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The Danish National Committee on Biomedical Research Ethics

The Role of Research Ethics Committees

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Chairman, National Ethical Committee, 2006 -

A Danish dilemma

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To conform -

or not to conform

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Conclusions I be sure to

- Distinguish between wet and dry registers
- Protect patient confidentiality, enforce pseudonymization
- Protect registers (dry) from distortion
- Allow for the revolution in bioinformatics
- Use informed consent, where it matters – wet
- Strengthen data security

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Current status Danmark

- Distinction between dry (databases) and wet (biobanks) registers
- Establishing and
- any use of dry registers, incl research, decided by Data Safety Board, since 2003 no ethical approval of use for research
- Establishing biobanks (research bb, clinical bb) decided by Data Safety Board,
- use for research must have ethical approval

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Why differentiate between wet and dry registers?

- Because requirements for consent are different
- The uncle test
  - Biobank material: ask for permission
  - Pseudonymized, dry data: only data safety concerns, if any
- Present Danish legislation is based on this distinction

Dry registers

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- **Danish registers are unique**
  - **Uniqe CPR numbers since 1965**

- **Access is possible to data from many different sources, collected for all sorts of purposes**
  - Connected via CPR
  - Pseudonymized before delivery to researcher

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Why is informed consent irrelevant in research on dry registers?

Rationale: Common sense

- Autonomi/selfdetermination is exercised in the patient's decisions about his own diagnostics and treatment AND participation in research projects as subject or as source of tissue

BUT

- Autonomy/selfdetermination does not apply to the historical record of the patient's interaction with the health care system and healthcare personnel

Why is it so?

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- Autonomy is forward directed, and the sovereignty of the patient is unquestioned

WHEREAS

- the health care record is a historical and legal document, containing documentation of clinical data, and important evidence if disputes about adverse events arise
- and pseudonymized, electronically accessible healthcare data is the ”clinical experience” of the 21st century

BUT OF COURSE

- the patient decides acces to his IDENTIFIABLE data

The crucial point

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- **FACT**: When dry data is produced from wet stage, it happens with the patient's consent, either to diagnosis and treatment, or to research.

- **ANALYSIS:** Subsequently the dry data is part of a common domain, where a patient is entitled to privacy but not to sovereignty regarding data substance or use

- **SUGGESTION FROM MANY SIDES:** Protection of patient interests and oversight can be provided by research ethical committees.

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Protection

We must protect patients from disclosure of their identifiable data

We need to protect our registers from distorsion due to incompleteness and biased withdrawal

Danish dry registers in important studies

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- Abortion and risk of breast cancer
- MFR vaccination and autism
- Twin studies

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A Modest (Real Estate) Proposal

So Mr. Big Thinker has a way out: the US should dump the National Children's Study and, instead, buy Denmark. I'm talking the whole country. The advantages should be obvious. The Danes already have a successful 100,000-baby cohort, plus (pay attention here, US) a system of health and death registries that allows complete lifetime follow-up of the cohort at virtually no added expense. Denmark provides everything an epidemiologist could ask for – and the US could stop banging its head against the wall

Where does the US find the cash sell Florida.

Paediatric and Perinatal Epidemiology 2011

View points that should not be taken into account

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- Demanding informed consent before use of pseudonymized data
- Neglecting that demand for informed consent distorts datasets
- Believing that worry about data safety is a relevant argument for informed consent
- Believing that controlled access to psedonymized data compromizes patients' privacy

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What do we ask for

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- **Rules must be consistent across domains:** Routine clinical work, quality assurance, research
- **Effective pseudonymization and improved data safety**
- **Efficient gathering and use of clinical experience**
- **Compatible with technological developement:** Genomic medicine; big data

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What do we need to do ?

In Danmark: A limited number of adjustments of current regulation

- Emphasize the dry/wet distinction
- Reintroduce requirement for ethical approval in some registry research projects
- Drop requirements for destruction of data (persondataloven) and adjust rules concerning access in relation to purpose

n wet and dry registers

Comments to draft document

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This document concerns access to health data and biobanks not only for research puposes, but for all other purposes

This is much more challenging, but if handled carefully also of great merit

Data acces as part of clinical practice is directed by the potential benefit to patients

Research projects are for the common good, research subjects rarely benefit directly – requirements are more stringent

n wet and dry registers

Comments to draft document

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Clarify

3 . . and associated data . .

13 . . as individuals . .

18 & 20 . . .dedicated . .

Change required

3 . . both give rise to the same concerns . .

9, 15 & 17 . . identifiable . .

15 . . given the opportunity to decide . .

. . who will have . . .

19 . . anonymous . .

21 . . approve all use . . .

26.1 & 26.3 . . purpose . . length of time

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