Ethical principles in reusing patient data and patients' information needs

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Introduction

1. Psychology

UNIVERSITY OF AMSTERDAM

2. Meta-science in Psychology

TILBURG UNIVERSITY

3. Meta-science in Medicine

BIH Berlin Institute of Health @Charité

Research questions

1. What ethics-related information do patients want from registries?
2. What preferences do patients have about how ethics-related information is communicated by registries?

Study 1

3. What ethics-related information do registries currently provide?

Study 2

Ethics-related information

- Governance & Conflicts of Interest
- Consent Mechanisms
- Privacy & Data Protection
- Use & Access Policies
- Handling of Incidental Findings
- Research Transparency

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EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

Joint Action 3

MILESTONE

Milestone 5.15 Final validated Standards Tool for Registries in HTA prepared

Date of submission	30-09-19
Work package	5
Activity Centre	Post-Launch Evidence Generation (PLEG) and Registries – Strand B2
Author(s)	National Institute for Health and Care Excellence, NICE (UK) Croatian Institute of Public Health, HZJZ (Croatia) Agency for Health Quality and Assessment of Catalonia, AQuAS (Spain) French National Authority for Health (Haute Autorité de Santé), HAS (France) - *work package lead*
Dissemination level	Public

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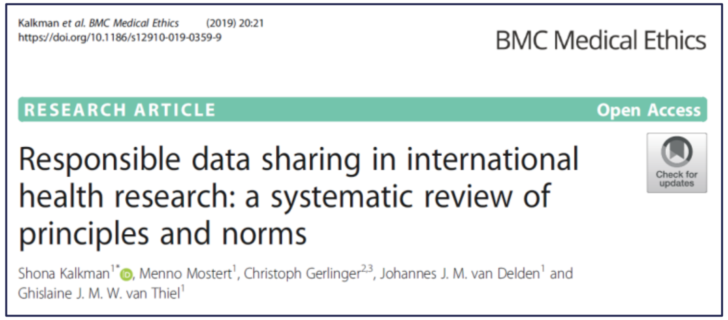

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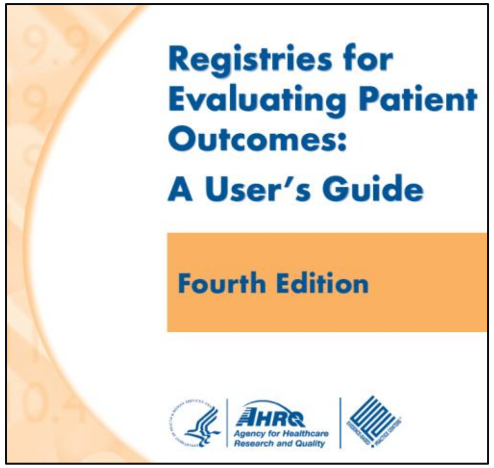
BMC Medical Ethics

RESEARCH ARTICLE Open Access

Responsible data sharing in international health research: a systematic review of principles and norms

Shona Kalkman[1*], Menno Mostert[1], Christoph Gerlinger[2,3], Johannes J. M. van Delden[1] and Ghislaine J. M. W. van Thiel[1]



Registries for Evaluating Patient Outcomes: A User's Guide

Fourth Edition

Study 1: Interviews with MS patients

- Interviews with MS patients and MS patient representatives
- 60-90 minutes via Teams

Total participants = 21	
Gender	***n*** **(%)**
Woman	13 (61.9)
Man	8 (38.1)
Country	***n*** **(%)**
Belgium	4 (19.0)
Croatia	2 (9.5)
Denmark	4 (19.0)
Germany	2 (9.5)
Greece	2 (9.5)
Netherlands	2 (9.5)
Portugal	1 (4.8)
Serbia	2 (9.5)
Spain	2 (9.5)

Total participants = 21	
Age	**average [min; max]**
	48.8 [31; 80]
MS Duration	**average [min; max]**
	16.9 [3; 30]
Representative	***n*** **(%)**
Yes	14 (66.7)
No	7 (33.3)
Registry Enrol.	***n*** **(%)**
Yes	11 (52.4)
No	7 (33.3)
Not sure	2 (9.5)
NA	1 (4.8)

Conclusions

Important deciding factors for participation: Who, what/why, which

“What i think we need to know? Where is the data going? So that's my only thing.” – Participant 33

“But it would be important to know what exactly are they going to do with my data. So what are the questions in layman's English? Explain what you want to achieve and why.” – Participant 64

Conclusions

Information on personal or aggregate results was seen as a strong benefit of participation

“I don't think that it needs to be any kind of reward any kind of financial incentive or anything like that. Really, just knowing that you're participating in something that will be helpful and beneficial to other patients.” – Participant 14

“[I want to know] what is done with that information to show that it's not just sitting there for researchers to research, but there's actually an output” – Participant 20

Conclusions

Trust emerged as a key factor in terms of information needs and communication preferences

“I would normally accept entry into registries which are already part of trusted institutions of some kind. For example, known universities or the public system.” – Participant 7

“Especially as a person with a chronic illness, I wouldn't want to have to get that level of information. If I didn't have an initial feeling of trust, I just wouldn't go into it.” - Participant 7

“Via the channels that patients trust . So that's either their medical people or like [...] you know patient organizations, patient advocates” - Participant 65

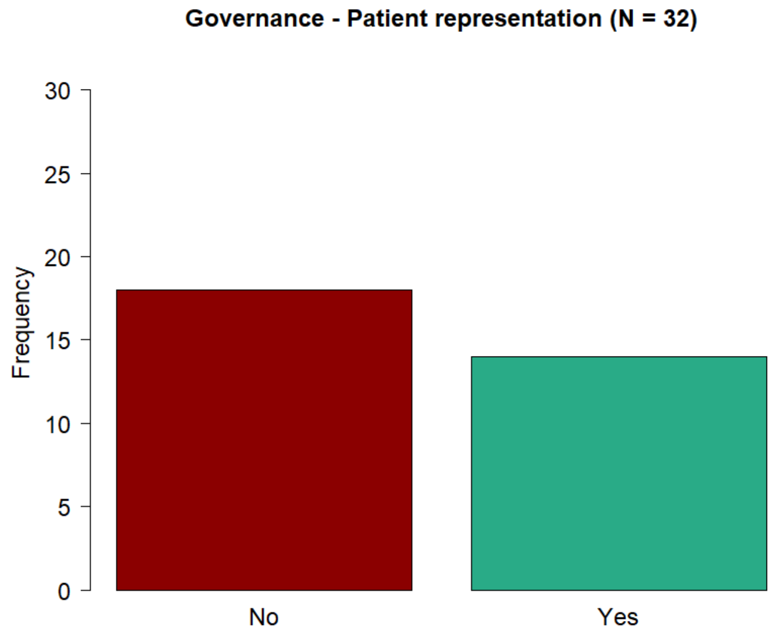
Study 2: Assessment of registry websites

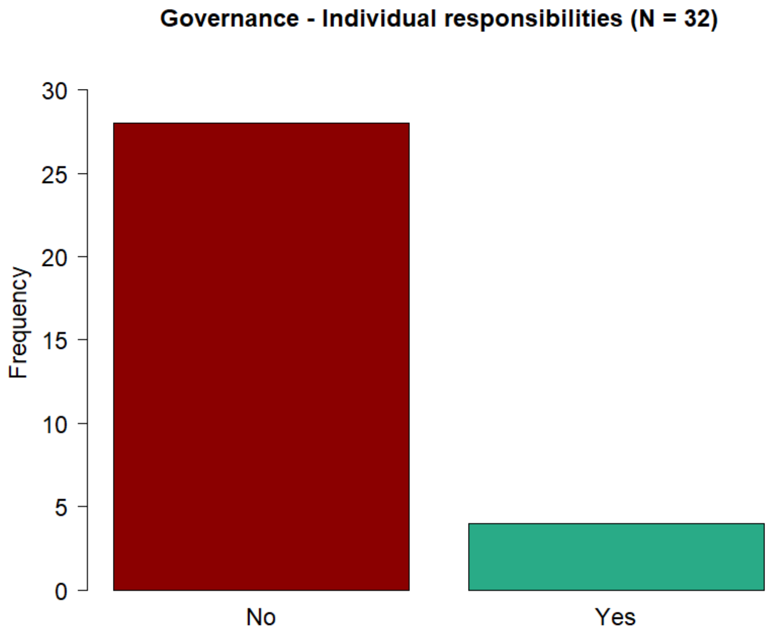
Sr. No	Display Name	Type	Geographical origin
1	BIKER	Data Source	Transnational
2	BioReg-Austria	Data Source	Austria
3	CPRD	Data Source	United Kingdom
4	Calliope	Data Source	France
5	DA Germany	Data Source	Germany
6	DAPI database	Data Source	Germany
7	DHR	Data Source	Germany
8	DKCC - Skin Cancer	Data Source	Netherlands
9	Danish Registries (access/analysis)	Data Source	Denmark
10	Dravet-SCN1A-PCHD19 Registy	Data Source	Transnational
11	Drugs and Pregnancy Finland	Data Source	Finland
12	EBMT	Data Source	Transnational
13	EHDN - REGISTRY	Data Source	Transnational
14	EHR - Blood disorder	Data Source	United Kingdom
15	EMBARC	Data Source	Transnational
16	ESID Registry	Data Source	Transnational
17	EUROMAC	Data Source	Transnational
18	Enroll-HD	Data Source	Transnational
19	EudraVigilance	Data Source	Transnational
20	European Porphyria Registry (EPR)	Data Source	Transnational
21	FranceCoag - Haemophilia	Data Source	France
22	GalNet	Data Source	Transnational
23	GePaRD	Data Source	Germany
24	German CF Registry	Data Source	Germany
25	German MS-Register	Data	Germany

51 registry databases assessed using a checklist of 26 questions:

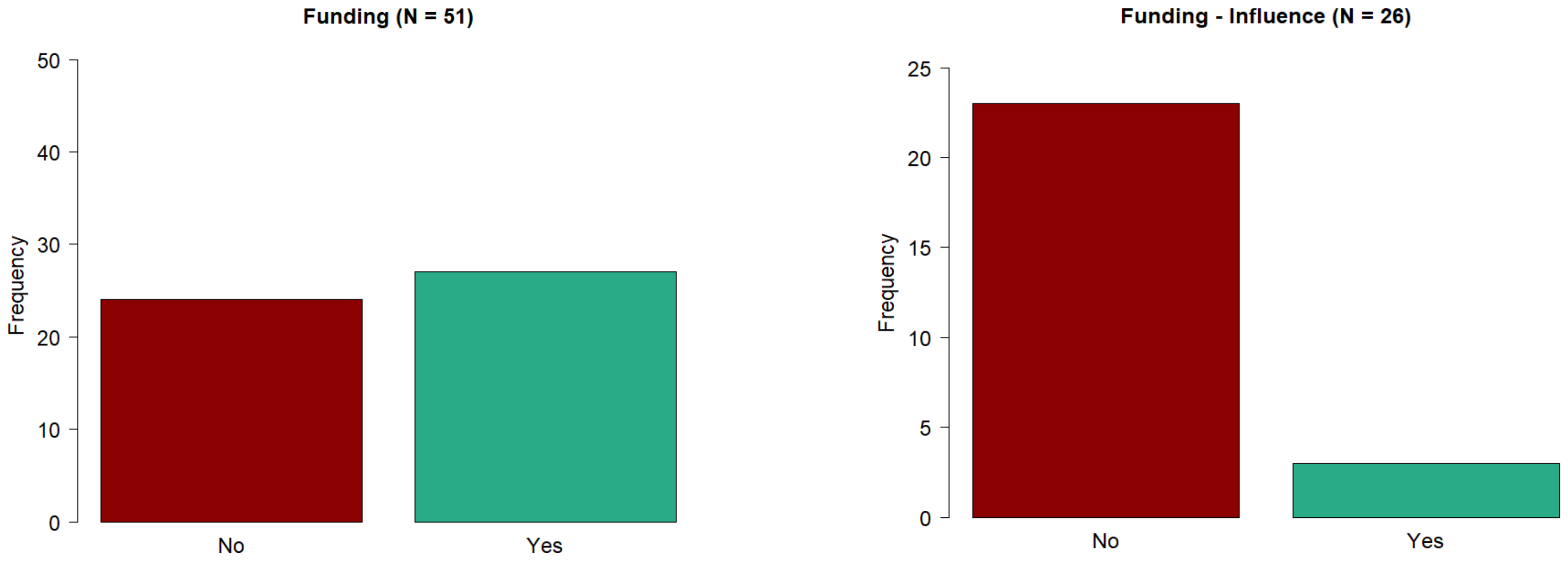
1) Governance (3 questions)
2) Conflicts of Interest (2 questions)
3) Informed Consent (9 questions)
4) Privacy (3 questions)
5) Use-and-Access (9 questions)

Governance

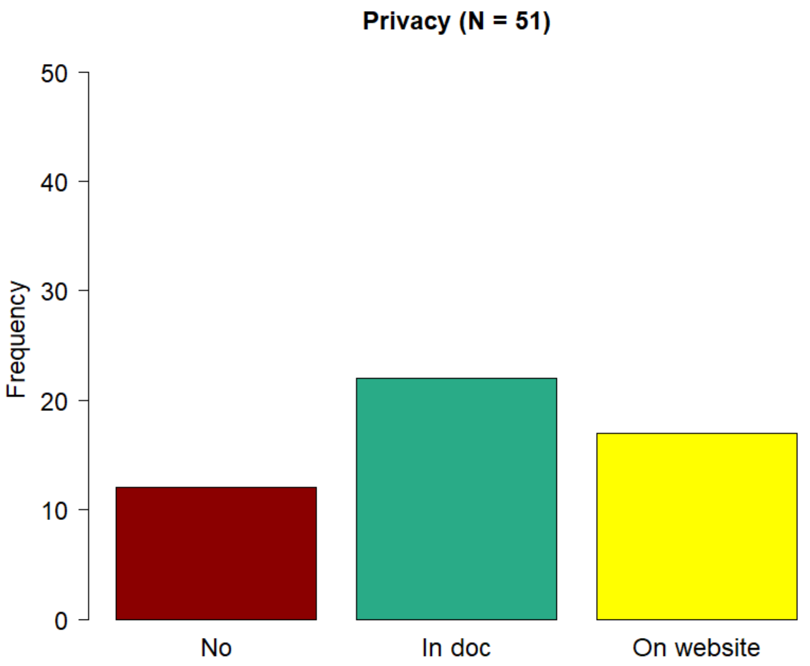

Governance - Patient representation (N = 32)

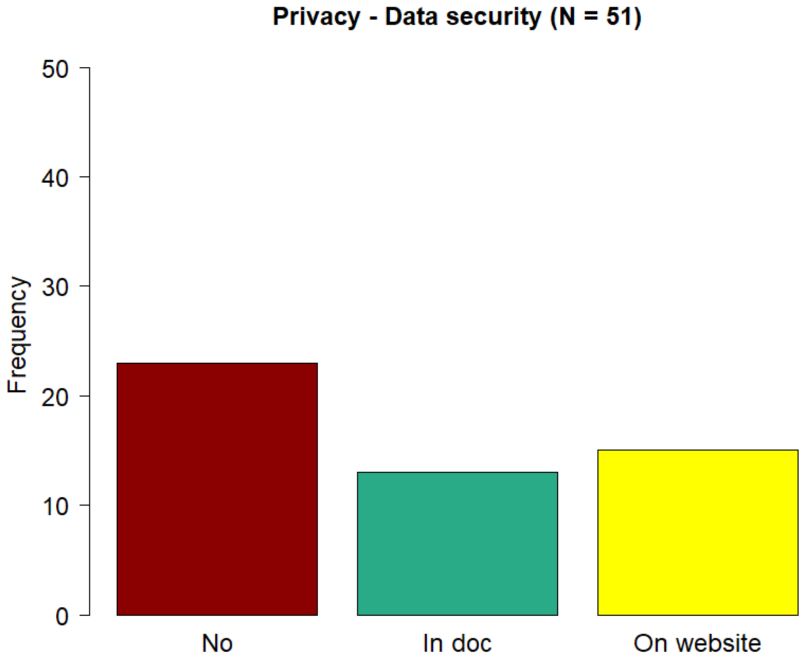

Governance - Individual responsibilities (N = 32)

Funding


Funding (N = 51)
Frequency
0
10
20
30
40
50
No
Yes
Funding - Influence (N = 26)
Frequency
0
5
10
15
20
25
No
Yes

Privacy & Data security





Conclusions Study 2

- Registries provide basic ethics information, but fail to mention important details that are emphasized in existing guidelines.

- Limitation: We did not assess actual practices
- Open question: Do the guidelines really map onto patient preferences?

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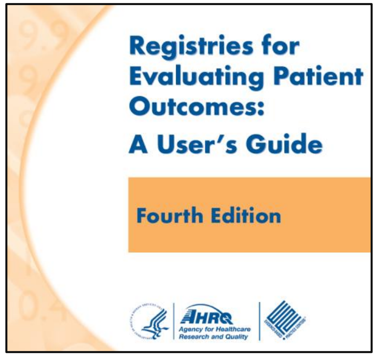

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AHRQ Agency for Healthcare Research and Quality

Overarching conclusions

- Patient registries need to cater to the preferences of patients because without patients there are no patient registries

- Do registries need to provide more (detailed) information?
  - No: Trust as a heuristic
  - Yes: Information creates trust