Online International Symposium on Clinical Research (Trials)

Theme:
International Clinical Research (Trials) during COVID-19 era:
- Should we suspend or continue? -

Day 1: March 11, 2021 15:25 – 18:40 JST (06:25 - 09:40 UTC)

Day 2: March 12, 2021 15:25 – 17:55 JST (06:25 – 08:55 UTC)

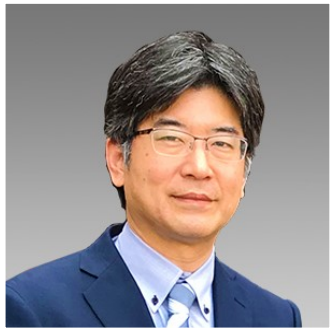
Day 1:
March 11, 2021

March 11, 2021	
15:25	**Opening** Moderator**: Marlinang Siburian**, NCGM/DIT
15:30 – 15:35	**Opening Remarks** **Norihiro Kokudo** (President, NCGM)
15:35 –15:45	Developing and maintaining an international clinical trial network activity. **Tatsuo Iiyama** (Director, Department of International Trials)
Session 1 15:45 – 18:40	**The New normal for Clinical research (trials).** Chair: **Hamana Mieko**, NCGM/DIT Co-chair: **Muchanga Sifa**, NCGM/DIT
15:45 –16:05	Impact of COVID-19 on Infectious diseases research (trials) **Norio Ohmagari** (Director, Disease Control and Prevention Center, NCGM)
16:05 –16:25	Impact of COVID-19 on cancer clinical trials **Kenichi Nakamura** (Director, National Cancer Center)
16:25 – 16:45 (10:25 -10:45 Nairobi)	“Clinical trials in resource limited settings: An example of Leishmaniaisis East Africa Platform (LEAP). **Monique Wasunna** (Director, Drugs for Neglected Diseases Initiative, Africa Regional Office)
Keynote speech 16:45 – 17:15 (8:45 – 09:15 Paris)	Impact of the COVID-19 pandemic on the management of the Intensive Care and the battle of implementing treatment for a new and unknown disease. **Mehran Monchi**, (Head of Department of Intensive Care Medicine, Melun General Hospital, France)
17:15- 17:35	Clinical Research between Thailand and Japan in orthopedics **Tsuyoshi Murase** (Division of Medicine, Graduate School of Medicine, Associate Professor, Osaka University)
17:35- 17:55	Collaborative study of Prospective, MUlticenteR, Observational StUdy of the PatIenTs with Heart Failure with Preserved Ejection Fraction (PURSUIT HFPEF) between Japan and Cambodia **Daisaku Nakatani** (Head of Global Clinical Research Support Group, Department of Medical Innovation, Osaka University Hospital)
17:55- 18:15 (15:55 – 16:15 Bangkok)	Malaria elimination during COVID-19 era **Srivicha Krudsood** (Professor, Department of Tropical Hygiene, Mahidol University)
18:15 -18:35	Clinical trials for devices and IVD other than COVID-19 device -Malaria **Shigeyuki Kano** (Director, Department of Tropical Medicine and Malaria, Research Institute, NCGM)
18:35 – 18:40	Wrap up

OPENING

Opening Remarks

Norihiro Kokudo (President, NCGM)



Developing and maintaining an international clinical trial network activity.

Tatsuo Iiyama (Director, Department of International Trials)

Session 1: 15:45 – 18:40
The New normal for Clinical research (trials)

Chair: Hamana Mieko, NCGM/DIT
Co-chair: Muchanga Sifa, NCGM/DIT

Short CV

Dr. Norio Ohmagari is acting as Director, AMR Clinical Reference Center and Director, Disease Control and Prevention Center of National Center for Global Health and Medicine (NCGM), Japan.

Dr. Ohmagari has completed his clinical fellowship in Infectious Diseases at University of Texas-Houston. After serving as chief of the Division of Infectious Diseases at the Shizuoka Cancer Center, in 2011 Dr. Ohmagari moved to NCGM which is one of six national medical centers in Japan with infectious diseases as main objective.

At NCGM, Dr. Ohmagari has been acting as Director of the Disease Control and Prevention Center since 2012. He also serves as the director of AMR Clinical Reference Center, which is commissioned by Ministry of Health, Labor and Welfare, Japan.

Dr. Ohmagari is engaged in the care, prevention and research of infectious diseases from a global perspective. As a physician, Dr. Ohmagari is directly involved in the clinical management of patients with infectious diseases.

Dr. Ohmagari is also actively working on activities with controlling antimicrobial resistance in Japan. At the same time, Dr. Ohmagari is working on the on-site response in infectious disease crisis management in Japan.

Abstract

Impact of COVID-19 on Infectious diseases research (trials)

In the event of an outbreak of an emerging infectious disease,
it is important to collect clinical information as soon as possible and to conduct research and development of therapeutic agents.

In order to conduct research and development promptly,
it is necessary to conduct international joint clinical trials in order to secure the number of cases and to promote research and development in multiple countries.
During the COVID-19 epidemic, we have conducted several international collaborative trials with NIH and faced this difficulty.

The first clinical trial (ACTT-1) was our first international clinical trial, but thanks to the NIH team coming to Japan in February 2020, the preparation for the clinical trial went very smoothly and we were able to start the clinical trial in Japan within one month of the start of preparation.

For the second trial, the ITAC trial, all the preparations for the start of the trial were done remotely, as the pandemic had already prevented us from communicating with the research network team in Australia. A number of challenges arose during the preparation phase, some of which may have been due to the fact that the preparation had to be done remotely.
The experience of the clinical trials under COVID-19 is expected to change the way international clinical trials are conducted in the future.

Session 1: 15:45 – 18:40
The New normal for Clinical research (trials)

Chair: Hamana Mieko, NCGM/DIT
Co-chair: Muchanga Sifa, NCGM/DIT

Short CV

Dr. Kenichi Nakamura, is the Director of the Department of International Clinical Development at the National Cancer Center Hospital in Tokyo.

He holds a PhD in Medicine from Kyoto University.
His expertise is on Clinical Trial Methodology, Clinical Trial Operation, Clinical Trial Regulation.
He provides comprehensive support activities to ensure the smooth implementation of high-quality oncologic studies in Japan and overseas.

He is the Board member of the Japanese Society of Clinical Trials and Research and the Vice-chairman of the Institutional Review Board in the National Cancer Center.

He is well published in peer review journals mainly on cancer research.

Abstract

Impact of COVID-19 on cancer clinical trials

Japan Clinical Oncology Group has about 50 ongoing clinical trials and the patient accrual speed slowed down temporarily after the outbreak of COVID-19. The monthly patient accrual on May and June decreased by 10-20%, but got back to normal soon after that.

While the patient accrual of industry-sponsored global trials were seriously impacted by COVID-19, the impact on Japanese academic cancer trials was limited.
The largest impact of COVID-19 on cancer trials is difficulty to visit participating site for monitoring/audit.
Since many institutions restricted site visit monitoring/audit during the state of emergency, industry- and academic sponsors have started to pursue remote-monitoring, but the procedures have not yet been standardized well.
In fact, various methods are being tested such as telephone call, online video filming of electric health record (EHR) and direct access on EHR.

Now that ICH-E6 is being amended globally and flexible monitoring is supposed to be allowed in the amendment, we should consider how we can assure the data reliability without relying on intensive on-site monitoring.

In response to the pandemic, PMDA has issued such notification as direct drug shipping to patient's home, online check-up, contract enabling external sites to perform a part of the protocol treatment; however, most of them were difficult to be utilized in cancer clinical trials.

Session 1: 15:45 – 18:40

The New normal for Clinical research (trials)

Chair: Hamana Mieko, NCGM/DIT
Co-chair: Muchanga Sifa, NCGM/DIT

Short CV

Dr. Monique Wasunna is the Director, Drugs for Neglected Diseases Initiative Africa Regional Office.
She is a physician, an infectious disease and tropical medicine specialist.

She is the Founding Chairperson of the Leishmaniasis East Africa Platform which promotes clinical research and capacity building for this neglected and deadly disease.

Prior to joining DNDi, Dr Wasunna worked at the Kenya Medical Research Institute where she rose from the position of an Assistant Research Officer to that of the Acting Director and Chief Executive Officer.

She holds a Bachelor of Medicine and Surgery degree from the University of Nairobi, an MSc and a PhD in medicine from the London School of Hygiene and Tropical Medicine and a diploma in Tropical Medicine and Hygiene from the Royal College of Physicians of London.

She is a former member of the International Bioethics Committee of UNESCO.

She is well published in peer review journals.

Abstract

“Clinical trials in resource limited settings: An example of Leishmaniaisis East Africa Platform (LEAP)

DNDi is a patients’ needs driven, not-for-profit research and development (R&D) organization that develops safe, effective, and affordable medicines for neglected diseases afflicting millions of the world’s poorest people.

DNDi’s R&D pipeline encompasses a full range of drug development, from early research and preclinical through to phase I, II, III and IV clinical trials (CTs) for diseases such as African sleeping sickness, leishmaniasis, Chagas disease, filarial diseases, mycetoma as well as paediatric HIV and hepatitis C.
Clinical trials are critical in providing evidence of efficacy and safety of innovation.

CTs are specialized studies that are highly regulated by international and national laws to ensure safety of study participants and the attainment of credible data for registration and policy change. DNDi has extensively worked with partners to conduct CTs in Low-and middleincome countries (LMICs) carrying the highest burden of neglected diseases.

Clinical research platforms such as the Leishmaniasis East Africa Platform (LEAP), created by DNDi, have been fundamental in identifying patients’ needs, R&D gaps, strengthening and sustaining clinical research capacity and facilitating access to new treatments. Since inception, LEAP has carried out eleven CTs and delivered treatment options for visceral leishmaniasis patients. Building CTs research capacity, knowledge sharing, and infrastructure improvement are key requirements in LMIC countries for success. Challenges in carrying out CTs in LMIC include fragmented capacity, different cultures and regulatory environments, long periods of ethics review and civil unrest. COVID-19 pandemic has impacted the ongoing CTs. Measures have been put in place to mitigate this impact.

Session 1: 15:45 – 18:40

The New normal for Clinical research (trials)

Chair: Hamana Mieko, NCGM/DIT
Co-chair: Muchanga Sifa, NCGM/DIT

Short CV

Dr Mehran Monchi is the Head of the Department of Intensive Care Medicine at Melun General Hospital in Paris.

Prior to joining Melun General Hospital, He has been working at different University Hospitals of France and Belgium.

He holds a Bachelor Degree from Medical University of Grenoble in France and two postgraduate Diploma; one in Endocrinology and Metabolism from Necker University Paris V and another in Intensive care Medicine from Paris-Sud University.
He also holds a Master of Science in Biology and Technology of artificial Nutrition.

His research focus mainly on: Renal Replacement Therapies (and Regional citrate anticoagulation), Cardiac arrest, Inhaled anesthetics in intensive care, and Infectious diseases.

He is well published in peer review journals with 5 publications last year.

Abstract

Impact of the COVID-19 pandemic on the management of the Intensive Care and the battle of implementing treatment for a new and unknown disease.

Located in the greater Paris area and supporting around 500 000 inhabitants, our ICU includes 22 beds allowing mechanical ventilation and 12 step-down beds.
During the two "waves" of the Covid-19 pandemic in France, we were able to increase the capacity up to 60 ICU beds. We used large stocks of personal protective equipment secured inside our hospital since the 2009 influenza pandemic.

The ICU staff contamination by Covid-19 was about 20%, including extra hospital contaminations. The ICU team was strengthened by Anesthesiologists, medical students, operating room nurses and student nurses.
The main clinical challenges during the first wave of an unknown disease were unusual very sticky secretions plugging tracheal tubes, a very high frequency of pulmonary thrombo embolism, low antibiotic levels in the lung of mechanically ventilated Covid-19 patients, episodes of bacteremia due to digestive ischemia, sedative drugs shortage and the lack of effective antiviral treatment for severe patients. Some of these issues have been resolved by pragmatic approaches.
During the two waves, we made some studies on steroids, sedative drugs, non-invasive ventilation, anticoagulation and anti-inflammatory drugs for Covid-19.
The media coverage of the disease was very focused on some topics such as hydroxychloroquine, advocated by the presidents of the USA and Brazil, without a clear scientific basis and inducing requests by the patients' proxies. Emotional stress and team burnout were frequent during the two waves.

After the two waves, some ICU nurses wished to no longer work in the ICU, but also, some students discovered the ICU and wished to come back after graduation.

Session 1: 15:45 – 18:40

The New normal for Clinical research (trials)

Chair: Hamana Mieko, NCGM/DIT
Co-chair: Muchanga Sifa, NCGM/DIT

Short CV

Dr. Tsuyoshi Murase, is an Associate Professor and Vice Chairman of the Department of Orthopaedic Surgery, Osaka University Graduate School of Medicine.

He specializes in hand and upper extremity surgery.
He is also involved in research on computer simulation surgery, which he has been developing for the past 20 years with a continuously awarded public research grant. He has been working on international collaboration with other Asian countries.

He holds a PhD on Orthopedics surgery and has been resident at Osaka University and at Institut Francais de la Main.

He has served on the executive board of the Japanese Society for Surgery of the Hand and as editor of major journals.

He is member of many scientific societies including the Japanese Orthopaedic Association, the American Society for Surgery of the Hand, the Japanese Society for Surgery of the Hand, etc.

He is well published in peer review journals

Abstract

Clinical Research between Thailand and Japan in orthopedic

Fractures around the forearm and elbow often heal in a deformed state. The resulting deformity of the limb can cause pain, range of motion impairment, and instability in adjacent joints, interfering with activities of daily living. Although accurate correction has ben difficult to achieve with conventional surgical techniques.

We have been developing a surgical method of correcting upper limb deformity using a patient- specific surgical guide and osteosynthesis plate that enables accurate surgery based on preoperative computer simulation. After achieving excellent results in clinical trials in Japan, we have been conducting joint studies with Thailand with the aim of expanding our technology overseas.

Based on the MOU between Osaka University and the Thai Ministry of Public Health, a clinical study plan was designed, and with financial support from Japan's AMED, a series of on-site demonstration surgeries and cadaver trials have been conducted.

Due to the digital technology-based nature of this treatment, online approaches are particularly suitable. Image data is sent online from Thailand, and preoperative simulation, design, and manufacturing are performed in Japan. To further facilitate communication between the two countries, we are building a dedicated cloud system called "Bone Cloud". The system is equipped with online data transfer functions, 3D viewing of simulations, and commenting functions, allowing advanced treatment planning to be carried out like a social networking service.

Given the restrictions on local activities due to the spread of coronavirus infections, online and cloud-based approaches will become even more important.

Session 1: 15:45 – 18:40

The New normal for Clinical research (trials)

Chair: Hamana Mieko, NCGM/DIT
Co-chair: Muchanga Sifa, NCGM/DIT

Short CV

Dr. Daisaku Nakatani is a Specialized Associate Professor in both the Department of Cardiovascular Medicine and Medical Innovation at Osaka University.

He is the head of the Global Clinical Trial Support Office, Department of Medical Innovation. He has been striving and leading his Department to create academe-initiated clinical research projects for local and international settings. He aims at minimizing the lag concerning the access of pharmaceuticals, medical devices, and regenerative medicinal products between neighboring countries and Japan.

Prior to joining his current position, He has been working as an officer of the advanced medical service system for the Ministry of Health, Labor and Welfare where He contributed to get approval for huge number of clinical trials with specified medical care coverage under the advanced medical service system.

He holds a PhD on Epidemiology and Preventive Medicine for cardiovascular disease from Osaka University and worked as Postgraduate fellow at Stanford University, Center for Cardiovascular Technology.

He is well published in peer review journals with 10 publications since last year.

Abstract

Collaborating study of Prospective, MUlticenteR, Observational StUdy of the PatIenTs with Heart Failure with Preserved Ejection Fraction (PURSUIT HFPEF) between Japan and Cambodia.

Heart failure with preserved ejection fraction (HFpEF) is recognized worldwide as a different aspect of heart failure to that with reduced ejection fraction (HFrEF) and accounts for more than 50% of all heart failure patients.

To date, there are no established treatment strategy to improve outcomes in patients with HFpEF, unlike the case of HFrEF. In order to clarify patient characteristics, treatment and long-term outcomes in patients with HFpEF, we have organized HFpEF registry with an affiliated 30 hospitals of Osaka University Hospital in Japan since 2016. As of end of February 2021, more than 1,500 patients were enrolled to the registry.
Using the registry data, we have shown that elevated N-terminal pro-brain natriuretic peptide (NT-proBNP) level at the convalescent stage was associated with an increased risk of one-year outcomes in patients with HFpEF, suggesting that NT-proBNP guided therapy in clinical practice may be helpful to improve outcomes for HFpEF.

In Cambodia, cardiovascular disease is among the leading causes of death. Furthermore, it appeared health insurance system has not been well disseminated across the country. We believe that collaborating registry study of HFpEF between Cambodia and Japan may contribute to improve health care and clinical practice, leading to improve quality of life as well as life-expectancy in both countries. Therefore, we are now starting to prepare the collaborating study. In this meeting, we would like to introduce and share our project.

Session 1: 15:45 – 18:40
The New normal for Clinical research (trials)

Chair: Hamana Mieko, NCGM/DIT
Co-chair: Muchanga Sifa, NCGM/DIT

Short CV

Dr. Srivicha Krudsood is a senior physician with experience in clinical management of malaria including clinical trials. As her expertise, she is also a temporary advisor of World Health Organization (WHO) in clinical management of malaria, members of many committees such as country coordinating mechanism (CCM), technical advisory committee of Thai Ministry of Public Health (MOPH), advisory board of Thai nation antimalarial committee and also invited lecturer and speaker on clinical tropical medicine and malaria.

Dr. Srivicha has also conducted research in the field of clinical management of malaria, not only the clinical trials on antimalarial agents but also the clinical aspect including pathophysiology of malaria. One of the clinical trials which this antimalarial has been recommended globally is Artemether-Lumefantriene. Two studies (Artemether-Lumefantriene and Tafenoquine) had been audited and approved by the food and drug administration, United States of America (US FDA). In addition, her practice focuses on clinical management of complicated malaria especially G6PD deficiency.

She is Diplomate of the Thai Board of Internal Medicine
She holds a Master of Science in Clinical Tropical Medicine from Mahidol University after her graduation from Far Eastern University of the Philippines.

She is well published in peer review journals.

Abstract

Malaria elimination during COVID-19 era

Session 1: 15:45 – 18:40
The New normal for Clinical research (trials)

Chair: Hamana Mieko, NCGM/DIT
Co-chair: Muchanga Sifa, NCGM/DIT

Short CV

Dr. Shigeyuki Kano, honoris causa of Mahidol University, Thailand, is Director of the Department of Tropical Medicine and Malaria, Research Institute, NCGM, Japan.

He is also serving Professor at various universities including University of Tsukuba, Japan; Mahidol University, Thailand, and University of the Philippines Manila.

He is contributing to the world malaria elimination program by being appointed Technical Review Panel Member of the Global Fund or Scientific Advisory Group Member of the NIH research grant, International Centers of Excellence for Malaria Research.

His main research field is in Lao PDR where he has been conducting genomic epidemiological studies on drug resistant malaria as Head of the Lao-Japan Parasitology Lab in the Institut Pasteur du Laos for more than 5 years under JICA project.

He holds a PhD from Gunma University, Japan.

He is member of many academic societies including the Japan Association for International Health, the Japanese Society of Travel and Health, the Japanese Society of Clinical Parasitology, American Society of Tropical Medicine and Hygiene, Royal Society of Tropical Medicine and Hygiene etc.

He is well published in peer review journals.

Abstract

Clinical trials for devices and IVD other than COVID-19 device –Malaria

Clinical trials for innovative IVDs for malaria - Do we need to find out more malaria parasites under COVID-19 pandemic?

Now, the number of infections of the Corona virus has amounted more than 100 million which is as large as half number of worldwide malaria cases per year. Indeed, the number of deaths from the COVID-19 has counted no less than 2.5 million which is coming close to the total number of deaths from AIDS, tuberculosis and malaria. While the tropical countries have made significant improvement in their health system performance, the COVID-19 pandemic presents a huge risk of reversing gains already made in the health sector. In fact, the COVID-19 pandemic has interrupted program implementation of activities owing to restrictions on movement and lockdowns. If the current COVID-19 pandemic continues, interventions for malaria control could be affected severely and the number of the cases and deaths from malaria will be doubled.

Despite this circumstance, we cannot stop eliminating malaria from the endemic areas, because malaria is still posing biggest burden to the people in the world. No matter what disaster may come, we have to find out malaria patients and treat them promptly and properly. For that, we need new innovative IVDs, namely XN-31, an automatic flowcytometry-based hematology analyzer to measure the parasite-infected erythrocytes quantitatively, and PURE-LAMP method for accurate detection of malaria parasite DNA. We have started clinical trials for the 2 IVDs under the link agreement between NCGM and Faculty of Tropical Medicine, Mahidol University. The reason why we are continuing the application of these IVDs to the field condition, even in the COVID-19 era, is to be discussed.

Day 2:
March 12, 2021

March 12, 2021	
15:25-15:30	**Opening** Moderator: **Hamana Mieko**, NCGM/DIT
Introductory note 15:30 – 15:50	Regulatory perspectives for the R&D on COVID-19 **Mika Togashi**, Principal Coordinator, Office of International Programs, PMDA, Japan.
Keynote speech: 15:50 – 16:20	**Wataru Sugiura,** Director, Center for Clinical Sciences, NCGM
Session 2 16:20 – 17:55	**COVID-19 clinical studies** **- Learning from front-line health workers-** Chair: **Muchanga Sifa**, NCGM/DIT Co-chair: **Marlinang Siburian**, NCGM/DIT
16:20 – 16:40 (08:20 -08:40 Kinshasa)	COVID-19 at Kinshasa University Clinics (CUK): Epidemioclinical profile and mortality predictors **Mandina Ndona,** Director, Institute for Research in Health Science (IRSS), Senior Coordinator of the COVID-19 Response at the Kinshasa University Clinics, DRCongo
16:40 –17:00 (15:40 -16:00 Manilla)	COVID-19: Perspectives on The Philippine experience **Jubert Benedicto** (Chief of Critical Care Units Management Team (CCU-MAT)
17:00 –17:20 (15:00 – 15:20 Jakarta)	What is the contribution of Clinical Trials during COVID-19 era: Opportunities and constraints at hospital site … **Vivi Lisdawati** (Director of Research on Infectious and Communicable Diseases, Sulianti Saroso - Infectious Disease Hospital, Indonesia)
17:20 –17:40	The experience of clinical research at the NCGM site **Sho Saito** (Clinical Investigator, Disease Control and Prevention Center, NCGM)
17:40 –17:47	Young researcher observations on the management of Covid-19 in Bangladesh **Tania Tabassum** (Global Clinical Research Support Group, Department of Medical Innovation, Osaka University Hospital)
17:47-17:52	**Wrap up**
17:52–17:55	**Closing note** **Masato Ichikawa,** NCGM/DIT

Introductory note

Short CV

Ms. TOGASHI Mika is a Principal Coordinator, Office of International Programs, PMDA in Japan.

She is a pharmacist and holds a master's degree in Pharmacy.

After working at the Ministry of Health, Labour and Welfare, she joined PMDA and was in charge of QMS (Quality Management System) for medical device and IVD, such as inspections of manufactures and assessments of certification bodies.

Since April 2019 she has been a member of the current division.

Abstract

Introductory note:
Regulatory perspectives for the R&D on COVID-19

It is difficult to prepare emerging disease such as COVID-19 in advance. At the first stage of pandemic, treatment for COVID-19 was not available and medicines approved for other indications were used as off-label use.

Usually, medicine is developed from non-clinical to clinical in a stepwise manner, and it takes for several years. However, in such cases early access of the products is required by citizens, and consequently it is essential to collaborate with regulatory authorities in other countries.

In addition, since R&D, review and launch for COVID-19 medicines and vaccines is conducted within a short time, it is important to monitor them through product life cycle.

As an approach to what I mentioned above, I will introduce regulatory agility for clinical study under COVID-19 pandemic, Special Approval System and RMP System.

Keynote speech

Short CV

Dr. Wataru Sugiura is the Director of the Center for Clinical Sciences, National Center for Global Health and Medicine.
He is also serving as Guest Lecturer and Researcher at the Joint Research Center for Human Retrovirus Infection, Kumamoto University, at the AIDS Research Center, National Institute of Infectious Diseases
And at the Department of Infectious Diseases and Immunology, Nagoya Medical Center.

Dr Waturu Sugiura has a wide working experience form Public Universities, at the National Institute of Infectious Diseases (NIID), and private Pharmaceutical companies.
His research focus mainly on AIDS and other Human Retrovirus infections.

He is serving as Editor of the Journal of AIDS Research (official journal of the Japanese Society for AIDS Research), Acting Chief Director of Japanese Society for AIDS Research, and Editor of AIDS Patients Care and STDs.

He holds a PhD from Hamamatsu University, Japan

He is well published in peer review journals.

Abstract

Keynote speech

Session 2: 15:45 – 17:55

COVID-19 clinical studies
- Learning from front-line health workers-

Chair: Muchanga Sifa, NCGM/DIT
Co-chair: Marlinang Siburian, NCGM/DIT

Short CV

Dr. Mandina Ndona is Associate Professor at the Department of Internal Medicine at University of Kinshasa, DRCongo.

She also serves as the Scientific Director at the Institute for Research in Health Science (IRSS), Senior Coordinator of the Covid-19 Response at the Kinshasa University Clinics and Expert in the National Committee for the elaboration of the COVID-19 treatment guidelines.

She holds a Master of Sciences in infectious Diseases and a PhD from University of Kinshasa. She also holds a Post graduate Diploma in Malaria from the University of the Mediterranean in France.

Abstract

COVID-19 at Kinshasa University Clinics (CUK): Epidemioclinical profile and mortality predictors

The Democratic Republic of Congo declared its first case of COVID-19 on 10 March 2020 in Kinshasa. Several hospitals in the city of Kinshasa have been designated to care for patients with COVID-19, among them the Kinshasa University Hospital (CUK). The response to the pandemic has been slow to take hold, gradually strengthened by the support of traditional partners and the central government. The impact of these interventions has contributed to an improvement in the management of COVID-19 at the CUK.

The objectives of this study were to determine the socio-demographic and clinical characteristics of patients with COVID-19, as well as the associated factors and predictors of mortality.

This is a consecutive case series of all patients admitted to the unit COVID-19 of CUK from 24 MARCH 2020 to 30 JANUARY 2021. A total of 574 patients were admitted to the CTCO on suspicion of COVID-19 of which 411 were confirmed by a COVID-19 RT-PCR test COVID-19.

Two waves were observed with a peak in May and December. The average age was 53 years (extremes 4 months and 88 years). Predominantly male 2M/1F, 52.7% had a severe form, co-morbidities present in 56% (hypertension and diabetes), 91% treated with Hydroxychloroquine and Azithromycin. Lethality was 34.1%, and predictors of mortality were age $\geq$ 60 years, coma, a SaO2 $\leq$ 95%, the severe form of disease.

Conclusion: Male patient aged 50, hypertensive and/or diabetic was the profile of the majority of cases. Very high lethality with early hospital mortality.

Session 2: 15:45 – 17:55

COVID-19 clinical studies
- Learning from front-line health workers-

Chair: Muchanga Sifa, NCGM/DIT
Co-chair: Marlinang Siburian, NCGM/DIT

Short CV

Dr. Jubert P. Benedicto is a pulmonary critical care specialist primarily connected with the University of the Philippines-Philippine General Hospital and Lung Center of the Philippines.

He has been an acknowledged clinician and astute researcher and is very well-respected by his peers and the academic community.

During the COVID-19 pandemic, he has been at the forefront volunteering his expertise especially in the management of hospitalized critically-ill patients.

As head of the Critical Care Units Management Action Team of PGH, he is very instrumental in orchestrating the prompt and crucial response of the whole ICU staff that so far served almost 2,500 patients in the past seven months.

He is also a constant speaker in continuing medical education sessions organized by various professional groups.

He is also active in various media guesting in the Philippines in order to spread accurate information on COVID-19 and its management.

Abstract

COVID-19 MANAGEMENT IN THE PHILIPPINES

University of the Philippines-Philippine General Hospital

COVID-19 has been an elusive pandemic with an enormous and debilitating effect that goes beyond the health of the afflicted individual. Its effect on the society has been crippling. Its management principles have been constantly evolving and implementing them at the clinics and hospital will always need a lot of assistance.

The Philippines is a country made up of over 1,700 islands. Each province has its unique set of challenges in terms of accessibility and available resources. The national government has put out policies that attempted to grapple with this pandemic at various fronts and at all levels. A “whole society approach” is ideal yet very challenging.
A pragmatic framework anchored on science is being tried and adjusted based on contextual realities.

This short session will attempt to provide participants a unique glimpse of the Philippine COVID-19 landscape and its specific set of management dilemmas and potential solutions.

Session 2: 15:45 – 17:55

COVID-19 clinical studies
- Learning from front-line health workers-

Chair: Muchanga Sifa, NCGM/DIT
Co-chair: Marlinang Siburian, NCGM/DIT

Short CV

Dr Vivi Lisdawati is the Director of Human Resources, Education and Operational at Sulianti Saroso Infectious Disease Hospital.

Responsible for facilitating the need of research management at Sulianti Saroso IDH since 2016, including clinical trial on Covid-19 since 2020.

Prior to her current position, She has served as Leads national research on vector borne diseases and national facilities based survey on Privat Clinical Laboratory group.
She was also Research Coordinator for TB group on Indonesian Health National Survey and Principal Investigator on developing molecular diagnostic for rapid detection of Lung TB using specific primers designed based on epidemiology data.
She got national patent as Inventor of the specific primer for LAMP method.

She has been graduated from the Faculty of Pharmacy, University of Indonesia as Pharmacist and Master Degree in Natural Herbal Science Program.
She received the PhD from Faculty of Medicine, University of Indonesia on Biomedical Science Program.

She has been member of many National Organizations including the Material Transfer Agreement committee, The National Biobank Committee, National Consortium on Vaccines Research, etc.

Abstract

What is the contribution of Clinical Trials during COVID-19 era: Opportunities and constraints at hospital site …

During the pandemic of Covid-19, given the new type of Coronavirus (SARS-CoV-2), there was a dilemma about dealing with this situation. Regarding global data in early January 2021 with a total positive case of more than 100 million people and the cure rate around 64 million, clinical trials of management Covid-19 have become a global priority. On the one hand, the protection of health workers must be considered, the strict implementation of health protocols while considering ethics and quality of research is something that must be considered in conducting research.

With more than 1.3 million positive cases and more than 35,000 deaths, the implementation of the clinical trial in Indonesia is part of the main solution to overcoming the Covid-19 problem. Sulianti Saroso Hospital as a referral hospital for infectious diseases in Indonesia has more than 1,100 inpatients who are confirmed positive for Covid-19 by the end of January 2021, with clinical symptoms categories are moderate (72%), severe (15%) and critical (9%).

Several multicenter studies have taken place, including the International Randomized Trial for Additional Care for Covid-19 (WHO Solidarity Trial). The preliminary results have been published in the New England Journal and had been used as an update of WHO's guideline on the clinical management of Covid-19 patients and have also been used at Sulianti Saroso Hospital as part of SOC for patients.

Regarding that the results of clinical trial that are very useful for improving the management of Covid-19 in patients, a number of studies are still being conducted to date, including Convalescent Plasma Transfusion Therapy and the Application of Mesenchymal Stem Cells. Therefore, the opportunities for proper clinical management of Covid-19 is likely to be obtained.

Session 2: 15:45 – 17:55

COVID-19 clinical studies
- Learning from front-line health workers-

Chair: Muchanga Sifa, NCGM/DIT
Co-chair: Marlinang Siburian, NCGM/DIT

Short CV

Dr. Sho Saito is Clinical Researcher and Physician at the Disease Control and Prevention Center, National Center for Global Health and Medicine, Japan

Prior to his current position, He has been a Researcher and fellow at the Shizuoka Cancer Center and at the Department of Infectious Diseases, University of Yamanashi, respectively.

DR Saito is certified Infectious Diseases Doctor and Pediatrician.
He is member of the Japanese Association for Infectious Diseases and the Japan Pediatric Society.

Abstract

The experience of clinical research at the NCGM site

Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) was first reported in China in December 2019, and Japan confirmed its first case of coronavirus disease (COVID-19) in January 2020. In the global pandemic of COVID-19, we have conducted many researches at NCGM and through global collaboration to elucidate the actual status of COVID-19.

We participated in a global clinical trial in collaboration with the US NIH in February 2020, which demonstrated the efficacy of the antiviral drug remdesivir. The research collaboration with the NIH has been continued. We conducted the second trial with the NIH and clarified the efficacy of the immunosuppressive agent baricitinib. As of January 2021, a randomized controlled trial to compare the efficacy of baricitinib to dexamethasone is underway. We are also participating in a global clinical trial to clarify the efficacy of immunoglobulin.

In March 2020, we established a large-scale COVID-19 registry (COVIREGI-JP), and as of January 2021, we have collected detailed clinical information on 24,017 cases at 872 sites in Japan. Characteristics of patients in the country have been clarified, and more information has been gathered through further researches using the registry. Research on COVID-19 sequelae has also progressed, revealing that 27% of patients still have some sequelae four months after onset.

We began collecting plasma from patients who had recovered from COVID-19 in May 2020 and plan a randomized control trial (COVIPLA-RCT) to determine the efficacy in February 2021. We will continue to contribute to the global effort to counter COVID-19 through diligently pursuing research.

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Short CV

Dr. Nisa Tania Tabassum is Master student at the Global and Innovative Medicine, Osaka University

She has been supporting research as Specially appointed researcher at Osaka University.

Her current research focuses on Health risk factors assessment for both non-communicable diseases and communicable diseases among university students in Japan and ASEAN
Prior to joining her current position, She has been a Medical Interpreter.
She holds a Bachelor in dental Surgery from Sylhet M.A.G Osmani Medical College of Bangladesh.

Abstract

Young researcher observations on the management of Covid-19 in Bangladesh

The novel coronavirus (SARS-CoV-2) is holding the headlines worldwide since early 2020 due to its unprecedented speed of transmission and case fatality ratio.

Whilst many developed nations faced impulsive health-system downfall, Bangladesh, a medium income country with overburdened population and fragile medicare infrastructure, tried its farthest to combat the pandemic. Infections remained low until the end of March followed by an accelerated upward trend up to mid-December in 2020.

In the interim, government has executed miscellaneous strategies indexing from COVID-19 classic preventive approaches to nationwide lockdown, educational institution closure, teleworking, foreigner entry bans etc.
Occasional controversies and rumors were not uncommon all-round the period pointing mismanagement, economic loss, insufficient PCR testing, corruption in the healthcare system and frequent death of COVID-19 front liner doctors.

Confronting all those allegations, Bangladesh kept the COVID-19 new case and death tally curve earthward since December 2020 and started Covid-19 nationwide vaccination drive aiming to inoculate 3.5 million people in February 2021.

Regionalization of the healthcare system, combining exhaustive and integrated measures is helping Bangladesh to scrap COVID-19 in a less restricted and non-shutdown situation, with sustaining the economy of the country.

CLOSING NOTE