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Ethical issues in registry-based research

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My presentation

- Research ethics generally: balancing of values, norms & interests
- What's in the balance in registry research?
 - Value of research, respect for autonomy & personal integrity
- Potential threats to valuable registry research
- Suggestions for the future

Research ethics: balancing interests

- E.g. in Declaration of Helsinki: two potentially conflicting interests: protecting research subjects (e.g. protecting personal data) and research interests (including societal gains in the longer run)
- In the balance on a general ethical level: **consequences** (such as health and quality of life) and **restrictions on actions**
- Limits to what can be done to individuals for the good of science
 - Unacceptable harms and risk exposures
 - Disrespectful behavior (“with respect for human dignity”)
- Research ethics generally: no “one solution fits all” – what you should do depends on what’s in the balance in each specific case
 - Proposals that there are simple solutions to this ‘balancing’ issue imply one-sidedness regarding relevant interests

Costs: autonomy and personal integrity

- **No direct physical risk** with participation in registry research
- Little risk of harm due to information getting into the wrong hands
- “Moral cost”: registry research without informed consent means not respecting autonomy and personal integrity interests
- Respect for **autonomy** – respect for the individual’s right to decide about things that particularly concern that individual
 - Standard cases: individual to say yes/no to offered examinations and treatments in healthcare; yes/no to offered participation in research
- Respect for **personal integrity**: involves respect for a personal sphere free from uninvited intrusion or interference
 - Standard case: the individual gets to decide who should access his/her personal information

Costs: autonomy and personal integrity (II)

- The Swedish practice of approving registry research without informed consent involves a practical judgment of the relative importance of rights to autonomy and personal integrity compared to that of research (if it is a proper ethical judgment)
 - Autonomy/integrity interests don't go away just because we have a practice to let them weigh lighter against research interests
 - even if the practice is ethically acceptable, there is a cost involved
 - Present practices can be questioned – maybe they are wrong; maybe some registry research should be approved and others not
 - Regardless, some humility is in place: present practices at the mercy of the silent approval of society – this attitude may change quickly

Potential threats to valuable registry research

- **Singlemindedness of EU authorities**
 - Only protection of personal data is considered, no research interests
- The General Data Protection Regulation
 - Only allow registry research with informed consent?
(suggestion that the 'research exception' be removed)
 - Right to erase personal data? Goes against good registry quality
 - Use of data only for what was initially stipulated?
 - Effects depend on the interpretation
 - A common European Data Protection Board
 - Leaves Swedish registry research at the mercy of EU
(which, in general, has a different cost-benefit ratio)

Potential threats to registry research (II)

- **Singlemindedness of Swedish authorities**
- The Swedish Data Inspection Board
 - Focus on one aspect only: interests of individuals to have sensitive personal information protected (which, in general, is good)
 - Has the final say on the handling of such information in Sweden
 - With only one interest to defend, costs to research become irrelevant to their decisions → their mission threatens registry research
- On the other hand: Swedish Committee directive Dir. 2013:8 (on registry-based research) – the explicit purpose is to see to research interests while considering the individuals' interest in protecting their personal integrity

Potential threats to registry research (III)

- Carelessness & arrogance of registry researchers
 - It is important to remember that involuntary participation in registries – and participation in registry research without informed consent has a (moral) cost
 - Registry researchers need to have a serious plan – and attitude – if people disagree with their priorities
 - Research ethics is not directed by consequentialist thinking only, in order to protect the individual from being exploited in the name of “common interests”
 - Forcing anyone to participate in research is unadvisable – and probably wrong in all but exceptional cases; electronic overview?
 - Reasonable attitude: there will be ‘business as usual’ for registry research only as long as the general public’s trust is maintained
 - You have to do your part in trying to maintain that trust

Where should you take it from here?

- Maintain that there are two kinds of interests in the balance; not only that of protecting the autonomy and personal integrity of the individual, but also an important research interest
 - This is a living political issue (in Sweden and within EU), and it is unclear how it will end
- Be open and specific about how registry-based research is valuable; “Research is important” doesn’t work for everyone
- Don’t get carried away as researchers – think in two steps:
 - Is it justifiable to promote registry research in the present way?
 - What strategy? Is the short-term ‘most research friendly’ choice also best promoting research interests in the long run – or might it be counterproductive because it opens up for massive future criticism?