

On the Origin of Samples: Pathogen Provenance and the Rise of the Material Transfer Agreement

Submitted to the *Journal of Science & Law* for consideration as an Opinions article.

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The opinions expressed here are those of the author and do not necessarily reflect those of the Australian Defence Force.

Total: 1,161 words

Keywords:

1. Convention on Biological Diversity
2. Nagoya Protocol
3. Access and Benefit-Sharing
4. Genetic Resources
5. Sovereignty

Abstract:

The purpose of this Opinions article is to inform scientists of the access and benefit-sharing (ABS) laws that could encroach on their ability to obtain pathogen samples for research purposes. The United Nations' *Convention on Biological Diversity* (CBD) reaffirms the sovereign right of states over their genetic resources and recommends that access to such resources occur on mutually agreed terms and with the prior informed consent of eligible providers. This creates the conditions for a *quid pro quo* on genetic resources, essentially transforming them into articles of trade. The CBD cedes the authority to determine the terms of access to genetic resources, including pathogens, to national governments and this has created a patchwork of domestic ABS regulations around the globe. This article posits that the current ABS regime creates unacceptable incentives to avoid benefit-sharing obligations that could irreparably skew the scientific record. Scientists may restrict their research to samples collected from countries with lax ABS policies, or might even be tempted to misrepresent the provenance of pathogen samples to avoid entering into protracted and potentially expensive benefit-sharing negotiations. The article concludes that one solution might be to use Material Transfer Agreements as a chain-of-custody tool until such time as policymakers can reconcile the ambiguities and inconsistencies of international pathogen sharing regulations.

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Michelle F. Rourke

In scientific analyses, there is one thing more troubling than data without context: data with an erroneous context. In pathogen research, sample provenance is everything. Without provenance details like host species, tissue type and geographical location, a microbial sample is largely useless.

It goes without saying that data derived from samples of unknown or dubious origins ought to be dismissed outright. But when testing samples from old collections and using data from collaborators or open datasets, it is difficult to confirm the provenance of those samples or data. Errors of this nature are undoubtedly rare and statistically nominal. Ideally, unintentional provenance inaccuracies like misidentification or simple transposition errors will eventually be recognized and amended. But the self-correcting nature of science is not infallible and there is little doubt that provenance errors have left an enduring imprint on the scientific record.

This is the damage that is done unintentionally, without planning or malevolence. But if there emerged an incentive to lie about sample provenance, the damage to the scientific record could be both undetectable and potentially disastrous.

As important as sample provenance is to pathogen research, it is becoming ever more important for legal reasons (and the underlying pecuniary motives). The issue of where

scientists obtain their pathogen samples is becoming a minefield of political and policy complications.

Access to genetic resources is dealt with under the United Nations' *Convention on Biological Diversity* (CBD).¹ Adopted in 1992, the CBD has been ratified by all UN member states, with the notable exception of the United States of America.²

This framework treaty and its associated *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization* (Nagoya Protocol),³ reaffirms the rights of individual nation states to assert sovereignty over the genetic materials found within their territories. The framework creates the conditions for a bilateral *quid pro quo* for the transnational access and benefit-sharing (ABS) of genetic resources.

The effect is that nation states can claim sovereignty over any bacteria, viruses, viroids, prions, fungi or any derivatives, isolated from samples originating from within their territorial borders. While sovereignty does not confer exclusive ownership rights, the nation state does have the right to dictate the terms of access to those genetic resources and the CBD confirms this.⁴

The CBD defers to individual states to prescribe the exact conditions of these bilateral transfers. In order to access genetic resources from a particular country, you must abide by the domestic legislation of that country. In this respect, the USA's resistance might be for naught as they will have to comply with the country of origin's ABS laws irrespective of whether they ratify the CBD.

Human genetic material is excluded from the remit of the CBD. While there is some dispute as to whether this exclusion should extend to pathogenic materials derived from human samples,⁵⁻⁷ the CBD leaves it to individual nations to determine which genetic resources attract benefit-sharing obligations under their domestic ABS legislation.⁸

Furthermore, there is debate as to whether non-commercial research into pathogens should attract the same regulation as commercial use (it is worth noting that the growing university-industrial complex has seen the line between commercial and non-commercial use indelibly blurred).^{7,9} Again, the fact remains that nation states themselves are the arbiters of what uses are, and what are not considered subject to regulation at the domestic level.

This patchwork of jurisdictions and regulations created by the CBD stands to create a major problem for the scientific record. The domestic ABS policies adopted around the world can range from positively stifling to non-existent.¹⁰ For scientists searching for novel pathogens, surveying the microbiomes of migrating animal species, tracking the transnational spread of known microbes or searching for the origins of virulent pathogen strains, the incentive is to conduct this work on samples isolated from within countries with amenable or lax ABS laws.

This generates two very disturbing implications: first, many countries that are already scientifically disadvantaged stand to be further neglected in the scientific record. Secondly, and perhaps most worryingly, it creates an inducement to obfuscate or misrepresent the provenance of particular pathogen samples.

For example, if a sample of scientific interest and value can be found transnationally, then scientists might elect to take such samples only from the territory with greater access freedoms, introducing selection bias. Moreover, if a sample is taken from within the border of a country with stringent access regulations, it may appear easier to falsely indicate that the sample was sourced from an adjacent, less rigid jurisdiction. A seemingly minor alteration to the stated geographical provenance of a sample might avoid benefit-sharing obligations, but the concern is that if such a practice were to become relatively commonplace it could irreparably skew the scientific record.

Many researchers will already be familiar with the near-ubiquitous Material Transfer Agreements (MTA) that accompany transfers of cell lines, cytokines, antibodies and pathogen samples between research institutions. For most institutions, this is a means of ensuring appropriate attribution and at this point, it is typically proprietary materials that attract requests of compensation, monetary or otherwise. The next logical step, as authorized by the CBD, is the compensation for access to pathogenic resources transferred between nation states.

In light of these problems, the MTA could soon double as a chain-of-custody tool, identifying not only prior informed consent and mutually agreed contractual terms, but confirming the provenance of the transferrable materials. The MTA too, will not be invulnerable to alteration or misrepresentation.

The key message is that movement of pathogenic samples (and other genetic resources) is no longer an unrestricted free-for-all. This is not without precedent; many would remember the situation that arose in 2007 when Indonesia claimed sovereignty over its H5N1 avian

influenza samples, denying access to the World Health Organization (WHO).^{5,11} This resulted in the adoption of the *Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits* in 2011 (PIP Framework).¹² The PIP Framework created a WHO-regulated multilateral ABS system, employing the use of two Standard Material Transfer Agreements (SMTAs): the first to assign access from the sovereign state to the WHO and the second to transfer samples from the WHO to third parties such as vaccine manufacturers.¹³ While the PIP Framework created a multilateral access system for potentially pandemic influenza strains, all other human pathogens were lamentably left within the ambit of the CBD.⁸

It is regrettable that the gift-economy that lay at the very heart of science for centuries is steadily giving way to policy restrictions and commercial interests. Researchers must be prepared for and try to reconcile the influence that the patchwork of international ABS laws might have on the scientific record and research processes. Scientists need to engage in the development of ABS policy both internationally and nationally to ensure that the very laudable goals of these laws can be achieved without encroaching unnecessarily on the practice of science and, most importantly, without permanently skewing the scientific record.

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