Palliative Care, Trials and COVID-19 Tribulations

First-hand experience shared by the experts at ground zero

By Institute for Clinical Research, NIH MY

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First-hand experience sharing from the experts at ground zero

Cheng Hoon Chew, Yan Yee Yip, Syahirah Farhana Mohd Saleh, Khairul Nisa' Ishak, Anis Suraya Muhamad Nawawai, Chun Keat Chew, Ting Soo Chow, Richard Boon Leong Lim, Bak Leong Goh, Pik Pin Goh, Kalaiarasu M. Peariasamy

Live Webinar Series on Webinar Series on Demystifying Phases in Clinical Trials & COVID-19 Updates

Published by Institute for Clinical Research, NIH MY, 2021

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PALLIATIVE CARE, TRIALS AND COVID-19 TRIBULATIONS.

First Edition, 2021.

Cite as: Cheng Hoon Chew, Yan Yee Yip, Syahirah Farhana Mohd Saleh, Khairul Nisa' Ishak, Anis Suraya Muhamad Nawawai, Chun Keat Chew, Ting Soo Chow, Richard Boon Leong Lim, Bak Leong Goh, Pik Pin Goh, Kalaiarasu M. Peariasamy (2021) PALLIATIVE CARE, TRIALS AND COVID-19 TRIBULATIONS. Kuala Lumpur, Malaysia: Institute for Clinical Research, NIH MY.
DOI: doi.org/10.5281/zenodo.5497225
ISBN: 9781005279332 (International) / 9789671694046 (Malaysia)

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Preface

The COVID-19 pandemic started more than a year ago, but until today, we did not have a definitive cure for this disease. The SARS-CoV-2 virus constantly mutated over time, infecting more people and causing tremendous stress on the existing scarcity of healthcare resources all around the world.

Here, the experts from ground zero will share their first-hand experience of clinical trials looking for a cure for COVID-19, like the WHO's Solidarity Trial and the role of palliative care in COVID-19 as part of humanitarian crisis management.

This book contains a lightly edited transcript from the live webinar series on Malaysia's experience in WHO's COVID-19 Solidarity Trial and COVID-19 updates in Palliative Care on 21st July 2021. The speakers for this webinar were Dr. Chow Ting Soo, a Consultant Physician and Infectious Disease Consultant at the Hospital Pulau Pinang and Dr. Richard Lim Boon Leong, a Consultant Palliative Medicine Physician and Head of the Palliative Care Unit, Selayang Hospital, Malaysia. Prof. Dr. Goh Bak Leong, a Senior Consultant Nephrologist, also the Head of the Nephrology Department and Clinical Research Centre, Serdang Hospital and Dato' Dr Goh Pik Pin, former director of the Institute for Clinical Research (ICR) co-chaired this webinar session. The transcript was prepared by Ms.Khairul Nisa' Ishak, Ms.Anis Suraya Muhamad Nawawai, Ms.Syahirah Farhana Mohd Saleh, Ms. Yip Yan Yee and Dr. Chew Cheng Hoon from the Institute for Clinical Research, NIH Malaysia. This is intended for sharing among healthcare professionals, not for the public.

The objective of the webinar series was to disseminate clinical knowledge and experts' experience to medical practitioners. This is also a Continuing Professional Development (CPD) activity for all health care providers and allied health personnel in Malaysia. This weekly live webinar was organized by the Institute for Clinical Research (ICR), National Institutes of Health (NIH) Malaysia.

“Solidarity Trial - challenges and success” by Dr. Chow Ting Soo, Penang General Hospital

Thank you, Dato’ Dr. Goh. I am going to share my slides and like Dato’ Goh has already mentioned, this is a very special and unique trial that Malaysia is proud to be one of the countries that are involved in it. I am going to share with you our experiences, the success and challenges, that we met during this whole one year of clinical trial experience.

Introduction

As an introduction, Solidarity Trial is an international clinical trial designed and is led by WHO (World Health Organization) and their partners. The objective is to identify a quick and fast way to an effective treatment for COVID-19. You know that this COVID-19 pandemic started in January of last year, up until today, there is not even one single agent identified which can effectively treat COVID-19, as far as we are concerned right now.

This is one of the largest international randomized trials for COVID-19 treatment, and it enrolled almost 12,000 patients. Out of 500 hospitals signed up, there were about 300 active hospital sites involved in the trial, in over 30 countries.

What is Solidarity Trial?

This is a multi-centre, open-label and randomized trial. It evaluated four medications, which were hoped to treat COVID-19 at that time including (i) Hydroxychloroquine; (ii) Lopinavir/Ritonavir (the brand name Kaletra); (iii) Interferon and; (iv) Remdesivir, versus standard of care.

So, we identified the patients, and they were randomized to receive either Hydroxychloroquine, Kaletra (Lopinavir/Ritonavir), versus Lopinavir/Ritonavir Interferon, and later Interferon only, or Remdesivir.

This trial looked at three important outcomes in COVID-19 patients, where the majority of primary outcomes were (i) mortality in 28 days; (ii) the need for assisted ventilation and; (iii) duration of the hospital stay.

Why Does it Work?

So, why does it work? It actually simplified all the trial procedures. This is because when we were at the peak of the pandemic, we knew that all the doctors in hospitals were very busy. We cannot have a very complicated trial procedure. Hence, all the trial procedures were simplified to be as simple as possible.

Once approval was obtained through the regulatory and ethical board, we used electronic entry to obtain informed consent from the patients, followed by online randomization. All done by computer-based. This has cut short a lot of paperwork process.

Unique Clinical Trial

The inclusion criteria are (i) all confirmed COVID-19 patients; (ii) age 18 years and above; (iii) they must be hospitalized; (iv) able to give consent; (v) not known to receive any of the study drugs; (vi) without anticipated transfer to elsewhere within 72 hours; (vii) in physician's view; there was no contraindication for any study drug.

It included all COVID-19 severity. It can be mild to moderate, or even those patients on oxygen, inclusive patients on a ventilator except those who are critically ill, the clinicians thought the patients will not survive in the next 72 hours. The standard of care arm is according to the local guidelines of each of the countries.

It is very important that each country will have to set its local guidelines because it is the standard of care arm versus investigational product plus standard of care.

For example, the patients in the standard of care arm, including those on steroids or Tocilizumab. Then, the patients on an investigational product arm are allowed to receive steroids or Tocilizumab. This is a special kind of trial design because this is an adaptive trial. This means that, when we see unpromising drugs, these drugs can be dropped, and other drugs can be included.

Hydroxychloroquine and Kaletra or Lopinavir/Ritonavir arms were discontinued on the June 20, 2020 and July 14, 2020 respectively because the committee realized that interim analysis shows futility towards a further development for these two drugs because it did not show any positive outcomes in the prevention to death or prevention to mechanical ventilator days. Interferon was later dropped on October 16, 2020. In the end, we are left with Remdesivir versus standard of care.

Therefore, you can see that in the Solidarity report, the Remdesivir arm actually has over 1,000 patients recruited.

The Success Part of This Trial

The success of this trial was that it streamlined all the trial initiation due to public health emergencies. We know that this pandemic is spreading fast, and we need to come up with a solution, whether it works or not.

This trial managed to get the fastest ethics clearance by the Medical Research and Ethics Committee (MREC) within five days, thanks to Dato' Dr. Goh Pik Pin, former director of Institute for Clinical Research (ICR) and the ICR team's effort. The trial also received fast-tracked Clinical Trial Import Licence (CTIL) clearance by the National Pharmaceutical Regulatory Agency (NPRA), Malaysia within seven days, evaluated by eight reviewers from the NPRA working day and night.

We also received RM81,000 study grant. Centre for Clinical Trial (CCT), ICR located in Ampang Hospital has distributed all the investigational products efficiently to all study sites in four days. Thanks for the teamwork.

Streamlining the Clinical Trial Process

I would like to share with you the timeline (Figure 1). As you can see, none of our clinical trials will get approval this fast. For MREC approval we applied in early April, and we obtained the approval 4 days later. NPRA approval was achieved within seven days. We managed to distribute all the investigational products to the clinical sites within 4 days.

	Project Activity	Start	End	Status
1	MREC approval	06/04/2020	10/04/2020	Achieved
2	NPRA approval	10/04/2020	17/04/2020	Achieved
3	IMP distribution to Sites	4/5/2020	8/5/2020	Achieved

Figure 1: Timeline for Solidarity Trial.

We recruited a total of 217 patients; 63 of them were on Remdesivir, 30 of them were on Hydroxychloroquine, 47 on Lopinavir/Ritonavir, 5 on Interferon, and 72 of these patients were on the standard of care.

We received very good support from nine major MOH hospitals led by Datuk Dr. Suresh Kumar, Infectious Disease (ID) Physician with nine ID Physicians as trial investigators. There were a total of 62 co-investigators facilitated by researchers from the ICR.

Clinical Trial Team

I would like to acknowledge our team members. Without them, this trial will not run as successfully as it is in Malaysia (Figure 2 - 5). We have nine state hospitals as trial sites, led by the infectious disease consultant of that hospital.

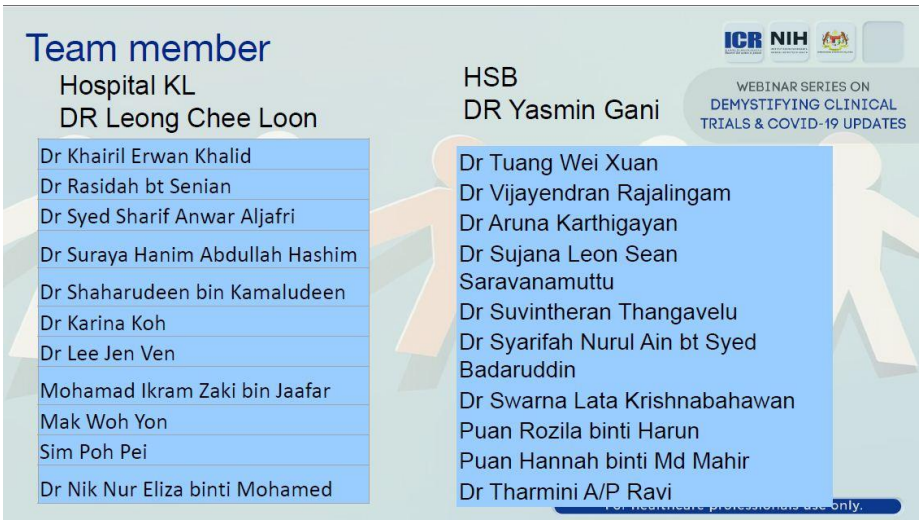


Figure 2: The team member from Kuala Lumpur Hospital and Sungai Buloh Hospital.

Figure 3: The team member from Penang General Hospital and Melaka Hospital.

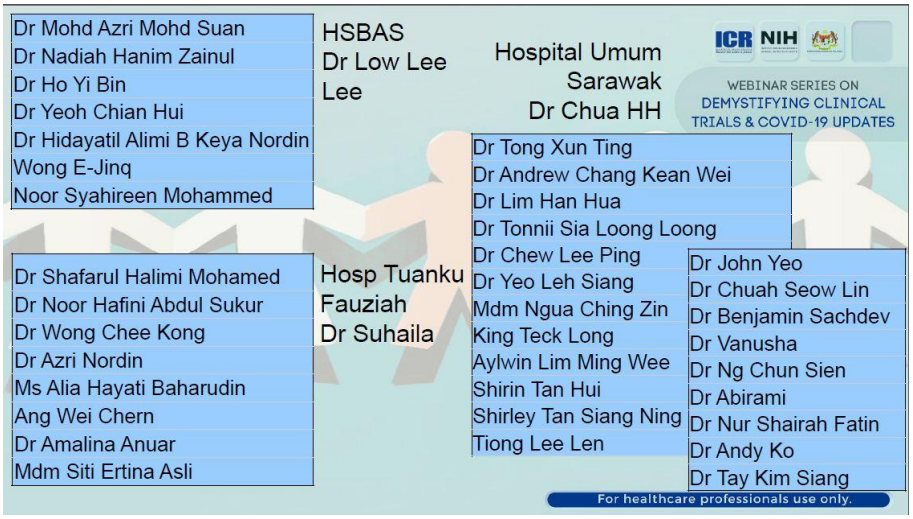


Figure 4: The team member from Sultanah Bahiyah Hospital in Alor Setar, Tuanku Fauziah Hospital in Perlis and Sarawak General Hospital.

Figure 5: The team member from Tengku Ampuan Afzan Hospital and Queen Elizabeth Hospital.

Publication

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 FEBRUARY 11, 2021 VOL. 384 NO. 6

Repurposed Antiviral Drugs for Covid-19 — Interim WHO Solidarity Trial Results

WHO Solidarity Trial Consortium*

ABSTRACT

Figure 6: Research paper of "Repurposed Antiviral Drugs for Covid-19 - Interim WHO Solidarity Trial Results" was published in The New England Journal of Medicine. https://www.nejm.org/doi/full/10.1056/NEJMoa2023184

The final results were published in The New England Journal of Medicine on February 11, 2021 (Figure 6) and it has changed the clinical practice in many countries.

Clinical Trial Innovations

I would like to say that the innovations were so great in this study because this was the first study to allow virtual consent taking.

We only have one hard copy of the consent form for the patient. Once the patient understood and signed the consent, we taught the patient to use a mobile phone - scanner app to take the photo of the consent and save as a PDF file. Then the patient sent the file to our mobile phones, and we uploaded the PDF consent form to the electronic Case Report Form (eCRF) website. Hence, this way, we can minimize COVID-19 exposure of the investigators without compromising the Good Clinical Practice (GCP) principles at the same time.

This trial was one of the largest trials of COVID-19. We have contributed about 200 over patients out of 12,000 patients globally. It had a fast-tracked record in approval.

We had regular meetings with the international counterparts. All the countries agreed to meet because it is a global trial. Some of us had to sacrifice our nighttime because of many countries with different time zones like European countries etc. Every Wednesday at 9:30PM Malaysian time, all the investigators would meet on the Zoom platform. Then we discussed issues about investigational products, re-distribution, eCRF issues, sharing difficulties and success stories among each of the countries.

Monitoring was done by pharmacists and experienced ICR study monitors. We went through a stringent monitoring record as well.

Regarding the web-based CRF, we used Castor's EDC (Electronic Data Capture), a simple data entry system. It started with inclusion criteria of eligibility, then consent file upload. Next, we chose the available investigational product on our site. It has a simple medical history, classification of the COVID-19 disease severity data entry fields. Then, randomization. Later on, we keyed in the treatment outcomes. That's about it. So, it was very adaptive and simple trial data entry without going through the nitty-gritty of traditional long clinical trial paperwork.

Challenges

Shipment of Investigational Product

One of the challenges was that the shipment of investigational products to Malaysia was delayed due to the lockdown locally and internationally, involving other countries.

Temperature excursion - Interferon and Hydroxychloroquine

There was also a need to improve on temperature excursion. I remember that there was one whole batch that was quarantined and not able to be used because the temperature excursion for that batch of medicine was actually exceeded.

Trial administration challenges

There was also trial administration challenges due to time-zone differences with WHO Geneva. We needed to coordinate large-scale trials under MCO, and this was a big challenge.

One of the challenges was busy clinical settings as well. It was very difficult to recruit patients when the doctors were all running around. In terms of consent uploading, patients had to be a bit tech-savvy to take the photo of the consent using mobile scanner app to convert it into PDF file before we can upload to CRF platform.

"Standard of Care" arm

Investigators' concern on "standard of care" arm was one of the major challenges that we had. The standard of care means nothing at all versus an investigational product. Hence, it tends to have a selection bias. The clinicians will try not to recruit the very severe or the critically ill ones as much as possible. As a result, most of the patients recruited were those with milder severity, like on nasal prongs Oxygen. None of our patients recruited were mechanically ventilated from the beginning.

So, we had to overcome these challenges. We had discussions in the team, and shared experiences, and made sure everything was running well.

What is the Next Step?

So, what is the next step?

From Solidarity Trial, we know that Hydroxychloroquine, Interferon, Kaletra (Lopinavir/Ritonavir), and even Remdesivir, may not show any differences in the mortality prevention of the mechanical ventilation days and also hospitalization days.

So, the next step is called Solidarity Plus. We are awaiting approval again. They have three more new drugs that are intended to be used in Solidarity Plus. At this time, more countries will be involved to find a solution together on how to treat COVID-19 effectively.

Hope

We still hope to get antiviral or anti-inflammatory treatment for those who are actually facing cytokine release storms, whether to use anti-TNF (tumour necrosis factor) monoclonal antibodies or any other medications. We are still hoping that Solidarity Plus will give us the answer.

Test, Trace, Treat, Time to Vaccinate

So at this moment, we have no effective treatment available. To control this pandemic, we need to "Test, Trace and Treat" and not forgetting step number four, "time to vaccinate," because I think vaccination is the only way out of this pandemic (Figure 7).

Figure 7: Four steps to control COVID-19 pandemic

Thank you very much.

Reference

Slide presentation: Solidarity trial - challenges and success by Dr. Chow Ting Soo. https://www.slideshare.net/ICRInstituteForClini/solidarity-trial-challenges-and-success

Video: https://www.youtube.com/watch?v=Fr0-KBZX9xA

Podcast: https://www.podpage.com/clinical-updates-in-covid-19/malaysias-experience-in-whos-covid-19-solidarity-trial-palliative-care-in-covid-19/

“Palliative Care in COVID-19” by Dr Richard Lim Boon Leong, Selayang Hospital

Thank you very much, Prof. Dr. Goh Bak Leong for the kind introduction. A very good afternoon, ladies and gentlemen. I am indeed very thankful to the NIH for allowing me to speak this afternoon. What I am going to talk about has nothing to do with demystifying clinical trials, but I do hope that what I have to share may be able to support many of my colleagues and all of us working in the frontline when we face the challenges of day-to-day work in our COVID-19 wards.

Introduction

We know that since the beginning of this year and around March, we have actually had quite a number of cases and a rising number of cases. Today we also know that the situation is indeed quite dire, and a lot of our ICUs are actually more than 100% utilized, and we are actually facing quite a lot of challenges in this current condition. I guess the truth is that when we become quite overwhelmed, we do have a lot of very difficult decisions that need to be made.

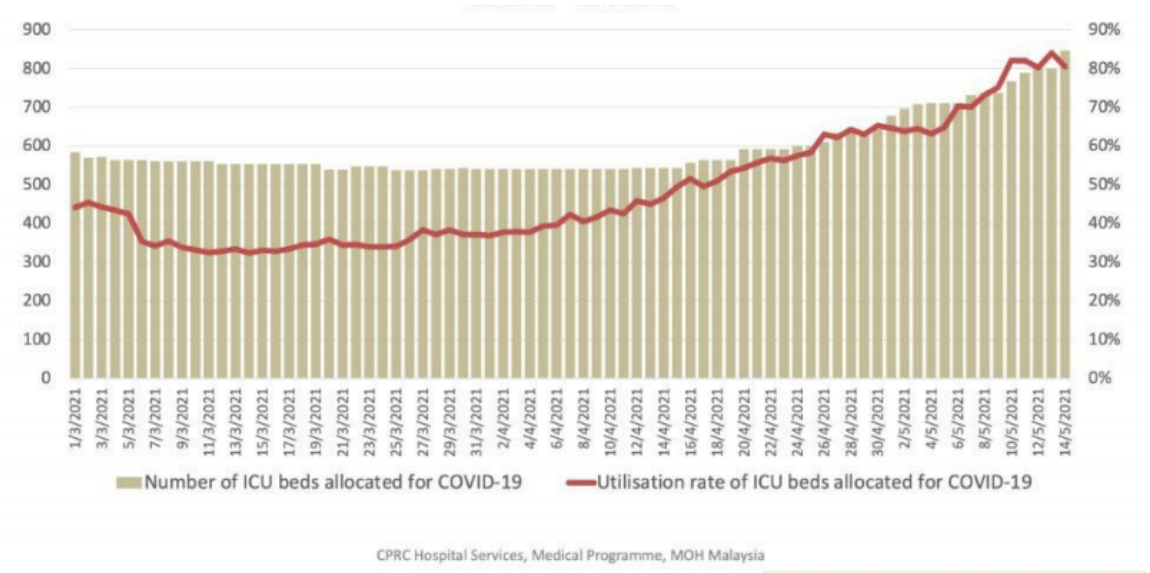


Figure 8: Total ICU beds allocated for COVID-19 patients and the utilization rates (Malaysia) from March 2021 to May 2021

Right from the beginning of the pandemic when it was very severe in Europe and North America, the New England Journal of Medicine (NEJM) actually came up with this publication talking about the challenges of ventilator allocation in a pandemic. Following that, this year in March 2021, the Malaysian Society of Intensive Care came up with a consensus statement "A Clinical Guidance to Decision-making for Critically Ill COVID-19 patients" talking about ICU admission and life-sustaining treatments.

I think that when the situation gets sometimes overwhelmed, that resource limitation creates a situation where we do not want to face a certain situation. Unfortunately, due to these limitations, we have to make difficult decisions. Indeed, the practice of triaging is something worldwide that has been practised in situations of humanitarian emergencies and crisis.

Figure 9: Recommended triage categories in humanitarian emergencies and crises

WHO has guidance to talk about triaging when resources are limited in a crisis. It is indeed something that may have to be accepted. The truth is, palliative care must also be part of that response when we are facing humanitarian emergencies in crisis. It is a tragedy indeed when someone actually passes on because of COVID-19, but it is even more tragic if their pain and suffering is not relieved. While we are working in those very difficult situations, and sometimes we do despair because we do not want to be in this situation, but we should never despair to the point of forgetting our humanitarian duty to care for those who suffer.

Definition of Palliative Care

Palliative care is an approach that improves the quality of life of patients and their families facing problems associated with life-threatening illness. Definitely, severe COVID-19 is indeed a life-threatening condition.

Just a few months before the pandemic actually hit the world in 2020, we actually launched our “National Palliative Care Policy and Strategic Plan 2019-2030”. I think that it is only appropriate that in the time of this pandemic, we still carry on with that duty to care for people, especially in their most difficult situations.

The Role of Palliative Care in COVID-19

The role of palliative care in COVID-19 is actually coming from patients who had pre-existing life-limiting conditions such as incurable cancer, and now they developed COVID-19. They do need to be cared for and that care needs to be continued even when they are in a COVID-19 isolation ward.

The second role would be when patients develop severe COVID-19, and their prognosis is very poor because of the disease severity. We do need to make sure that at the very least we ensure that they are comfortable, keep them calm, and less distressed.

Now, the third role is something that has yet to evolve, and we may be seeing more of this as the pandemic subsides. That would be COVID-19 survivors who develop long COVID syndrome, where they may have prolonged kinds of symptoms of breathlessness and fatigue.

I think that at that time we also really need to look at how we can improve the quality of life for this kind of patient. But for today, I am going to talk about the very acute situation that we are facing right now in our wards, where patients are actually having very severe symptoms and problems.

Who Requires Palliative Care?

When you are going into COVID-19 wards, who are the patients who require palliative care? (i) I think that all patients with severe COVID-19 with low oxygen saturations or on oxygen therapy should be someone that you need to look out for; (ii) any patients who have distressing symptoms of dyspnoea, restlessness, severe cough and pain; (iii) those who have pre-existing advanced malignancies or chronic medical illnesses requiring symptom management and; (iv) for those whereby we feel that the prognosis may be very poor and uncertain, and there may be a situation where for some reason we cannot actually escalate therapy. So, this is where we need to think of palliative care.

Misconception of Palliative Care

Now, I want to explain something because I think that there is often a great misconception about the term "palliative care". People tend to think that it always means something like terminal care or end-of-life care, but I would like to actually kind of clarify this misconception.

Today, we talk about an integrated model of palliative care, where palliative care actually must happen concurrently alongside disease-modifying treatments. Just because the patient still has active interventions, such as antiviral, steroid therapy, and even ventilation support, it is still valid to actually consider palliative care interventions to keep them comfortable throughout their journey, throughout their trajectory as they face this very difficult illness.

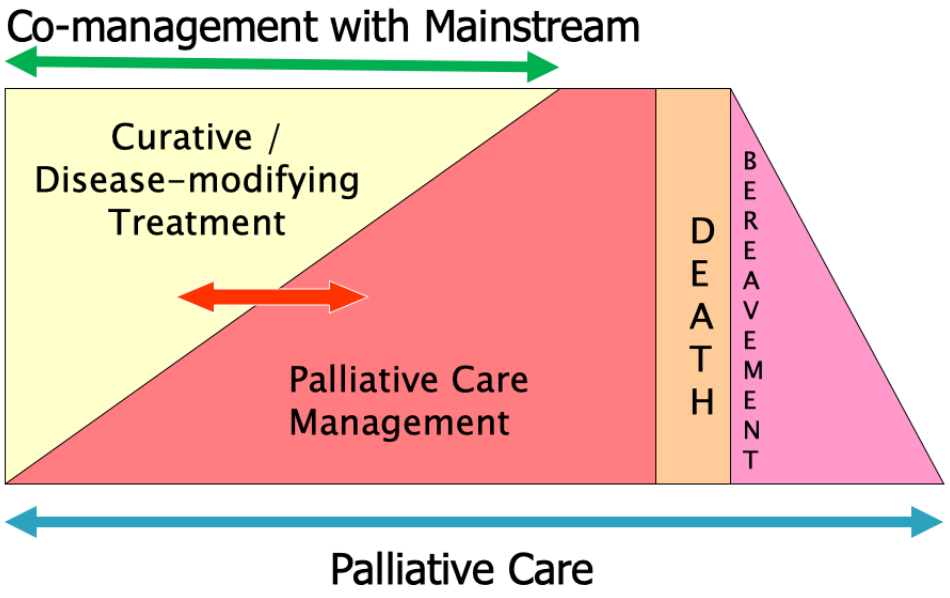
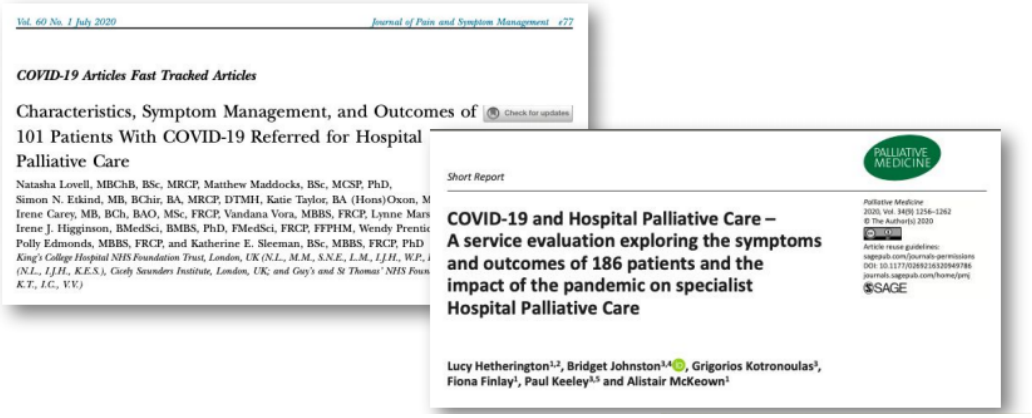


Figure 10: Integrated Model of Palliative Care

What are the Main Distressing Symptoms?



Vol. 60 No. 1 July 2020 Journal of Pain and Symptom Management e77

COVID-19 Articles Fast Tracked Articles

Characteristics, Symptom Management, and Outcomes of 101 Patients With COVID-19 Referred for Hospital Palliative Care

Natasha Lovell, MBChB, BSc, MRCP, Matthew Maddocks, BSc, MCSP, PhD, Simon N. Etkind, MB, BChir, BA, MRCP, DTMH, Katie Taylor, BA (Hons)Oxon, M Irene Carey, MB, BCh, BAO, MSc, FRCP, Vandana Vora, MBBS, FRCP, Lynne Mars Irene J. Higginson, BMedSci, BMBS, PhD, FMedSci, FRCP, FFPHM, Wendy Prentic Polly Edmonds, MBBS, FRCP, and Katherine E. Sleeman, BSc, MBBS, FRCP, PhD

King's College Hospital NHS Foundation Trust, London, UK (N.L., M.M., S.N.E., L.M., I.J.H., W.P., (N.L., I.J.H., K.E.S.), Cicely Saunders Institute, London, UK; and Guy's and St Thomas' NHS Foun K.T., I.C., V.V.)

Short Report

PALLIATIVE MEDICINE

COVID-19 and Hospital Palliative Care – A service evaluation exploring the symptoms and outcomes of 186 patients and the impact of the pandemic on specialist Hospital Palliative Care

Lucy Hetherington[1,2], Bridget Johnston[3,4], Grigorios Kotronoulas[3], Fiona Finlay[1], Paul Keeley[3,5] and Alistair McKeown[1]

Palliative Medicine 2020, Vol. 34(9) 1256–1262 © The Author(s) 2020

SAGE

Figure 11: The main distressing symptoms from two studies done in the United Kingdom.

Two studies were done in the United Kingdom, looking at patients requiring palliative care. They found that breathlessness is the primary symptom, with about 66 - 69% of patients being breathless. The second most common symptom that you actually deal with is agitation/restlessness (42 - 48%), followed by delirium (10 - 24%), cough (4 - 9%), and pain 21 - 22%).

Hospital Selayang's experience N=46 from 1-30 June 2021

Dyspnoea	Delirium & Restlessness	Cough	Pain
31(68.9%)	11(24%)	1 (2%)	3(6.7%)

For healthcare professionals use only.

Figure 12: The percentage of main distressing symptoms shown by patients with severe COVID-19 in Selayang Hospital.

In Selayang Hospital, we have been caring for patients with severe COVID-19 as well and our team has been trying to collect some data. The Figure 12 is some of the data that we have from June 2021. We can see that symptom prevalence is about the same as in those studies from the UK.

Symptom Management in Severe COVID-19

Dyspnoea

Now, I am going to talk about symptom management in severe COVID-19 starting off with dyspnoea, because it is the commonest symptom that you will face. When we look at dyspnoea, we need to actually be able to assess the patient to see how comfortable they are or how distressed they are, and to do that you need to look at the respiratory rate, the use of accessory muscles, SpO_2, and the heart rate whether they are restless or not.

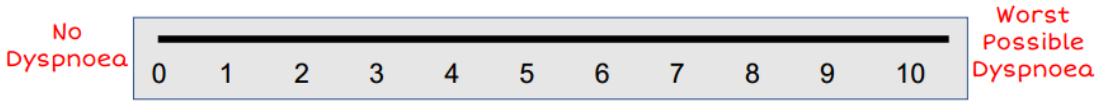


Figure 13: The scale used for dyspnoea management.

If the patient can actually do a self assessment, you can ask them how breathless they are, on a scale of zero to ten. Zero meaning no dyspnoea and ten, the worst possible they can imagine, just like doing a pain score.

For many patients, they may not be able to verbalize, and it is hard for them to understand the dyspnoea score. For such patients, we can use the non-verbal assessment (Figure 14). This is a useful tool. It has eight parameters that you can look at and help you to determine whether someone is very distressed or not, with their breathlessness, looking at the heart rate, respiratory rate, restlessness, breathing patterns, and how they are looking.

NON-VERBAL ASSESSMENT				
Variable	0 points	1 point	2 points	
Heart rate / minute	< 90 beats	90 – 109 beats	≥ 110 beats	*Score 6 or more should be addressed appropriately.* *Medications should be titrated until score below 6.*
Respiratory rate / minute	≤ 18 breaths	19 – 30 breaths	> 30 breaths	
Restlessness: non-purposeful movements	None	Occasional slight movements	Frequent movements	
Paradoxical breathing pattern: abdomen moves in on inspiration	None		Present	
Accessory muscle use: rise in clavicle during inspiration	None	Slight rise	Pronounced rise	
Grunting at end-expiration: guttural sound	None		Present	
Nasal flaring: involuntary movement of nares	None		Present	
Look of fear	None		Eyes wide open, facial muscles tense, brow furrowed, mouth open, teeth together	

Figure 14: The eight parameters used for non-verbal assessment in patients with severe COVID-19.

With these eight parameters, you can have a total of 16 points. How do you use it? Let's say, if you have a score of 6 or more, this patient is not comfortable enough. This patient is actually kind of distressed, and you need to start addressing that appropriately and titrate your medications until the patient gets more comfortable. Normally, that would be a score of less than 6.

Dyspnoea Management

For those who can still swallow, the management of dyspnoea would be to use an Opioid (aqueous morphine) would be the primary or mainstay is 2 - 3 mg, 6 - 8 hourly, and PRN. You can gradually titrate that to 4 hourly and PRN. But many patients when they are very ill, they might have difficulties swallowing, so you can use subcutaneous Morphine, at half of the dose, 1 - 2 mg, 6 - 8 hourly, and PRN, gradually titrate it to 4 hourly.

Sometimes in the wards, the nursing staff can also be very overwhelmed, so it is not easy to give four-hourly medications always on time. Hence, if you want, you can actually use a continuous infusion of subcutaneous/intravenous morphine, and typically we use about 10 - 15 mg over 24 hours.

Now, for those with renal impairments, you can use fentanyl instead of morphine. You can dilute the Fentanyl and make an infusion of 4mcg/h. You can titrate that by increasing the infusion by 2 mcg/h every 6 hours until the patient is more comfortable, and normally you would not need to use more than 12 mcg/h.

If the patient has anxiety, restlessness, and is still distressed, you can add a benzodiazepine like midazolam or lorazepam. Typically, we use a combination in our infusion of morphine, 10 - 15 mg, and midazolam, 5 - 10 mg over 24 hours.

Happy Hypoxemia

Now, just a word about happy hypoxemia. I think that all of us who manage COVID-19, you would have seen this phenomenon where SpO_2 and PaO_2 are low, but the patient does not feel dyspnoeic. In situations like this, you do not need to start the opioids based on the SpO_2 alone, only treat it if the patient is having dyspnoea.

What we know is that patients who have this happy hypoxemia, they actually at some point, when the lung gets worse, they will actually feel dyspnoeic. Sometimes that transition can be very acute and very severe. So, please make sure that you write up subcutaneous Morphine 2.5 mg with Midazolam 2.5 mg PRN to stand by just in case the nurses need to give something to the patient when they become very breathless or restless all of a sudden.

Delirium and Restlessness

Moving on to delirium and restlessness, which is the second most common problem. You may see patients with delirium (i) they have got confused speech; (ii) hallucinations; (iii) reversal sleep patterns and; (iv) trying to get on and off the bed. While restlessness/agitation, (i) they are moving all around; (ii) they are pulling off their lines and their masks and; (iii) they are kicking violently on bed.

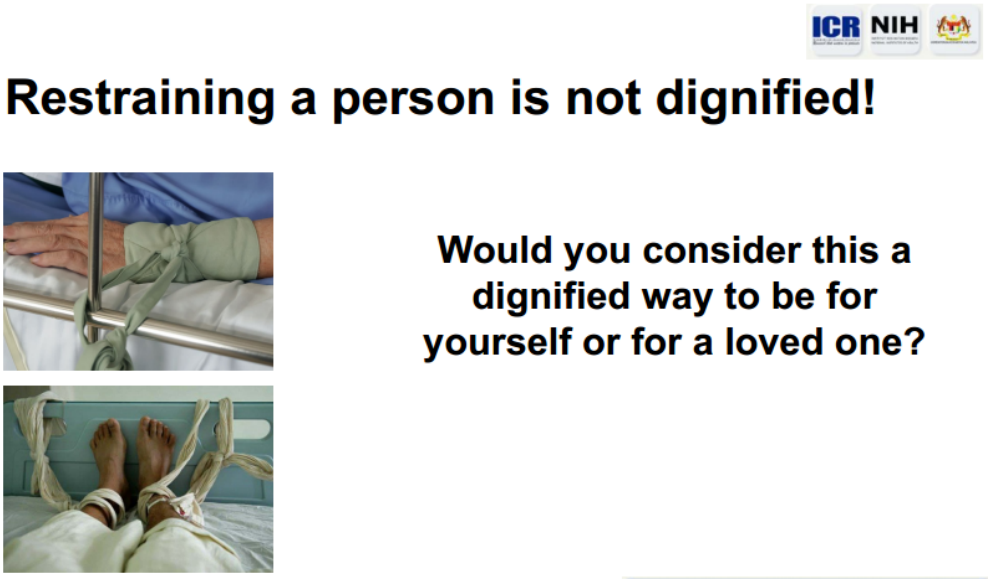


Figure 15: Restrain patients in bed.

So, in situations like this, I think many of you may be familiar with the need to have to restrain patients in a bed. If you look at this, just think about it and consider, do you think that this is a very dignified way for yourself or your loved ones to be at the end of one's life?

So, if we can, we should try and treat the delirium and restlessness. Hopefully then, we may be able to take off those restraints. For delirium, we commonly use Haloperidol 0.5 - 1 mg at night and PRN, you can give it every 30 minutes to 1 hour. You can actually titrate up the dose 1 - 2 mg at night depending on how many PRN doses they take. Most of the time, patients do not need more than 5 mg in 24 hours. It is much less than those with schizophrenia or severe psychosis.

If they are very restless, I would normally prefer to try to get the patient calm immediately by using intravenous Midazolam 0.5 - 1 mg and titrate it every 5 - 10 minutes until the patient is calm. After that, put them on subcutaneous Midazolam 2.5 mg PRN. If they have very persistent restlessness and are still very distressed, then I would consider using an infusion of 10 - 20 mg over 24 hours.

Other Symptoms

Now, other symptoms like pain. If they have got pre-existing pain because they got cancer or something else, I do hope that patients could continue all of their pain medications even while they are in the COVID-19 wards. If the patient is on Morphine, and they develop renal failure, then you can convert to transdermal Fentanyl. For further guidance on the dosages and how to treat, please refer to the CPG on "Management of Cancer Pain" and "Pain Management Handbook" that are available.

Secondly, coughing can sometimes be distressing. Initially, you can use some simple cough syrups, but if it is very persistent, aqueous Morphine 2 - 3 mg TDS/QID is something that can be helpful. Sometimes patients get very distressed at night because they are coughing, and they cannot sleep, so you can give a night dose.

Thirdly, respiratory secretions can also be distressing. We normally use an anticholinergic like Buscopan or Glycopyrrolate, whichever you can actually get.

Are Opioids and Sedatives Safe to Use in Severe COVID-19?

Now, after talking about breathlessness, cough and pain, you can see that Morphine and other Opioids, as well as sedative medications are very important in the palliative management of patients with severe COVID-19. So, these are the medications that would be useful in your ward. Very often I think that clinicians might actually be concerned because patients with severe COVID-19, they are hypoxic. Is it safe to use these medications in severe COVID-19?

So, extrapolating from data which we have in the palliative care setting, when they looked at using these medications in patients with chronic lung disease, like COPD, interstitial lung disease and others. They have concluded that low dose opioids at a dose of up to 30 mg/day, does not increase the kind of complications and mortality in COPD patients even if they have hypercapnia and interstitial lung disease.

The systematic reviews showed that there are no significant or clinically relevant respiratory adverse effects of opioids for chronic breathlessness if we are managing patients appropriately using low doses and titrating it according to the symptoms and need.

Communication

Building a Connection and Rapport in Full PPE

I think this is a very important part of palliative management as well. Because of the pandemic, I think many of us have become very used to wearing full PPE in our wards. This can sometimes seem like a barrier to your connection with the patient, but you can still build rapport with the patient, if you (i) speak clearly and look directly at the patient through your face shield; (ii) allow patients to speak and listen to them; (iii) use gestures of body contact like holding the hand such as kindly touch where appropriate even if you are gloved and gowned; (iv) adjust your position so that you can approximate to the patient's eye level and; (v) learn to use empathic statements to acknowledge emotions like '*I know you must be feeling very frightened here by yourself*' or '*I can see that you are very worried about your father's condition*.'

Phone/Video Family Conferencing

Now, we know that breaking bad news ideally should be done in person, face-to-face, but because of the pandemic, we have also had to learn how to use technology like video conferencing.

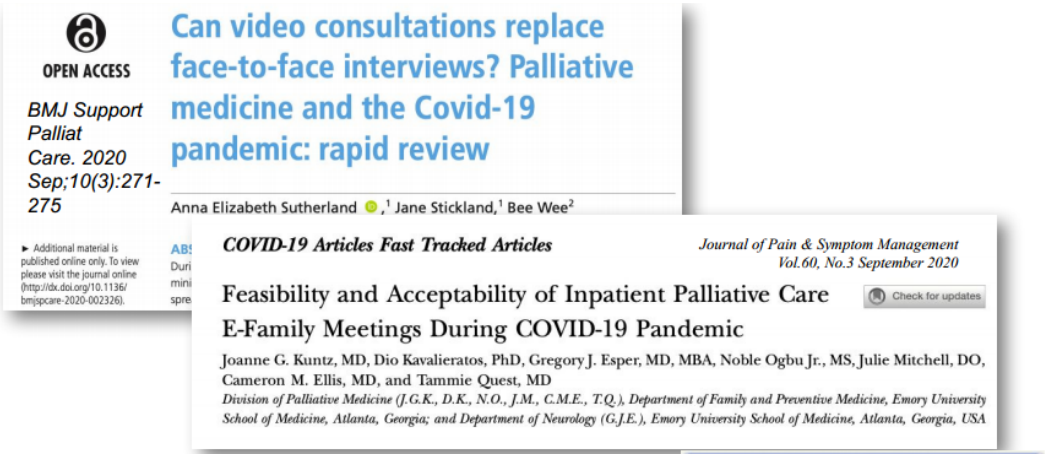


Figure 16: Studies shown the effectiveness of using technology to communicate during palliative care management.

Research has shown that video consultation is effective, accessible, and acceptable to patients and their families in terms of communication. What we also know is that communicating via video consultation can enhance the therapeutic presence of healthcare professionals compared to just a phone call alone. So, for those who actually have access to the internet and if you have a phone or iPad that you can use to do a video call, that would be great.

Breaking Bad News Using SPIKES

Just a bit about breaking bad news. We commonly use a protocol called the SPIKES protocol. It is a six-step protocol. So, you can remind yourself, when you start out, always prepare yourself, make sure you know all the details of the case, introduce yourself and your role in the patient's care.

We should always ensure that the person you are talking to is in a safe place, and you are not calling them while they are driving a car. Then, check what the patient knows, then explain why you are calling them, and fire a warning shot if you are going to give bad news. Then, provide the information without using any medical jargon. Be very clear and direct. Most importantly, acknowledge their feelings and validate their emotions, showing empathy. Finally, you can clarify whatever questions they may have and also tell them when to expect another update.

S- etting	• Prepare and know all details of case. • Introduce yourself & your role in the patient's care. • Ensure they are in a safe place (not driving a car).
P-erception	• check what family knows so far.
I-nvitation	• Explain why you are calling. • Provide a warning shot if you are giving bad news.
K-nowledge	• provide information/bad news, do not use jargon. • Be clear and direct.
E-mpathy	• Acknowledge feelings & validate emotions.
S-ummary	• Clarify any questions they have. • Also tell them when they can expect another update.

Figure 17: The protocol used when breaking bad news to the family of the patients.

Empathy

I just want to highlight something about empathy. I think this is really an important thing to think about when we are facing this kind of situation. Many patients with severe COVID-19 have passed on, they are isolated from their families. Even towards their funeral, they have to stay at a distance. So, just try and imagine how you would feel, if you are not able to be with someone that you truly love, especially in their last moments? What are some of the things that you might wonder.

Was he comfortable?

Was she frightened and feeling all alone?

Was he properly cared for?

Did he have enough to eat?

These are some of the things that families may often think about, and we need to help them find some closure when they are thinking about their family members.

Goals when Video Conferencing with Family Members

When we communicate, it is important that we (i) allow the family to see the patient and his condition; (ii) allow them to speak to the patient. Even if the patient cannot speak back, you can put the phone close to the patient's ear and tell them to just speak into the phone; (iii) reassure the family that the patient is not alone and being cared for and; (iv) clarify any concerns that the family may have.

In the end, the key message that you want to give to them is that the patient is comfortable, calm, not alone, and cared for until the very end. So, that is all I had to say.

Thank you very much, everyone, for your attention.

Reference

Slide presentation: Palliative care in COVID-19 by Dr. Richard Lim Boon Leong. https://www.slideshare.net/ICRInstituteForClini/palliative-care-in-covid19-249823089

Video: https://www.youtube.com/watch?v=Fr0-KBZX9xA

Podcast: https://www.podpage.com/clinical-updates-in-covid-19/malaysias-experience-in-whos-covid-19-solidarity-trial-palliative-care-in-covid-19/

Q&A Session

1. ***Prof. Dr. Goh Bak Leong:*** **What are the new drugs that will be investigated in Solidarity Plus?**

   Dr. Chow Ting Soo:

   Solidarity Plus is currently looking at three medications: (i) anti-malarial drug, Artesunate that suggested that there is an entry inhibitor for the virus to enter the cell. It will be used in intravenous form; (ii) monoclonal antibodies called Infliximab; (iii) Imatinib. These are all anti-inflammatory drugs that the development group found as fairly promising drugs that we are going to use. It will be an open-label, randomized trial versus standard of care. In other words, it is actually at a very early stage right now, as none of the countries have started because we are in the stage of getting approval.

2. ***Prof. Dr. Goh Bak Leong:*** **Is Ivermectin one of the drugs that will be tested in the future Solidarity trial?**

   Dr. Chow Ting Soo:

   The answer is no. It is not in the development group or not thinking of getting Ivermectin onboard.

3. ***Dato' Dr. Goh Pik Pin:*** **Dr. Richard, I know you advocate that patients, although at the end-of-life or with end-organ disease, should go for COVID vaccination. What is the reason for doing that?**

   Dr. Richard Lim Boon Leong:

   Thank you very much Dato' Dr. Goh Pik Pin for the question. I think it is still very important and very valid for someone even if you have some kind of life-limiting condition like an end-organ failure or even cancer, just still be vaccinated. Why? This is because I think that the vaccination can actually help to prevent or protect you from a very severe kind of illness.

   Sometimes in that situation, hopefully you may not actually need to be in a hospital isolation ward. Many patients sometimes get sick, and they are in the isolation ward, and they are away from the family. It is very isolating and kind of miserable to spend that last moment away from their loved ones. We also have cases where people have advanced cancer, and now they developed COVID-19. They would prefer to stay at

home, as you know patients who are Category 1 and Category 2, they still can stay at home, and they can be with their family where they can get the care and the love that they need. When they develop worsening symptoms and become Category 3 or Category 4, some of them have to be admitted to the hospital, and from that point on they become very isolated.

Hence, I think it will be very useful, and we hope that many patients will be able to at least spend more time with their loved ones at home.

4. ***Dato' Dr. Goh Pik Pin:*** **Would MOH consider traditional medicine for COVID-19 trial? For example, Thailand has started *Andrographis Paniculata* in Thailand.**

   Dr. Chow Ting Soo:

   I think I will take this question because it looks like a research basis thing. To all these medications, we cannot use it in the context of treatment because you need real clinical data to support the use. This is because anything that is out of the norms, even though some medications that we repurposed it, it would also need approval from the Director General of Health regarding the use of out of indication use. So whatever it is, we cannot just use it based on anecdotal reports or based on case reports without proper trial evidence.

   In some of our COVID-19 patients, we see they may have transaminitis as well. If we are not careful with the use of these medications, then the alanine aminotransferase (ALT) can go up very high. So, is it because of the medication that caused the ALT to go up very high, or could it be the COVID-19 disease instead?

   Hence, I will still think that for all the medicines that we want to use, we must have some basic evidence to show that it is beneficial before we just use it.

5. ***Prof. Dr. Goh Bak Leong:*** **Dr. Chow, let's go back to this Solidarity Trial. We know that this WHO trial is a Phase 3 and Phase 4 clinical trial design during an emergency, as you mentioned. So that it can fast track. It is also repurposing or repositioning the existing medications for new indications, and it is also adaptive. It is much more welcome during this pandemic.**

   However, we must admit that there are quite a number of detractors regarding this trial. The very fact that during the early implementation of this trial, I think they were on, off and then on again regarding Hydroxychloroquine. For example, the position

statement and then subsequently withdrawal of other interventional drugs, even though the enrolment is very simplified. Therefore, when the preliminary result was published, it received quite a number of criticisms. Would you like to comment on that? Do you think that this type of trial has its inherent weakness or is a strength?

Dr. Chow Ting Soo:

It's either way. It's a double-edged sword. I would say that Dr. Goh BL is very sharp but in order for us to come to a conclusion, I think adaptive trials like solidarity is the way to go in the pandemic.

The design of the trial is to get us 'fast and furious' to get a result to know whether it worked or not, but at the same time it is a drawback because some of us are biased because it is an open-label study. In fact, I would have to admit that a lot of clinicians avoid recruiting patients who are a little bit more severe category because we are worried if it gets randomized into standard of care. This is our country's experience.

If you look at the overall percentage of the patients recruited in the solidarity trial, in terms of oxygen requirement, if it is quite high (30%-40%).

So, I would say that it is needed, and it is beneficial that we need to do this in order to get the answer fast, and we can actually go and move on to see and look for another medication rather than dwelling onto a drug that might not be effective.

Furthermore, we know that Hydroxychloroquine has a lot of arrhythmias issues. So, at that time, we actually look at the QTc intervals. In fact, doctors and medical officers were taught about QTc and everybody was actually measuring the QTc at that time. I still remember all those painful ECG readings and my medical officer had to take the photo from the mobile phone, and we calculated the QTc intervals.

Prof. Dr. Goh Bak Leong:

I agree with you, Dr. Chow. Whether a treatment works or not, should leave it to science rather than popular demand. I think that is what is the concern currently as there are a lot of people trying to lobby for treatment A, treatment B to be used in patients. We should stick to science.

6. ***Prof. Dr. Goh Bak Leong:*** **I have a question for Dr. Richard. We know that this is a very challenging time. Healthcare professionals usually very much rely on in-person as well as non-verbal cues to facilitate our communication to judge empathy and compassion. You have mentioned that there is a role for remote**

communication, but I think remote communication is challenging for people, particularly with low literacy as well as those with very few digital literacy skills or people with hearing problems, especially during this COVID-19 pandemic. Would you like to share with us how you overcame this?

Dr. Richard Lim Boon Leong:

Alright, thank you very much, Dr. Goh Bak Leong. Well, I would say that, I won't say that we can overcome it to make it ideal to the normal setting that we are used to. Of course, there will always be those challenges of not being able to have that certain body language, but I do think that you can try and optimize whatever you can use.

Sometimes we can try to speak clearly and try to modulate our voice. Sometimes with certain body gestures, you may not have that body language, when we are actually on the video conferencing, you still can use your facial expression and your intonation of voice to try and build that sense of rapport with the person you are communicating with. I think that the patient's families do understand the limitations that we have, and I feel that well from our experience. The communication that we had, while it may not be optimal, but I think that people can still be appreciative.

I think most importantly, we have to be very sincere about what we say. We need to assure them that we are doing what we can, and we are not abandoning your loved one. I think that is one of the things that people fear the most, the fear of abandonment. We need to reassure them by telling them that we are there, and we will be caring for your loved one. Whatever we need to do, we will try to ensure that the patients will always be comfortable, which also is our primary goal. I guess that is what you can do, and I do hope that if we say this and really mean it, people will accept it and understand it.

7. ***Prof. Dr. Goh Bak Leong:*** **Currently in Malaysia, is there any palliative care guidance or clinics for long COVID-19 syndrome experienced by COVID-19 survivors?**

Dr. Richard Lim Boon Leong:

Well, in terms of palliative care guidance, yes, there are quite a few guidelines that you can actually refer to. We have come up with some guidance from Selayang Hospital, and recently we put it up on the internet to try and give people something to use.

What you say is very true, that I think healthcare workers do feel very stressed because we are facing a situation where we want to do the best that we can for patients. Sometimes there are so many limitations, and we are so overwhelmed, but I

think that when we are not able to do the best that we have been trained to do, sometimes it can be very demoralizing. So if we can, at least provide comfort, care and dignity to our patients. At least, I hope that provides some form of comfort also to our colleagues, especially to the younger doctors who feel "*what are we doing?*" or "*are we doing enough?*" So, at least we can do that bare minimum.

I think there were a few questions also mentioned long COVID-19. From the definition, they talked about it being patients who have prolonged symptoms more than 12 weeks or 3 months. I think that we don't have the data on the percentage of patients who have long COVID-19 syndrome just yet. Things are still evolving, but what we are seeing right now are patients who have had very severe and organizing pneumonia. Many of them are still very breathless on oxygen, and it takes quite a while for them to wean off the oxygen. It requires a lot of rehabilitation. We do not have the definite answers on how long the symptoms will last; how long it takes for them to recover, or whether these will be very long-term and persistent. Right now, the more desperate need is actually dealing in the acute setting.

8. **Is there a possibility for COVID-19 patients who are in Category 1 (asymptomatic) to develop long COVID-19 symptoms later on? Have there been such cases in Malaysia?**

   Dr. Chow Ting Soo:

   I think Dr. Richard already mentioned the data is very scarce for Malaysia. But when you look at international trials, it is not rare and uncommon for asymptomatic patients to actually experience long COVID-19 symptoms, especially anxiety and depression. I think, it is because people avoid those patients who were diagnosed with COVID-19 positive. That is the reason why most of them who are in Category 1 and are asymptomatic would experience long COVID-19 symptoms in terms of mental health. Overseas data showed about one fifth of them or 20%, but this is not pertaining to those who are long-term oxygen-therapy group of patients. As you know, long COVID-19 symptoms can have mental illness.

9. ***Dato' Dr. Goh Pik Pin:*** **Is there any cut-off point at which stage palliative patients are not suitable for COVID-19 vaccination?**

   Dr. Richard Lim Boon Leong:

   I did a previous webinar on the vaccination on palliative care*, you can refer to that. But what we talked about was that what is most important is the prognosis of the person. You need to be familiar with some of the prognosticating tools which you can use. If you estimated that this patient would not survive more than one month, then

probably you would not recommend vaccination, as they would not survive long enough to have the vaccine to be effective. Normally, if we think the patient has at least 2 to 3 months of survival, then perhaps they would benefit from vaccination.

*Note:
If you are interested to find out more about the webinar on COVID-19 vaccination for palliative care, please visit this webpage:
https://clinupcovid.mailerpage.com/resources/z5s9z0-covid-19-vaccination-overview-wha

Closing Remarks

Dr. Richard Lim Boon Leong

I do hope that all of my colleagues out there who are working really hard to care of all our patients in wards, (I'm taking care of a COVID-19 ward as well, and I do know how tiring it can be) do remember that humanitarian duty that we have to care for people who are suffering. Sometimes, it might feel like there is so much more that we have to do; if we can just do that minimum, I think people would at least feel better about it, and they will appreciate it. Thank you.

Dr. Chow Ting Soo

I would like to thank the audiences who have listened to us. I would like to emphasize that most of us who are treating COVID-19, we know we are agitated when there is no known medication that can prevent the progression. In fact, if we know there is one, we will use it; but we have to use evidence-based and not emotionally based. I would like to re-emphasize that everything we do has to be based on evidence-based medicine and science. Thank you.

Dato' Dr. Goh Pik Pin

Since I'm representing the community hospice, I would like to say the same message when our hospice doctors and nurses visit patients or have a video conference. It is very sad to see the end of life patient whom the family is taking care of so well at home, then they suddenly get infected with COVID-19. Hence, they need to be sent away to hospital. It is heartbreaking because when they go to the hospital, it will certainly not be the same as how the family is taking care of their loved ones at home. Also, due to the body condition, most likely, they will not be able to pull through. So, when the ambulance takes their loved one away, it may be the last time they see the patient alive.

Therefore, we plead to all healthcare workers, take care of yourself, your family, your seniors at home and tell people to take care because it is such a situation now that we certainly had to take care of ourselves and our mental health. I see many young doctors out there (referring to webinar participants), do take care of yourself and your mental health. Talk to people if you need help.

I would like to thank our speakers and all of you who are here. Please join us next week for Dato' Dr. Chang Kian Meng, Consultant Haematologist at Sunway Medical Centre, who was also the former Chairperson of Medical Research and Ethics Committee (MREC) when he was working with MOH Malaysia. He will talk about

“Introduction to Phase 2 & 3 clinical trials”. Next, we also have Dr Salina Abd Aziz, Technical Service Head of Psychiatry and Mental Health Services and the Chairperson of Medical Research and Ethics Committee (MREC). She will talk about “Social Media, the New Tool in Clinical Trial”.

With that, I want to thank Prof. Dr. Goh Bak Leong and the big strong team in ICR who made the webinar such a success and shared important information and first hand, personal experience which cannot be obtained from the textbook. Prof. Dr. Goh Bak Leong and I are most happy to have chaired this session.

If you can’t watch this webinar live, you can look into the website. Thank you very much.

Prof. Dr. Goh Bak Leong

Thank you. It was a wonderful session. Thank you for having me.

The Panellists

Moderators

Prof. Dr. Goh Bak Leong is a Senior Consultant Nephrologist. He is the Head of Nephrology Department and Clinical Research Centre, Serdang Hospital, Malaysia. He is an internationally recognized expert in interventional nephrology. He has published numerous original articles in international peer-reviewed journals in the field of general nephrology, dialysis and transplantation. He has presented a great number of scientific papers in international meetings and congresses.

He is the Local Chair of the World Congress of Nephrology 2022 in Kuala Lumpur (WCN'22) and the Co-Chair of 17th Congress of the Asian Society of Transplantation (CAST 2021). He has published and presented a great number of scientific papers in peer review journals, international meetings and congresses. He is also the Editor of Malaysian Dialysis & Transplant Registry. He is instrumental in introducing nephrologist initiated PD catheter insertion programme in Malaysia and many neighbouring countries. He has served as a member of Working Party on PD Access Guidelines and also dedicated as an international trainer of PD to the nephrologists from Asia Pacific such as Singapore, Brunei, Indonesia under ISPD Asian Chapter fellowship programme.

Dato' Dr Goh Pik Pin, former director of the Institute for Clinical Research (ICR), has served as a medical doctor and Ophthalmologist at MOH since 1988. Dr. Goh is currently one of the directors of Kasih Hospice Foundation. She retired from civil service in 2020, and currently she dedicates her time in charity work and spirituality.

She found her calling in providing a free service for people who need end-of-life care, as well as encouraging the public to adopt a positive outlook on death. Her wish is to see more compassionate community where people help each other In meaningful living and peaceful death.

Recently, she volunteered and helped in the first NGO COVID-19 National Immunization Programme (NIP) at the KL Tzu-Chi Jing Si Hall.

Speakers

Dr. Richard Lim Boon Leong is a Consultant Palliative Medicine Physician and Head of Palliative Care Unit, Selayang Hospital.

He is the National Head of Service for Palliative medicine in the Ministry of Health Malaysia and the chairman for subspecialty fellowship training committee in Palliative Medicine. He is also the assistant secretary in Malaysian Hospice Council. Dr Richard is a Senior Lecturer and Examiner for Advanced Diploma in Palliative Care nursing Curriculum, MOH.

Dr. Chow Ting Soo is currently Consultant Physician and Infectious Disease Consultant at the Infectious Disease Unit of the Hospital Pulau Pinang, Malaysia. She is also the Penang State Infection Prevention and Control Coordinator since 2016.

She has served on the working committee's for Clinical Practice Guidelines for HIV infected pregnant ladies and Clinical Practice Guidelines in Dengue Management. Dr Chow has been appointed as committee members for Pandemic Influenza Preparedness Plan for Penang State, and also hospital level. She is also a member of antimicrobial team (AMT) in Hospital Pulau Pinang and is interested in Antibiotic Stewardship Program at hospital level.

She has also been appointed to be the lead Investigator in Malaysia for WHO Solidarity trial in COVID-19 pandemic. Dr Chow has also gained experience as an invited speaker at several local and regional conferences including National AIDS Congress 2008, International Infectious Disease Forum 2011 and many more. She has also participated in a number of clinical research trials for HIV treatments and antibiotics in the past 10 years and has been published in international peer reviewed journals.

Click the link below to view the panellists' information and details of the webinar:
https://clinupcovid.mailerpage.com/resources/w5b4h7-palliative-care-in-covid-19-malay

How to join the webinar?
No need to register. Just join us live on the designated date and time using your preferred social media account or one of the options below. Don't forget to use app.sli.do to ask questions. As usual our event code is **#hcsmMY**

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About the Publisher

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National Institutes of Health (NIH), Ministry of Health Malaysia,

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The COVID-19 pandemic started more than a year ago, but until today, we did not have a definitive cure for this disease. The SARS-CoV-2 virus constantly mutated over time, infecting more people and causing tremendous stress on the existing scarcity of healthcare resources all around the world.

Here, the experts from ground zero will share their first-hand experience of clinical trials looking for a cure for COVID-19, like the WHO's Solidarity Trial and the role of palliative care in COVID-19 as part of humanitarian crisis management.

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