

The State of
**Laboratory
Biosafety and
Biosecurity**
in the Southern African
Development Community
(SADC) Region

**Workshop
Proceedings
Report**

19 – 20
March 2018



**science
& technology**

Department:
Science and Technology
REPUBLIC OF SOUTH AFRICA



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June 2018

ISBN: 978-0-6399410-2-8
DOI <http://dx.doi.org/10.17159/assaf.2018/0027>

Published by:

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The Academy of Science of South Africa (ASSAf) was inaugurated in May 1996. It was formed in response to the need for an Academy of Science consonant with the dawn of democracy in South Africa: activist in its mission of using science and scholarship for the benefit of society, with a mandate encompassing all scholarly disciplines that use an open-minded and evidence-based approach to build knowledge. ASSAf thus adopted in its name the term 'science' in the singular as reflecting a common way of enquiring rather than an aggregation of different disciplines. Its Members are elected on the basis of a combination of two principal criteria, academic excellence and significant contributions to society.

The Parliament of South Africa passed the Academy of Science of South Africa Act (*No 67 of 2001*), which came into force on 15 May 2002. This made ASSAf the only academy of science in South Africa officially recognised by government and representing the country in the international community of science academies and elsewhere.

This report reflects the proceedings of the The State of Laboratory Biosafety and Biosecurity in the Southern African Development Community (SADC) Region held on 19 – 20 March 2018 in Johannesburg, South Africa. Views expressed are those of the individuals and not necessarily those of the Academy nor a consensus view of the Academy based on an in-depth evidence-based study.

A photograph of a person in a white lab coat and gloves working in a laboratory. The person is holding a petri dish with a red agar medium. The background shows laboratory equipment, including a rack of test tubes and a petri dish. The image is framed by a large, stylized circular graphic with a blue and orange border.

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ACRONYMS AND ABBREVIATIONS

AfBSA	African Biological Safety Association
ARC	Agricultural Research Council
ASSAf	Academy of Science of South Africa
AU	African Union
BioFISA	Biosciences Finnish-South Africa Partnership Programme
BoBS	Botswana Bureau of Standards
BSL	Biological safety laboratory
BVI	Botswana Vaccine Institute
CDC	Centre for Disease Control and Prevention
DAFF	Department of Agriculture, Forestry and Fisheries
DHET	Department of Higher Education and Training
DoH	Department of Health
DRC	Democratic Republic of Congo
DST	Department of Science and Technology
FMD	Foot-and-mouth disease
GIS	Geographic information system
GMO	Genetically modified organism
IHR	International Health Regulations
JEE	Joint External Evaluation
LMO	Living modified organism
NBA	National Biotechnology Authority
NICD	National Institute of Communicable Diseases
NPC	Non-Proliferation Council
NRF	National Research Foundation
OHS	Occupational health and safety
PPE	Personal protective equipment

RAEIN	Regional Agricultural and Environmental Innovations Network
SACIDS	Southern African Centre for Infectious Diseases and Surveillance
SADC	Southern African Development Community
SANBio	Southern Africa Network for Bioscience
SARS	Severe acute respiratory syndrome
SOP	Standard operating procedure
STI	Science, technology and innovation
UN	United Nations
UNSCR	United Nations Security Council Resolution
US	United States
WHO	World Health Organisation

ACKNOWLEDGEMENTS

This proceedings report is the product of a two-day workshop (19 –20 March 2018) on The State of Laboratory Biosafety and Biosecurity in the Southern African Development Community (SADC) region which was held at Emperor's Palace, Johannesburg.

The Academy's Standing Committee on Biosafety and Biosecurity plays a crucial role with respect to science advice in the area of biosafety and biosecurity and its function includes creating platforms for: engaging in productive exchange of ideas; raising awareness and developing an understanding of biosafety and biosecurity; evaluating existing mechanisms to control and prevent the deliberate, natural or accidental spread or outbreak of infectious diseases and responding to regional biosafety and biosecurity issues. The main goal of this committee is that of responsible science use through the correct implementation of biosafety and biosecurity measures.

The Academy of Science of South Africa (ASSAf) would thus like to acknowledge the members of this Standing Committee for their guidance, participation and contribution towards this workshop. The Committee members are: Prof Iqbal Parker, Chairperson (University of Cape Town); Dr Rachel Chikwamba (Council for Scientific and Industrial Research); Prof Daniel du Toit (Tshwane University of Technology); Dr Chandre Gould (Institute for Security Studies); Dr Nosiphiwe Ngqwala (Rhodes University); Prof Anton van Niekerk (Stellenbosch University) and Dr Jacqueline Weyer (National Institute for Communicable Diseases).

The speakers from the SADC region countries are also acknowledged for their valuable contributions, shedding light on the state of biosafety and biosecurity in their countries and for their overall participation in the workshop. The speakers were: Prof Justin Masumu (Democratic Republic of the Congo); Dr Martha Kandawa-Schulz (Namibia); Dr Gerald Mahloane (Lesotho), Dr Motlalepula Pholo (Botswana); Prof Abednego Dlamini (Swaziland); Dr Roshan Abdallah (Tanzania); Mr Christopher Simuntala and Dr Paul Zambezi (Zambia); Dr Jonathan Mufandaedza (Zimbabwe); Ms Victoria Kachimera (Malawi); Prof Gerald Misinzo (Tanzania); Ms Mandry Ntshani (South Africa) and Ms Delille Wessels (South Africa).

ASSAf's appreciation is also extended to Dr Ereck Chakauya, Dr Hennie Groenewald and Prof Diran Makinde for their support, assistance and contribution to the project.

All workshop participants (Listed in Appendix II) are acknowledged for greatly enriching the discussions and the future direction of laboratory biosafety and biosecurity in the SADC region.

The financial support received from the Department of Science and Technology (DST) is also acknowledged.

The ASSAf secretariat's contributions throughout the project is hereby acknowledged and Ms Heather Erasmus, the scribe from Write Connection, is thanked for her contribution in drafting the report.

Prof Roseanne Diab
ASSAf Executive Officer

EXECUTIVE SUMMARY

The 2003 rapid spread of the severe acute respiratory syndrome (SARS) from Hong Kong to Canada highlighted the threat of disease outbreaks resulting from global inter-connectedness (Bond *et al.*, 2013). This showed how easily highly contagious diseases can move across the world and across national boundaries. The Southern African Development Community (SADC) region has also experienced disease outbreaks over the years which have crossed national boundaries. Currently (2018), the Democratic Republic of the Congo (DRC) is experiencing an Ebola outbreak which already has fatalities and has been reported to have spread beyond the initial affected area (WHO, 2018).

Therefore, due to our inter-connectedness and the rapid movement of people and animals across borders it is crucial to develop, strengthen and implement strategies that cut across national boundaries in order to ensure biosafety and biosecurity in the SADC region.

The World Health Organisation (WHO) defines laboratory biosafety as practices, procedures and proper use of equipment and facilities in order to assure the safe handling, storage and disposal of potentially harmful biological material (pathogens and their products). These practices and procedures are crucial when managing diseases outbreaks as laboratory biosafety also includes measures to prevent harm caused by accidental exposure to dangerous pathogens (WHO, 2006). Biosecurity, on the other hand, refers to measures to protect against both unintentional and intentional use of (potentially) dangerous pathogens and toxins, including the malicious use of biotechnology (WHO, 2006).

In an effort to ascertain the state of laboratory biosafety and biosecurity in South Africa, the Academy of Science of South Africa (ASSAf) undertook a consensus study on the topic. This was done through the Academy's mandate of undertaking studies on matters of public interest with a view towards providing evidence-based scientific advice to relevant stakeholders. In 2015, a consensus study report on *The State of Biosafety and Biosecurity in South Africa* (<http://research.assaf.org.za/handle/20.500.11911/58>) was published. The report made a number of recommendations for South Africa and these were aimed at improving laboratory biosafety and biosecurity issues.

One of the overarching recommendations made was that the report findings and recommendations needed to be considered and discussed at the SADC region level through a symposium/workshop. This was also based on the findings that highlighted the importance of cross-border issues when it comes to biosafety and biosecurity. Hence, the main aim of this two-day workshop was to create a platform where countries in the SADC region could engage in a productive exchange of ideas in relation to existing mechanisms and challenges relating to laboratory biosafety and biosecurity in the region.

Workshop Objectives

The key objectives for this two-day workshop were to:

- Discuss issues of laboratory biosafety and biosecurity importance for the region.
- Strengthen existing collaborations/networks and establish new ones.
- Exchange information and knowledge.
- Chart the way forward.

Workshop Structure

The workshop included formal presentations and facilitated discussions. This workshop proceedings report is a summary of these plus the suggested way forward. All countries in the SADC region were invited to present on the state of laboratory biosafety and biosecurity in their respective countries. Ten out of the 16 SADC countries presented at the workshop. The speakers relied heavily on the WHO's Joint External Evaluation (JEE) of International Health Regulations (IHR) Core Capacities' country reports as guidance for their presentations.

Workshop participants and speakers included scientists, policymakers, non-government representatives and other key role players in the field of biosafety and biosecurity in the SADC region.

Workshop Outcomes

The workshop objectives were met.

The four key challenges that were found to be common across all SADC countries that participated were:

- Lack of or inadequate (and fragmented) legislation, regulations and guidelines relevant to laboratory biosafety and biosecurity.
- Limited or lack of capacity – including infrastructure, resources and human capacity.
- Lack of or limited training programmes on laboratory biosafety and biosecurity.
- Low level of awareness about laboratory biosafety and biosecurity, especially among researchers/scientists.

Based on the challenges identified it was suggested that:

- Advantage should be taken of the current political will and commitment towards the IHR to lobby for resources to support and ensure the development of safe and secure laboratory infrastructure and a competent laboratory workforce.
- The WHO JEE for IHR tool and country findings should be used as a framework to develop interventions, including the development of a sustained local/regional capacity for training.
- There is a need for a regional map of existing assets, identifying strengths and capacity as well as gaps in order to then expand and strengthen what already exists.
- Workshop outcomes should be communicated to the SADC Secretariat through the Department of Science and Technology (DST) in order to ensure that laboratory biosafety and biosecurity are given priority and that there is buy-in from governments in the region

References

- 1 Bond KC, Macfarlane SB, Burke C, Ungchusak K and Wibulpolprasert S. 2013. The evolution and expansion of regional disease surveillance networks and their role in mitigating the threat of infectious disease outbreaks. *Emerging Health Threats Journal*, 6:10. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3557911/>.
- 2 World Health Organisation. 2018. Ebola virus disease. Available from: <http://www.who.int/ebola/en/>.
- 3 World Health Organisation. 2006. Biorisk management: laboratory biosecurity guidance. Available from: http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf

DAY ONE

SESSION ONE: Opening, Background to ASSAf, the Project and Expected Outcomes

Prof Roseanne Diab: ASSAf Executive Officer

Facilitated by Dr Ereck Chakauya: Southern Africa Network for Bioscience (SANBio) and Dr Hennie Groenewald: Biosafety South Africa

Objectives for Day One

Day One mainly served as an introduction to the state of laboratory biosafety and biosecurity in South Africa and other SADC countries through the exchange of information delivered via presentations.

1.1 Opening and Welcome Remarks

Prof Diab extended a warm welcome to the workshop participants on behalf of the ASSAf President, Prof Jonathan Jansen, and the SADC secretariat. She thanked:

- DST for funding the workshop.
- The ASSAf secretariat for organising the workshop and undertaking travel logistics.
- The ASSAf Standing Committee on Biosafety and Biosecurity for its guidance.

She anticipated that the discussions would greatly enrich knowledge about the state of biosafety and biosecurity in the SADC region and help to direct future initiatives in this area.

1.2 Background to ASSAf, the Project and Expected Outcomes

1.2.1 Background to ASSAf

Prof Diab said that ASSAf was launched in 1996 and is recognised as the official national science academy through the ASSAf Act (No 67 of 2001), as amended. Its two mandates are:

- to generate evidence-based solutions to national and global challenges;
- to honour distinguished scholars in all fields of scientific enquiry.

ASSAf currently (2018) has 541 Members representing all science disciplines. These Members are the core asset of the Academy and they give of their time and expertise voluntarily. ASSAf is governed by a Council of 13 members. The ASSAf secretariat is organised into four programmes:

- Governance and Administration.
- Science Advisory.
- Liaison.
- Scholarly Publishing.

1.2.2 Background to the Project

She indicated that in 2010 the ASSAf Standing Committee on Biosafety and Biosecurity, under the Chairmanship of Prof Iqbal Parker, decided to undertake a consensus study on the state of biosafety and biosecurity in South Africa. The main purpose of undertaking consensus studies at ASSAf is to provide evidence-based recommendations to policymakers. Prior to the initiation of this consensus study, the key government departments were consulted and the United States (US) Defence Threat Reduction Agency's Cooperative Biological Engagement Programme funded the study.

She explained that a ten-member panel of experts, led by Prof Jill Farrant (University of Cape Town), undertook this study between 2012 and 2015, with the final report officially launched in July 2015. Individual meetings were held with the DST and the National Research Foundation (NRF), and the Department of Health's (DoH) Communicable Diseases Directorate was also consulted in terms of the implementation of the report's recommendations. Prof Diab indicated that one of the recommendations was that a SADC-wide workshop on biosafety and biosecurity should be held in order to discuss and consider the report's findings and recommendations in a regional context.

She added that the consensus study report is thus the backdrop for this workshop, the key objectives of which were to:

- Discuss issues of biosafety and biosecurity importance for the region.
- Strengthen existing collaborations/networks and establish new ones.
- Exchange information and knowledge.
- Chart the way forward.

1.2.3 Expected Outcomes

- A better understanding of the state of laboratory biosafety and biosecurity in the region.
- How the challenges can be addressed and how opportunities for responsible science use can be strengthened.
- Based on the workshop deliberations, the development of a framework for a proposed in-depth evidence-based study focused on the state of laboratory biosafety and biosecurity in the SADC region.

SESSION TWO: The State of Biosafety and Biosecurity in South Africa Consensus Report

Prof Iqbal Parker: ASSAf Committee Chair & University of Cape Town

Prof Parker gave a presentation on the ASSAf report that was released in 2015.

2.1 Study Goals and Methodologies

Prof Parker highlighted the goals of the study which were to:

- Make sustainable and evidence-based recommendations to the South African government and the scientific community by identifying the weaknesses and gaps in existing legislation and its implementation; the implementation of biosafety and biosecurity in laboratories, and existing measures and capacity to detect and control the spread of infectious diseases.

- Raise awareness of existing measures (including practices and legislation), with the aim of reducing the risks associated with dual use research and to engage the life science community in a dialogue about biosafety and biosecurity.

He added that study methodologies included panel discussions, consultations with various stakeholders, a survey that utilised a WHO template, a workshop, internet searches, interviews and literature reviews on existing policies and guidelines across various departments. He highlighted the three main areas of the report:

2.2 Regulatory Framework

Objectives

- To undertake an assessment of existing legislation and regulations relevant to biosafety and biosecurity in South Africa in order to identify strengths, weaknesses and gaps in the laws and their implementation.
- To conduct a review of infectious agents and related regulations governing research and use of these infectious agents in order to identify, collate and review current South African governmental regulations, policies and guidelines for detecting, identifying, controlling and preventing the natural, accidental or deliberate spread of infectious agents.

Findings

- The categorisation of hazardous pathogens is unclear and inconsistent.
- Responsibilities are divided between several government departments resulting in split and confused responsibilities.
- Interpretations surrounding domestic and international differences regarding biological safety laboratory (BSL) levels are varied.
- There is uncertainty regarding implementation of the available domestic legislation.
- There is insufficient funding and inadequate trained personnel and facilities with respect to quarantine and inspection.

- Human resources to inspect shipments entering and exiting the country are limited.
- There is an inability to identify a single comprehensive list of all infectious agents that pose a threat to public health relevant to South Africa, be it from accidental or deliberate spread.
- Long delays in drafting and promulgating regulations.

2.3 Implementation of Biosafety and Biosecurity Practices

Objectives

- Map and capture the details of the facilities, institutions and companies that make up the life science community in South Africa (including animal, plant and human health facilities).
- Undertake an assessment (using a WHO survey template) of how the life science community in South Africa implements the ethical, biosafety and biosecurity practices at these facilities.

Findings

The key findings from this exercise were categorised into five broad areas:

- **Biosafety and Biosecurity:** A disconnect between knowledge and practical implementation was found.
- **Ethics:** South African research scientists were found to not perceive the importance of basic research ethics training and education (including scientific misconduct).
- **Science and Policy:** Poor communication between policymakers and scientists, pointing to an overall lack of knowledge and training in national and international laws relevant to the life sciences was also identified.
- **Openness and Transparency:** Scientific collaboration is largely encouraged within institutions but less likely to be encouraged between institutions. Financial accountability is common within institutions, but there is less openness about funding sources.
- **Staff Retention:** There was a perception that insufficient efforts are made to retain the skills of senior staff. Less than half of all junior research staff surveyed felt consistently supported and nurtured.

2.4 Responsiveness in Managing Infectious Disease Outbreaks

Objective

To assess responsiveness in terms of managing infectious disease outbreaks in South Africa.

Findings

- The implementation of strategies to detect, identify, record, manage and prevent disease outbreaks at a national level is present.
- South Africa is very experienced in responding to disease outbreaks (especially those caused by dangerous pathogens).
- Regulations are in place.
- There is relatively good communication between sectors, but poor coordination at national and provincial level.
- There is a good system for data collection and availability in some sectors.
- The relationships between sectors are good and clear structures and guidelines exist for managing disease outbreaks.
- There is a lack of adequately trained and available personnel, as well as a lack of funding for outbreak control and prevention.
- There is an absence of good surveillance data, especially for the human and plant sectors, and there is no proper control of animal movement.
- There is a lack of regular monitoring and inspection of facilities and confusion with respect to the lists of infectious agents.

Prof Parker then summarised the overarching key findings and recommendations which were categorised into four broad areas.

2.5 Overarching Key Findings and Recommendations

2.5.1 Improving the Capacity to Detect and Respond to Infectious Disease Outbreaks

- The life science facilities database compiled during the survey

should be considered a national asset and its development and maintenance should be DST's responsibility.

- The DoH, DST, the Department of Agriculture, Forestry and Fisheries (DAFF) and other relevant agencies collectively need to determine whether a comprehensive list of infectious agents would be a helpful tool for policymakers.
- The DoH needs to ensure that health care professionals are made aware of the statutory requirement to notify and improve the current system to ensure accurate reporting of notifiable conditions.

2.5.2 Education and Awareness Raising

- The NRF and the Department of Higher Education and Training (DHET) should consider means to ensure the inclusion of research ethics training in the training of all scientists.
- The DoH should consider drafting regulations to require that relevant laboratory staff undergo biosafety training that includes an assessment of competence.
- The Council for the Non-Proliferation of Weapons of Mass Destruction should develop and disseminate (digitally and in print) details of the relevant national and international laws to all research and diagnostic facilities and all educational facilities in South Africa.
- The NRF should require researchers to demonstrate familiarity with the relevant terms when submitting applications for research that could be considered dual use. Institutional research ethics committees should require evidence of such an assessment having taken place before ethical approval is granted for research, including research not involving human and animal subjects.

2.5.3 Ethics Review

- The National Health Research Ethics Council should take the findings of this study into consideration in the process of revising the research guidelines.
- Funding agencies should take ownership of addressing general research guidelines for all life science research.

- All research institutions undertaking life science research should consider developing and applying a code of conduct for researchers and training should include a comprehensive ethics component and reference to all relevant national and international laws, regulations and conventions.

2.5.4 Scientific Openness and Transparency

- The NRF should actively encourage inter-institutional collaboration through establishing incentives.
- The NRF and the DST should encourage universities and research institutions to acknowledge funders of their research in publications in the interests of accountability and transparency.

Prof Parker concluded by saying that the recommendations of particular relevance to the DST and NRF were discussed with relevant officials in October 2015.

Response from the Agricultural Research Council (ARC), Ms Delille Wessels, ARC

Ms Delille Wessels gave a response highlighting what the ARC has done since the release of the ASSAf report in 2015. Some of the initiatives undertaken so far include:

- Establishment of an Institutional Biosafety and Biosecurity Committee comprising researchers at all levels, quality management experts and members from supporting disciplines. The committee operates independently from the Ethics Committee and takes regulatory requirements into account. Its decisions in respect of biosafety and biosecurity aspects are fed through to the Ethics Committee, which makes the final decision based on its own set of procedures.
- All researchers at the ARC are required to attend training in ethics.
- A train-the-trainer course in biosafety and biosecurity has taken place and a training unit has been put in place to offer courses in biosafety and biosecurity in SADC countries and other parts of Africa. She added that the impact of the course was being assessed.

- Attention has been drawn to the many regulations and laws relating to biosafety and biosecurity that already exist in South Africa.
- The ARC is working with the South African Non-Proliferation Council (NPC) to ensure that procedures are in place to ensure that control of pathogens is enforced and that conflict of interest is addressed.

She added that the ARC has a large animal health diagnostic and research component under the One Health concept. She concluded by suggesting that other research facilities should begin by taking small steps towards implementing and managing biosafety and biosecurity practices. Further, that a concerted effort should be made by all African countries to celebrate International One Health Day in a meaningful way and to support the opportunity for the African continent to host the One Health World Conference.

Summary of Discussion

The facilitated discussion was summarised as follows:

- It was emphasised that researchers and university ethics and biosafety committees should all bear the responsibility of identifying potential dual-use activities.
- The potential overlap between life science biosafety and food safety environments introducing genetically modified organisms (GMOs) was noted.
- It was remarked that the uptake of the report's recommendations for public awareness purposes has not been as good as anticipated. Biosafety and biosecurity should be taken up as part of the NRF's work to improve public understanding of biotechnology.
- It was indicated that biosecurity issues relating to chemical, nuclear and biological weapons have to do with national security and this information should not be in the public domain, but the country's ability to deal with matters of biosecurity should be open for public scrutiny.
- It was remarked that the ASSAf report showed that implementation of biosafety and biosecurity practice is fragmented.

- It was explained that the ASSAf study mostly focused on life sciences and not on health specifically, but certain pathogens (human and animal) were investigated.
- Further elaboration or study in terms of liability from a legal perspective and the degree of awareness of those responsible where there is liability was recommended.
- It was noted that most African countries have participated in the WHO JEE for IHR and that this should be the key driver to bring momentum to the implementation of aspects of biosafety and biosecurity in Africa.
- It was indicated that following the release of the ASSAf report in 2015, a number of global events created the momentum to drive the need for biosafety and biosecurity from the One Health approach:
 - The One Health Forum was initiated in 2014 as part of DoH's national outbreak response team; it includes players from DAFF, the National Institute of Communicable Diseases (NICD), universities and other agencies that deal with potential outbreaks in the country.
- In South Africa the BSL 3 and BSL 4 laboratories are regulated and inspected by DAFF.
- Even though working with dangerous pathogens is strictly regulated, it was noted that downstream regulation is lacking, with many facilities lacking control over access to laboratories and there is poor record keeping in terms of who handles the pathogens or tracking of - the pathogens.
- It was emphasised that the NICD, ARC, the Medical Research Council, the NRF, universities and other institutions have all been consulted about the ASSAf report.
- Swaziland remarked on the high number of commercially driven research institutes and laboratories in South Africa and the fact that Swaziland's research institutes are in the public sector and at universities while industries in the private sector have their own laboratories for their own use.
- It was highlighted that the interpretation of dual-use research of concern differs from country to country and the control of it from a policy perspective would have to define research that

is considered to be of “concern” as everything has a dual use nature.

- It was indicated that the requirements for transfer of materials internationally have always been in place in South Africa, however, there is a lack of awareness of the relevant legislation.
- The list of controlled agents drawn up by the NPC does not necessarily apply to all government departments and thus any discussions on a consolidated list would have to take into consideration the mandates of the different government departments and how the control of the listed agents would be practically implemented.

SESSION THREE: The State of Biosafety and Biosecurity in the Remaining SADC Countries

3.1 Democratic Republic of the Congo

Prof Justin Masumu: *Université Pédagogique Nationale*

Prof Masumu presented an overview based on an internal self-assessment that utilised the WHO JEE for IHR tool completed by the country in 2016. He added that the assessment was led by the Ministry of Health together with experts from other ministries.

He highlighted that the assessment focused on laboratories and that it used the following two indicators:

- i. The existence of government biosafety and biosecurity systems for human, animal and agriculture facilities.
- ii. Biosafety and biosecurity training and practices.

The key strength identified, with respect to indicator (i), was about the handling of highly pathogenic and dangerous agents kept at reference laboratories, access to these facilities and transportation of dangerous material. The challenges identified, also with respect to indicator (i), included:

- Lack of legislation and regulations on biosafety and biosecurity at national level.
- Very low level of application of basic biosafety and biosecurity measures and the absence of an information management system to track dangerous agents.

The key challenges identified in terms of indicator (ii) were about:

- The absence of a formal training programme on biosafety and biosecurity.
- The low level of awareness about biosafety and biosecurity among scientists. However, training is available for people who handle dangerous agents in the laboratory and those involved in response to diseases such as Ebola.

Prof Masumu added that the areas that were highlighted as in need of improvement concerned:

- Legislation, regulation and standard operating procedures (SOPs).
- Formal training programmes, awareness for scientists, communication and coordination between laboratories.
- The extension of biosafety and biosecurity measures to provincial and private laboratories.

Prof Masumu also presented an overview of the use of biosecurity measures implemented during the eight Ebola outbreaks in the DRC since 1976. He mentioned that delays in response time varied between 15 days and five months. Other challenges he highlighted included that:

- Patient management in the field is conducive to nosocomial infections.
- Application of biosafety measures is poor due to the lack of training and resources.
- Working conditions are poor and these include lack of water, electricity and personal protective equipment (PPE).
- Inappropriate transportation of dead bodies and burial methods.

He mentioned that the laboratory for Ebola analysis – the National Institute for Biomedical Research – focuses on training. To date there have not been incidents of laboratory contamination and infection among laboratory technicians and 'Ebola fighters' in the field.

3.2 Namibia

Dr Martha Kandawa-Schulz: University of Namibia

Dr Kandawa-Schulz's presentation was also based on an internal self-assessment that utilised the WHO JEE for IHR tool completed by the country in 2016. The Ministry of Health and Social Services and the National Commission for Research Science and Technology contributed information towards the completion of the JEE assessment.

She mentioned the four specialised laboratories in Namibia: Namibia Institute of Pathology, Central Veterinary Laboratory, National GMO Testing Laboratory and Namibian Standards Institution Testing Centre.

Dr Kandawa-Schulz indicated that the challenges that were identified in the assessment included:

- Limited local capacity and poor collaboration between laboratories within the country and in the region.
- Fragmented national legislative frameworks and the lack of legislation to address both biosafety and biosecurity.
- Poor cross-sector coordination and the need to update regulations to accommodate both human and animal health.
- Lack of regulations and guidelines on how to handle and transport dangerous pathogens and how to protect personnel in the laboratory against infections.
- Inconsistency in the inventory of pathogens.
- Poor inter-ministerial agency communication and cooperation.
- Government to support research, handling and testing in biosafety and biosecurity.

Dr Kandawa-Schulz then indicated issues that were highlighted as needing improvement:

- Identification of dangerous pathogens and how to keep them secure.
- Measures to protect researchers and the community, and awareness thereof.

- Monitoring of pathogens.
- Detection systems (especially at entry points to the country).
- Information on the available laboratories in connection with specific agents.

3.3 Lesotho

Dr Gerard Mahloane: Ministry of Agriculture and Food Security

Dr Mahloane indicated that the WHO JEE for IHR assessment results showed that Lesotho's challenges include:

- Lack infrastructure, resources and human capacity.
- Lack of expertise to train and implement biosafety and biosecurity measures and practices.
- Lack of legislation that regulates laboratories, which are viewed as an extension of veterinary and human laboratory services.

He mentioned that as a result of the WHO JEE for IHR assessment, a multi-sectoral committee (led by the Ministry of Health) was established to develop an action plan for anti-microbial resistance and this committee has held a number of meetings. Dr Mahloane added that the Lesotho government has highlighted the need to invest in a BSL 2 laboratory as the country's only accredited laboratory.

Other issues highlighted by Dr Mahloane included:

- The need for specific legislation that addresses biosafety and biosecurity.
- Lesotho is in the process of enacting new legislation that includes the Biosafety Bill, Animal Health and Production Draft Bill, Food Safety Draft Bill and Radiation Bill.

Dr Mahloane indicated that Lesotho has not yet embraced the One Health approach, but does collaborate in a number of areas, such as anthrax and rabies initiatives. The country also has an emergency preparedness strategy for highly pathogenic avian influenza. Also, the Ministry of Environment is involved in a multi-country project to strengthen institutional capacity of living modified organisms (LMOs) testing in support of the decision-making processes in biosafety regulatory systems.

3.4 Botswana

Dr Motlalepula Pholo: Department of Agricultural Research

Dr Pholo highlighted that the Botswana Bureau of Standards (BoBS) is responsible for standardisation and quality assurance of all scientific products, laboratory practices and international movement of commodities at the national level. BoBS is the national contact point for all SADC programmes.

She listed the accredited facilities that play a biosafety and biosecurity role in Botswana:

- Botswana National Veterinary Laboratory – deals with disease diagnosis, research, food quality assurance and training, and facilitates surveillance programmes for notifiable diseases.
- Botswana Meat Commission Laboratory – deals primarily with chemical analysis microbiological analysis, and food and animal feedstock analysis.
- Botswana Vaccine Institute (BVI) – does research on foot-and-mouth disease (FMD) and other viruses in the region and manufactures vaccines to safeguard the beef trade.
 - BVI adheres strictly to international vaccine standards and has been the sub-Saharan Africa Regional Reference Laboratory for FMD since 1985.
 - BVI has a record of being a secure site with no major biosafety accidents or risks.
- Medical laboratories located in some public and private hospitals – deal with chemistry, haematology, blood reserves, microbiology and serology.
- Botswana Harvard HIV Reference Laboratory – a central facility for processing and testing of clinical specimens.
 - Monitors changes in the regional HIV epidemic and non-communicable diseases, conducts research and surveillance activities, and serves as a training facility.
- Water Utilities Laboratory.

She said the country's regulatory framework related to biosafety and biosecurity addresses the prevention and control of animal diseases, plant protection and public health.

Dr Pholo highlighted the challenges experienced by laboratories (particularly academic research laboratories and non-accredited laboratories) and these include:

- Non-compliance to policies and standards.
- Absence of designated laboratory biosafety officers, limited emergency response plans and training programmes .
- Inappropriate waste disposal, inadequate availability or use of PPE.
- Poor use, operation and maintenance of biosafety equipment.

She concluded by recommending that:

- There is a need to create awareness of biosafety and biosecurity at the national level.
- There is also a need to prevent delays in drafting and enacting national biosafety and biosecurity legislation, which have implications for the efforts being made to mainstream biosafety and biosecurity on the national agenda.
- Biosafety guidelines and policies need be developed.
- Diagnostic laboratory infrastructure needs to be improved to ensure compliance to national and international standards and training needs.
- The essential need to establish national associations and networks in biosafety and biosecurity in order to create awareness across sectors.

3.5 Swaziland

Prof Abednego Dlamini: University of Swaziland

Prof Dlamini said that various ministries in Swaziland play a role in issues of biosafety and biosecurity in the country. He added that Swaziland responded to the United National Security Council Resolution 1540 (UNSCR 1540) by submitting a list of domestic legislation in respect of biosafety and biosecurity, as well as regional instruments.

He highlighted that the challenges in terms of biosafety and biosecurity in Swaziland relate to:

- The need to develop a legal framework.
- Documenting the status of biosafety and biosecurity.
- Developing baseline data and a database of experts and institutions working on biosafety and biosecurity.
- Poor coordination.
- UNSCR 1540 list is deficient and needs to be updated.

3.6 Tanzania

Dr Roshan Abdallah: Agricultural Innovation Research Foundation

Dr Abdallah indicated that biosafety and biosecurity is implemented by various ministries in Tanzania with the Department of Environment as the custodian of the biosecurity and biosafety issues. She added that a manual for emergency measures (an appendix to the Environment Management Regulations 2009) provides detailed and structural information on emergency responses to the unauthorised release of certain agents.

She said that the Biosafety Legal and Institutional Framework is approached from a value chain perspective and includes:

- The Biotechnology/Biosafety Policy of 2010.
- The Environment Management Act 2004, as well as numerous committees.

Dr Abdallah indicated that the Tanzania National Biosafety Committee was established in 2008 and comprises representatives and experts from government, non-governmental organisations, tertiary institutions and the private sector. She added that the Tanzania National Biotechnology Advisory Committee promotes and oversees biotechnology issues.

Dr Abdallah said that the Tanzanian government is committed to the application of biotechnology and development of biosafety measures to support and facilitate regional harmonisation and co-operation for the development of knowledge and skills, harmonised guidelines, sharing of facilities, and to prioritise the application of biosafety and biosecurity measures.

3.7 Zambia

Mr Christopher Simuntala and Dr Paul Zambezi: National Biosafety Authority

Mr Simuntala said that the WHO JEE for IHR assessment was undertaken in 2017 in Zambia. He said that the country has a national biosafety and biosecurity system at all reference laboratories and that dangerous pathogens get identified at various P3 laboratories according to best practices. He also indicated that biological risk management training and educational outreach gets conducted by the various institutions. The country has appropriate international laboratory licensing and pathogen control measures.

However, he added that biosafety and biosecurity systems are fragmented due to the absence of a legal framework (national regulations and guidelines) and that the key observations from the WHO JEE were:

- Biosecurity legislation and regulation needed to be developed.
- A fragmented implementation of biosafety mechanisms.
- The need to establish collaborations and networking mechanisms and for technical assistance to build human capacity and infrastructure.
- There is a need for certification of institutions handling micro-organisms and LMOs.

In terms of strengths, the WHO JEE noted:

- The availability of regulatory frameworks for biosafety.
- The existence of a National Biosafety Authority mandated to undertake registration of institutional biosafety committees.
- The existence of sustainable biosafety and biosecurity systems that allowed for a monitoring plan.
- The ability to conduct risk assessment and management.
- The existence of legal mandates to train and sectorial training in institutions on biosafety and biosecurity.

Mr Simuntala said the priority areas for action include:

- Assessment and revision of existing legislation on biosafety so that biosecurity issues are fully addressed.
- Preparation of a national plan for the high containment laboratories such as BSL 2 and BSL 3 laboratories, including maintenance of existing laboratories, establishing new laboratories and the proper accreditation of such laboratories.
- Conducting a training needs assessment for biosafety and biosecurity and developing a common curriculum and the train-the-trainer programme.
- Strengthening networking and collaboration among stakeholders in different sectors so that a whole-of-government biosafety and biosecurity system is fully implemented.

3.8 Zimbabwe

Dr Jonathan Mufandaedza: National Biotechnology Authority

Dr Mufandaedza indicated that Zimbabwe's National Biotechnology Authority (NBA) Act addresses all issues relating to biosafety and biosecurity. He added that the NBA serves as the national focal point for the Biosafety Clearing House and is mandated to protect the public through the management of potentially harmful technologies and undertakings, and to register facilities that are utilised for the development, production, use or application of biotechnology. Dr Mufandaedza said that most laboratory facilities in Zimbabwe operate under BSL 1 and BSL 2 conditions. He said that compliance with national biosafety guidelines and regulations is compulsory and most facilities operating in Zimbabwe are accredited with other regulatory bodies.

He said that as part of mainstreaming biosafety into curricula, the NBA is involved in developing and reviewing biosafety programmes at universities and government departments and progress has been made towards the establishment of a biosafety and biosecurity map for Zimbabwe.

Dr Mufandaedza highlighted these areas of concern for the NBA:

- Limited infrastructure capacity, especially to develop a National Biosafety Reference Laboratory.

- Limited collaboration among agencies dealing with biosafety and biosecurity issues.
- Limited awareness and education activities to do with biosafety and biosecurity.

He further added that the challenges present opportunities to:

- Mainstream biosafety and biosecurity awareness activities within national and regional platforms.
- Review legislation related to biosafety and biosecurity taking into account new developments in life sciences.
- Undertake joint developments, research and enforcement of biosafety and biosecurity regulations locally and regionally.
- Mainstream biosafety and biosafety issues in tertiary and school curricula.
- Strengthen and harmonise domestic biosafety and biosecurity regimes in SADC countries.
- Exchange biosafety and biosecurity personnel in the SADC region.

He said that the future aspirations include:

- The establishment of National Biosafety Reference Laboratories from BSL 1 to BSL 4.
- Policy development to clarify the biosafety and biosecurity roadmap.
- Resource mobilisation for awareness, education, collaboration, monitoring and surveillance in laboratory biosafety and biosecurity in Zimbabwe.

3.9 Malawi

Ms Victoria Kachimera: Department of Environmental Affairs

Ms Kachimera indicated that Malawi has laboratories for animal health, water, food, two biotechnology testing laboratories. She added that the country was also in the process of setting-up other laboratories such as the National Dosimetry Laboratory. She said that specific legislation is in place to deal with the environment,

biotechnology, food and plants, however, the extent to which it provides for issues of biosafety and biosecurity is not clear.

Ms Kachimera said that the WHO JEE for IHR assessment was conducted by the Malawi Ministry of Health in 2015 and the strengths that were identified included:

- The existence of laboratory capacity to detect and confront infectious diseases of public health importance at national level.
- Participation in an international network to cover diagnostic capacity for rare pathogens.

The weaknesses identified were:

- Inadequacies relating to equipment and supplies, training in specialised areas, infrastructure and laboratory capacity for surveillance of notifiable diseases.
- Insufficient laboratory and surveillance capacity.
- Systems that were not consistently operational.
- Limited implementation of existing strategies, guidelines and protocols.
- Lack of coordination and cooperation.

Ms Kachimera added that in terms of biosecurity, Malawi is party to various international conventions and is in the process of developing national legislation on chemical, nuclear and biological weapons. However, she further added that the government is focusing on more relevant matters, such as chemicals and to a certain extent nuclear in terms of its relationship with the International Atomic Energy Agency.

She concluded by saying that the country has not conducted an overall assessment of its state of biosafety and biosecurity. Also, that the current legislation would have to be amended or reviewed or new regulations and guidelines would have to be drafted to incorporate issues of biosafety and biosecurity.

Summary of Discussion

- It was suggested that the existing collaborations and networks within SADC be made known to all.
- The DRC explained what it had done to achieve the results presented in terms of preventing nosocomial transmissions and biosafety/biosecurity incidents given their resource constraints:
 - Prof Masumu said that the early symptoms of Ebola are similar to those of other diseases prevalent in the DRC thus making it very difficult to identify Ebola at the beginning of an outbreak with clinicians continuing to treat patients without taking precautions and getting infected.
 - He added that once it clear that people are dying, samples are then analysed and Ebola is established as the cause. Then the national team of Ebola fighters and some specialists go to the field to provide PPEs and to teach people how to use them.
 - Prof Masumu highlighted that everything is done to prevent nosocomial infections but most of these infections happen before the national team of Ebola fighters goes to the field and that these stop once the team begins its work in the field.
- In response to what additional regulations were required in Namibia given that a Biosafety Act has been in place since 2006, Dr Kandawa-Schulz indicated that new regulations were required in order to deal with biosecurity issues.

Dr Groenewald concluded day one discussions by thanking all the speakers and indicating further opportunities for discussions on day two.

DAY TWO

SESSION FOUR: Challenges and Opportunities for Improving Biosafety and Biosecurity in SADC

Facilitated by Dr Hennie Groenewald: Biosafety South Africa

Objectives for Day Two

Dr Groenewald highlighted that Day Two would focus on:

- Challenges and opportunities to improve biosafety and biosecurity in the SADC region and how these can be addressed and strengthened.
- Identifying key priorities, collaborations and stakeholders.

He added that the discussions would also contribute to the WHO JEE for IHR assessment of laboratory biosafety and biosecurity status in the SADC region and the identification of priorities, existing networks and possible complementary activities and initiatives, which would be brought together under the four main areas used in the ASSAf report: (i) ethics, (ii) regulatory frameworks, (iii) implementation, and, (iv) responsiveness (Listed in Appendix I).

4.1 Towards a Sustainable Structure for Supporting Disease Surveillance and Risk Management of Epidemics in Africa **Prof Gerald Misinzo: Southern African Centre for Infectious Diseases, Tanzania**

Prof Misinzo said that the Southern African Centre for Infectious Diseases (SACIDS) was established in January 2008 as a consensus agreement by numerous founding institutions throughout Africa to address the infectious disease burden through the One Medicine/ One Health collaboration. He said that the SACIDS vision is to have an African society protected from devastating infectious diseases affecting the health of humans, animals and ecosystems and its core strategy is to address this burden within the context of:

- Capacity limitations.
- Involvement of a virtual centre to draw human and infrastructural resources across the region.
- Having an Africa-led agenda and a community of practice that group students, researchers and mentors based on the area of expertise.

Prof Misinzo said that SACIDS aims to bridge discoveries of research with smart partners at national research institutions in order to influence policy in an informed manner. The SACIDS Business Plan 2020 aims to have a:

- Regional One Health Forum.
- Regional One Health Research Platform.
- Regional Centres of Excellence.

He mentioned that currently there are two SACIDS Centres of Excellence for Infectious Diseases and that the impact is focused on communities with regards to containing diseases at the source. The SACIDS' mission is to be able to build research competencies focusing on molecular biology, analytical epidemiology and social sciences which are meant to address a set of diseases grouped in communities of practice. Prof Misinzo further added that SACIDS' theory of change involves the use of syndromic surveillance using digital technology (in the form of an app called AfyaData) coupled with genomics-based diagnostic tools and epidemiological risk modelling and socio-anthropology.

Prof Misinzo said that the SACIDS virtual centre:

- Provides an added advantage by linking institutions and allowing for sharing of resources and expertise.
- Serves as a One Health centre to tackle human and animal diseases at source using mobile deployable technologies. SACIDS wants to be at the forefront and develop diagnostics that can be owned by institutions in Africa.
- Allows for sharing of expertise, best practices and team supervision and mentorship.

Prof Misinzo concluded by saying that biosafety and biosecurity training is part of transferable and life-long skills training and is delivered at summer schools and forms part of the MSc curriculum.

4.2 Challenges and Opportunities for Improving Biorisk Management in SADC

Dr Jacqueline Weyer: NICD

Dr Weyer presented practical examples of what happens when biosafety and biosecurity measures are not implemented or applied correctly at laboratories. She focused on several cases of laboratory acquired infections and indicated that the various types of exposure were due to ill-functioning equipment in laboratories. She further highlighted these relevant statistics:

- The US reports that only five out of 1 000 laboratory workers develop laboratory acquired infections annually while there are no such statistics for African laboratories.
- Africa has the highest burden of infectious diseases in the world and by inference Africa's laboratory workers are the most exposed to infectious agents.
- More than 90% of accredited laboratory facilities are located in South Africa while 37 countries in Africa have no accredited facilities.
- More than 50 of the BSL 4 facilities globally are found in countries that do not present the natural home of the formidable viral haemorrhagic fevers – which is Africa – while Africa only has two BSL 4 facilities serving the whole continent.
- Africa, therefore, relies on international parties to dictate the type of research being done on these agents and diseases and also relies on researchers outside of Africa to find solutions to problems in Africa.

She mentioned that biosafety and biosecurity challenges are considered from the perspective of the optimal balance between the four primary controls of biosafety: PPEs, work place practices, administration (or leadership) and engineering (laboratory structure in accordance with BSL criteria). She suggested that countries with limited resources needed to mitigate the risks by focusing on SOPs and operational controls.

Additional key points made by Dr Weyer:

- Although guidelines, standards and regulatory framework are lacking, there is much regulation in place across the SADC region and it will be difficult to develop a single piece of legislation that includes every aspect of biosafety and biosecurity for the region because this does not exist anywhere else in the world.
- It is necessary to consider what is available internationally (in the form of guidelines or standards) that explains how things should be done but resource constraints and the environment in the African context must be taken into account.
- The SADC minimum laboratory standards should be used as a basis for developing biosafety and biosecurity guidelines for SADC, taking into account existing legislation and making it practical and simple for laboratories to comply and to be enforced.
- In terms of BSL 3 and BSL 4 laboratories, the capacity to construct and commission these has to be sourced from outside Africa as the necessary expertise is not available in the continent and their maintenance is a serious issue. Innovative engineering solutions in Africa for African conditions have to be considered.
- In terms of human resources, biosafety engineers and biosafety professionals/officers are not recognised in Africa and there is no career path in this area, therefore, a platform needs to be developed for scientists or laboratory professionals to specialise in biosafety and biosecurity.
- Management of laboratories in Africa is very difficult mainly due to financial constraints and thus reliance is often on external funding. Therefore, a top-down approach to biosafety and biosecurity in laboratories has value.

4.3 Way Forward Based on the WHO JEE of IHR Core Capacities **Dr Jacqueline Weyer: NICD**

Dr Weyer stressed that the way forward in the SADC region needs to be strongly based on the IHR requirements and the WHO JEE because there is political commitment to this international regulation

and countries that have not yet gone through this evaluation will do so in due course.

Background on the IHR and the WHO JEE Process

- IHR is a legally binding international regulation that looks at prevention, detection, control and response with relation to the international spread of diseases. It was established in 2005 and approximately 200 countries are signatories.
- Initially countries had to report to the WHO by completing a self-assessment and periodic submissions of checklists, but this method was replaced by the JEE.
- The JEE allows countries to do their own self-assessments in an evidence-based manner (by allocating scores to the criteria) and they are then subjected to an external audit process. The WHO appoints experts to visit countries to investigate the self-assessments.
- The JEE process is on-going with approximately 70 countries having already completed (to date) the first round.
- The JEE framework is a multi-risk approach to health and health security.
- The WHO and the international community deems laboratory biosafety and biosecurity of such importance that these form a separate package within the JEE framework and countries are required to adhere to the WHO's comprehensive definition of biosafety and biosecurity, namely:
 - **Target:** A whole-of-government national biosafety and bio-security system is in place, ensuring that especially dangerous pathogens are identified, held, secured and monitored in a minimal number of facilities according to best practices; biological risk management training and educational outreach are conducted to promote a shared culture of responsibility, reduce dual-use risks, mitigate biological proliferation and deliberate use threats, and ensure safe transfer of biological agents; and country specific biosafety and biosecurity legislation, laboratory licensing, and pathogen control measures are in place and appropriate.

- **Measured by:** The number of countries that have completed a national framework and comprehensive oversight system for pathogen biosafety and biosecurity, strain collections, containment laboratories and monitoring systems that includes identification and storage of national strain collections in a minimal number of facilities.
- **Desired impact:** The implementation of a comprehensive, sustainable and legally embedded national oversight program for biosafety and biosecurity, including the safe and secure use, storage, disposal, and containment of pathogens found in laboratories. A minimal number of holdings across the country, including research, diagnostic and biotechnology facilities. A cadre of biological risk management experts that possess the skillset to train others within their respective institutions. Strengthened, sustainable biological risk management best practices that are in place using common educational materials. Rapid and culture-free diagnostics that are promoted as a facet of biological risk management. The transport of infectious substances should also be taken into account.

WHO JEE Outcomes

Dr Weyer said that the outcomes from the JEE assessments biosafety and biosecurity action package from seven SADC country reports (to date) show either no capacity or very limited capacity in terms of the core competencies for biosafety and biosecurity as is required by the IHR.

Conclusion

Dr Weyer's concluding remarks were that:

- The JEE tool and country findings should be used as the framework to develop interventions and find a collective way forward in the SADC region.
- There is a need for contextualised guidelines and standards that are practical and fitting for the African environment.
- Advantage should be taken of the current political will and commitment towards the IHR to lobby for resources to support and ensure the development of safe and secure laboratory infrastructure and a competent laboratory workforce.

- It is necessary to develop sustained local/regional capacity for training and move away from using *ad hoc* international opportunities to sustain the development of capacity required by the laboratory workforce.
- Training programmes need to be a requirement in universities and on-the-job training is also required.
- Leadership in biorisk management in Africa must be stimulated, possibly through a mentorship programme at postgraduate level at universities to support a top-down approach.

Summary of Discussions

- It was noted that the JEE exercise could be used as an opportunity to obtain resources especially for infrastructure and that the work done (and legislation) in the area of safety in the nuclear energy sector could be applied to laboratory biosafety and biosecurity.
- The difficulty in addressing sustainable resources for biosafety and biosecurity on a regional or global scale was highlighted.
- It was mentioned that the NICD's BSL 4 laboratory, which is shared with the rest of the continent as a strategic capacity for diagnosis and research in viral haemorrhagic fevers, is not yet recognised as a national asset in South Africa. This was highlighted as important to elevate the ownership of the facility beyond the individual institute where it is hosted.
 - It was noted that reference or BSL 3 laboratories in other countries are national and regional assets.
 - It was suggested that South Africa should have discussions with the University of Pretoria's Faculty of Veterinary Sciences and government about all BSL 3 laboratories being declared national assets.
- It was remarked that the construction and improvement of laboratories is mostly donor-funded and that applications submitted by African countries are tactical rather than strategic.
- It was noted that efforts are spread thinly across many laboratories rather than improving national capabilities for addressing disease outbreaks.

- There was a clarification that Africa's disease conditions are not only due to the lack of laboratory infrastructure but that there are many contributing factors such as poverty, socio-economic issues and the state of the health systems. Further to this, the availability of laboratories, specifically high security and maximum security laboratories, form part of the overall health system problem.
- It was suggested that investment in public health would contribute to the prevention and control of diseases and that fresh thinking was necessary to view the burden of diseases as an opportunity to develop diagnostics, vaccines and so forth.
- It was mentioned that the Regional Agricultural and Environmental Innovations Network-Africa (RAEIN-Africa) coordinated a project that equipped laboratories in six partner countries in SADC to develop their laboratories in terms of infrastructure equipment, physical facilities and training of personnel. Furthermore, even though these laboratories are specifically for LMOs' biosafety, their value is in science and biotechnology.
- It was remarked that government does not view laboratories as assets and that discussions should also be around what can be done to ensure continuity and sustainability of donor funded initiatives.
- It was stressed that political will and commitment by government at national and regional levels and strong leadership are essential and that other sectors (such as tourism) should be mobilised to join discussions on issues of health.
- It was concluded that the JEE scores of countries in the SADC region are worrying and the importance of ongoing evaluations was stressed.

SESSION FIVE: South Africa's Role as Chair of SADC for 2018

Ms Mandry Ntshani: DST

Ms Ntshani mentioned that South Africa is the Chair of SADC for the period of August 2017 to August 2018. She added that as the Chair, South Africa is expected to identify a theme as well as projects that will be adopted to guide the implementation of the SADC work programme. Ms Ntshani added that South Africa's theme is: Partnering with the Private Sector in Developing Industry and Regional Value Chains. She said that the DST's plans for SADC Chairmanship are aligned to the SADC Industrialisation

Strategy and Roadmap (2015 – 2063) with regard to the private sector as a key driver of industrialisation in the region.

Ms Ntshani said the pillars of SADC industrialisation are:

- Mineral beneficiation.
- Agro-processing.
- The pharmaceutical sector.

She further added that renewable energy plays a vital role in the manufacturing process, adding value and promoting regional value chains. Science, technology and innovation (STI), skills development and entrepreneurship training are key for the development of these value chains. The DST has identified projects to support the key pillars of the SADC Industrialisation Strategy and Roadmap.

The key DST-led SADC Chair initiatives mentioned were as follows:

- Implementation of the SADC Industrialisation Strategy and Roadmap through Commercialisation of Nutritious Instant and Ready-to-Mix Product from Indigenous Food (Agro-processing).
- SADC Energy Foresight and Assessment study (renewable energy).
- SADC Engineering Needs and Numbers study.
- SADC Cyber-Infrastructure Framework.
- SADC Women In Science Engineering and Technology Charter.
- Strengthening Research and Innovation Management in SADC.
- STI Policy Training for SADC parliamentarians.
- Southern Africa Innovation Support programme.
- Africa Innovation Summit 2 would be hosted in June 2018.

Ms Ntshani concluded by saying that the DST has developed a STI action plan that outlines STI programmes to support the SADC STI Industrialisation Strategy Action Plan and plans to host a Joint Meeting of SADC Ministers responsible for Education and Training as well as STI in June 2018. These Ministers meet annually to review progress on the implementation of key regional STI programmes and initiatives. Finally, South Africa plans to hand over a progress report on SADC STI deliverables to Namibia (incoming SADC chair) in August 2018.

Summary of Discussion

- It was noted that none of the DST-led SADC Chair initiatives had a focus on regional programmes focusing of laboratory biosafety and biosecurity and health issues.
- It was further remarked that South Africa does have many relevant bilateral relationships with different African countries; SANBio was highlighted:
 - o SANBio is an initiative largely limited to the SADC Region which hosts a range of initiatives that support science and science development. Other SANBio activities are in indigenous knowledge-based products and agriculture. It was also mentioned that there are additional initiatives driven by other countries; for example, five health networks in sub-Saharan Africa are driven by the German government and the European Union funds programmes on pharmaceutical value chains in the SADC region.
- It was mentioned that an expanded scope of biosafety (food safety) issues will be reflected in the 2018 SANBio business plan.
- Ms Ntshani indicated that the DST has committed funding for the implementation of the initiatives she presented and that some SADC countries also contribute financially through the hosting of workshops in their countries.
- It was mentioned that the DST, together with other stakeholders, is considering ways of sustaining the Biosciences Finnish-South Africa Partnership Programme (BioFISA) initiative beyond the initial four years. The DST also supports the New Partnership for African Development flagship programmes and has partnered with the government of Finland in terms of BioFISA.
- The issue was raised as to whether SADC has programmes relating to biorisk assessment and biosecurity in the same manner that the African Union (AU) has programmes looking at the impact of genetic technology
- It was pointed out that the minimum laboratory standards initiative for the SADC region, led by Prof Sibanda from the SADC secretariat, does not mention biosafety and biosecurity explicitly but that it could be the basis for biosafety and biosecurity standards for the region.

SESSION SIX: Overarching Facilitated Discussion and Way Forward

Workshop participants agreed that an approach to guidelines for biosafety and biosecurity for the SADC region should be based broadly on the IHR framework using the WHO JEE tool.

The following crucial points were raised:

- Biosafety and biosecurity ought not to be looked at as part of quality but that the focus should be on the safety and security aspect.
- Dr Mufandaedza indicated that Zimbabwe's National Biosafety Act does not only focus on GMOs alone but also on new and emerging technologies and their potential risk, with each authority given some form of responsibility in terms of biosafety and biosecurity. He stressed that other SADC countries could learn from the Zimbabwe IHR country report.
- It was noted that generally, Biosafety Acts tend to focus only on GMOs and that laboratory biosafety should not be brought into that discussion. Furthermore, it was noted that the scope of laboratory biosafety is too broad to be captured in one piece of legislation and should rather be addressed at the level of guidelines and be separated from GMO biosafety.
- It was emphasised that all the aspects of the WHO's comprehensive definition of biosafety and biosecurity need to be addressed in a regional framework.
- It was further emphasised that international guidelines need to be interpreted by each country in the context of its own national priorities.
- Ownership and leadership (at all levels) was noted as one of the key issues that needs to be clarified and it was indicated that it will be necessary to identify a specific body to take practical leadership in the individual countries, possibly in the form of a multi-representative coordinating body that is responsible for establishing the guidelines.
- It was stressed that the workshop report will need to be forwarded to the relevant individuals and institutions that are responsible for

compliance with IHR and development of national biosafety and biosecurity frameworks.

- It was emphasised that the implementation of a regional framework or guidelines for biosafety and biosecurity should not be with ASSAf as this does not fall within the Academy's mandate.
- It was indicated that a neutral body, such as the DST, should take leadership as a government department provides a level of authority that a committee or university/institutions would not have. However, Mr Durham explained that the DST could not take the lead as it does not implement.
- It was then suggested that the workshop outcomes will need to be communicated to the SADC secretariat through the DST in order to ensure that laboratory biosafety and biosecurity are given priority and that there is buy-in from governments in the region.
- Mr Durham offered to raise the issues internally at the DST in order for the matter to be taken to SADC for further discussion and to put forward laboratory biosafety and biosecurity as key issues that need to be addressed as part of the Africa health research initiative.
- It was remarked that unless SADC fully understands the economic cost of the burden of both human and animal diseases, the need for guidelines for biosafety and biosecurity for the region will not be taken seriously. Therefore, governments need to be convinced that this is an issue of state and regional security.
- It was noted that even though many countries do not have specific legislation relating to biosafety and biosecurity, all countries have occupational health and safety (OHS) legislation. Therefore, as there is an overlap between OHS legislation and what is required in respect of biosafety and biosecurity it should then be acknowledged that although laboratory biosafety and biosecurity principles are specialised, they are part of OHS.
 - o Mr Durham explained that OHS issues are dealt with by the South African Department of Labour, DoH and DAFF and that no single authority can take the lead in this area.
- It was emphasised that there is a need for a regional map of existing assets, identifying strengths and capacity as well as gaps in order to then expand and strengthen what already exists.

- o It suggested that a starting point would be to collate the JEE findings from the various country reports then build on the work already done and the commitments already made in terms of the JEEs.
- It was suggested that laboratory biosafety and biosecurity training be taken care of at the regional level but that the upgrading of laboratories (to at least a minimum standard) and improving the capacity of the people be done at the national level.
- As most SADC countries have completed the JEE assessments and each country now needs to develop an action plan informed by stakeholders and multi-sectoral committees within countries across departments, SADC thus needs to project the current status of biosafety and biosecurity and use this to track progress in terms of addressing the issues identified nationally.
- It was noted that one of the strategic pillars of the Africa Centres for Disease Control and Prevention (Africa CDC) is laboratory strengthening with components of biosafety, biosecurity and laboratory information systems. Therefore, Africa CDC's political backing must be leveraged to improve health in the continent as this is a crucial component for buy-in at heads of state level.
- It was added that the existing SADC laboratory biosafety and biosecurity networks would need to comment on and possibly lead this initiative and that the initiative would have to be discussed with and endorsed by SADC. Also, that the African Biological Safety Association (AfBSA) would be able to give an indication of what biosafety and biosecurity in SADC region is all about.
 - o The relevant existing SADC laboratory biosafety and biosecurity networks and complementary initiatives/organisations were then listed as follows:
 - i. SACIDS
 - ii. AfBSA
 - iii. Public Health Association of South Africa
 - iv. South African Biorisk Association and national biosafety associations in other countries
 - v. International Federation of Biological Safety Associations
 - vi. African Society for Laboratory Medicine

- vii. Regional collaboration among competent authorities for Cartagena Protocol on Biosafety
- viii. SANBio
- ix. Sub-Saharan health networks (Germany funded)
- x. Veterinary statutory network (training)
- xi. RAIEN-Africa
- xii. African Biosafety Network of Expertise.

Dr Groenewald emphasised that the IHR framework has to do with guidelines and not legislation and does not intend to change national priorities. Therefore, a regional framework would require national systems to identify national priorities that feed into the regional level. He further said that the best people to take ownership and responsibility to structure biosafety and biosecurity in each country would be those already actively involved in the JEE for IHR processes in their countries.

Prof Diab explained that ASSAf's role is to convene workshops that bring together experts and to give advice to government on what they could potentially do and which programmes to implement for the future. She added that ASSAf's role does not include implementation. Her suggested way forward was that:

- ASSAf could re-convene a group whose task would be to identify follow-up studies or to draw attention to some of the important messages and recommendations from the workshop so that they do not fall away.
- ASSAf could work with the DST to try and raise the profile of these issues with the SADC secretariat in order to address some of the gaps highlighted.

CLOSING REMARKS

Prof Iqbal Parker: University of Cape Town

Prof Parker prefaced his remarks with a statement that it was encouraging to see that the issues of laboratory biosafety and biosecurity were being addressed and that the increased use of the JEE for IHR assessment has heightened awareness of laboratory biosafety and biosecurity in the SADC region.

Prof Parker said that the ASSAf secretariat would send out a survey/questionnaire to all participants to provide them with an opportunity to:

- Raise issues that were not addressed during the workshop.
- Suggest a way forward and make recommendations in order for the committee to plan the next steps.

Participants were urged to respond to the survey and also to forward the information from workshop to appropriate decision-makers to ensure their involvement in the discussions on laboratory biosafety and biosecurity measures for the SADC region.

Prof Parker suggested that given that a number of key stakeholders were not present at the workshop, it may be useful to convene a workshop with all the SADC partners and other stakeholders to get a comprehensive view of what should be done regarding a way forward. Furthermore, ASSAf would be willing to engage its Academy partners in the SADC region to come on board and use their influence to lobby governments in their respective countries to participate in and accelerate discussions on biosafety and biosecurity measures, and to act as a catalyst to move the discussions forward.

Prof Parker thanked all participants for the fruitful discussions and for having set time aside to be part of the important workshop.

APPENDIX i

WHO JEE Assessments in the SADC Region: Feedback

Participants provided their inputs stemming from the JEE for IHR assessment conducted in their countries by looking at strengths, weaknesses, challenges and opportunities. These were categorised into four areas (and they are in addition to the issues already covered by the previous presentations):

i. Ethics

- Each country should identify the training areas that are specifically needed and ways to address the requirements for each country can be discussed once there is a list of all the possible options for training.
- ARC's online course on the ethics of biosafety and biosecurity could be used as a basis for further training.
- The focus of research ethics at universities is not dual-use potential and the biosafety and biosecurity aspect of dual-use and there should be a clear distinction between research ethics and ethics relating to laboratory biosafety and biosecurity.
- Institutional biosafety committees (or similar) within institutions responsible for reviewing research proposals prior to a grant application should also identify dual-use potential in terms of biosafety and biosecurity ethics.
- Funding agencies should insist that research institutions that receive funding must have an institutional biosafety committees (or similar) in place to undertake reviews as this should not be the responsibility of a centralised or government department.
- The University of Namibia offers a module on biosafety, intellectual property rights and ethics, which are going to be amended to incorporate biosafety in general instead of focussing on GMOs alone.
- Ethics review committees should be an apex authority, independent from universities and researchers.

ii. Regulatory Frameworks (Regional)

- Existing legislation could be gathered and reviewed by a small team to identify the aspects that need to be incorporated in the 'model legislation' that all SADC countries could aspire to. The legislation should be benchmarked globally with international best practice and presented to the AU for adoption as the standardised legislative framework for the continent.
- It was however noted that such a 'model legislation' will take a long time to be adopted and it will be more preferable to:
 - Set-up a system whereby one country can borrow certain provisions from another country's legislation (if it is advanced and has been tested).
 - Have a coordinating framework where there is commitment from countries to work together, but where final decisions are taken at national level.
- International laws that are binding to SADC countries should help various countries identify the compliance gaps in their own legislation.

iii. Implementation

- The Common Market for Eastern and Southern Africa ensures implementation through memoranda of agreement with member countries and implementation of biosafety and biosecurity could be dealt with in a similar way.
- Several vehicles or instruments for implementation (such as SACIDS) are already in place and people in the networks/play a pivotal role in implementation.

iv. Responsiveness

- The DRC's example of responsiveness to Ebola outbreaks can be used as a model, specifically in terms of building capacity to respond to such events.
- Each country should have national emergency operation centres as response mechanisms and for surveillance purposes. Pathogens emanating from different countries could be imported to a regional operation centre with transmission from the national

mechanisms. The regional capacity would be based on the national capacity of each country.

General laboratory biosafety and biosecurity priorities (and uncertainties)

It was highlighted that the training needs must:

- o Be appreciative of differences between academic laboratories, research institute laboratories and hospital laboratories, between human and animal health, and between training needs according to areas of focus (e.g. human health, detection, border control).
- o Be institutionalised, ongoing, sustainable, locally focussed and take into account existing ongoing training activities.
- o Make use of local experts to help develop local training and train-the-trainers.
- Have the right stakeholders and include private laboratories in order to take the right direction towards developing guidelines for biosafety and biosecurity.

Other matters that were raised included:

- Improving the legal framework and ensure harmonisation of laws within each country.
- Defining process issues, in terms of specimen transfer between countries, as well as process mapping.

APPENDIX ii

List of Workshop Participants

	Surname	Name	Organisation/Institution
1.	Abdallah	Roshan	Agricultural Innovation Research Foundation, Tanzania
2.	Barros	Eugenia	Eugenia Barros Biosciences and Consulting
3.	Brandt	Christopher	ARC
4.	Chakauya	Ereck	SANBio
5.	Chin	Graham	National Institute for Occupational Health (NIOH)
6.	De Abreu	Cecilia	NICD
7.	Dlamini	Abednego	University of Swaziland, Swaziland
8.	Du Plessis	Desiree	NICD
9.	Durham	Ben	DST
10.	Gomba	Noncy	NIOH
11.	Groenewald	Hennie	Biosafety South Africa
12.	Howard	Wayne	NICD
13.	Huna	Bulelwa	Department of Labour
14.	Jansen van Rijssen	Wilna	Private
15.	Jones	David	NIOH
16.	Kachimera	Victoria	Department of Environmental Affairs, Malawi
17.	Kandawa-Schulz	Martha	University of Namibia, Namibia
18.	Keetch	David	Goldamer Consulting cc
19.	Lekoape	Kelebohile	Bayer Crop Science
20.	Liphoto	Mpho	National University of Lesotho, Lesotho

	Surname	Name	Organisation/Institution
21.	Luketa	Luboya	Vision-Initiative for the Development in Africa
22.	Madzivire	Godfrey	Council for Geoscience
23.	Mahloane	Gerard	Ministry of Agriculture & Food Security, Lesotho
24.	Maimela	Betty	Department of Environment Affairs (DEA)
25.	Mallon	Warren	Department of Labour
26.	Manakele	Sipokazi	Non-Proliferation Secretariat, DTI
27.	Maphalala	Gugu	Ministry of Health, Swaziland
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36.	Mnyulwa	Doreen	RAEIN-Africa
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38.	Mokoatle	Mann	Agricultural Research Council
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40.	Mundadi	Joseph	Institute for Rural Development-University of Venda
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42.	Ngqwala	Nosiphiwe	Rhodes University
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45.	Parker	Iqbal	UCT
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	Surname	Name	Organisation/Institution
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48.	Potgieter	Anna	NIOH
49.	Raman	Jaishree	NICD
50.	Raseleka	Keneilwe	DAFF
51.	Simuntala	Christopher	National Biosafety Authority, Zambia
52.	Singh	Tanusha	NIOH
53.	Singh	Larissa	NIOH
54.	Sithebe	Patricia	North-West University
55.	Smith	Marshagne	NICD
56.	Theron	Riette	DAFF
57.	Trataris-Rebisz	Anastasia	NICD
58.	Tshidada	Ntakadzeni	DEA
59.	van der Walt	Wynand	FoodnCrop Bio
60.	van Niekerk	Anton	Stellenbosch University
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66.	Hlwatika	Zuki	
67.	Mandawana	Marvin	
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