

COVID-19 Update

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Questions

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- Prescriptions for zithromax and hydroxychloroquine have skyrocketed across the nation. Is there any role for these medications for outpatients, either prophylactically or for treatment? Please also discuss other treatments being advocated such as zinc.

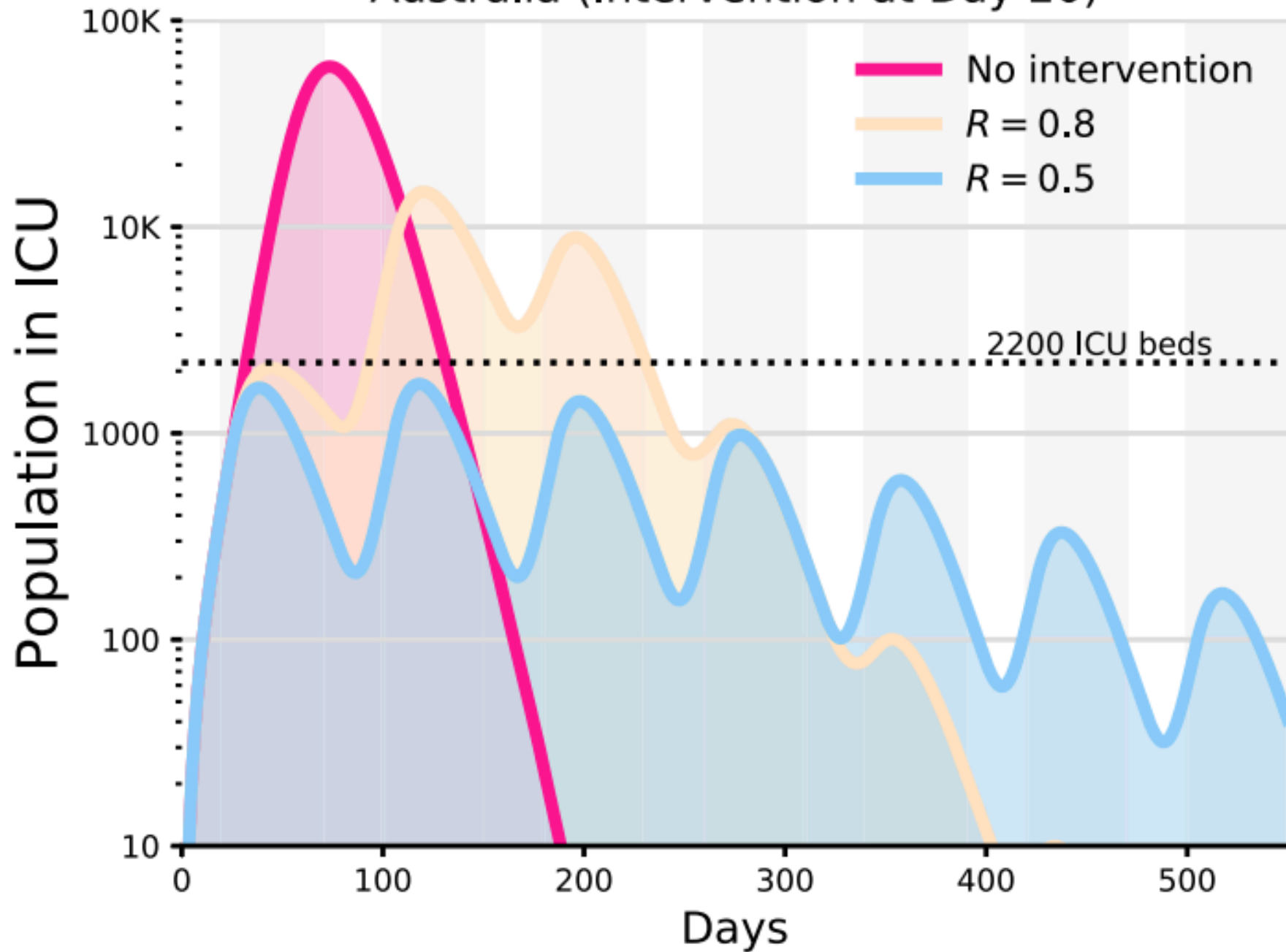
Dynamic interventions to control COVID-19 pandemic: a multivariate prediction modelling study comparing 16 worldwide countries

- Non-pharmacological interventions (NPI) have been the mainstay for controlling the COVID-19 pandemic.
- While NPIs are effective in preventing health systems overload, these long-term measures are likely to have significant adverse economic consequences
 - Many countries are currently considering to lift the NPIs
- Dynamic NPIs, with intervals of relaxed social distancing, may provide a more suitable alternative,
 - But the ideal frequency and duration of intermittent NPIs, and the ideal “break” when interventions can be temporarily relaxed, remain uncertain
- Multivariate prediction model, based on up-to-date transmission and clinical parameters, to simulate outbreak trajectories in 16 countries, from diverse regions and economic categories.
- In each country, we then modelled the impacts on intensive care unit (ICU) admissions and deaths over an 18-month period for following scenarios:
 1. No intervention
 2. Consecutive cycles of **mitigation** measures followed by a relaxation period
 3. Consecutive cycles of **suppression** measures followed by a relaxation period.

Dynamic interventions to control COVID-19 pandemic: Definitions

1. **Mitigation cycle:** a combination of measures, such as general social distancing measures, hygiene rules, case-based isolation, shielding of vulnerable groups, school closures or restricting of large public events; target $R = 0.8$ followed by
 - a) Relaxation period comprising of case-based home isolation of positive cases and shielding of vulnerable groups
2. **Suppression cycle:** Additional measures of strict physical distancing, including lockdowns; target $R = 0.5$ followed by
 - a) Relaxation period (as defined above)
3. Continuous suppression measure with no relaxation.

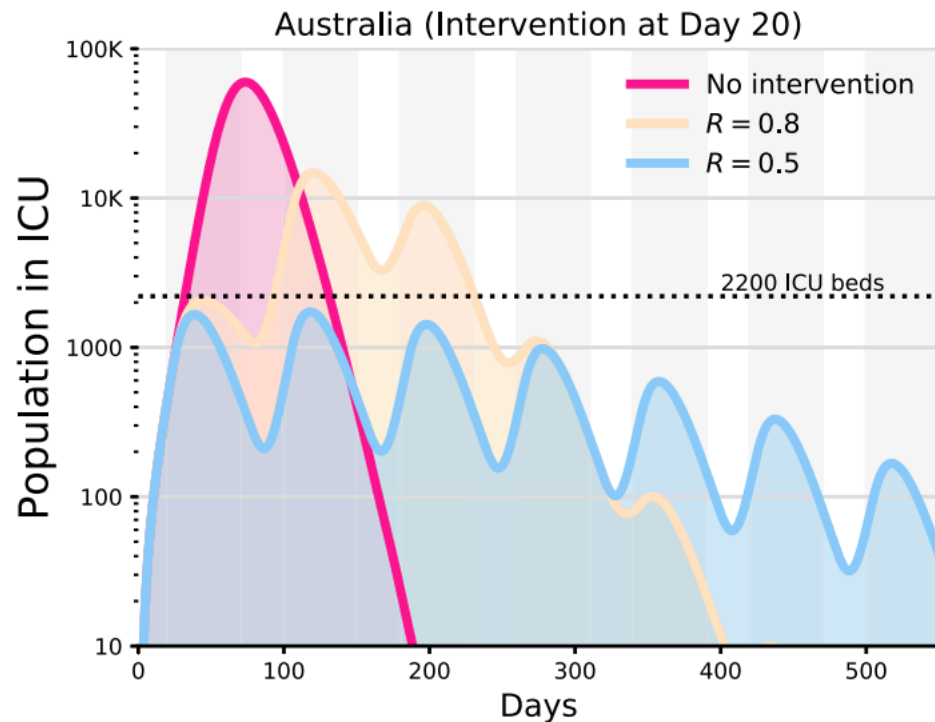
Australia (Intervention at Day 20)



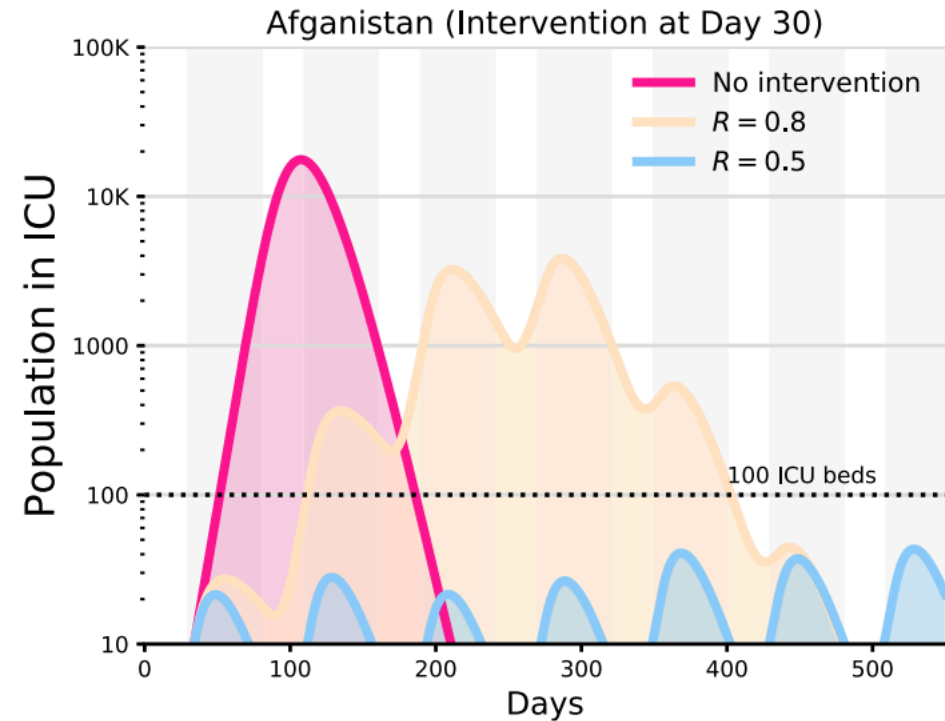
Dynamic interventions to control COVID-19 pandemic: a multivariate prediction modelling study comparing 16 worldwide countries

European Journal of Epidemiology (2020) 35:389–399 <https://doi.org/10.1007/s10654-020-00649-w>

High Income Country



Low Income Country

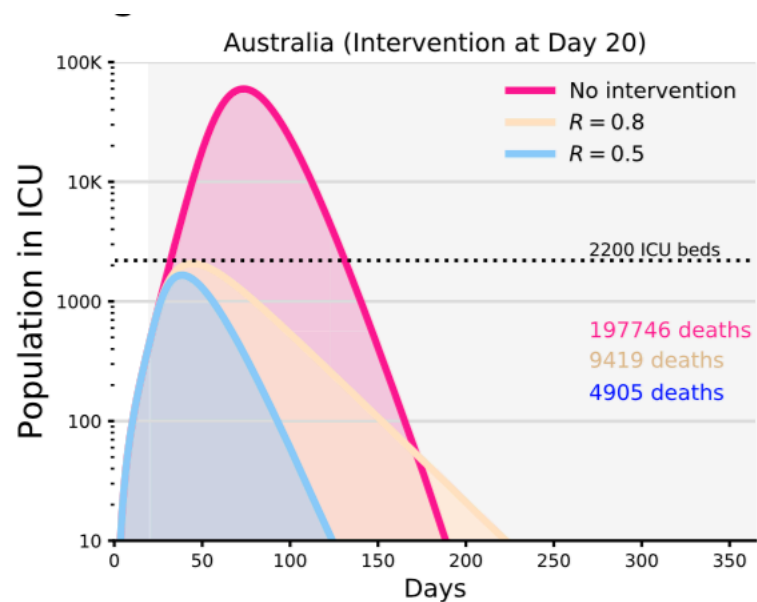


Mitigation: $R=0.8$
Suppression: $R=0.5$

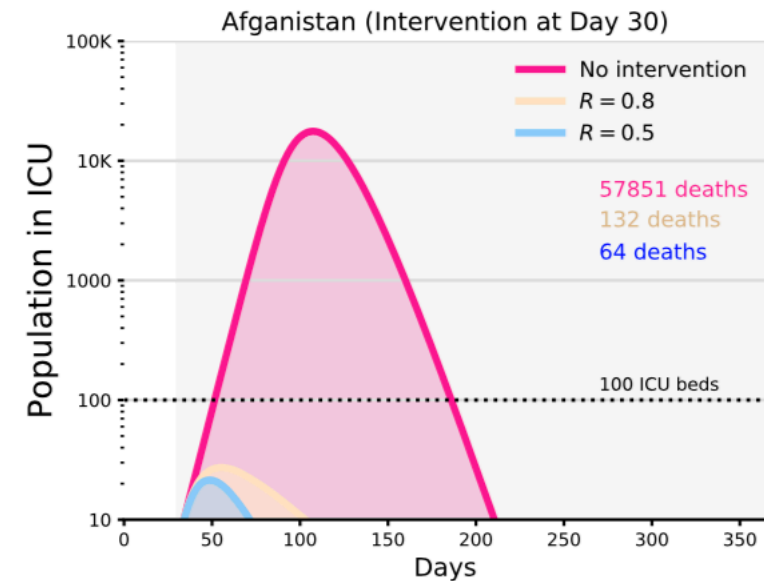
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High Income Country



Low Income Country



Mitigation: $R=0.8$

Suppression: $R=0.5$

Dynamic interventions to control COVID-19 pandemic: Conclusions

- We found that dynamic cycles of 50-day **mitigation** followed by a 30-day relaxation reduced transmission, however, were unsuccessful in lowering ICU hospitalizations below manageable limits.
- By contrast, dynamic cycles of 50-day **suppression** followed by a 30-day relaxation kept the ICU demands below the national capacities.
- Additionally, we estimated that a significant number of new infections and deaths, especially in resource-poor countries, would be averted if these dynamic suppression measures were kept in place over an 18-month period.
- This multi-country analysis demonstrates that intermittent reductions of R below 1 through a potential combination of suppression interventions and relaxation can be an effective strategy for COVID-19 pandemic control.
- Such a “schedule” of social distancing might be particularly relevant to low-income countries, where a single, prolonged suppression intervention is unsustainable. Efficient implementation of dynamic suppression interventions, therefore, confers a pragmatic option to: (1) prevent critical care overload and deaths, (2) gain time to (2) gain time to develop preventive and clinical measures, and (3) reduce economic hardship globally.

Questions

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- Prescriptions for zithromax and hydroxychloroquine have skyrocketed across the nation. Is there any role for these medications for outpatients, either prophylactically or for treatment? Please also discuss other treatments being advocated such as zinc.

Percentage increase in dispensed prescriptions from February to March 2020:

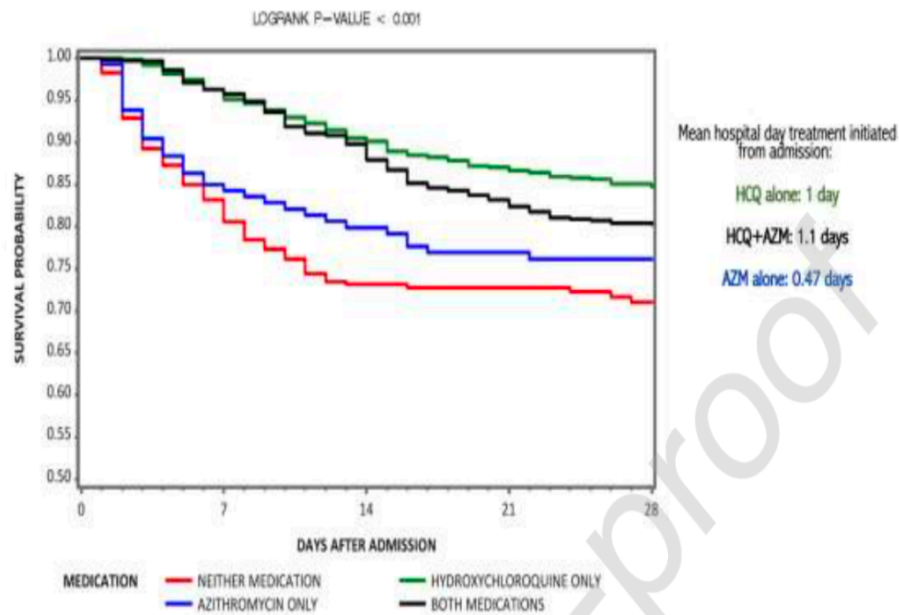


Healio 

Reference: Shehab N, et al. *JAMA Intern Med.* 2020;doi:10.1001/jamainternmed.2020.2594.

Treatment with Hydroxychloroquine, Azithromycin, and Combination in Patients Hospitalized with COVID-19: Henry Ford COVID Task Force

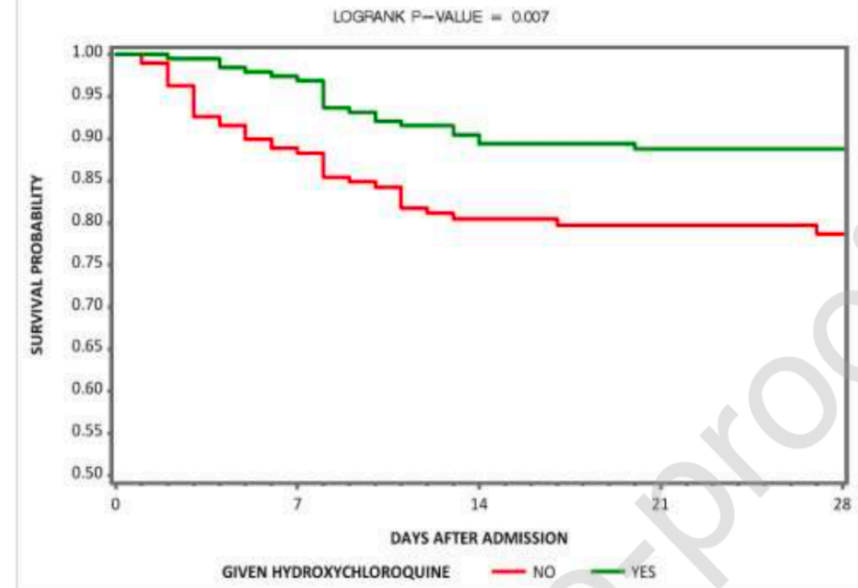
KAPLAN-MEIER SURVIVAL CURVES BY HYDROXYCHLOROQUINE/AZITHROMYCIN STATUS



NUMBER AT RISK (IN HOSPITAL)

	ADMISSIONS	DAY 7	DAY 14	DAY 21	DAY 28
BOTH MEDICATIONS	783	751 (498)	675 (219)	593 (87)	490 (37)
HYDROXYCHLOROQUINE ONLY	1202	1144 (564)	999 (176)	786 (60)	463 (15)
AZITHROMYCIN ONLY	147	120 (31)	108 (8)	99 (2)	86 (1)
NEITHER MEDICATION	409	317 (117)	212 (16)	156 (6)	110 (3)

KAPLAN-MEIER SURVIVAL CURVES BY PROPENSITY MATCHED HYDROXYCHLOROQUINE STATUS



NUMBER AT RISK (IN HOSPITAL)

	ADMISSIONS	DAY 7	DAY 14	DAY 21	DAY 28
GIVEN HYDROXYCHLOROQUINE	190	184 (84)	164 (16)	146 (8)	111 (2)
NOT GIVEN HYDROXYCHLOROQUINE	190	158 (49)	118 (7)	98 (2)	72 (1)

Treatment with Hydroxychloroquine, Azithromycin, and Combination in Patients Hospitalized with COVID-19

Limitations

- Retrospective, non-randomized, non-blinded study design.
- Information on duration of symptoms prior to hospitalization was not available
- Inclusion bias
 - “The combination of hydroxychloroquine + azithromycin was reserved for selected patients with severe COVID-19 and with minimal cardiac risk factors”
 - More patients in the control group were older, hypoxic and had comorbidities
 - Our results also require further confirmation in prospective, randomized controlled trials that rigorously evaluate the safety, and efficacy of hydroxychloroquine therapy for COVID-19 in hospitalized patients.

Pros

- Large cohort (n= 2541)
- High rate of comorbidities
 - Overall mortality 18 %
- Multivariate analysis performed using Cox regression modeling and propensity score matching to control for potential

NIH halts clinical trial of hydroxychloroquine

Study shows treatment does no harm, but provides no benefit



What

A clinical trial to evaluate the safety and effectiveness of hydroxychloroquine for the treatment of adults hospitalized with coronavirus disease 2019 (COVID-19) has been stopped by the National Institutes of Health. A data and safety monitoring board (DSMB) met late Friday and determined that while there was no harm, the study drug was very unlikely to be beneficial to hospitalized patients with COVID-19. After its fourth interim analysis the DSMB, which regularly monitors the trial, recommended to the National Heart, Lung, and Blood Institute (NHLBI), part of NIH, to stop the study. NHLBI halted the trial immediately.

Table 2. Outcomes of Hydroxychloroquine Therapy for Postexposure Prophylaxis against Covid-19.*

Outcome	Hydroxychloroquine (N=414) <i>number (percent)</i>	Placebo (N=407)	P Value
Confirmed or probable Covid-19	49 (11.8)	58 (14.3)	0.35
Laboratory-confirmed diagnosis	11 (2.7)	9 (2.2)	0.82
Symptoms compatible with Covid-19	48 (11.6)	55 (13.5)	0.46
All new symptoms	57 (13.8)	59 (14.5)	0.84
Any hospitalization	1 (0.2)	1 (0.2)	0.99
Death	0	0	—

* Symptoms were adjudicated by four infectious disease physicians, who were unaware of the trial-group assignments, in accordance with U.S. Council of State and Territorial Epidemiologists case definition of probable Covid-19 after an epidemiologic link with a close contact.¹⁵ (Descriptions of the symptom complex are provided in the Supplementary Appendix.) The median number of new symptoms reported in the hydroxychloroquine group was 4 (interquartile range, 2 to 6), as compared with 3 (interquartile range, 2 to 5) in the placebo group.

Effectiveness of
Hydroxychloroquine
for SARS-COV-2

Zinc for COVID 19?

ANTIVIRAL AGENTS

- [BALOXAVIR](#)
- [CHLOROQUINE PHOSPHATE](#)
- [FAVIPIRAVIR](#)
(Avigan®, Favilavir)
- [HIV PROTEASE INHIBITORS](#)
(e.g., LPV/RTV, Kaletra®)
- [HYDROXYCHLOROQUINE](#)
(Plaquenil®)
- [NEURAMINIDASE INHIBITORS](#)
(e.g., oseltamivir)
- [REMDESIVIR](#)
- [UMIFENOVIR](#) (Arbidol®)

SUPPORTING AGENTS

- UPDATED • [ANAKINRA](#) (Kineret•)
- [ASCORBIC ACID](#)
- [AZITHROMYCIN](#)
- UPDATED • [BARICITINIB](#) (Olumiant®)
- UPDATED • [COLCHICINE](#)
- UPDATED • [CORTICOSTEROIDS](#) (general)
- UPDATED • [INHALED PROSTACYCLINS](#)
- UPDATED • [INTERFERONS](#)
- [METHYLPREDNISOLONE](#)
(DEPO-Medrol®, SOLU-Medrol®)
- UPDATED • [NITRIC OXIDE](#) (inhaled)
- UPDATED • [RUXOLITINIB](#) (Jakafi®)
- [SARILUMAB](#) (Kevzara®)
- [SILTUXIMAB](#) (Sylvant®)
- [SIROLIMUS](#) (Rapamune®)
- [TOCILIZUMAB](#) (Actemra®)

OTHER

- [ACE INHIBITORS, ANGIOTENSIN II RECEPTOR BLOCKERS \(ARBs\)](#)
- UPDATED • [ANTICOAGULANTS](#)
- UPDATED • [COVID-19 CONVALESCENT PLASMA](#)
- UPDATED • [FAMOTIDINE](#)
- [HMG-CoA REDUCTASE INHIBITORS](#)
(statins)
- [IMMUNE GLOBULIN](#)
- [IVERMECTIN](#)
- [NEBULIZED DRUGS](#)
- [NICLOSAMIDE](#)
- [NITAZOXANIDE](#)
- [NONSTEROIDAL ANTI-INFLAMMATORY AGENTS \(NSAIDs\)](#)
- [TISSUE PLASMINOGEN ACTIVATOR](#)
(t-PA; alteplase)



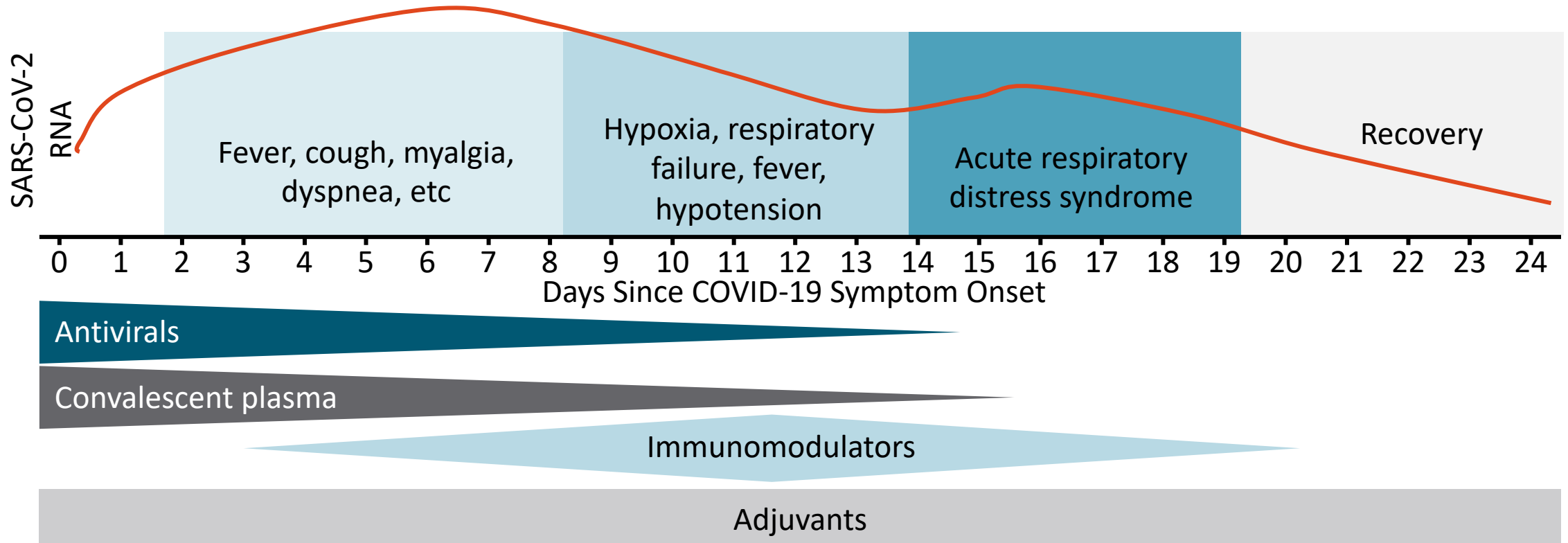
Retrospective observational study to compare hospital outcomes among patients who received hydroxychloroquine and azithromycin plus zinc versus hydroxychloroquine and azithromycin alone.

- **Methods:**
 - Patients being treated from March 2, 2020 through April 5, 2020.
 - Excluded if they were treated with other investigational medications.
- **Results:**
 - The addition of zinc sulfate did not impact the length of hospitalization, duration of ventilation, or ICU duration.
 - In univariate analyses, zinc sulfate increased the frequency of patients being discharged home, and decreased the need for ventilation, admission to the ICU, and mortality or transfer to hospice for patients who were never admitted to the ICU.
 - After adjusting for the time at which zinc sulfate was added to our protocol, an increased frequency of being discharged home (OR 1.53, 95% CI 1.12-2.09) reduction in mortality or transfer to hospice remained significant (OR 0.449, 95% CI 0.271-0.744).
- **Conclusion:** This study provides the first in vivo evidence that zinc sulfate in combination with hydroxychloroquine may play a role in therapeutic management for COVID-19.

• PROBLEMS WITH THIS STUDY

- Retrospective observational
- No control group
 - Patients without treatment not included
- Is zinc beneficial for COVID or does Zinc decrease mortality due to hydroxychloroquine and azithromycin?

Timing of Treatment in Relation to Onset of Symptoms



Optimal timing of therapeutic use unknown; proposed schematic based on medication type, potential for direct antiviral effect, mitigation of cytokine storm, or nonspecific adjuvant effect

IDSA Recommendations on Treatment and Management of Patients With COVID-19

- Overarching goal: recruit patients into ongoing trials to provide needed evidence regarding efficacy and safety of potential therapies

Treatment of Patients Admitted to the Hospital With COVID-19	
Recommended for hospitalized patients with severe disease*	<ul style="list-style-type: none">■ Remdesivir[†]■ Glucocorticoids
Recommended in the context of a clinical trial	<ul style="list-style-type: none">■ (Hydroxy)chloroquine■ Convalescent plasma
Recommended only [‡] in the context of a clinical trial	<ul style="list-style-type: none">■ (Hydroxy)chloroquine + azithromycin■ Lopinavir/ritonavir■ Tocilizumab
Suggests against outside the context of a clinical trial	<ul style="list-style-type: none">■ Famotidine

Note: Among patients admitted to the hospital, corticosteroids recommended in the context of a clinical trial for ARDS due to COVID-19 but suggested against for COVID-19 pneumonia.

*Severe illness defined as SpO₂ ≤ 94% on room air, and those who require supplemental oxygen, mechanical ventilation or ECMO. [†]For patients on supplemental oxygen but not on mechanical ventilation or ECMO, the panel suggests 5 days of remdesivir (vs 10 days). [‡]Addition of “only” indicates increased uncertainty and/or potential for harm.



NIH Guidelines: Investigational COVID-19 Treatments

Antivirals

Guidance	Treatment
Recommends for hospitalized patients with severe* COVID-19	<ul style="list-style-type: none"> Remdesivir
Insufficient data to recommend for or against for patients with mild to moderate COVID-19	<ul style="list-style-type: none"> Remdesivir
Recommends against	<ul style="list-style-type: none"> High-dose chloroquine (600 mg BID for 10 days)
Recommends against except in context of clinical trials	<ul style="list-style-type: none"> (Hydroxy)chloroquine Hydroxychloroquine + azithromycin Lopinavir/ritonavir or other HIV protease inhibitors

Immune-Based Therapies

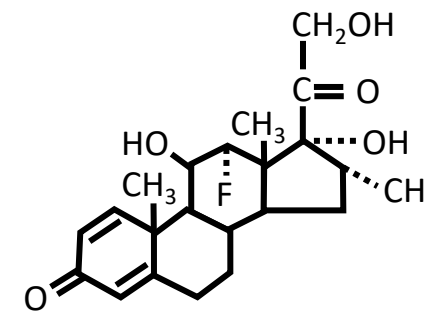
Guidance	Treatment
Recommended in patients with COVID-19 who require supplemental oxygen or who are mechanically ventilated	<ul style="list-style-type: none"> Dexamethasone
Insufficient data to recommend for or against	<ul style="list-style-type: none"> Convalescent plasma SARS-CoV-2 immune globulins IL-1 inhibitors IL-6 inhibitors
Recommends against except in the context of clinical trials	<ul style="list-style-type: none"> Non-SARS-CoV-2–specific IVIG Immunomodulators (eg, IFNs or JAK inhibitors)

*Severe defined as SpO₂ ≤ 94% on ambient air at sea level, requiring supplemental oxygen, mechanical ventilation, or ECMO.

Dexamethasone

- Dexamethasone is a corticosteroid with anti-inflammatory effects that has been used to treat allergies, asthma, dermatitis, rheumatic disorders, MS, other autoimmune disorders, etc
- Can be administered IV or orally
- Contraindicated by FDA in patients with systemic fungal infections
- Pregnancy category C

- **Warnings:** can cause elevation in blood pressure, left ventricular free wall rupture in patients with recent MI, adrenocortical insufficiency, increased susceptibility to infection, and cataracts/glaucoma with possible damage to the optic nerve



Randomised Evaluation of COVID-19 thERapY (RECOVERY) Trial Among Hospitalised Patients

- Hospitalized patients with clinically suspected or laboratory confirmed SARS-CoV-2
 - Initial recruitment was in patients ≥ 18 yrs of age but age limit was removed on 5/9/2020
- Patients randomized to usual care plus: no additional treatment, **lopinavir/ritonavir, dexamethasone, hydroxychloroquine (HCQ), or azithromycin**
 - Factorial design with simultaneous allocation to no additional tx vs **convalescent plasma**
 - If progressive disease (hyper-inflammatory state), subsequent randomization to no additional treatment vs **tocilizumab**
- > 11,500 patients enrolled from > 175 NHS hospitals in UK

6/8/2020: recruitment to dexamethasone arm halted because sufficient patient numbers enrolled to establish potential benefit

<https://www.recoverytrial.net>. <https://www.recoverytrial.net/files/hcq-recovery-statement-050620-final-002.pdf>.

https://www.recoverytrial.net/files/recovery_dexamethasone_statement_160620_final.pdf. Horby. medRxiv. 2020;[Preprint].

Note: This study has not been peer reviewed.



Slide credit: [clinicaloptions.com](https://www.clinicaloptions.com)

RECOVERY Trial: Patient Baseline Characteristics

Characteristic	Treatment Allocation		Respiratory Support at Randomization		
	Dexamethasone + Usual Care (n = 2104)	Usual Care Only (n = 4321)	No Oxygen (n = 1535)	Oxygen Only (n = 3883)	Invasive Mechanical Ventilation (n = 1007)
Mean age, yrs (SD)	66.9 (15.4)	65.8 (15.8)	69.3 (17.6)	66.7 (15.3)	59.0 (11.5)
▪ < 70	1142 (54)	2506 (58)	660 (43)	2149 (55)	839 (83)
▪ ≥ 70 to < 80	467 (22)	860 (20)	338 (22)	837 (22)	152 (15)
▪ ≥ 80	495 (24)	955 (22)	537 (35)	897 (23)	16 (2)
Male sex, n (%)	1338 (64)	2750 (64)	892 (58)	2462 (63)	734 (73)
Median time from symptom onset to randomization, days (IQR)	8 (5-13)	9 (5-15)	6 (3-10)	9 (5-12)	13 (8-18)
SARS-CoV-2 PCR result,* n (%)					
▪ Positive	1702 (81)	3553 (82)	1198 (78)	3144 (81)	913 (91)
▪ Negative	213 (10)	397 (9)	182 (12)	398 (10)	30 (3)
▪ Not yet known	189 (9)	371 (9)	155 (10)	341 (9)	64 (6)

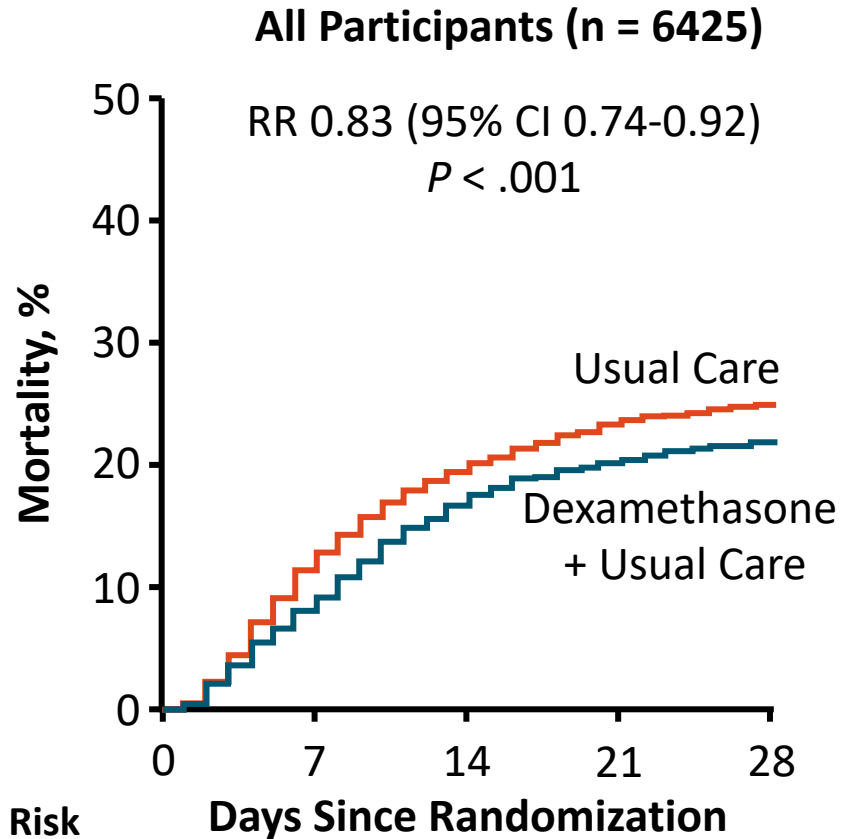
*SARS-CoV-2 test results assessed on follow-up form, so unknown for some at time of analysis.



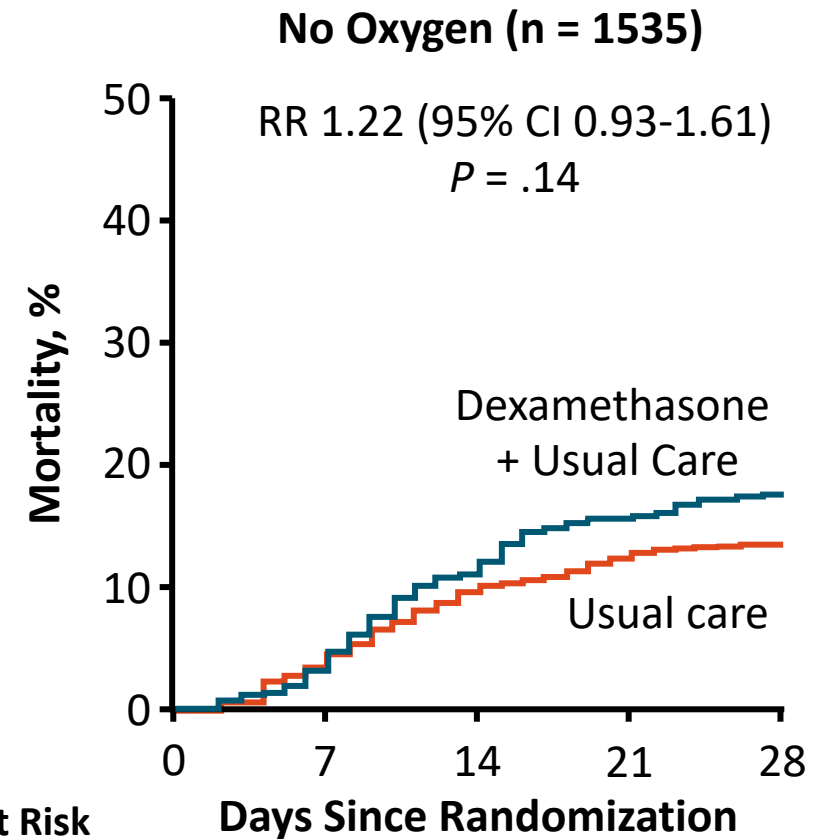
RECOVERY Trial: Comorbidities

Previous Disease, n (%)	Treatment Allocation		Respiratory Support at Randomization		
	Dexamethasone + Usual Care (n = 2104)	Usual Care Only (n = 4321)	No Oxygen (n = 1535)	Oxygen Only (n = 3883)	Invasive Mechanical Ventilation (n = 1007)
Diabetes	521 (25)	1025 (24)	342 (22)	950 (24)	254 (25)
Heart disease	586 (28)	1171 (27)	519 (34)	1074 (28)	164 (16)
Chronic lung disease	415 (20)	931 (22)	351 (23)	883 (23)	112 (11)
Tuberculosis	6 (< 0.5)	19 (< 0.5)	8 (1)	11 (< 0.5)	6 (1)
HIV	12 (1)	20 (< 0.5)	5 (< 0.5)	21 (1)	6 (1)
Severe liver disease	37 (2)	82 (2)	32 (2)	72 (2)	15 (1)
Severe kidney impairment	167 (8)	358 (8)	120 (8)	253 (7)	152 (15)
Any	1174 (56)	2417 (56)	911 (59)	2175 (56)	505 (50)

RECOVERY Trial: Mortality With Dexamethasone + Usual Care vs Usual Care Alone



No. at Risk	0	7	14	21	28
Dexamethasone	2104	1860	1670	1595	1547
Usual Care	4321	3700	3329	3154	3053

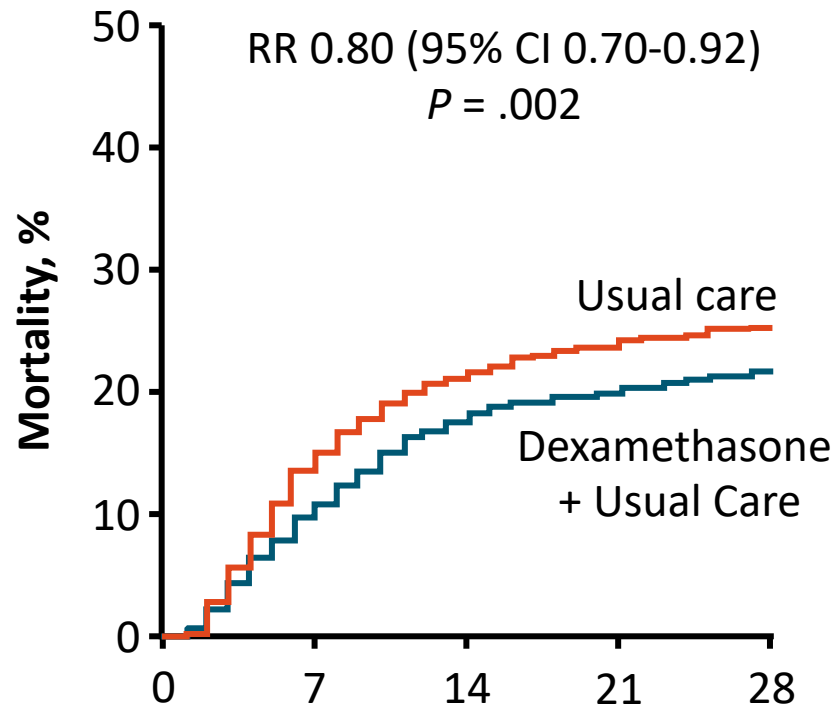


No. at Risk	0	7	14	21	28
Dexamethasone	501	463	420	394	383
Usual Care	1034	969	890	856	832



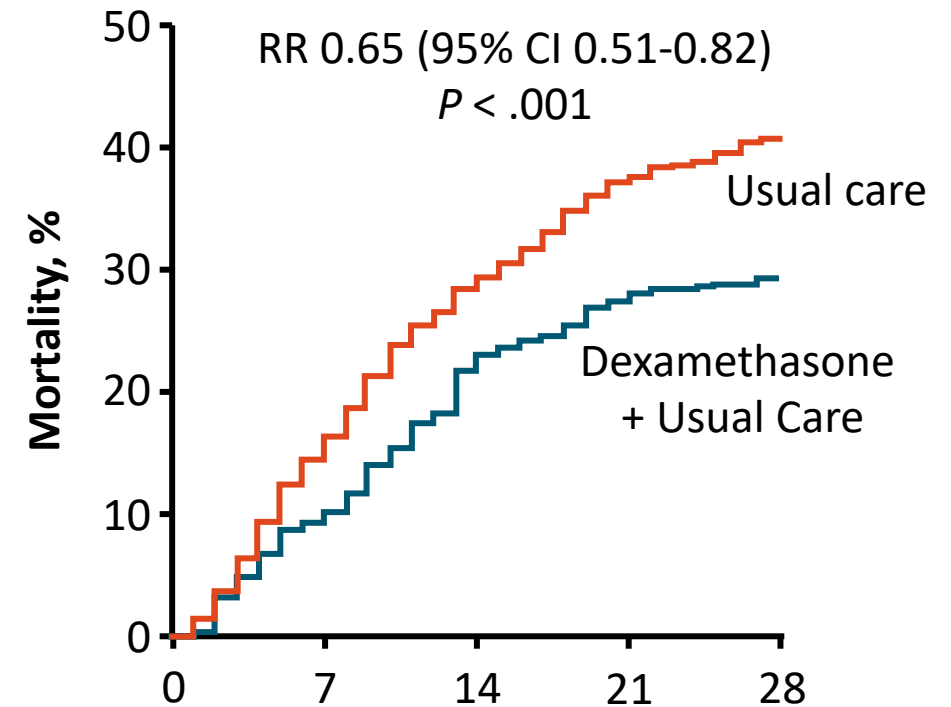
RECOVERY Trial: Mortality in Patients On Oxygen or Mechanical Ventilation ± Dexamethasone

Oxygen Only (n = 3883)



No. at Risk	0	7	14	21	28
Dexamethasone	1279	1107	1004	971	940
Usual Care	2604	2162	1965	1880	1832

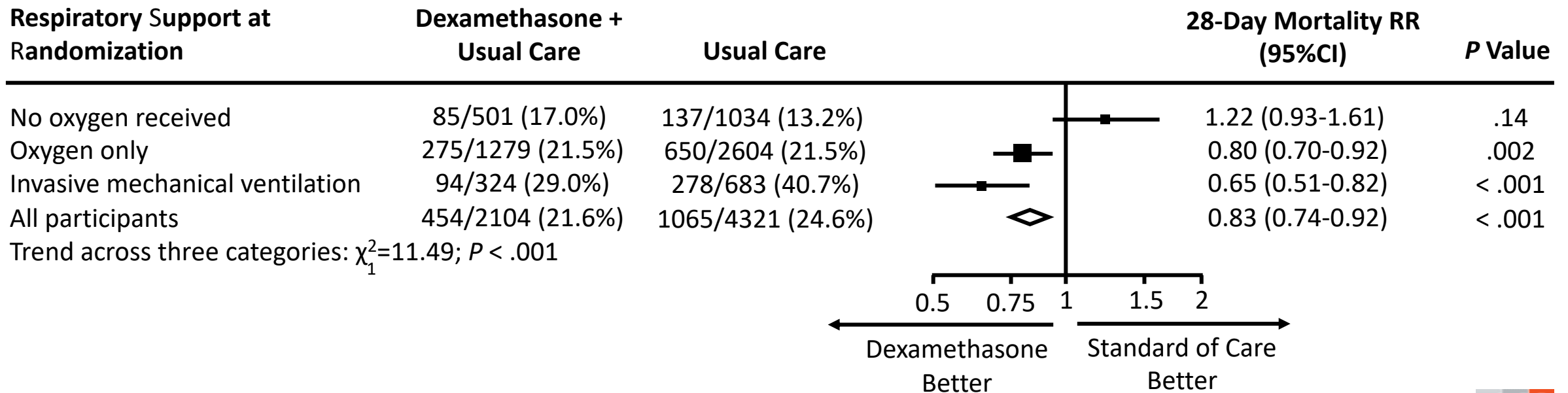
Invasive Mechanical Ventilation (n = 1007)



No. at Risk	0	7	14	21	28
Dexamethasone	324	290	246	230	224
Usual Care	683	569	474	418	389

RECOVERY Trial: Preliminary Primary Outcome Results With Dexamethasone

- Patients who received dexamethasone plus usual care (n = 2104) vs patients who usual care alone (n = 4321)
- Data suggest 1 death prevented by treatment of ~ 8 ventilated patients or ~ 25 patients requiring oxygen alone



RECOVERY Trial: Secondary Outcomes

Outcome, n/N (%)	Dexamethasone + Usual Care	Usual Care Only	RR* (95% CI)	P Value
Discharged from hospital within 28 days	1360/2104 (64.6)	2639/4321 (61.1)	1.11 (1.04-1.19)	.002
Receipt of invasive mechanical ventilation or death [†]	425/1780 (23.9)	939/3638 (25.8)	0.91 (0.82-1.00)	.049
▪ Invasive mechanical ventilation	92/1780 (5.2)	258/3638 (7.1)	0.76 (0.61-0.96)	.021
▪ Death	360/1780 (20.2)	787/3638 (21.6)	0.91 (0.82-1.01)	.07

*RR = rate ratio for outcomes of 28-day mortality and hospital discharge and risk ratio for outcome of receipt of invasive mechanical ventilation or death. RR estimates and 95% CI adjusted for age. [†]Analyses exclude those on invasive mechanical ventilation at the time of randomization.

NIH and IDSA COVID-19 Guidelines Updated to Include Dexamethasone for Severe Disease



NIH*

- The Panel recommends using dexamethasone (at a dose of 6 mg per day for up to 10 days) in patients with COVID-19 who are mechanically ventilated (AI) and in patients with COVID-19 who require supplemental oxygen but who are not mechanically ventilated (BI)
- The Panel recommends against using dexamethasone in patients with COVID-19 who do not require supplemental oxygen (AI)

IDSA

- For hospitalized patients with severe[†] COVID-19, the panel suggests glucocorticoids rather than no glucocorticoids. (Conditional recommendation, Moderate certainty of evidence)
 - Dexamethasone 6 mg IV or PO for 10 days (or until discharge if earlier) or equivalent glucocorticoid dose may be substituted if dexamethasone unavailable. Equivalent total daily doses of alternative glucocorticoids to dexamethasone 6 mg daily are methylprednisolone 32 mg and prednisone 40 mg
- For hospitalized patients with COVID-19 without hypoxemia requiring supplemental oxygen, the panel suggests against the use of glucocorticoids. (Conditional recommendation, Low certainty of evidence)

*Recommendation rating: A = Strong; B = Moderate; C = Optional. Evidence rating: I = ≥ 1 randomized trials with clinical outcomes and/or validated lab endpoints; II = ≥ 1 well-designed, nonrandomized trials or observational cohort studies; III = Expert opinion. [†]Severe illness is defined as patients with SpO₂ \leq 94% on room air, and those who require supplemental oxygen, mechanical ventilation, or ECMO.

NIH: Additional Considerations With Dexamethasone

New
Slide

Recommendation

- Unknown if other corticosteroids will have a similar benefit. Of note: dose equivalencies for dexamethasone 6 mg daily = prednisone 38 mg, methylprednisolone 32 mg, and hydrocortisone 160 mg
- The RECOVERY trial included very few pediatric and pregnant patients
- Remdesivir was not part of the RECOVERY trial; safety/efficacy of coadministering remdesivir and dexamethasone unknown
- Patients were not given dexamethasone in the RECOVERY trial if deemed unsuitable for corticosteroid therapy for any reason; review the patient's medical history and assess potential risks/ benefits
- Patients should be closely monitored for adverse effects, including hyperglycemia and secondary infections
- Systemic corticosteroids may increase risk of reactivation of latent infections (HBV, herpes viruses, TB)
- Dexamethasone is a moderate CYP3A4 inducer, which may reduce the concentration and efficacy of some medications; clinicians should review current medications to assess potential interactions
- In other coronavirus outbreaks (MERS and SARS), corticosteroid use associated with delayed virus clearance

Key Therapeutic Classes Under Investigation for Treatment of COVID-19

Antivirals

Baloxivir
Convalescent plasma
Favipiravir
(Hydroxy)chloroquine
Interferon
Lopinavir/ritonavir
Nitazoxanide
Oseltamivir
Remdesivir
Ribavirin

Immunomodulators

Corticosteroids
IL-1 inhibitors (eg, anakinra)
IL-6 inhibitors (eg, tocilizumab)
Intravenous immunoglobulin
JAK inhibitors (eg, baricitinib)

“Appropriate management strategies for patients with COVID-19 are a rapidly evolving therapeutic challenge, and the optimal agents (if any) to treat infection or prevent progression to critical illness remain ill-defined.”