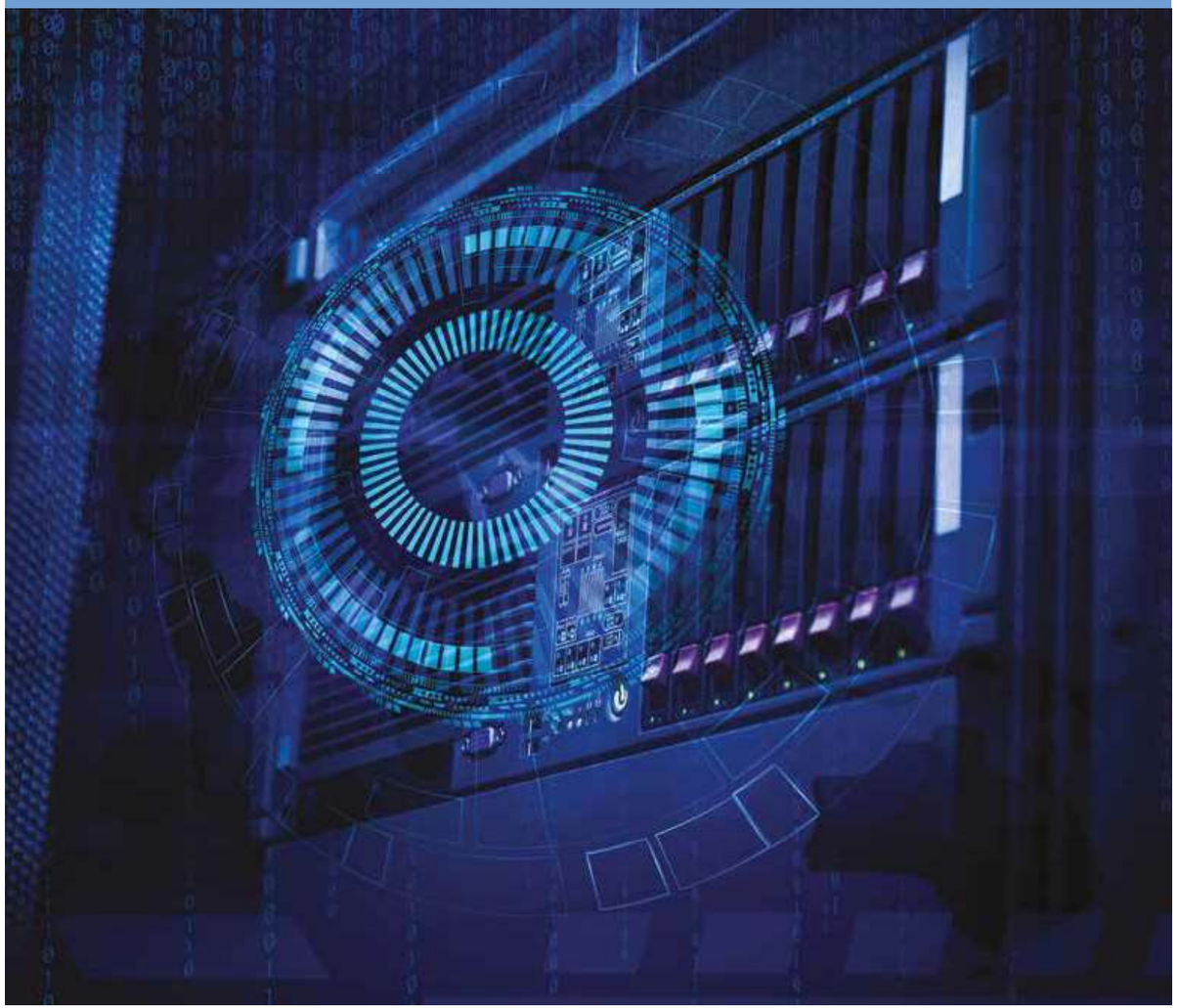
Considering ethical questions emerging from new forms of data

An expert group of the Organisation for Economic Cooperation and Development (OECD) considered ethical issues arising from research use of new forms of data, including so-called 'big data'. It provided a set of high-level recommendations that could underpin a system for the ethical governance of research. *Christa van Zyl* outlines the results.



These days, everything we do in electronic format leaves a digital trace. Transactions that are carried out, administrative information and even our movements can be collected and stored in ways that such little bits of information – or data – can be further processed, organised and interpreted.

This kind of analytical work can help researchers to uncover patterns of behaviour, systematic neglect, or rapid change that had not been noticed before. The benefits can be remarkable, but in the course of such research, personal, sensitive and potentially damaging information can be uncovered.

Whereas many countries have legislation to protect personal information – in South Africa, for instance, we have the Protection of Personal Information Act (4 of 2013), which promotes the protection of personal information by public and private bodies – there are also provisions that allow for exceptions, such as when data involving personal information are used for research.

This kind of exception, in the interest of good and useful research, implies that there is an expectation that researchers will be responsible and take into account ethical considerations when dealing with information of a more personal nature. But it cannot be taken for granted that researchers will always know how to anticipate and deal with ethical issues that may emerge when dealing with new forms of data as part of their research.

This was the issue of concern of the expert OECD group, who developed a high-level set of guidelines and recommendations for the ethical management of research, set out in a report entitled *Research ethics and new forms of data for social and economic research*.

Why 'new forms of data'?

The expression 'new forms of data' was deliberately chosen over the term 'big data', which is related but not entirely similar. 'New forms of data' may include data that are 'big', such as data from internet usage, tracking data, satellite and aerial imagery. It may also include many other forms of data that had not necessarily been generated or collected with a research purpose in mind but have tremendous research potential in terms of further research and analysis. Examples include government transactions, registration records and commercial transactions.

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In its report, the expert group identified various role players who can help to establish and strengthen an environment where research involving new forms of data is encouraged, but in a context where there is due consideration for, and adherence to, ethical principles.

The recommendations also address various role players, including researchers proposing to use new forms of data for social research; those who control access to new forms of data with research potential; those who employ researchers; and those who fund researchers; as well as entities at the national level with responsibility for the oversight of research ethics.

What could research organisations do?

To provide some guidelines for researchers and research organisations, the report recommends the following:

- Applying for research funding – national and multi-national research funding agencies should ensure that researchers have shown in their research plan that they are cognisant of the relevant legal frameworks that may impact upon their access to and use of personal data for research; understand the adequacy of such legislation to protect the privacy of data subjects; and understand their legal responsibilities in relation to data collection, storage, processing, and sharing.
- Institutional control – a suitable constituted ethics review body (ERB) to ensure that their policy and practice can cover the assessment of respect and privacy issues in proposals for data access and sharing where existing legal frameworks may not provide adequate protection for the data subjects, or where the data and/or research cross national boundaries.
- The responsibility of researchers – researchers should produce a brief statement to explain the general purposes and motivations for the research that evaluates the potential risks to individuals or groups associated with the data; the wording of the consent sought for data collection should be such that future research projects can use the data; and where research is deemed vital but consent is impossible, make available the proper information to those concerned before the research goes ahead.
- Understanding consent – data controllers, research funders, ethics review bodies and researchers should carefully consider the nature of consent obtained or required for the processing of personal data for research (has it been obtained? Is it valid for the specified research? If not, can it be obtained?).
- Non-consented research use – where consent for research use of personal data is not possible or would impact

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severely upon potential research findings of crucial societal importance, ethics review bodies should evaluate the potential risks and benefits of the proposed research. If the proposed project is deemed ethically and legally justified without consent being obtained, ethics review bodies should ensure that public information is made available about the research and the reasons why consent is not deemed practicable and impose conditions that minimise the risk of inadvertent disclosure of identities.

- Individuals described to remain anonymous – research funding agencies should encourage further research on the development of statistical methods and software to provide anonymisation techniques.
- Public engagement – institutions that handle data should make available complete information about how and where the data is gathered or bought and to what other agencies, if any, data is sold or made available; and
- Building and monitoring trust with the public – research funding agencies and other national and international agencies should consider building public awareness and legitimacy concerning the use of new forms of data in social science research.

The report concludes by stating that some readers may view the recommendations as creating obstacles, inhibiting research based on new forms of data. On the contrary, the recommendations in this report are intended to be useful for all those involved in social science research, whether as researchers, reviewers, funders, data controllers/holders, publishers or policy makers.

The intention is to highlight the kind of support that is available to help avoid pitfalls even before they are encountered.

'Social scientists conduct their research in an atmosphere of trust, and trust will be eroded if there is a perceived misuse of personal data by some within the research community. An overarching aim for the recommendations presented in this report is to uphold this trust relationship between social scientists and the public.'

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The full report of the expert group can be accessed at http://bit.ly/2l0co5d

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KHANYISA: Community-based interventions to **increase** HIV testing and treatment uptake among MSM

Men who have sex with men (MSM) are at high risk for HIV acquisition and transmission and face significant barriers in gaining access to health-care services. *Nancy Phaswana-Mafuya, Stefan Baral* and *Travis Sanchez* are leading a team of investigators embarking on an implementation science study that aims to improve HIV care outcomes of South African MSM living with HIV infection.

A range of evidence-based interventions aimed at improving the general health and wellbeing of MSM is available but their optimal implementation within existing service provision settings has not yet been demonstrated. Moreover, much of the programming and research to date has focused on the prevention of HIV acquisition with less attention to strategies to better support MSM living with HIV.

Implementation science is the study of methods to promote the integration of research findings and evidence into healthcare policy and practice. '*Khanyisa*: A new HSRC collaborative study to leverage community and peer-based approaches to impact the HIV treatment cascade among men who have sex with men in South Africa' uses community-based approaches and other MSM to ensure that those on antiretroviral therapy (ART) adhere to treatment and achieve viral load suppression. *Khanyisa* means 'light' in Xhosa.

Khanyisa seeks to contribute to improvement of HIV care outcomes of South African MSM living with HIV infection by:

- implementing a package of interventions that reach MSM living with HIV infection, linking them to health services, initiating them on ART and supporting them in remaining in care and being adherent to their treatment regimens; and
- assessing uptake, feasibility, acceptability, and coverage (implementation science effectiveness trial) at each stage of the HIV continuum of care and treatment cascade that will ultimately be scalable within sub-Saharan African HIV care settings

Khanyisa's methods

Khanyisa examines the effectiveness of the service package among MSM aged 18 years and older in six sites, namely: Port Elizabeth, Cape Town, Moloto, Pietermaritzburg, Springs and Letsitele. The project kicked off in June 2016.

MSM receive a service package that is staggered (single-step wedge design). A stepped-wedge trial is a form of randomised controlled trial that involves sequential but random rollout of an intervention over multiple time periods. The package includes point-of-care (POC) with medical diagnostic testing at *Khanyisa* 'non-clinic' sites, HIV testing, CD4 testing, treatment initiation and peer-navigation services.

Three sites, called immediate intervention sites, based in Port Elizabeth, Cape Town and Pietermaritzburg, are receiving immediate POC. The three delayed intervention sites, based in Moloto, Limpopo and Springs, currently receive POC HIV testing, linked to local clinics for standard care.

The delayed intervention sites will receive the comprehensive package six months later. All participants will be followed passively through National Health and Laboratory Services (NHLS) and clinic records for a period of 12 – 24 months after enrolment to determine the study's primary HIV care outcome, which is suppressed HIV viral loads below 40 copies/ml within six months of initiating treatment).

Enrolment started in June 2016. Since inception the team has screened 1 123 MSM, tested 1 023 for HIV and identified 184 (18%) MSM living with HIV. Among MSM living with HIV, 133 (72%) were newly diagnosed.

The Centres for Disease Control and Prevention (CDC) funds the HSRC to conduct this study. The study is led by researchers from the HSRC, Johns Hopkins University, Emory University, National Institute of Chronic Diseases and the Desmond Tutu HIV Foundation.

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