Ethical and legal challenges of artificial intelligence and big data

Dr. med. Susanne Driessen
President swissethics

21 January 2020
1. Ethics committees and ethical principles

2. Generation of data and knowledge

3. Legal challenges of Artificial Intelligence (US / EU / CH)

4. Ethical challenges

5. Chain of responsibilities
Swiss ethics committees (EC)
Research: Responsibility of ECs

GCP 3.2: The EC should consist of a reasonable number of members, who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed trial.

HRA art. 51: …EC shall assess whether research projects and the conduct thereof comply with the ethical, legal and scientific requirements…
Ethics: Question of good action in the social context

**Deontology** (deon: «duty»):
ethics of duty, morality, the necessary, the desired

**Teleology** (telos: «aim»):
utilitarianism, consequentialist theory

the will
the well-being
# Principles of biomedical ethics

<table>
<thead>
<tr>
<th>autonomy («Autonomie»)</th>
<th>beneficence («Fürsorge»)</th>
</tr>
</thead>
<tbody>
<tr>
<td>voluntas aegroti suprema lex</td>
<td>salus aegroti suprema lex</td>
</tr>
<tr>
<td>justice («Gerechtigkeit»)</td>
<td>non maleficence («Nicht-Schaden»)</td>
</tr>
<tr>
<td>suum cuique</td>
<td>primum non nocere</td>
</tr>
</tbody>
</table>

# Morality and legality (Emanuel Kant)

<table>
<thead>
<tr>
<th></th>
<th>legality</th>
<th>«morality» (ethics)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setting</td>
<td>«passive» obligatory action</td>
<td>«active» duty</td>
</tr>
<tr>
<td>Quality</td>
<td>following laws</td>
<td>morally valuable</td>
</tr>
<tr>
<td>Verification</td>
<td>external legal conformity</td>
<td>according to categorical maxim</td>
</tr>
</tbody>
</table>

Source: modified after Giovanno Maio; Mittelpunkt Mensch: Ethik in der Medizin, 2012

«right»  «good»
Ethical requirements

- social or scientific value
- scientific validity
- fair subject selection
- favourable risk-benefit ratio
- independent review
- informed consent
- respect for potential and enrolled subjects

E. Emanuel, JAMA 2000; 283: 2701-2711
Value of Artificial Intelligence

«Data analytics, AI, and machine learning are about identification. But they have little role in establishing the structures, cultures and incentives necessary to change the behaviours of clinicians and patients.»

E. Emanuel, JAMA 2019; 321: 2281-2282
Task of «transition»

Big Data, Artificial Intelligence → Changing of behaviour

Question of responsibility
The global landscape of AI ethics guidelines

Anna Jobin, Marcello Ienca and Effy Vayena*

86% Transparency
81% Justice and fairness
71% Non maleficience and responsibility
56% Privacy
49% Beneficence
40% Freedom and autonomy
33% Trust
15% Dignity
7% Solidarity
Human Research Act (HRA)

Art. 1 Purpose

1 The purpose of this Act is to protect the dignity, privacy and health of human beings involved in research.

2 It is also designed to:
   a. create favourable conditions for research involving human beings;
   b. help to ensure the quality of research involving human beings;
   c. ensure the transparency of research involving human beings.
Research 2016 – 2018 (CH)

Source: Human research in Switzerland 2018 published by FOPH, data from BASEC, swissethics
Frequency of genetic analysis: All approved projects in 2018

- 2368 total projects
- 218 genetic
- 218 total projects genetic
- 200 human genetic
- 13 bacterial genetic
- 5 human-bacterial genetic

- no genetic 90.8%
- genetic 9.2%
- human genetics 91.7%
- human-bacterial genetics 2.3%
- bacterial genetics 6.0%
Legal challenges of AI

General legal issues:
- Data protection, GDPR, manipulation

Decision making process: personal decision to machine logics:
- Algorithm: Watson, Ultromics, Arterys, Optellum
- Apps
- Robots

«De-Personalization» of responsibility:
- New doctor-patient relationship
- Question of personal liability?

Source: C.W. Lüchinger: Apps, Algorithmen und Roboter in der Medizin: Haftungsrechtliche Herausforderungen, Swisslex, Schultes Verlag, HAVE 2019
1. The International Medical Device Regulators Forum defines software as a medical device as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.

2. The FDA … considers medical purpose as those purposes that are intended to treat, diagnose, cure, mitigate, or prevent disease or other conditions.
Locked and changing algorithms

- «locked algorithms»
- «changing algorithms» / «deep learning algorithms»:
  - two stages: learning and updating
  - changing behavior: addition of new input types or adding new cases
  - update occurs when the new version of the algorithm is deployed

Aim: safe and effective software
GMLP: Good Machine Learning Practice
How to deal with changing algorithms?

- «deep learning algorithms»: researchers submit a *predetermined change control plan* in premarket submissions

- includes the types of anticipated modifications: how to deal with changes in a controlled manner:
  «Algorithm Change Protocol»

«This potential framework allows for the FDA's regulatory oversight to embrace the iterative improvement power of artificial intelligence and machine learning-based software as a medical device, while assuring patient safety.»
Risk adapted approach (FDA)

**Figure 1: SaMD IMDRF risk categorization**

<table>
<thead>
<tr>
<th>State of healthcare situation or condition</th>
<th>Significance of information provided by SaMD to healthcare decision</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Treat or diagnose</td>
</tr>
<tr>
<td>Critical</td>
<td>IV</td>
</tr>
<tr>
<td>Serious</td>
<td>III</td>
</tr>
<tr>
<td>Non-serious</td>
<td>II</td>
</tr>
</tbody>
</table>

SaMD: Software as a Medical Device

Categories:
- I: very low risk
- II: low risk
- III: intermediate risk
- IV: high risk
Apps: FDA definition

Apps for medical purposes:
according to active regulations for «Medical Devices»
- research context
- routine clinical use

Apps with no medical purposes are Apps:
- for administrative support of a health care facility
- for maintaining or encouraging a healthy lifestyle
- that serve as electronic patient records
- for transferring, storing, converting formats, or displaying data
- that provide certain, limited clinical decision support
EU-Standards

- Definitions comparable to FDA
- Focusses on GDPR and data security
- Empowers patients and gives them rights
- Problem in research: «right to be forgotten»
- But: GDPR emblematic to address novel digital challenges
Ethikkommission des Kantons St. Gallen (EKSG)

- HRA
  - with persons
    - clinical trial
      - IMP
        - cat. A
        - cat. B
        - cat. C
      - MD
        - cat. A
        - cat. C
      - other clinical trial
        - cat. A
        - cat. B
  - non-clinical trial
    - cat. A
    - cat. B
  - without persons «further use»
    - health related personal data
    - biologic. material
    - deceased persons
    - embryos, fetuses

«safety issues»

ClinO

HRO
Ethical requirements to use AI

- unbiased input data
- input data representing target population
- unbiased algorithms (inner logic of algorithms)
- transparent algorithms
- fair and understandable consent procedure

«augmented intelligence»: not replacing humans (the doctor) but complementing and enhancing the competence by using AI
1. Understand users, their needs and the context
2. Define the outcome and how the technology will contribute to it
3. Use data that is in line with appropriate guidelines for the purpose for which it is being used
4. Be fair, transparent and accountable about what data is being used
5. Make use of open standards
6. Be transparent about the limitations of the data used and algorithms deployed
7. Show what type of algorithm is being developed or deployed, the ethical examination of how the data is used, how its performance will be validated and how it will be integrated into health and care provision
8. Generate evidence of effectiveness for the intended use and value for money
9. Make security integral to the design
10. Define the commercial strategy
Ethical issue: Informed consent

*study specific consent*
known objectives
assessable risks for specific studies

*general consent («broad consent»)*
without specific research purpose
unknown, future questions
e-consent, dynamic – transparent consent

benefits for participants and science:

reciprocal interaction
better participation, empowerment
abolition of doctor-patient asymmetry
right to get a copy of the data
recontacting, change of use, e.g. additional sample
connection with other research platforms
publication of results
Individual

preserving personal interests
control and participation
autonomy
informational self-determination
sovereignty
no abuse or commercialization

Society

using opportunities for the common good
access and transparency
solidarity and fair distribution
Patient doctor relationship...

supporting diagnosis
supporting clinical decisions

... machines do not replace interactions...

January 2, 2018

*What This Computer Needs Is a Physician*

Humanism and Artificial Intelligence

Abraham Verghese, MD; Nigam H. Shah, MBBS, PhD; Robert A. Harrington, MD

*Author Affiliations*

....in the era of AI

- Meaningful dialogue between doctors and patients
- Importance of personal contact and interaction
- Doctors must communicate and explain and inform patients of AI and machine learning
- Try to increase trust and acceptance
## Liability of doctors

<table>
<thead>
<tr>
<th>Scenario</th>
<th>AI recommendation</th>
<th>AI accuracy</th>
<th>Physician action</th>
<th>Patient outcome</th>
<th>Legal outcome (probable)</th>
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<tbody>
<tr>
<td>1</td>
<td>Standard of care</td>
<td>Correct</td>
<td>Follows</td>
<td>Good</td>
<td>No injury and no liability</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td>Rejects</td>
<td>Bad</td>
<td>Injury and liability</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>Incorrect (standard of care is incorrect)</td>
<td>Follows</td>
<td>Bad</td>
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W. Nicolson Price, S. Gerke, I Glenn Cohen, Potential Liability for Physicians using Artificial Intelligence, JAMA, Oct. 4, 2019

very high competence of doctors!
# Liability of doctors

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<tr>
<td>5</td>
<td>Nonstandard care</td>
<td>Correct (standard of care is incorrect)</td>
<td>Follows</td>
<td>Good</td>
<td>No injury and no liability</td>
</tr>
<tr>
<td>6</td>
<td></td>
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<td></td>
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<tr>
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Chain of responsibility (1)

Data level
moral responsibility of the researcher
producing unbiased and transparent data

Artificial intelligence level
researcher, software innovation,
institutions, universities, hospitals

Ethical and regulatory authority level
applying legal and ethical requirements and standards
ensure patients rights, Code of Conduct
Chain of responsibility (2)

Medical personal responsibility level
medical decisions in face of AI

Society and politic level
solidarity principle
adapations of the laws

Global level
Ethical principles remain the same in a
changing system
Ethikkommission des Kantons St. Gallen (EKSG)