

“Responding to the Pandemic Together” Programme

Event 22: Key considerations for developing COVID-19 treatments: learning from the past and planning for the future

Delivered by the FIP Pharmacy Practice Research Special Interest Group



Moderator

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@VGC_AF



Welcome to the “Responding to the Pandemic Together” events

FIP’s Special Online Programme on COVID-19

These webinars aim to

- I. Provide relevant information and the pharmacy workforce on Coronavirus SARS-CoV-2/COVID-19
- II. Share and discuss strategies and approaches adopted across pharmaceutical Organisations – in response to the pandemic - including our Member States
- III. Describe sector or area-specific approaches adopted across pharmaceutical science, practice and education
- IV. Engage frontline workers of pharmaceuticals and how they know about the realities facing them around the world.
- V. Discuss the implications of the pandemic on supply, shortages that have been exacerbated by COVID-19, and
- VI. Consider the impact of this disease on patients across age groups and with concurrent conditions.
- VII. Assess and discuss the evidence behind treatments and the process of developing therapies, vaccines and tests.



To share ideas on webinar topics we should feature, or if you'd like to share your story on dealing with the pandemic please email

lina@fip.org

Important Links & Resources

FIP Covid-19 Information Hub

A comprehensive FIP webpage containing all of our resources and outputs relating to COVID-19, including recordings of previous webinars.

Link: <https://www.fip.org/coronavirus>

FIP Facebook Group: “COVID-19 & pharmacy”

Link: <https://www.facebook.com/groups/covid19andpharmacy/>

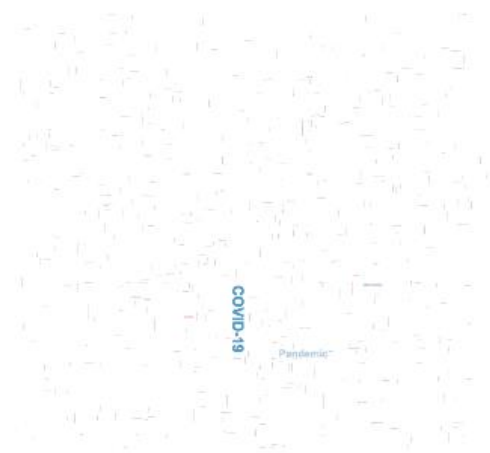


Announcements

FIP Digital Events House Rules

1. This webinar is being recorded and live streamed on Facebook
2. The recording will be **freely available** at www.fip.org/coronavirus and on our YouTube channel
3. You may ask questions by typing them into the Q&A box
4. Your feedback is welcome (webinars@fip.org)

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Economic Clinical

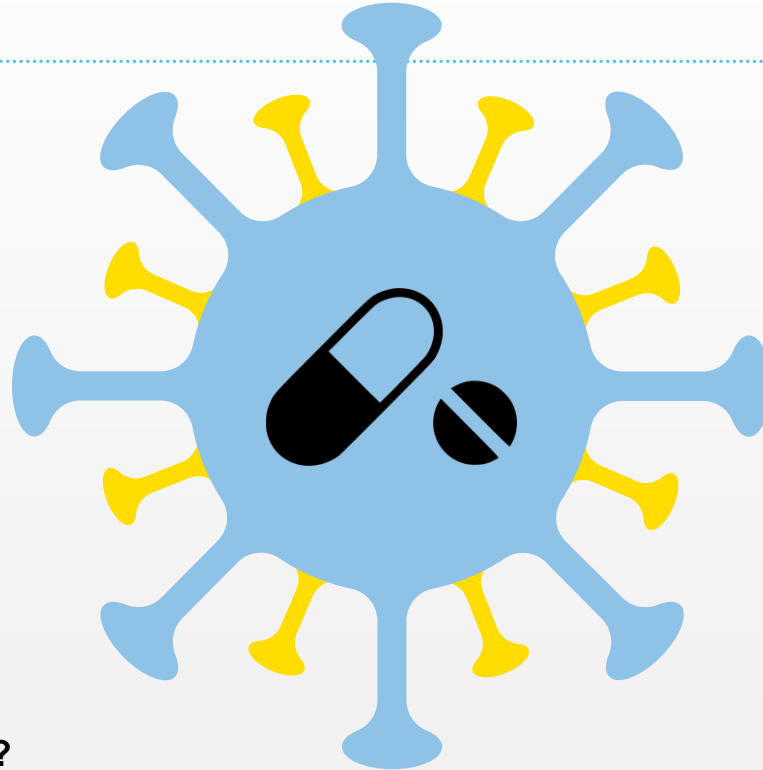
Remdesivir stockpiling?

Remdesivir vs dexamethasone?

Cost effectiveness of antivirals for influenza-like illnesses?

What are the costs and economic implications from the health care system perspective?

What is the disease burden of COVID-19?



What is the current evidence on COVID-19 treatments?

What are the key clinical trials?

What are the Solidarity trial (WHO) and Recovery trial (UK) assessing?

Repurposed vs novel drugs?

Learning Objectives

- To evaluate the current state of clinical research and the potential for developing curative treatments for COVID 19
- To summarise the key consideration when developing treatments for pandemics of respiratory illnesses
- To assess the potential clinical and economic value of COVID19 treatments

Speaker 1

Syed Shahzad Hasan, PhD

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Shahzad_Tweets



COVID-19 Pandemic

Background

- A novel coronavirus, identified as severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), has caused an outbreak of the novel coronavirus disease 2019 (COVID-19) in December 2019.
- No pharmaceutical products have yet been shown to be safe and effective for the treatment of COVID-19.
- Drugs for COVID-19 treatment
 - Repurposed drugs
 - Novel drugs?
- Drugs for the management of critical COVID-19 cases
- Vaccines for Prevention

COVID-19 Pandemic

Different Phases and Transmission

Phases	Transmission	Treatment	Preventative measures
Asymptomatic	?	-	mask wearing + physical distancing
Pre-symptomatic	Possible	-	mask wearing + physical distancing
Mild	Possible	Symptomatic treatment Hospitalised? Standard care? Trial drugs?	mask wearing + physical distancing
Moderate	Possible	Hospitalised Standard care Trial drugs	mask wearing + physical distancing
Severe	Possible	Hospitalised Standard care Trial drugs	mask wearing + physical distancing

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COVID-19 Pandemic

Key Clinical Trials

SOLIDARITY TRIAL (WHO)


- As of 3 June 2020, more than 3500 patients have been recruited in 35 countries, with over 400 hospitals actively recruiting patients.
- Remdesivir
- Lopinavir/Ritonavir and
- Lopinavir/Ritonavir with Interferon beta-1a
- Hydroxychloroquine (dropped)

RECOVERY TRIAL (UK)

- Over 11,000 patients have been randomised to the following treatment arms, or no additional treatment:
- Lopinavir-Ritonavir
- Low-dose Dexamethasone
- Hydroxychloroquine (dropped)
- Azithromycin Tocilizumab
- Convalescent plasma.


COVID-19 Pandemic

Repurposed drug/therapy

Drug	Evidence
<p>Treatment Chloroquine (CQ) and hydroxychloroquine (HCQ)</p> <p>Control/Comparator Placebo Usual care Lopinavir/ritonavir</p> 	<p>Antimalarials and disease-modifying antirheumatic drug for rheumatoid diseases.</p> <p>Investigated after the first SARS-CoV infection</p> <p>Both drugs have demonstrated in vitro antiviral activity against SARS-CoV-2 (Liu et al., 2020; Wang et al., 2020; Yao et al., 2020)</p> <p>Clinical use of CLQ in the treatment of COVID-19 associated pneumonia in China (Gao et al., 2020)</p> <p>First trial on thirty-six COVID-19 patients with a mixed sample of asymptomatic or mild or moderate or severe cases (Gautret et al., 2020).</p>


COVID-19 Pandemic

Repurposed drug/therapy

Drug	Evidence
<p>Treatment Chloroquine (CQ) and hydroxychloroquine (HCQ)</p> <p>Control/Comparator Placebo Usual care Lopinavir/ritonavir</p> 	<p>Eight trials on HCQ/CLQ: six on treatment and two on prophylaxis.</p> <p>Results are conflicting, lacked statistical significance and baseline disease severity or comorbidities in many cases, and recruited a fairly small patients group.</p> <p>RECOVERY TRIAL No significant difference in the primary endpoint of 28-day mortality (25.7% HCQ vs. 23.5% usual care). There was also no evidence of beneficial effects on hospital stay duration or other outcomes.</p> <p>SOLIDARITY TRIAL WHO Solidarity Trial dropped HCQ</p>


COVID-19 Pandemic

Repurposed drug/therapy

Drug	Evidence
Treatment Lopinavir/Ritonavir	Lopinavir was identified as having in vitro inhibitory activity against SARS-CoV, (Chu et al, 2004; Chen et al, 2004; Wu et al, 2004)
Control/ Comparator Standard care	No significant difference between Lopinavir/Ritonavir and standard care or arbidol (umifenovir) in mild/moderate COVID-19 for incidence of viral negative conversion at D7 (Li et al, 2020) .
 The image shows the packaging for Kaletra (Lopinavir/Ritonavir). On the left is a white cardboard box with an orange band, labeled 'Kaletra® Lopinavir/Ritonavir 200 mg/50 mg 120 film-coated tablets'. To the right is a white plastic bottle with a white cap, also labeled 'Kaletra® Lopinavir/Ritonavir 200 mg/50 mg 120 film-coated tablets'. In front of the bottle are three yellow, diamond-shaped tablets.	No significant difference between Lopinavir/Ritonavir and standard care for incidence of viral negative conversion at D7 and incidence of clinical improvement at D7 (Cao B, 2020): . Osborne et al (2020) found no clear benefit for the use of lopinavir-ritonavir compared to standard of care in severe COVID-19


COVID-19 Pandemic

Repurposed drug/therapy

Drug	Evidence
<p>Treatment Lopinavir/Ritonavir</p> <p>Control/ Comparator Standard care</p> 	<p>RECOVERY TRIAL</p> <p>A total of 1596 patients were randomised to lopinavir-ritonavir and compared with 3376 patients randomised to usual care alone.</p> <p>No significant difference in the primary endpoint of 28-day mortality (22.1% lopinavir-ritonavir vs. 21.3% usual care).</p> <p>No evidence of beneficial effects on the risk of progression to mechanical ventilation or length of hospital stay.</p>


COVID-19 Pandemic

Repurposed drug/therapy

Drug	Evidence
Treatment Remdesivir	Remdesivir is a broad-spectrum antiviral (Wang et al, 2020).
Comparator Placebo	Lower efficacy in comparison to monoclonal antibody therapies in Ebola virus disease (Mulangu et al)
	No significant difference for viral negative conversion, clinical improvement, clinical recovery and all-cause mortality at D7 and D14-D28 (Wang Y et al, 2020) No significant difference for time to death among moderate to critical cases but found significant difference for clinical recovery and for all-cause mortality at D14-D28 (Beigel et al, 2020) Clinical use in severe cases of COVID-19 in a hospital setting or as emergency use in critically ill COVID-19 patients

COVID-19 Pandemic

Repurposed drug/therapy

Drug	Evidence
Treatment Favipiravir (FPV)	FPV selectively inhibits RNA polymerase, which is necessary for viral replication
Control Group Arbidol Lopinavir/Ritonavir Darunavir/Cobicistat Baloxavir	Clinical recovery rate does not significantly differ between FPV group and Arbidol group (61% vs 52%) for total, moderate (71% vs 56%) and severe patients (6% vs 0%) (Chen et al)
	No significant difference for clinical improvement among mild/moderate patients between FPV vs Lopinavir/Ritonavir + Arbidol + Interferon-a or Baloxavir for viral negative conversion or clinical improvement (Lou Y et al). A significantly higher improvement rate in chest imaging and faster viral clearance in FPV arm plus interferon- α than LPV/RTV group plus IFN- α (Cai et al)

COVID-19 Pandemic


Novel Drugs and Targets

Drug	Evidence
Novel drugs	<p>β-D-N4-hydroxycytidine (NHC, EIDD-1931) - broad-spectrum antiviral activity against various unrelated RNA viruses including influenza, Ebola, and CoV</p> <p>Sheahan et al discovered that NHC</p> <ul style="list-style-type: none">• potently inhibits coronavirus replication in cell lines• is highly active against coronavirus in primary human airway epithelial cell cultures• is effective against remdesivir (RDV)-resistant coronaviruses



COVID-19 Pandemic

Novel Drugs and Targets

Drug	Evidence
Novel drugs	<p data-bbox="454 300 1742 371">Add-on approach to dismantle the host cell machinery that enables the virus to infect the host cell and spread from one cell to another</p> <p data-bbox="454 436 1742 507">Host cell proteases as potential drug targets – Glycopeptide antibiotics (Teicoplanin), Factor Xa inhibitors (rivaroxaban, apixaban & edoxaban), etc</p> <ul data-bbox="454 573 1742 644" style="list-style-type: none"><li data-bbox="454 573 1742 606">• Dexamethasone inhibits protease activity (Crossland et al., 2010)<li data-bbox="454 606 1742 644">• HCQ/CLQ inhibits protease activity by increasing endosomal pH (Wang et al., 2020) 

COVID-19 Pandemic

Novel Drugs and Targets

Drug	Evidence
Novel drugs	
Neutrophil Elastase Inhibitors (e.g sivelestat)	<p>Fig. 1 Mechanism of action of neutrophil elastase inhibitors in COVID-19. indicates block. ARDS acute respiratory distress syndrome</p>

Speaker 2

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Disclaimer

- The views expressed in this presentation are my own and not those of my employer(s)
- No conflicts of interests to declare

COVID-19 Pandemic

The “infodemic”

- Over 2400 clinical studies related to COVID-19 (ClinicalTrials.Gov)
- Over 28,400 publications using the keyword “COVID-19”(PubMed)



Credit: WHO/Sam Bradd

COVID-19 Pandemic

From trials to Market



- *Regulatory approval*
 - *Randomised controlled trials (RCTs)*

- *Post-Marketing Surveillance*
 - *Observational studies*

• *Market access*

- *Clinical effectiveness evidence*
- *Cost effectiveness evidence*
- *Budget impact*

• *Clinical Guidelines*

- *Clinical effectiveness evidence*
- *(Cost effectiveness evidence)*
- *(Budget impact)*

Pharmaceutical Benefits Scheme



TLV

TANDVÅRDS- OCH
LÄKEMEDELSFÖRMÅNSVERKET

IQWiG



Zorginstituut Nederland

NICE National Institute for
Health and Care Excellence



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Research and Development Costs and funding for ongoing trials

Cost of drug development

- The median cost of bringing a new drug to market was **\$985 million**, and the average cost was **\$1.3 billion**.
- Previous studies have placed the average cost of drug development as high as **\$2.8 billion**.
- Public funding (NIH, NIHR, WHO) enabled R&D into COVID-19 treatments to be accelerated



COVID-19 Pandemic

Speed vs Rigour

Speed is Not Always a Good Thing!

- This is the time for global and national payers to revert to known and tested mechanisms such as health technology assessment (HTA) for assessing comparative clinical and cost effectiveness of medical technologies, placing their faith on evidence, value for money, and due process.



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Healthcare Technologies and COVID-19: Speed is Not Always a Good Thing

JUNE 29, 2020

Kalipso Chalkidou, Damian Walker, Richard Sullivan, Edwine Barasa, Dalia Dawoud, Francis Ruiz, Benjamin Uzochukwu, Y-Ling Chi, Peter Baker, Hiral Anil Shah, Justice Nonvignon and Amanda Adler

https://www.cgdev.org/blog/healthcare-technologies-and-covid-19-speed-not-always-good-thing?fbclid=IwAR2jo98ZLSvhkATeNImix-MpJXW7Dx7Gdmq9xKoab04gBN-mX6vO_LEvyCs

COVID-19 Pandemic

Speed vs Rigour

High-profile article retractions

- The Lancet and New England Journal of Medicine
- Hydroxychloroquine for the treatment of COVID-19
- Confusion and knee-jerk reactions!



ADVANCING PHARMACY WORLDWIDE



WHO halts hydroxychloroquine trial for coronavirus amid safety fears

3 June



Malaria drug taken by Trump could raise risk of death and heart problems, study shows



WHO to resume hydroxychloroquine trial after earlier halt over safety concerns

4 June

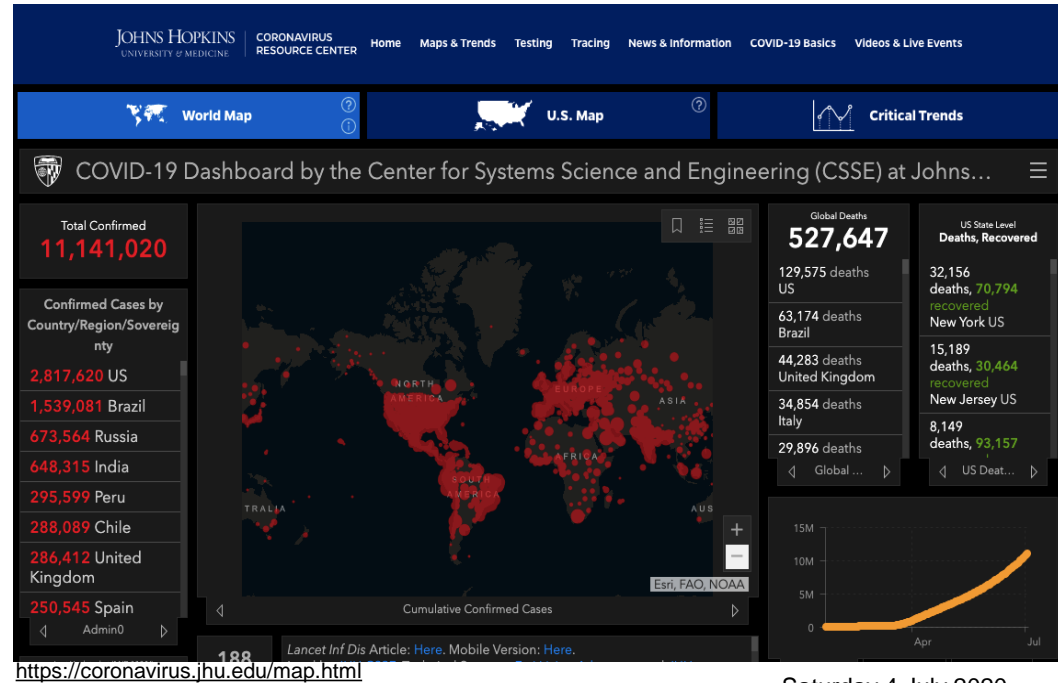


Questions raised over study claiming drug linked to higher rate of mortality and heart problems in Covid-19 patients

COVID-19 Pandemic

The disease burden

- Over 10 million cases & 500,000 deaths worldwide
- Excess mortality and quality-adjustment
- Complications and long-term damage (VTE, pulmonary fibrosis, new onset diabetes, neurological and psychological impact)



Saturday 4 July 2020

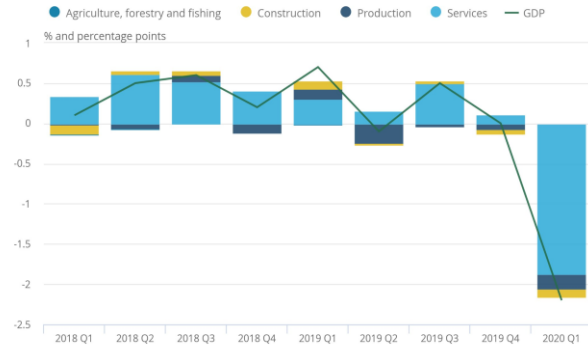
COVID-19 Pandemic

The economic impact

From local to global level

There was a widespread fall in output across the services, production and construction sectors in the first quarter

UK, Quarter 1 (Jan to Mar) 2018 to Quarter 1 (Jan to Mar) 2020

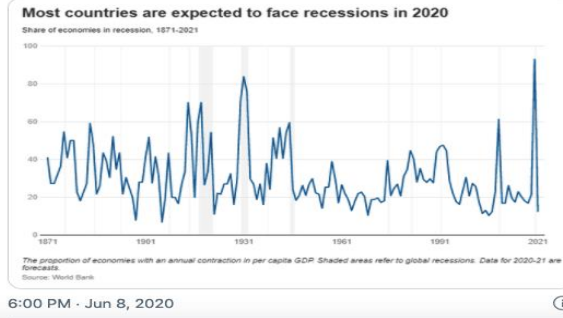


Source: GDP quarterly national accounts, UK: January to March 2020

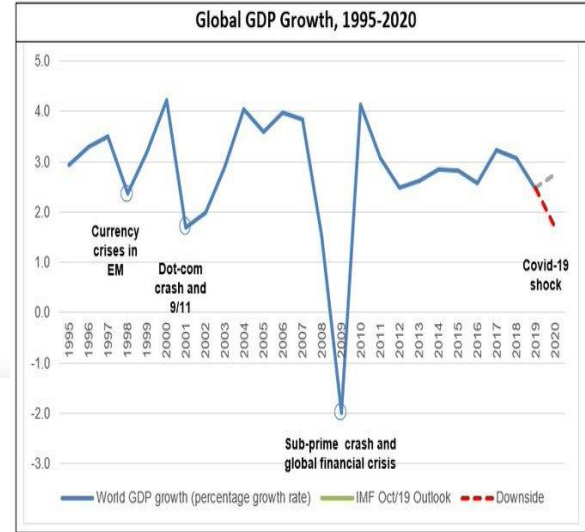
Office for National Statistics



The #COVID19 pandemic shock is expected to cause the global economy to contract 5.2% this year—the deepest recession since WWII. The speed of forecast downgrades suggests a further downward revision is possible.
[wrlid.bg/hODC50A1XQ4 #WBGEP2020](https://www.worldbank.org/en/news/press-release/2020/06/08/global-gdp-growth-2020)



6:00 PM · Jun 8, 2020



The coronavirus outbreak could cost the global economy up to \$2 trillion this year. (U.N.)

COVID-19 Pandemic

The value of a death averted

- Average fiscal value per death of **Int\$ 444,626***
- As of Saturday 4 July 2020, **Total of Int\$ 234,630,918,704**

A comparison of fiscal value of human lives lost from COVID-19 in China: assuming China's and world's highest life expectancies (in 2020 Int\$ or PPP)

Age group	Fiscal value of human lives lost at 3% discount rate and assuming the China's average life expectancy of 76.4 years (Int\$)	Fiscal value of human lives lost at 3% discount rate and assuming world's highest life expectancy of 87.1 years (Int\$)
25–49 years	584,440,699	659,302,851
50–64 years	256,924,436	351,570,998
65 years and above	82,981,659	142,929,376
Total	924,346,795	1,153,803,224
Average fiscal value per death	356,203	444,626
Average fiscal value per person in population	0.655895	0.819

*Kirigia, J. M., & Muthuri, R. (2020)

COVID-19 Pandemic

Cost effectiveness of antivirals- a review

- **Aim:** inform COVID-19 drug development efforts and identify key drivers of cost effectiveness

- **Methods:**
 - **Systematic review** of published **economic evaluations** of **antivirals** (as a class) for *pandemics and outbreaks of influenza-like illnesses*

 - Search first run on 26 March 2020 (currently being updated) and limited to recent 10 years.

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Cost effectiveness of antivirals- Findings

- **Findings:**

- *14 full economic evaluations from **USA, Australia, UK, France, Netherlands, Canada and China***
- *Compared **antiviral treatment** to other **pharmaceutical and non-pharmaceutical** strategies including **vaccination, antiviral prophylaxis, social distancing, school closures as well as combinations of these strategies***
- *All covering use in the **H1N1** outbreak*

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Cost effectiveness of antivirals- Findings

- **Findings:**
 - The most commonly-used regimen **oseltamivir** 75 mg given twice daily for 5 days.
 - In 3 studies, **zanamivir** was used in a sensitivity analysis. Other agents used included **peramivir**
 - **Antiviral treatment** was found to be either **cost saving** or **cost effective** at the study-specific willingness-to-pay thresholds.
 - **Empirical** treatment or treatment based on **clinical judgment** emerging as the most likely to be cost effective compared to **test-guided treatment**
-

COVID-19 Pandemic

Cost effectiveness of antivirals- Key considerations

- **Antiviral treatment** assumed to start early (48 hours from start of symptoms)
- Main **drivers** of cost effectiveness:
 - *Antiviral effectiveness*
 - **Prevalence**
 - *Viral basic reproduction number (**R0**)*
 - *Case fatality rate (**CFR**)*
 - *Level of **adherence** to other non-pharmaceutical strategies (e.g. social distancing, hand washing)*
 - **Antiviral cost**

COVID-19 Pandemic

Timing is key!

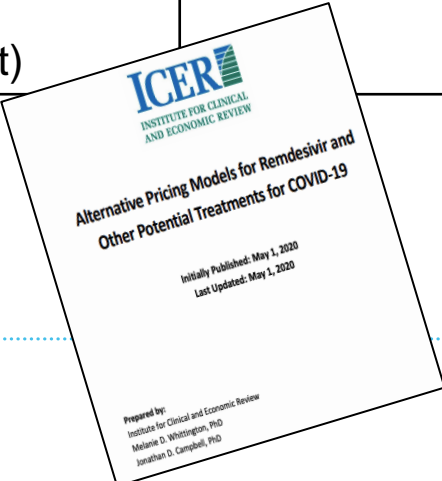
remdesivir	vs	dexamethasone
<p>The NEW ENGLAND JOURNAL of MEDICINE 22.05.2020</p> <p>ORIGINAL ARTICLE</p> <p>Remdesivir for the Treatment of Covid-19 — Preliminary Report</p> <p>J.H. Beigel, K.M. Tomashek, L.E. Dodd, A.K. Mehta, B.S. Zingman, A.C. Kalil, E. Hohmann, H.Y. Chu, A. Luetkemeyer, S. Kline, D. Lopez de Castilla, R.W. Finberg, K. Dierberg, V. Tanson, L. Hsieh, T.F. Patterson, R. Paredes, D.A. Sweeney, W.R. Short, G. Touloumi, D.C. Lye, N. Ohmagari, M. Oh, G.M. Ruiz-Palacios, T. Benfield, G. Fätkenheuer, M.G. Kortepeter, R.L. Atmar, C.B. Creech, J. Lundgren, A.G. Babiker, S. Pett, J.D. Neaton, T.H. Burgess, T. Bonnett, M. Green, M. Makowski, A. Osinusi, S. Nayak, and H.C. Lane, for the ACTT-1 Study Group Members*</p>	<p>medRxiv 22.06.2020</p> <p>THE PREPRINT SERVER FOR HEALTH SCIENCES</p> <p>Effect of Dexamethasone in Hospitalized Patients with COVID-19: Preliminary Report</p> <p>Comments (12)</p> <p>Peter Horby, Wei Shen Lim, Jonathan Emberson, Marion Mafham, Jennifer Bell, Louise Linsell, Natalie Staplin, Christopher Brightling, Andrew Ustianowski, Elias Elmohi, Benjamin Prudon, Christopher Green, Timothy Felton, David Chadwick, Kanchan Rege, Christopher Fegan, Lucy C Chappell, Saul N Faust, Thomas Jaki, Katie Jeffery, Alan Montgomery, Kathryn Rowan, Edmund Juszczak, J Kenneth Baillie, Richard Haynes, Martin J Landray, RECOVERY Collaborative Group</p> <p>doi: https://doi.org/10.1101/2020.06.22.20137273</p> <p>This article is a preprint and has not been peer-reviewed [what does this mean?]. It reports new medical research that has yet to be evaluated and so should not be used to guide clinical practice.</p>	
<p>Branded (Gilead Sciences)</p>	<p>Generic</p>	
<p>200 mg day 1, 100 mg days 2–10 (IV)</p>	<p>6 mg, once daily for up to 10 days</p>	
<p>Hospitalised patients with severe COVID-19 (Multinational, n=1063)</p>	<p>Hospitalised patients with severe COVID-19 (UK, n=6425)</p>	

COVID-19 Pandemic

Timing is key!

Remdesivir	vs	Usual care
Mortality: Hazard ratio: 0.70 (0.47–1.04) (NS) Median recovery time: – 4.0 day (NS)		-
Value-based price (VBP): \$4,460 per course of treatment* (assuming mortality benefit)		-

*ICER, May 2020



COVID-19 Pandemic

Timing is key!

Remdesivir vs Dexamethasone	
<p>Mortality: Hazard ratio: 0.70 (0.47–1.04) (NS) Median recovery time: – 4.0 day (NS)</p>	<p>Mortality: reduced by ~20-33% depending on subgroup Age-adjusted rate ratio: 0.83 (95% CI: 0.74-0.92)</p>
<p>VBP: \$2,520 - \$2,800 per course of treatment* Assuming mortality benefit</p>	<p>\$14.87 per course of treatment*</p>

*ICER, June 2020

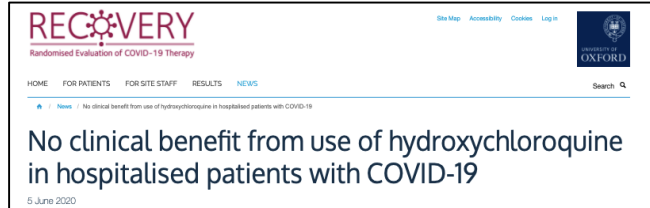


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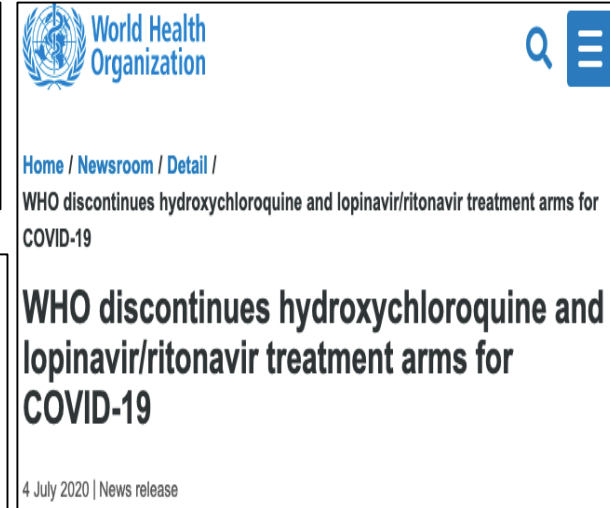
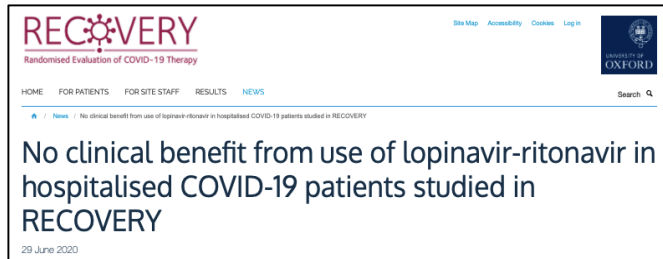
Choosing Wisely!

If not effective, it is not cost effective

- Hydroxychloroquine



- Lopinavir/ritonavir



In hospitalised patients with severe COVID-19

COVID-19 Pandemic

Supply and demand

- **Repurposed** drugs and their use in **other indications**
- **Manufacturing capacity** is a rate limiting step
- **Stockpiling** and **export restrictions**



Copyright: FeatureChina 2020

US secures world stock of key Covid-19 drug remdesivir

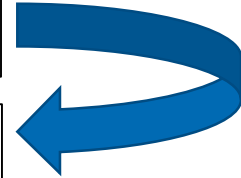
No other country will be able to buy remdesivir, which can help recovery from Covid-19, for next three months at least



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Australia secures stockpile of coronavirus drug remdesivir after US hoards supplies



COVID-19 Pandemic

Remdesivir stockpiling - Should the rest of the world really care?

No:

- Likely **overpriced given its efficacy data**

\$2,340 for 5-day course

“Future studies of remdesivir, including earlier treatment in patients with COVID-19 and higher-dose regimens or in combination with other antivirals or SARS-CoV-2 neutralizing antibodies in those with severe COVID-19 are needed to better understand its potential effectiveness.”

(Wang et al. 2020)

- Production **cost-recovery price** estimated to be \$10 per 10-day treatment course *(Hill et al. 2020)*



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US purchases world stocks of Remdesivir—why the rest of the world should be glad to be at the back of the queue

July 3, 2020

The remdesivir story may actually be good news for the rest of the world, argues James M Brophy  149 

<https://blogs.bmj.com/bmj/2020/07/03/as-the-us-purchases-world-stocks-of-remdesivir-why-the-rest-of-the-world-should-be-glad-to-be-at-the-back-of-the-queue/>

COVID-19 Pandemic

Remdesivir stockpiling - Should the rest of the world really care?

Generic manufacturing

Voluntary Licensing Agreements for Remdesivir

Gilead has signed non-exclusive voluntary licensing agreements with generic pharmaceutical manufacturers based in Egypt, India and Pakistan to further expand supply of remdesivir. The agreements allow the companies – Cipla Ltd.; Dr. Reddy's Laboratories Ltd.; Eva Pharma; Ferozsons Laboratories; Hetero Labs Ltd.; Jubilant Lifesciences; Mylan; Syngene, a Biocon company; and Zydus Cadila Healthcare Ltd. – to manufacture remdesivir for distribution in 127 countries. The countries consist of nearly all low-income and lower-middle income countries, as well as several upper-middle- and high-income countries that face significant obstacles to healthcare access. The regulatory approval status of remdesivir varies by country, and the distribution of remdesivir within each country listed below is subject to local laws and regulations.

<https://www.gilead.com/purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir>

COVID-19: Hetero, Cipla get nod to manufacture, market antiviral drug remdesivir

Cipla and Hetero Labs have already entered into non-exclusive licensing agreements with US pharma giant Gilead Sciences, which is the patent holder of the drug remdesivir.

India's Hetero prices generic remdesivir for Covid-19 treatment at Rs5,400 per vial

India has approved the generic versions made by Cipla and Hetero for restricted emergency use in severe Covid-19 cases.

INDIA Updated: Jun 25, 2020 13:11 IST

Feature: Egyptian pharmaceutical firm produces antiviral Remdesivir to distribute in 127 countries

Source:Xinhua Published: 2020/7/3 11:26:5



 A lab technician holds the coronavirus disease (COVID-19) treatment drug "Remdesivir" at Eva Pharma Facility in Cairo, Egypt, June 25, 2020.

COVID-19 Pandemic

Remdesivir stockpiling - Should the rest of the world really care?

But:


- As a **principle**, should not be acceptable
- Good to have an **alternative** for those who can't have **dexamethasone**

“No-one is safe until everyone is safe”

COVID-19 Pandemic

Be prepared, more to come!

Comparative effectiveness studies- Real-World Evidence



Project SCYLLA


SARS-Cov-2 Large-scale Longitudinal Analyses

Objective: The aim of this study is to assess the comparative safety and effectiveness of all emerging drug therapies used in COVID-19 treatments ...



- ... administered during hospitalization and prior to intensive services.
- ... administered during hospitalization after initiating intensive services.
- ... administered after COVID-19 positive testing and prior to

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Safety of hydroxychloroquine, alone and in combination with azithromycin, in light of rapid wide-spread use for COVID-19: a multinational, network cohort and self-controlled case series study

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This article is a preprint and has not been peer-reviewed [what does this mean?]. It reports new medical research that has yet to be evaluated and so should not be used to guide clinical practice.

COVID-19 Pandemic

Be prepared, more to come!

- Consider **effectiveness and safety results alongside costs**, and compare to **all relevant alternatives** not only “doing nothing”
- Collect data on **resource use and costs** alongside clinical outcomes
- **“Living” cost effectiveness analyses**
 - *“Living” economic models that can be updated with new data as they emerge*



COVID-19 Pandemic

Take-home messages

- Keep up to date with the “**key**” **clinical trials (SOLIDARITY and RECOVERY)**. These are the ones that will shape the COVID-19 treatment landscape.
- Innovative **pricing approaches** need to be considered to guarantee **access** and **affordability**
- Consider trials for **mild-moderate** COVID-19

Thank You!

Question Time

Please use the chat board to log your questions & comments.



Thank you for participating!

Please provide your feedback through the 4-question survey that will appear to you at the end of the event