

CMSA

The Colleges of Medicine of South Africa NPC

Nonprofit Company (Reg No.1955/000003/08) Nonprofit Organisation (Reg. No. 009-874 NPO) Vat No. 4210273191

27 Rhodes Avenue, PARKTOWN WEST, 2193 Tel: +27 11 726 7037: Fax: +27 11 726 4036

> www.cmsa.co.za Academic.Registrar@cmsa.co.za

> > January 2022

JOHANNESBURG OFFICE EXAMINATIONS & CREDENTIALS

ANNEXURE A

FC Path(SA)Virology Curriculum

Overall Outcomes

At the end of formal training, the virologist should have gained knowledge, expertise, skill and a certain degree of experience as a:

- 1. Scholar, demonstrating a commitment to the practice of Clinical Virology through continuous learning, teaching undergraduates and postgraduates and engaging in research.
- 2. Professional, demonstrating a commitment to the health services and society through ethical practice, high personal standards of behaviour, accountability to the profession, good clinical and laboratory practice in the practice of clinical virology.
- 3. Collaborator, working effectively with other health care professionals such as inter-disciplinary consultation with clinicians, pathologists, scientists, technologists and health care workers to provide high-quality patient care
- 4. Medical Expert, applying medical knowledge, laboratory and clinical skills to provide high-quality patient care by providing independent clinical advice in the practice of clinical virology.
- 5. Leader, engaging with all stakeholders to provide excellent laboratory services to enable high-quality health care services and patient care through clinical, managerial and scholarly activities in Clinical Virology
- 6. Communicator, forming relationships with colleagues and other health care professionals which facilitates gathering and sharing of essential information for effective health care in Clinical Virology
- 7. Health Advocate, contributing expertise and influence when working with patient populations to improve health services by determining and understanding needs, representing others when required, and support the mobilization of resources to effect changes in Clinical Virology

Basic Virology

Understanding structure, classification & replication of viruses

- 1. Virus morphology including symmetry, nature of envelopes, functions of virus-encoded proteins and protein structure
- 2. International Committee on Taxonomy of Viruses (ICTV) and criteria used for virus classification
- 3. Mechanisms by which viruses enter cells and interactions with cellular receptors
- 4. Replication strategies of viruses using the Baltimore classification
- 5. Diversion of cellular resources to viral replication
- 6. Release of viruses from cells and spread to other cells
- 7. Viral genetics genome organization, variation and diversity

Pathogenesis

Understanding how virus infection results in disease

- 1. Routes of transmission of viruses routes of spread of virus from one host to another
- 2. Specific host and virus factors which influence pathogenesis and outcome of infection
- 3. Principles of productive and non-productive infection
- 4. Viral cell tropism, virus-host interactions, host immune responses and immunopathology, and shedding of virus from the host
- 5. Factors responsible for persistent viral infections
- 6. Mechanisms underlying viral latency
- 7. Mechanisms underlying viral oncogenesis
- 8. Apply knowledge of pathogenesis to inform management of infection

Viral Immunology

Understanding the principles of the immune system by applying to viral infections

- 1. Components and functions of innate and adaptive immune systems in relation to virus infections
- 2. Mechanisms of antigen processing and recognition by humoral and cellular adaptive immune response
- 3. Effector pathways triggered by antigen recognition, including induction of antibodies, cytokines (including mechanisms of action of interferons) and cellular cytotoxicity
- 4. Virus strategies to evade host immune responses
- 5. Causes and consequences of primary and secondary immunodeficiency
- 6. Role of the immune response in pathogenesis of viral disease

Antivirals

Understanding the use of antivirals for treatment and prophylaxis in clinical practice based on evidence and policies

- 1. Current guidelines on antiviral drugs and use in practice including DOH EDL/STG including prescribing processes, role of pharmacy and committees, antiviral costs
- 2. Appropriate selection of an antiviral or combination of antivirals for management of viral infection based on clinical presentation and results of other investigations
- 3. Mechanisms of action of antivirals
- 4. Pharmacodynamic and pharmacokinetics spectrum of activity, adjustments for renal and hepatic impairment
- 5. Interactions of antivirals with each other and with other drugs
- 6. Differences in antiviral use across range of patients, including immunocompetent, immunocompromised, neonate, infant and child, pregnant, elderly
- 7. Using antivirals 'off-licence'
- 8. Principles of empirical use of antivirals for common infections and syndromic presentations, before laboratory results are available
- 9. Mechanisms of resistance to antiviral. Phenotypic and genotypic tests for resistance. Interpret sequence data. Local resistance patterns
- 10. Dose, route of administration, duration of treatment, adverse effects, compliance, using alternative drugs when resistance appears
- 11. Safety contraindications, potential side effects and monitoring appropriately, clinical features of toxicity, use in allergy, pregnancy, children and individuals with deranged liver or kidney function
- 12. Drug level measurement
- 13. Principles of development of new antiviral

Viral Vaccines

Understanding the principles of vaccination in preventing viral diseases

- 1. Classification and use of all licensed viral vaccines in SA
- 2. Advantages and disadvantages of various types of vaccines e.g. live attenuated, inactivated, recombinant, DNA vaccines
- 3. SA and WHO, GAVI schedules for vaccination against viral diseases- EPI Role National Immunization Technical Advisory Group (NITAG) and National Advisory Group on Immunization (NAGI) in assessing evidence to inform vaccination policy
- 4. Recommendations for vaccination of healthcare workers
- 5. Vaccination protocols for patients with reduced immunity
- 6. Use of vaccines in post exposure prophylaxis e.g., rabies, hepatitis A, hepatitis B
- 7. Use of vaccines to boost pre-existing immunity e.g., VZ
- 8. Safety profiles of vaccines and adverse effects reporting of vaccine-related incidents to SAHPRA. Advantages and disadvantages of vaccination
- 9. Effects of vaccination on viruses e.g., antibody selection pressure
- 10. Assays testing for immunity pre- and post-vaccination: available methods and limitations
- 11. Effects of vaccination on a population e.g., herd immunity, age shifts in natural infection
- 12. Active and passive immunisation in prevention and in managing outbreaks
- 13. Approaches to vaccine development, including rapid development of vaccines in response to emerging infections e.g., pandemic influenza, novel coronavirus infections, use of viruses as vaccine vectors
- 14. Vaccine surveillance programmes e.g., global influenza networks and surveillance programmes for vaccine preventable infections including role in disease eradication
- 15. Initiatives in vaccine development against viruses such as CMV, HSV, HIV, HCV
- 16. Clinical trial processes for vaccines
- 17. Nature of vaccine adjuvants
- 18. Mechanisms underlying vaccine-induced pathology
- 19. Potential of therapeutic vaccines

Immunoglobulins

Understanding the role of immunoglobulins to prevent and treat viral infections

- 1. Passive immunisation using immunoglobulins
- 2. Current guidelines on using immunoglobulins in practice
- 3. Immunoglobulins used for prophylaxis and adjunctive therapy such as monoclonal and polyclonal antibodies
- 4. Storage conditions for immunoglobulins
- 5. Duration of immunoglobulin prophylaxis/therapy eg RSV, CMV pneumonitis, Lassa fever
- 6. Immunoglobulin replacement therapy in immunodeficiency states
- 7. Principles of immunoglobulin preparation and the prevention, removal and inactivation of potential pathogens
- 8. Informed consent for immunoglobulin prophylaxis and treatment where appropriate
- 9. Immunoglobulin pharmacokinetics dose, route of administration, interactions with vaccines, adverse effects

Travel Related Infections

Applying principles of epidemiology and vaccination in providing advice about pre-travel precautions

- 1. Epidemiology including geographical patterns of disease and risk factors for acquisition
- 2. Clinical features of imported diseases, including severe diseases such as VHFs, zoonotic and arboviral infections
- 3. Current guidelines and information resources e.g. vaccination guides, websites
- 4. Travel history to develop a differential diagnosis including risk assessment appropriate to traveller, consideration of specific groups (e.g. elderly, immunosuppressed) and hazards of specific types of travel
- 5. Availability, benefits and limitations of specialised diagnostic tests selection and interpretation
- 6. Dealing with severe diseases e.g. VHFs and IPC issues
- 7. Use, availability, efficacy and safety of relevant vaccines
- 8. Medico-legal issues involved including International Health Regulations Act, 1974

Clinical Syndromes

Applying the principles of Clinical Medicine in the diagnosis and management of common clinical syndromes caused by viruses

Knowing and understanding of the principles and practice of clinical virology as applied to pathogenesis, clinical approaches, natural history, epidemiology, laboratory investigations, differential diagnosis, treatment, prevention including vaccination and relevant IPC issues, prognosis:

Developing competency in:

- 1. Taking relevant clinical history, performing clinical examination, and using relevant investigations to establish a differential diagnosis and likely diagnosis
- 2. Recommending and interpreting appropriate investigations and subsequently interpreting the results to guide the management
- 3. Applying information from history, examination and investigations to appropriately manage patients with viral infections
- 4. Applying relevant local, regional, national guidelines especially those from specialty societies to manage viral infections.
- 5. Adjusting management plans depending on progress

Management of HIV Infection

Recognizing and managing HIV infection including viral coinfections in the HIV infected patient

- 1. Pathogenesis
- 2. Epidemiology prevalence and incidence, national surveillance
- 3. Risks of transmission after exposure by sexual and non-sexual exposure strategies for risk reduction
- 4. Clinical features and natural history disease staging AIDS related infections and diseases
- 5. Risk reduction for opportunistic infections e.g. behavioural change, chemoprophylaxis and vaccination
- 6. Management of viral coinfections such as Herpesviruses, HPV, Parvovirus
- 7. Demonstrate communication skills which allow patients, relatives/carers and others, including those at HIV risk, to participate in management decisions

Applying laboratory testing in the HIV positive patient

- 1. Current diagnostic and monitoring techniques clinical utility. Select and interpret accurately laboratory tests, significance of results and limitations
- 2. Clinical and laboratory manifestations of immune deficiency
- 3. Consent for testing and maintaining confidentiality
- 4. Natural history of HIV-1 and HIV-2 infections to enable appropriate test selection at different stages of infection
- 5. Interpretation of diagnostic tests such as ELISAs and molecular tests including false positive and negative results
- 6. Antiretroviral drug resistance testing
- 7. Therapeutic drug monitoring 8. Perform laboratory tests including ELISAs, point of care tests, nucleic acid amplification and sequencing

Advising on prevention and management of HIV exposure

- 1. Rationale and appropriate drug regimens for PREP/PEP, including specific groups such as pregnant women, possible source virus resistance to certain drugs/drug classes
- 2. National guidance on post exposure prophylaxis
- 3. Restrictions on working and risks associated with HIV-infected health care workers
- 4. Management of those at risk of multiple HIV exposures
- 5. Anti-retroviral agents in the prevention of mother-to-child transmission

Managing antiretroviral therapy in HIV infected patients

- 1. DOH Guidelines for appropriate treatment and interventions
- 2. Pharmacokinetics, mechanism of action, dosage, dosing
- 3. Laboratory tests used in monitoring response and in informing use of certain drugs
- 4. Monitoring using viral load
- 5. Optimizing patient adherence
- 6. Therapeutic drug monitoring
- 7. Mechanisms of resistance and cross resistance
- 8. Genotypic resistance testing interpretation including using available resources e.g. Stanford database
- 9. Management of patients with detectable HIV viral load including blips and virological failure
- 10. Reasons for a detectable viral load in patient on ART
- 11. Side effects of treatment regimens
- 12. Management of antiretroviral drug interactions
- 13. Medico-legal issues in HIV/AIDS HPCSA Rules

Managing HIV-viral hepatitis coinfection

- 1. Epidemiology of viral hepatitis including hepatitis A, B, C, D, E
- 2. Natural history of HBV & HCV in HIV infection complications, morbidity, mortality, prognosis
- 3. Screening & vaccination against HAV & HBV
- 4. Problems with interpreting laboratory tests
- 5. Initial assessment and monitoring of hepatitis B and C
- 6. Antiviral treatment of viral hepatitis and impact on ART
- 7. Use resistance data resources to inform treatment decisions
- 8. Side effects of treatment regimens
- 9. Safely starting and stopping ART and therapy for viral hepatitis

Viral Hepatitis

Identifying and understanding viral causes of acute and chronic viral hepatitis by applying to management

- 1. Natural history of HAV, HBV, HDV, HCV HEV infections in immunocompetent and immunocompromised children and adults- complications, morbidity, mortality, prognosis
- 2. Epidemiology HBV & HAV in Africa & SA
- 3. Clinical approach to patient with suspected acute viral hepatitis differential diagnosis, investigations and management
- 4. Effects of other viruses such as HDV and HAV, effects of drugs, toxins and alcohol use on chronic viral hepatitis
- 5. Role of other viruses in chronic infection e.g. HEV in the transplant patient
- 6. Notification of viral hepatitis infection to DOH
- 7. Prevention strategies including vaccination, management of vertical transmission risk, risk reduction from sharps injuries, spread of HBV and HCV in renal dialysis setting

Applying laboratory testing in the patient with chronic viral hepatitis

- 1. Laboratory tests used in diagnosis and monitoring of viral hepatitis. Significance of results and limitations. Interpret ELISAs and molecular tests including false positive and negative results
- 2. Perform laboratory tests used in management of viral hepatitis including ELISAs, point of care tests, nucleic acid amplification and sequencing
- 3. Role of genotyping for patients and in epidemiology

Managing treatment of patients with chronic viral hepatitis

- 1. Treatment options for HBV and HCV, current and in development, including immunomodulatory drugs, directacting antivirals and therapeutic vaccination
- 2. Effective use of antivirals in chronic viral hepatitis
- 3. Monitoring responses to treatment using viral load and reasons for a detectable viral load
- 4. Management of side effects and appropriate adjustments to treatment
- 5. Management of antiviral interactions with other drugs especially ART and in immunocompromised
- 6. Management of patient with a liver transplant and control of viral hepatitis in these patients

- 7. Patient compliance to treatment regimens
- 8. Resistance data in informing treatment decisions
- 9. Safely stop therapy
- 10. Management of HBV and HCV in the immunocompromised including strategies for preventing and managing HBV reactivation

Rabies

Applying the principles of Clinical Medicine in the diagnosis and management of exposures to animals (especially dogs) with suspected Rabies

- 1. Classification of Rabies and Rabies related viruses especially those isolated in South Africa.
- 2. Epidemiology of human rabies in South Africa cycles in animal vectors, transmission to humans
- 3. Pathogenesis and immune responses
- 4. Management of humans exposed to possible rabies: wound care, using Rabies IG and vaccine including schedule of administration, timing, dosage, route of administration and handling of source animal
- 5. Clinical features and natural history of rabies in humans.
- 6. Investigation of a patient with suspected rabies including types of specimens required and available assays, interpretation of results.
- 7. Management of a patient with suspected or confirmed rabies
- 8. Post-mortem diagnosis of rabies in humans
- 9. Notification
- 10. Prevention prep and pep
- Medico-legal issues including relevant legislation for humans and animals Animal Diseases Act, 1984 (Act No. 35 of 1984)
- 12. Rabies control strategies in animals

Polio and Eradication

Applying the principles of Clinical Medicine in the diagnosis and management of AFP and principles of Epidemiology in eradicating Polioviruses.

- 1. Polio physical properties, structure, classification, replication, genetics
- 2. Epidemiology transmission, age, SA, Global
- 3. Clinical features natural history, risk factors, post-polio syndrome, diagnosis, management
- 4. Clinical approach to a child with AFP
- 5. Pathogenesis
- 6. Laboratory testing
- 7. Polio vaccines
 - a) OPV types mOPV, bOPV, tOPV, VAPP, molecular basis of VDPVs (c,i,a) and reversion
 - b) IPV
 - c) Advantages vs disadvantages
 - d) Safety and efficacy vaccine immune responses
 - e) Switching from OPV to IPV, using both vaccines
- 8. Eradication
 - a) Elimination vs Eradication
 - b) WHO GPEI
 - c) Africa ARCC
 - d) South African NCC, NTF, NPEC, NAC
 - e) AFP surveillance, stool adequacy, vaccine coverage, uptake
 - f) Containment in the Community, Environment, Pharmacy ie OPV vaccine stocks,
 - g) Laboratory such as Clinical Pathology, Virology and PEF labs

Viral Infections of the Gastro-Intestinal Tract

Applying the principles of Clinical Medicine in the diagnosis and management of viral infections of the gastro-intestinal tract

- 1. Classification of viruses which cause GE in Africa and South Africa
- 2. Pathogenesis
- 3. Epidemiology of viral GE including patterns of outbreaks, patterns of endemic infections
- 4. Clinical approach to a child with viral GE
- 5. Prevention rotavirus vaccine including impact on epidemiology of rotavirus incidence and prevalence patterns
- 6. Role of the laboratory in surveillance

Viral Haemorrhagic Fevers (VHFs)

Applying the principles of Epidemiology, Clinical Medicine and IPC in the management of suspected or confirmed VHF.

- 1. Classification of viruses which cause clinical spectrum of fever, arthritis, rash and/or encephalitis and VHFs common in Africa and South Africa
- 2. Epidemiology including transmission routes, vectors, ecology, surveillance, outbreaks in Africa, screening of patients presenting to healthcare facilities during an outbreak, movement of suspected and confirmed cases
- 3. NICD and NDOH Guidelines, WHO Guidelines
- 4. Pathogenesis
- 5. Clinical presentation including suggestive clinical features and differential diagnosis,
- 6. Reporting and notification of suspected VHF according to Notifiable Medical Conditions (NMC) and using the Case Notification Form
- 7. Infection Prevention and Control including standard precautions, using PPE, patient isolation , design of isolation units, disinfection, waste management and environmental hygiene
- 8. Specimen handling including collection, packaging, transport, NICD Request and Case Investigation forms
- 9. Specimen handling in laboratory on site including preparation and precautions in the laboratory and performing clinical pathology essential testing
- 10. Role of reference laboratory such as NICD and BSL-4 facility in laboratory diagnosis
- 11. Patient Management
- 12. Post-mortem
- 13. Managing Exposures
- 14. Staff Monitoring and surveillance of contacts

Viral Infections of the Skin and Mucous Membranes

Applying the principles of Epidemiology and Clinical Medicine in the management of patients with viral infections of the skin and mucous membranes

- 1. Classification of viruses which cause skin and mucous membranes infections in South Africa
- 2. Epidemiology including transmission routes, impact of vaccination on disease patterns
- 3. Vaccines measles, rubella, VZV
- 4. Surveillance
- 5. Outbreaks
- 6. Clinical approach to skin and mucous membrane lesions including natural history, clinical features, differential diagnosis, treatment with antivirals
- 7. Pathogenesis
- 8. Laboratory testing of skin and/or mucous membrane biopsy, blood and other specimens

Viral Infections of the Respiratory Tract

Applying the principles of Epidemiology and Clinical Medicine in the management of patients with viral infections of the Respiratory Tract

- 1. Classification of viruses which cause Respiratory Tract infections in South Africa
- 2. Epidemiology including transmission routes, impact of vaccination on disease patterns
- 3. Vaccines Influenza, COVID-19
- 4. Surveillance
- 5. Outbreaks
- 6. Clinical approach to Respiratory Tract infections including natural history, clinical features, differential diagnosis, treatment with antivirals
- 7. Pathogenesis
- 8. Laboratory testing of Respiratory Tract specimens

Viral Infections of the Central Nervous System (CNS)

Applying the principles of Epidemiology and Clinical Medicine in the management of patients with viral infections of central nervous system

- 1. Classification of viruses which cause CNS diseases in Africa and South Africa
- 2. Clinical approach to meningitis, encephalitis, myelitis including natural history, clinical features, differential diagnosis, treatment with antivirals, prognosis
- 3. Pathogenesis
- 4. Laboratory testing of CSF, blood and other specimens
- 5. Chronic diseases
- 6. Prion diseases structure and replication of prions, pathogenesis, clinical presentation, host genome polymorphisms, diagnostic tests, anti-prion therapy

Viral Infections of the Genital Tract

Applying the principles of Epidemiology and Clinical Medicine in the management of patients with STIs due to viral infections

- 1. Classification and Epidemiology of viruses which cause STIs in South Africa
- 2. Clinical approach to viruses which cause STIs such as HSV, HPV
- 3. Pathogenesis of HPV infections such as warts and cervical carcinoma
- 4. Pathogenesis of HSV
- 5. Interaction of HIV and HSV
- 6. Interaction of HIV and HPV
- 7. Laboratory testing of genital specimens such LBC and other specimens
- 8. Management including use of antivirals

Viral Infections in Immunocompromised Patients

Diagnosis and management of viral infections in individuals with immunodeficiency other than that due to HIV infection

- 1. Causes of primary and secondary immune deficiencies including immunosuppressive drugs, transplantation, concurrent immunosuppressive infections, intensive care settings
- 2. Infection risks in immunodeficient individuals and reducing risk including active and passive vaccination and antiviral prophylaxis
- 3. Differential diagnosis of viral infection bacterial, parasitic, fungal, immune reconstitution syndromes
- 4. Assays for diagnosis and monitoring viral infections
- 5. Specific issues in immunodeficiency which increase complexity of management of viral infections e.g. drug interactions, on-going immune deficits resulting from chemotherapy
- 6. Antivirals and adjunctive therapies in managing these patients including monitoring treatment response, adverse effects of antivirals, antiviral levels to optimise therapy

7. Preventing and treating viral infections in patients with: solid organ tumours, haematological malignancy, solid organ transplantation, bone marrow transplantation, chronic diseases associated with immune deficits due to disease process and/or management with immunosuppressive agents (e.g. liver, renal, rheumatology, respiratory)

Viral Infections in Pregnant Women, Fetus & Neonate

Applying the principles of Clinical Medicine in the diagnosis and management of viral infections in pregnant women, fetus & neonate

- 1. Classification of viruses which cause infections in Africa & SA
- 2. Pathogenesis
- 3. Epidemiology prevalence & incidence, national surveillance
- 4. Clinical approach differential diagnosis, investigations & management
- 5. Natural history, morbidity & mortality, complications, prognosis
- 6. Laboratory Testing
- 7. Prevention IPC, Vaccination

Viral Infections in Adult & Paediatric ICU

Applying the principles of Clinical Medicine in the diagnosis and management of viral infections in adult & paediatric ICU

- 1. Classification of viruses which cause infections in Africa & SA
- 2. Pathogenesis
- 3. Epidemiology prevalence & incidence, national surveillance
- 4. Clinical approach differential diagnosis, investigations & management
- 5. Natural history, morbidity & mortality, complications, prognosis
- 6. Laboratory Testing
- 7. Prevention IPC, Vaccination

Emerging & Re-Emerging Viral Infections- Influenza, Coronaviruses, Arboviruses

Applying the principles of Clinical Medicine in the diagnosis and management of emerging viral infections

- 1. Classification of viruses which cause infections in Africa & SA
- 2. Pathogenesis
- 3. Epidemiology prevalence & incidence, national surveillance
- 4. Clinical approach differential diagnosis, investigations & management
- 5. Natural history, morbidity & mortality, complications, prognosis
- 6. Laboratory Testing
- 7. Prevention IPC, Vaccination

Viral Infections of the Kidney

Applying the principles of Clinical Medicine in the diagnosis and management of viral infections of the kidney

- 1. Classification of viruses which cause infections in Africa & SA
- 2. Pathogenesis
- 3. Epidemiology prevalence & incidence, national surveillance
- 4. Clinical approach differential diagnosis, investigations & management
- 5. Natural history, morbidity & mortality, complications, prognosis
- 6. Laboratory Testing
- 7. Prevention IPC, Vaccination

Viral Infections of the Heart

Applying the principles of Clinical Medicine in the diagnosis and management of viral infections of the heart

- 1. Classification of viruses which cause infections in Africa & SA
- 2. Pathogenesis
- 3. Epidemiology prevalence & incidence, national surveillance
- 4. Clinical approach differential diagnosis, investigations & management
- 5. Natural history, morbidity & mortality, complications, prognosis
- 6. Laboratory Testing
- 7. Prevention IPC, Vaccination

Viral Infections of the Eye

Applying the principles of Clinical Medicine in the diagnosis and management of viral infections of the eye

- 1. Classification of viruses which cause infections in Africa & SA
- 2. Pathogenesis
- 3. Epidemiology prevalence & incidence, national surveillance
- 4. Clinical approach differential diagnosis, investigations & management
- 5. Natural history, morbidity & mortality, complications, prognosis
- 6. Laboratory Testing
- 7. Prevention IPC, Vaccination

Role of viruses in Transfusion Medicine

Applying the principles of Clinical Medicine in the diagnosis and management of viral infections involved in transfusion medicine

- 1. Classification of viruses which cause infections in Africa & SA
- 2. Pathogenesis
- 3. Epidemiology prevalence & incidence, national surveillance
- 4. Clinical approach differential diagnosis, investigations & management
- 5. Natural history, morbidity & mortality, complications, prognosis
- 6. Laboratory Testing
- 7. Prevention IPC, Vaccination

Viruses involved in Pyrexia of Unknown Origin

Applying the principles of Clinical Medicine in the diagnosis and management of viral infections involved in Pyrexia of Unknown Origin

- 1. Classification of viruses which cause infections in Africa & SA
- 2. Pathogenesis
- 3. Epidemiology prevalence & incidence, national surveillance
- 4. Clinical approach differential diagnosis, investigations & management
- 5. Natural history, morbidity & mortality, complications, prognosis
- 6. Laboratory Testing
- 7. Prevention IPC, Vaccination

Viral Infections in Occupational Health

Managing Health Care Associated Infections and/or incidents

- 1. International, national and local policies on occupational health issues in virology (HBV, HCV, HIV, rubella and VZV)
- 2. Principles of risk assessment and safe work practices of healthcare workers to prevent viral diseases in health care workers by using standard precautions, prevention of sharps/splash exposures, safe injection practices, source and protective isolation, aseptic non-touch technique

3. Management. .../

- 3. Management of health care workers following accidental exposure to blood borne viruses including post-exposure prophylaxis, follow-up protocols, reporting and medico-legal aspects.
- 4. Audits of clinical practice including training, keeping accurate and detailed clinical records
- 5. Legislation related to OHS Compensation for Occupational Injuries and Diseases Act, 1993; Occupational Health and Safety Act, 1993

Medico-Legal Aspects

Understanding the medico-legal aspects of practice in clinical virology

- 1. HPCSA legislation, guidelines, rules and regulations on Good Clinical practice such as responsibility, accountability, informed consent, confidentiality and disclosure in terms of professional conduct and patient care including reasonable practice and practicing in good faith
- 2. Relevant legislation such as National Health Act, NHLS Act, Labor Relations Act especially the aspects regarding HIV/AIDS, Health Professions Act, Protection of Personal Information Act

Research Methods

Applying knowledge of basic research methods

- 1. Basic biostatistics which includes concepts of sampling and sample size, normal distribution ie mean, median and mode, risk, relative risk and odds ratio, probability values and confidence intervals as applied to categorical and continuous variables
- 2. Different types of study design and applications to clinical virology
- 3. Research Ethics and GCP, GLP

Undertaking a research project

- 1. Agree on a suitable project with supervisor
- 2. Undertake a literature review and critically appraise publications
- 3. Write a research proposal
- 4. Apply for research ethics approval if required
- 5. Obtaining Research funding and manage project including costs
- 6. Critically appraise and interpret study results including statistical data
- 7. Acquire new laboratory skills required for a laboratory-based project
- 8. Acquire analytical skills relevant to project results
- 9. Clear concise accurate records of the findings
- 10. Dissemination of research findings
- 11. Present project satisfactorily
- 12. Write up project ideally with aim of publication

Virology Laboratory Practice

Laboratory Management

Understanding how to manage a laboratory

- 1. Organization of virology laboratory services funding, management, pressures for change in the configuration of laboratory services
- 2. Importance of clinical governance in virology
- 3. Managing workload and financial pressures in the laboratory
- 4. Role of SANAS, HPCSA in regulation and guidance of laboratory practice
- 5. Regulatory issues relevant to laboratory practice including Data Protection, National Health Act, NHLS Act, HPCSA Act
- 6. Advancing techniques including cost, impact on human resources and workflow
- 7. Role of the LIS, from sample requesting to issuing of reports including advantages and limitations

- 1. Provide effective clinical leadership in a Virology service
- 2. Effectively work with laboratory staff to ensure the laboratory is run in an efficient, safe and cost-effective way
- 3. Lead the management and investigation of non-conformances, especially when these may pose a clinical risk
- 4. Provide a clinical lead on service improvement, including evaluation of new techniques or practices
- 5. Provide clinical input into the configuration of IT systems
- 6. Manage changing configuration of laboratory services
- 7. Train, appraise and mentor staff, and deal with staff in difficulty
- 8. Audit existing laboratory or clinical practices in order to improve services
- 9. Demonstrate good presentation, speaking and negotiation skills
- 10. Function as an independent worker at the bench which includes manual dexterity
- 11. Organisation of work, time management and the use of laboratory protocols.

Laboratory Health and Safety

Managing health and safety issues in the laboratory

- 1. Laboratory bio-safety level criteria principles of universal precautions, hazard groups and containment levels
- 2. Laboratory hazards and precautions against them
- 3. Risk assessment for dealing with category 3 and 4 viruses and how to handle these viruses
- 4. Manage patients potentially infected with category 3 and 4 viruses
- 5. Safe transport of specimens including national and international transport of infectious biological material ie current requirements for specific diseases eg viral hepatitis, HIV, VHFs
- 6. Principles of Biological safety cabinets decontamination and monitoring air flow
- 7. Sterilisation and disinfection including procedures for hospital related instruments and virological waste disposal.
- 8. Health & Safety legislation and translation to local best practice eg *Hazardous Substances Act, 1973; Foodstuffs, Cosmetics and Disinfectants Act, 1972*
- 9. IPC risk assessment
- 10. Vertical and horizontal audits to identify health and safety issues within laboratory
- 11. Investigating Non-conformances in response to health and safety issues
- 12. Prepare written reports on health and safety issues/incidents

Pre-analytical Processes

Identifying and understanding specific requirements of the pre-analytical phase

- 1. Select most appropriate investigations for individual patient
- 2. Scope of tests required for diagnosis of important clinical syndromes, including merits and limitations
- 3. Safe collection of specimens, appropriate specimen types and volumes, appropriate categorisation of risk, packaging, transportation and storage requirements
- 4. Specimen acceptance and rejection. Dealing with specimens which fail to meet criteria
- 5. Customer Satisfaction Surveys to involve users in establishing test repertoire
- 6. Informing users of appropriate test selection and specimens for different clinical scenario
- 7. Introducing an additional test or to alter an existing protocol

Post-analytical Processes

Understanding and appreciating the importance of correctly recording, interpreting and relaying the results of laboratory investigations and diagnostics

- 1. Keeping concise, accurate, confidential, and legible records of laboratory investigations in terms of SA legislation and HPCSA guidance
- 2. Result reporting mechanisms secure and confidential use electronic, written, fax, verbal communication interpret and authorise release of results communicate results clearly and promptly producing a report containing appropriate interpretative comments using the LIS

- 3. Management of clinical problems guided by laboratory results explain results comprehensively in conjunction with results from other specimens and other investigations such as radiology, biochemistry, haematology
- 4. Clinical implications of laboratory results for patient, IPC, public health and medico-legal situations
- 5. Record advice accurately in LIS
- 6. Identifying critical results which need urgent discussion with other clinicians
- 7. Ensure chain of evidence is maintained for medico-legal specimens
- 8. Establish and audit turnaround times

Analytical Phase

Understanding and appreciating the importance of correctly performing and using laboratory investigations for diagnostics

- 1. Principles, uses and limitations of laboratory assays (manual, automated and Point-of-Care) including molecular and serological, and novel diagnostics
- 2. Using of NICD as a reference laboratory
- 3. Following SOP use time effectively and efficiently to achieve optimal turnaround time
- 4. Auditing technical process involved in testing
- 5. Distinguishing significant positive and negative results
- 6. Recognising self-limitation and to seek advice from appropriate sources
- 7. Directing specimens to appropriate reference laboratories in situations where a higher level of virological expertise is required
- 8. Adapting and changing working practices according to best practice or new guidelines

Viral Serology

Understanding specific requirements of the analytical phase in viral serology testing

- 1. Principles of immunoassays for antigen and antibody detection including manual and automated ELISAs, immunochromatographic assays, immunoblots. a. ELISA performance characteristics, advantages and disadvantages of different ELISA formats e.g. direct, indirect, capture, effect of different antigen types e.g. recombinant, whole virus lysate, problems of interpretation of assays e.g. factors (including rheumatoid factor) which influence IgM assays
- 2. Perform ELISAs, immunoblot
- 3. Interpret results of: ELISAs, immunochromatographic assays, immunoblot, neutralisation tests for confirmation e.g. HBsAg
- 4. Assay verification using quality control parameters for individual test run and series of test runs over time
- 5. Confirmatory assays: antigen, antibody and combined antigen/antibody detection assay results, reproducibility of a significant result on additional samples
- 6. Additional testing to aid interpretation of initial results eg testing earlier and later samples, IgM/IgG/IgA testing, avidity testing, immunoblot
- 7. Confirmation by additional serological or molecular tests e.g. multiple serological assays, PCR

Molecular Virology

Understanding specific requirements of the analytical phase in PCR testing

- 1. Performing nucleic acid extraction methods, qualitative and quantitative PCR
- 2. Principles of Nucleic acid extraction methods and amplification assays such as PCR
- 3. PCR performance characteristics
- 4. Conventional PCR using gel electrophoresis
- 5. Real time PCR
- 6. Advantages and disadvantages of different PCR formats
- 7. Effect of different factors on quality of PCR results
- 8. Laboratory design and workflow to minimise amplicon contamination
- 9. Differences between Qualitative & Quantitative PCR

- 10. Optimizing PCR design primers, set up & trouble shoot new PCR assays
- 11. Components of PCR
- 12. Clinical utility of current diagnostic & monitoring techniques
- 13. Selection of tests based on clinical profiles
- 14. Significance of results & limitations
- 15. Interpretation of diagnostic tests including false positive & negative results
- 16. Interpreting & integrating additional molecular &/or serology results
- 17. Using additional tests to aid interpretation of initial results eg quantitative PCR, sequencing
- 18. Assay verification quality control parameters for individual test run & series of test runs over time
- 19. Confirming reproducibility of a significant result on additional samples

Understanding specific requirements of the analytical phase in sequencing

- 1. Principles of sequencing conventional and new generation
- 2. Steps in preparing a specimen for sequencing
- 3. Effect of different factors on quality of sequencing results
- 4. Sequencing performance characteristics
- 5. Advantages and disadvantages of different sequencing systems
- 6. Optimizing sequence data
- 7. Interpretation of sequences
- 8. Verification using quality control parameters for individual test run and series of test runs
- 9. Confirming reproducibility of a significant result on additional samples
- 10. Using IT software to run sequencing reactions, interpret sequences, perform phylogenetic analysis
- 11. Bioinformatics applied to viruses principles of phylogenetic analysis and molecular epidemiology of viruses

Quality Management Systems (QMS)

Understanding QMS in the laboratory by applying to Virology Laboratories

- 1. Principles of good laboratory practice and laboratory accreditation
- 2. Requirements for laboratory accreditation according to ISO15189
- 3. Principles of Quality Management Systems
- 4. Internal quality assurance
- 5. External quality assurance Programs such as NEQAS, RCPA, QCMD, NICD PTS
- 6. LIS data handling including advantages and limitations of LIS and data protection
- 7. Team work to facilitate laboratory management and accreditation which may include attendance of local or national management courses.
- 8. Horizontal and vertical audits
- 9. Validation or verification of assay performance
- 10. Advantages and disadvantages of diagnostic laboratory techniques including cost, throughput, automation, technology, false reactivity
- 11. Measures of diagnostic accuracy, including test sensitivity, specificity, positive and negative predictive values, accuracy and precision
- 12. Uncertainty of measurement
- 13. Accurate calibration of equipment
- 14. Importance of confirmatory assays where appropriate
- 15. Limitations of an individual laboratory and need for appropriate referral

Public Health Principles in Relation to Viral Diseases

Applying the Principles of Public Health Management to prevent and control viral diseases

- 1. Public health aspects of vaccine-preventable infections and benefits of vaccination
- 2. Herd immunity in relation to vaccine failure
- 3. Epidemiology of food and waterborne infections
- 4. Virology support in a public health emergency
- 5. Report writing to communicate with other colleagues
- 6. Notification of viral diseases as per National Health Act
- 7. Evidence based advice to Public Health and other clinical colleagues

Understanding principles of outbreak management and applying to viral infections

- 1. Principles of outbreak investigation in the community
- 2. Principles of establishing case definition using concepts of exposure, infection and disease
- 3. Principles of hypothesis-generation and testing when investigating an outbreak
- 4. Steps involved in recognising, investigating and controlling outbreaks
- 5. Current laboratory assays, including molecular typing, epidemiological methods used in outbreak investigations
- 6. Using reference laboratories and other expert resources appropriately when investigating and managing an outbreak
- 7. Basic statistical methods used in outbreak recognition, investigation and management, including design of studies such as case control studies. Interpret statistical data and make recommendations for interventions for outbreak control
- 8. Advise appropriately on investigations and management, including closure of hospital beds, hospital wards, institutions such as schools
- 9. Relevant authorities in organising an emergency response
- 10. Analyse data to provide updates

Demonstrating

- 1. Excellent communication skills in liaising with all healthcare staff in relation to an outbreak and in dealing with clinical colleagues and the public
- 2. Good organization, clear and concise report writing
- 3. Leadership in working with diverse professional colleagues in outbreak management

Understanding surveillance data and applying to practice in virology

- 1. Surveillance methods for viral infections in the hospital and community
- 2. National and global viral surveillance programmes e.g. AFP, measles, influenza, arboviruses
- 3. Data analysis to offer interpretation of trends in virus transmission and appropriate intervention strategies

Epidemiology

Understanding concepts in epidemiology and applying to viral diseases

- 1. Epidemiology of viral diseases including molecular and sero-epidemiology
- 2. Impact of interventions such as vaccination on epidemiology of viral infections including herd immunity and globalisation
- 3. Reservoirs, sources, routes of transmission of viruses implicated in community and hospital acquired infections
- 4. Interactions between host, environment and viruses
- 5. Emerging and re-emerging virus infections including case definitions, causes, epidemiology and management of these diseases
- 6. Epidemiology of vaccine preventable viral diseases including international, national and local eradication initiatives.

Infection Prevention and Control (IPC) in Hospital and Community

Understanding infection prevention and control (IPC) to reduce risk of acquiring viral infections and to control its spread.

- 1. Principles of IPC in healthcare settings applied to viral infections
- 2. Evidence for practices of IPC
- 3. Local, national and international guidelines for IPC in healthcare settings
- 4. Principles of IPC in community eg nursing homes, hospices, child care facilities etc
- 5. Responsibilities of healthcare facilities for IPC ?relevant legislations and guidelines
- 6. Responsibilities of individual members in healthcare facilities regarding monitoring, responding to, and resourcing IPC needs
- 7. Principles of patient isolation including various sterilisation and disinfection processes
- 8. Special precautions needed for handling patients with VHFs
- 9. IPC procedures required to contain viruses in healthcare settings
- 10. Importance of non-clinical areas in IPC
- 11. "Chain of Infection" in IPC: virus, reservoir (patient, healthcare worker, environment), portal of exit, portal of entry, transmission route, host risk factors
- 12. Prevent transmission of viruses hand hygiene, Personal Protective Equipment (PPE) and isolation
- 13. Principles of environmental control cleaning, disinfection, sterilization of patient care equipment
- 14. Potential for transmission of viruses in clinical settings such as risks associated with air flow and ventilation in high care areas, isolation facilities, sterilisation and disinfection processes
- 15. Design concepts relevant to IPC assess new and renovated facilities in healthcare
- 16. Settings
- 17. Role of IPC in procurement of new equipment
- 18. Surveillance methods, data extraction, analysis to monitor trends in IPC appropriate interventions based on surveillance data interpretation
- 19. Processes involved in undertaking IPC inspections, analysing findings and providing a judgement on quality of IPC processes adopted by institution, Report and policy writing skills
- 20. Adverse outcomes due to non-conformance to IPC procedures Investigate non-conformances in IPC
- 21. Analyse and disseminate results of in-depth audits of policies and practices related to IPC

JOHANNESBURG January 2022