1981 - Council of Europe Convention no 108

- Protection of individuals with regard to the automatic processing of personal data
  - Data is collected and treated lawful
  - Filed for specified, explicit and legitimate purposes
  - Data must be relevant and sufficient, and not excessive
  - Data must be accurate and if necessary kept updated
  - Data to be filed in a format that only allow identification of persons needed to fulfil the purpose

Public health studies under threat

Explicit consent difficult to obtain

- 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

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

- The codes of conduct in medical and epidemiological research should be considered separately

Why not informed consent?

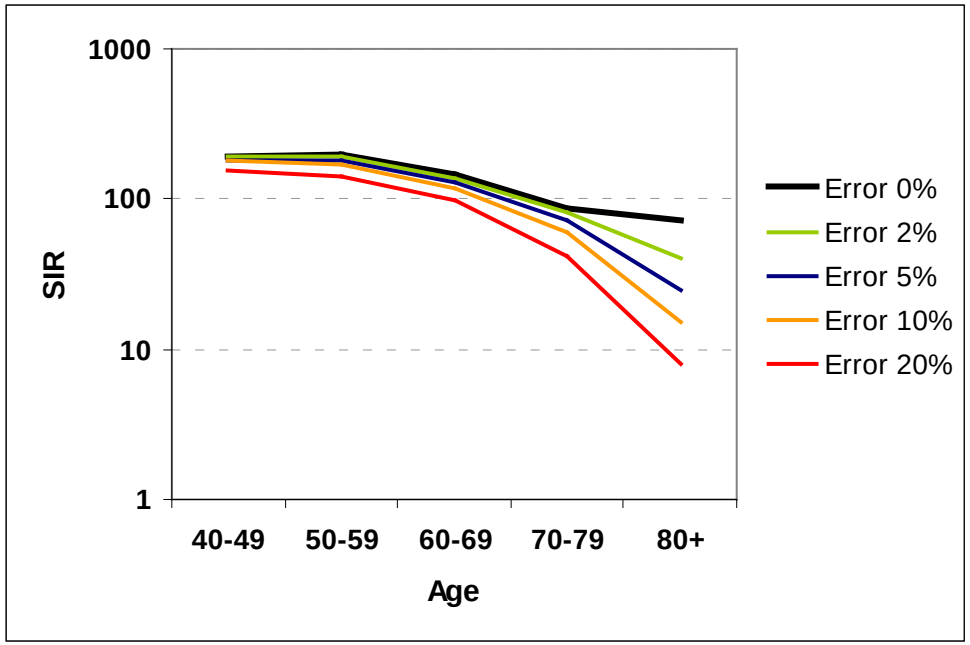
- Representativity & generalization
  - Avoid bias – selective loss (Low response rates)
- Solid conclusions
  - Need for power and statistical strength
- Completeness
  - Few cases may determine risk
  - Loss in linkage may bias results
- All population
  - Disproportionate effort

- The legitimacy of weighting practicability, or feasibility, in deciding whether it is necessesary to seek individual consent for retrospective (registry, biobank or clinical note based) studies should also be endorsed with the WMA declaration.

What if we miss a link!

Influence of missed link to mortality – by error proportion

(E. Pukkala)



Germany NRW cancer registry linkage study 150000 records
Pseudonyms: 1% linked wrongly 2% Not linked at all

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

Why not TTP ⟹ encryption

- Uncertainty about linkages
- Errors in ID may radically change "ID"
- Researchers lose track of data and responsability for key variables "ID"
- Third party increase time, costs and uncertainty on the linked data
- At the outset Public Health researchers are considered criminal or careless neglecting existing law.

Quality Issues

- Anonymous or pseudo anonumous data are not preferable to identifiable data and cannot be satisfactory for the purpose of a health database.
- Evidently security measures to avoid unintended disclosure apply.

Derogations in the new EU regulation- Who decides public interest?

- Articles 81.2 and 81.3 are 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 apply

Why not specify the need for use of the best possible method to achieve results – it concerns yours and my life!

Freedom of Research and Ethics

- No research without ethics
- Without research no ethics

- Ethics is about the good life (Aristoteles)

- Research contributes by promoting and creating the basis for the good life

(E.Tiedeman, previous Chair of the Natl. Ethics Committee of Denmark)

- Research on health data can be done in an unethical way – which should be avoided
- Research on data of low or uncertain quality should also be avoided
- Failure to do health research is also unethical – and devastating for public health

Does one size fit all?

https://plus.google.com/+MarMDog/posts/JFV3qCDXsy6