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Data for a learning health care system

History, values and forward looking

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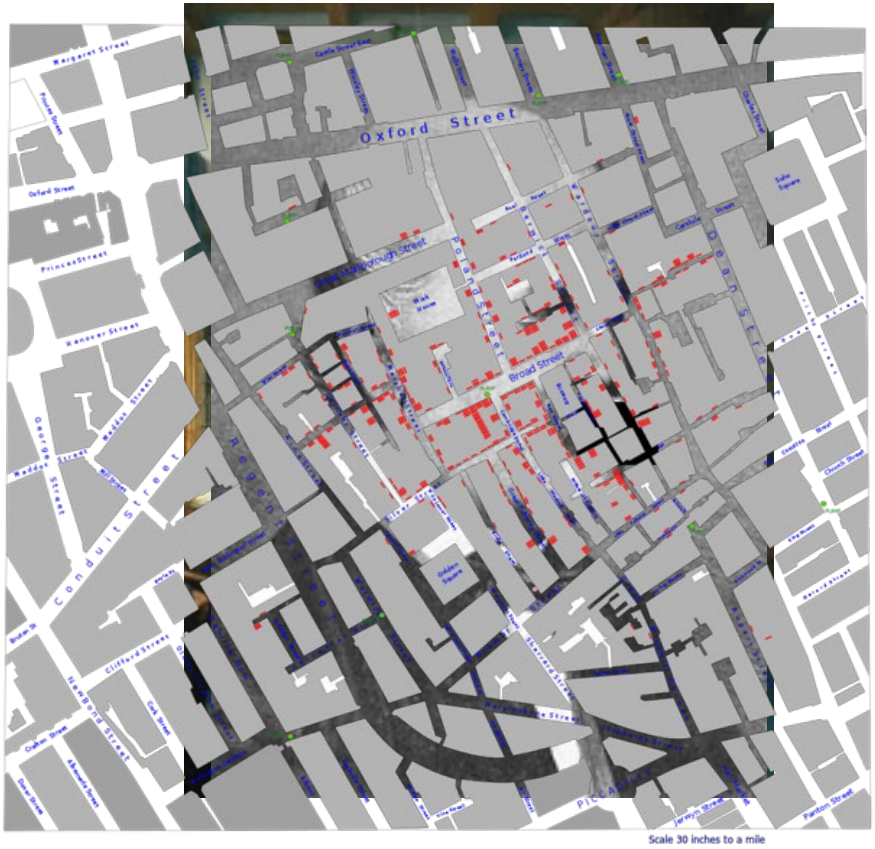
Outline

- When did it start….
  - A long time ago
- More recent
  - Discussion about Dutch Act on the treatment contract
- Still further use as the exception to the rule (in the Netherlands)
- A giant leap since then ….
  - Recognition of what existed or should exist already
- Yet, still quality feed-back-research divide
- Then about values……or ‘ELSI’
- My ideas about both

A long time ago

- Porter the Greatest benefit to mankind
- Modern turn with empirical methods
  - medicine is also society
- Learning with an eye on performance
  - Semmelweis
    - You also need basic science
  - John Snow
    - You need unbiased statistics



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A huge lump in time


Codering kan beroepsgeheim bij medisch onderzoek waarborgen

BRIEVEN

- 1994 Bill on the ‘treatment contract’, patient rights
  - Medical confidentiality first
- Epidemiologists and chair privacy board: heated discussion about further use of patient data for ‘research’
- We got a letter published, proposing a compromise
  - A lower threshold for the exemption to consent if the data, while still personal, were not with direct identifiers, ‘coded’
- A long story short: government made an change in the law which is now 7:458 BW
  - Btw: bias was recognised there as reason not to ask for consent if……
- Yet, further use was still seen as the exception to the rule…

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Another jump in time

- Gradually the epidemiological view got hold
- The discussion around the GDPR has paradoxically contributed to this
  - The Nordic countries showed how their disease registries worked
- In the Netherlands we started with (governance of) quality registries
- Though there was not a legal basis for quality registries at first, this was less contested
  - Also in present GDPR 9.2.i
- The discussion between the more strict (self-determination oriented) and less strict (solidarity oriented)
  - Both sides met during intensive discussions new Code of Conduct
    - Nearly 2 years

Striking the right balance between privacy and public good

On Jan 17, the UK's Academy of Medical Sciences issued a report, *Personal data for public good: using health information in medical research*, on the use of individual medical information for research purposes. The report highlights the tension between the vital need to respect the privacy of patients and the important task of medical research using large population datasets.

Growing concerns about privacy have spawned a great many laws and regulations governing the use of personal data, as spelled out, for example, in the UK's Data Protection Act and the EU Clinical Trials Directive. These regulations are complex in themselves, but the various ways in which they are interpreted increase complications for researchers, with the result that important and worthy projects can be long delayed or blocked entirely.

Similar concerns have been raised in the USA since the implementation in 2003 of the Health Insurance Portability and Accountability Act (HIPAA), which established standards for the confidentiality of identifiable health information. HIPAA's "common rule" governs research and specifically requires written informed consent from patients, even for so-called de-identified data for projects that combine quality improvement (QI) with research (these have not generally required consent in the past). Some US researchers have argued that HIPAA regulations can inhibit research and increase its cost, or skew data collection and therefore bias the results.

Likewise, the Academy's report argues that overregulation and overly cautious interpretation of regulation is stifling important research. It points to landmark epidemiological work—such as Sir Richard Doll's 1947 finding of the link between smoking and lung cancer—that would not have been possible without a large database of patients' records.

The UK is particularly well placed to undertake database research because large numbers of people use the National Health Service (NHS) and electronic medical records are starting to be widely used. The obstacles in the way of potentially important medical advances are therefore all the more frustrating.

To remedy these problems, the Academy's report makes recommendations, which *The Lancet* strongly endorses, in five areas. First, it claims that identifiable data can be used if the research to be undertaken is necessary and balances privacy concerns with public benefit. The report also recommends simplifying the process of assessing proposals so that researchers can get clear and timely decisions about their projects, all of which should be done under a code of practice, to be developed. It suggests that immunity from liability for data controllers should be considered, and recommends that the needs of researchers, not just those of practitioners, should be incorporated into ongoing development of the information technology programme of the NHS. Finally, patients, in formal groups and among the general public, must be engaged in discussion and debate. A group that has been established as a temporary statutory body, the Patient Information Advisory Group, should be thoroughly reconfigured, with one of its key roles being active facilitation of research.

More generally, the public needs to be engaged about how medical records are used and how research is done. The Academy's report points to a paucity of evidence about patients' preferences for and attitudes towards participating in research, and calls for more involvement with the public to get a fuller and more accurate picture of their views. One bioethicist, John Harris (University of Manchester, UK), has even argued that patients are morally obliged to participate in research projects, as a "mandatory contribution to public goods", at least for research that is aimed at preventing serious harms and providing important benefits. Harris also claims that in the absence of knowledge about an individual's actual preferences, it is justifiable to assume that a person would want to participate in research. Such "opt-out" schemes have been proposed as default options for database study recruitment.

Better public education about how research works and about the benefits that can accrue from investigation of population data is urgently needed, as is the need to convey the message that advances in diagnostics and therapeutics are being held up by bureaucratic legislation. When patients are convinced that their personal information is being used under rigorously controlled conditions and in accordance with best research practices, they are likely to agree to give up a small amount of individual privacy for the greater societal good that can come from population research. The future of our health depends on it. ■ *The Lancet*

For the **AMS report** see http://www.acmedsci.ac.uk/p47.html

www.thelancet.com Vol 367 January 28, 2006 275

404 JME Carter P, *et al. J Med Ethics* 2015;**41**:404–409. doi:10.1136/medethics-2014-102374 BMJ

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Quality registries…..

- My take:
  - Be as compliant as possible
  - Patients except best possible care,
  - Dare to use those data for research as well
  - Admittedly also influenced by my take on the meaning of patient data
    - But then stricter rules kick in
    - But as you have them already, can be based on opt-out
  - Certainly don’t write evident nonsense
    - Such as that all hospitals are controllers of the quality registry

Developments

- The health care provider –processor – quality registry triangle was invented
  - DICA, LROI
- NIVEL imported the learning health care system concept (USA) to the Netherlands
  - Dinny de Bakker, Robert Verheij
- Covid underscored the necessity of learning
  - While existing therapies are taken for granted with incremental change, here they had to be found anew.
- Recognition of obstacles in the Netherlands and the EHDS

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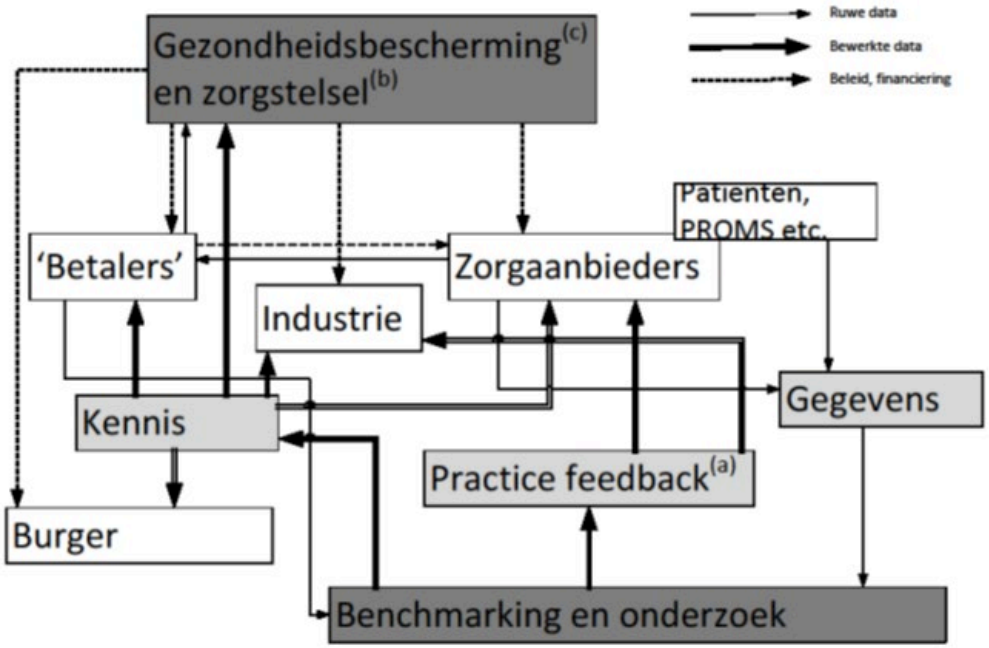
Dataflow for a learning health care system (2017, proceedings Dutch Ass. Health Law)



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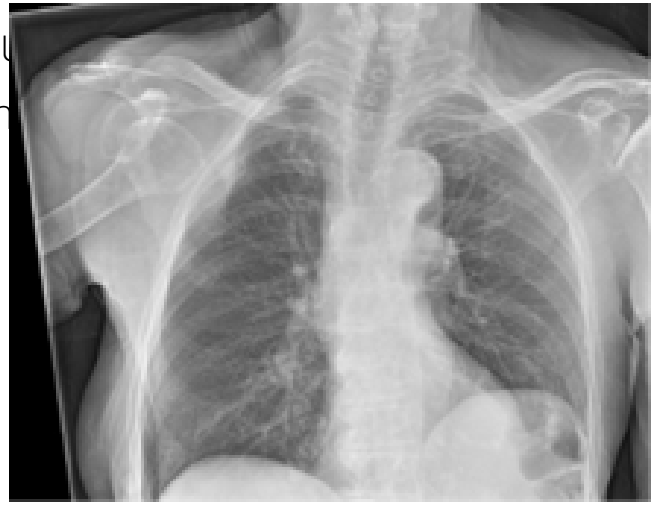
Some takes from that chapter



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Partial uptake….

- Draft bill on quality registers mentions bias
- Yet, in the Code of Conduct we had to defend ‘bias’
  - Department of health: researchers' problem not a research problem
  - and remained narrow exception
- Quality – research divide
- We don’t have anything for disease registries yet
- Research consent with some narrow exceptions
- There are more ‘obstacles’

How to get it right ??

- Thorough discussion
  - What are health data
  - Also a meaning outside health care but also health p

Underlying values …..

- Which goes beyond ELSI stoplight discussion
- But reflects upon the kind society we want
- In HEAP project we are working on that in limited v health
  - HEAP is one the exposome projects

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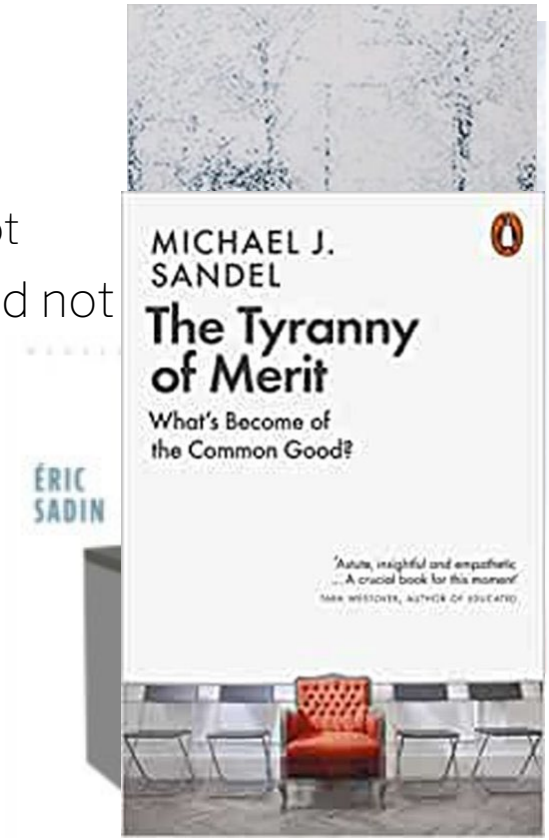
What do we want, what are ‘we’

- Patient rights movement started as an emancipatory movement
  - As may others
- Could only thrive or at l
- Yet, ‘my rights’ can also
  - As it should still be a soc
  - With the rule of law
  - With responsibilities to
  - That is where self-deter
- Before that in this cont

Yet, that is an extremely difficult balance

- Our neoliberal society created an inherent paradox
  - The illusion that the world in controllable while in fact it is not
- You are at the centre while in fact you are not and should not
- You can make and should make while in fact you ca
- And why should you, multiple ways to lead a good li



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Review of Sandel

- The implicit claim is that vulnerability and mutual recognition can become the basis of a renewed sense of belonging and community. It is a vision of society that is the very opposite of what came to be known as Thatcherism, with its emphasis on self-reliance as a principal virtue.

Back to further use

- Caught in the ‘ELSI’ debate
- But the prevalent ELSI debate is from a philosophical point ‘flat’
- Basic assumptions are not challenged
- Underlying political philosophy is hardly expressed
- Becomes a cheap amalgam of self-determination and some mitigation when that would become too detrimental to others

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So what's next…

- Not a grand new theory here
- Some basic principles for health care
- That is 'we' medicine
- Our dependency from each other
  - In the health care system
  - In care and cure
  - In our common future
  - The 'soft' principles by Sandel..

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And from that follows…

- If certain basics are met, patients are expected to contribute
- Basics
  - Data safety
  - Not against an individual
  - Assurance of the public good
- We can only safely say that against a background of rights protection in general
- And yes, if not opted out
  - But not because of residual self-determination
  - But as right to health care comes first and those who don't trust it, shouldn't be deterred from access

Concluding remarks

- Health care and health protection ‘learn’
- But we should learn as well
- Starts in my opinion with what kind of society we want
- I gave a bold, unfashionable view
  - Dutch parliament would not agree anymore
  - Also ‘left’ caught in neoliberal ‘me’
- I am sure that the unbiased panel will tell me how wrong I am
- But first more practical discussions
- Thanks for your attention