Cancer control threatened by proposed European data protection legislation – counter acted by data driven advocacy

Hans H. Storm, Medical Director, Danish Cancer Society

Abstract code: 315 AO3

Disclosure of Interest: None Declared
Lancet Oncology editorial 26/11/2014

CONCORD global cancer survival

Linda C Harlan, Joan Warren, NCI USA:

“Legal and regulatory issues and privacy concern could restrict registration of cancer patients and access to data for research…

Proposed legislation seems counterproductive to the goal diminishing suffering and death from cancer…

What is gained by restricting access is unclear … the loss to society is much clearer”
Proposed privacy regulation

Substitute for Directive 95/46 EC

• INFORMED CONSENT - but derogation for health and research in articles 81.2 and 81.3

Still problematic:

• Exemption for informed consent for reasons of public interest in the area of public health if it serves a high public interest, if that research cannot possibly be carried out otherwise.

• Pseudonymisation applies
Public health studies under threat

Explicit consent difficult to obtain – millions of people to contact over several decades – already in registries

Audit
- Cancer screening programmes
- HPV vaccination programmes
- Survival & outcome research

Occupational hazards and cancer
- Nuclear power and other radiation
- EMF – mobile phone’s etc.

Environment
- Social inequality
- Risk factors identified in large groups

Hans H. Storm; Danish Cancer Society
Personal data & health research

The nature and regulation of research

Clinical – selected individuals
- Informed consent
- Scientific ethical committee system operates
- Data inspection agencies or other authorities

Epidemiological – populations
- Often involves very large if not all population
- Register based – data linkage – no contact to individuals
- Data inspection + patient right law + ethical committee

Biological data
- A combination of clinical and epidemiological

Hans H. Storm; Danish Cancer Society

Project specific
How long does it last?
Repeat for secondary use
Why not informed consent in public health research and some clinical research?

Loss of representativeness & generalization
- Avoid bias – selective loss (Low response rates)

No solid conclusions
- Need for power and statistical strength

Poor completeness
- Few cases may determine risk
- Loss in linkage may cause bias

All population
- Disproportionate effort
Who to convince the regulation proposal may cost future lives?

- European Commission Services (2 years advocacy)
- European Parliament Committee members dealing with the Commission proposal and national MEP’s
- Council of ministers – national ministers for Health, Research and Justice
- Consumer advocates – privacy advocates – population
- Networks of health and research professionals
- Ethics and data protection advocates/agencies
How?

- or what we did and continue to do!

- Explain the problem in lay terms
- Build cases on existing and completed population based studies i.e. real data – real problems – impact on health
- Visualise what will be missed, impossible and subject to wrong conclusions under a restrictive regulation
- Circulate information widely and openly
- Stick to facts, avoid “politics” and personal opinions
- Be open to counterparts arguments
Case example -
Mobile phones, Android, IPhones, IPads

• A “life” support system – communication - widely used
• Cancer risk suspected from link masts, phones etc. – EMF influence on cells in culture in labs –

AO3 315 Melbourne, 4 December 2014
Mobile phone study results

Public Health study – Denmark

• All mobile phone subscribers on file, years of use, traffic – i.e. individual exposure data.
• Several hundred thousand individuals studied.
• No increased cancer risk found!
• But imagine how life would be without wireless technology – just think of all the appliances exposing us to EMF.
Pseudonymisation – if we miss a link!

Influence of missed link to mortality – by error proportion (E. Pukkala)

Germany NRW cancer registry linkage study:

150,000 records full ID linked

Re-linked by Pseudonyms:
1% linked wrongly
2% Not linked at all

Cummulative errors!
Results of advocacy

Personal letters, “coffee” meetings, newspapers, conferences, scientific papers, debates, ministers – justice/research/health – explaining consequences for health and progress

• Huge network build – sharing information and action (ESMO; ENCR; ECL; EU research councils etc.)
• European Parliament vote - lost due to bloc vote despite MEP attempts to support a research/cancer control view
• Council negotiation seems to support our view
• Commission services support achieved(DG SANCO/Research)
• Trialogue EP; EC; CE in 2015 will determine if we were finally successful.
Thank you

Beware confidentiality issues and data protection may impede the possibility to function and to do research!