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Dutch Legislation on Further Use in Context

Outline

- GDPR and Dutch legislation
- Translation into a Code of Conduct
- Challenges for the Code of Conduct
- Relatively restrictive Dutch legislation
- Little to no room for ‘bias problem’
- Ongoing COREON project on bias
- Dutch legislation compared to rest of EU
- The way forward ?

A disclaimer

1. Co-drafter of the Code of Conduct
- Within confines legislation to get it approved
2. A legal researcher (partially) for a fee for most projects
- We are a foundation but there is also something as salaries and work/life balance
3. As a researcher in ethics and jurisprudence
- More free, even less work life/balance though

Legislation, only the headlines

- Starts with the General Data Protection Regulation
- Relates to all data processing
- EU wide applicable
- When the GDPR was drafted:
  - Much discussion about its impact on research
- Certain exemptions for public health directly in the GDPR or to be implemented in national law
- Dutch legislation, some preceding the GDPR

The Code of Conduct

- Legislation has ambiguities
  - Various interpretations from strict to less strict
- Dutch Code of Conduct on data processing for health research
  - Aims to translate relevant EU/Dutch legislation into practical guide for researchers
  - Follows the research data life cycle
  - Solves the ambiguities
- At the same time must be legally compliant to be approved by AP
- 2 layers
  - Understandable for researcher
  - Legal explanation

Process Code of Conduct

- Core group writes
- Sounding board and COREON give feed-back
- Started spring last year
- Difficult to get it right
- Solving ambiguities always leads to new questions
- Public consultation end of June
- More at:
- https://www.coreon.org/codegoedgedrag/
  (in Dutch)

Consent main issue

GDPR

- Consent in the sense of the GDPR is not the only legal basis to process data for research
- However, if GDPR consent it must meet criteria of informed and specific
- One time consent (broad consent) is deemed not GDPR consent if not constantly updating participant with at least the option to object
  - Downplaying R. 33

Dutch

- **Consent for further use is basis**
  - But what consent?
- For exemptions two Acts must be combined
  - The act on the treatment contract
    - Medical confidentiality
    - Consent if patient data would be released to a 3 party, such as a researcher
    - With a relatively narrow exception to this consent for research
      - The so called (not) opt-out inclusion for further use
    - That exemption has been used to the max in the Netherlands
  - The GDPR implementing Act (UAVG)
    - Relatively narrow exemption to GDPR consent for research
      - If impossible or would be disproportional
      - Costs do not count

Consent and exceptions with further use

- Tendency of many to go from opt-out to generic consent
  - Patient gives generic consent when being admitted or other appropriate moment
  - Not GDPR consent
- Indeed, is in line with Dutch legislation
  - Hence preferred option in the Code of Conduct
- That generic consent has exceptions
- One of them in the Act on treatment contract (WGBO)
  - If the research becomes biased because of this

Does bias count?

- Department of health:
  - No, problem for researchers not of the law
    - ???
  - WGBO (1994) is old fashioned, gives more exceptions than ‘we’ want today
  - Very much in the consent above all mode
- Sounding board
  - Researchers exaggerate
  - If then only very exceptionally and burden of proof on researchers

Hence the COREON Bias Project

- Literature search on bias through informed consent in observational research
- Older paper by Kho et al.
- Is there more and newer ?
- Still ongoing
- And we could use help of epidemiologists
  - Especially for a modelling study
- Though hardly funds
  - Contact: eb.vanveen@mlcf.eu

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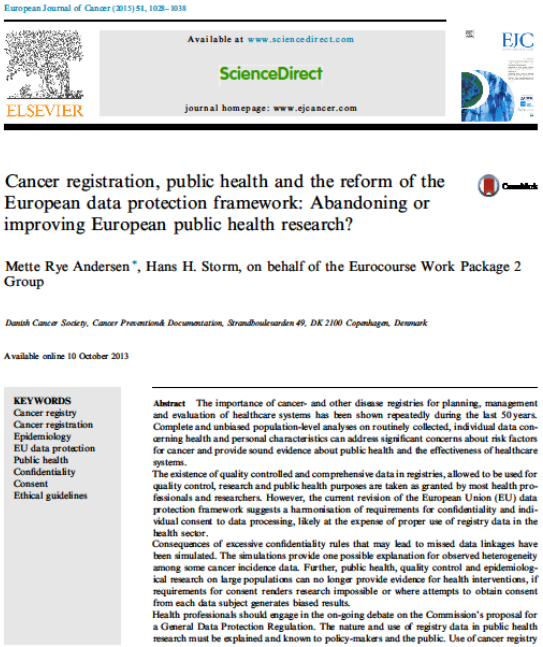
Some preliminary results as I see them

- For cohort studies with volunteers, longer follow-up
  - Even though sample might not be fully representative not a problem for internal validity of results
  - Well, you know what you don't know
- Yet, with further use
- Cancer registries become biased /unreliable
- Two studies:

2 papers, left unreliable results in cancer registry because of focus on ‘anonymise’, felt because on written consent



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Cancer registration, public health and the reform of the European data protection framework: Abandoning or improving European public health research?

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KEYWORDS
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Confidentiality
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Ethical guidelines

Abstract The importance of cancer- and other disease registries for planning, management and evaluation of healthcare systems has been shown repeatedly during the last 50 years. Complete and unbiased population-level analyses on routinely collected, individual data concerning health and personal characteristics can address significant concerns about risk factors for cancer and provide sound evidence about public health and the effectiveness of healthcare systems.

The existence of quality controlled and comprehensive data in registries, allowed to be used for quality control, research and public health purposes are taken as granted by most health professionals and researchers. However, the current revision of the European Union (EU) data protection framework suggests a harmonisation of requirements for confidentiality and individual consent to data processing, likely at the expense of proper use of registry data in the health sector.

Consequences of excessive confidentiality rules that may lead to missed data linkages have been simulated. The simulations provide one possible explanation for observed heterogeneity among some cancer incidence data. Further, public health, quality control and epidemiological research on large populations can no longer provide evidence for health interventions, if requirements for consent renders research impossible or where attempts to obtain consent from each data subject generates biased results.

Health professionals should engage in the on-going debate on the Commission’s proposal for a General Data Protection Regulation. The nature and use of registry data in public health research must be explained and known to policy-makers and the public. Use of cancer registry

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Bias in survival estimates created by a requirement for consent to enter a clinical breast cancer registry

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ABSTRACT

Background: A requirement for consent for inclusion may bias the results from a clinical registry. This study gives a direct measure of this bias, based on a population-based clinical breast cancer registry where the requirement for consent was removed after further ethical review and data could be re-analysed.

Methods: In Auckland, New Zealand, the population-based clinical breast cancer registry required written patient consent for inclusion from 2000-2012. A subsequent ethical review removed this requirement and allowed an analysis of consented and non-consented patients. Kaplan-Meier survival to 10 years (mean follow-up 5.1 years, maximum 13.9 years), demographic and clinical characteristics were compared. Of 9244 women with invasive cancer, 926 (10.4%) were not consented, and of 1642 women with ductal carcinoma in situ, 245 (14.9%) were not consented.

Results: Survival was much higher for consenting patients; invasive cancer, 5 year survival 83.2% (95% confidence limits 82.2-84.1%) for consenting patients, 57.1% (53.0-60.9%) for non-consenting, and 80.8% in all patients. Analyses based only on consenting patients overestimate survival in all patients by around 2% at 2, 5, and 10 years. Non-consented patients were older, more often of Pacific ethnicity, had fewer screen-detected cancers, and more often had metastatic disease; they less frequently had primary surgery or systemic treatments.

Conclusion: Data from a registry requiring active consent gives an upward bias in survival results, as non-consenting patients have more extensive disease, less treatment, and lower survival. To give unbiased results active consent should be not required in a clinical cancer registry.

1. Introduction

The Auckland Breast Cancer Registry was established in June 2000 by a voluntary group led by clinicians to collect demographic, clinical and pathological data on all newly diagnosed patients with breast cancer in the Auckland region (population around 1.4 million in 2016), and to document follow-up and outcomes [1,2]. The registry is population-based, including all newly diagnosed patients with primary breast cancer resident in the defined region, and is regularly linked to the statutory national cancer registry, and to national mortality data to ascertain deaths [1,2]. From 2000-2012, individual written consent was required for patients to be included in the registry. Clinicians were requested to present the project to potential participants when seen in a clinic, and patients were asked to sign the consent form with a supporting signature by a witness. The consent form assured patients that their demographic information and data on their cancer data, treatment and follow-up would be collected using a key-coded technique suitable for potentially identifiable data, and only anonymised/unidentifiable data would be used for research and audit activities and for presentation or publication. The consent form provided assurances that there was a strict protocol to ensure confidentiality, and that participation was voluntary and would not affect the patient’s care. Patients were usually approached for consent at their first visit to the specialist clinic. For some patients the process was delayed but the consent process was completed by first therapy, within 90 days of diagnosis.

By 2010, the registry management group was aware that consent was not being obtained from approximately 10% of patients. To achieve greater completeness, the group requested a review by the national statutory Health and Disability Ethics Committee, operated by the Ministry of Health, on whether the requirement for consent was

Abbreviations: C, consented; NC, non-consented; DCIS, ductal carcinoma in situ; LCIS, lobular carcinoma in situ; NHI, National Health Index number

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Where does The Netherlands stand with consent as the baseline

Disease registries with research aim not based on consent

- Belgium (cancer)
- Greece
- Czechia
- France, partially
- All Nordic countries
- Certain Baltic states

Further use of pseudonymised data without consent

- France (with opt-out)
- Italy (certain hospitals, thick opt-out)
- Belgium
- UK
- Spain
- Austria
- All Nordic countries
- Certain Baltic states

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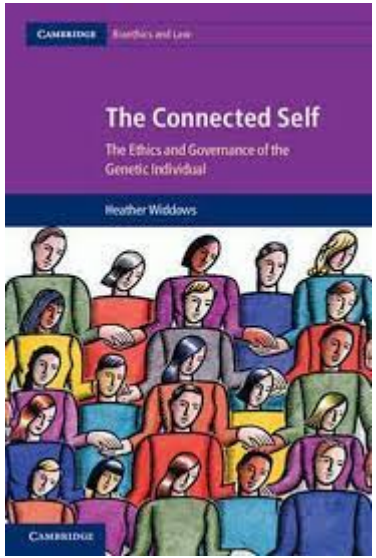
Now, with my last hat, pseudonymised data

- Data are of the patient
- Autonomy, self-determination
- Government grabs ‘my data’
- Results might lead to discrimination
- Data breach might occur
- I don’t trust it

- Data were generated by the health care system and also/most of all reflect objective medical data
- You decide about others
- It does not…
- We have laws against that and more will profit
- Not how we have organised it
- There is opt-out

Inspiring



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Final remarks

- Pseudonymised data should be used under opt-out system
- Against the current of present liberal ideology of ‘me’ and ‘mine’
  - Restores ‘we’ medicine
  - Basis of European solidarity based health care systems
- But only if:
  - Focus on public good
  - Via bona fide research
  - In interaction with main stakeholders
  - Transparent and accountable procedures by research institutions
- How and more ?

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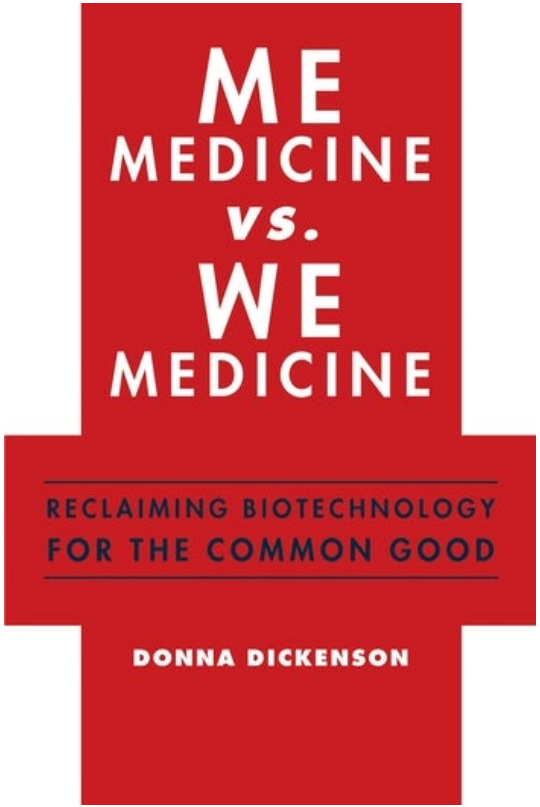
Also inspiring



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Thank you for your attention

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