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Privacy and ethical considerations related to human genome sequences in public health data sets

Claudia Emerson, PhD

Professor, Department of Philosophy
Director, IEPI

Accelerating the Use of Pathogen Genomics and Metagenomics in Public Health:
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Discussion Points

- I. Privacy implications: balancing individual and public interests
- II. Ethical considerations in public health surveillance activities
- III. Managing/mitigating ethical risks

Assumptions:

- unconsented data collection
- human genomic information is present in collected samples, e.g., from wastewater, environmental samples (including 'human genetic bycatch')
- Other health information may be present, e.g., data on communicable and non-communicable disease, substance use, demographic data...and metadata

I. Privacy Implications

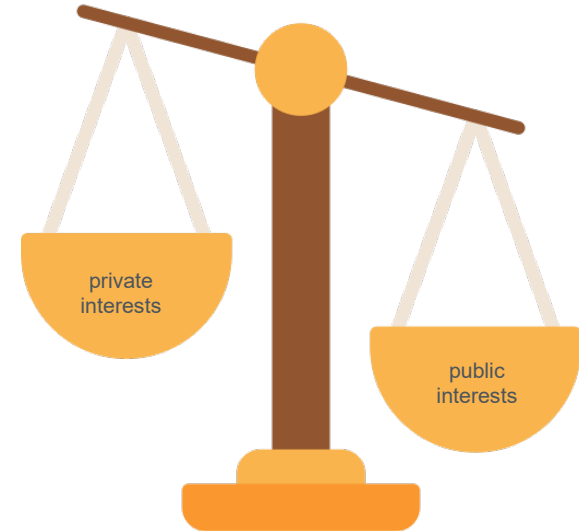
For individuals and communities

- More than just theoretical risk: samples may include identifiable information in genomic sequences or in conjunction with other data, particularly metadata
- Potential identification may result in stigma, discrimination, perpetuate existing inequities, and raise questions of fairness (e.g., data is used to justify restrictions; results in unintended consequences, including socio-economic)

For public health actors

- Determining the nature and scope of obligations 1) to balance privacy protection with duty to 'act on data' and share further; 2) to be responsive to findings

Need to balance risks and benefits



I. Privacy Implications: a Case Study

- In Wisconsin, Shafer et al narrowed down to 30 individuals (out of 100,000) the source of a cryptic lineage of SARS-CoV2 in wastewater
- Several ethical concerns raised:
 - Potential identification of a single individual shedding virus
 - Undiagnosed chronic shedding warrants linkage to care

Considerations and response

- Minimize risks and maximize benefits
 - Manage disclosure risks, engagement with affected constituency (many discussions between PH leaders and Employment leaders)
- Consultation with local officials and bioethicist
- Impacted persons (employees in the facility) offered RT-PCR testing
- Transparency about data and results management

Note → PH surveillance activities are distinct from research and norms of human participant research do not apply



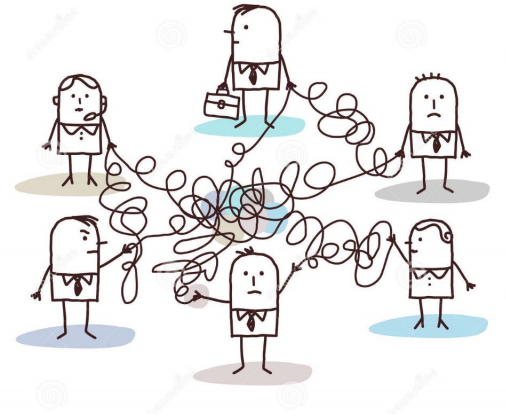
II. Ethical Considerations in Public Health Surveillance Activities

- Public health surveillance is recognized as a duty (WHO, 2017)
- Pathogen genomics (indeed multi-omic technologies) may be transformative for public health, and therefore attending to the ethical challenges raised is essential for realizing benefits
- Issues raised include:
 - privacy risks to individuals and communities
 - fairness in distribution of benefits and burdens
 - considerations of justice in remediating or responding to harms
 - inclusiveness of historically marginalized populations
 - responsiveness to community health needs
 - ethical data management, inclusive of data sharing

II. Ethical Considerations in Public Health Surveillance Activities

Additionally, and critically

- awareness of complex socio-cultural environment
- awareness of trust/erosion of trust, and confidence in PH
- equitable partnerships → equitable participation in the research enterprise, capacity strengthening, and attribution, particularly when LMIC partners are involved
- resource allocation
- time is an ethical issue!



III. Managing Ethical Risks

- Adopt best practices for ethical data management and privacy protection: sample size, deidentification, data security (monitor and control access; formal agreements for access and transfer)
- Manage expectations (public, partners, etc.)
 - Engage with communities, develop relationships
 - privacy may not be the most useful concept in public health context → confidentiality
 - understand obligations of the various actors
 - translation of benefits (public, partners)
- Clear communication, particularly with respect to benefits and risks (w/ public satisfies a principle of reciprocity)
- Draw on existing guidance (e.g., *WHO Guidelines on ethical issues in PH surveillance, 2017; GA4GH*)
- When the public health/ research boundary is too blurry, seek ethics approval (seek consent where practically feasible)
- Lessons from similar contexts or analogous cases → knowledge sharing

III. Managing Ethical Risks

- Anchoring pathogen genomic surveillance programs in the values that underpin public health
 - Promotion of the public good / common good
 - Respect for persons and communities
 - Solidarity
 - Equity
 - Justice in global partnerships



Thank you

Grace Gabber, PhD Student

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