The GDPR and clinical registries

Is it really that bad ?

MedLawconsult

Tilec Tilburg Law and Economics Center
AXON science based lawyers
EJRR European Journal of Risk Regulation
The Legal Publisher lexxion Berlin

It very much depends

- Def. of personal data
- Informed consent, when
- Derogations
  - 81 for health and clinical registries
  - 83 , for research
- ‘Implementing’ acts
- Case study, brief

Discussions

- Council, IMCO
- Personal data too broad
- Too many implementing acts
- 81 and 83 are left untouched

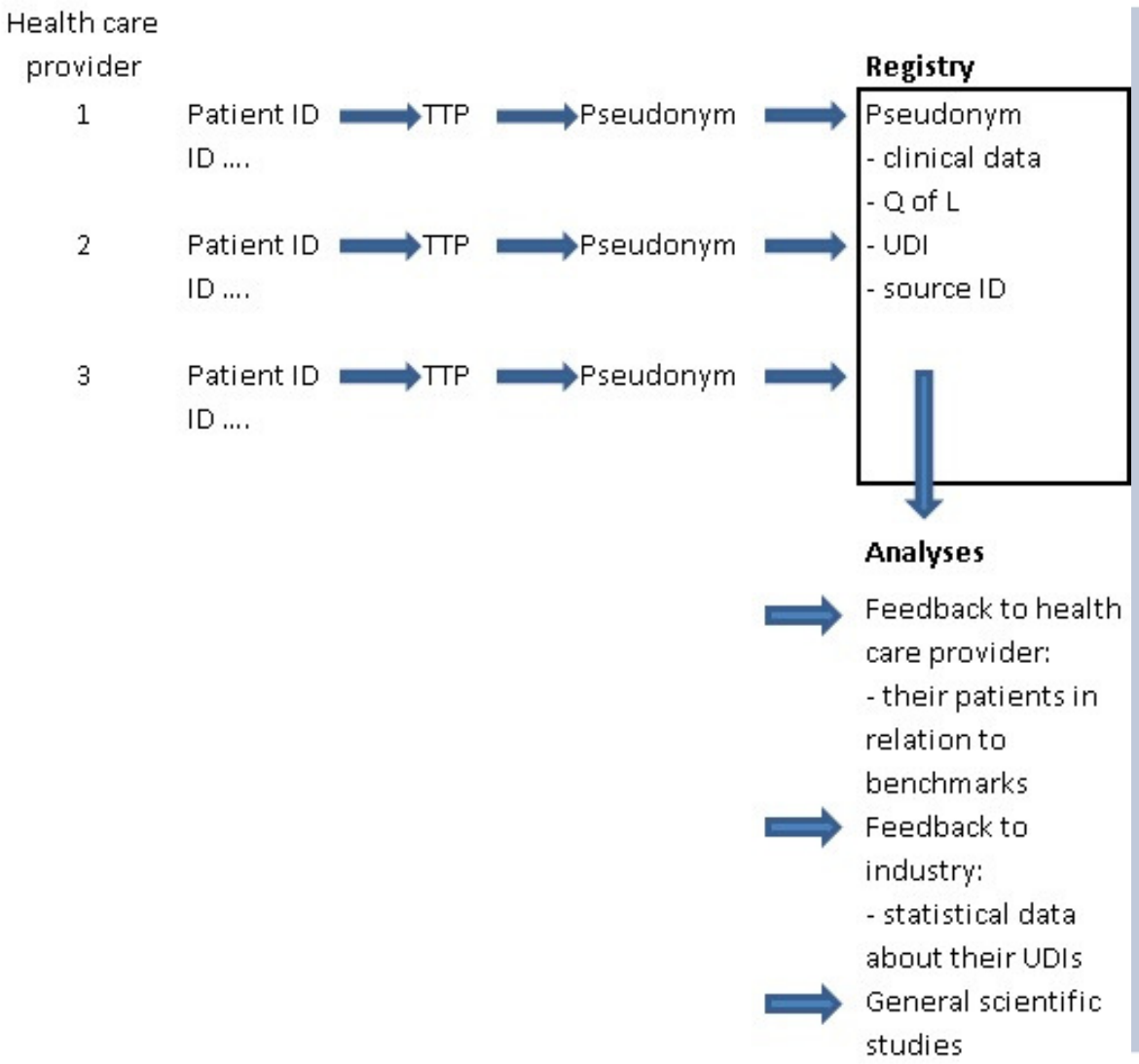
- LIBE
- Broadens def of personal data
  - Also when persons can be ‘singled out’ through pseudonym
- Sharpens informed consent
- Restricts very much 81 and 83
- Gives the EDPB more powers

Problems

- Informed consent often does not work
  - Report Patient data for health research , ch. 10
- Anonymous data do not work at all and patients certainly must be ‘singled out’
- More than balancing autonomy-public good
- One sided focus on data self determination neglects that patients profit for earlier advances in medicine and health
- Does not take into account contextual approach to privacy

A case study of a clinical registry

- A chain of data:
  - Industry, physicians and others, clinical registry and back
  - Longitudinal follow-up
  - All patients
  - Various sources (physiotherapists)
  - Pooling of data
  - Analysing them
    - Case mix control, comorbidity
    - Epidemiological techniques
    - Feed-back to health care providers and industry
  - But what data and how


Health care provider
1
Patient ID ID ....
TTP
Pseudonym
2
Patient ID ID ....
TTP
Pseudonym
3
Patient ID ID ....
TTP
Pseudonym
Registry
Pseudonym
- clinical data
- Q of L
- UDI
- source ID
Analyses
Feedback to health care provider:
- their patients in relation to benchmarks
Feedback to industry:
- statistical data about their UDIs
General scientific studies

Personal data in registry ?

- 2 aspects:
  - Pseudonym
  - Detail of data under pseudonym
    - Indirectly identifiable, grey area, high threshold
- Pseudonym
  - One way *or* two way
  - 95/46 also 2 way can be anonymous (WP 2010/1)
  - GDPR, EC: personal data (1 way in principle not)
  - Many: too broad, as 95/46
  - LIBE: also 1 way personal data

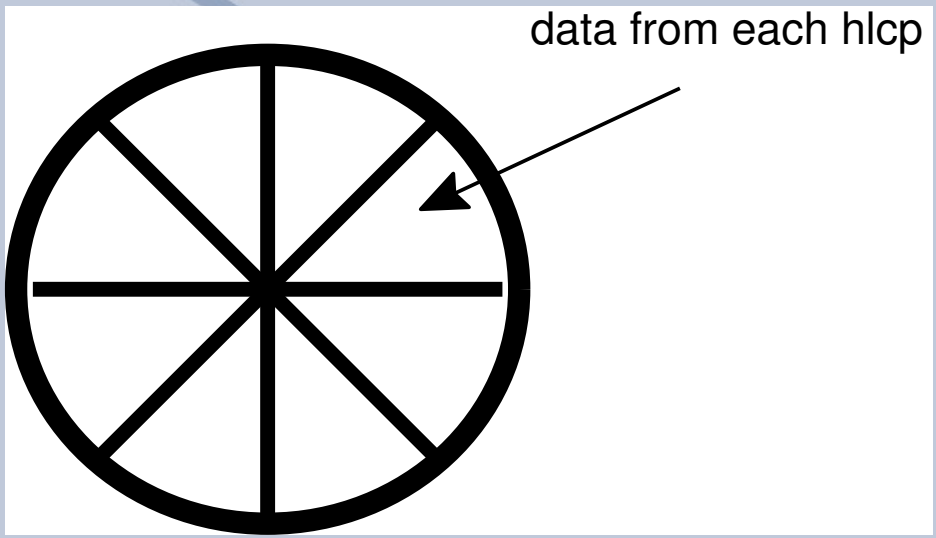
If personal data: what next

- Informed consent
- Exemptions 81,83

Or,

- Controller (each physician) –processor ('holder' of the registry) construction
- for no too complicated registries with 1 type of source…otherwise processor > controller
- Requires good reglementation, contracts

Controller Processor cake model



Visible – the icing on the cake
Substance – data where each source remains controller.
Icing derived from substance

Conclusions

- Reglementation about governance is always necessary
  - Purpose, access, science and output
  - Who may do what with the data under what circumstances
- Not direct access to industry but output to, according reglementation
- Databank right
- Much might still be possible under GDPR
- If LIBE comes to their senses

References

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- Position paper of EUROCOURSE about the draft GDPR: http://www.eurocourse.org/index.htm?do_id=934&mi_id=1324