



An Australian Government Initiative

DEMENTIA RESEARCH

Participating in Dementia Research: Making the Decision.

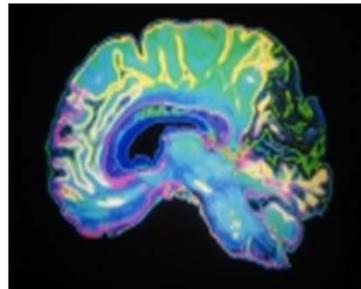
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Translating dementia research into practice

Dementia: An international issue for humanity



Definitions

- ***“Decisional capacity is a precious component of personhood and is progressively diminished in dementia’.***¹
- **The ability to continue to make autonomous decisions about everyday matters and important issues²**
- **The abilities related to decisions³**
- **“Something I don’t want to lose” (Madge, 89)**
“ Having my say” (Louise, 77)
“ You’ve still got all your marbles” (Joe, 88)

¹ Beattie, E.R.A. (2009) Research Participation of Individuals with Dementia: Decisional Capacity, Informed Consent, and Considerations for Nurse Investigators. *Research in Gerontological Nursing*, 2 (2)

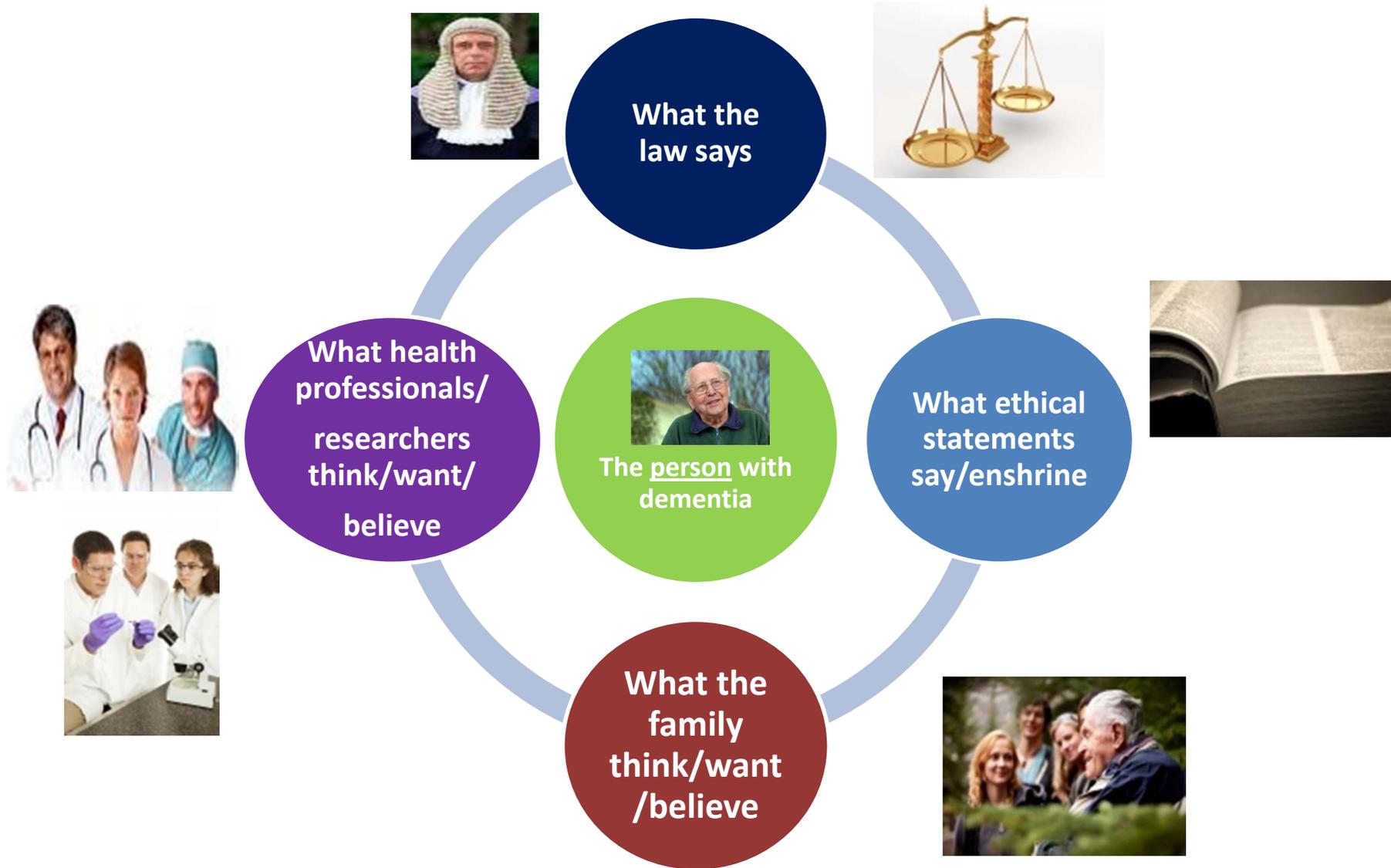
² Appelbaum, P.S. 2007. “Assessment of Patient's Competence to Consent to Treatment.” *New England Journal of Medicine*, 357:1834-40.

³ Buchanan, Alec. 2004. “Mental Capacity, Legal Competence and Consent.” *Journal of the Royal Society of Medicine*, 920: 415-420.

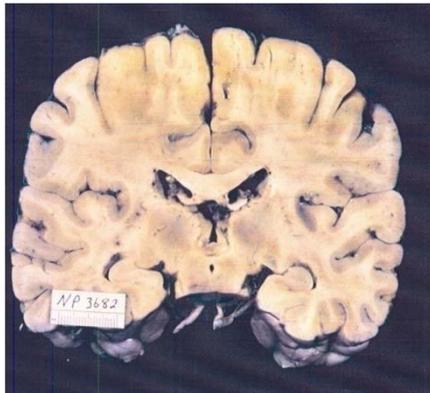
What are we talking about?



Complex!



Why is it complex?



Dementia causes progressive impairment of critical cognitive skills that underpin the ability to make decisions

BUT

Not immediately upon getting the disease
Not for all decisions all the time

?



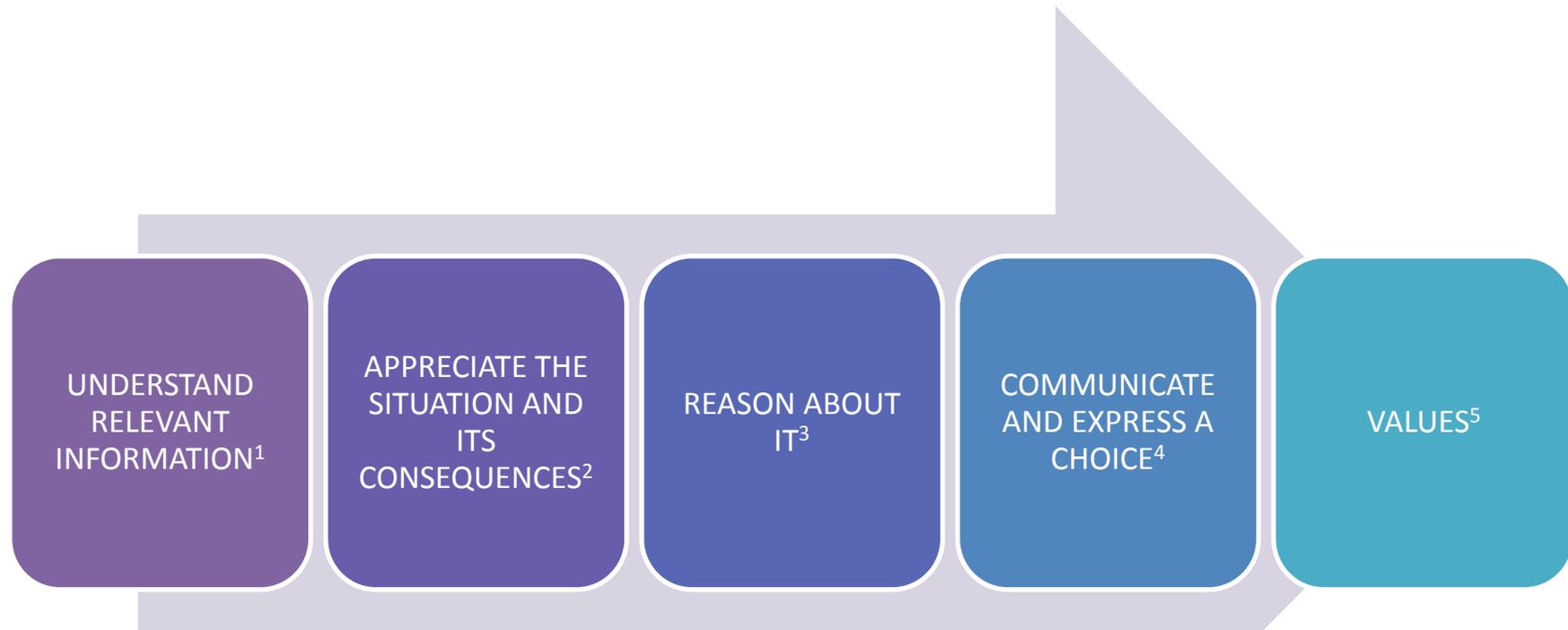
Pre-diagnosis

Diagnosis

Death



Components of decision-making capacity



(Grisso & Appelbaum 1998, 37-42¹⁻⁴; Buchanan & Brock, 1987, 24-25⁵)

A simpler view - the 4 C's

- *Context*

Does the person with dementia understand the situation they are facing?

- *Choices*

Does the person with dementia understand their range of options?

- *Consequences*

Does the person with dementia understand the possible ramifications of choosing various options?

- *Consistency*

Does the person with dementia fluctuate in their understanding of choices?

Here and There

The USA

- Regulations allow research with adults with impaired decisional capacity based on consent by their legally authorized representative [LAR]
- Regulations defer to the states for defining LARs, and few states have done so
- Guidance about how to enhance the Informed Consent process for such individuals
- Specific ASSENT requirement
- There is no consensus on how much special protection is needed when people are enrolled in surrogate-based research (SBR)

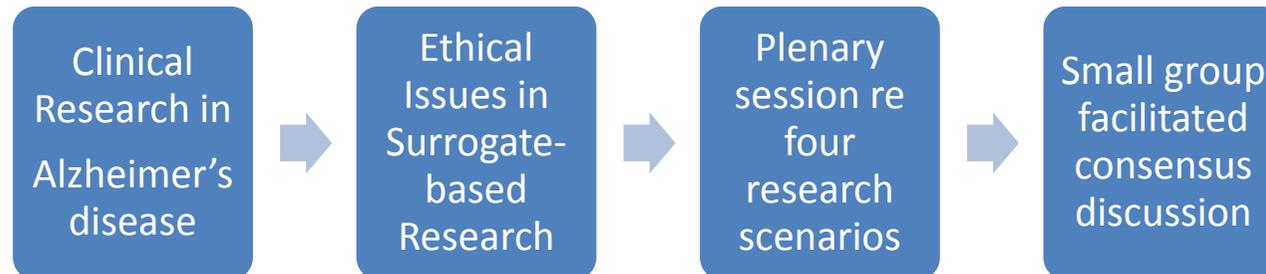
Australia

- National Ethics Statement
- Proxy (surrogate) status for research participation decisions → Power of Attorney for adults with impaired decisional capacity
- Limited specific instructions about how adults with decision making limitations should be protected
- No specific guidance about how to enhance the Informed Consent process for such individuals
- No specific ASSENT requirement
- No existing mechanism for discussion about special protection when people are enrolled in research for which they did not make the decision.

Why and Who

- **Research involving incapacitated persons with dementia entails complex scientific, legal and ethical issues**
- **Traditional surveys of views on the ethics of such research is challenging**
- **We assessed the impact of democratic deliberation (DD), involving balanced, detailed education and peer deliberation, on the views of carers of persons with dementia.**
- **178 current and recent carers in the US.**
- **Half in an INTERVENTION group; Half in a CONTROL group.**
- **Recruited using the mailing lists of the local Alzheimer Association (AA) and an AD research centre, AA chapter newsletter, University Research web portal**

- **Participants were randomized to either a survey-only group (control group) or to the DD session group (DD group)**
- **Those in the DD group came for a full day**



What we did

- We assessed the acceptability of family-surrogate consent for dementia research (“surrogate-based research”) from two perspectives:
 1. a whole of society [societal policy] perspective
 2. the personal perspectives of deciding for a loved one or for oneself (surrogate and self-perspectives)
- assessed at baseline, immediately post-DD session, and 1 month after DD date, for four research scenarios of varying risk-benefit profiles.
- Control group did survey only, related to their views.

The Four Research Studies

- Varied and increasing levels of risk of harm to the person with dementia
- A lumbar puncture study
- A randomized clinical trial (RCT) for a new medication,
- A vaccine trial,
- An early-phase gene-transfer trial

The Survey

- “Suppose you wanted to give a close family member instructions for the future, in case you ever became unable to make decisions for yourself. Would you say you would want to participate in the study?” (self perspective);
- “Suppose you have a loved one who has Alzheimer’s disease and cannot make decisions for himself or herself. Would you give permission for your loved one to be part of this study?” (surrogate perspective)
- “How much freedom or leeway would you give the close family member to go against your preference, and instead enroll/not enroll you in the study?” (self perspective) **no leeway**, **some leeway**, or **complete leeway**

The Outcomes

- At baseline, a majority in both the DD and control groups supported a policy of family consent for dementia research in all research scenarios.
- The support for a policy of family consent for surrogate-based research increased in the DD group, but not in the control group. The change in the DD group was maintained 1 month later.
- In the DD group, there were transient changes in attitudes from surrogate or self-perspectives.
- In the control group, there were no changes from baseline in attitude toward surrogate consent from any perspective.

Intensive, balanced, and accurate education, along with peer deliberation provided by democratic deliberation, led to a sustained increase in support for a societal policy of family consent in dementia research among those responsible for dementia patients.

What next?

- **DCRC:CC studies in progress and planned**
 1. **What does decisional capacity mean for people with dementia and their carers?**
 2. **How do people with dementia and their carers make decisions about end of life issues and what support do they need to do so?**
 3. **How do people with dementia and their carers make decisions about research participation and what support do they need to do so?**

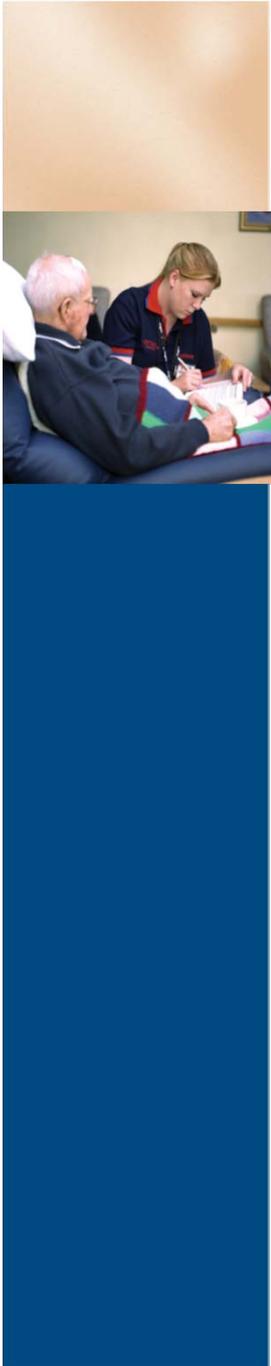
Rights and Questions

- Nature and purpose
- Explanation of procedures
- Discomfort and risks
- Benefits , if any
- Other studies?
- Support and treatment if harmed?
- Right to ask questions
- Quit at any time without penalty
- Receive a signed, data copy of what you consented to
- Make an informed decision without feeling pressure, obligation or coercion
- Hear about the general results
- What is the study trying to find out?
- Why would I want to do this?
- What kinds of tests/exams do I have to have?
- Will there be any unpleasant side effects
- When, how, how often?
- Is this study safe?
- \$\$\$ to me? Any perks?
- Do I feel any pressure obligation or coercion from the researcher?
- What if I change my mind?
- How will I/we know if he/she changes mind?
- How will I hear about results?



Macarthur Capacity Assessment Tool Clinical Research: MacCAT-CR

- Appelbaum & Grisso (2001)
- Duration: 15-30 minutes
- Semi structured interview
- Solid validity and reliability data
- Most empirical support
- Standardized: Uses hypothetical vignettes
- Addresses all four elements of decision making capacity
- Training is required to administer and published manual provides scoring guidelines
- Must be scored during the interview so appropriate follow up questions can be asked or requested for clarification elicited



Evaluation to Consent Measure (ESC)

- **Developed by Resnick et al. (2007)**
- **5-item questionnaire after education about the research project but before the formal consent process**
- **Duration: 5-10 minutes (brief) interview style**
- **Highly correlated with MacCAT-CR**
- **Assesses only the domain of understanding**
- **Good inter-rater reliability and evidence of reliability and validity**
- **Specifies text of probe questions but allows disclosures and acceptable responses to be tailored to administer and score**

Psychometric Testing

- MMSE no longer acceptable: too global and broad
- Assessment must be more person centred. Tests of decisional capacity tend to be exclusively cognitive in nature and orientation.
- Specific to situations, time, actual care decision to be made and the patient.
- MacCAT-T not designed to incorporate reasons and values. Tan et al. (2003) study highlights need for situational and person centred approach