

MEDICINE AND THE LAW

Exporting DNA – striking a balance between preventing exploitation and promoting innovation

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DNA contains the blueprint of life. Variations in the script determine the great diversity that characterises our planet. As the analysis of large datasets derived from DNA reveals the hidden secrets of normal and abnormal structure and function as well as our ancestry, the movement of DNA between research laboratories is becoming commonplace. DNA is a resource that can be used for the benefit or to the detriment of the individuals and communities from which it is derived. But can DNA be treated as a simple commodity? How do we deal with questions such as sovereignty, discrimination and commercialisation? What underlies the current trends in attempting to regulate the movement of DNA? And how can we achieve a balance between preventing exploitation and promoting innovation? This brief overview attempts to contextualise the current landscape in South Africa with regard to the DNA that is destined to leave our shores.

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Given the great genetic diversity of South Africa (SA)'s population and our high burden of disease, researchers and industry are keen to access the information contained in the DNA of our people. DNA from southern Africans is highly coveted, especially that derived from indigenous populations such as the San. Considered to be one of the oldest living populations on the planet, the San originate from the original hunter-gatherer populations that roamed the subcontinent before the arrival of populations from the north, either by land or by sea.

Preventing exploitation

With its history of colonisation and exploitation, Africa is now pushing back.^[1] Many countries are tightening up the processes required for the export of DNA, and SA is no exception.^[2] Our legislation clearly states that all DNA that leaves our shores requires an export permit in order to do so.^[3] In the past, this was all that was required. This has allowed for the mass export of DNA, particularly by pharmaceutical companies conducting clinical trials, often for purposes of undertaking pharmacogenetic analyses.^[4] However, as the problem of exploitation is still fresh in the minds of many South Africans, and with the realisation that this information could be used in the design of pharmaceuticals that might ultimately find their way back to the country and be used to treat its diverse peoples, the question arises whether this cycle could become a form of exploitation itself, if not correctly managed.

In response to these issues, which are now uppermost in the minds of many of the country's regulators, the requirements for export of DNA are increasing. It is no longer sufficient just to complete an export permit request form supplied by the National Department of Health (NDoH); additional documentation that would apparently limit this exploitation is now required. This includes: (i) a material transfer agreement (MTA) that details what will be done with the DNA and how the information derived therefrom will be used; and (ii) where appropriate, approval from a research ethics committee when the DNA is being used for research purposes (Department of

Health, personal communication 14 October 2016). Three important points that complement the above need to be considered: (i) the details in the MTA must reflect what is stipulated in the informed consent document, and the latter should ideally form part of the submission to the NDoH, although this is not a formal requirement at present; (ii) additional information regarding commercial exploitation of the data and possible benefit-sharing arrangements must be dealt with in the MTA; and (iii) information on the ownership/custodianship of the DNA (and its eventual destruction) and the data derived therefrom should be clearly set out.

There is a lack of agreement between the DoH, the research community, genetics service providers and industry regarding the need for an MTA. As a result, a discretionary approach has been requested based on whether or not the activity for which the DNA will be utilised is fee-for-service, research or has commercial intent.

Ownership of DNA and data is a thorny issue for which there is at present no consensual view.^[2] It is not only important in the context of intellectual property ownership and commercialisation, but also with regard to judgemental and discriminatory attitudes that impact negatively on the individuals or populations concerned. The notion of genomic sovereignty, which refers to the need to regulate ownership of human genetic resources, is an area of intense debate.^[5-7] So is the notion that commercialisation of DNA, which is derived from cells that constitute organs and tissues, could be viewed as 'trading', which in the context of organs is clearly not well viewed. And what about the data that are derived from DNA? How should these be viewed, since they not only contain information that may be of importance from the point of drug metabolism (in the case of pharmacogenetics), but can literally be used to 'reconstruct' an entire person and are likely to reveal that individual's strengths and vulnerabilities? In the absence of oversight, nothing prevents the custodians of the DNA from utilising it for purposes other than those for which it was initially intended. Part of an oversight mechanism should be to ensure that the emerging and increasingly accepted norms governing informed consent should be adhered to.^[8]

Promoting innovation

Should we hinder the progress of science by restricting access to information that might, in the right hands, lead to the discovery of the next blockbuster drug? Should we not adopt a more liberal and open policy that would speed up the already rapid rate of discovery, ultimately to the benefit of all humankind?

Striking a balance

The answer probably lies somewhere in between. Individuals and populations that have been subjected to decades of repression and exploitation will tend to be protective of their assets (including DNA and the data derived therefrom), and this is understandable. Time, improvements in quality of life and the transfer of appropriate information will be required to alleviate some of the suffering generated by the ills of the past. Those who utilise DNA for research purposes and ultimately for commercial gain should be sensitive to the needs of the individuals and populations from whom the DNA originated. This means, for example, that the wholesale export of DNA by the pharmaceutical industry must be tempered by a set of checks and balances that include recognition of the source of the DNA and acknowledgement of the benefits that may be derived therefrom. If this argument is followed through to completion, mechanisms should be put into place to ensure that this recognition translates into tangible benefits to the affected communities. These benefits may take many forms that do not necessarily need to be monetary, but at the very least should influence pricing of the medications that emerge, which will be used on the very same populations that contributed to their design.

In summary, with the advent of next-generation sequencing, the power of computational biology (including bioinformatics) and

the ability to manage large sets of data from which very precise information can be derived,^[9] care should be taken to strike a balance between preventing exploitation and promoting innovation. Only by considering all the facts at hand and by anticipating possible future scenarios will we be able to ensure that human suffering is limited, whether it be through illness or through less tangible factors such as exploitation and discrimination. A brave and exciting new era is unfolding as technology opens up multiple new avenues that existed previously only in the realms of science fiction, and we should ensure that we are alert to the opportunities and do not miss or sink the boat.

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