Anticipating the ELSI of the NIH Human Virome Program

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The Virome

*"Biologists estimate that **380 trillion viruses are living on and inside your body** right now—10 times the number of bacteria. Some can cause illness, but many simply coexist with you. Scientists' rapidly expanding knowledge makes it clear that . . . our bodies are really superorganisms of cohabitating cells, bacteria, fungi and, **most numerous of all, viruses**."* *

Advancing understanding of the human virome is a U.S. cross-institutional national priority. CDC's Pathogen Genomics Centers of Excellence; NIH's Common Fund-supported Human Virome Program (HVP); and National Institute of Allergy and Infectious Diseases Genomic Centers for Infectious Diseases support projects that will comprehensively capture the role of viruses in the human body. This investment trio reflects the enormous clinical and public health potential of expanding our understanding of human viruses, providing unexpected insights into individual and population health. This team is examining how ELSI scholars can keep up with advances in viromic science and technology.

ELSI and the Virome

Anticipating ELSI of the HVP can be informed by comparisons with HGP and HMP	HGP[1]	HMP[2]	HVP[3]
Privacy/confidentiality/unique identifiability of genetic information Molecular surveillance enabling cluster detection and response, ethics of phylogenetics	✓	✓	✓
Psychological/other impact of individual or group stigmatization Potential for stigmatization based on particular virome characteristics	✓	✓	✓
Reproductive issues, including complex, potentially controversial procedures	✓	✓	
Clinical research issues, including consent & return of results Bacteriophage first-in-human trials raise concerns about consent, safety and equity	✓	✓	✓
Uncertainties associated with gene tests for susceptibilities and complex conditions Public uncertainty re: complex genetic interactions among viruses, hosts, & vectors	✓	✓	✓
Conceptual & philosophical implications of human responsibility, free will vs genetic determinism, concepts of health and disease. Social implications of viral nomenclature; new challenges to ideas of self, normality, abnormality, purity & contagion; and what it means to be human	✓	✓	✓
Health and environmental issues concerning genetically modified foods & microbes Waste-water surveillance	✓	✓	✓
Commercialization, property rights, accessibility of data & materials At home virus testing kits; intellectual property	✓	✓	✓
Physical safety concerns Concerns about laboratory escape & gain-of function virulence factor studies		✓	✓
Justice concerns including diversity of subjects, data sharing, access to testing	✓	✓	✓

[1] Human Genome Project, [2] Human Microbiome Project, [3] Human Virome Project

How to anticipate empirically

1. **Discover** what the general public thinks about the concept and potential harms & benefits of characterizing the human virome.
2. **Examine** the views of virologists, viromics researchers, and other relevant professionals regarding the most salient ELSI issues in viromics research.
3. **Engage** scientists, clinicians, and the general public to develop educational materials for various audiences to counteract potential misunderstanding yet and acknowledge the uncertainties in current knowledge of the virome.
4. **Develop** cases to explore ELSI issues in any translation from research to treatment, e.g., phage therapy issues regarding ownership; biospecimen and data sharing; treatment cost; equity in access; global reach and representativeness.

* Pride, D. (2020). Viruses can help us as well as harm us. *Scientific American*, *323*(6), 46-53.