

EUROCOURSE

Optimisation of the Use of Registries for
Scientific Excellence in research



Data protection and ethicals: obstacles to cancer registry research in Europe?

Work package 2 - Danish Cancer Society (H.H.Storm)

Subcontractor: MedlawConsult (The Hague NL) (E-B v Veen)



Confidentiality & ethics



WP2; Why activities on privacy and ethics

- Confidentiality and protection of the individual is acknowledged and guarded by registries.
- Heterogeneous implementation of Directive 95/46/EC.
 - Barriers for registration and collaborative registry research is created with consequences public health and cancer control.
- We believe a dialogue and collaboration with the custodians of the Directive 95/46/EC is needed.
 - It should be based on a survey of the actual situation and include;
 - A description of various research scenarios – what is possible and what is not and what should be!
 - Take into account surveys of the public opinion.



Confidentiality & ethics



WP-2 Objectives

1. **Explore legal & ethical issues** of cancer registry activities & research alone and on linked data.
2. **Revise existing** and define a **code of conduct** (privacy & ethics) for registry based research including data quality aspects.
3. Establish an **overview of European legislation** and practice in relation to point 1 above.
4. **Identify barriers** to the use of data from Biobanks, Screening monitoring and Clinical databases with cancer registry data.
5. Develop **proposals to remove barriers in data protection** laws for public health research using registries in Europe for the benefit of public health and cancer control.
6. Establish a standing committee on data protection and ethics supervising the research use of the combined data from European cancer registries.



Confidentiality & ethics



Obstacles to conducting epidemiological research in the UK general population

Hester J T Ward, Simon N Cousens, Blaire Smith-Bathgate, Margaret Leitch, Dawn Everington, Robert G Will, Peter G Smith

BMJ 2004;329:277-9

Summary points

Issues of patient confidentiality are hampering epidemiological research

Wider debate is required about the use of medical records to identify eligible individuals

Ethics committees should weigh the benefits to society against costs to the individual when considering studies

Use of public funds should be considered as part of the cost to society if a study cannot recruit participants by the most effective method



Confidentiality & ethics



Consent, confidentiality, and the Data Protection Act

Amy Iversen, Kathleen Liddell, Nicola Fear, Matthew Hotopf, Simon Wessely

Overly strict interpretation of the law is hampering epidemiological research. Here, one research team shows why regulators and organisations holding data should adjust their approach

BMJ 2006;332:165-9

Summary points

The UK Data Protection Act (1998) is changing the way that medical research is conducted

The law allows personal information to be used and disclosed without explicit consent, subject to certain safeguards, when it is impractical to obtain consent and an important public interest is at stake

Despite this, some data controllers continue to interpret the law in a restrictive way

The main barriers to epidemiological research are that people cannot be contacted or are approached by proxies who know little about the study

Adverse events or detriment from participation in this type of research are extremely rare



Confidentiality & ethics



Results of cancer registry survey on legislation

Number of total answers	100
	The preliminary result from the report dated 30-09-2010 was based on 73 answers.
No reply from 4 countries of the 27 EU countries	Sweden, Luxembourg, The Czech Republic, Latvia.



Confidentiality & ethics



Registry description

Registry type (2.1.1) (freq)	71 Regional registry 28 National registry 1 Non population-based
Tumor specialisation (2.1.2) (freq)	91 All tumors 4 Haematopoietic 3 Digestive 1 Nervous system 1 Respiratory
Age specificity (2.1.3) (freq)	91 All ages 9 Paediatric



Confidentiality & ethics



Some results regarding law on privacy

Does the law on privacy apply to cancer registrations?	86 yes 14 no
In which <u>countries</u> does the <u>national registry</u> answer that the law on privacy do <u>not</u> apply to cancer registrations	Belgium Cypres
In which countries/regions is there a disagreement or different answers in answering "Does the law on privacy apply to cancer registrations?"	Italy (11 yes, 5 no) Spain (9 yes, 2 no) Switzerland (3 yes, 3 no) UK (3 yes, 2 no) Belgium (1 yes, 1 no)



Confidentiality & ethics



What about exemptions?

Does the law provide exemption from the requirement for consent for <u>registration</u>?	Yes: 51 No: 29
Does the law provide exemption from the requirement for consent for <u>research</u>?	Yes: 36 No: 40
Disagreement between exception for research and registration: (when answering both questions)	22 registries



Confidentiality & ethics



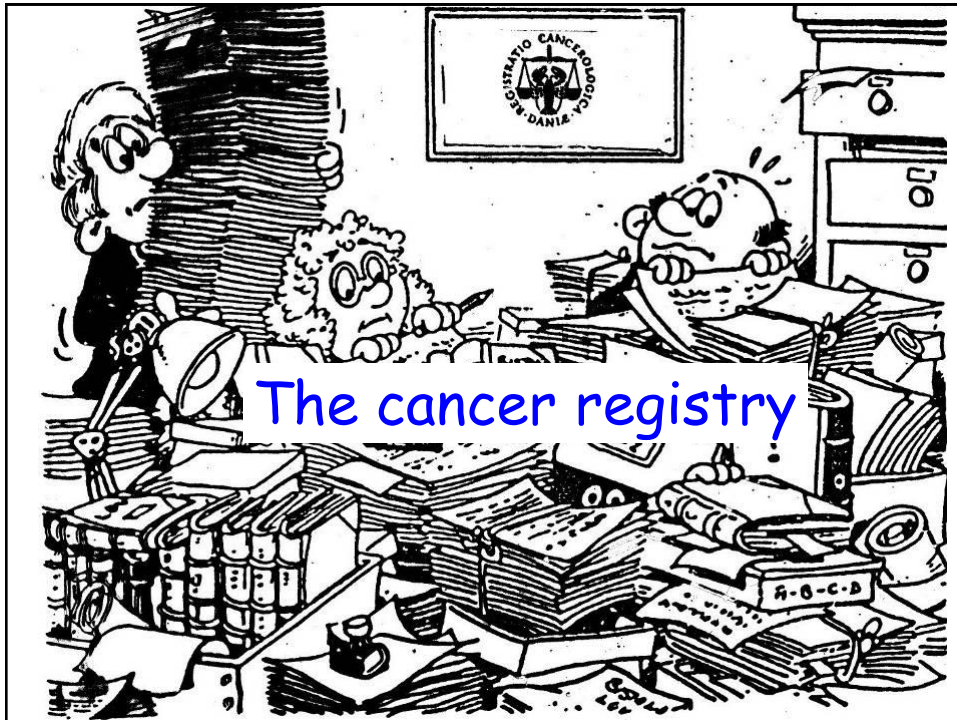
Where are the link's between

- Ethics
- Privacy/confidentiality
- Cancer registries
- Biobanks
- Screening
- Clinical databases
- Research



Confidentiality & ethics





Purpose of a cancer registry

- Accurate account of cancer in a defined population.
- Analysis of incidence and temporal changes, between geographical areas, occupations, population groups etc.

Purpose of a cancer registry

- Accurate account of cancer in a defined population.
- Analysis of incidence and temporal changes, between geographical areas, occupations, population groups etc.
- **Accurate estimates of therapeutic results in cancer (survival).**
- **Provide the basis for research.**



Confidentiality & ethics



Calum Muir quote



It is **unethical** to collect and **store data that cannot be used** or is not used for the purpose it was collected.

–

Such cancer registries or rather “data cemeteries” will be of **low quality** and useless.



Confidentiality & ethics



Ethics

- Vary in time
- Vary by place and culture
- Privacy is an integrated part
- No technical solution available!
 - Trust
 - Communication on what, why and how we do
 - Openness
 - Demonstrate awareness on ethics and confidentiality



Confidentiality & ethics



The problem

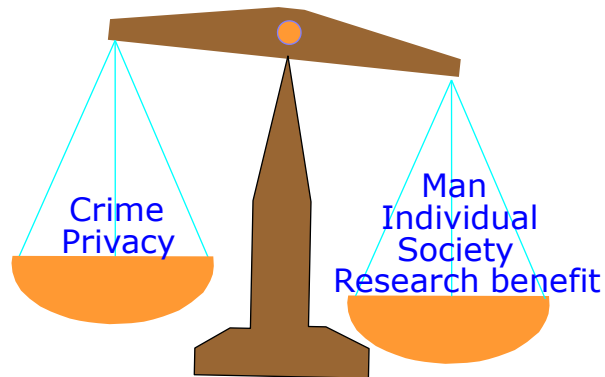
Nüremberg code 1947



Helsinki delarations



Good epi practice



Confidentiality & ethics



Data Protection Directive EC 95/46 purpose:

- 1995 (95/46/EC) Data Protection Directive – **informed consent**
- Protection of individuals on processing of personal data.
- Free movement of such data (internal market)
- Implementation date 25 October 1998



Confidentiality & ethics



Directive EC 95/46 implementation

- Definitions vary on:
 - Personal data
 - Encoded/pseudonymised data
 - Deceased persons included
 - Disclosure (German law limits to 3rd party)
 - Controller
 - Consent
 - Exception (police/journalism "terror")
 - **Research purposes** (from no safeguards to special authorization)



Confidentiality & ethics



Personal data & health 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



Confidentiality & ethics



Why not informed consent?

- Representativity & generalization
 - Avoid bias – selective loss
- Solid conclusions
 - Need for power and statistical strength
- Completeness
 - Few cases may determine risk
 - Loss in linkage may bias results
- All population
 - Disproportionate effort



Confidentiality & ethics



Informed consent - derogation

- EC 95/46 – art 7 & art 8.3

“in preventive medicine, management and care in health, in public health and in scientific research” where informed consent entail a disproportionate effort”

- In Denmark §10 on research and law on patient rights (now included in the Health Law)



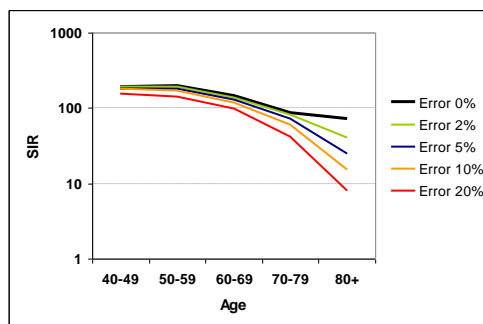
Confidentiality & ethics



What if we miss a link!

Influence of missed link to mortality – by error proportion

(E. Pukkala)



Leukaemia risk in airline pilots - Denmark:
 5 cases - significant increased risk
 4 cases - no significant risk - but elevated SIR



Confidentiality & ethics



Where is the risk ?

- Improper disclosure depends on two things:
 - Value of the data
 - Number of people who have access
- 150 persons (Ames NEJM 2002) see a patient record in a hospital stay – **authorisation? Law? Sharing with ?**



Confidentiality & ethics



Confidentiality & ethics

- Is it a technical problem ?
- Can we use technical solutions to the problem ?
- Who are we protecting and why?
 - The “criminal” from disclosure
 - The society/individual from the criminal



Confidentiality & ethics



Trust

- We must be open and clear about what we do.
- We must demonstrate high ethical and confidentiality standards
- We must continue to be part of the debate
- We must continue to demonstrate the usefulness of our activities



Confidentiality & ethics



The European perspective

- If we follow the intensions of the directive EC 95/46 and the "Nordic" tradition and behaviour-
- Ethics, privacy, registries and research will be a powerful symbiosis for the benefit of public health, prevention, early diagnosis and cancer control.
- If not – Calum Muir's statement on ethics and registration, unfortunately will be true and many European lives unnecessary lost in the future due defunct studies and spurious conclusions.



Confidentiality & ethics



Frattini: EU Commission 28 January 2007 - amended

- We need to balance access to data for those protecting our **health**, security fighting crime **and diseases** with protecting privacy rights.
- The threat presented by terrorist organisations (**incl. tobacco, obesity industry etc.**) creates a new balance with fully respecting privacy and data protection rights.
- 2010 –rumours that the Commission is ready to make the above changes.



Confidentiality & ethics



DG SANCO: Data protection and public health – 7/4 2011

- Awareness of benefits and threats of dealing with medical data – populations unaware of role of dataprotection on public health.
- Alliances - EU parliament, NGO, Patients org, Cancer societies.
- Influence revision of directive – exemptions for health research made obligatory – new §
- Clear definitions – avoid ambiguity and false strict interpretation of clauses.
- Clear distinction between confidentiality and security of data.
- Not only medical data is relevant – all personal data.



Confidentiality & ethics



DG SANCO cont..

- Do not accept a worse situation for data protection
 - Anonymous data do in reality not exist with modern computing power and skills.
 - Accept modern computing both enables better possibilities for securing data against unintended use.
- Do not create a massive bueraucracy - transparency
- Consent is not defined and may be transferred to a regularatory body in public health research.



Confidentiality & ethics

