

International Society for Pharmacoepidemiology

African Regional Interest Group (AfRIG)

# 3rd Annual Conference on PHARMACOEPIDEMIOLOGY IN AFRICA

**5-9 JUNE 2023 CAPE TOWN, SOUTH AFRICA** University of Cape Town



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#MeetInSouthAfrica

NATIONAL CONVENTION BUREAU





### Welcome to Cape Town, South Africa

Cape Town, lovingly referred to as the "Mother City" is located at the southern tip of Africa. It is the place of golden beaches, bountiful vineyards and the majestic Table Mountain. It is a top holiday destination attracting visitors from all over the world. As a visitor, you can lose yourself in all the beauty the city has to offer (many do!) though you can also plan your trips to the many historical and cultural sites.

Cape Town also offers state-of-the-art conference facilities, accommodation, infrastructure and plenty of opportunities to do business.

#### Things To Do

We know that your time is limited when attending a conference, but if you plan on travelling to Cape Town, we recommend visiting a few of our top attractions:

**Table Mountain:** The ride on the aerial cableway is a gentle one: the rotating state-of-the-art cable car takes visitors from the lower station to the top in around 5 minutes. You will be 1000 m above the city, and here in this unique location, you will find rock hyrax, lizards, butterflies and the odd porcupine. There is also a wide array of birdlife flying above great patches of fynbos, the Cape's indigenous flora. Atop the mountain is a self-service buffet cafe while you can always pack a picnic and enjoy what still is part of a national park.

#### Find out more - https://tablemountain.net/



**Robben Island** is visited every year by thousands of people keen to understand and honour the important aspects of South Africa's history that the island represents.

#### Find out more - https://www.robben-island.org.za/

**V&A Waterfront** is a precinct in the city center that offers a wide variety of attractions and activities to enjoy. From arts and culture, such as the Zeitz Museum of Contemporary Art Africa (MOCAA) to more leisurely pursuits such as a sunset cruise on one of the chartered boats berthed here or restaurants and shopping. Do pay a visit to The Watershed with local products, arts and crafts.

#### Find out more - https://www.waterfront.co.za/

**Kirstenbosch National Botanical Garden** is one of the great botanic gardens of the world. Few gardens can match the sheer grandeur of the setting of Kirstenbosch with the slopes of Table Mountain as a backdrop. In summer, the gardens host open-air concerts and tickets usually sell fast. **Find out more - https://www.sanbi.org/gardens/kirstenbosch/** 

**Cape Winelands** are for wine tasting, and a trip here is one of the best ways to spend a day in Cape Town. Combine the delicious wines with some of the most beautiful landscapes on earth, century-old architecture, and awe-inspiring food, and it's no surprise that it's one of Cape Town's most beloved activities for visitors and locals alike.

#### Find out more - https://www.sa-venues.com/attractionswc/ capewinelands-attractions.htm

**Cape Point** is the scenic outlook where rugged rocks and sheer cliffs tower more than 200 metres above the sea and cut deep into the ocean, providing a spectacular background for the park's rich biodiversity. Cape Point falls within the southern section of Table Mountain National Park. The natural vegetation of the areas – fynbos – comprises the smallest but most diverse of the world's six floral kingdoms.

Find out more - https://capepoint.co.za/

#### **Getting Around**

All your options for Cape Town locomotion:

http://capetownblog.org/getting around cape town/

https://www.capetown.travel/travel wise/





# **General Information**

#### **Conference Venue**

University of Cape Town, Graduate School of Business and Conference Centre

9 Portwood Road, Victoria and Alfred Waterfront, Cape Town



#### Directions from Cape Town International Airport:

- Take the N2 from the Airport to Town
- Carry on pass the Southern Sun Waterfront Hotel on your left, and at the second set of traffic lights, turn right into Helen Suzman Boulevard
- Take the right-hand lane that leads to a small set of traffic lights leading into Portswood Road
- Turn right into Portswood Road
- The GSB Conference Basement Parking can be reached by taking the first road on one's right-hand side.
- Please follow the GSB signs until you reach the security boom (Entrance 1)
- Hotel Guest Parking can be reached by taking the 2nd entrance on one's right hand side when coming down Portswood Road (towards the Waterfront Entrance 2)
- The UCT Academic Conference Centre Parking will be the 3rd entrance on one's right-hand side (Entrance 3)



#### Joining Online

Sessions being held in the main auditorium are being broadcast live via Zoom. Onsite delegates and online delegates who have registered for this option will be sent their login details via email.

If you have not received your login details via email, please contact Yvonne.brown@uct.ac.za

#### Welcome Reception

Join the welcome reception on the rooftop terrace of the UCT GSB conference centre. Meet the other conference attendees and enjoy the breathtaking nighttime scenery from the rooftop. Finger foods and beverages will be served and are included in your conference fee.

The welcome function is being held on the rooftop from 18:00 – 20:00 on Wednesday, 7 June 2023.



#### Gala Dinner

#### **Pigalle Restaurant**

57 Somerset Road, Green Point | +27 21 421 4848

The gala dinner is being held at Pigalle restaurant from 18:30 – 22:30.

Dinner tickets are R650.00 – Please check with registrations if you have registered and paid for your dinner ticket.

Complimentary shuttles will run from the conference centre entrance to the restaurant from 18:15 – 22:30.





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### Welcome Message

# Thank you to the Local Host Committee and the Planning Committee for their commitment and dedication to developing an outstanding program.

On behalf of the International Society for Pharmacoepidemiology (ISPE), the African Regional Interest Group (AfRIG) and the Medicines Utilisations Research in Africa (MURIA) Group, we welcome you to ISPE AfRIG and MURIA's 3rd Annual Conference on Pharmacoepidemiology in Africa, which is taking place in Cape Town, South Africa.

This year's conference features world-renowned speakers and promises an exciting package of foundational and advanced training in Pharmacoepidemiology, Pharmacovigilance, Drug Utilization Research, abstract and poster presentations, as well as thought-provoking topics in plenary and symposia sessions. A special highlight of the conference is the "Presidents' Forum", a once in a lifetime live conversation with ISPE presidents (past, present, and future) to give the audience a panoramic view of the origins of the field of Pharmacoepidemiology, ISPE, key organizational initiatives, accomplishments, and vision, and to provide an opportunity for audience interaction with the panelists. We hope you enjoy every session of the conference.



**Prof Tobias Gerhard** FISPE ISPE President Rutgers University



Dr Kwame Appenteng FISPE ISPE AfRIG Chair Boehringer-Ingelheim

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### **Local Organising Committee**



**Prof Karen Cohen** University of Cape Town Division of Clinical Pharmacology



**Prof Ilse Truter** Nelson Mandela University Department of Pharmacy



**Prof Johanita Burger** North-West University School of Pharmacy Medicine Usage in South Africa (MUSA)

### **Scientific Program Committee**

Kwame Appenteng (Chair) Boehringer Ingelheim

**Irene Murimi- Worstell** (**Co-Chair**) Massachusetts College of Pharmacy and Health Sciences

Macarius Donneyong Ohio State University

**Dr. Julius Asubonteng** Regeneron Pharmaceuticals, US

Joseph Fadare Ekiti University, Nigeria

Ilse Truter Nelson Mandela University

**Johanita Burger** North-West University, South Africa

**Daniel Ankrah** Korle-Bu Teaching Hospital, Ghana **Karen Cohen** University of Cape Town, South Africa

Paul Coplan Johnson & Johnson, US

Rachael DiSantostefano Johnson & Johnson, US

**Chioma Ejekam** Lagos University Teaching Hospital, Nigeria

**Brian Godman** SIPBS, Glasgow, UK; SMU, Pretoria, South Africa and Ajman University, UAE

Amanj Kurdi University of Strathclyde, UK

Hannelie Meyer Sefako Makgatho Health Sciences University, South Africa **Didier Nzolo** University of Utrecht, People's Republic of Congo

**Olayinka Ogunleye** Lagos State University College of Medicine, Nigeria

Maribel Salas Daiichi Sankyo, US

Daniel Kajungu Makerere University

Ibrahim Oreagba University of Lagos

**Sylvia Opanga** University of Nairobi, School of Pharmacy

Natalie Schellack North West University

#### Francis Kalemeera

## Keynote Speaker

**Brian L. Strom** is chancellor of Rutgers Biomedical and Health Sciences (RBHS) and the executive vice president for health affairs at Rutgers University. Chancellor Strom was formerly the executive vice dean of institutional affairs, founding chair of the Department of Biostatistics and Epidemiology, founding director of the Center for Clinical Epidemiology and Biostatistics, and founding director of the Graduate Program in Epidemiology and Biostatistics, all at the Perelman School of Medicine of the University of Pennsylvania (Penn).

Chancellor Strom earned a bachelor of science in Molecular Biophysics and Biochemistry from Yale University in 1971 and then a medical degree from the Johns Hopkins University School of Medicine in 1975. From 1975–1978 he was an intern and resident in internal medicine, and from 1978–1980 he was a National Institutes of Health (NIH) fellow in clinical pharmacology at the University of California, San Francisco. He simultaneously earned a master of public health degree in Epidemiology at the University of California, Berkeley. He has been on the faculty of the University of Pennsylvania School of Medicine since 1980. The Center for Clinical Epidemiology and Biostatistics (CCEB) that he created at Penn includes over 550 faculty, research and support staff, and trainees. At the time he stepped down, CCEB research received nearly \$49 million per year in extramural support. Its total budget was approximately \$67 million.

Although Chancellor Strom's interests span many areas of clinical epidemiology, his major research interest is in the field of pharmacoepidemiology, i.e., the application of epidemiologic methods to the study of drug use and effects. He is recognized as a founder of this field and for his pioneer work in using large automated databases for research. He is the editor of the field's major text (now in its fifth edition) and editor-in-chief for Pharmacoepidemiology and Drug Safety, the official journal of the International Society for Pharmacoepidemiology. As one of many specific contributions, his research was pivotal in prompting the American Heart Association and American Dental Association to reverse 50 years of guidelines and recommend against the use of antibiotics to prevent infective endocarditis instead of recommending for this widespread practice. In addition to writing more than 580 papers, and 14 books, he has been the principal investigator for more than 275 grants, including over \$115 million in direct costs alone. Chancellor Strom has been invited to give more than 400 talks outside his local area, including presentations as the keynote speaker for numerous international meetings. He has been a consultant to NIH, the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention, the United States Pharmacopeia, the Association of American Medical Colleges, the Joint Commission, foreign governments, most major pharmaceutical manufacturers, and many law firms.



#### **Chancellor Brian Strom**

Chancellor, Rutgers Biomedical and Health Sciences Executive Vice President for Health Affairs, Rutgers, The State University of New Jersey

# Thank you to our volunteer reviewers

Adebola Ajao Amanj Kurdi Brian Godman Chioma Ejekam Clarise Ambale Dan Kajungu Daniel Ankrah David N Kimonge Macarius Donneyong Emma Kalk Francis Kalemeera Greshon Rota Hanlie Steyn Ibrahim A Oreagba Ilse Truter Irene Murimi-Worstell Israel A Sefah Ismaeel Yunusa Johanita R Burger Joseph Fadare Julius Asubonteng Kwame Appenteng Luciane Lopes Martie S Lubbe Martine Vorster Maribel Salas Nadiya Alnoor Jiwa Fredy Brice Simo Nemg Olayinka Ogunleye Onyinye Akunne Dami Onasanya Paul Coplan Rachael DiSantostefano Rianda Joubert Sylvia Opanga Nyambura Wanjiru Korir Felicia Williams

### Special Thank you

We would like to thank the following people for committing their time and resources to make the conference a success!

Vincent Lo Re Stan Edlavitch Lisa Pont James Vrac Tobias Gerhard Arnold Chan Brian Strom Tobi Gerhard Ian Douglas Chioma Ejekam Maribel Salas Paul Coplan Ushma Mehta Mary Beth Ritchey Nkengafac Villyen Motaze Duduzile Ndwandwe

### **Workshops Schedule**

#### **Monday 5 JUNE**

Delegates selecting Pharmacoepidemiology must attend days 1 & 2 to receive a certificate

	BREAKAWAY RM 3   Venue 4	BREAKAWAY RM 1   Venue 5	BREAKAWAY RM 2   Venue 6
08:00 - 10:00	Introduction to Pharmacoepidemiology Prof Ian Douglas	Applied drug utilisation research, including ATC DDD Methodology Prof Ilse Truter & Prof Johanita Burger	<b>Introduction to Biostatistics</b> Dr Chioma Ejekam
10:00		TEA BREAK	
10:30 - 12:00	Introduction to Pharmacoepidemiology Prof Ian Douglas	Applied drug utilisation research, including ATC DDD Methodology Prof Ilse Truter & Prof Johanita Burger	<b>Introduction to Biostatistics</b> Dr Chioma Ejekam
12:00		LUNCH BREAK	
13:00 - 15:00	Introduction to Pharmacoepidemiology Prof Ian Douglas	Introduction to Evidence- Based Health Care and Systematic Reviews Prof Villyen Motaze & Dr Duduzile Ndwandwe	<b>Introduction to Biostatistics</b> Dr Chioma Ejekam
15:00		TEA BREAK	
15:30 - 17:00	Introduction to Pharmacoepidemiology Prof Ian Douglas	Introduction to Evidence- Based Health Care and Systematic Reviews Prof Villyen Motaze & Dr Duduzile Ndwandwe	<b>Introduction to Biostatistics</b> Dr Chioma Ejekam

# Pre-Conference Workshops Schedule

#### **TUESDAY 6 JUNE**

Delegates selecting Pharmacoepidemiology must attend days 1 & 2 to receive a certificate

	BREAKAWAY RM 3   Venue 4	BREAKAWAY RM 1   Venue 5	BREAKAWAY RM 2   Venue 6
08:00 - 10:00	<b>Applied Pharmacoepidemiology</b> Prof Ian Douglas	Tools and approaches for developing functional Pharmacovigilance systems in Africa Dr Ushma Metha & Dr Marabel Salas	<b>Biostatistics applied to Pharmacoepidemiology</b> Prof Lisa Pont
10:00		TEA BREAK	
10:30 - 12:00	<b>Applied Pharmacoepidemiology</b> Prof Ian Douglas	Tools and approaches for developing functional Pharmacovigilance systems in AfricaDr Ushma Metha & Dr Marabel Salas	<b>Biostatistics applied to</b> <b>Pharmacoepidemiology</b> Prof Lisa Pont
12:00		LUNCH BREAK	
13:00 - 15:00	Applied Pharmacoepidemiology Prof Ian Douglas	The Epidemiology of Medical Devices and Surgical Procedures: Innovations and OpportunitiesProf Paul Coplan & Prof Mary Beth Ritchey	<b>Biostatistics applied to</b> <b>Pharmacoepidemiology</b> Prof Lisa Pont
15:00		TEA BREAK	
15:30 - 17:00	Applied Pharmacoepidemiology Prof Ian Douglas	The Epidemiology of Medical Devices and Surgical Procedures: Innovations and Opportunities Prof Paul Coplan & Prof Mary Beth Ritchey	<b>Biostatistics applied to</b> <b>Pharmacoepidemiology</b> Prof Lisa Pont

### Workshops

#### DAY 1 | MONDAY 5 JUNE 8:00 - 17:00

Introduction to Pharmacoepidemiology

DAY 2 | **TUESDAY 6 JUNE** 8:00 - 17:00 Applied Pharmacoepidemiology

#### WORKSHOP OUTLINE

#### Basic Pharmacoepidemiology, Intermediate Pharmacoepidemiology: Further ways to deal with confounding

**Basic Pharmacoepidemiology:** This course will introduce participants to the fundamentals of pharmacoepidemiology, including; Measures of disease and measures of association, key study designs in pharmacoepidemiology, bias and confounding. Each topic will be covered by a 45 minute talk, followed by a 30 minute practical where participants will be able to put into practice the concepts they are learning. It is aimed at people who are familiar with or have an interest in the drugs industry, drug safety, drug regulation, or the study of medicine/vaccine safety. No prior expertise in epidemiology is required.

**Intermediate Pharmacoepidemiology: Further ways to deal with confounding:** This course will introduce participants to two methods for dealing with confounding which are frequently used in pharmacoepidemiology. First we will cover propensity scores; what they are, how they are used, the assumptions involved in using them and how they compare with other methods for dealing with confounding. Following a 1 hour talk, participants will explore the concepts we have covered in small groups. Second we will cover case only study designs and introduce the self-controlled case series and case cross-over designs to participants. We will explore both methods, their underlying assumptions, and some examples of their application. Following a 1 hour talk, participants will have an opportunity to gain practical experience in thinking through self-controlled design features in small group discussions. We will assume all participants in this course are already familiar with core concepts in epidemiology including cohort and case control designs, bias and confounding and multivariable adjustment for confounding.

Delegates selecting Pharmacoepidemiology must attend day 1 & 2 to receive a certificate



**Prof Ian Douglas** London School of Hygiene and Tropical Medicine

**Ian Douglas** is an epidemiologist, currently funded by GlaxoSmithKline. He initially studied physiology and completed a PhD in Manchester. Since then, he has spent several years at the UK Medicines  $\delta$  Healthcare Products Regulatory Agency and in the pharmaceutical industry investigating the adverse effects of drugs - both in clinical trials and post-marketing. He completed the MSc in epidemiology at LSHTM in 2005.

Prof Douglas is interested in pharmacoepidemiology, and in particular, how large primary care databases can be used to investigate the effects of drugs - both harmful and beneficial. He is exploring methodologies to minimize some of the biases inherent in the research of drug effects, and his main current areas of interest include case-only approaches to study design, the use of non-interventional data to estimate intended treatment effects, quantitative bias analysis, and the application of high dimensional propensity scores in electronic health data.

## Workshops

#### DAY 1 | **MONDAY 5 JUNE 8:00 - 12:00**

Applied drug utilisation research, including ATC/DDD Methodology

#### WORKSHOP OUTLINE

#### Applied Drug Utilisation Research, including ATC/DDD Methodology

This workshop will be presented in two 90 minute sessions:

Introduction to drug utilisation research: Methodology and application

#### • WHO ATC/DDD methodology in DUR: A hands-on experience

This applied course will focus on the foundation elements of drug utilisation research (DUR). Topics focussed on will include study designs used in DUR, identification of DUR data sources, and discussion of data source strengths and limitations, choice of outcome measures and the role of DUR in health care provision and policy.

The application of the World Health Organization (WHO) Anatomical Therapeutic Chemical/Defined Daily Dose (ATC/DDD) Methodology in DUR will provide participants with the basic theory of the ATC/DDD classification system together with practical exercises. The workshop is designed to improve the understanding and application of the ATC/DDD Classification System.

This course is aimed at healthcare professionals and researchers who are involved in prescribing, formulary management, essential medicine lists, drug utilisation and related fields, and who wish to obtain a basic knowledge and skills in the practical application of DUR and the ATC/DDD system. A hands-on, interactive approach will be followed in the workshop.



**Johanita Burger** BPharm, MPharm, PhD

Medicine Usage in South Africa (MUSA) Faculty of Health Sciences, North-West University Potchefstroom, South Africa

Johanita Burger is a registered pharmacist and professor in the Department of Pharmacy Practice, School of Pharmacy, at the North-West University (NWU). She obtained a bachelor's degree in Pharmacy, a master's degree in Pharmacy Practice, and a doctorate in Pharmacy Practice at the NWU. She has been involved in under- and post-graduate teaching to pharmacy students since 2001 and regularly acts as an external examiner for post-graduate students at local and international universities. She serves as a full-time researcher in the research entity, Medicine Usage in South Africa (MUSA) at the Faculty of Health Sciences at the NWU, where she coordinates the Master of Pharmacy in Pharmacy with Pharmacovigilance and Pharmacoepidemiology post-graduate programme. She has supervised 36 master's and 2 doctoral studies, with 10 master's and 8 doctoral studies in progress. She is a C3-rated South African National Research Foundation (NRF) researcher and has co-authored/authored 38 papers in peer-reviewed journals and several national and international conference contributions. She has been a member of the International Society for Pharmacoepidemiology (ISPE) since 2013 and served on the Board of Directors for the South African International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Chapter for the 2016-2018 term. She is a founding member of the Medicines Utilisation Research in Africa (MURIA) group and one of the Southern African regional leads for the ISPE Africa Chapter. Her main research fields are pharmacy practice, drug utilisation research, pharmacoepidemiology, and pharmacoeconomics.

# Pre-Conference Workshops



**Ilse Truter** BDCom, BPharm, MSc, PhD, FISPE Distinguished Professor in

Pharmacy

Leader: Drug Utilization Research Unit (DURU)

Director: School of Clinical Care & Medicinal Sciences Faculty of Health Sciences, Nelson Mandela University South Africa

Ilse Truter is a Distinguished Professor at Nelson Mandela University (NMU). She is a staff member of the Department of Pharmacy and leader of the Drug Utilization Research Unit (DURU) at NMU. Since July 2020, she is also the Director of the School of Clinical Care & Medicinal Sciences in the Faculty of Health Sciences at NMU. Ilse holds two doctorates (in Pharmacy and Business Management), and is a registered pharmacist. She has successfully completed the international accredited Travel Medicine Course (WITS University), and is a member of the WHO International Working Group for Drug Statistics Methodology since 2017 and the WHO International Expert Working Group (EWG) for the Identification of Medicinal Products (IDMP) since the end of 2022. Ilse has authored 135 peer-reviewed research articles, four chapters in books, and 163 articles in local/professional journals. She is a National Research Foundation (NRF) C2rated researcher. Her research field is pharmacoepidemiology (including drug utilisation research and pharmacoeconomics), and clinical pharmacy. llse is an elected member of the South African Pharmacy Council, a member of Pharmaceutical Society of South Africa, and a council member of the South African Association of Health Educationalists (SAAHE). Ilse is also a fellow of the International Society for Pharmacoepidemiology (ISPE) and a member of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR). She is a founding member of the Medicines Utilisation Research in Africa (MURIA) group, and one of the regional leads for the ISPE African Regional Interest Group (AfRiG). Ilse has supervised 24 masters' degrees and 13 doctoral studies. She is a registered assessor, evaluator for the Council on Higher Education (CHE) in South Africa, and reviewer for the NRF. She has conducted training on drug utilisation research methodology in several African countries, serves as moderator and external examiner for local and international universities, and is an Associate Editor of the International Journal of Pharmacy Practice and Associate Editor (Asia-Africa-Middle East Region) of the journal Pharmacoepidemiology and Drug Safety.

## Workshops

#### DAY 1 | MONDAY 5 JUNE 13:00 - 17:00 Introduction to Evidence-Based Health Care and Systematic Reviews

#### WORKSHOP OUTLINE

#### Introduction to Evidence-Based Health Care and Systematic Reviews

Evidence-based practice is a process that includes the consideration of all available evidence on the effectiveness of interventions, alongside patient values and preferences, as well as clinical expertise, to help make decisions about which health care policies and practices to implement. Well-conducted systematic reviews provide reliable evidence, by identifying and evaluating all relevant research studies and synthesizing their results, while applying rigorous and explicit methods to minimize bias and random error in research. This workshop aims to increase awareness about the need for evidence-based practice, and how to access and interpret evidence from systematic reviews. All categories of health care professionals can apply the principles of evidence-based practice when carrying out their daily duties and would benefit from this workshop.

During this workshop you will learn to:

- 1. Outline the principles of evidence-based health care.
- 2. Describe the features of a good systematic review.
- 3. Search The Cochrane Library and Medline to access systematic reviews.

A combination of presentations and practical exercises will be used to convey the workshop content and participants are encouraged to bring their laptops.



#### Prof Nkengafac Villyen Motaze

Associate Professor of Epidemiology at Medicine Usage in South Africa in the Faculty of Health Sciences at the North-West University **Nkengafac Villyen Motaze** is a medical epidemiologist with experience in a wide variety of domains in healthcare, including post-graduate epidemiology training, pharmacoepidemiology, infectious disease epidemiology, clinical epidemiology, and public health. He has an excellent understanding of the healthcare context in Sub-Saharan Africa, having carried out a variety of research and operational functions in several countries of the African continent.

Prof Motaze obtained a Doctor of Medicine degree (MD) in 2007 at the University of Yaoundé 1 in Cameroon. He went on to obtain an M.Sc degree in Clinical Epidemiolgy (2013) and a Ph.D. in Epidemiolgy (2021), both at Stellenbosch University. Since February 2022, he is currently an Associate Professor of Epidemiology at Medicine Usage in South Africa in the Faculty of Health Sciences at the North-West University, Potchefstroom campus. Prof Motaze is the author/ co-author of 20 refereed/peer-reviewed articles, the author of 1 book and has presented at several national and international conferences. He has successfully supervised/co-supervised 6 masters students who graduated from Stellenbosch University, the University of Pretoria and University of the Witwatersrand. He has examined 4 Master studies and is currently an associate editor for the Cochrane Effective Practice and Organisation of Care (EPOC) review group and a reviewer for several scientific journals including; PlosOne, Vaccines, Proceedings in Obstetrics

# Pre-Conference Workshops

and Gynecology, International journal of environmental research and public health, Human Vaccines and Immunotherapeutics and Healthcare. Prof Motaze has occupied several teaching roles. He was a teaching assistant with the Faculty of Medicine and Health Sciences, Stellenbosch University, from June to December 2013. He then served as a guest lecturer for the South African Field Epidemiology Training Program since 2018 and a guest lecturer for the Master of Science in Medicine in the field of Vaccinology program. He has served on two advisory committees: the Scientific Advisory Committee, South Africa Field Epidemiology Training Program (SAFETP) from 2018 onwards and the World Health Organization SAGE Working Group on Measles and Rubella from 2017 to 2018.



Dr Duduzile Ndwandwe Deputy Director, Cochrane South Africa, SAMRC **Duduzile Ndwandwe** is a Deputy Director of Cochrane South Africa, an intramural unit of the South African Medical Research Council (SAMRC). She is a project leader of the Clinical Trials Registry portfolio (Pan African Clinical Trials Registry (PACTR) and South African National Clinical Trials Registry (SANCTR)). She is also a leader of the vaccine implementation research portfolio of the Unit in which she conducts primary and secondary research on vaccine-related topics. Her research expertise is in vaccinology and clinical trial registration. Her research centres on systematic reviews and the broader scope of evidence-informed decision-making. She also conducts EIDM training for stakeholders such as the National Advisory Group on Immunisation in Africa, students, and policymakers. She has been involved in numerous working groups at a national and international level providing her expertise in evidence-informed decision-making.

She has published in peer-reviewed high-impact factor journals. Additionally, she participates in community engagement projects and knowledge sharing, where she serves as a non-executive director and board chair of Eh! Woza, a non-profit organisation that seeks to advance community engagement on relevant public health issues such as COVID-19 and TB.

## Workshops

DAY 1 | **MONDAY 5 JUNE** 13:00 - 17:00 Introduction to Biostatistics

#### WORKSHOP OUTLINE

#### Basic Biostatistics for Pharmacoepidemiology

This session will focus on basic biostatistical techniques in pharmacoepidemiology research. A hands-on approach including the use of descriptive statistics and univariate methods for quantifying and testing associations between exposures and outcomes will be explored.



#### Dr. Chioma Ejekam

African Centre of excellence for Drug Research, Herbal medicine Development and Regulatory Science (ACEDHARS) University of Lagos

Centre for Infection Control and Patient Safety (CiCaPS), College of Medicine of the University of Lagos **Chioma Ejekam** is a consultant public health Physician and an expert in Pharmacovigilance and Pharmacoepidemiology – FMCPH, MWACP, MSc, MPH,MD. Dr. Ejekam is a member of Faculty at the Center for Infection Control and Patient Safety (CiCaPS)College of Medicine, University of Lagos and the African Centre of excellence for Drug Research, Herbal medicine Development and Regulatory Science (ACEDHARS) of the University of Lagos. She teaches MSc pharmacovigilance and post-graduate diploma in infection prevention and control.

Dr. Chioma Ejekam has over 15 years' experience in the field of public health. She has managed several multi-country projects as a lead investigator with local and international partners.

Dr Chioma Ejekam has contributed remarkably to the development of pharmacovigilance and pharmacoepidemiology in public health programs especially in Africa. She is the current Co-lead of West Africa for the International Society of Pharmacoepidemiology (ISPE-AfriG).

She has several peer-reviewed publications in her portfolio.

## Workshops

DAY 2 | **TUESDAY 6 JUNE 8:00 - 12:00** 

Tools and approaches for developing functional Pharmacovigilance systems in Africa

#### WORKSHOP OUTLINE

#### Regulatory and Programmatic Pharmacovigilance Systems in Africa

This training session will provide an overview of practical pharmacovigilance methodologies including detection and assessment of safety signals, risk management, and programmatic systems that have been used globally and in African settings to support robust collection, evaluation, and response to safety data on the performance of medicinal products. This interactive workshop will encourage discussion and brainstorming among participants to develop locally responsive approaches to pharmacovigilance.



**Ushma Mehta** Pharm.D, DrPH

Centre for Infectious Disease Epidemiology and Research (CIDER)



Maribel Salas MD MSc, DSc, FACP, FISPE Daiichi Sankyo **Ushma Mehta** has been practicing pharmacovigilance since 1996. She has been involved in regulatory pharmacovigilance, serving as the manager of the spontaneous reporting system in South Africa and more recently as a member of the SAHPRA Board. She has supported the development of pharmacovigilance systems for HIV, Malaria, Immunization and maternal and child health programmes across the globe. She is co-PI of the UBOMI BUHLE pregnancy exposure registry project, which aims to monitor the safety of public health medicines (e.g. antiretrovirals) used in pregnancy. She is also a member of the WHO Advisory Committee on the Safety of Medicinal Products (AcSOMP).

Maribel Salas is an Executive Medical Director, Therapeutic Area Lead of the Specialty Medicine, Clinical Safety and Pharmacovigilance Department at Daiichi Sankyo Inc. located in New Jersey, USA. She is a medical doctor with a specialty in Internal Medicine and epidemiologist with more than 20 years of experience in pharmacovigilance and pharmacoepidemiology. Dr. Salas holds degrees in Medicine, Internal Medicine, Outcomes Research, Epidemiology, Clinical Epidemiology, and Pharmacoepidemiology. She is the current president of the North American Society of Pharmacovigilance (NASoP), an ISoP Chapter, and an Adjunct Scholar at the University of Pennsylvania and at Rutgers University, USA. Dr. Salas worked in the Internal Medicine Department, Hospital of Specialties, and Preventive Medicine Department at the University of Alabama at Birmingham (UAB). She was a full-tenure professor at the School of Public Health (SOPH), UAB. She joined the Patient Safety Departments at AstraZeneca Pharmaceuticals followed by Pfizer Inc, Merck Research Laboratories, and lately, Daiichi Sankyo Inc. Dr. Salas has mentored fellows, MSc, and doctoral degree students of pharmacoepidemiology. Dr. Salas obtained various federal grants, worked with multiple large databases "big data" and "real-world data", has published more than 100 scientific articles published in peer-reviewed journals, and has more than 1000 citations in the scientific literature.

# Workshops

#### DAY 2 | **TUESDAY 6 JUNE** 13:00 - 17:00

The Epidemiology of Medical Devices and Surgical Procedures: Innovations and Opportunities

#### WORKSHOP

The Epidemiology of Medical Devices and Surgical Procedures: Innovations and Opportunities



### **Paul Coplan** ScD, MBA, FISPE

VP, Head of Medical Device Epidemiology and Real World Data Sciences

Office of Chief Medical Officer and Medical Devices Companies

Adjunct Assistant Professor, Department of Biostatistics, Epidemiology and Informatics, University of Pennsylvania Perelman, School of Medicine, Philadelphia, PA 19104 **Paul Coplan** is the Vice President of Epidemiology and Real-World Data Sciences for Medical Devices at Johnson and Johnson, leading a team of 30 epidemiologists, data programmers and health service researchers. Paul completed a Master's in Public Health at the University of Massachusetts, Amherst, a Doctor of Science in Epidemiology and Biostatistics at Harvard School of Public Health, and an MBA at Wharton Business School at the University of Pennsylvania.

Paul has been a pioneer in using epidemiology and real-world evidence to develop new vaccines, medicines and medical technology, to assess their safety and effectiveness after marketing, and in using real world evidence for market access and label expansion purposes. He has helped develop 9 widely used vaccines, 9 medicines and several medical devices. In addition, Paul has taught Epidemiology at the University of Pennsylvania Perelman School of Medicine as an adjunct professor for the past 22 years. He has authored over 100 peer-reviewed scientific articles and 500 international medical conference presentations, conducted studies in 15 countries and has worked with the FDA, EMA, Chinese, Canadian and other national regulatory authorities.

Paul is a member of the National Evaluation System for Health Technology's Data Quality Workgroup and the Medical Device Innovation Consortium Science of Patient Input Steering Committee. He has led pre-competitive initiatives for collaboration between companies, regulators and academics in creating benefitrisk frameworks for medical product evaluations; assessing the safety of HIV medications, vaccines, and opioid analgesics; establishing clinical trial infrastructure in Africa and Southeast Asia for HIV vaccine and microbicide trials; building and evaluating Risk Evaluation and Mitigation Strategies (REMS); and epidemiologic evaluation of cobalt-containing orthopedic implants.

# Pre-Conference Workshops



#### Mary Beth Ritchey PhD, MSPH, FISPE

Associate Research Professor, Center for Pharmacoepidemiology and Treatment Science, Institute for Health, Health Care Policy and Aging Research, Rutgers University

Associate Professor, Rutgers School of Public Health, Rutgers University **Mary Beth Ritchey** is a part-time Associate Research Professor at PETS where she conducts pharmacoepidemiology research, teaches, and mentors students/ fellows in pharmacoepidemiology methodology. Outside of PETS, she is the Principal and Owner of Med Tech Epi, LLC where she conducts strategic evidence generation planning and analysis of health care databases for regulatory decision-making under contract with pharmaceutical and medical device clients.

Dr. Ritchey is an innovative and dynamic epidemiologist with over 15 years "realworld evidence" observational research experience across government, industry, and academia in study design and implementation. She is adept with scientific, technical, and logistical aspects of conducting regulatory-grade feasibility, utilization, safety, and effectiveness studies of medical products. Dr. Ritchey is experienced leading international multi-stakeholder teams for research, strategic planning and coordination of scientific programming, agenda-setting, and decision-making. She has proficiency in garnering efficiency in a continuous learning environment, specifically medical product safety and real-world evidence, through review of research processes and clarification of stakeholder needs.

Dr. Ritchey is a Fellow of in the International Society of Pharmacoepidemiology (ISPE), Associate Editor for Pharmacoepidemiology and Drug Safety (PDS) and serves on the Executive Operations and Scientific Oversight Committees for the Medical Device Epidemiology Network (MDEpiNet) public private partnership with FDA.

# Workshops

#### DAY 2 | **TUESDAY 6 JUNE** 8:00 - 17:00 Biostatistics applied to Pharmacoepidemiology

#### WORKSHOP

Biostatistics applied to Pharmacoepidemiology



#### Prof Lisa Pont FISPE

Associate Professor & Team Lead Medicines Use Research in Aged Care (MURAC)

Discipline of Pharmacy, Graduate School of Health University of Technology Sydney (UTS) Sydney, Australia **Lisa Pont** is a registered pharmacist and Professor in the Discipline of Pharmacy, Graduate School of Health at the University of Technology Sydney. She has a PhD in Clinical Pharmacology on Quality Use of Medicines from the University of Groningen in The Netherlands where she explored the development and validation of prescribing indicators for measuring quality of prescribing in general practice.

### DAY 1 | Wednesday 7 JUNE

	AUDITORIUM	BREAKAWAY ROOM 1   Venue 5	BREAKAWAY ROOM 2   Venue 6
8:00		Registration	
08:30 - 10:00	Welcome Message Kwame Appenteng KEYNOTE PLENARY Chancelor Brian Strom Shirley Collie - Discovery Health Nicolas Crisp (Virtual) MODERATOR Paul Coplan	No Session	No Session
10:00		TEA BREAK	
10:30 - 11:30	SYMPOSIUM - Real-World Evidence in the African region: Challenges Jopportunities Maribel Salas Introduction Johanna Meyer & Maribel Salas Aspects of RWE/RWD Johanita Burger Existing databases in Africa and impact on the type of studies to conduct Ilse Truter Classification of coding systems and other potential solutions to existing databases	<ul> <li><b>Oral Presentations -</b> <b>Drug Utilisation Research</b></li> <li><b>Hlayiseka Mathevula</b> Retrospective medicine utilisation review of unlicensed and off-label medicine use in children 0-2 years of age in academic hospitals, Gauteng, South Africa</li> <li><b>Onyinye Akunne</b></li> <li>Medicine Prescription Patterns in Health Care Facilities in Limpopo, South Africa</li> <li><b>Marco Falco</b></li> <li>Perceptions of and practical experience with the National Surveillance Centre in managing medicines availability amongst users within public healthcare facilities in South Africa</li> <li><b>MODERATOR</b></li> <li><b>Joseph Fadare</b></li> </ul>	<ul> <li>Oral Presentations - Pharmacoepidemiology</li> <li>Paul Coplan</li> <li>Racial Disparities in Post- Traumatic Treatment of Tibial Fractures – A US Claims Database Analysis</li> <li>Thiyani Mthombeni</li> <li>Point-prevalence survey of antibiotic prescribing for inpatients at regional hospitals in Limpopo, South Africa: A baseline for antibiotic stewardship interventions</li> <li>Chioma Ejekam</li> <li>The quality, supply, storage and use of uterotonics for the prevention of post-partum Haemorrhage in the Northern regions of Ghana – a survey of the healthcare providers' perspectives</li> <li>MODERATOR Julius Asubonteng</li> </ul>
11:30		LUNCH BREAK/POSTER	

	AUDITORIUM	BREAKAWAY ROOM 1   Venue 5	BREAKAWAY ROOM 2   Venue 6
13:00 - 14:30	<ul> <li>VACCINE PLENARY Working towards a healthy Africa: Evidence for strengthening vaccination programmes</li> <li>Prof Marc Mendelson</li> <li>Vaccination: A vital pillar of antimicrobial stewardship</li> <li>Prof Jonny Peter</li> <li>Hypersensitivity reactions: A rare adverse event following immunisation</li> <li>Dr Clare Cutland</li> <li>Active COVID-19 safety surveillance in Africa: Update and lessons learnt</li> <li>Prof Sara Cooper</li> <li>Building public confidence in vaccination: Moving beyond a reliance on information-based responses</li> <li>MODERATOR</li> </ul>	<b>No Session</b>	No Session
	Hannelie Meyer		
14:30		TEA BREAK	
15:00 - 16:00	SYMPOSIUM - Medicine Use Evaluation (MUE) implementation in the public health sector, Western Cape Yasmina Johnson & Mosedi Namane MUE implementation process, lessons learned, MUEs implemented and policy implications Marc Blockman Ethical considerations of presenting routinely collected or service-level data findings	Oral Presentations - HIV/AIDS Priyadarshini Arnab Severe efavirenz-associated neurotoxicity: a retrospective cohort study Suniti Sinha Risk factors for liver injury in South African adults taking first-line antiretroviral therapy: a retrospective cohort study Tinashe Mashanyare Self-reported adherence to antiretroviral therapy among patients at a provincial hospital in South Africa MODERATORS Karen Cohen & Irene Murimi-Worstell	<ul> <li>Oral Presentations - A Medley from Across Africa</li> <li>Phumzile Skosana Antimicrobial Management of Skin and Soft Tissue Infections among Surgical Wards in South Africa: Findings and Implications</li> <li>David Kimonge The economic impact of antimicrobial stewardship in a hospital setting: The case for Gertrude's Children's Hospital, Nairobi, Kenya</li> <li>Monicah Karara Health-related quality of life among adults with type 2 diabetes on herbal verbal versus conventional antidiabetic medicines in Nairobi, Kenya</li> <li>Bronte Davies Health systems determinants of delivery and uptake of maternal vaccines in low and middle- income countries: A qualitative systematic review</li> </ul>

MODERATOR Chioma Ejekam

#### **3rd Annual Conference on PHARMACOEPIDEMIOLOGY IN AFRICA 2023** CAPE TOWN, SOUTH AFRICA

	AUDITORIUM	BREAKAWAY ROOM 1   Venue 5	BREAKAWAY ROOM 2   Venue 6
16:00 - 16:30	MEET A COLLEAGUE/ EXPER	<b>RT</b> [Round Table Discussions with Lead	ling Pharmacoepidemiologists]
18:00 +		Welcome Reception	

END Day 1

### DAY 2 | THURSDAY 8 JUNE

	AUDITORIUM	BREAKAWAY ROOM 1   Venue 5	BREAKAWAY ROOM 2   Venue 6
8:00		Registration	
08:30 - 10:00	PHARMACOVIGILANCE PLENARY		
10:00	<b>Dr Alex Dodoo</b> Status of Pharmacovigilance in Africa ( <b>Virtual</b> )		
	<b>Dr Rachida S. Bencheikh</b> Pharmacovigilance system in Morocco ( <b>Virtual</b> )		
	<b>Prof Rebecca Zash</b> The Tsepamo study: Neural- Tube Defects and Antiretroviral Treatment Regimens in Botswana (Virtual)		
	Dr. Helen Ngajide (Virtual)		
	<b>Dr Ushma Mehta</b> Pregnancy registries in South Africa		
	MODERATORS Maribel Salas & Sylvia Opanga		
10:00		TEA BREAK	
10:30 -	SYMPOSIUM -	Oral Presentations -	Oral Presentations - Covid-19
11:30	Methodological issues for monitoring the safety of Medicinal Products in Pregnancy in Africa. Sponsored by the UBOMI	Pharmacovigilance Thuli Makhene Assessment of pharmacovigilance guidelines in the Southern African	<b>Joseph Fadare</b> Short-Term Covid-19 Vaccine Adverse Effects Among Adults in Ekiti State, Nigeria
	BUHLE Project	Development Community. A document review Nana Akosua Ansah	Andrew Gray Impact of the COVID-19 pandemic on the utilisation of specific

Ushma Mehta Pinning down medicines exposures in pregnancy

#### Emma Kalk

Surveillance and analytical issues in determining the Background rates of Congenital Anomalies

#### Thoko Malaba

Pitfalls and possibilities for determining accurate gestational dating of exposures and outcomes

#### **Dr Barbara Laughton**

Beyond Birth – tools for neurodevelopmental assessment

Barriers and facilitators to vaccine adverse event healthcare workers' reporting in Ghana-a qualitative study

#### Maforah Matlala

The completeness of adverse drug reactions in South Africa: An analysis in Vigibase®

#### **Christabel Khaemba**

Safety Surveillance during the implementation of Mass Drug Administration by the Neglected Tropical Diseases (NTD) Program for Elimination of Lymphatic Filariasis, Kenya

MODERATOR **Kwame Appenteng**  medicines in the South African public sector

#### Dan Kajungu

A solution for active reporting of adverse events following immunization (AEFI) with COVID-19 vaccines in Uganda

#### Trudy Leong

Adaptive complex systems to mobilise rapid evidence-informed decision-making for the National treatment guidelines for COVID-19 in South Africa

MODERATOR Ibrahim Oreagba

	AUDITORIUM	BREAKAWAY ROOM 1   Venue 5	BREAKAWAY ROOM 2   Venue 6
11:30		LUNCH BREAK/POSTER	
13:00 - 14:30	PRESIDENTS FORUM Chancellor Brian Strom Prof Stan Edlavitch Prof Vincent Lo Re Prof Tobias Gerhard Prof Lisa Pont MODERATORS Kwame Appenteng & Solomon Iyasu	No Session	No Session
14:30		TEA BREAK	
15:00 - 16:00	SYMPOSIUM - Causality assessment of serious adverse events following COVID-19 immunization: Lessons from South Africa to maintain public confidence in vaccination Hannah Gunter, Marione Schönfeldt, Sipho Dlamini & Johanna C Meyer Introduction and causality assessment process conducted by the National Immunization Safety Expert Committee using the World Health Organization's methodology Presentation of three cases with Guillain-Barré syndrome (GBS) following vaccination with COVID-19 Vaccine Janssen, including case investigations, clinical data, and causality assessment classification Communication on causality assessment outcomes	Getting Funded: A Workshop on writing successful grants to support your research MODERATOR Ilse Truter	<b>No Session</b>
16:00 - 16:30	MEET A COLLEAGUE/ EXPER	<b>RT</b> [Round Table Discussions with Leadi	ing Pharmacoepidemiologists]
18:00 +		Social/Dinner	

END Day 2

### DAY $3_{|\text{Friday 9 June}}$

	AUDITORIUM	BREAKAWAY ROOM 1   Venue 5	BREAKAWAY ROOM 2   Venue 6
8:00		Registration	
08:30 - 10:00	ANTIMICROBIAL STEWARDSHIP PLENARY Aislinn Cook Current antimicrobial prescribing patterns across Africa Dr Tiyani Sono Purchasing of antibiotics without prescription across Africa and ways to address them Prof Karen Barnes Data to inform global malaria policy Dr Theunis Avenant Ethics in AMS in LMICs (Virtual) MODERATOR Natalie Schellack		
10:00		TEA BREAK	
10:30 - 11:30	SYMPOSIUM - Current State and Management of HIV in Africa Joseph Fadare Overview of HIV/AIDS in Africa: The impact of pharmacotherapy on disease burden and prognosis Andrew Gray The impact of HIV on medicines policies Linda Gail Bekker Managing the HIV/AIDS patient in Africa: Important points to consider, and the promise of vaccines Vincent Lo Re Pharmacoepidemiology of Antiretroviral Therapy Among People with HIV and Viral Hepatitis Coinfection MODERATORS Karen Cohen & Irene Murimi-Worstell	<b>No Session</b>	SYMPOSIUM - Improving Healthcare in Sub-Saharan Africa through Continuing Professional Development (CPD) and E-learning in Pharmacy Neelaveni Padayachee Translating CPD knowledge into practice Nicola Wearne Inter professional working relationship MODERATOR Philip Harrison
11:30		LUNCH BREAK/POSTER	

	AUDITORIUM	BREAKAWAY ROOM 1   Venue 5	BREAKAWAY ROOM 2   Venue 6
13:00 - 14:30	AfRIG/MURIA MEMBERSHIP MEETING	No Session	No Session
14:30		Closing remarks	

END Conf/Departure

### **Concurrent Sessions:** Symposia /Workshops

#### Real-world evidence in the African region: challenges and opportunities

#### Ilse Truter<sup>1</sup>, Johanita Burger<sup>2</sup>, Johanna Meyer<sup>3</sup>, Maribel Salas<sup>4</sup>

<sup>1</sup>Nelson Mandela University, Summerstrand, Gqeberha, South Africa. <sup>2</sup>North-West University, Potchefstroom, South Africa. <sup>3</sup>Sefako Makgatho Health Sciences University, GaRankuwa, Pretoria, South Africa. <sup>4</sup>DSI and U Pennsylvania, Basking Ridge and Philadelphia, USA

#### Abstract

Including real-world evidence (RWE) in regulations worldwide has impacted the evolution of methods and forced the development and improvement of available medical data for decision-making. In low- and middle-income countries, the COVID-19 pandemic highlighted the need for having a harmonised system to track the distribution of vaccines and monitor their safety and effectiveness. Africa, in particular, lacked RWD to make urgent decisions. Until now, RWE has been used for different purposes, such as to support coverage decisions by healthcare organisations, develop guidelines for use in clinical practice, monitor post-marketing safety data and adverse events, and design clinical trials. However, to use RWD for decision-making, governments and decision-makers need to have access to high-quality RWD for patient management and/or the delivery of healthcare. Furthermore, the need for complete, consistent, and quality data compels decision-makers to be innovative by using mobile devices or other technologies.

#### **Objectives:**

To provide the current status of RWE and RWD in general and in the African region and to provide potential opportunities and solutions to existing challenges. Decision-makers in the health sector would benefit from the symposium.

#### Description:

- 1. Introduction
- 2. General aspects of RWE/RWD
- 3. Existing databases in Africa and impact on the type of studies to conduct
- 4. Classification of coding systems and other potential solutions to existing databases
- 5. Discussion and questions
- 6. Conclusion

### **Concurrent Sessions:** Symposia /Workshops

### Medicine use evaluation (MUE) implementation in the public health sector, Western Cape

#### Yasmina Johnson<sup>1</sup>, Mosedi Namane<sup>2,3,4</sup>, Marc Blockman<sup>5,6</sup>

<sup>1</sup>Medicine Management, Western Cape Government Health and Wellness, Cape Town, South Africa. <sup>2</sup>Senior Family Physician, Vanguard Community Health Centre, Western Cape Government Health and Wellness, Cape Town, South Africa. <sup>3</sup>A/Prof Family Medicine Division, University of Cape Town, Cape Town, South Africa. <sup>4</sup>Pharmacy and Therapeutics Committee & Medicine Use Evaluation Committee, Western Cape Government Health and Wellness, Cape Town, South Africa. <sup>5</sup>Department of Medicine, Division Clinical Pharmacology, University of Cape Town and Groote Schuur Hospital, Cape Town, South Africa. <sup>6</sup>Chair, Human Research Ethics Committee, Faculty of Health Sciences, University of Cape Town, Cape Town, South Africa

#### Abstract

Background: A Medicine Use Evaluation (MUE) is a quality improvement program which employs a criteria-based and structured approach aimed at evaluating and improving medicine use throughout the healthcare system (prescribing, dispensing, administration). The principal functions of MUEs include analysing practice performance, highlighting areas of practice that are of concern and implementing interventions for improvement; ultimately to promote rational prescribing to improve patient health outcomes.

Objectives: Several MUEs have been implemented that informed policy in the Western Cape public health sector. This symposium will unpack the lessons learned, pitfalls, successes and ethical considerations of implementing MUEs, specifically in a resource-constrained environment with limited information technology.

Researchers, policy-makers, quality assurance practitioners, doctors, pharmacists, nurses, etc., interested in monitoring medicine prescribing performances and implementing data-driven interventions to improve medicine use will find this symposium beneficial.

Description: This symposium will present and discuss the MUE implementation process followed in the Western Cape public health sector, lessons learned, examples of MUEs executed and their relevant policy implications. Importantly also, the ethical considerations of presenting findings derived from routinely collected or service-level data will be highlighted and discussed.

#### Outline

- 1. MUE implementation process, lessons learned, MUEs implemented and policy implications.
- 2. Ethical considerations of presenting routinely collected or service-level data findings.

### **Concurrent Sessions:** Symposia /Workshops

#### Methodological issues for monitoring the safety of Medicinal Products in Pregnancy in Africa. Sponsored by the UBOMI BUHLE Project

#### Ushma Mehta, Emma Kalk, Thoko Malaba

University of Cape Town, Cape Town, South Africa

#### Abstract

Globally, there has been an acceleration in the availability of multiple new treatments for multiple diseases of major public health impact, such as HIV, TB, Malaria, Diabetes, COVID-19, and autoimmune/inflammatory allergic conditions. It is becoming increasingly difficult to determine the impacts of many interacting conditions and treatments on women of childbearing potential and their children. The need for general adaptable pregnancy surveillance systems relevant to the African region can't be overstated. This symposium methodological issues that need to be considered when designing surveillance systems for monitoring the performance of medicines used in pregnancy, particularly in relation to birth outcomes. The challenges and possibilities of obtaining accurate data on medicine exposures, gestational dating, birth outcomes, particularly congenital disorders and assessment of growth and neurodevelopment in African settings will be discussed, reflecting on the importance of the close relationship between pharmacoepidemiology and health systems strengthening.

#### Outline

- 1. Introduction and welcome
- 2. Pinning down medicines' exposures in pregnancy
- 3. Pitfalls and possibilities for determining accurate gestational dating of exposures and outcomes
- 4. Surveillance and analytical issues in determining the Background rates of Congenital Anomalies
- 5. Beyond Birth tools for neurodevelopmental assessment
- 6. Questions, Thanks and Closure

### **Concurrent Sessions:** Symposia /Workshops

# Causality assessment of serious adverse events following COVID-19 immunization: Lessons from South Africa to maintain public confidence in vaccination

#### Hannah M Gunter<sup>1</sup>, Marione Schönfeldt<sup>2</sup>, Sipho Dlamini1, Johanna C Meyer<sup>3</sup>

<sup>1</sup>University of Cape Town, Cape Town, South Africa. <sup>2</sup>National Department of Health, Pretoria, South Africa. <sup>3</sup>Sefako Makgatho Health Sciences University, Pretoria, South Africa

#### Abstract

Background: Vaccine safety surveillance is an important pharmacovigilance activity for monitoring vaccine safety. Performing causality assessment of reported serious adverse events following immunization (AEFI) by using a structured methodology is a vital measure to ensure that the benefits of immunization are maintained in the interest of public health and efficient vaccination programmes. Proper case investigation of previous medical history and interpretation of patient clinical data by experts is essential to determine a valid diagnosis and subsequent causality classification. Transparent communication with the public regarding serious AEFI is important to maintain public confidence in vaccines and prevent all AEFI from being misinterpreted as caused by the vaccine.

Objectives: To describe the process of performing causality assessments for AEFI; to illustrate the importance of clinical data in causality assessment; to highlight the key findings of causality assessment for three illustrative cases; to describe communication initiatives to maintain confidence in vaccination following serious AEFI. Clinicians, researchers, decision-makers, and healthcare workers involved in or wanting additional expertise in recognizing, reporting and/or referring cases with suspected AEFI would benefit by attending this symposium.

#### **Description:**

- 1. Introduction and causality assessment process conducted by the National Immunization Safety Expert Committee using the World Health Organization's methodology
- 2. Presentation of three cases with Guillain-Barré syndrome (GBS) following vaccination with COVID-19 Vaccine Janssen, including case investigations, clinical data, and causality assessment classification
- 3. Communication on causality assessment outcomes
- 4. Discussion with a question-and-answer session
- 5. Conclusion
### **Concurrent Sessions:** Symposia /Workshops

## Improving healthcare in Sub-Saharan Africa through continuing professional development (CPD) and e-learning in pharmacy

#### Philip Harrison<sup>1</sup>, Sylvia Opanga<sup>2,3</sup>, Lucas Nyabero<sup>4</sup>

<sup>1</sup>Square Foundation and Academy, Montreal, Canada. <sup>2</sup>University of Nairobi, Nairobi, Kenya. <sup>3</sup>Square Foundation, Montreal, Canada. <sup>4</sup>Pharmaceutical Society of Kenya, Nairobi, Kenya

#### Abstract

Background: Pharmacists have a pivotal role in health care delivery both because they are often the first health care professional that the patient sees and because they complement physicians and nurses to improve health care outcomes. The Square Foundation is making a small contribution to pharmacy education by supporting students and by providing an e-learning program to help continue professional development CPD), which includes coaching on how to work as a team and emphasises on practical aspects of clinical pharmacy, which are not often a focus in different teaching curricula across Africa. Additionally, CPD varies considerably across the 46 countries in the region, but this presents a huge opportunity to benefit from the collective knowledge and experience.

Methods: We propose a symposium at the ISPE AfRIG 2023 meeting in Cape Town in June 2023 which would address the scope of pharmacy practice, knowledge and inter-professional collaboration. All members of those registering for the AfRIG meeting would be welcome, we will extend invitations to schools of pharmacy, pharmaceutical societies and other bodies such as ministries of health and pharmaceutical councils who have a vested interest in optimizing pharmacist's role in delivering health care, which may encourage the participation of those who do not normally attend an ISPE meeting.

Expected outcomes: We expect to come up with a roadmap to supplement already existing pharmacy education in Africa as well as harmonise CPD programs, to better enhance pharmacy education and practice.

### **Concurrent Sessions:** Symposia /Workshops

## Getting Funded: A Workshop on writing successful grants to support your research

#### Kimberly McKeirnan

Washington State University, Spokane, USA

#### Abstract

Writing fundable grant proposals is an integral part of developing a successful research portfolio. Funding can enable researchers to conduct large-scale and impactful research projects, the results of which can lead to system change in practice. This workshop will include tips for writing grant proposals that lead to successful funding, including differentiating between goals, objectives, hypotheses, and specific aims; articulating your vision throughout the proposal; creating budgets and budget narratives; and identifying potential funding sources.

Dr. Kimberly McKeirnan, Director of the Center for Pharmacy Practice Research at the Washington State University College of Pharmacy and Pharmaceutical Sciences, will lead participants through active learning exercises designed to provide opportunities for consideration of personal grant funding goals, identification of potential funding sources, and creation of fundable proposal ideas. Tips and best practices for different sections of a grant proposal will be discussed so that after completion of this workshop, the learner will be better prepared to identify potential grant funding sources and develop a competitive proposal.

### **Concurrent Sessions:** Oral Presentations

CATEGORY | Drug Utilisation Research

## Retrospective medicine utilisation review of unlicensed and off-label medicine use in children 0-2 years of age in academic hospitals, Gauteng, South Africa

#### Hlayiseka Mathevula<sup>1</sup>, Moliehi Matlala<sup>2</sup>

<sup>1</sup>Sefako Makgatho Health Sciences University, Pretoria, South Africa. <sup>2</sup>Sefako Makgatho Health Sciences University, Pretoria, South Africa

#### Abstract

Background: Information on off-label and unlicensed medicines used in South African children is limited. Offlabel/unlicensed use of medicines is very common in paediatric medicine because few medicines are specifically formulated for children. Off-label/unlicensed medicines use can lead to issues of efficacy, quality, and safety, as well as raise liability issues in the event of adverse events, exposing physicians to potential legal penalties. This research aimed to determine the prevalence of off-label/unlicensed medicines used for paediatric patients in South Africa.

Method: This was a retrospective medicine utilisation study point prevalent study (PPS) of paediatric (0-2 years) patients hospitalised in selected public hospitals in Gauteng Province, South Africa. Data were collected over two days in three academic public hospitals. Demographics, duration of treatment, diagnosis, and medicines prescribed were collected from patient medical records using a mobile application.

Results: A total of 184 patient records were reviewed from three academic hospitals. A total of 592 medicines were dispensed, of which 379 (64.0 %) were used on-label and 213 (36.0 %) were used off-label/unlicensed. The most prevalent medicines used off-label/unlicensed were Multivitamins (n=32, 15.0 %), Ampicillin (n=15, 7.0%), Caffeine (n=15, 7, 0%), and Gentamycin (n=9, 4.2 %).

Conclusion: The frequency of unlicensed/off-label medicine prescribing shown in this study is consistent with the literature and can be considered high. This practice is likely to affect paediatrics across South Africa, and attention is needed to prevent these children from continuing to be deprived of their basic human rights to quality, safe, and effective medicines.

### **Concurrent Sessions:** Oral Presentations

CATEGORY | Drug Utilisation Research

#### Medicine prescription patterns in healthcare facilities in Limpopo, South Africa

#### Onyinye Akunne<sup>1</sup>, Vutomi Valoyi<sup>2</sup>, Yasmina Johnson<sup>3</sup>, Renier Coetzee<sup>1</sup>

<sup>1</sup>School of Public Health, University of the Western Cape, Cape Town, South Africa. <sup>2</sup>School of Pharmacy, University of the Western Cape, Cape Town, South Africa. <sup>3</sup>Western Cape Department of Health, Cape Town, South Africa

#### Abstract

Background: Periodic prescription audit is necessary to improve the quality of medicine use and curb irrational prescribing.

Objectives: To describe the prescription patterns of medicines in health facilities in the Limpopo province using the World Health Organization (WHO) prescribing indicators.

Methods: This retrospective cross-sectional study evaluated prescription quality using the WHO/INRUD prescribing indicators in hospitals in Limpopo using convenience sampling. The average number of drugs per encounter, percentage of drugs prescribed by generic name, percentage of encounters with an antibiotic prescribed, percentage of prescriptions with an injection prescribed and rate of medicines prescribed from the essential drug list (EML) were evaluated. At least 30 patient encounters per 20 facilities were included in the analysis. All outpatients prescribed medications were included in the study.

Results: Patient information was reviewed between October 2018 and December 2018. Age ranged from 1 - 103 years (Mean  $\pm$  SD = 44  $\pm$  24; Males = 44%; Females = 56%). An average of 4.3 medicines per patient was encountered. About 43% of medicines were prescribed by generic name; 28% and 8% of prescriptions contained one or more antibiotics and injections, respectively. About 90% of the medications prescribed were on the EML.

Conclusions: While the percentage of injections and antibiotics prescribed in the outpatient clinics were within acceptable limits, the number of medicines per patient encounter and prescription by their generic name continues to be an issue. Most medications prescribed conformed with the EML. Interventions to improve the quality of medicine prescriptions are needed.

### **Concurrent Sessions:** Oral Presentations

CATEGORY | Drug Utilisation Research

#### The quality, supply, storage and use of uterotonics for the prevention of postpartum Haemorrhage in the Northern regions of Ghana – a survey of the healthcare providers' perspectives

#### Chioma Ejekam<sup>1,2</sup>, Neimatu Adjabui<sup>3</sup>, Wilfred Agongo<sup>3</sup>, Kwasi Boateng<sup>3</sup>, Jude Nwokike<sup>4</sup>

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#### Abstract

Background: The quality and proper use of uterotonics for the management of PPH by healthcare providers (HCP) in LMIC countries, including Ghana, remain a concern.

Methods: Descriptive cross-sectional study of 800 HCPs who administer uterotonics or are involved in the supply chain management of medicines in the health facilities (HCF), from public and private HCFs in 4 regions of Northern Ghana – Northern, North-East, Upper East and Upper West. Data was collected using a mixed method - interviewer-administered questionnaire and objective uterotonics verification at HCFs.

Results: 26.8% of the HCPs combined uterotonics for the prevention of PPH, contrary to the national guidelines. 6.3% of the respondents use  $\geq$ 20IU of oxytocin for the prevention of PPH. 16% of the respondents use the national recommended 600µg of misoprostol for the prevention of PPH. Of the 89.6% of HCPs that had stored their oxytocin in refrigerators at the HCFs, 62.0% were within 2-8oC on verification of the storage temperature. Of the 86.0% that stored misoprostol in a dry place at room temperature, only 22.8% had temperatures within the recommended storage of  $\leq$ 30°C and 7.4% stored at a humidity of 55-65%. Significant proportions of the oxytocin brands available at the HCFs were labelled to be stored at room temperature (25-30°C). 18%, 55%, 86% of oxytocin, misoprostol and ergometrine, respectively, at HCFs are sourced from private medicines stores.

Conclusion: Evidence shows inappropriate dose administration of uterotonics, verified inappropriate storage conditions, multiple uses of uterotonics, and open sourcing of uterotonics, and these are potential pointers to poorquality uterotonics.

### **Concurrent Sessions:** Oral Presentations

CATEGORY | Drug Utilisation Research

#### Perceptions of and practical experience with the National Surveillance Centre in managing medicines availability amongst users within public healthcare facilities in South Africa

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#### Abstract

Background: Medicine availability remains a challenge in South Africa's public healthcare sector. The National Surveillance Centre (NSC), a web-based performance monitoring and evaluation tool, provides visibility of medicines across the value chain. Ascertaining NSC users' perceptions and experiences in managing medicines availability is essential to sustaining and enhancing availability and access.

Objective: To determine the perceptions of, and experience with, the NSC in the management of medicines' availability within public healthcare facilities in South Africa.

Methods: A descriptive, quantitative study design was used to survey 169 active NSC users electronically. A pre-tested, self-administered questionnaire using Google Forms was emailed to users, including a mandatory consent statement. Data collected included sociodemographic, reporting systems, NSC access and use, training and overall feedback. Microsoft Excel® was used to calculate frequencies and percentages for categorical variables and to code and categorise responses to open-ended questions. Ethics clearance was obtained.

Results: Overall, 114/169 (67.5%) active users responded. Most used the NDoH stock visibility system (SVS) (66.7% medicine; 51.8% PPE), COVID-19 SVS (64.9% vaccines), or RxSolution (57.0% manually; 42.1% API). Respondents focused on medicines availability and reporting compliance, with the integrated medicine availability dashboard and COVID-19 vaccine dashboard being popular. The NSC was perceived to improve data quality and access. Areas for improvement identified: internet connectivity; retraining; dashboard standardisation; additional data points and reports; expanding user adoption.

Conclusions: While the NSC is effective in monitoring and improving medicines availability, further efforts are needed to address challenges and enhance medicines management in South Africa's public healthcare system.

### **Concurrent Sessions:** Oral Presentations

CATEGORY | Pharmacoepidemiology Potpourri

## Racial Disparities in Post-Traumatic Treatment of Tibial Fractures – A US Claims Database Analysis

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#### Abstract

Background: Tibial fractures requiring surgery can lead to long-term morbidity. Racial disparities in post-trauma care are not well documented.

Objective: Evaluate racial differences in healthcare utilization of patients following surgically-treated tibial fractures in the USA.

Methods: Patients from the IBM® MarketScan® Medicaid database with surgically-treated tibial fractures were identified from 10/1/2015 to 12/31/2020 (Surgery date = index). Outcomes included healthcare utilization (medication use, reoperations) and diagnoses of complications, up to 2 years post-index. Covariates used to match Black and White cohorts included demographics, comorbidities, fracture types, and procedural characteristics (propensity score matching, caliper = 0.1). Survival analyses (Kaplan-Meier and Cox Proportional Hazard models) were performed.

Results: 12,680 patients were identified. Before matching, Black patients were younger (< 35 years old: 18.8% Black vs 12.5% White) with generally more severe fractures (Open fractures: 21.8% Black vs 15% White; Gustilo III fractures: 7.3% Black vs 5.0% White). Matched cohort analyses showed that, despite similar complication rates, White patients were more likely to have reoperations within 2 years post-index compared to Black patients (hazard ratio (HR)= 1.14 (95% confidence interval (CI): 1.02-1.27), p = 0.013). Black patients were less likely than White patients to be prescribed antibiotics, strong opioids, or antidepressants (antibiotics: Black: 70% vs White: 80%, p < 0.001; strong opiates: Black: 6.9% vs White: 13%, p < 0.001; antidepressants: Black: 36% vs White: 52%, p < 0.001).

Conclusions: Racial disparities were observed in the treatment of low-income patients with tibial fractures, indicating treatment gaps for improvement.

### **Concurrent Sessions:** Oral Presentations

CATEGORY | Pharmacoepidemiology Potpourri

## Comparative effect of four antimalarial treatments on haematocrit in children in Southwest Nigeria

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#### Abstract

Background: Anaemia in malaria has both central (dyserythropoiesis) and peripheral causes (phagocytosis of both infected and uninfected erythrocytes and haemolysis). Some antimalarial drugs also cause intravascular hemolysis leading to anemia. However, it is often difficult to disentangle the anemia effect of malaria from its treatments. The aim of this study was carried out to compare the change in hematocrit following four antimalarial treatments.

Methods: Data were extracted from 313 case record forms of children that met the eligibility criteria aged 3-119 months enrolled in antimalarial clinical trials in Southwest Nigeria between 1998 and 2014. Change in haematocrit level from baseline through 28 days follow-up period were compared among children treated with artemether-lumefantrine (82), artovaquone-proguanil (41), artesunate-amodiaquine (156) and chloroquine (34). Repeated measures analysis was done by fitting a general linear model (GLM).

Results: The median age of the study population was 25 months and 54% were males. The mean differences (95% CI) in haematocrit from baseline were 4.7% (95% CI = 3.6, 5.8), 4.4% (95% CI = 2.7, 6.0), 3.8% (95% CI = 3.0, 4.7) and 2.4% (95% CI = 0.5, 4.4), for artemether-lumefantrine, artovaquone-proguanil and artesunate-amodiaquine and chloroquine, respectively. Using the general lineal model, repeated measure analysis showed that there were significant differences in the mean haematocrit level over the 28-day follow-up among the four treatment groups (p<0.05).

Conclusions: All children experienced increases in haematocrit after treatment, artemether-lumefantrine appearing to result in a greater increase in haematocrit than other antimalarial drugs.

### **Concurrent Sessions:** Oral Presentations

CATEGORY | Pharmacoepidemiology Potpourri

# Point-prevalence survey of antibiotic prescribing for inpatients at regional hospitals in Limpopo, South Africa: A baseline for antibiotic stewardship interventions

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#### Abstract

Background: Monitoring antibiotics prescribing in hospitalised patients is essential for antimicrobial stewardship activities. Antibiotic prescribing data in regional hospitals in South Africa, including Limpopo Province, is inadequate due to early studies' overrepresentation of tertiary hospitals.

Objective: To describe antibiotic use and identify antibiotic stewardship implementation improvement areas in regional hospitals of Limpopo Province, South Africa.

Methods: Using an adapted point-prevalence survey, a cross-sectional descriptive study design was applied between September and November 2021 to gather data from hospitalised patients' files in five regional hospitals in Limpopo Province. On study days, all patients with antibiotic prescriptions in the wards at 8 a.m. were included. Antibiotic use was calculated as proportions.

Results: Of 804 inpatients surveyed, 261 (32.5%) were prescribed 416 antibiotics. Pneumonia (n (104/416, 23.6%) and skin and soft tissue (89/416, 19.3%) were the most common diagnosis for antibiotic prescriptions. The top three antibiotic agents prescribed were metronidazole (91/416, 21.9%), ceftriaxone (86/416, 20.7%) and amoxicillin with enzyme inhibitor (77/416, 18.5%). Access antibiotics accounted for 70.2% (292/416) of prescriptions, and Watch antibiotics for 29.5% (123/416). Most (365/416, 87.7%) antibiotics prescribed were parenteral formulations. The reason for prescribing and the treatment plan were documented in 64.9% (270/416) and 21.4% (89/416) of prescriptions, respectively.

Conclusions: In Limpopo Province regional hospitals, one in every three hospitalised patients was on at least one antibiotic prescription. Antibiotic stewardship interventions could target antibiotic prescribing in pneumonia, medicine utilisation review for Watch antibiotics (e.g. ceftriaxone), implementation of early intravenous to oral switch, and educational interventions to improve prescribing quality.

### **Concurrent Sessions:** Oral Presentations

CATEGORY | HIV/AIDS

#### Severe efavirenz-associated neurotoxicity: a retrospective cohort study

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#### Abstract

Background: Efavirenz is associated with neuropsychiatric symptoms. Severe neurotoxicity has been reported, but the clinical phenotype and risk factors are poorly defined.

Objectives: We describe the clinical phenotype of severe efavirenz-induced neurotoxicity and explore risk factors for its development.

Methods: We retrospectively identified adults with supratherapeutic efavirenz concentrations (>4 mg/L) obtained in routine clinical care at five hospitals in Cape Town, South Africa. Clinical and laboratory data at the time of efavirenz quantification were extracted from medical records. Logistic regression was performed to identify associations with neuropsychiatric symptoms and severe neurotoxicity (Division of Allergy and Infectious Diseases altered mental status or ataxia  $\geq$  Grade 3).

Results: 81 patients were included; 28 (34.6%) were male, and 49 (60.5%) had concomitant isoniazid exposure. Median efavirenz concentration was 12.1 mg/L (interquartile range (IQR) 6.6-20.0). The most frequent neuropsychiatric manifestations were ataxia in 20 patients and psychomotor slowing in 24. Neuropsychiatric symptoms were associated with longer duration of efavirenz therapy, aOR 1.3 per 180-day increment (95% confidence interval (CI), 1.0-1.7); higher efavirenz concentrations, aOR 1.2 per 1 mg/L increase (95% CI, 1.0-1.4); and isoniazid exposure, aOR 8.2 (95% CI, 2.5-26.7). Severe neuropsychiatric symptoms occurred in 47 (75%) patients. Odds of severe symptoms were 1.2-fold higher (95% CI, 1.1-1.4) per 1 mg/L increase in efavirenz concentration.

Conclusion: There was a concentration-effect relationship for severe neurotoxicity which occurred after prolonged efavirenz therapy.

Contribution: We highlight the clinical heterogeneity and morbidity of efavirenz-associated neurotoxicity.

### **Concurrent Sessions:** Oral Presentations

CATEGORY | HIV/AIDS

## Risk factors for liver injury in South African adults taking first-line antiretroviral therapy: a retrospective cohort study

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#### Abstract

Background: Hospital surveys found that drug-induced liver injury is a leading adverse reaction resulting in hospitalisation and death in people living with HIV (PLHIV) in South Africa.

Objectives: To determine incidence of, and risk factors for, liver injury and liver injury-related hospital admissions in PLHIV on antiretroviral treatment (ART).

Methods: We conducted a retrospective analysis of PLHIV aged >18 years in the Aid for AIDS cohort who commenced ART between July 2011 and September 2018. We described the incidence of, and associations with, liver injury (ALT <sup>3</sup> 120 IU/L) and hospitalisation for liver injury (hospitalisation between 3 days before and 7 days after ALT <sup>3</sup> 120 IU/L, with an ICD10 code compatible with drug-induced liver injury).

Results: We included 94,094 PLHIV; median age was 38.4 years; 42.6% were male, and 88.6% were on efavirenzbased ART. Incidence of liver injury and hospitalisation for liver injury was 0.95 (95% confidence interval (CI) 0.91-0.99) and 0.06 (0.05-0.07) per 100 person-years, respectively. Adjusted hazard ratios (aHRs) (95% CI) for liver injury and hospitalisation for liver injury, respectively, were 15.3 (12.1-19.3) and 6.27 (3.11-12.6), for antituberculosis drug exposure; aHRs were 1.63 (1.31-2.02) and 1.50 (0.70-3.20), for efavirenz-based ART and 2.74 (2.04-3.69) and 3.48 (1.24-9.73) for nevirapine-based ART compared to protease inhibitor-based ART; adjusting for age, sex, CD4 count and viral load at ART initiation, and alcohol-induced pathology.

Conclusions: Exposure to antituberculosis drugs was strongly associated with liver injury and hospitalisation for liver injury. Safer antituberculosis treatment regimens are needed for PLHIV.

### **Concurrent Sessions:** Oral Presentations

CATEGORY | HIV/AIDS

## Self-reported adherence to antiretroviral therapy among patients at a provincial hospital in South Africa

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#### Abstract

Background: Adherence to antiretroviral therapy (ART) is critical in South Africa due to the high costs of second and third-line ART and universal test-and-treat policies.

Objectives: To determine self-reported ART adherence and sociodemographic factors influencing it.

Methodology: A cross-sectional study of 96 adults who completed a self-reported adherence questionnaire. Data were analysed using SPSS® version 27.

Results: The mean age of the participants was  $44.56\pm12.03$  years, 57% were female, 74% unemployed, 84% were parents, 78% were on first-line ART and 34% were on ART for 2–5 years. Participants showed high self-reported adherence (mean= $9.47\pm1.16$  out of 10), low missed doses (mean= $1.59\pm1.32$ ), were very sure of their responsibility when taking ART (mean= $3.31\pm0.57$ ) with high subjective knowledge of HIV/AIDS (mean= $3.02\pm0.70$ ). General support was satisfactory (mean= $3.72\pm0.82$ ), and specific support was somewhat satisfactory (mean= $2.98\pm1.16$ ). Only 23% reported alcohol consumption, and traditional medicine use as an alternative or additional therapy to ART was infrequent ( $1.11\pm0.35$  and  $1.01\pm0.10$ , respectively). The primary reason for missed doses was lack of food to take with ART (mean= $1.20\pm0.65$ ). Few missed appointments were reported, with the primary reason being the inability to afford transportation to the hospital (mean= $1.11\pm0.478$ ). Adherence scores positively correlated with responsibility (p=0.000, r=.374) and knowledge (p=0.008, r=.275) but negatively with alcohol consumption (p=0.015, r=-.249) and ART interruption for traditional medicines (p=0.039, r=-.215). Gender, employment, and parenting had no significant effect on adherence.

Conclusion: These results may offer insights into the determinants of adherence to ART and developing interventions to improve adherence in HIV-positive individuals.

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### **Concurrent Sessions:** Oral Presentations

CATEGORY | HIV/AIDS

#### Prevalence and reporting of adverse drug reactions among human immunodeficiency virus-infected patients assessing healthcare at secondary care hospitals in Kwara-central Senatorial District, Nigeria

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#### Abstract

Background: Adverse drug reactions (ADRs) are major causes of morbidity, hospital admission and mortality in human immunodeficiency virus (HIV)-infected patients. Dearth of information on the prevalence and reporting of ADRs in Kwara-Central Senatorial District, Nigeria, attracted concerns.

Objective: To assess the prevalence and reporting of ADRs among HIV-infected patients assessing care at secondary care hospitals in Kwara-Central Senatorial District, Nigeria.

Methods: This multi-centered cross-sectional study was conducted in three secondary care hospitals. Based on Fischer formula, 310 eligible HIV-infected patients were allocated proportionally to each hospital and consecutively sampled. Pretested structured questionnaire was researcher-administered to these patients, and the Key Informant Interviews (KIIs) were conducted for the Doctors, Pharmacists and Nurses that provide healthcare for these patients. Descriptive and inferential statistics were used for quantitative data analyses. Significance level was set at P<0.05. Qualitative data analysis involved literal transcription of the audio-recorded KIIs, and presentation was in an ethnographic summary.

Results: Prevalence of ADR in HIV-infected patients on antiretroviral therapy (ART) was 43.5%. Antiretroviral (ARV) treatment regimen has a statistically significant association with the occurrence of ADRs (P<0.05). ARV regimen commonly associated with ADRs is Tenofovir/lamivudine/efavirenz (34.2%). Severity of ADR mostly experienced was moderate, with clinical manifestations such as headache, dizziness, skin rash, pruritus, and abdominal pain. There was non-availability and non-utilization of ADR reporting forms by healthcare practitioners.

Conclusion: Prevalence of ADRs among HIV-infected patients on ART is of public health concern. Pharmacovigilance units should be institutionalized in all secondary care hospitals.

### **Concurrent Sessions:** Oral Presentations

CATEGORY | A Medley from Across Africa

#### Antimicrobial Management of Skin and Soft Tissue Infections among Surgical Wards in South Africa: Findings and Implications

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#### Abstract

Introduction: Skin and soft tissue infections (SSTIs) are one of the most common infectious diseases requiring antibiotics. However, complications of SSTIs may lead to overprescribing and subsequent antibiotic resistance. Consequently, monitoring prescribing alignment with current recommendations from the South African Standard Treatment Guidelines (STG) is necessary to improve care.

Method: This study evaluated prescriptions of antibiotics for skin and soft tissue infections (SSTIs) in a leading South African tertiary public hospital between April and June 2021.

Results: Sixty-seven patient files were reviewed, and it was found that the most common co-morbidities among patients with SSTIs were hypertension and chronic osteomyelitis. The most diagnosed SSTIs were surgical site infections (35.1%), wound site infections (23%) and major abscesses (16.2%). Blood cultures were performed on 40.3% of patients, with Staphylococcus aureus (32.7%) and Enterococcus spp (21.2%) being the most common pathogens cultured. The most prescribed antibiotic for empiric treatment was cefazolin (46,3%), followed by gentamycin, ciprofloxacin and rifampicin being prescribed at 17.5%, 11.3% and 8.8%, respectively. In 55.2% of cases, treatment complied with South African Standard Treatment Guidelines (STGs) recommendations.

Conclusion: Overall, Staphylococcus aureus is the most common cause of SSTIs, and empiric treatment should be initiated. Subsequently, culture sensitivity testing should be performed to enhance adherence to STGs and improve patient care.

### **Concurrent Sessions:** Oral Presentations

#### CATEGORY | A Medley from Across Africa

## The economic impact of antimicrobial stewardship in a hospital setting: the case for Gertrude's Children's Hospital, Nairobi, Kenya

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#### Abstract

Background: Implementing antimicrobial stewardship (AMS) programs require financial resources, and it is important to understand the economic and financial impact of these initiatives. There is a paucity of data on the economic impact of AMS programs in Kenyan hospitals.

Objective: To investigate the economic impact of implementing antimicrobial stewardship interventions at Gertrude's Children's Hospital in Nairobi, Kenya.

Methods: Mixed-method study. Economic impact of the AMS program was evaluated through a review of retrospective pre-post data on antimicrobial consumption and costs. Changes in antibiotic consumption and cost were done through simple calculations, estimating frequency and percentage differences between two or more values and charts were created through Excel. Shapiro Wilk test was used to analyze whether data were normally distributed, and depending on the distribution, the paired t-test or Wilcoxon signed rank test was utilized for statistical analysis using STATA 13.0.

Results: An overall -25.4% decrease in consumption of selected antibiotics was observed between the pre-AMS phase (2015-2018) to post-phase (2019-2022), from 137.8 DDDs to 112.4 DDDs. Consumption of imipenem/cilastatin (-81%), meropenem (-54.7%), and vancomycin (-54.4%). Cefotaxime (44%) and clindamycin (22%) injections increased consumption. Antimicrobial Shillings Per Patient Day (AMSD) decreased by 9.3% in the first year (2018) and a further drop of 33.3% in 2019. There was a slight increase in 2020 (0.5%). AMSD increased in 2021 by 4.2%; 2022 saw a drop in AMSD by 29.2%.

Conclusion: AMS program implementation at Gertrude's Children's Hospital was associated with a decreased consumption and cost of target antibiotics.

### **Concurrent Sessions:** Oral Presentations

CATEGORY | A Medley from Across Africa

## Health-related quality of life among adults with type 2 diabetes on herbal versus conventional antidiabetic medicines in Nairobi, Kenya

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#### Abstract

Background: Patients with type 2 diabetes often seek both conventional and herbal treatment for glycemic control. Health-related quality of life in these patients has not been previously evaluated in Kenya.

Objective: To compare health-related quality of life (HRQOL) in patients with type 2 diabetes on herbal versus conventional antidiabetics.

Methods: A cross-sectional study was conducted among 80 diabetic patients attending a conventional treatment clinic and 37 patients receiving care in a herbal clinic in Nairobi, Kenya. The WHOQOL-BREF tool was used to assess the health-related quality of life. The HRQOL scores were compared by the non-parametric Mann-Whitney test. Multiple Linear Regression (MLR) was used to identify the sociodemographic and clinical factors affecting the various domains of HRQOL.

Results: The mean overall quality of life scores were 50% and 75% in the herbal and conventional treatment groups, respectively (p<0.001). Domain-specific analysis found the level of education (P= 0.010) and physical activity (p=0.001) as determinants of the physical domain of HRQOL. Microvascular complications negatively affected the psychological domain of the patient's life (p=0.010). Gender affected both the social (p=0.037) and the environment (0.033) domains of the patients' lives. Older age (p=0.004) and alcohol intake(p=0.048) had significant adverse effects on the patient's environmental domain, while residing in urban areas (p= 0.026) favoured this aspect of the patient's health.

Conclusions: We reported higher HRQOL scores among patients on conventional therapies. Modifiable factors can be a focus for improving the quality of life among patients receiving either regimen.

### **Concurrent Sessions:** Oral Presentations

CATEGORY | A Medley from Across Africa

## Health systems determinants of delivery and uptake of maternal vaccines in low and middle-income countries: A qualitative systematic review

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#### Abstract

Background: Maternal vaccination is considered a key component of the antenatal care package for improving maternal and child health. Low- and middle-income countries (LMICs) fall short of global targets to prevent maternal and neonatal deaths, with a disproportionate burden of vaccine-preventable diseases and gaps in delivering quality health services. Strategies towards ending preventable maternal mortality necessitate a health systems approach to adequately respond to these needs. This review explores the health systems' determinants of the delivery and uptake of essential maternal vaccines in LMICs.

Method: We conducted a qualitative systematic review of articles on maternal vaccination in LMICs, published between 2009 and 2021 in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis guidelines. Thematic analysis was conducted to identify key themes in the literature, interpreted within a health systems and immunization conceptual framing that explores the system's determinants influencing maternal vaccines.

Results: Our search yielded 1242 records, of which 47 were included, covering 28 LMICs. Most of the included studies were from South America (28/47) and included pregnant women as the primary study population (38/47). The studies explored Influenza (25/47) and Tetanus toxoid (18/47) vaccines predominantly. The findings suggest that systems hardware (lack of clear policy guidelines, ineffective cold-chain management, limited reporting and monitoring systems) are barriers to vaccine delivery. Systems software (healthcare provider recommendations, increased trust, higher levels of maternal education) are enablers of maternal vaccine uptake.

Conclusion: Findings show that formulation, dissemination and communication of context-specific policies and guidelines on maternal vaccines should be a priority for decision-makers in LMICs.

### **Concurrent Sessions:** Oral Presentations

CATEGORY | Pharmacovigilance

#### Assessment of pharmacovigilance guidelines in the Southern African Development Community. A document review

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#### Abstract

Background: Pharmacovigilance (PV) guidelines have not been harmonized in the Southern African Development Community (SADC) region, resulting in a heterogeneous array of requirements by National Medicines Regulatory Authorities (NMRAs).

Purpose: To compare the PV guidelines of SADC member states to international guidelines and recommend steps for aligning PV practice within the SADC region.

Methods: We utilized a 73-item checklist to assess the PV guidelines of the SADC member states. Checklist parameters were rated using binary scoring.

Results: Only seven (Botswana, Mauritius, Namibia, South Africa, Tanzania, Zambia and Zimbabwe) of the 16 SADC member states had guidelines to assess. Of these, only four had supporting legislation. All seven NMRAs' guidelines require reporting of local serious adverse drug reactions (ADRs). Four NMRAs implemented device vigilance; none specified submission timelines for ADRs associated with substandard or falsified medicines. Only three NMRAs required electronic transmission of individual case safety reports in the E2B (.xml or gateway) format. Five NMRAs mandated safety monitoring during interventional clinical trials. Five NMRAs required aggregate reporting through periodic safety update reports. Only two NMRAs required submission of the development safety update report. Regarding risk management, four NMRAs required notification of actions taken by foreign NMRAs and four NMRAs expected to review dear healthcare professional letters prior to distribution by the marketing authorization holder (MAH).

Conclusions: PV guidelines of Botswana, Mauritius, Namibia, South Africa, Tanzania, Zambia and Zimbabwe are not harmonized. Harmonizing these guidelines would establish common process standards and allow for synchronized submissions of comparable data to SADC NMRAs

### **Concurrent Sessions:** Oral Presentations

CATEGORY | Pharmacovigilance

### Barriers and facilitators to vaccine adverse event health care workers' reporting in Ghana-a qualitative study

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#### Abstract

Background: The increasing incidence of novel vaccine-preventable diseases like COVID-19 has led to an increase in the number of vaccines given globally. Vaccine hesitancy has risen due to fears of vaccines causing harm. Health systems in Africa have generally relied on spontaneous reporting of adverse events following immunization (AEFIs) to monitor vaccine safety.

Objectives: This study explored barriers and facilitators to AEFI reporting through health care workers (HCWs) in northern Ghana.

Methods: In a cross-sectional exploratory qualitative research study, 27 in-depth interviews were conducted among key stakeholders, including district health directors, pharmacovigilance officers, health facility heads and pharmacists in 5 administrative regions between March and May 2021. Purposive sampling method was used to select participants for the interviews. The interviews were recorded, transcribed, and coded into themes using QSR NVivo 12 software to aid thematic content analysis.

Results: Barriers such as lack of feedback from the national pharmacovigilance centre, high staff attrition rate, inadequate training, cumbersome reporting forms and complex AEFI reporting App affected AEFI reporting. Participants said that continuous AEFI education and sensitisation of health workers as well as collaboration among the public, health workers and the national pharmacovigilance authority, would facilitate AEFI reporting. More funds and resources should be committed to improving reporting.

Conclusions: Improved collaboration between all stakeholders, timely feedback from the national pharmacovigilance authority, training and adequate resources would improve AEFI reporting. This will restore public trust in vaccine safety and curb vaccine hesitancy.

### **Concurrent Sessions:** Oral Presentations

CATEGORY | Pharmacovigilance

## The completeness of adverse drug reactions in South Africa: An analysis in Vigibase®

#### Mafora Florah Matlala<sup>1,2</sup>, Martie Lubbe<sup>1</sup>, Hanlie Steyn<sup>1</sup>

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#### Abstract

Background: The efficiency of a spontaneous adverse drug reaction (ADR) reporting system is directly related to its ability to identify signals, which is dependent upon the quality of ADR reports received.

Objectives: To evaluate the completeness of ADR reports received by the Pharmacovigilance Unit of the South African Health Products Regulatory Authority (SAHPRA) according to the vigiGrade completeness score.

Methods: A cross-sectional, descriptive study of all reports received by SAHPRA during 2017 that were submitted to VigiBase® was conducted. Data were first analysed using descriptive statistics. Measures of central tendency for continuous variables were displayed as means and corresponding standard deviations or errors of the mean. The one-way analysis of variance (ANOVA) was used to compare mean completeness scores. A VigiGrade score > 0.8 is considered well-documented.

Results: The mean completeness score for the 8438 reports received was 0.456 (SD = 0.221). Only 11.3% of reports had a completeness score > 0.8. The completeness of reports submitted by consumers or non-health professionals did not significantly differ from reports by physicians, pharmacists or other healthcare professionals ( $d \le 0.2$ ). Time-to-onset of the reaction could not be calculated for 10 795 (52.82%) of the reported events. The outcome of the reaction was not indicated in 923 (10.94%) of the reports.

Conclusions: Core clinical elements needed for causality assessment are often missing from reports. The completeness of reports submitted by consumers is comparable to those submitted by healthcare professionals. The completeness of reports is generally low. Therefore, multiple measures are recommended to improve reporting.

### **Concurrent Sessions:** Oral Presentations

CATEGORY | Pharmacovigilance

#### Safety surveillance during the implementation of mass drug administration by the Neglected Tropical Diseases (NTD) Program for Elimination of Lymphatic Filariasis, Kenya

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#### Abstract

Introduction: Mass Drug Administration (MDA) with the standard dual therapy of Diethylcarbamazine and Albendazole (DA)was instituted in 2002. However, the safety surveillance of DA had never been conducted, and no single adverse event was reported to the national pharmacovigilance centre as of October 2018. The Neglected Tropical Disease (NTD) Program piloted the use of Ivermectin, Diethylcarbamazine and Albendazole (IDA) triple therapy in two highly endemic counties.

Methodology: The NTD Program collaborated with the Pharmacy and Poisons Board and adopted the Pharmacovigilance reporting tools that were appended to both the trainer of trainer's manuals and community drug distributors' handbooks. PPB provided numbers for individuals to call with any queries regarding AEs. Cohort Event Monitoring (CEM) was also conducted to identify and compare the incidence of adverse events (AEs) between the dual and triple therapy in the Kaloleni and Miritini sub-counties. A total of 10,010 and 10,411 participants in the Kaloleni and Jomvu sub-counties were actively followed up after receiving DA and IDA, respectively, in the CEM.

Result: A total of 5807 and 3102 AEs were reported by 2839 and 1621 individuals in the IDA and DA groups, respectively. The incidence of experiencing one or more AEs was significantly higher (p<0.0001) in IDA (27.3%; 95%CI, 26.4%-28.2%) compared to DA (16.2%;95%CI, 15.5–16.9%) group.

Conclusion: Adverse events are associated with MDA medicines for LF. Taking IDA is associated with a higher incidence of AEs. Integration of pharmacovigilance into MDA programs is critical for the early detection and management of AEs.

### **Concurrent Sessions:** Oral Presentations

CATEGORY | COVID-19

## Short-term COVID-19 vaccine adverse effects among adults in Ekiti State, Nigeria

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#### Abstract

Background: The COVID-19 pandemic has caused disruptions to the functioning of societies and their health systems. Data show that the vaccines are good at preventing severe forms of COVID-19 disease. This study determined the safety profile of the COVID-19 vaccine in Ado-Ekiti, Ekiti State, Nigeria.

Methods: This descriptive cross-sectional study was carried out between May to July 2021 among individuals who received the first dose of the first batch of the Astra-Zeneca COVID-19 vaccines at Ekiti State University Teaching Hospital, Ado-Ekiti, Nigeria. Questionnaires were fed into the Open Data Kit form, which was used to take data on the side effects of the COVID vaccine. The Statistical Package for Social Sciences (SPSS Inc., Chicago, IL) version 23.0 version (IBM Corp., Armonk, N.Y, USA) was used for data analysis.

Results: Out of over 1,000 individuals who were approached, 758 respondents completed the study. A large percentage (57.4%) of those that received their jabs at this site were healthcare workers. Adverse effects were reported in 70.8% of the participants, with most adverse effects manifesting on the first day of the vaccination.

The most common adverse effect was soreness at the injection site (28.5%), followed by fatigue (8.6%). There was no report of severe adverse effects (such as anaphylactic reactions, thrombosis, myocarditis, transient myelitis and Guillen-Barre syndrome).

Conclusion: The Oxford/AstraZeneca COVID-19 vaccine was well tolerated in the study population, with only mild adverse effects manifesting. This outcome has promising implications towards the improvement of COVID-19 vaccine uptake in our immediate environment and Nigeria.

### **Concurrent Sessions:** Oral Presentations

CATEGORY | COVID-19

## Impact of the COVID-19 pandemic on the utilisation of specific medicines in the South African public sector

### Andrew Gray<sup>1</sup>, Fatima Deedat<sup>2</sup>, Fathima Essop<sup>2</sup>, Caitlin Nero<sup>2</sup>, Ogochukwu Nwoye<sup>2</sup>, Mesuli Sibiya<sup>2</sup>, Thobile Valiphathwa<sup>2</sup>

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#### Abstract

Introduction: COVID-19 posed significant challenges for health systems in relation to the selection and use of medicines. In South Africa, the National Essential Medicines List Ministerial Advisory Committee on COVID-19 Therapeutics was responsible for reviewing the emerging evidence on the medicines proposed for the treatment of COVID-19. The objective of this study was to describe the utilisation of specified COVID-19-related medicines in the South African public sector in three calendar years (2019, 2020 and 2021).

Methods: Procurement data for selected medicines were obtained from the National Surveillance Centre. Changes in utilisation were described in terms of the defined daily doses per 100 000 uninsured population per day, per quarter and per annum, per province. Ethical approval was obtained from the UKZN Biomedical Research Ethics Committee (BREC/00004292/2022).

Results: Utilisation of dexamethasone, recommended for patients with severe or critical COVID-19, increased in all provinces from 2019 to 2021, except for the Eastern Cape, Gauteng, and North West, where utilisation decreased. Utilisation of enoxaparin increased in all provinces from 2019 to 2020 and in all provinces (except for Eastern Cape) from 2020 to 2021. However, the use of azithromycin, which was not recommended, increased across all provinces from 2020 to 2021. Utilisation of colchicine, also recommended against, increased in all provinces apart from Mpumalanga between 2020 and 2021.

Conclusion: There is evidence that some recommendations from the NEML MAC on COVID-19 Therapeutics were implemented, but also that medicines recommended against were used in increased volumes during the pandemic.

### **Concurrent Sessions:** Oral Presentations

CATEGORY | COVID-19

## A solution for active reporting of adverse events following immunization (AEFI) with COVID-19 vaccines in Uganda

#### Dan Kajungu

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#### Abstract

Background: During pandemics and mass vaccination campaigns, large numbers of people are quickly vaccinated. Coincidental adverse events following immunization (AEFIs) can derail the implementation of vaccination programs. Adverse events are primarily monitored through a passive system that relies on healthcare providers waiting for patients to report any adverse events. This has bottlenecks leading to notoriously poor reporting rates. The objective was to set up a platform for enabling patient-centered reporting of AEFIs after COVID-19 vaccines in Uganda.

Method: A platform with a phone application that enables vaccine recipients to actively report any adverse event after the COVID-19 vaccine was developed. USSD code (\*284\*16#) was used by recipients to answer questions after being shown how to use it. After 3 days, an SMS was sent to the recipient's phone number asking them to use that code to answer a few prompts about their experience after vaccination. Any type of phone can report using all networks.

Results: 6842 vaccine recipients were recorded, 4987 (73%) attempted the code and 2719 (55%) were successful, while 2182 (44%) were incomplete, and 86 failed. 3362 AEFI reports were uploaded, but 611 (18%) were either invalid or duplicates and were removed. Of the 2751 valid AEFI reports considered, 1520 (55%) reported at least one event, and 293 reported none.

Conclusion: The public is able to report AEFIs irrespective of the type of phone they own. The AEFIs reported are comparable with what was observed in clinical trials. This cohort presents a potential opportunity for monitoring the long-term effects of vaccines.

### **Concurrent Sessions:** Oral Presentations

CATEGORY | COVID-19

## Adaptive complex systems to mobilise rapid evidence-informed decision-making for the National treatment guidelines for COVID-19 in South Africa

Trudy Leong<sup>1,2</sup>, Natasha Gloeck<sup>1,2</sup>, Taryn Young<sup>3,2</sup>, Andy Gray<sup>4</sup>, Karen Cohen<sup>5</sup>, Renee de Waal<sup>6</sup>, Andy Parrish<sup>7</sup>, Michael McCaul<sup>3,2</sup>, Ameer Hohlfeld<sup>1,2</sup>, Solange Durao<sup>1,2</sup>, Millidhashni Reddy<sup>8</sup>, Helene Theunissen<sup>1,9</sup>, Gary Reubenson<sup>10</sup>, Joy Oliver<sup>1</sup>, Tamara Kredo<sup>1,2</sup>

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#### Abstract

Background: The COVID-19 pandemic highlighted the critical need for expedient access to high-quality evidence to inform clinical management and medicine procurement decisions in South Africa (SA). Through extensive collaboration between National Department of Health (NDOH), National Essential Medicines List Ministerial Advisory Committee (NEML-MAC) on COVID-19 Therapeutics, and SA-GRADE Network, co-led by Cochrane-SA and Centre for Evidence-Based Health, we produced rapid evidence reviews informing National COVID-19 management Guidelines.

Objectives: To describe the collaboration between evidence providers and service users, which incorporated timely evidence-informed decision-making processes, for COVID-19 therapeutics in SA.

Methods: Inter-organisational collaboration using a structured yet flexible approach produced relevant rapid evidence syntheses valuable to decision-making. Cochrane's rapid review methodology was adapted to local needs. NEMLC-MAC prioritised review questions, and teams conducted reviews (searching, appraising, and summarising evidence) to inform NEML-MAC recommendations using the GRADE Evidence-to-Decision-Framework. Recommendations, shared with the NDOH, were then translated into COVID-19 policy and funding decisions, and rapid review reports were published.

Results: We produced 69 reports (including updates) and recommendations for 33 therapeutics. We developed methods for credible, transparent reporting, which continue to evolve. Duplication was minimised by partnering with global evidence producers. Recommendations were presented to the NDOH COVID-19 response team and reports published on NDoH website (health.gov.za/COVID-19-rapid-reviews).

Conclusion: Effective partnership between evidence producers and service users, working flexibly with tight timelines and continuously evolving evidence, was key for rapid evidence-informed decision-making. Continuous communication and collaboration are necessary to ensure sustainability, expedite the uptake of evidence-informed recommendations and strengthen emergency health crisis preparedness.

### **Poster Sessions**



## Pregnancy increases CYP3A enzymes activity as measured by the 4β-hydroxycholesterol/cholesterol ratio

#### Eulambius Mathias Mlugu<sup>1</sup>, Omary M Minzi<sup>2</sup>, Appolinary A.R. Kamuhabwa<sup>2</sup>, Ulf Diczfalusy<sup>3</sup>, Eleni Aklillu<sup>4</sup>

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#### Abstract

Background: During pregnancy, changes in cortisol and other hormones can affect the activity of CYP3A enzymes.

Objective: The aim was to investigate the effect of pregnancy and CYP3A5 genotypes on CYP3A enzyme activity using plasma  $4\beta$ -hydroxycholesterol ( $4\beta$ -OHC)/cholesterol (Chol) ratio, a known biomarker.

Methods: The study enrolled 110 Tanzanian pregnant women and 59 non-pregnant women as controls. Plasma  $4\beta$ -OHC and Chol levels were measured in the second and third trimesters for pregnant women and once for non-pregnant women using gas chromatography-mass spectrometry. Genotyping for CYP3A5 (\*3, \*6, \*7) was also performed. The Wilcoxon Signed-Rank Test and Mann-Whitney U test were used to compare the median  $4\beta$ -OHC/ Chol ratio between trimesters in pregnant women and between pregnant and non-pregnant women, respectively. The repeated-measure ANOVA was used to evaluate the effect of the CYP3A5 genotypes on the  $4\beta$ -OHC/Chol ratio in pregnant women.

Results: This study found no significant effect of pregnancy status or the CYP3A5 genotype on the cholesterol level. However, the plasma 4 $\beta$ -OHC/Chol ratio significantly increased by 7.3% from the second trimester to the third trimester (p = 0.02). Pregnant women had a significantly higher mean 4 $\beta$ -OHC/Chol ratio than non-pregnant women (p <0.001). In non-pregnant women, the mean 4 $\beta$ -OHC/Chol ratio was significantly lower in carriers of defective CYP3A5 alleles (\*3, \*6 or \*7) as compared to women with the CYP3A5\*1/\*1 genotypes (p = 0.002).

Conclusion: Pregnancy increases CYP3A enzyme activity in a gestational-stage manner. The CYP3A5 genotype predicts CYP3A enzyme activity in the black Tanzanian population but not during pregnancy-mediated CYP3A enzyme induction.

### **Poster Sessions**

P2

#### Effectiveness of intermittent preventive treatment with dihydroartemisininpiperaquine against malaria in pregnancy in Tanzania: A randomized controlled trial

#### Appolinary Kamuhabwa<sup>1</sup>, Eulambius Mlugu<sup>1</sup>, Omary Minzi<sup>1</sup>, Eleni Aklillu<sup>2</sup>

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#### Abstract

Background: Plasmodium falciparum's resistance to sulfadoxine-pyrimethamine (SP) poses a threat to intermittent preventive treatment in pregnancy with SP (IPTp-SP) for preventing malaria and adverse birth outcomes.

Objective: This study aimed to investigate the effectiveness of monthly dihydroartemisinin-piperaquine (IPTp-DHP) compared to IPTp-SP.

Methods: The study involved 956 pregnant women from moderate malaria transmission areas in Tanzania who were randomized (1:1) to receive either IPTp-DHP or IPTp-SP. The primary outcome was the prevalence of histopathologically confirmed placental malaria and secondary outcomes were overall malaria at delivery, symptomatic malaria parasitemia during pregnancy, and adverse birth outcomes. Data were analyzed according to the intention to treat the population in which all participants allocated to a treatment group at enrolment were included.

Results: The prevalence of histopathologically confirmed placental malaria was significantly lower in the IPTp-DHP group (2.5%) than in the IPTp-SP group (8.2%) p< 0.001. Maternal malaria at delivery was significantly lower in the IPTp-DHP group (8.2%) than in the IPTp-SP group (18.2%) p< 0.001. The incidence per person-years at risk for symptomatic malaria (0.02 vs 0.12, p = 0.002) and parasitemia during pregnancy (0.28 vs 0.67, p < 0.001) were significantly lower in the IPTp-DHP group. Although the prevalence of any adverse birth outcomes was not significantly different between groups, the prevalence of LBW was significantly lower in the IPTp-DHP group (4.6% vs 9.6%, P = 0.003).

Conclusion: This study provides evidence to support that monthly IPTp-DHP could be an alternative to IPTp-SP, especially in areas with a high level of P. falciparum resistance to SP.

### **Poster Sessions**

# P3

#### The battle against prescribing cloxacillin and dispensing flucloxacillin: Prescription review from orthopeadic patients with bone and joint infections

#### Phumzile Skosana, Mankoana Masetla

Sefako Makgatho Health Sciences University, Pretoria, South Africa

#### Abstract

Introduction: Flucloxacillin and cloxacillin are first-line treatments in bone and joint infections; however, with the potency difference of flucloxacillin, it is important to know how to dispense the flucloxacillin and still meet the required bone and joint penetration to treat orthopaedic conditions. This study aimed at comparing the dispensing of flucloxacillin when cloxacillin was prescribed with interventions.

Methodology: This was a prospective interventional study conducted at a tertiary hospital in South Africa. Patient prescriptions from the orthopaedic clinic were reviewed after they were dispensed in comparison to standard treatment guidelines. Doctors were consulted on any changes and interventions necessary.

Results: A total of 44 patients were reviewed, of which 24 received a prescription with cloxacillin or flucloxacillin prescribed. According to the South African STG: for bone and joint infections, Flucloxacillin 1g QID should be issued. 46% of the 24 patients were prescribed Cloxacillin 1g QID which was dispensed as Flucloxacillin 500mg QID. All these were discussed with the Dr and corrected. The second highest prescribed dose with 29% was Cloxacillin 2g QID which was dispensed as Flucloxacillin 1g QID and therefore, no interventions were needed. Only 3 prescriptions 13% prescribed according to the local guideline. The remaining 12% were 2 prescriptions where the dosing interval was incorrect and the remaining was for a very low dose of Cloxacillin 500mg which was dispensed as 250 mg Flucloxacillin. These were all corrected by consulting the doctor.

Conclusion: Adherence to local guidelines can help in the rational prescribing of antimicrobials.

### **Poster Sessions**



# Efficacy and safety of praziquantel and dihydroartemisinin-piperaquine combination for treatment and control of intestinal schistosomiasis: A randomized, non-inferiority clinical trial

#### Rajabu Hussein Mnkugwe<sup>1</sup>, Omary Minzi<sup>1</sup>, Safari Kinung'hi<sup>2</sup>, Appolinary Kamuhabwa<sup>1</sup>, Eleni Aklillu<sup>3</sup>

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#### Abstract

Background: Praziquantel (PZQ) alone is insufficient for the control and elimination of schistosomiasis, partly due to its poor efficacy against juvenile worms.

Objective: To assess the safety and efficacy of PZQ and dihydroartemisinin-piperaquine (DHP) combination therapy for treatment of intestinal schistosomiasis.

Methods: This was a randomized clinical trial in which 639 Schistosoma mansoni-infected children were enrolled. Two stool samples were collected on two consecutive days at baseline, 3 and 8 post-treatment and analyzed using the thick smear Kato Katz method. The primary outcome was cure rates at 8 weeks of post-treatment.

Results: At 3 weeks of post-treatment, cure rates were 88.3% and 81.2% for the combination therapy and PZQ alone, respectively (p < 0.01). At 8 weeks, there was a significant drop in the cure rates in PZQ alone to 63.9% compared to 81.9% in combination therapy (p < 0.0001). ERR at 8 weeks post-treatment was significantly higher in the combination therapy 93.6%, compared to 87.9% in the PZQ alone (p = 0.01). On both Univariate and Multivariate regression analysis, the type of treatment received was a significant predictor of cure at week 8 post-treatment. Overall, 30.8% of participants experienced mild and transient adverse events. There was no significant difference in the overall occurrence of adverse events between the two treatment groups.

Conclusion: PZQ and DHP combination therapy is safe and more efficacious compared to PZQ alone for the treatment and control of intestinal schistosomiasis hence should be considered the best alternative for school-based MDA programs in schistosomiasis endemic areas.

### **Poster Sessions**



## Effect of dihydroartemisinin-piperaquine on the pharmacokinetics of praziquantel for treatment of Schistosoma mansoni infection

### Omary Mashiku Minzi<sup>1</sup>, Rajabu Hussein Mnkugwe<sup>2</sup>, Eliford Ngaimisi<sup>3</sup>, Safari Kinung'hi<sup>4</sup>, Appolinary A.R. Kamuhabwa<sup>1</sup>, Eleni Aklillu<sup>5</sup>

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#### Abstract

Background: Currently, praziquantel (PZQ) is the only available drug used for mass drug administration (MDA) in the control and elimination of schistosomiasis in endemic areas. However, PZQ does not kill immature worms, so the combination of PZQ and dihydroartemisinin-piperaquine (DHP) was tested.

Objective: To assess the systemic exposure of PZQ and its enantiomers in the presence of DHP.

Methods: A randomized clinical trial was conducted among 64 Schistosoma mansoni-infected school children in Northern Western Tanzania. The study participants were treated with either single dose PZQ alone (n = 32) or single dose PZQ plus 3-days full dose of DHP (n = 32). Plasma samples were collected at 0, 1, 2, 4, 6, and 8 hours post-dose PZQ and its concentrations were quantified using UPLCMS/MS. Bio inequivalence was concluded when the 90% CI of GMRs of PZQ + DHP to PZQ ratio for a pharmacokinetic parameter was not entirely within the acceptable bioequivalence limits of 0.80–1.25.

Results: The geometric mean (GM) (90% CI) of AUCO-• for PZQ +DHP to PZQ for PZQ was 2.18 (1.27, 3.76). The GMR (90% CI) of Cmax of PZQ + DHP to PZQ were 1.75 (1.15, 2.65). The 90% CI of the GMRs for both AUCs and Cmax were outside the acceptable range 0.80-1.25, indicating that the two treatment arms were not bioequivalent. Similar trends were observed in R and S enantiomers.

Conclusion: DHP co-administration significantly increases systemic exposure of PZQ and its enantiomers hence making DHP+PZQ combination therapy a better alternative for MDA programs.

### **Poster Sessions**



## Determinants/predictors of QT abnormalities in patients on psychotropic medications in a Nigerian Tertiary Hospital

**Opeyemi Ojo<sup>1,2</sup>, Adekunle Ajayi<sup>3</sup>, Akande Ajayi<sup>1</sup>, Joseph Fadare<sup>1</sup>, Samuel Dada<sup>1</sup>, Olatunji Olaoye<sup>2</sup>** <sup>1</sup>Ekiti State University, Ado-Ekiti, Ekiti State, Nigeria. <sup>2</sup>Ekiti State University Teaching Hospital, Ado-Ekiti, Ekiti State, Nigeria. <sup>3</sup>Ekiti State University, Ado-Ekiti, Ekiti State, Nigeria

#### Abstract

Background: Cardiovascular disease is a major global burden and a leading cause of premature death among patients with severe mental illness. Over time, research and clinical practice have paid increased attention to the impact of psychiatric medications on cardiac repolarization. In a resource-limited setting, it is common for psychotropic medications to be initiated and maintained in an outpatient setting without baseline or follow-up ECG. This study evaluated the determinants and predictors of QT abnormalities among patients taking psychotropic drugs.

Methodology: We conducted a cross-sectional study in a population of 150 psychiatric patients on psychotropics and 75 controls. We studied the effects of various psychotropic drugs on QT dispersion (QTd) and corrected QT interval (QTc) as well as correlation with the types and dosages of psychotropic drugs used. All the subjects had detailed clinical examination and resting electrocardiogram (ECG) at 25mm/sec done. QTc was determined using the Bazett formula and QTd was determined by subtracting the shortest from the longest QT in 12-lead ECG.

Results: The prevalence of prolonged QTc and QTd, as well as the mean QTc and QTd were significantly higher in patients than in the control group. The mean QTc was significantly higher in patients on typical antipsychotics compared to those on atypical antipsychotics. Age, heart rate and antipsychotic dose in chlorpromazine equivalent were predictors of QTc, with the heart rate being the most powerful predictor among them.

Conclusion: Psychotropic drug use is associated with QTc and QTd prolongation with age, heart rate and antipsychotic dose as predictors of QTc.

### **Poster Sessions**



## Root cause analysis of bleeding and thrombosis events in patients on warfarin in South Africa and Uganda

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#### Abstract

Background: Anticoagulation control in African patients on warfarin is poor. Warfarin requires individualised dosing and may cause severe adverse events.

Objective: To identify root causes of thrombosis/bleeding in patients using warfarin.

Methods: We identified patients on warfarin with thrombosis and/or bleeding at 4 sites in Cape Town, South Africa and Kampala, Uganda, between July 2021 and June 2022. We conducted Root Cause Analysis. Data from record reviews and patient interviews were discussed at multi-disciplinary team meetings.

Results: We identified the following issues:

South Africa: A 33-year-old woman with mechanical valve replacement bled intra-abdominally due to a supratherapeutic international normalised ratio (INR). Clinic attendance was erratic; transport was unaffordable. Language barrier impaired patient education. Dose was tripled inappropriately and follow-up was delayed by the summer holidays.

A 52-year-old man with deep vein thrombosis (DVT) died after a fall and intracranial bleeding. Unsteady gait due to previous cerebrovascular accident increased fall risk. Alcohol abuse impaired adherence.

Uganda: A 32-year-old woman with atrial fibrillation had supra-therapeutic INR with haemoptysis. She self-funded warfarin and could not afford INR monitoring costs.

A 66-year-old woman with a femur fracture received no thrombosis prophylaxis and developed a DVT and pulmonary embolus (PE). On warfarin, she required a transfusion for gastrointestinal bleeding. After warfarin was recommenced, she defaulted due to the high pill burden and fear of bleeding and died after a second PE.

Conclusions: We identified several causes of adverse events, providing useful insights to improve anticoagulation services. Costs of warfarin, INR monitoring and transport posed barriers to INR control.

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### **Poster Sessions**



## Improving the quality of anticoagulation control at the warfarin outpatient clinic of Windhoek Central Hospital, Namibia

Moses Thikukutu<sup>1</sup>, Lauren Jonkman<sup>1</sup>, Bonifasius Singu<sup>1</sup>, Mwangana Mubita<sup>1</sup>, Roger Verbeeck<sup>1</sup>, Fenny Shidhika<sup>2</sup> <sup>1</sup>University of Namibia, School of Pharmacy, Windhoek, Namibia. <sup>2</sup>Ministry of Health and Social Services, Windhoek, Namibia

#### Abstract

Background: The patient's mean time in the therapeutic range (TTR) at the Warfarin Outpatient Clinic of Windhoek Central Hospital (WCH) has been reported to be suboptimal (29.4%). The intervention study was undertaken to improve anticoagulation control at the clinic.

Objective: To compare anticoagulation control in the intervention and the historical control group.

Methods: A prospective cohort design was used.

Interventions to improve anticoagulation control involved pharmacist-directed therapy. The main outcome measure was the TTR computed using the Rosendaal method. Binary logistic regression was used to identify factors associated with poor anticoagulation control. A between-groups comparison of anticoagulation control was based on the paired and unpaired patient cases. A p-value < 0.05 was considered statistically significant.

Results: A total of 330 patients were part of the present study (control (215) and intervention (115)). The majority (63.4%) of the patients in the intervention group were females. The mean ( $\pm$  SD) age was 45  $\pm$  17 years. The top three prevalent clinical indications for warfarin in the intervention study were deep vein thrombosis (49.6%), mitral valve replacement (13.9%), and pulmonary embolism (13%). Only the baseline INR (OR 0.22 [95%CI: 0.06-0.64]) and heart failure co-diagnosis (OR 3.9 [95%CI: 0.03-0.89]) were significant predictors of poor anticoagulation control in the intervention group. The Mann-Whitney U test showed an 18% (p<0.050) improvement in the median %TTR when the unpaired cases between the groups were compared. The paired t-test showed a 10% (p=0.220) improvement in the mean %TTR when the groups were compared.

Conclusion: Interventions involving pharmacist-directed warfarin therapy are associated with improved anticoagulation control.

### **Poster Sessions**



## Efficacy and safety of dolutegravir (DTG)- and efavirenz (EFV)-based antiretroviral regimens: A retrospective study

#### Ibrahim Oreagba, Muyiwa Adedeji, Sulaimon Akanmu

University of Lagos, Lagos, Nigeria

#### Abstract

Background/Objectives: Dolutegravir-based regimen was recently adopted in Nigeria as the first-line treatment for ART-naïve PLWH. However, data are sparse about its safety and efficacy in the Nigerian population to justify its use as a replacement for other regimens. This study was aimed at comparing the efficacy and safety of dolutegravir (DTG)-and efavirenz (EFV)-based antiretroviral regimens.

Methods: The study was a retrospective observational study in the cohorts of treatment naïve individuals at the point of entry into ART programme and started on either DTG- or EFV-based regimen between 30- and 36-month study period. Electronic medical records containing sociodemographic, clinical, treatments, hematologic, and viral load data of PLWH who were enrolled into the HIV treatment program at the Centre for Integrated Health Programs (CIHP), Lagos University Teaching Hospital (LUTH) were extracted and retrospectively analyzed. Specifics on the proportion of patients with viral load suppression (VLS) < 50 copies/ml, log10 drop VL, change in CD4 from baseline, adverse events (AEs), adherence and drug-drug interaction (DDI) were determined.

Results: More patients on DTG-based ART significantly had better HIV-1 RNA VLS, better log drop in VL, and fewer adverse events compared to EFV-base regimen. Adherence, the percentage change in weight and CD4+ counts from baseline to follow-up were, however, comparable.

Conclusion: This retrospective comparative study confirmed DTG-based ART to have better efficacy and safety profiles over EFV-based ART. The outcome further justifies its adoption in poor resource settings of sub-Saharan Africa.

### **Poster Sessions**



## The use of antibiotics in patients diagnosed with COVID-19 at a referral hospital in Namibia

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#### Abstract

Background: Use of antimicrobials in patients without evidence of bacterial infection is associated with the emergence of antimicrobial resistance, which is expected with irrational use of antibiotics in non-COVID-19 patients as in COVID-19 patients.

Objectives: To explore the use of antibiotics in COVID-19 in-patients treated at a referral hospital in Namibia.

Method: A quantitative, descriptive cross-sectional study design was used. Data were collected from files of COVID-19 in-patients at the COVID unit of a referral hospital from January 2021 to December 2021. The data were analysed using SPSS v26.0.

Results: A total of 198 patient files were reviewed. The prevalence of antibiotic use was 85%. The average number of antibiotics per patient was 1.82±0.641. A total of 306 antibiotics were prescribed. Of these, 53% and 47% were WATCH and ACCESS antibiotics, respectively. Augmentin and azithromycin were the two most commonly prescribed antibiotics: 44% and 39.22%, respectively. About 39% of antibiotics were not prescribed according to COVID-19 treatment guidelines.

Conclusions: The prevalence of antibiotic use among COVID-19 patients admitted at a referral hospital in Namibia was high. Non-compliance to both local and WHO COVID-19 guidelines was observed. There is a need to strengthen local antimicrobial stewardship programs and education among healthcare workers in order to decrease morbidity and mortality from infectious disease outbreaks and pandemics.

### **Poster Sessions**



## vigiGrade® Completeness of pharmaceutical industry insulin adverse event reports from Africa and the Middle East

Charity R N Mlotshwa, Johanita R Burger, Martine Vorster, Dorcas M Rakumakoe, Marike Cockeran Medicine Usage in South Africa, North-West University, Potchefstroom, South Africa.

#### Abstract

Background: Completeness of individual case safety reports (ICSRs) for insulin is vital for the timely identification of safety signals.

Objective: To assess the completeness and report completeness-associated variables of pharmaceutical industry insulin ICSRs in Africa and the Middle East

Methods: Unique post-marketing insulin ICSRs in the Novo Nordisk® safety database from January-December 2018 were compared using the vigiGrade® completeness score and assessed for associations between case variables (seriousness, reporter type, and source of report) and report completeness.

Results: Overall, 4863 ICSRs were analysed, and 59.9% were from the Middle East. The mean vigiGrade® score was 0.58. Middle Eastern ICSRs had higher mean scores than African ICSRs (0.65 vs 0.46; p<0.001). Completeness scores peaked at 0.32, 0.70, and 1.00 (Middle East) and 0.35 and 0.50 (Africa). Serious ICSRs achieved higher mean scores than non-serious reports in the Middle East (0.77 vs 0.63; p<0.001) and Africa (0.47 vs 0.46; p=0.14). Solicited ICSRs achieved higher mean scores than spontaneous reports in the Middle East (0.70 vs 0.43; p<0.001) and Africa (0.48 vs 0.42; p=0.004). ICSRs from physicians and other HCPs had significantly higher mean scores (0.89 and 0.82) than consumers and pharmacists (0.49 and 0.33) in the Middle East (p<0.001). In Africa, consumer- and pharmacist-reported ICSRs had higher mean scores than physicians and other HCPs reports (0.47, 0.47, 0.39 and 0.37, respectively; p<0.001).

Conclusions: Pharmaceutical industry insulin ICSRs completeness and the missing information affecting completeness in Africa and the Middle East differ. Completeness of ICSRs was associated with event seriousness, report source, and reporter type.
### **Poster Sessions**

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### Factors that act as enablers or barriers towards adverse drug reaction reporting from pharmacists' perspectives in public health sector facilities in Botswana

#### Idah Seepo<sup>1,2</sup>, Martha Susanna Lubbe<sup>1</sup>, Fransina van Niekerk<sup>1</sup>, Hanlie Steyn<sup>1</sup>

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#### Abstract

Background: Underreporting of adverse drug reactions (ADRs) is a problem in Botswana, where the Botswana Medicines Regulatory Authority relies mainly on spontaneous reporting.

Objectives: We aimed to identify factors that act as enablers or barriers towards ADR reporting in public health sector facilities in Botswana from the perspectives of pharmacists.

Methods: A quantitative, descriptive, cross-sectional study was conducted using an online structured questionnaire. Thirty-eight of the 110 pharmacists employed in public health sector facilities in Botswana responded to the survey (34.5% response rate). The data obtained were analysed using both descriptive and inferential statistics. Due to the small number of observations in each category and the violation of the assumption of normality, we performed nonparametric statistics.

Results: Barriers towards ADR reporting were summated in three subscales. The median time and complexity barrier score was lower than the median awareness barrier score and median PV system-related barrier score. Items that evaluated the enablers or strategies to improve ADR reporting were categorised into three subscales, of which training of all stakeholders received the highest median score, followed by improving ADR reporting process/system and legal obligation and incentives. The barriers towards ADR reporting and strategies to improve ADR reporting scores were compared according to gender, age category, years of practice, facility of practice and positions of the pharmacists. Our results indicated that none of the differences between groups were statistically significant (p-value > 0.05).

Conclusions: This study identified pharmacists' perspectives on ADR reporting. Several measures to improve ADR reporting by pharmacists are recommended.

### **Poster Sessions**



#### Health facility obstacles responsible for most missed infant vaccinations in South Africa: Results of the National Household Infant Vaccination Coverage Survey conducted in 2019

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#### Abstract

Introduction: In 2017, South Africa (SA) was one of 10 countries with more than 100 000 under-vaccinated children. Thus in 2019, the National Department of Health's Expanded Programme on Immunisation (EPI-SA) conducted a national household infant vaccination coverage survey in all 52 districts of SA.

Objectives: This study investigated the reasons for missed infant vaccinations, proportion of reasons related to health facility obstacles (HFOs) and vaccine hesitancy (VH); and identified districts requiring capacity building to increase vaccination coverage.

Method: This retrospective, descriptive study used data collected for the 2019 national EPI-SA coverage survey. Free text reasons data were coded and added to existing coded data. The final codes were categorised into HFOs, VH and other categories. Epi Info<sup>™</sup> was used for descriptive analysis. Ethical clearance was obtained from Sefako Makgatho University Research Ethics Committee.

Results: Caregivers gave one or more reasons for 90.6% (3 576/3 946) of children who had missed one or more vaccines. Reasons were categorised as HFO (67.9%); personal reasons (34.6%); reason unknown by caregiver (3.9%); VH (2.5%); lack of motivation (1.4%); unclear reasons (0.4%); and lack of information (0.1%). HFOs and VH affected children living in 51 and 23 districts, respectively. HFOs accounted for >50% of missed vaccinations in 42 of 51 districts. In 19 of the 42 districts, >70% of missed vaccinations were caused by HFOs.

Conclusion: The study provides EPI-SA with district-level information that can be used for targeted capacity building in order to increase infant vaccination coverage in South Africa.

### **Poster Sessions**



#### High fully immunised under one-year-old coverage achieved despite vaccine stock-outs and demotivated caregivers – a good news story from a rotavirus surveillance site in the Bojanala Platinum District of North West Province, South Africa

#### Loretta C. Ogbonna<sup>1</sup>, Johanna C. Meyer<sup>1,2</sup>, Mapaseka Seheri<sup>3</sup>, Rosemary J. Burnett<sup>3,2</sup>

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#### Abstract

Introduction: The fully immunised under one-year-old coverage (FIC) reported by the South African District Health Information System for the Bojanala Platinum District of North West Province was 73.8% in 2017/18 and 71.7% in 2018/19. The reasons for FIC being below the national FIC target of 90% were unknown.

Objectives: To investigate individual vaccine coverage; FIC; and reasons for missed routine vaccinations among children aged 12-35 months attending a primary healthcare clinic (PHC), which is a rotavirus surveillance site in the Bojanala Platinum District in the North West Province, in 2015-2019.

Method: This retrospective study used secondary rotavirus surveillance data (2015-2019) from the Sefako Makgatho Health Sciences University (SMU) Diarrhoeal Pathogens Research Unit. Data were collected from 554 copies of Road to Health Booklets and case report forms of children aged 12-35 months. Data were analysed using Epi Info<sup>™</sup>. SMU Research Ethics Committee granted ethics clearance.

Results: Individual vaccine coverage ranged between 96.8% (third-dose pneumococcal conjugate vaccine) and 99.5% (birth-dose oral polio vaccine), with 89.2% FIC. Sixty children missed 128 vaccinations, mainly because of vaccine stock-outs (30.2%) and caregivers being demotivated (25.7%).

Conclusion: The FIC of 89.2% almost reached the national and global target of 90%. Being a rotavirus surveillance site may explain the better-than-average performance of this PHC. However, addressing vaccine stock-outs, education of caregivers and advocacy for vaccination at every encounter could further improve FIC at this clinic and ensure sustained access to vaccination services.

### **Poster Sessions**



#### Comparative assessment of the Knowledge, Attitude, And Practice of pharmacovigilance among medical, pharmacy and nursing university undergraduates in South-West Nigeria

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#### Abstract

Spontaneous reporting of adverse drug reactions (ADR) is an established method of monitoring and preventing further occurrence of ADR. Lack of adequate exposure to pharmacovigilance education during undergraduate education is recognized as one major cause of ADR under-reporting globally. This study assessed the knowledge, attitude and practice of ADR reporting among medical, nursing, and pharmacy students in selected tertiary institutions in South-West Nigeria.

Methodology: A descriptive, questionnaire-based cross-sectional study conducted among 4th and 5th year undergraduate students of Nursing and Pharmacy and students between 4th and 6th year in Medicine from five Nigerian universities between October and December 2021. The knowledge aspect of the instrument was scored (/10) to enable quantitative assessment, while frequencies and proportions were used to assess attitude and practice.

Results: A total of 711 undergraduates comprising 345 medical, 262 pharmacy and 104 nursing students, completed the survey with a mean age of 24.6 years. Medical students (3.09/10) had the highest knowledge score, followed by nursing students (2.37/10) and pharmacy students (2.03/10). More nursing students (63.5%) had observed ADRs during their training than pharmacy (29.5%) and medical students (17.1%). The ADR reporting form (yellow form) was known to pharmacy students (30.2%) in comparison to nursing (19.2%) and medical students (15.2%).

Conclusion: The knowledge and practice of undergraduate students of medicine, pharmacy and nursing about ADR and its reporting were poor. While medical students showed a bit of theoretical knowledge, nursing students seem to have more practical experience regarding observation and reporting.

### **Poster Sessions**



### Role of community pharmacists in counselling on the sale and use of CAM products as immune stimulants during the COVID-19 pandemic

Ilse Truter, Raj Naidoo, Elz-Mari Du Plessis, Melanie Felix, Cheswin Lottering, Nontobeko Ramathibela, Gamelihle Mbambo, Isa Viteka, Mlibokazi Ntlombeni, Vongani Chavalala, Letswalela Teffo, Amatle Rooimes, Nompilo Shabangu, Zizibele Tomose

Nelson Mandela University, Gqeberha (previously Port Elizabeth), South Africa

#### Abstract

Background: An increase in demand for immune system stimulants was observed since the onset of the COVID-19 pandemic. Little information is available on the role of pharmacists in their sale and use.

Objectives: To determine the role of pharmacists in the sale and use of immune system stimulants, which form part of over-the-counter complementary and alternative medicine (CAM) products and therapies in pharmacies.

Methods: An online survey was conducted in August 2022. A sample of 110 community pharmacies in the Eastern Cape Province, South Africa, was selected (response rate was 16.4%). Data were analysed using Microsoft Excel®.

Results: Most respondents (61.1%) indicated that the popularity of CAM increased during the two years preceding the study. Counselling on these products included drug-CAM interactions (38.9% of respondents), as well as counselling on the dosing of immune stimulants. Vitamin C, vitamin D and zinc were indicated to have made a positive contribution to patients' health during the pandemic. Selenium and vitamin A were also mentioned. Vitamins and minerals were used as add-on therapy. The positive effect of Echinacea was mentioned by 66.7% of respondents. Supplements containing nicotinamide and quercetin were popular. Most respondents (70.6%) stated that the demand for immune stimulants returned to normal when the COVID-19 restrictions in South Africa were lifted. Other popular CAM therapies included eucalyptus oil, Artemisia afra (African wormwood) and steaming. Mind-spirit therapies assisted patients in maintaining a healthy immune system.

Conclusions: Pharmacists indicated that the pandemic was an eye opener and showed the potential held by CAM.

### **Poster Sessions**



#### Pharmacoepidemiology modules in the curriculum of medical schools in Nigeria: What is the current reality?

#### Joseph Fadare<sup>1,2</sup>, Olayinka Ogunleye<sup>3</sup>, Oluwadamilola Onasanya<sup>4</sup>, Macarius Donneyong<sup>5</sup>

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#### Abstract

Introduction: The total essence of pharmacoepidemiology is to improve the rational use of medicines and reduce adverse drug reactions among the populace. Physicians play key roles in the prescribing of drugs and counseling of patients regarding drug use, hence medical schools present an important and strategic opportunity for prescriber training in pharmacoepidemiology. However, a recent study identified pharmacoepidemiology research as being deficient in the Sub-Saharan African region. There is a paucity of information about the pharmacoepidemiology content of medical school curricula in Nigeria.

This study evaluated whether pharmacoepidemiology modules are included in the current curriculum of undergraduate medical schools in Nigeria.

Methodology: Using purposive sampling, we conducted a cross-sectional study of 10 out of the 37 accredited medical schools affiliated with universities in Nigeria. The current curricula of selected schools were downloaded from their website or obtained from focal persons in the respective institutions. Content analysis of the curricula was employed. The inclusion or otherwise of modules in pharmacoepidemiology in the curricula was noted and recorded on a specially designed proforma.

Results: The curricula of 10 medical schools from the six geo-political zones of Nigeria were analyzed. All had modules on adverse drug reactions and pharmacovigilance. Pharmacoepidemiology was not listed as a separate module in any of the curricula from the selected medical schools.

Conclusion: The curricula of selected medical schools in Nigeria did not include any taught modules in pharmacoepidemiology. There is a need for a review to include pharmacoepidemiology, given its importance in medicine safety.

### **Poster Sessions**



## The cost of treating breast cancer from the provider's perspective in a public tertiary academic hospital in South Africa

#### Christianah Kikelomo Oladayo, Moliehi Matlala, Sibanda Mncengeli

Sefako Makgatho Health Sciences University, Pretoria, South Africa

#### Abstract

Background: Breast cancer (BC) is the leading cause of death in reproductive-aged women and the high medical and financial costs burden patients and society. In a resource-constrained country like South Africa, understanding the total cost of BC care is crucial for health funders. Only a few studies have assessed the financial impact of BC in the South African public sector.

Objective: To determine the direct cost of BC treatment in a public hospital.

Method: A descriptive retrospective study using a data collection tool was conducted on the files of adult BC patients. A micro-costing approach and a 'time-in-motion' method was used to calculate all medical costs related to the management of BC from the perspective of the provider. Data captured using Microsoft ExcelTM, were imported to SPSS version 26 for descriptive statistical analysis. Ethical clearance for the study was granted by the Sefako Makgatho University Research Ethics Committee (SMUREC/P/66/2021: PG) and permission to conduct the study was obtained from the Hospital's CEO.

Results: The direct cost of treating 364 BC patients was R4 676 969.30. The average cost was R12 847.80 per patient. Chemotherapeutic drugs, administrative costs and laboratory tests were the major cost drivers. Most patients were under 55 years (CI: 54.09;56.83), 39% had stage 3B BC. Hypertension (34.6%) and RVD (18.4%) were the two most prevalent comorbidities.

Conclusion: Early detection and treatment of BC can lower the disease cost. A comprehensive, robust, and wellintegrated health system is necessary to achieve this.

### **Poster Sessions**



#### Role of South African community pharmacists in wound care

Ilse Truter, Janet Barry, Lara Cunningham, Alicia de Lange, Tifany Floors, Donnay Fourie, Sithembile Gumbi, Felicia Lategan, Leselo Mohale, Phelelani, Mazibuko, Lukhanyo Ngalo, Sikelela Pangomso, Lisa-Nicole Scholtz, Zanele, Tose

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#### Abstract

Background: Acute, chronic and diabetic wounds can lead to financial and emotional burdens for patients. Pharmacists are well positioned in the community to identify wound types, their aetiology, and risk factors of wounds to recommend suitable treatment that promotes optimal healing.

Objectives: The primary aim of the study was to investigate the role of South African community pharmacists in acute and chronic wound care.

Methods: An online questionnaire survey was conducted during August 2022 using QuestionPro®. Stratified random sampling was used to select 350 from a total of 3240 community pharmacies in South Africa. The response rate was 56 (16.0%). The data was analysed in Microsoft Excel® and descriptive statistics were calculated.

Results: Acute wounds commonly seen were burn wounds (61.8%, n=34), abrasions (58.2%, n=32) and surgical incisions (40.7% n=22). Half of the respondents (n=28) had adequate knowledge about acute wound care. A third (30.4%) of respondents indicated that they provide patients with chronic diabetic wound care advice at least once a week. Most participants (51.8%, n=56) educate themselves through reading journal articles to stay up to date with diabetic wound management. As much as 70% (n=46) of respondents were in favour of an increased focus on wound care services in their community pharmacies.

Conclusion: Community pharmacists in South Africa play an important role in acute and chronic wound care services. Greater focus should be placed on training programmes and workshops to better equip pharmacists with knowledge necessary to assist patients with wound care management and education.

### **Poster Sessions**

## P20

#### Estimating COVID-19 vaccine uptake in Africa

#### Kate Gillespie, Serena Santoni, Shayla Smith, Bobby Reiner Institute for Health Metrics and Evaluation (IHME), Seattle, USA

#### Abstract

Throughout the COVID-19 pandemic, the Institute for Health Metrics and Evaluation (IHME) at the University of Washington was at the forefront of tracking factors related to COVID-19 and developing models that enabled decisionmakers to project the trajectory of the pandemic and quantify its toll. This work builds on IHME's expertise as the coordinating center for the Global Burden of Disease study, the most comprehensive effort to date to systematically measure all diseases and many risk factors that contribute to health loss globally.

Multiple vaccines were developed and deployed to populations globally in response to the COVID-19 pandemic. These vaccines have different dosing regimens, variable effectiveness, and wane at different rates. While brand-specific data would enable better characterization of the immune landscape due to vaccination, the vast majority of reported vaccine uptake data is brand-agnostic and existing sources suffer from a high degree of missingness for many locations and time periods.

Absent brand-specific data on vaccine uptake for many locations in the world, IHME developed a stepwise estimation approach to quantify brand-specific vaccine uptake as a function of predicted vaccine supply, distribution, and hesitancy, yielding estimates of COVID-19 vaccine coverage by day and location (for all locations modeled by IHME) for 10 brands and a residual "other" category. Estimates by brand were calibrated to IHME's estimates of vaccine uptake overall. Using these estimates, this abstract will describe COVID-19 vaccine uptake in the African continent and for all modeled countries in Africa between December 1, 2020 and June 30, 2022.

### **Poster Sessions**



## Health information systems used during COVID-19 vaccine introduction in South Africa: A pharmaceutical management perspective

#### Marione Schonfeldt<sup>1,2</sup>, Johanna C Meyer<sup>1,3</sup>, Rosemary J Burnett<sup>3,4</sup>

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#### Abstract

Background: COVID-19 vaccine introduction in South Africa required various health information systems (HIS) to monitor vaccine utilisation, distribution, uptake and adverse events following immunisation (AEFI).

Objectives: To identify the HIS used to monitor vaccine utilisation, distribution, uptake and AEFI; To describe how HIS strengthened the pharmaceutical management of COVID-19 vaccines.

Methods: A qualitative, exploratory study based on a theoretical framework, using in-depth interviews with key role players. The study population included key informants who had extensive involvement, knowledge and experience with COVID-19 vaccine introduction in South Africa. This included pharmaceutical policy specialists, pharmaceutical services managers, supply chain experts, regulatory pharmacists and other key role players functioning within pharmaceutical services at national level.

Results: The various HIS introduced or enhanced during COVID-19 vaccine introduction included the Electronic Vaccination Data System, Master Facility List, Stock Visibility System and the Med Safety App. These HIS ensured the equitable distribution of safe and effective vaccines and access to quality immunisation services. Pharmaceutical planning and management of COVID-19 vaccines were improved through the use of various HIS, and data points were combined from HIS to facilitate monitoring of vaccine utilisation, distribution, vaccine uptake and AEFI.

Conclusions: The use of new or enhanced HIS strengthened pharmaceutical management of COVID-19 vaccines with varying degrees of success. HIS are essential for managing a pharmaceutical response to pandemics in terms of vaccine allocation, distribution and safety monitoring. HIS should continuously improve to meet user needs, allow for integrated reporting, and provide access to information.

### **Poster Sessions**



### Content analysis of cosmeceutical advertisements in women's magazines in South Africa

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#### Abstract

Background: Cosmeceuticals are topical cosmetic-pharmaceutical hybrid products that enhance beauty through constituents that provide additional health-related benefits. Cosmeceutical products are commonly advertised in the media.

Objectives: To analyse the advertisements for cosmeceutical products in women's magazines in South Africa to better understand which messages are conveyed to consumers.

Methods: Advertisements for cosmeceuticals in 12 printed South African women's magazines published in 2022 were analysed using content analysis. All skincare advertisements were identified. A data collection tool in Excel® was used to capture variables relating to each magazine, as well as each advertisement. Data were independently captured by two investigators, where after responses were compared and consensus reached. Semiotic analysis was conducted where appropriate.

Results: A total of 133 advertisements were analysed. Three categories were identified, namely moisturiser, antiaging and hyperpigmentation products. Most magazines contained advertisements for moisturisers. Anti-ageing advertisements often used a "before and after" picture to give a visual presentation of what consumers could expect when using the product. Six magazines contained advertisements for hyperpigmentation products (with active constituents such as retinol, hyaluronic acid and aloe vera). These constituents are known to be effective for the treatment of hyperpigmentation. Many advertisements referred to the natural properties of products (using words such as "natural", "cruelty-free", "organic"). Advertisements often contained emotive language.

Conclusion: Insight was provided into how consumers are exposed to cosmeceuticals in the lay media. Ample use was made of pictures and symbolism. The desire to be attractive by using natural products was a subliminal theme identified.

### **Poster Sessions**

# P23

### Using microlearning via WhatsApp for ART training of South African healthcare workers: early uptake data from a mixed method, cluster-randomised study

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#### Abstract

Background: Management of HIV changes with new developments, so guidelines are regularly updated. Ongoing training of healthcare workers (HCWs) is vital for optimal patient care. This has traditionally been face-to-face, at centralised points. Distance, cost and lack of resources reduce uptake.

Objective: To design and test the efficacy, acceptability, and feasibility of WhatsApp-based HIV training for HCWs. This abstract presents early data on the uptake and acceptability of training in the intervention arm.

Methods: A pragmatic, mixed-methods, cluster-randomised study: six 15-minute, 'live', lessons over three weeks for nurses; four for community health workers (CHWs). HCWs in 50 clinics in the Eastern Cape were invited to join during explanatory visits to each clinic. Acceptability was assessed using post-training online surveys, WhatsApp interaction analysis and focus groups and described using proportions.

Results: Invitation uptake was good: 232/293 (79%) of nurses and 207/271 (76%) of CHWs agreed to join the study. In the intervention group, nurses' attendance of the 'live' sessions ranged from 27/101 (27%) to 51/101 (51%); CHWs 27/97 (28%) to 53/99 (54%) across the lessons. One nurse and three CHWs left the WhatsApp groups during the intervention. Two weeks later, 97/101 (96%) of nurses and 86/98 (88%) of CHWs had read the lessons. Interim descriptive data of the post-training surveys showed 66/67 (99%) of nurses and 70/71 (99%) of CHWs enjoyed the training, saying they would participate in this kind of training if it were held weekly.

Conclusions: WhatsApp-based HIV training for HCWs is feasible and well attended and received.



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