Balanced data for research consent, opt out, bias and exchange

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Outline 1

- GDPR:
  - Main provisions
    - Anonymous versus personal data
    - Pseudonymised data
  - Exceptions in national law
  - Cooperation via a processor
    - Conditions for a processor

Outline 2

- Autonomy versus public good
- Prevailing trend in ethics
- Why exceptions in national law
- We need evidence !
  - Not easy to get funded
  - Some examples

GDPR

- General data protection regulation
  - Entry into force 25-2-2018
- Extensive regulation
  - Will replace national privacy laws except when national exemptions
    - Which still have to comply with basic principles
- 0nly applies to personal data
  - What are those
  - Are all pseudonymised data personal data

Personal data versus anonymous data

- Personal data :
  - Any information relating to an identified or identifiable natural person
    - Not only name but also identification number, location data, an online identifier or factors relating to …identity of the person
  - Whether that identification can be the case account should be taken to all means likely reasonably used… , including *singling out*,

When ….

- Art. 29 WP 2014 on anonymisation techniques
  - Very strict standard
  - Criterion *Reasonably* not re-identifiable abandonned
  - Context is not important unlike ICO rapport from 2012
  - Anonymisation should be irreversible
- But EMA about anonymisation:
  - The process of rendering data into a form which does not identify individuals and where identification is *not likely to take place*.

Court of Justice EU 19 October (C-582/14)

- Dynamic IP adresses (no singling out, P)
- not be the case if the identification of the data subject was prohibited by law or practically impossible on account of the fact that it requires a disproportionate effort in terms of time, cost and man-power, so that the risk of identification appears in reality to be insignificant
  - In many cases prohibited by law, meaning identification P explicitly forbidden
  - Much more reasonably approach

Pseudonymised data in GDPR

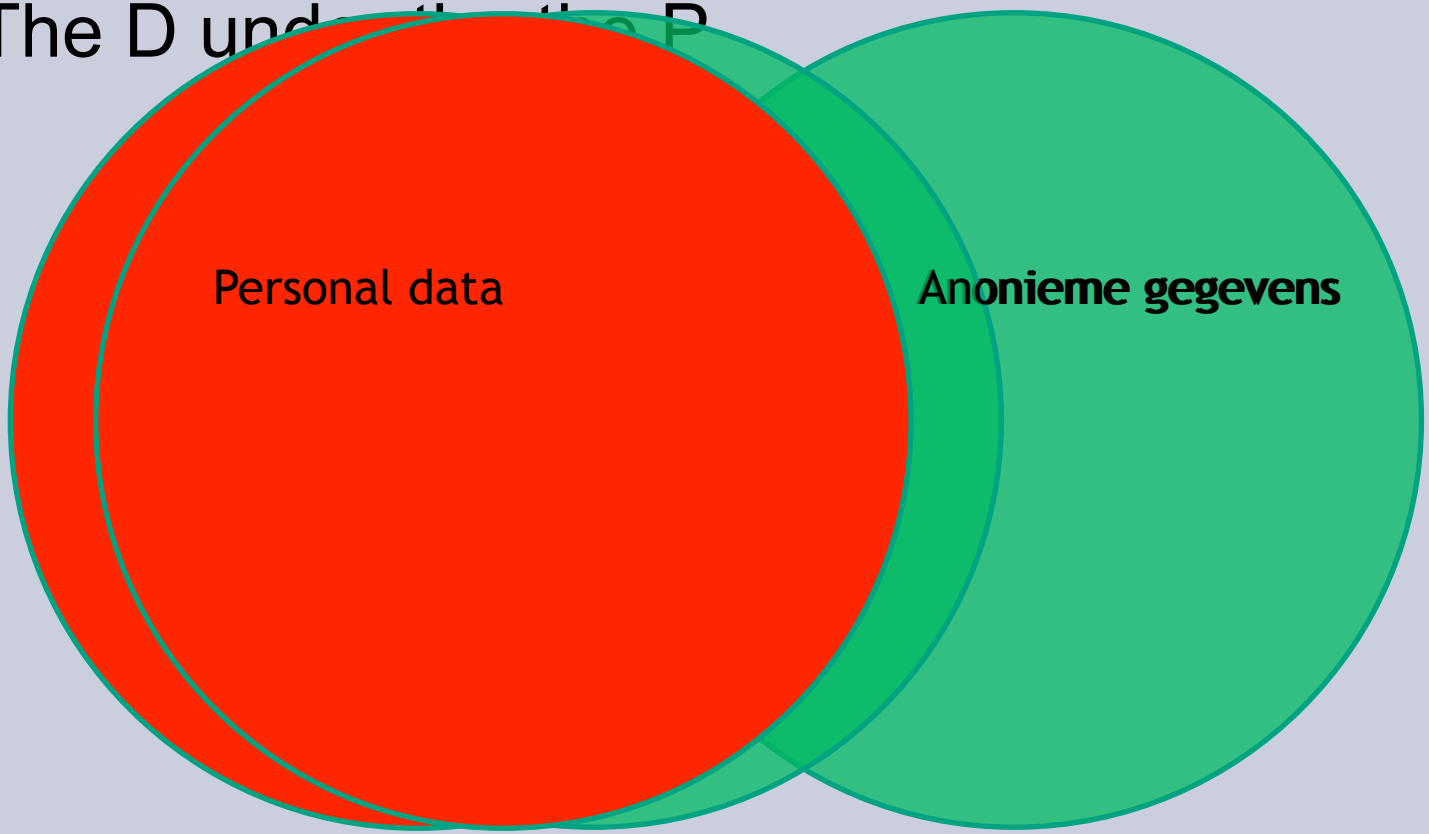
- Processing of *personal data* where personal data can no longer be attributed to a subject without the help of additional information which is kept separately in a safe way
- This explicitly means that not all pseudonymised data are now personal data
  - That would reverse the argument
- They are personal data and then a PET is used to make them more ‘safe’

More about pseudonymised data

- Distinguish the P from the D
  - Pseudonym under which research Data
- P must be safe and by law not be allowed to reverse back
- D must not be indirectly identifiable
- Not when leaving the source
- And not when combined in research database with data from other sources

Yet anonymous research data have become theoretical

- The D und[illegible] P



Principles

- As in present Directive but stronger and more explicit
  - Legal ground and fair & transparant processing
  - Purpose limitation
    - Scientific research is not incompatible 5.1b
  - Data minimisation & privacy by design
  - Accurate
  - Storage limitation
    - Except for scientific research if….
  - Integrity & confidentiality
  - *Accountable*

Other principles

- Consent (specific….)
  - Unless another legal ground
- Always must be able to show what data are being used on what legal ground for what purposes
  - Administrative accountability requirements will increase
- Always apply as much privacy by design
- Keep data secure

Data about health and genetic data

- In principle explicit consent
  - Distinguishes between health and genetic so now for both…
- Unless national law necessary for
  - Provision of health care or the administration of the health care system
    - if professional secrecy
  - Public interest in public health, cross border threats to ph, safety and quality of the health care system
  - Scientific and statistical purposes 89.9
    - Both with safeguards

Context 1, recital 125

The processing of personal data for archiving purposes in the public interest, or scientific and historical research purposes or statistical purposes should be subject to appropriate safeguards for the rights and freedoms of the data subject pursuant to this Regulation. These safeguards should ensure that technical and organisational measures are in place in order to ensure, in particular, the principle of data minimisation. The further processing of personal data for archiving purposes in the public interest, or scientific and historical research purposes or statistical purposes is to be carried out when the controller has assessed the feasibility to fulfill those purposes by processing data which does not permit or no longer permit the identification of data subjects, provided that appropriate safeguards exist (such as, for instance, pseudonymisation of the data). Member States should provide for appropriate safeguard to the processing of personal data for archiving purposes in the public interest, or scientific and historical research purposes or statistical purposes. …(*next slide*)

Recital 125 vervolg

- Member States should be authorised to provide, under specific conditions and in the presence of appropriate safeguards for data subjects, specifications and derogations to the information requirements, rectification, erasure, to be forgotten, restriction of processing and on the right to data portability and the right to object when processing personal data for archiving purposes in the public interest, or scientific and historical research purposes or statistical purposes. *The conditions and safeguards in question may entail specific procedures for data subjects to exercise those rights if this is appropriate in the light of the purposes sought by the specific processing along with technical and organisational measures aimed at minimising the processing of personal data in pursuance of the proportionality and necessity principles.* The processing of personal data for scientific purposes should also comply with respect to other relevant legislation such as on clinical trials.

89. 1 en 2

- Scientific research in public interest shall be subject to appropiate safeguards for rights of subject
  - In particular data minimisation
- Possibly pseudonimisation when purposes are attainable
- Derogations are possible
- On consent and….

much more, limitations of rights

- 14 to notify data subject that you recieved data from another controller
- 15: to access
  - See also art. 11…(solves paradox)
- 16: to rectification
- 17a: to limit data processing
- 19: to object
- 17 ‘to be forgotten’ not in 89.2 (but already in 17)

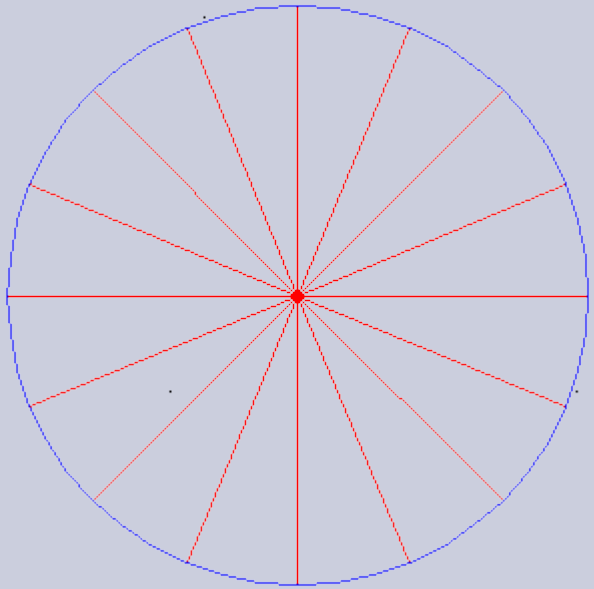
Hence, please national legislation

- But that might differ
  - And even if not, consent modalities might have differed at each data source
- We still want to combine data on transnational level
  - If a deconcentrated system or ‘datashield’ like method issufficient
    - Bringing the questions to the data at the source
- Then the data at the combined database might be held by a *processor*

The data controller and processor

- Controller is who determines the purposes and means of the data processing
- Processor processes personal data on behalf of the controller
  - No consent needed to have data processed by a processor
- Controller is the “boss”
  - There can be more than one controller
  - Yet it should always be clear whom the subject can address for his rights

Partitioned at the processor



- Each controller has its own partition
- Processor follows controller
- Also that analyses can be done its partition and other partitions
- Processor can be anywhere in Europe

(solid EU law)

Conditions for the processor

- must be based on a contract
  - Describing what data are processed for which purposes
- must be able to safely process data
  - A.o. ISO 27001
- sub-processing only after agreement with controller
- Acting on documented instructions from the controller unless obliged otherwise by law
- Assist controller in meeting its obligations
  - Data breach

The processor

- Various models
  - Can offer SaaS, PaaS etc.
- Rights model who has access to what data
  - Can perform analyses on behalf of controllers

  Or
  - Researchers work only within platform
    - With only statistical results out
  - Or release raw data on behalf of controllers
- Must always allow for an audit trail of the processing of the data

Yet in research a combined database

- Multiple controllers
  - Each with background national law, provenance of the data and consent mechanisms
- To submit data from each partition, each controller must agree
- If there would be one body to agree, that would become the new controller
  - Transfer of data to where new controller is situated
  - Legislation and consent modality must allow this
- But if controllers would mandate a body…

Governance

- No clear answer yet
- Can be done
- With safeguards
  - For what decisions clearly delineated
  - Notification of those
  - Possible to object
  - Blockchain ??
- Hence, complicated governance at the multiple controllers with 1 processor

A step back

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Though ‘further use’ is acknowledged yet…

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META CONSENT – A FLEXIBLE SOLUTION TO THE PROBLEM OF SECONDARY USE OF HEALTH DATA

THOMAS PLOUG AND SØREN HOLM

Keywords
Informed consent, meta consent, broad consent, specific consent, health data

ABSTRACT
In this article we provide an in-depth description of a new model of informed consent called ‘meta consent’ and consider its practical implementation. We explore justifications for preferring meta consent over alternative models of consent as a solution to the problem of secondary use of health data for research. We finally argue that meta consent strikes an appropriate balance between enabling valuable research and protecting the individual.

INTRODUCTION

The problem

The rapid increase in IT capabilities over the last 30 years have made it possible to store and analyse very large datasets, and accompanying developments in lab automation and analytic techniques have made it possible to easily extract ‘omics’ information from tissue samples. These two developments have together led to a situation in the health area where increasing amounts of personal health data is stored in an easily accessible form, and where this stored information has become increasingly valuable for research. A significant proportion of the research value is created by 1) the ability to use data that are primarily collected for administrative purposes (e.g. hospital episode data or prescription data), and 2) the ability to link data from different sources, either with other health data or with data outside the health area. There is a clear political will in many countries to try to maximize the research yield from the data under the banner of ‘Big Data’ or ‘The Learning Health Care System’.[1]

This, however, creates a set of ethical and regulatory problems. What regulatory structure will at the same time:

1. Protect the interests and autonomy of data subjects; and
2. Optimize the possibility to conduct valuable research

These problems are further complicated by the fact that the data sources that might have to be linked in a particular research project may have been originally collected at different times, for different original purposes, based on different legal justifications and under different consent regimes.[2] Going forward we can probably achieve some degree of harmonization of legal justifications and consent regimes, but it is unlikely that all relevant diversity between data sources can be removed. A solution will therefore have to deal adequately with the historical contingencies, as well as with continuing diversity among data sources.

In the following paragraphs we will briefly outline and criticise some of the suggested ‘solutions’ to the problem, before describing and defending a new solution ‘meta consent’. Some of the critical points raised about other solutions also need to be discussed in relation to meta consent and will therefore be discussed more extensively in later sections.

[1] Information Commisioner’s Office. 2014. Big Data and Data Protection [Internet]. Information Commisioner’s Office; Available from: https://ico.org.uk/media/for-organisations/documents/1541/big-data-and-data-protection.pdf; Institute of Medicine; 2012 *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America*. Washington DC: The Institute of Medicine.

[2] This problem is further exacerbated when old data sources are digitized.

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It is about autonomy and ‘my’ data/tissue in most of the ‘ethical’ debate

- Recent Taipei declaration of WMA
  - “My” data and tissue
  - Consent etc
    - For specific research should be specific
    - Consent for human dignity and preventing discrimination
  - Might be different after national legislation with democratic procedures etc,
  - but tide against “us”

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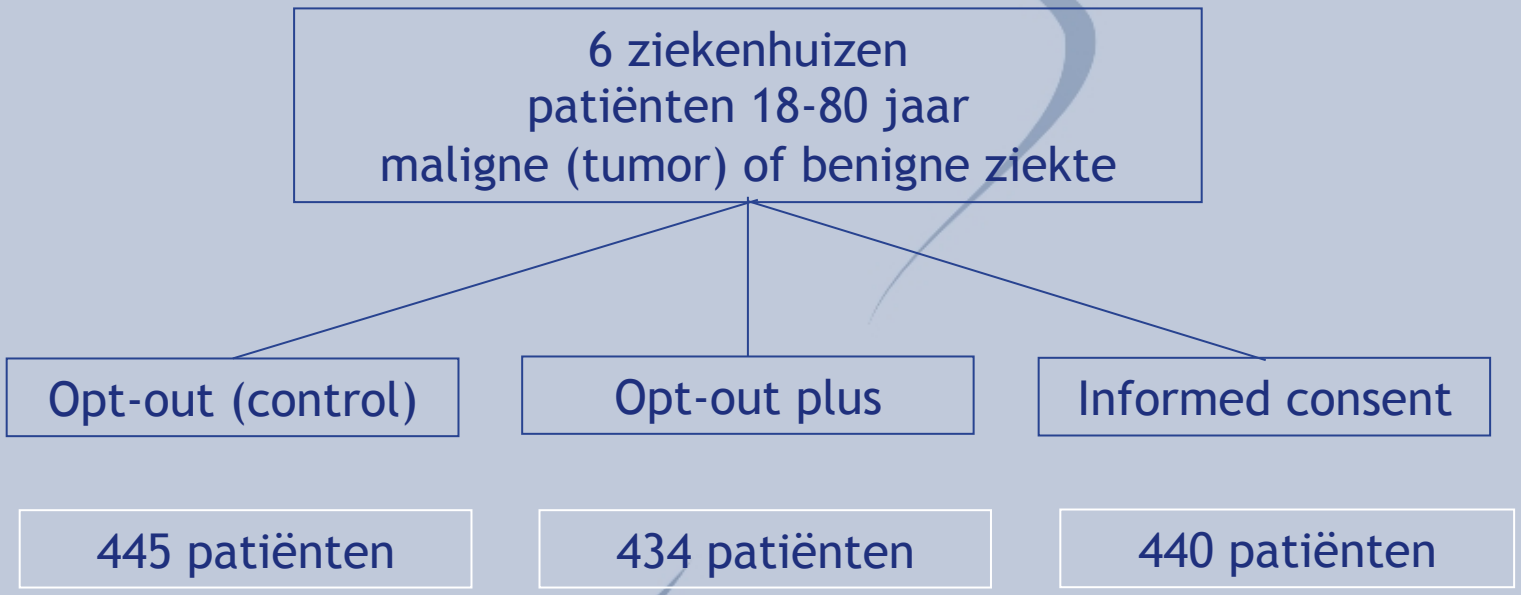
More ….

- Rothstein 2015 (*J Law Med Ethics*
  - No evidence of bias and anyhow informed consent for this observational research counts more
  - Ionannidis : can be bias but results might be lead to discrimination etc.
- As if
  - present practices are perfect
  - there weren't many bans on discrimination in W. rule of law societies
  - And if some results wouldn't empower individuals
- Yet, we need more evidence what we would loose

Consent studie met 3 procedures



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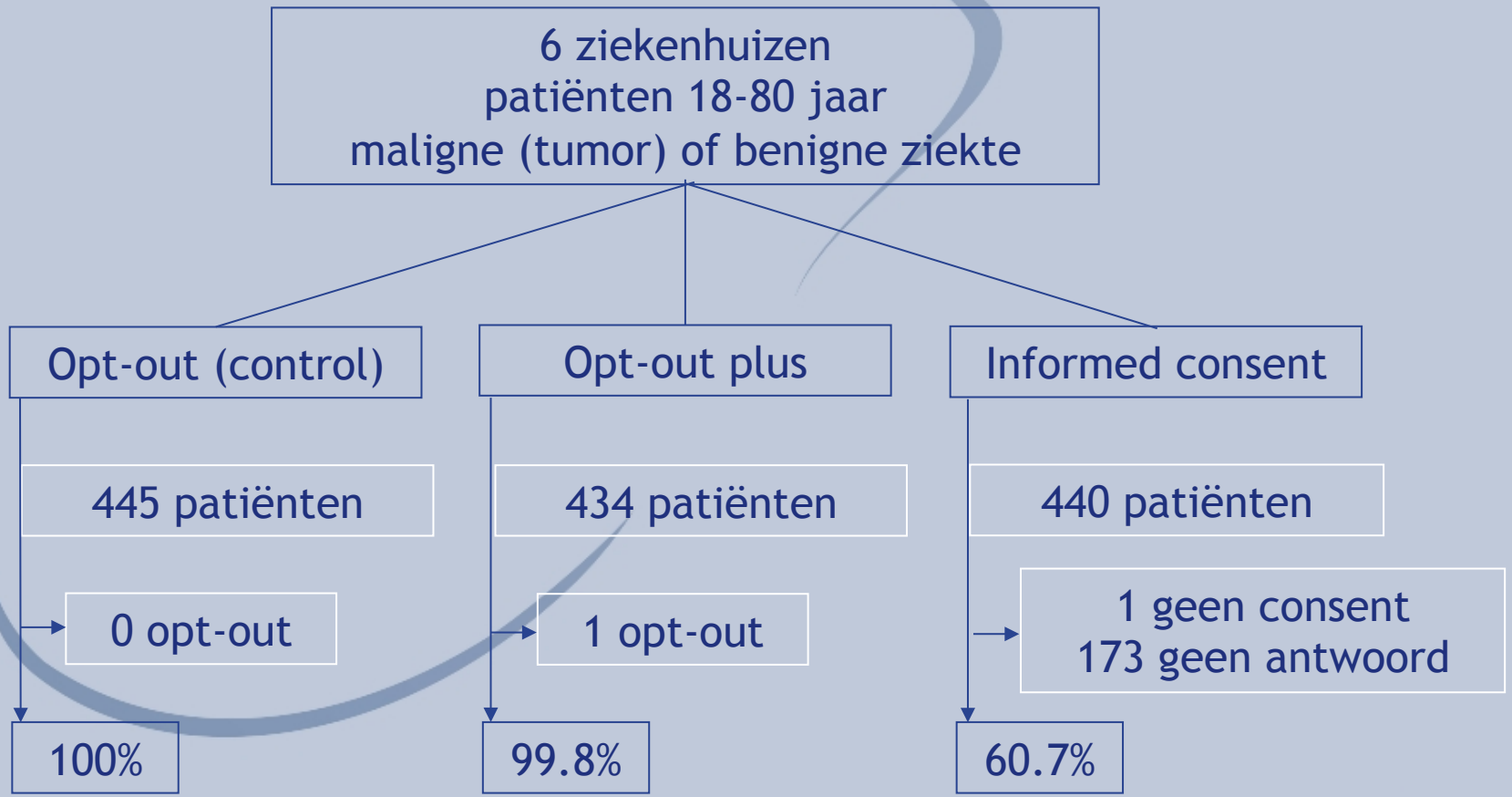
Rebers et al Plos One 2016

WHO really do object ?



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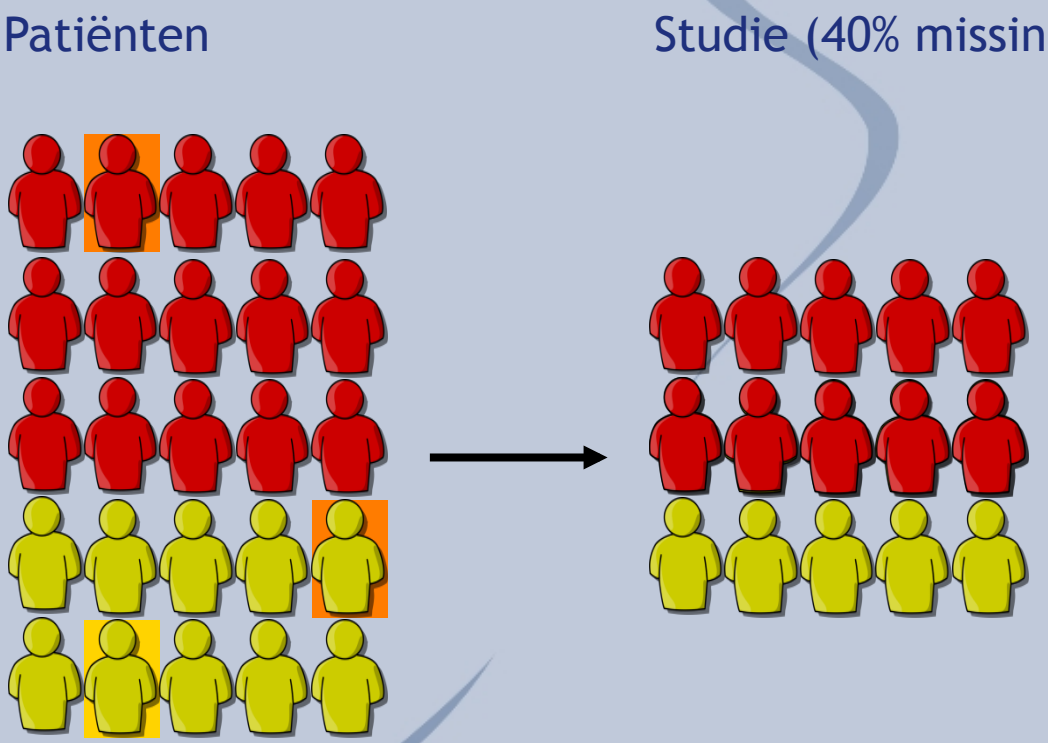
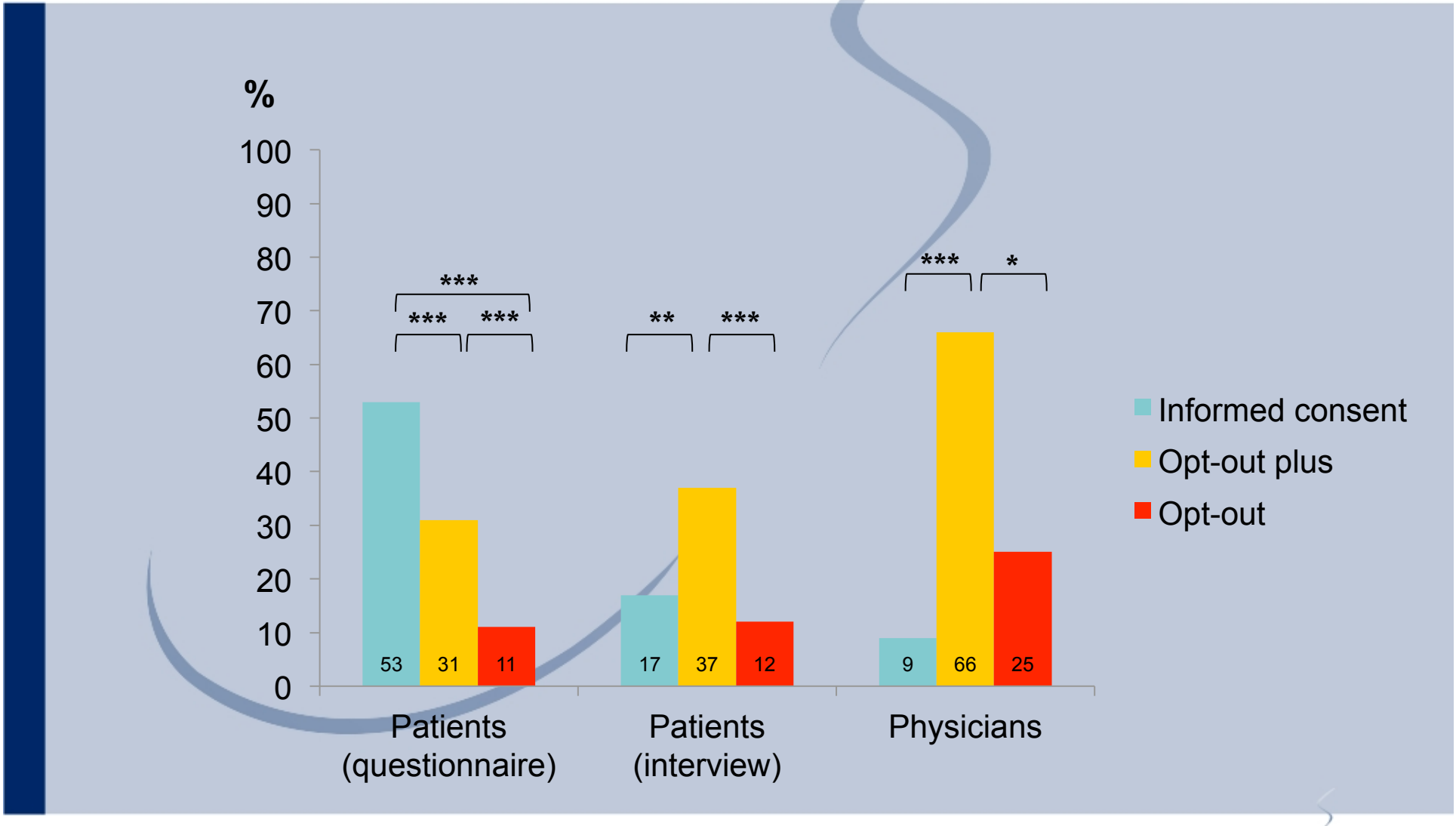
Wie missen we?



We missen specifieke patiënten en dit kan van invloed zijn op de klinische uitkomsten van

Wat vinden patiënten van de 3 procedures?



Chi-square tests. *: P<0.05, **: P<0.01, ***P<0.001

Rebers et al Plos One 2016

What's next

- Legal arrangements for cross country datasharing
  - Fairly easy
  - Depends on national law what data can be used for research
  - Complicated governance arrangements
    - Will those prevail in the present climate
- More 'against the current' bioethical research
- More recent empirical research on
  - 'bias' ,Patient 'real' wishes through focus groups good questions etc. (Coppen EJPH 2015)