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Ethical and Regulatory Issues in Dementia Research

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3 Key Issues

1. **Surrogate Consent**

1. **Preventive Research**

2. **Biobanks and notification**

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1. Surrogate Consent for Research in US

Permitted by federal law by "legally authorized representative"

- Defined by state laws
- Implemented by IRBs
- Variable, unclear, problematic

Gong et al, “Surrogate Consent” 2010, Critical Care Medicine

- Surveyed US IRBs regarding:
  - Permission for surrogate consent
  - Evaluation of risk level
  - Use of protections for vulnerable adults
  - Permission for non-beneficial research

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Gong, cont'd

- 6% ban all surrogate research
- 22% ban adult children consent
- 15 % ban non-beneficial research, regardless of risk level

- Random risk assessment
- Wide variability of protections
- No better function with state laws

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Current Status of Surrogate Consent Research

- Huge variability, no consensus
- Significant impediment to all dementia research
- Unclear level of effective protection
- Lack of clear federal guidance, state compliance

Better news for the future?

- Research on community values:
  - Support for surrogate consent
  - Support for dementia research
- Best practices:
  - Assessing consent capacity
  - Appointing surrogate
  - Assent/dissent
- Less clear:
  - Consent monitor

2. Preventive Research

- Opposite problem of patients without capacity
- Patients without symptoms

- US FDA regulations generally require proof of improved function to approve new drug

- How to apply to preventive medication, when success means continued lack of symptoms?

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Challenges of preventive research

- Little risk acceptable for well individuals
- Long term study required
- Large study group needed, with control group

- Compare to:
  - Vaccine research
  - HIV prevention
  - Hypertension

FDA proposal

- Permit interim measures
  - Biomarkers
  - Cognitive testing alone
  - Combined cognitive and functional measures
- Alternative trial models:
  - NY Times: anti-pharma

Reaction to FDA proposal

- Strong Support:
  - Alzheimer's organizations
  - Researchers in industry, academe
  - LEAD: 57 member coalition pro AD research
- Criticism:
  - NY Times Op Ed: "loosening guidelines"
  - Public Citizen: "disturbing,"
    - lack of non-pharm emphasis

3. Biobanks and data return

- Biobank proliferation
  - Stored/Leftover samples
  - Images
  - Clinical information
- Data Protection, Privacy
- Trust of community in research institution

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Biobanks and duty to community

- Multiple NIH funded studies
- Most biobanks (US and internationally) have no clear policy on return of research results and incidental findings
- Human subjects research and identifiability
- Proposed obligation to notify participants of:
  - Valid clinical data
  - Substantial risk related to health
  - Actionable

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Challenges in informing biobank participants of research results

- Raging debate on feasibility, ethics
- IF v IRR
- Define data requiring reporting
- Consent: standards, practices vary
- Primary research or secondary also?
- Retesting, with CLIA lab standards
- Counseling
- Expense

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23andMe as model

- Client pays for access to own data, notification
- Blanket consent for reuse of material
- What kills academic research sustains innovative corporation
- Room for new model for academic biobank?
  - Open access to new findings
  - Registration for re-contact, newsletters
  - Community engagement

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