

Summary of “Understanding the Global Gain-of-Function Research Landscape”

Gain- and loss-of-function (GOF and LOF) research have contributed to breakthroughs in vaccine development, genetic research, and gene therapy. At the same time, a subset of GOF and LOF studies involve high-risk, highly virulent pathogens that could spread widely among humans if deliberately or unintentionally released. **To maintain US competitiveness in this scientific area, policymakers seeking to regulate gain-of-function (GOF) research will need to develop balanced policies that effectively mitigate varying risk factors without preventing essential scientific studies.**

CSET analysts identified approximately 7,000 scientific publications that employ GOF or LOF research published in PubMed between 2000 and mid-2022. Our findings suggest that future policies will need to carefully consider the following:

- 1. GOF and LOF research are widely used in public health applications.**
Approximately 24 percent of the identified publications were related to vaccine development and the most-studied pathogens are those that cause a high global health burden, like flu viruses.
- 2. GOF and LOF research are intertwined and difficult to predict, so regulations that restrict GOF research will also restrict the less risky and largely benign LOF research.** GOF and LOF employ the same experimental techniques; LOF research is more frequent than GOF research and approximately 29 percent of identified studies involve both GOF and LOF research.
- 3. GOF research can be conducted without access to advanced gene editing technologies.** 21 percent of all publications we identified for this report use serial passaging to modify pathogens, which requires only basic laboratory equipment and materials and was more frequent for publications that result in GOF than those that result in LOF.
- 4. Risk varies among GOF studies, and should not be uniformly regulated.**
Factors like the pathogen and animal model used change the risk level of GOF research. Regulations will need to target the types of research that cause the most risk to account for these vital differences.

For more information:

- Download the report: <https://cset.georgetown.edu/publication/understanding-the-global-gain-of-function-research-landscape>
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