced utility

Preferences

Values

Quality of life



ELSI+: What, how?

- Is there an underlying construct, or set of constructs, for concepts covered by ELSI+ ?
- This lack of clarity lies at the heart of the challenge of integrating ELSI+ into HTA.



OBJECTIVE

- to identify the key concepts in the ELSI+ domain and their interrelationships, using the method of concept mapping.



METHODS

Concept mapping

- combines qualitative approaches with quantitative analytical tools to visually represent ideas and their relationships



Steps in Concept Mapping

- 1) Preparation
- 2) Generation of statements
- 3) Structuring of statements
 - *Sorting and rating tasks*
 - *Participants*
- 4) Concept mapping analysis
 - *Point map*
 - *Cluster maps*
- 5) Interpretation of maps

STEP 1: Preparation

- Scoping review
- Recruited participants
 - social science
 - bioethics
 - law
 - patient advocacy
 - health economics
 - HTA



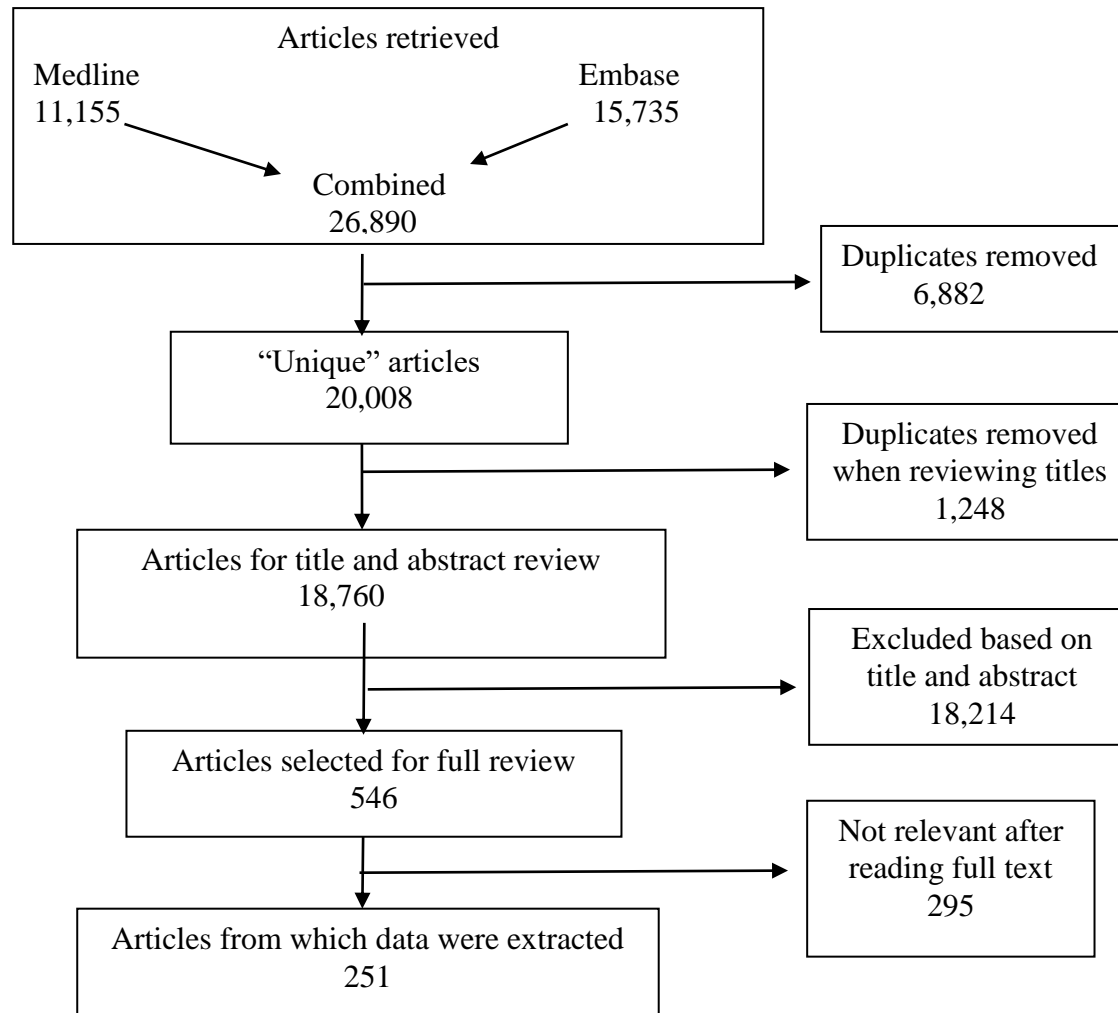
STEP 2: Generation of statements

Scoping Review

- search strategy developed by an experienced librarian and peer-reviewed
- Ovid MEDLINE and Embase, English language, January 1 2000 to March 2, 2017



Scoping review literature search January 2000- March 2017



Scoping Review

- Four reviewers independently reviewed the 251 articles and extracted ELSI+ concepts and ideas
- A list of approximately 300 ideas



STEP 2: Generation of statements

Brainstorming session

- 6 researchers/professionals, a patient advocate, across Canada
- discuss the relevance of the ELSI+ items found in the scoping review and to elicit any others.

5 scenarios from the literature were discussed:

1. screening for fetal abnormalities,
2. a drug for terminal cancer,
3. a universal vaccine,
4. telehomecare for chronic illness, and
5. genomics and genetic tests.

STEP 2: Generation of statements

Review and consolidation of items

- consolidated the approx. 300 ideas into 100 statements; further reduced to 80 statements

STEP 3: Structuring of statements

Sorting & rating tasks

- The Concept Systems® Global MAX™ software
- statements are entered as a list
- a randomization function shuffles them and assigns statement numbers.



Sorting & rating tasks

- **Sorting:** participants place the statements into groups based on common themes that make sense to them and then name the groups.



Sorting & rating tasks

- Rating:
 - “How important do you think that each of the issues below are to decisions about whether or not a technology should be adopted for use in Canada?”
- 5-point Likert scale
 - (1 = not at all important and 5 = extremely important)

Sorting & rating

Participant recruitment

- searched the websites of Canadian universities and HTA agencies,
- scanned the author lists of articles in the scoping review for Canadians
- sent e-mails describing the study to 133 potential participants.



Sorting & rating

Participant recruitment

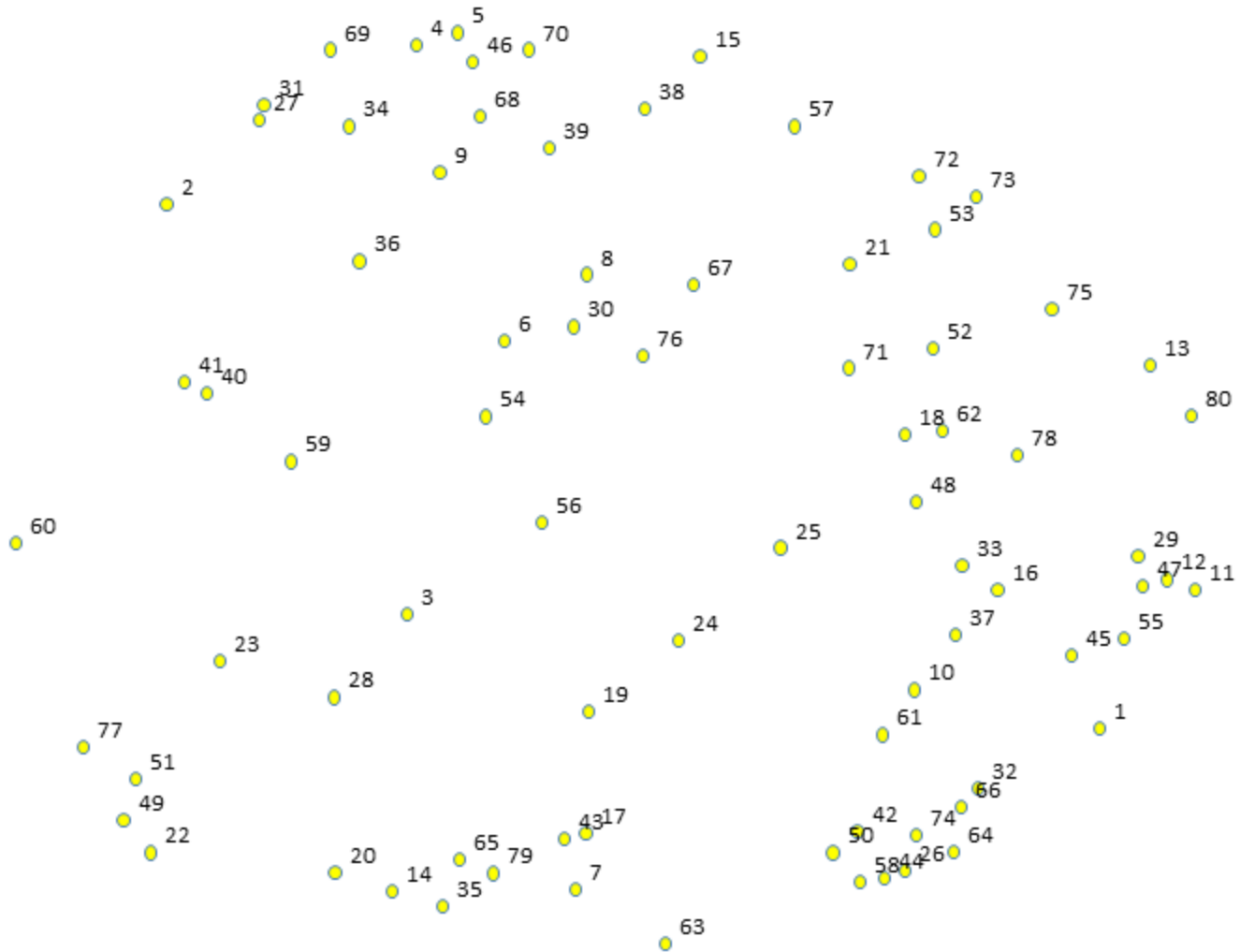
- 69 respondents expressed interest
- 48 returned consent forms,
- 38 completed the sorting task; 37 completed the rating task



Step 4: Concept Mapping analysis

- A point map locates each statement as a point on a two-dimensional (x,y) map, based on the frequency that statements were put in the same pile by the participants

Point map (80 statements; 38 participants)



Cluster maps

- Clusters represent different concepts,
- Statements within each cluster -same concept

- Target: >4 clusters



Cluster maps

- 2 members of the study team and 2 study participants reviewed the cluster maps.
- started with 16 clusters and observed which statements were merged to form 15 clusters.
- we independently recorded whether the merge made sense, and why it did or did not make sense

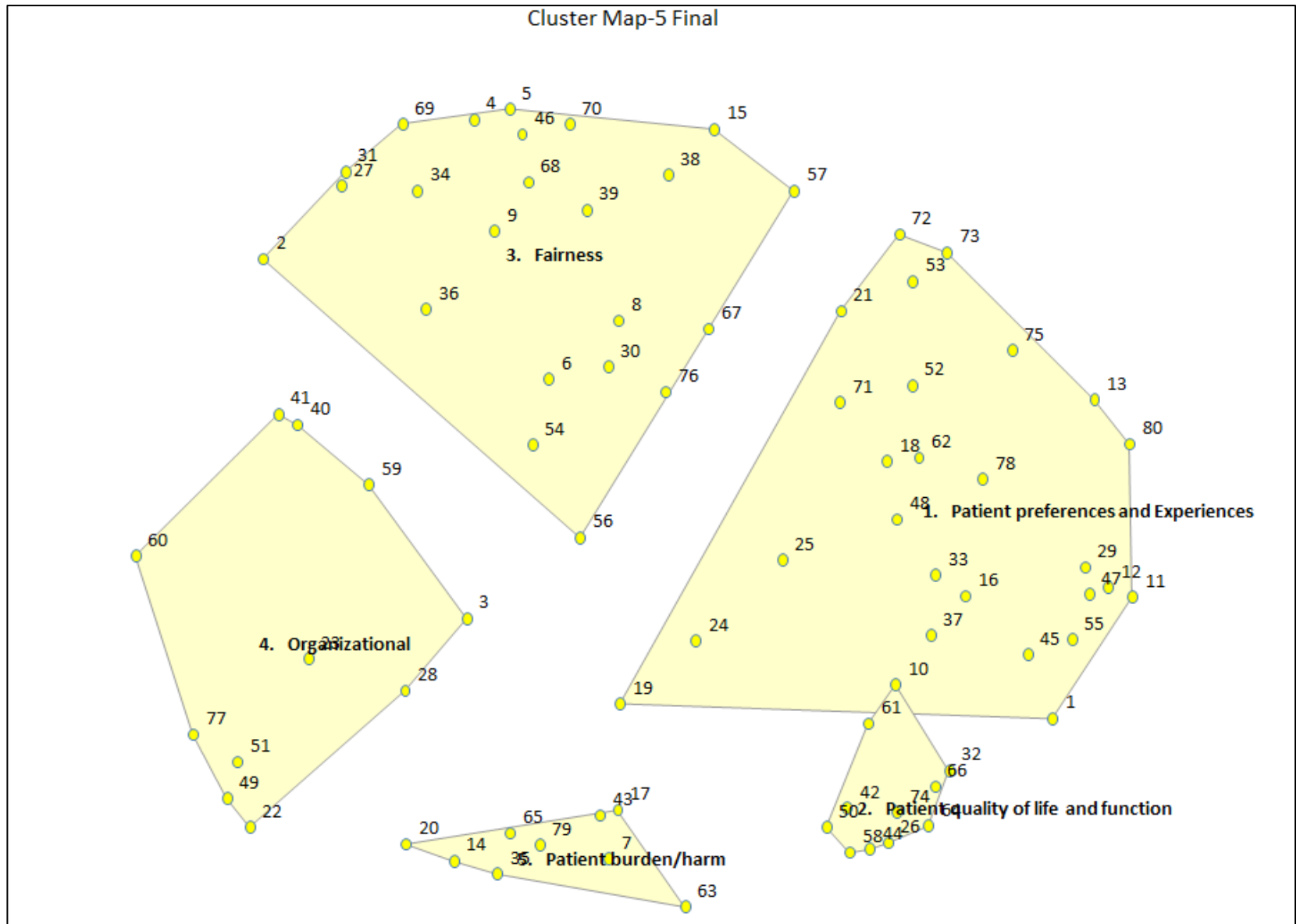


The 5-cluster map

- We reviewed the labels given to the clusters by the software and the statements within each
- We renamed 4 of the 5 clusters

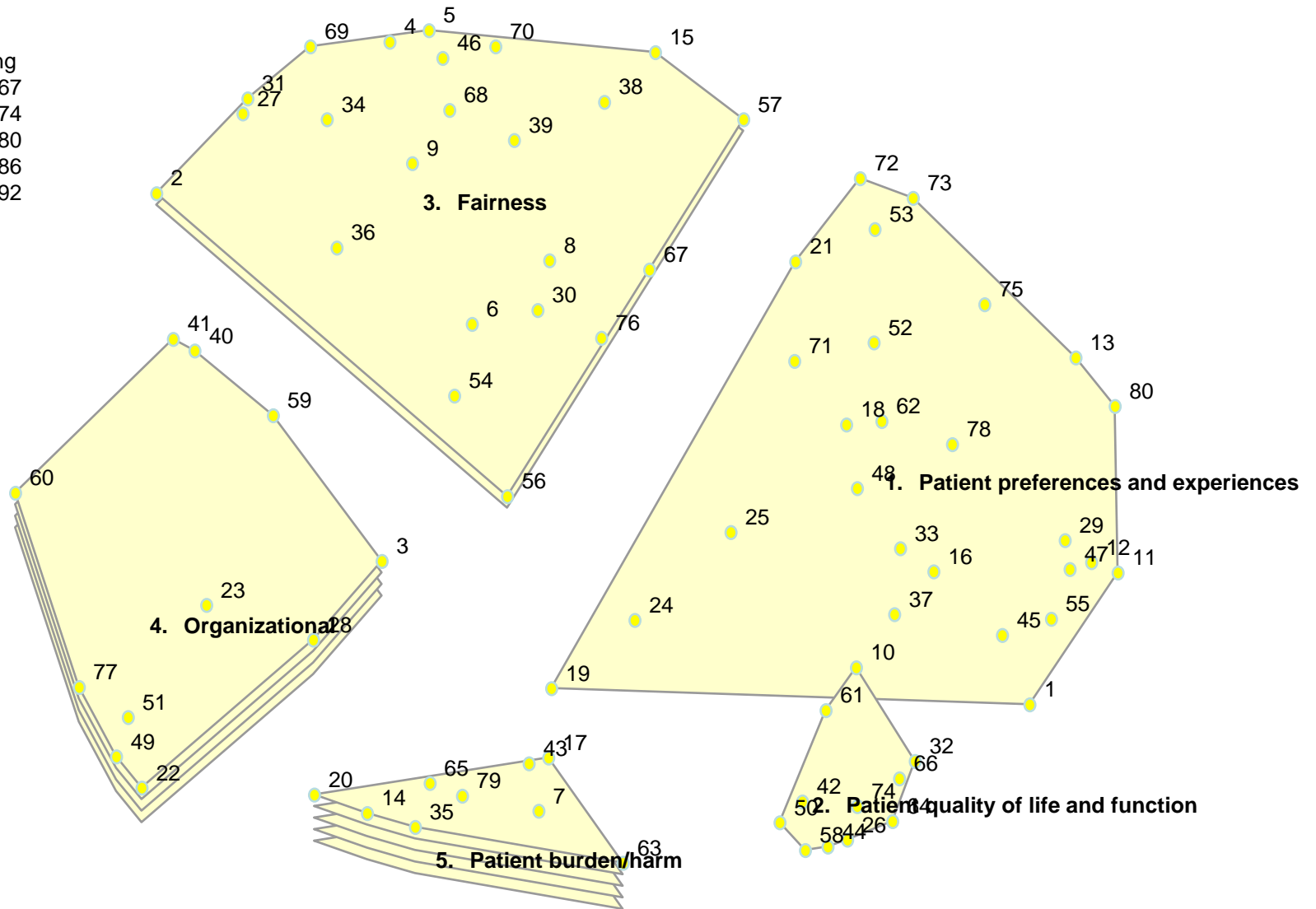


5-cluster ELSI+ map



Final cluster map with 5 clusters for ELSI+ with mean importance ratings

Layer	mean rating
1	3.61 to 3.67
2	3.67 to 3.74
3	3.74 to 3.80
4	3.80 to 3.86
5	3.86 to 3.92



Adding the importance ratings

- The mean importance ratings for clusters were all above 3.5 out of 5.
- ‘Patient burden/harm’ (3.92)
 - side effects, adverse events, inaccuracy of tests, ease of use
- ‘Organizational’ cluster (3.82)
 - legal liability, financial costs, privacy, informed consent, feasibility

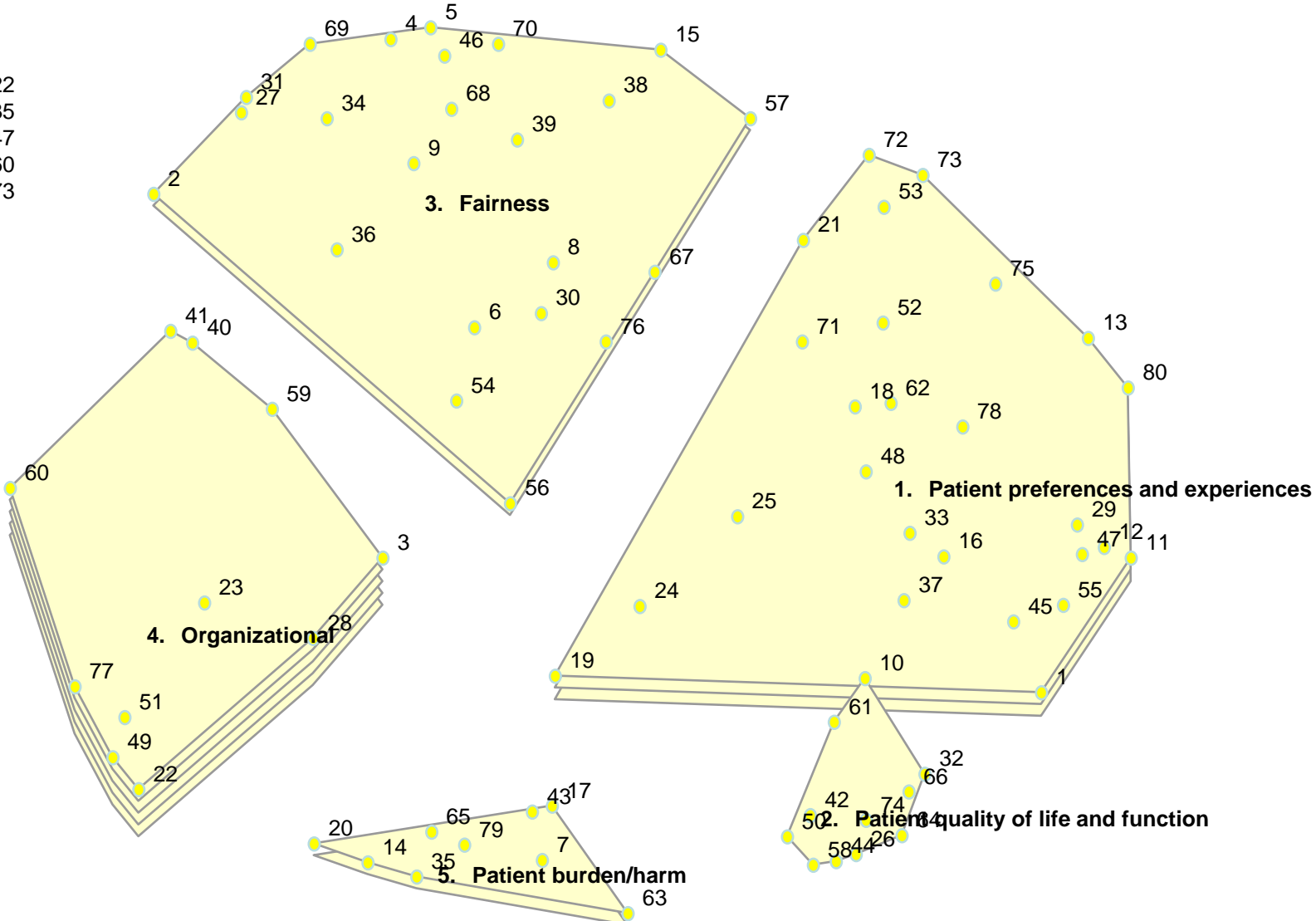
Bridging values

- bridging” analysis describes how well a statement reflects other statements in its vicinity on the map
- low bridging value
 - “anchor” - sorted with nearby statements
- high bridging value
 - sorted with distant statements

Cluster Bridging Map- 5 clusters

Cluster Legend

Layer	Value
1	0.09 to 0.22
2	0.22 to 0.35
3	0.35 to 0.47
4	0.47 to 0.60
5	0.60 to 0.73



Cluster	Statement	Bridging value
1. Preferences		0.36
37	realistic expectations	0.22
33	physician-patient relationship	0.22
16	interaction/relationship with health care provider	0.23
45	patient satisfaction	0.24
48	patient empowerment	0.25
29	patient expectations	0.25
62	desire to be treated as a whole person	0.25
71	respect for patients	0.29
78	patient involvement in decisions	0.3
47	adaptive preferences: patients adapt to disability	0.32
12	patient preferences for treatment	0.33
11	patient preferences for outcomes	0.34
55	patient self-efficacy	0.34
18	social stigma, embarrassment	0.34
24	communication with health care provider	0.36
1	quality of life	0.36
52	to be treated with dignity, respect, courtesy	0.37
25	consequences for family members	0.38
72	cultural beliefs and norms	0.41
75	autonomy, personal choice	0.44
19	difficult decisions arise after test results	0.44
73	religious beliefs	0.44
53	freedom of choice	0.49
21	people value life more at the end of life	0.51
80	preferences and values of family	0.53
13	desire to "fit in" with other people	0.58

2. Patient quality of life and function		3.61
50	relief from symptoms; time to relief from symptoms	4.22
58	effects on daily activities	4.08
64	effects on physical activities	4.03
66	effects on social function	3.75
42	amount of disruption to daily life	3.68
44	effects on mood, emotions	3.62
26	sleep; interference with sleep	3.54
74	anxiety and stress	3.54

3. Fairness		3.69
38	basic human rights	4.56
31	equity in access to treatment and healthcare	4.54
56	receiving accurate and adequate information	4.5
2	universal access	4.27
9	equity in health outcomes	4.14
46	balance between individual's benefit and societal good	4.08
69	maximum benefits for the most people	4.03
5	we should help the people who need help the most	3.89
54	confidentiality	3.86
67	discrimination because of illness	3.73
8	parents' responsibility to children	3.7
76	discrimination because of treatment	3.65
39	individual choice versus societal choice	3.57
4	solidarity; society is willing to share good and bad health	3.49
34	if the costs are equal, we should help many people with a common disease instead of a few people with a rare disease	3.49
68	preferences of general public (taxpayers, 'veil of ignorance') versus patients	3.47
70	individuals have a responsibility to society	3.43
30	discrimination because of genetic test results	3.41
15	society's acceptance of disability and illness	3.24
57	handicapped and disabled people have their own society and culture	3.11
36	children's rights to make their own choices	3.05
6	how much do life-style or behaviour choices cause disease or illness	2.92
27	rare diseases: if a few people need a very expensive treatment, we should help them regardless of cost	2.84

4. Organizational		3.82
77	feasibility of implementation and use	4.32
59	beneficence; do no harm	4.24
49	applicability to clinical practice	4.11
51	follow-up resources (eg., treatment, genetic counseling)	3.97
3	additional financial costs to patients or family	3.92
40	privacy of information	3.89
23	continuum of patient care	3.73
41	ability to obtain informed consent (ill, disabled)	3.68
60	legal liability and responsibility for malfunctioning equipment, technical problems	3.5

5. Patient burden/harm		3.92
17	risk of harm	4.51
63	side effects and adverse events	4.43
43	Burden of treatment or technology	4.05
79	risks of incorrect test results	4.03
14	false positive results = over-diagnosis, over-treatment	4
35	false negative results = false reassurance; patients disregard symptoms	3.81
20	ease of use; usability	3.73
65	risks of incidental findings from a test	3.43
7	potential for addiction or abuse of a drug	3.32

RESULTS: ELSI+ concept map

- Our final clusters were not completely congruent with the original “ELSI+” conceptualization.
- E.g. “ethics” principles were found in most of our clusters



RESULTS: ELSI+ concept map

Patient-centric conceptualization of ELSI+

- 3 of the 5 clusters addressed the patient perspective: preferences and experiences, quality of life and function, burden/harm.

Ethics (ELSI+)

- The 4 moral principles commonly use in principlalist approaches to ethics were found in all 5 clusters.
 - *beneficence*
 - Patient preferences and experiences cluster (patient satisfaction, patient preferences for outcomes),
 - Fairness cluster (maximum benefits for the most people, we should help the people who need help the most),
 - Organizational cluster (beneficence; do no harm).
 - *non-maleficence*
 - Patient burden/harm cluster (risk of harm, potential for addiction or abuse of a drug).
 - *autonomy*
 - Patient preferences and experiences cluster (freedom of choice, autonomy/personal choice, patient self-efficacy),
 - Fairness cluster (children's rights to make their own choices),
 - Organization cluster (ability to obtain informed consent (ill, disabled)).
 - *justice*
 - Fairness cluster (basic human rights, equity in access to treatment and healthcare, equity in health outcomes, universal access, balance between individual's benefit and societal good, individual choice versus societal choice).



Legal (ELSI+)

- Organizational cluster
 - legal liability and responsibility for malfunctioning equipment, technical problems
- Fairness cluster
 - discrimination because of illness, treatment, or genetic test results.



Social Values (ELSI+)

- Fairness-
 - equity, solidarity and population health
- Patient preferences and experiences-
 - patient-centred care
- Organizational
 - resource stewardship and resource sufficiency.



+ (ELSI+)

- 3/5 clusters were related to patients experiences
- Preferences and experiences,
- Quality of life and function,
- Burden/harm
- Organizational
 - additional financial costs,
 - privacy of information.
- Fairness
 - discrimination, disability, and receiving information



Implications

- academic disciplines that work within the ELSI+ domain (e.g. bioethics, social science, law, economics) cover a heterogeneous, but often overlapping, set of concepts, which would benefit from multi- and cross-disciplinary study.



Future work

- i) confirming these results with a larger and more comprehensive sample of respondents
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- ii) identifying research methods most associated with the study of each concept
- iii) creating a validated search string for identification of the relevant literature.



Questions

