Patient engagement & research ethics: tensions and opportunities

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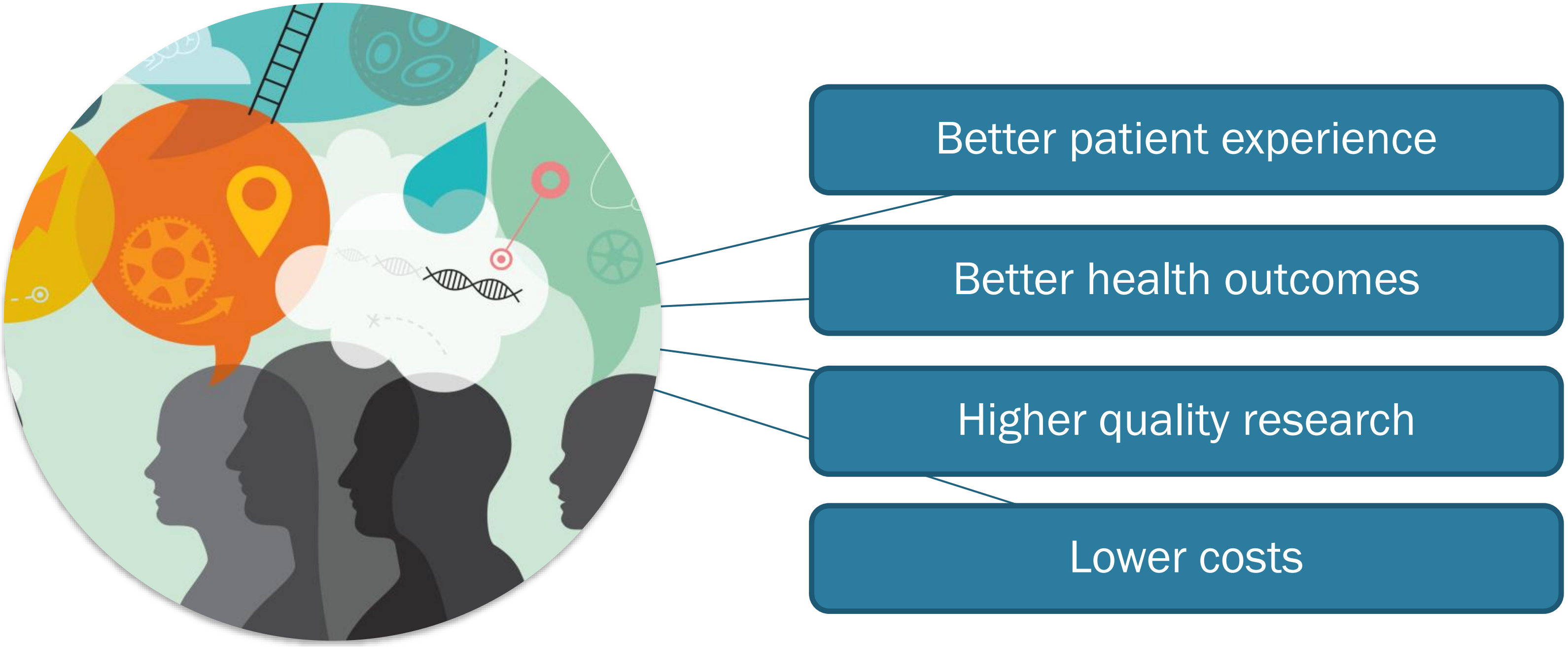
The benefits of engagement



- Better patient experience
- Better health outcomes
- Higher quality research
- Lower costs

"It was a bit of a watershed moment for me to go from being a lay medical grant reviewer to someone whose name was appearing as a team member on a research grant proposal. I will never forget how that felt to see my name on those papers. [...] It [...] meant a lot to me to be asked and included." L.L., 2016

When is patient engagement relevant?

Design

- Methodology
- Outcome
- measures
- Steering
- committee

Recruitment

- Methods
- Outreach

Data collection

- Research participants
- Peer data collection

Data analysis

- Member checking
- Interpretation

Dissemination

- Creation of KT materials
- Dissemination plan
- Active dissemination

The (unique?) case of dementia

Challenges	Strategies
Verbal communication impairment	Personalized methodology
Memory loss	Greater flexibility
Decision-making capacity	Preliminary meetings with person & carer
Emotional disposition	Research training

Hubbard G et al. 2003

Capturing the voice of the dementia patient community:

a sample initiative

Patient engagement activity setting

- 2016 Alzheimer Update, hosted by UBCH-CARD
- 370 attendees
- 15-minute interactive session, “the story of Pat”
- Average of 190 answers/question during session
- 160 placemat surveys

Priorities in patient engagement

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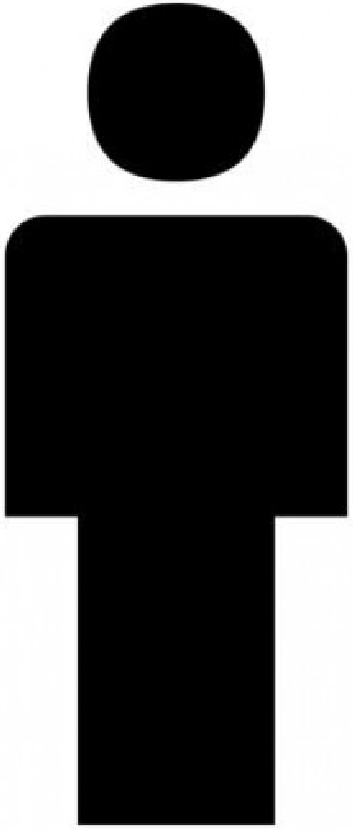
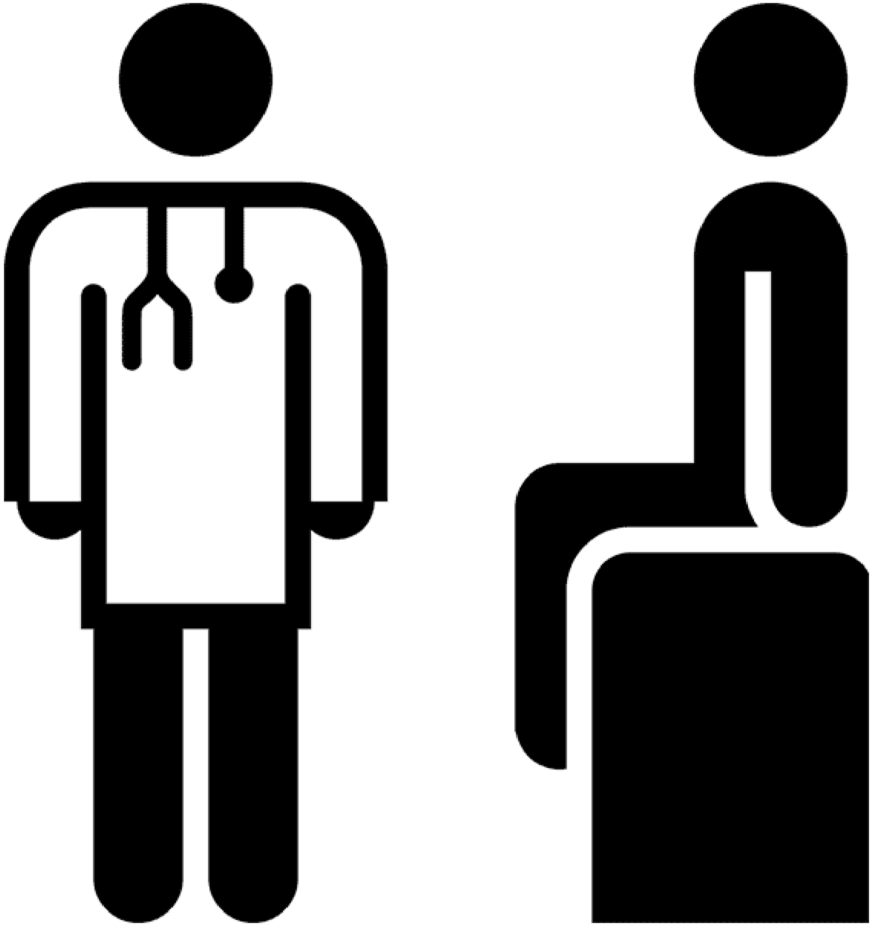
This is Pat.



Pat was just diagnosed with **Alzheimer disease** at the
UBC Hospital Clinic for Alzheimer
Disease and Related Disorders.

Pat is invited to participate in research.



Pat’s doctor mentions an ongoing clinical trial for a new drug to treat Alzheimer disease.

What do you think is the best reason to participate in research?

A. Pat will help scientists to **better understand** Alzheimer

B. Pat **might benefit** from the experimental treatment

C. Pat will **help future generations** with Alzheimer

D. Pat will be **followed more closely** by a doctor

E. I **don’t think Pat should** participate in research

What do you think is the **best reason** to participate in research?

A.	Pat will help scientists to **better understand** Alzheimer	30%
B.	Pat **might benefit** from the experimental treatment	**35%**
C.	Pat will **help future generations** with Alzheimer	26%
D.	Pat will be **followed more closely** by a doctor	9%
E.	I **don’t think Pat should** participate in research	0%

Therapeutic misconception

- Majority of dementia research is non-therapeutic, despite there being a therapeutic intention
- No difference in long-term outcomes between AD patients who participate in clinical trials and those who do not
- How can we mitigate therapeutic misconception?

Berghmans RLP & Meulen RHJT 1995; Albert SM et al 1997

What do you think is the **biggest obstacle** to participating in research?

A. Learning about **opportunities** to participate
B. The **fear** of undergoing all the tests
C. The possibility of experiencing **side effects**
D. The **cost and inconvenience** of traveling to the clinic

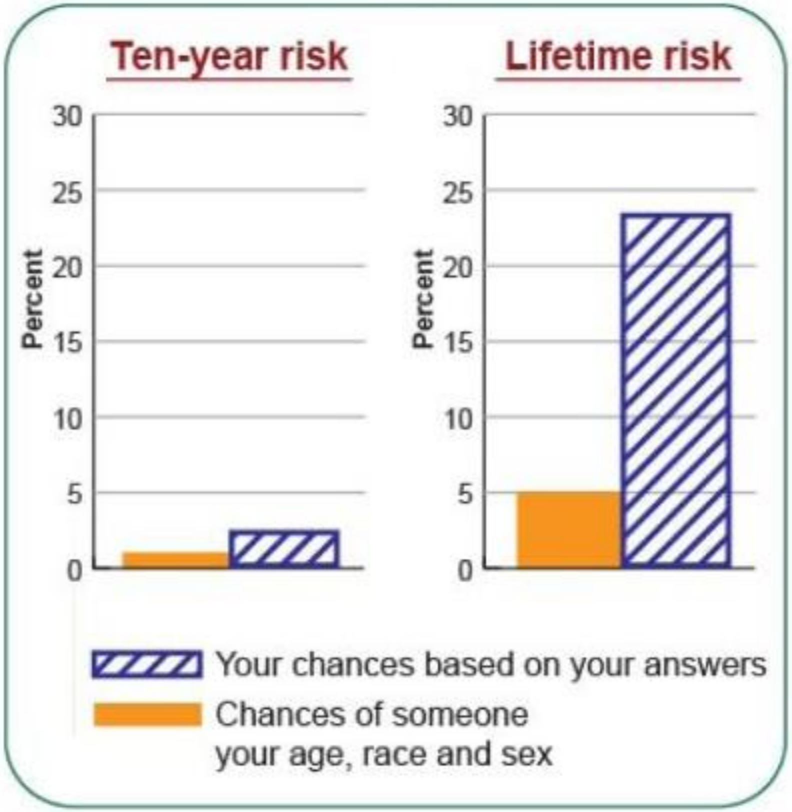
What do you think is the **biggest obstacle** to participating in research?

A. Learning about **opportunities** to participate	34%
B. The **fear** of undergoing all the tests	13%
C. The possibility of experiencing **side effects**	**38%**
D. The **cost and inconvenience** of traveling to the clinic	16%

Risk communication

- Many people do not understand risk and often misinterpret graphical displays of risk and associated terminology

- How can we improve risk communication in research?



Johnson CM & Shaw RJ 2012

Pat decides to enroll.

Before starting the study, Pat must give an informed consent: an agreement to participate based on the knowledge of the possible risks and benefits of the research.

If you were Pat

Would you prefer to learn about the risks and the benefits of the study by:

A. Discussing with your **doctor**
B. Discussing with the **research coordinator**
C. Reading a **form**
D. Watching a **video**

If you were Pat

Would you prefer to learn about the risks and the benefits of the study by:

A. Discussing with your **doctor**	24%
B. Discussing with the **research coordinator**	**60%**
C. Reading a **form**	4%
D. Watching a **video**	12%

Pat learns that s/he may not benefit from the research, but that there are risks.

How much risk do you think would be **acceptable**?

A. A chance of a **minor side effects** such as a stomachache
B. A chance of moderate **side effects** such as headache
C. A chance of **severe side effects** such as stroke
D. If there are any risks, Pat **should not participate** in the study

Pat learns that s/he may not benefit from the research, but that there are risks.

How much risk do you think would be **acceptable**?

A.	A chance of a **minor side effects** such as a stomachache	27%
B.	A chance of moderate **side effects** such as headache	**63%**
C.	A chance of **severe side effects** such as stroke	4%
D.	If there are any risks, Pat **should not participate** in the study	5%

Risk tolerance

- Linked to risk communication
- Evidence is mixed – depends on the population
- Balance between risk and magnitude of benefit, but… therapeutic misconception!

Pat agrees to participate.

- We have some questions for you about data banking.
- Please take a minute to answer the survey on your placemat during the break.
- We will collect them at the end of the morning.
- Thank you!

Share your opinion about research! Please answer the two questions below.

Question 1: I would be comfortable sharing this type of information with researchers, provided my name is not associated with it (check **all** that apply):

- My blood ○
- My DNA ○
- Images of my brain ○
- Images of my body ○
- My medical history ○
- My family history ○

Question 2: When you participate in research, who do you think researchers should share your data with? (check **all** that apply)

- ○ Other Canadian researchers working on Alzheimer disease
- ○ Researchers from outside of Canada working on Alzheimer disease
- ○ Other Canadian researchers working on other topics
- ○ Researchers from outside of Canada working on other topics
- ○ Companies in the pharmaceutical industry
- ○ Companies in other industries
- ○ Not-for-profit organizations

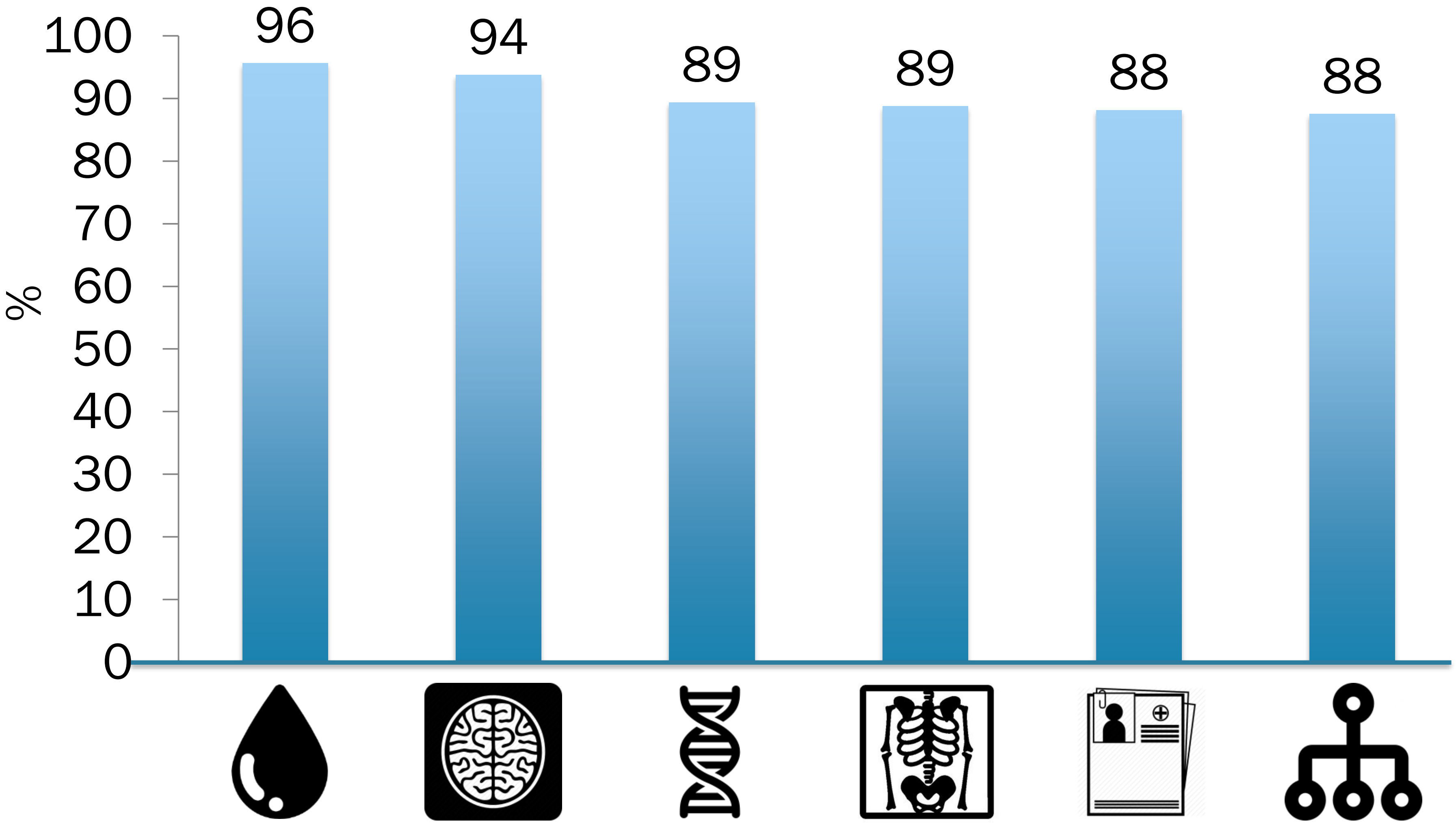
Thank you! Please leave the survey at your desk – we will pick them up.

Djavad Mowafaghian
CENTRE FOR BRAIN HEALTH

NATIONAL CORE FOR NEUROETHICS
LA NEUROÉTHIQUE
THE UNIVERSITY OF BRITISH COLUMBIA

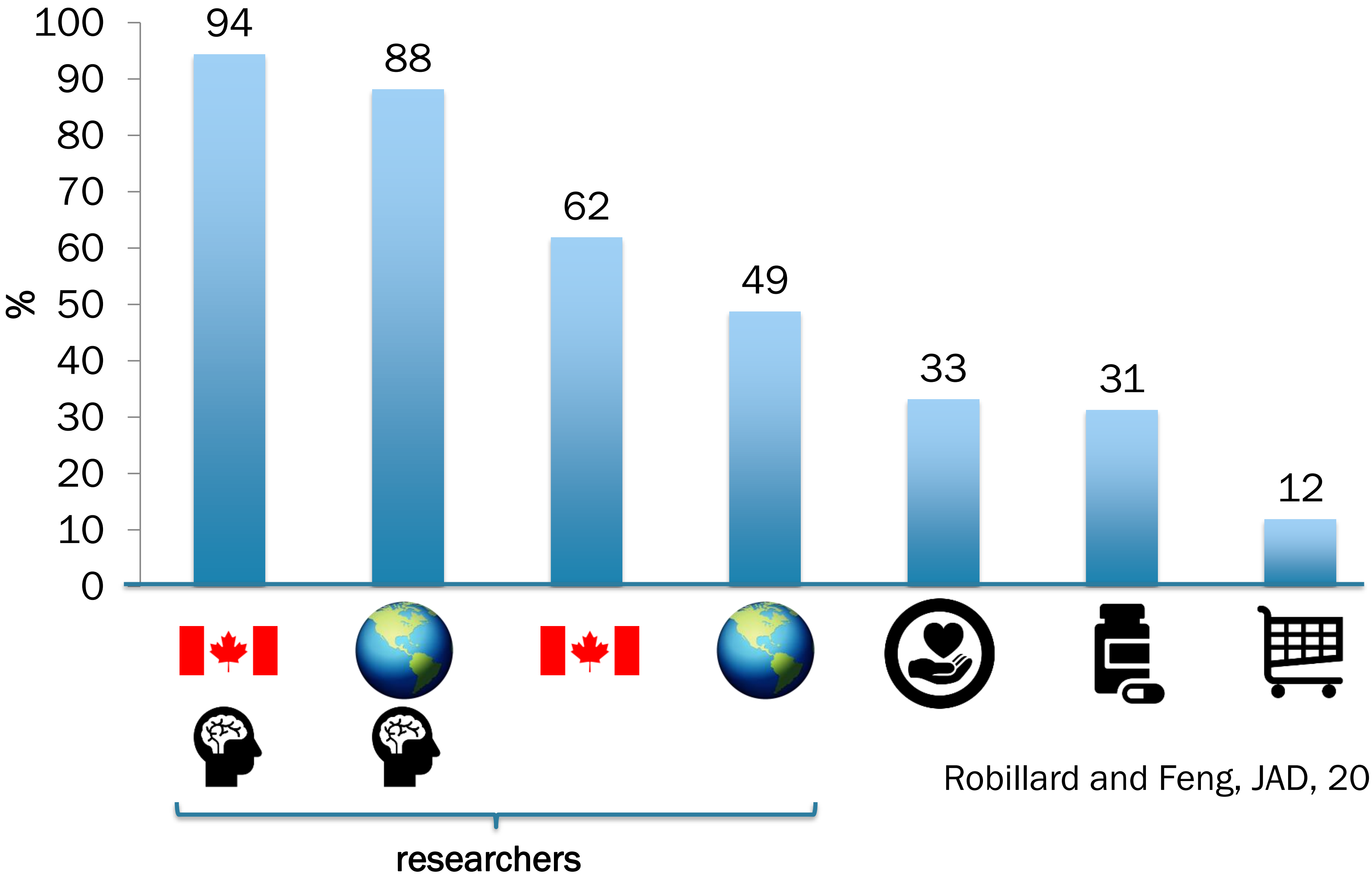
UBC

Placemat survey results



Robillard and Feng, JAD, 2017

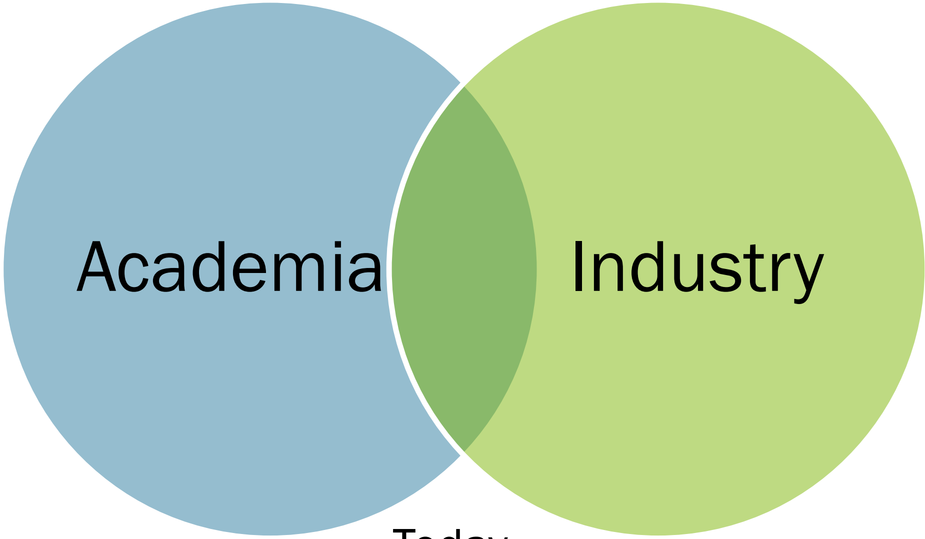
Placemat survey results



Robillard and Feng, JAD, 2017

Trust

In the olden days



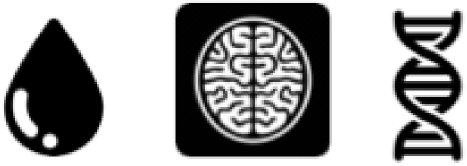
Today

Should we/how can we rebuild trust in the industry?

Pat undergoes some tests.

If you were Pat, would you want to know the results from the tests **for research purposes**?

A. Yes, I want results from **all the tests.**
B. I only want the results **if they provide information I can act on.**
C. No**, I don't want the results** from the tests.



Pat undergoes some tests.

If you were Pat, would you want to know the results from the tests **for research purposes**?

A.	Yes, I want results from **all the tests.**	**74%**
B.	I only want the results **if they provide information I can act on.**	26%
C.	No, **I don’t want the results** from the tests.	0%

Return of results

- REVEAL study: return of results not too stressful, not too impactful either
- What are the downsides of providing test results?
- How can we realistically mitigate these potential harms?

The UBC researchers would like to **share information** about research participants like Pat with other researchers.

How do you think the data should be shared?

A. **Anyone** should be able to access the data

B. **Any researcher** should be able to access the data

C. Researchers who want to use the data should **apply to a committee**

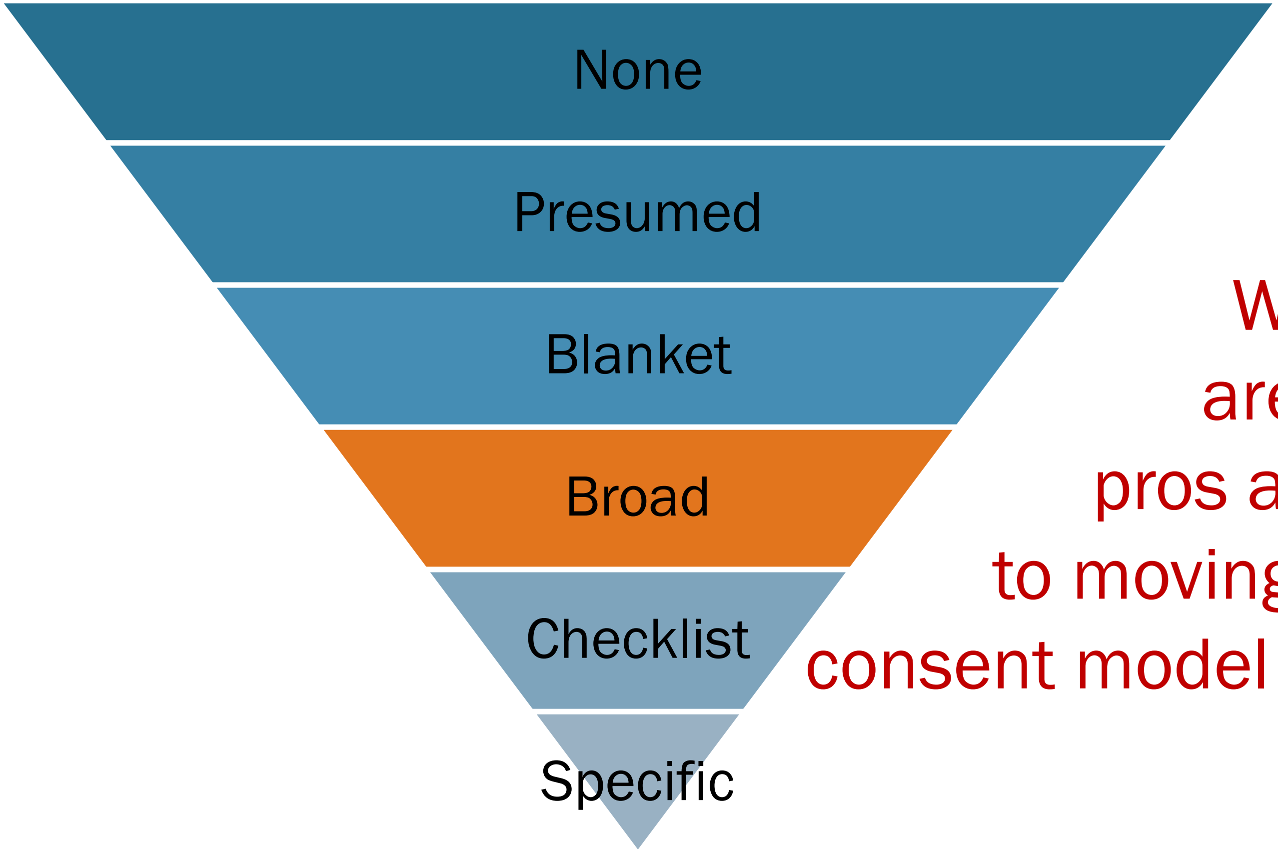
D. Researchers who want to use the data should **obtain consent directly from Pat**

E. **No one** outside of the original study should be able to use the data

How do you think the data **should be shared?**

A.	**Anyone** should be able to access the data	19%
B.	**Any researcher** should be able to access the data	**59%**
C.	Researchers who want to use the data should **apply to a committee**	6%
D.	Researchers who want to use the data should **obtain consent directly from Pat**	14%
E.	**No one** outside of the original study should be able to use the data	2%

The spectrum of consent



None

Presumed

Blanket

Broad

Checklist

Specific

What
are the
pros and cons
to moving to a broad
consent model for data sharing?

Let’s set the agenda

Which of the issues Pat faced do you think is **most important**?

A. Finding ways to **maximize research participation**
B. Improving the **consent** process
C. Determining **how much risk** is acceptable
D. Creating policies for how to **return test results**
E. Improving how we **share data**

Let's set the agenda

Which of the issues Pat faced do you think is **most important**?

A. Finding ways to **maximize research participation**	**47%**
B. Improving the **consent** process	3%
C. Determining **how much risk** is acceptable	25%
D. Creating policies for how to **return test results**	4%
E. Improving how we **share data**	21%

Summary

Ethics grounded in theory

Empirical evidence

Ethics grounded in needs and wishes of patient communities

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Patient engagement

QI or research?

Acknowledgements

2016 Alzheimer Forum participants for sharing their views and preferences about the research process

Trainees

Tanya Feng

Arlo Sporn

Jessica Jun

Jen-Ai Lai

Monica Ta

Julia Wu

Collaborators

Dr. Sherri Hayden

Anne Lyle

AGEWELL
Canada's technology and aging network

CCNA
Canadian Consortium on Neurodegeneration in Aging

CCNV
Consortium canadien en neurodégénérescence associée au vieillissement

CIHR IRSC
Canadian Institutes of Health Research
Instituts de recherche en santé du Canada

Vancouver CoastalHealth
Promoting wellness. Ensuring care.

BC Children's Hospital™

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