ARESA

ADVANCING RESEARCH ETHICS TRAINING IN SOUTHERN AFRICA

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ARESA Bioethics Leadership Program and Doctoral Candidates, Centre for Medical Law and Ethics (CMEL), Stellenbosch University

Dear REC Members

We are very pleased to circulate this issue of the ARESA Newsletter to you. We highlight here some of the important activities of the ARESA Bioethics Leadership Program for the past year. The 9th Annual ARESA seminar planned for 2020 was postponed to 2021 due to the COVID-19 pandemic. This newsletter issue contains highlights from the 9th Annual ARESA Seminar, which was held online via MS Teams from the 15th to 17th September 2021. Here, we present a flavor of the ARESA seminar proceedings through summaries of some of the presentations. We wish you happy reading!

Theresa Burgess, Francis Masiye and Shenuka Singh



Boitumelo Mokgatla, Victor Chalwe, Tiwonge Mtande and Joseph Ochieng




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HIGHLIGHTS FROM THE 9TH ANNUAL ARESA RESEARCH ETHICS SEMINAR 16th and 17th September 2021

For the first time in its history, the ARESA seminar was held fully online. This year, more than 70 delegates from various Southern African Research Ethics Committees (RECs) attended our annual seminar, and we were delighted to welcome back ARESA alumni. The theme for this year was 'Ethical challenges raised by COVID-19 in Southern Africa.' We had 3 plenary sessions namely, **ethical challenges with COVID-19 research, public health challenges on the African continent during COVID-19** and **regulatory and guideline updates: POPIA and SAGCP 2020**. At the end of each plenary session, the speakers engaged with attendees in an hour panel discussion. A wide range of stimulating talks on current and topical issues that have arisen during the pandemic were delivered by South African speakers (Assoc Prof Theresa Burgess, Assoc Prof Brian Allwood, Prof Jerome Singh, Prof Shenuka Singh, and Dr Gonasagrie Lulu Nair); and international speakers from the rest of Africa (Mr. Francis Masiye, Ms. Tiwonge Mtande, Assoc Prof Joseph Ochieng, Assoc Prof Victor Chalwe, and Prof Walter Jaoko).

Ethical issues in Public Health emergency research in South Africa: The case of COVID-19 – *Assoc Prof Theresa Burgess*

In the African context, RECs were further challenged by historical mistrust of research and potential impacts on COVID-19 related research participation and vaccine hesitancy, as well as the need to facilitate equitable access to effective treatments or vaccines for COVID-19. In the South African context, an absent National Health Research Ethics Council (NHREC) also left RECs without national guidance for a significant duration of the COVID-19 pandemic, leaving individual South African RECs to independently navigate their way through many complexities of COVID-19 research ethics. We conducted a qualitative descriptive study that explored the perspectives and experiences of RECs regarding the procedural, ethical, legal and health equity challenges of COVID-19 research in South Africa.

Numerous, significant ethical complexities and challenges were identified by South African RECs in the review of COVID-19 related research. While RECs are resilient and adaptable, reviewer and REC fatigue were major concerns. RECs may also be too dependent on traditional, individualistic principles and benchmarks for clinical research and a public health research ethics framework, where more weight is given to community and population interests may be needed. Further, comparative analysis between different countries is needed to develop the discourse around African RECs and COVID-19 research ethics issues.

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Conducting research on COVID-19 during the pandemic: a clinician/researcher perspective – *Assoc Prof Brian Allwood*

Prof Allwood shared a professional-personal story entitled "Capacity, Cowboys and Bravery A COVID Tale" – in his presentation, he asked the question how do we balance clinical responsibilities with the research responsibilities? Because as a clinician working in a government hospital, we have a huge patient load, we are required to open an established service, train undergraduate and postgraduate students, and then above all, required to conduct research.

In February 2020, before the first wave hit South Africa, two key areas needed intervention; first was the challenge of collecting data and doing research from the core phase of the pandemic. The second was the huge number of publications and filtering through what is good from what is just noise at the core phase.

Brian established a research response team which was made up of non-clinicians and clinician academics to help filter out what is good from what is bad. He indicated that a Morning Brief Scientific Review was initiated, which produced 70-morning briefs and >40 contributors from mid-March to mid-August 2021. As per Brian "The Stellenbosch University (SU) response team were able to help us write protocols and process data and enabled us to do research that we ordinarily cannot do in a clinical domain".

In a rapidly evolving pandemic like COVID-19, clinicians need to guard against 'outcome bias', which arises when a decision is based on the outcome of previous events without regard to how past events developed.

Experiences of REC members and administrators in Malawi in reviewing research protocols during the COVID-19 pandemic – Mr *Mr. Francis Masiye and Ms Tiwonge Mtande*

The COVID-19 pandemic has changed the research protocol review landscape globally. The most urgent challenge has been to rapidly review research protocols. In Malawi, research guidelines for ethical conduct of research during COVID-19 pandemic were developed by RECs and circulated to researchers. However, there is no national guidance on how RECs ought to operate during emergencies. Therefore, the study sought to explore experiences of REC members and administrators on REC's operations and common ethical issues generating debate during reviews of COVID 19 protocols in Malawi.

This was a cross-section qualitative study. Of the seven RECs in Malawi, three RECs were purposively selected. Twelve (12) REC members and 3 administrators participated in-depth interviews. The data was collected between February and April 2021. Data was transcribed verbatim and thematic analysis was used to analyze the data.

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The following were findings of the study: most participants reported that their RECs are yet to revise their SOPs to include rapid reviews; some participants reported that RECs in Malawi are operating in silos; and few participants reported that rapid review of COVID 19 protocols and virtual review meetings were being promoted by RECs, due to operational challenges.

In terms of ethical issues that generated debates, most participants highlighted the following issues: research participant remuneration; inadequate safety information for the conduct of clinical trials involving herbal medicines; challenges in adhering to ICH GCP for research conducted in routine clinical settings and issues related to a waiver of consent.

In summary, there is no national guidance for the conduct of research in emergency situations, which needs to be put into place urgently. During emergencies, it is also important for RECs to collaborate to promote safety and wellbeing of research participants. Finally, RECs should be flexible to embrace public health research ethics which differs from traditional research ethics and ICH GCP standards.

Impact of vaccine passports on LMICs during a public health emergency – *Assoc Prof Stuart Rennie*

The use of vaccine passports in a world marked by striking inequalities in global vaccine access is ethically controversial for obvious reasons.

When required for international travel, the use of vaccine passports unfairly prohibits the vast majority of those living in low- and middle-income countries from leaving their countries, which likely would have grave social, political, and economic effects. When required domestically for access to services and activities in LMICs, the use of vaccine passports is likely to be the privilege of a socio-economic elite, further widening gaps between the rich and the poor.

Nevertheless, bioethicists (predominantly from high-income countries) have argued that vaccine passports can be ethically acceptable even in the face of global vaccine inequity. How do they do this? This talk identified and critically examined five argumentative strategies commonly used to ethically justify vaccine passports: (1) compartmentalizing the global vaccine problem as a separate issue or too big an issue to tackle; (2) misleadingly framing vaccine passports as a rational, evidence-based policy based on individual risk; (3) claiming that use of vaccine passports adheres to the least-restriction principle; (4) arguing that the disadvantaged will (somehow) benefit from vaccine passports; (5) asserting that disallowing vaccine passports would be irrational. I argue that none of these strategies is convincing, which raises the question of why they are put forward in the first place.

The presence and nature of a high-income country bias in current bioethics discussions of vaccine passports is an area for future research.

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Health system responses and ethical challenges to the health needs of refugees: the case of the COVID-19 pandemic in Zambia – *Assoc Prof Victor Chalwe*

According to Prof Chalwe, this is the first qualitative study to investigate the health concerns and barriers to access COVID-19 services among refugees in Zambia. The findings highlight the need to address the specific needs of refugees at a systemic and individual level.

Based on the views of the participants interviewed, it can be concluded that the refugee population group is particularly affected by limited access to COVID-19 health care services. Inadequate human resources, lack of staff housing, and transport as well as inadequate electricity all contribute to limiting access to health care services. Financial constraints were identified as a main challenge in addressing the comprehensive health needs of refugees in Zambia. Prof Chalwe's findings underline the need for diversified funding and partnership for better financial sustainability of refugee COVID-19 initiatives.

Ethically, the pandemic has also highlighted how longstanding health, housing, financial and inequalities interact with the COVID-19 virus, exacting a disproportionate impact on those already facing disadvantage and discrimination.

COVID-19 vaccine uptake challenges in Kenya – Prof Walter Jaoko

The Government of Kenya (GoK) started administering the COVID-19 vaccine in March, and at the time of Prof Jaoko's presentation, only the AstraZeneca vaccine was available in the country. Kenya has approximately 50 million people, over 2.7 million vaccine doses have been administered by August 27, 2021, and only 2.9% of adults are fully vaccinated.

The planned rollout was in 3 phases to the eligible health care workers, teachers, uniformed forces; vulnerable population >50 years and >18 years with comorbidities; persons in settings such as hospitality & tourism industries. However, well-connected citizens were vaccinated before priority groups, and the Government allowed foreign diplomats to receive vaccines over Kenya's priority groups. There were reports of bribery, corruption, long queues, and priority groups not receiving their vaccine. "It's been a total nightmare. I've called eight different Government and private facilities today alone trying to schedule a vaccine appointment for my parents. Each facility has a different set of rules; some even charge for the vaccine – none had available appointments" – Suzanne Kidenda, Physician for Human Rights.

Vaccine hesitancy amongst Kenyans was reported at 25% in April 2021. These hesitancies were associated with age, level of education, concerns on vaccine safety & effectiveness, religious beliefs, social media influence (the primary source of information), lack of trust in Government, low perception of risk of infection.

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In summary, the ethical concerns around COVID-19 vaccine rollout in Kenya have been around equity, discrimination, fairness, autonomy, coercion, human rights, privacy, religious beliefs, and freedom of choice.

Protection of Personal Information Act (POPIA): how does POPIA impact on research during a pandemic – *Prof Jerome-Amir Singh*

What is distinctive about a pandemic is that they are rapidly evolving, requiring time-sensitive research review, time-sensitive evidence, regulatory flexibility, global data sharing, and collaboration. One of the crucial aspects of a pandemic is that the right to personal privacy must be weighed against the need for data access and data sharing, especially when the disease is a public health threat.

In a pandemic such as COVID -19, the rights of an individual must be weighed against the interests of the wider public which in this specific instance, the principles of public health ethics (which priorities public health) take precedence over medical ethics (which focus on the best interests of the individual).

The impact of PoPIA on research during a pandemic includes health data such as an individual's COVID status would qualify as special personal information in terms of PoPIA. Additional safeguards are required for the collection, processing and storage of special personal information.

The collection of personal information of persons infected with COVID-19 must be limited to a specific purpose (for example, to detect, contain and prevent the spread of COVID-19), and researchers are obliged to process the personal information of participants in a lawful manner.

PoPIA reinforces study participants rights to privacy and confidentiality. However, in the context of a pandemic such as COVID-19, this default position can change. SARS-COV-2 is classified as a category 1 notifiable disease that requires immediate reporting by the most rapid means available upon diagnosis. Regulations provide no exceptions for researchers. Therefore, PoPIA must be read in conjunction with other legislation.

Challenges to biobanking in LMICs during COVID-19 time to reconceptualize research ethics guidance for pandemic and public – *Prof Shenuka* Singh

Collecting samples during a public health emergency and storing these for future research are a public health imperative however ethical concerns related to biobanking seem particularly important to consider in light of COVID-19. These concerns include sharing of bio samples, benefit sharing and informed consent. Therefore, to ensure ethical biobanking practice, stakeholders (such as researchers, biobankers, or research ethics committees) need to be cognizant of the hidden complexities surrounding collection, storage and data sharing, and that appropriate planning occurs at a biobank governance level.

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There is a need for biobanks to strengthen access and the conditions or stipulations under which data are shared during the pandemic. Another layer of governance for the biobank could be a biosafety and biosecurity committee that is set up to review, assess and monitor biosafety and biosecurity risks.

Likewise, research ethics committees or IRBs should conduct careful risk-benefit assessments in the review of such research protocols. From an ethical perspective, a safe working environment would ensure that respect and dignity for researchers and biobanking staff are upheld.

With regards to the export of samples, there should be unambiguous material transfer agreements with clear specifications on how individuals' and communities' rights and interests can be protected.

Dissemination and return of results of research, protecting personal information – *Assoc Prof Joseph Ochieng*

Return of genomics testing results and associated incidental findings has been an issue of global debate although such debates and publications are limited in the African setting. Such data is essential on informing development of context specific ethical guidelines.

Appropriate feedback of results can only be achieved by clear regulation based on contextualized ethical guidelines.

The study assessed stakeholders' perceptions of if and how genetics and genomics testing results should be returned and the implications of such sharing of results in a Ugandan setting to inform development of context specific ethical guidelines. Although the researchers and research regulators are quite cautious, feedback of genetics and genomics testing results and associated incidental findings is needed by the public. Extending feedback to family particularly close ones is also acceptable. Reasons for feedback include the need to know their health conditions, plan and protect loved ones. Such feedback needs to be carried out appropriately hence the need for ethical guidelines. Issues to consider in the guidelines include adequate informed consent, meaningful community engagement, genetics counseling, careful assessment of the risks, benefits, and implications among others.

SAGCP 2020: What's new? – *Dr Gonasagrie Lulu Nair*

South Africa has significant expertise in the design and conduct of clinical trials. Local investigators have played an essential role in advancing global knowledge and impacting policy on several clinical and public health issues. At the same time, we have vulnerable populations from which our trial participants are recruited. It is therefore vital that all aspects of clinical trials are considered in the South African context. And this is the point of South Africa Good Clinical Practices (GCP) 2020.

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The Department of Health (DoH) guidelines on Ethics in Health Research 2015 cover the ethical aspects and infrastructure requirements for clinical research, while SA GCP 2020 covers practical issues related to implementation. The 2020 guidelines, which contain some revised and updated information, are more user friendly and take into account local realities and requirements.

Guidelines align with international guidelines such as International Council for Harmonization (ICH) GCP but were revised in collaboration with DOH, National Health Research Ethics Council (NHREC) and South African Health Products Regulatory Authority (SAHPRA).

Dr Nair's talk addressed the rationale for changes to the new guidelines, followed by a discussion of new sections, especially that related to conducting clinical trials during a pandemic and the use of electronic signatures in research.

The COVID 19 pandemic has impacted the implementation of clinical trials with modifications to protect research participant and staff safety becoming necessary. While it is expected that deviations from an approved protocol will occur due to adherence to public health and safety measures, these need to be reported to both ethics' committees and SAHPRA.

ARESA ALUMNI NEWS

- Dr George Rugare Chingarande has been awarded a Visiting Research Fellowship position at the National Institutes of Health (NIH).
- Dr Gonasagrie (Lulu) Nair has been appointed as a senior lecturer at the Centre for Medical Ethics and Law, Faculty of Medicine and Health Sciences, Stellenbosch University.
- Dr Blanche Pretorius has been appointed as the Head of Health Research Ethics Committees (HREC), Faculty of Medicine and Health Sciences, Stellenbosch University.

To view these plenary discussions and sessions, please visit the Centre for Medical Ethics and Law website, click on the link below

http://www.sun.ac.za/english/faculty/healthsciences/aresa/aresa-seminar/seminar-2021

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UPCOMING CONFERENCES

- 16th World Congress of Bioethics (WCB) Basel, Switzerland 20 – 22 July 2022