DigiMed Bayern Symposium, 05.12.2023

THE SOCIAL CONTRACT AND TRUST IN LARGE-SCALE GENOMICS INITIATIVES. COMPARATIVE PERSPECTIVES

Ruth Horn, Universities of Oxford and Augsburg

UK-FR-D GENE (Genomics and Ethics Network)

AGENDA

- Why does data-driven heathcare challenge public trust and the social contract between medicine and society?
- How do different countries (re)negotiate the social contract and maintain public trust?
  - Case study of data governance in England, France and Germany
- Conclusion: suggestions for how to maintain public trust

CHALLENGES OF DATA-DRIVEN HEALTHCARE

Genomics, i.e. data-driven healthcare, **challenges long-standing**

- **principles** of healthcare such as confidentiality, consent, and privacy
- **relationships** between clinical care and research; patients and healthcare professionals; public and private sector
- **understandings** of illness, health, risk, medical (un)certainty etc.
- **assumptions**, **expectations** and **responsibilities** of and between the healthcare system, patients and the public

➔ Requires rethinking of the 'social contract' (Lucassen et al. 2016) or 'social licence' (Carter at al. 2015) between medicine and society

SOCIAL CONTRACT AND TRUST

- Explicit and implicit **agreements** between citizens and the government / governing actors / public institutions
- Establishes each party's (healthcare institutions, professionals and patients) **rights and duties towards each other** and their **mutual expectations**
- Provides basis of **social order and trust** between the individual and public institutions

➢ Changes to established norms and values **challenge the social contract and the trust** that originates from it

(RE)NEGOTIATING THE SOCIAL CONTRACT

- How do countries (re)negotiate the social contract i.e. maintain public trust?
- **(Public) Trust**
  - citizens' belief in the commitment of public institutions to serve and promote the interests of the public

- Case-study
  - **Data governance** (data collection, privacy and consent modalities, and data access plans) in 3 European countries (England, France and Germany)

ENGLAND
DATA COLLECTION AND CONSENT MODALITIES

Genomics England

100KGP (2013) ➔ +500K Genomes (2018)

NHS Genomic Medicine Service (GMS) (2021)

- clinical care and recruitment for research

- **Consent materials (for clinical and research use)**
  - developed with stakeholders (incl. patient/participant representatives)
  - involvement of children, young people and adults who lack or have lost capacity
  - (i) use of pseudonymised data for research; (ii) recontact for further research; (iii) return of clinically applicable research results;
  - confidentiality not absolute; duty to consider relatives‘ interests

Commitment to **public engagement** across divers and broad populations

ENGLAND
DATA MANAGEMENT AND SHARING

National Genomic Research Library

- **„reading not lending data“**
  - data can be viewed and analysed, but not downloaded
  - answers are given only to the specific research question

- Data Accesss Committee (incl. participant representation)

- Data cloud service from Amazon Web Services based in the UK

➔ **Trusted Research Environment** to encourage public trust

FRANCE
DATA COLLECTION AND CONSENT MODALITIES

Plan France Médecine Génomique 2025 (PFMG)

- 235,000 genomes / year (from 2020)
- 4 pilot projects collecting data from patients with (1) cancer; (2) rare disease; (3) common disease; (4) general French population
- Centralised system for data analysis ('Data Collector Analyser')
- **Consent** regulated by the French Bioethics Laws (2021)
  - **clinical setting**: only for diagnosis, treatment or family history
  - **research setting**:
    - choice to receive additional findings
    - obligation to return relevant findings to relatives
    - where patient cannot express will/deceased testing may be undertaken, if in public interest

FRANCE
DATA MANAGEMENT AND SHARING

PFMG: building data-sharing collaborations

- Commitment to patients, French research and economic standing in international competition

- **French Health Data Hub (FHDH)**
  - unique entry point to access health data for research
  - data can only be remotely accessed and processed **on** the FHDH platform and **if** research is promoting 'public interests'
  - FHDH data stored in Microsoft's Azure cloud based in the US

➔ Strong focus on **experts** and no public engagement initiative exists

GERMANY
DATA COLLECTION AND CONSENT MODALITIES

- Centralising scattered data: no large integrated genome resources

- **National Research Data Infrastructure (NRDI) 2020:**
  - make data available and usable to researchers and scientists
  - provide long-term data storage, backup, and accessibility

- **German Human Genome-Phenome Archive (GHGA):**
  - development of rigorous data governance structure
  - translation of research findings into clinical routine
  - different conset modules for clinicians, researchers and institutions

➔ Emphasis on rigorous and trustworthy gouvernance

GERMANY
DATA MANAGEMENT AND SHARING

A two-tier model separating research and clinic

GHGA

- gen-/omics data from research/clinical trials
- FAIR principles - make data Findable, Accessible, Interoperable, and Reusable
- ELSI-team: develop consent and information materials through participant representatives' involvement and democratic forums

GENOMDE

- data from gene panels and WGS during clinical care
- to be set up to make clinical data accessible for secondary use in research

➔ Building public trust through transparency, accountability, reliable oversight, and patient/participant/public involvement

RE-VISITING THE SOCIAL CONTRACT

Historical, political and cultural factors shape each countries responses

- **UK:**
  - Emphasis on individual stakeholders to develop policies via upstream public debates and engagement
- **France**
  - Focus on a centralised model, law and experts representing a top-down governance approach
- **Germany:**
  - Background of historical experiences requires public consultations(democratic forums) and PPI for policy development

RE-VISITING THE SOCIAL CONTRACT

- Each country addresses emerging challenges in its **own way**
- **Communalities**:
  - Recognition that **trust** requires citizens to be informed about and understand what they agree to
    - **Transparency** and **accountability** (i.e., trustworthiness)
    - Uses of health data ought to generate **public benefit**

CONCLUSION

- Large-scale health data collection and management raise questions about **what is reasonable for citizens to expect of scientists and health systems**, in terms of use and management of their data
- Challenges are posed to public trust and need to be addressed by:
  1. **Transparent and accountable** governance programmes involving the public/patients
  2. **Trusted research environments**, transparent consent protocols placing patient benefit over economic benefit
  3. **Awareness** of concerns about **cross-border data transfer** due to incoherencies between regional, national, and supranational regulations

THANK YOU

ruth.horn@ethox.ox.ac.uk

ruth.horn@med.uni-augsburg.de