Pandemic Stewardship: New Roles and Contributions of Antimicrobial Stewardship Programs During COVID-19

Michael Stevens, MD, MPH, FACP, FIDSA, FSHEA
May 21, 2021
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@Dr_Mike_Stevens
Disclosures

• No relevant disclosures
Overview

• Describe novel activities that Antimicrobial Stewardship Programs (ASPs) have taken on during the COVID-19 pandemic
• Describe ASP collaboration with infection prevention programs during the pandemic
• Discuss implications from the pandemic on future ASP activities and program building
VCU HIPP
• 4 ID physician epidemiologists
• 10 infection preventionists
• 1 IT specialist
• 1 data curator analyst
• 1 microbiology technician

VCU ASP
• 2 ID physicians (1 adult, 1 peds)
• 4 pharmacy FTEs
• 5 total pharmacists
• 1 FTE for peds AS
• 0.1 IT FTE
Similarities and Differences Between ASPs and Infection Prevention Programs

**ASPs**

**Focus:** Improve antimicrobial use, ↓ resistance

**Strategies:** Antimicrobial Restriction a major strategy

**Personnel:** Pharmacists

**Infrastructure:** Use of 3rd party software platforms

**Need for leadership commitment**

**IPPs**

**Focus:** ↓ HAIs

**Personnel:** Infection Preventionists (IPs; often RNs)

**Strategies:** Audit & feedback

**Education**

**Metrics:** Focus on CDI

**Use process & outcome metrics**

**NHSN reporting**

Another ? for #IDtwitter: has your #AntimicrobialStewardship team been involved in #COVID19 response or preparation? Plz comment on what you think the implications are for ASPs/ the best way our community can help; plz RT & tag folks outside of the US, too; thanks!! #SARSCoV2

- Involved-directly: 29%
- Involved-peripherally: 28%
- Not involved: 40%
- Other (please comment): 3%

253 votes · 3 hours 13 minutes left
Involving antimicrobial stewardship programs in COVID-19 response efforts: All hands on deck

Michael P. Stevens, MD, MPH, ¹ Payal K. Patel, MD, MPH, ² and Priya Nori, MD ³

To the Editor—To our knowledge, no formal recommendations exist for the inclusion of antimicrobial stewardship programs (ASPs) in disaster planning or emergency response preparedness efforts.¹ A PubMed search utilizing the search terms “antimicrobial stewardship” AND “disaster planning” was performed on March 4, 2020, and yielded no results. ASPs are now ubiquitous. They often include pharmacists and physicians with advanced infectious diseases training, and they are a valuable part of hospital safety and quality programs. In some hospitals, compartmentalization of stewardship and epidemiology functions have developed over time to meet distinct institutional needs. However, domains should coalesce for purposes of emergency preparedness. The current SARS-CoV-2/COVID-19 outbreak highlights numerous
Antimicrobial Stewardship & COVID-19 Preparation/Response

- Collaboration w/ Epidemiology/Infection Prevention
  - Can assist w/ early case identification
  - Assist with communication
  - Opportunity to longitudinally link programs
- Diagnostic Stewardship
  - Coordinate w/ microbiology and Hospital Epidemiology for real-time interpretation of PCR test results
- Treatment
  - Assist in creating treatment guidelines
  - Anticipate & manage drug shortages
  - Assist in completing eIND and local IRB paperwork for emergency use agents (such as remdesivir)
  - Monitor/enhance compliance w/ local treatment guidelines
Overview

- Describe novel activities that Antimicrobial Stewardship Programs (ASPs) have taken on during the COVID-19 pandemic
- Describe ASP collaboration with infection prevention programs during the pandemic
- Discuss implications from the pandemic on future ASP activities and program building
ASP Involvement in COVID-19 Response Efforts

• Major ways Antimicrobial Stewardship Programs (ASPs) have been involved (not exhaustive):
  • Case identification and diagnostic stewardship of SARS-CoV-2 testing
  • COVID-19 treatment
    – Guidelines
    – Facilitating access to potential therapeutics
  • Outpatient pandemic stewardship
    – Preauthorization for potential therapeutics
    – Managing access process for monoclonal antibodies
  • Vaccine planning
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    – Guidelines
    – Facilitating access to potential therapeutics
  • Outpatient pandemic stewardship
    – Preauthorization for potential therapeutics
    – Managing access process for monoclonal antibodies
  • Vaccine planning
VCU Health: Early COVID-19 Experience

• March 16, 2020: first patient with confirmed COVID-19 admitted
• March 16, 2020: COVID-19 Command Center opens
• March 17, 2020: Dedicated Adult COVID-19 consult service established
Diagnostic Stewardship of SARS-CoV-2 Testing at VCU Health

- Infection preventionists and physician epidemiologists with HIPP team initially screened all possible patients

Infectious Disease Team
Utility of retesting for diagnosis of SARS-CoV-2/COVID-19 in hospitalized patients: Impact of the interval between tests

Michelle E Doll ¹, Rachel Pryor ¹, Dorothy Mackey ¹, Christopher D Doern ¹, Alexandra Bryson ¹, Pamela Bailey ¹, Kaila Cooper ¹, Emily Godbout ¹, Michael P Stevens ¹, Gonzalo Bearman ¹

Affiliations + expand
PMID: 32389155  PMCID: PMC72397

The electronic medical record and COVID-19: Is it up to the task?

Sangeeta R Sastry ¹, Rachel Pryor ¹, Jillian E Raybould ¹, Julie Reznicek ¹, Kaila Cooper ¹, Amie Patrick ¹, Shelley Knowlson ¹, Pamela Bailey ¹, Emily Godbout ¹, Michelle Doll ², Michael P Stevens ¹, Gonzalo Bearman ¹

Affiliations + expand
PMID: 32698924  PMCID: PMC7411438  DOI: 10.1017/ice.2020.358
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  • COVID-19 treatment
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    – Facilitating access to potential therapeutics
  • Outpatient pandemic stewardship
    – Preauthorization for potential therapeutics
    – Managing access process for monoclonal antibodies
  • Vaccine planning

Antimicrobial Stewardship & COVID-19 Preparation/Response

Can assist with early case identification
Assist with communication
Opportunity to longitudinally link programs
Coordinate with microbiology and Hospital Epidemiology for real-time interpretation of PCR test results

Diagnostic Stewardship

Assist in creating treatment guidelines
Anticipate & manage drug shortages
Assist in completing eIND and local IRB paperwork for emergency use agents (such as remdesivir)
Monitor/Enhance compliance with local treatment guidelines
COVID-19 Treatment Guidelines

- Created local treatment guidelines
- Collaborated with multiple other medical centers and reviewed guidance documents from China and Italy as well
- On 3/11/2020 we released our first treatment guidelines
  - Between 3/11/20-4/22/21 we updated these guidelines > 90 times
  - Document went from 6 pages → 35 pages
VCU ASP Adult COVID-19 Treatment Guidelines

These guidelines are based on the best available evidence and professional society guidelines. Although some “preprint” data are referenced, in general these guidelines include peer-reviewed data primarily, and include links to the most relevant literature. For questions regarding these guidelines please contact Mike Stevens via email (michael.stevens@vcuhealth.org) or pager 8422.

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<td>Admitted with COVID-19</td>
<td></td>
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</tbody>
</table>
Figure 1: VCU Health COVID-19 Treatment Options Flow Map

Updated 4/19/21

This figure depicts where various potential therapeutic options can be considered.

Treatment decisions are at the discretion of the clinical service with input from Infectious Diseases and Pulmonary & Critical Care Medicine as needed.

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Clinical Trials are in RED boxes; drugs available under FDA emergency use authorization (EUA) criteria are in PURPLE boxes; other (non-trial) options are in GREEN boxes; boxes with double lines = agents that are available to patients who are incarcerated.

Gray shading = targeting immune response.
Yellow shading = targeting virus directly.

*If dexamethasone/other corticosteroids are contraindicated EUA baricitinib can be substituted (in combination with remdesivir).

**Would give a one time dose of tocilizumab (8 mg/kg, up to 800 mg) for patients within 48 hours of the development of rapid progressive hypoxic respiratory failure requiring NIV or MV or high-flow O2 (>0.4 FiO2/30L/min oxygen flow) who also have a CRP of ≥ 7.5 mg/dL.

^The clinical trials teams are screening patients and will reach out to primary providers about potential enrollment. Primary teams can also put a clinical trial referral in CERNER (type in "Clinical Trials Referral").

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1. ACTIV-1 (infliximab OR abatacept OR canakinumab)
2. Convalescent Plasma (Clinical Trial: if NOT receiving EUA plasma)
3. CM-4620-E
4. Vitamin C
5. Brexanolone
## Key Updates: Table View

<table>
<thead>
<tr>
<th>Therapeutic</th>
<th>Available under EUA? (Date of EUA release)</th>
<th>Use outside of clinical trials recommended by IDSA and/or the NIH?</th>
<th>Use outside of clinical trials^ recommend at VCU Health?</th>
<th>Other comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remdesivir</td>
<td>Yes (8/28/20; but FDA approved for patients 12 years and older who weigh &gt; 40 kg)</td>
<td>Yes</td>
<td>Yes</td>
<td>Use not recommended in patients without hypoxia</td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Use not recommended in patients without hypoxia</td>
</tr>
<tr>
<td>Convalescent plasma</td>
<td>Yes (8/23/20; updated 2/4/21)</td>
<td>No</td>
<td>Yes^</td>
<td>Clinical trial use is favored for all patients except EUA use for patients who are s/p kidney and liver transplantation but only if recommended by Transplant ID consultation</td>
</tr>
<tr>
<td>Tocilizumab</td>
<td>No (but commercially available)</td>
<td>Yes; both IDSA and the NIH recommend use under certain circumstances (IDSA: 2/22/21 update; NIH: 3/5/2021 update)</td>
<td>Yes (as of 2/11/21; see Table 3b)</td>
<td></td>
</tr>
<tr>
<td>Bamlanivimab</td>
<td>No (FDA revoked EUA on 4/16/2021)</td>
<td>No</td>
<td>No</td>
<td>*Monotherapy no longer being distributed by federal government given issues with resistance</td>
</tr>
<tr>
<td>Baricitinib</td>
<td>Yes (11/19/20)</td>
<td>Yes</td>
<td>Yes^^(^</td>
<td></td>
</tr>
</tbody>
</table>
What’s New:

On 4/20/2021 monoclonal antibody therapy will be offered to outpatients with COVID-19 at high risk for disease progression as outlined in Table 1a. Providers with non-ER patients who desire screening for eligibility should contact ASP via pager 3144 between the hours of 8 AM and 4:30 PM (all days).

On 4/16/2021 the FDA revoked its Emergency Use Authorization for bamlanivimab (given alone). This is due to the high circulating percentage of SARS-CoV-2 variants that are resistant to bamlanivimab. There is still an FDA EUA in place for bamlanivimab/etesevimab but we prefer to use casirivimab/imdevimab when monoclonal antibody therapy is indicated as the latter is more active against SARS-CoV-2 variants.

On 4/14/2021 the IDSA released updated guidelines—now recommending against the use of convalescent plasma and recommending casirivimab/imdevimab or bamlanivimab/etesevimab in select outpatients at high risk for disease progression. At VCU Health convalescent plasma should only be given for patients with a h/o solid organ transplantation if recommended by Transplant ID consultation; no other (non-trial) use is recommended. In terms of casirivimab/imdevimab and bamlanivimab/etesevimab, VCU Health’s ASP does recommend use in select outpatients at high risk for disease progression (see Table 1a for use criteria). Providers with non-ER patients who desire screening for eligibility should contact ASP via pager 3144 between the hours of 8 AM and 4:30 PM (all days).

On 4/12/21 a preprint of the PRINCIPLE trial looking at inhaled budesonide for patients with COVID-19 in the community was released. This is a multicenter, open-label adaptive effectiveness RCT involving people > or = 65 or > or = 50 with comorbidities who were outpatient and < or = 14 days from symptom onset with suspected COVID-19 who were randomized to inhaled budesonide or usual care. There were 2 primary endpoints: time to self-reported recovery and hospitalization/death related to COVID-19 (both measured at 28 days from randomization). The results are from an interim analysis of 4,663 randomized patients; only 2,617 had SARS-CoV-2 testing. Of positive patients, 751 ultimately received budesonide (800 mcg bid for 14 days), 1,028 usual care and 643 “other interventions.” Time to recovery was shorter in the budesonide arm compared to the usual care arm (by a median of 3 days, HR 1.208, 95% CI 1.076-1.356); among those in the interim analysis with 28 day data, there were 59/692 (8.5%) COVID-19 related hospitalizations in the budesonide arm vs. 62/665 (9.3%) in the usual care arm (statistically significant).
Table 1a. Antiviral Agents

- Hydroxychloroquine, chloroquine, lopinavir/ritonavir and darunavir/cobicistat are no longer restricted (as of 9/15/2020). These agents should not be used to treat or prevent COVID-19.
- Remdesivir is restricted requiring Antimicrobial Stewardship Program (ASP: pager 3144) approval. Any remdesivir approval requests for greater than 5 days of therapy or in patients with a eGFR of < 30 will require ID consult approval (pager 9001).
- Tocilizumab is restricted requiring Pulmonary and Critical Care Medicine approval.
- The restriction process for remdesivir follows that of other restricted antimicrobials at VCU Health (from 9 PM-8 AM the drug can be ordered and a single dose given without approval—but the ordering team will need to page 3144 at 8 AM to request approval of additional doses). Overnight verifying pharmacists should verify that the patient has a COVID-19 PCR test within 14 days (either within the VCU Health system or outside our system if the ordering provider confirms this). Would not start remdesivir if the patient has significant baseline hepatitis or renal insufficiency (as defined in the table below).
- For patients with a pending COVID-19 PCR test whose providers wish to start treatment before the test returns, the provider should page the ID consult service (pager 9001). In general, no treatment will be approved until a patient has a positive COVID-19 PCR test.

<table>
<thead>
<tr>
<th>Anti-Virals</th>
<th>Dosing, Use Criteria and Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preferred</strong></td>
<td></td>
</tr>
<tr>
<td>Remdesivir&lt;sup&gt;3&lt;/sup&gt;</td>
<td>200mg IV x1, followed by 100mg IV q24h for total of 5-10 days</td>
</tr>
<tr>
<td><em>Restricted to Antimicrobial Stewardship Program (pager 3144) or ID Consult approval (pager 9001).</em></td>
<td></td>
</tr>
<tr>
<td><em>5 days is the default duration of treatment at VCU Health</em></td>
<td></td>
</tr>
<tr>
<td><em>Duration of treatment can be extended to 10 days based on ID consultant recommendation</em></td>
<td></td>
</tr>
<tr>
<td><em>Obtain baseline hepatic panel and daily while on remdesivir</em></td>
<td></td>
</tr>
<tr>
<td><em>Discontinue remdesivir if ALT &gt; 300 or ALT &gt; 150 with T.bili &gt; 2.6 or with eGFR &lt;30</em></td>
<td></td>
</tr>
</tbody>
</table>

<p>| Convalescent plasma&lt;sup&gt;3&lt;/sup&gt; | One unit (~200ml) of ABO-compatible convalescent plasma obtained from an individual who has recovered from COVID-19. Can be followed by subsequent units at provider discretion. |
| <em>Compassionate use; would use as directed by the Transplant ID Consult service. Routine use not recommended.</em> | |
| | <em>To order EUA COVID Convalescent Plasma, providers should:</em> |
| | 1. Review the EUA Fact Sheet for Healthcare Providers and also provide the patient or their legal authorized representative a copy of the Fact Sheet for Patients |
| | COVID-19 Convalescent Plasma remains in short supply nationwide; would use as directed by the COVID-19 ID Consult service |
| | In some instances only IND convalescent plasma will be available (not EUA convalescent plasma); please note: the IND consent process is DIFFERENT than that outlined above. When IND convalescent plasma will be released the clinical pathology resident on call will call the primary team to go over the details of the consent process. For IND units the person consenting needs to be told that this is an investigational product, and it needs to be written on the VCU transfusion consent form that this is an investigational product. IND units will NOT be marked as high or low titer |
| | &quot;IND cases tried under the guidance of CDC Criteria for use with eGFR &lt;30*&quot; |</p>
<table>
<thead>
<tr>
<th>Supportive Care</th>
<th>Dosing</th>
</tr>
</thead>
</table>
| **Dexamethasone**<sup>2</sup> | Dexamethasone 6 mg once per day (po or IV) for up to 10 days (or until discharge if earlier)  
- Open label use based on data released on 6/16/2020 from the RECOVERY trial showing a mortality benefit in patients requiring oxygen supplementation or mechanical ventilation  
- Recommended by the Infectious Diseases Society of America in its 6/25/2020 COVID-19 treatment guideline update for hospitalized patients with an \( \text{SpO}_2 \leq 94\% \) on room air requiring supplemental oxygen, mechanical ventilation or ECMO. They note an equivalent glucocorticoid (such as methylprednisolone or prednisone) can be substituted if dexamethasone is not available  
- *Patients receiving a short course of steroids may develop hyperglycemia, agitation and/or confusion, adrenal suppression and an increased risk for bacterial and fungal infections*  
- *Dexamethasone is associated with multiple potential drug interactions. See Addendum 3.* |
| **CM4620-204 (Auxora)**<sup>3</sup>  
*Investigational; PI = Dr. Paula Ferrada* | Being studied in a phase 2, multicenter, randomized, double-blind, placebo-controlled study |
| **ACTIV-1:**  
Infliximab (Remicade) | Being studied in a phase 3, multicenter, randomized, master protocol, multiple-arm, double-blind, placebo-controlled study ACTIV-1 IM through the National Center for the Advancement of Translational Science (NCATS). |
<table>
<thead>
<tr>
<th>Potential Therapy</th>
<th>Tolerability/Adverse Effects/Other Comments</th>
<th>Monitoring/Recommended Labs (in addition to routine labs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labs to order at time of admission</td>
<td>• N/A</td>
<td>• Recommend obtaining a CBC with differential, BMP, hepatic panel, CRP, PT/aPTT, fibrinogen, D-dimer, ferritin, LDH and CK at the time of admission</td>
</tr>
</tbody>
</table>
| Remdesivir | • Remdesivir is generally well tolerated  
• Self-limiting, reversible hepatotoxicity has been observed, which resolved after therapy cessation  
• Nephrotoxicity was observed in preclinical studies | • Recommend sending a CBC, BMP and hepatic panel daily if on remdesivir |
| Tocilizumab (Actemra) | • Use associated with potential for heightened risk for infection  
• Use in patients with active infection is a relative contraindication  
• Would not use in patients with known active tuberculosis | • Consider checking a QuantiFERON TB Gold test + strongyloides IgG Ab testing |
| Convalescent plasma | • Transfusion reactions possible  
• As with other blood products, there is a low risk for infections  
• Transfusion-related acute lung injury (TRALI) is possible | • Routine lab work |
| CM4620-IE (Auxora) | • Intravenous Infusion is generally well tolerated  
• Allergic reactions possible | • Routine lab work |
| Dexamethasone | • Prolonged use can cause adrenal suppression and hypercortisolism  
• Prolonged use associated with increased risk for infection (including secondary bacterial and fungal) | • Follow blood glucose values  
• Consider Strongyloides Ab testing, especially in patients with risk factors for chronic infection (history of walking |

### Addendum 1. COVID-19 Guidelines for Patients with Renal Transplantation

Authors: Megan Morales, MD, Nicole Vissichelli, MD, Kimberly Lee, PharmD and Mike Stevens, MD, MPH

Last Updated: April 15, 2021

#### Treatment of Non-Hospitalized Patients with Kidney Transplantation

<table>
<thead>
<tr>
<th>Clinical Presentation</th>
<th>Preferred Treatment</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asymptomatic</td>
<td>No direct treatment</td>
<td>Close monitoring at home with daily coordinator call and home pulse oximetry monitoring</td>
</tr>
</tbody>
</table>

#### Treatment of Hospitalized Patients with Kidney Transplantation

<table>
<thead>
<tr>
<th>Clinical Presentation</th>
<th>Preferred Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Convalescent Plasma¹</td>
</tr>
<tr>
<td></td>
<td>DVT prophylaxis per guidelines²</td>
</tr>
<tr>
<td></td>
<td>Reduce MMF* if possible</td>
</tr>
<tr>
<td></td>
<td>Dexamethasone 6 mg daily x 10 days</td>
</tr>
<tr>
<td></td>
<td>Remdesivir³,⁴</td>
</tr>
</tbody>
</table>

- **Symptomatic NOT hypoxic**
  - SpO₂ > 94% on room air
  - With any of the following:
    - Dyspnea or cough
    - RR > 30
    - Lung Infiltrates > 50%
    - WBC < 2.0

- **Symptomatic, hypoxic**
  - SpO₂ ≤ 94% on room air
Addendum 2. COVID-19 Guidelines for Patients with Liver Transplantation

Authors: Megan Morales, MD, Nicole Vissichelli, MD, David Bruno, MD, Kimberly Lee, PharmD and Mike Stevens, MD, MPH

Last Updated: April 15, 2021

### Treatment of Non-Hospitalized Patients with Liver Transplantation

<table>
<thead>
<tr>
<th>Clinical Presentation</th>
<th>Preferred Treatment</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asymptomatic</td>
<td>Stop MMF</td>
<td>Close monitoring at home with daily coordinator call and home pulse oximetry monitoring</td>
</tr>
</tbody>
</table>

### Treatment of Hospitalized Patients with Liver Transplantation

<table>
<thead>
<tr>
<th>Clinical Presentation</th>
<th>Preferred Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Convalenscent Plasma¹</td>
<td>DVT prophylaxis per guidelines²</td>
</tr>
<tr>
<td>Stop MMF</td>
<td>Dexamethasone 6 mg daily x 10 days</td>
</tr>
<tr>
<td>Remdesivir³,⁴</td>
<td></td>
</tr>
</tbody>
</table>

#### Symptomatic NOT hypoxic
- SpO₂ > 94% on room air
- With any of the following:
  - Dyspnea or cough
  - RR > 30
  - Lung Infiltrates > 50%

<table>
<thead>
<tr>
<th></th>
<th>X</th>
<th>X</th>
<th>X</th>
<th></th>
</tr>
</thead>
</table>

Addendum 3. Possible Bacterial Superinfection in Patients Admitted with COVID-19

Authors: Cathy Grossman, MD, Kimberly Lee, PharmD, Jihye Kim PharmD, Michael P. Stevens, MD, MPH
Last Updated: April 13, 2021

Background:

- This guidance document is focused on patients hospitalized with a NEW diagnosis of COVID-19 in the past 14 days. Recommendations are broken down by time frame of hospitalization (≤ 48 hours and > 48 hours), and by risk factors for infection with drug-resistant bacteria (e.g., MRSA and Pseudomonas aeruginosa/other MDR Gram negative organisms).

- Patients with COVID-19 who develop worsening respiratory disease later than 14 days after symptom onset, especially who received potentially immunosuppressing medications (like steroids, tocilizumab, et cetera), have increased risk for bacterial superinfection as well as fungal infections (e.g., invasive aspergillosis). Would consider consultation with Infectious Diseases as needed.

- Patients with baseline immunosuppression (from things like neutropenia, transplant-related medications, et cetera) are at risk for infection with a broader array of possible organisms. Would consider consultation with Infectious Diseases as needed.

Evaluation:

- We acknowledge that time from COVID-19 testing to result return varies, and that many patients with COVID-19 may present similarly to severe community-acquired pneumonia (CAP)
  - Patients hospitalized with COVID-19 can develop hypoxic respiratory failure, viral pneumonia and can also develop ARDS. Diagnosing concomitant bacterial superinfection in these patients can be challenging.
  - The following diagnostic findings may indicate increased risk for bacterial superinfection:
Addendum 4. Daily Dexamethasone and Potential Drug-Drug Interactions

Author: Patricia Pecora Fulco, PharmD, BCPS, FASHP, AAHIVP
Last Updated: July 8, 2020

- Daily dexamethasone is now being used as an adjunctive therapy for the treatment of COVID-19.
- Dexamethasone may alter the metabolism of numerous medications resulting in potential sub-therapeutic levels of these other drugs (see Table 1); dexamethasone is a strong inducer of cytochrome P450 (CYP) 3A4 and a moderate inducer of CYP 2C9 and p-glycoprotein.

Table 1. Potential Drug-Drug Interactions with Dexamethasone and Other Medications

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Medication Examples (not inclusive)</th>
<th>Effect of Dexamethasone on Metabolism</th>
<th>Recommendations for Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antiretrovirals</td>
<td>Integrase inhibitors [II: Bictegravir, Elvitegravir/cobicistat]</td>
<td>II level may ↓</td>
<td>Consult ID for alternative ART recommendations.</td>
</tr>
<tr>
<td></td>
<td>Non-nucleoside reverse transcriptase inhibitors [NNRTIs: doravirine, rilpivirine]</td>
<td>NNRTI level may ↓</td>
<td>Consult ID for alternative ART recommendations.</td>
</tr>
<tr>
<td>Protease inhibitors</td>
<td>PI level may ↓</td>
<td></td>
<td>Consult ID for alternative ART recommendations.</td>
</tr>
</tbody>
</table>
Addendum 5. COVID-19 Clinical Trials Referral Ordering Process in CERNER

If you would like your patient screened for possible COVID-19 clinical trial enrollment, please place an order in CERNER for this (type in “Clinical Trials Referral”) and select “COVID-19 (CRC)” under “Area Requested.” You can identify the specific trial you are interested in having the patient screened for or just indicate you would like the patient screened for all COVID-19 clinical trials.
### Table 3a. Quality of Evidence Behind Available Medications for COVID-19: Antiviral Agents*  

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Status of Medication Use for COVID-19 at VCU Health</th>
<th>Mechanism of Action</th>
<th>Currently Available Data/Comments on Potential Harm</th>
<th>Qualitative Assessment of Quality of Current Evidence^</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ANTIVIRALS</strong></td>
<td></td>
<td></td>
<td></td>
<td>HIGH</td>
</tr>
<tr>
<td>Remdesivir^^</td>
<td>• Two phase 3 randomized clinical trials (closed)</td>
<td>• Broad-spectrum antiviral nucleotide prodrug</td>
<td>• Multiple RCTs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Commercial access now available</td>
<td></td>
<td>• The ACTT-1 trial (a double-blind, randomized, placebo-controlled trial of 1062 patients) showed remdesivir was associated with a median time to recovery of 10 days versus 15 with placebo (RR for recovery 1.29; 95% CI 1.12-1.49, P&lt;0.001). There was no mortality benefit. Further analysis revealed that the benefit was in patients on oxygen but NOT requiring O2 via HFNC, NIV, MV or ECMO appear to benefit most.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• On 10/22/2020 the FDA approved remdesivir for use in hospitalized patients with COVID-19</td>
<td></td>
<td>• Open label phase 3 trial of 584 patients with moderate COVID-19 pneumonia (infiltrates + RA O2 saturation &gt; 94%) revealed 5 days of RDV better than standard of care in terms of clinical status improvement by day 11 (OR 1.65, 95% CI: 1.09-2.48, p = 0.02); this improvement was only 9.7% over the standard of care baseline, however. There was no significant difference in terms of clinical improvement by day 11 for the 10</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Medication is restricted and has to be approved by ASP (pager 3144) or ID (pager 9001)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Summary: available peer-reviewed, RCT data suggest a possible clinical benefit in terms of time to recovery.  

**Patients on oxygen via nasal canula who are NOT requiring O2 via HFNC, NIV, MV or ECMO appear to benefit most.**  

Available RCT data do not show a mortality benefit.  

IDSA does NOT recommend use in patients with a room air oxygen saturation > 94% (as of 11/22/20 update)
<table>
<thead>
<tr>
<th>Therapy</th>
<th>Status of Medication Use for COVID-19 at VCU Health</th>
<th>Mechanism of Action</th>
<th>Currently Available Data/Comments on Potential Harm</th>
<th>Quality of Current Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IMMUNOMODULATING/ANTI-INFLAMMATORY AGENTS</strong></td>
<td></td>
<td></td>
<td></td>
<td>HIGH</td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>• Being used off-label</td>
<td>• Immunomodulatory effects</td>
<td>• <strong>RECOVERY trial</strong> data: 2,104 patients randomized to dexamethasone (6 mg po or IV once daily x 10 days) vs 4,321 randomized to usual care; dexamethasone arm with 22.9% 28 day mortality versus 25.7% in usual care arm (RR 0.83, 95% CI: 0.75-0.93, p&lt;0.001); for patients requiring mechanical ventilation, 29.3% died in the dexamethasone group vs. 41.4% in the control group (RR 0.64; 95% CI: 0.51-0.81); for those receiving oxygen supplementation but not on mechanical ventilation there were 23.3% vs. 26.2% deaths (RR 0.82, 95% CI 0.72-0.94). There was no benefit in patients who were not requiring oxygen at the time of randomization.</td>
<td></td>
</tr>
</tbody>
</table>
Running Notes by Drug

A. **Remdesivir**: remdesivir is a prodrug metabolized via CYP3A4, concomitant CYP3A4 inhibitors should be avoided if possible.
   a. Data from 53 patients who received remdesivir via compassionate use was published in the NEJM on 4/10/2020; in this cohort 68% had an improvement in their oxygen status and there was an overall mortality of 13%; 23% of patients had mild to moderate elevations in ALT/AST or both; there was no control group.
   b. A RCT in from China of 237 patients did not show any clinical benefits for RDV but was underpowered (see Wang et al, The Lancet).
   c. On May 1, 2020, the FDA released a EUA for remdesivir for hospitalized patients who are hypoxic (SpO2 ≤ 94% on room air and requiring supplemental oxygen); https://www.fda.gov/media/137564/download.
   d. The ACTT-1 trial (a double-blind, randomized, placebo-controlled trial of 1062 patients) showed remdesivir was associated with a median time to recovery of 10 days versus 15 with placebo (RR for recovery 1.29; 95% CI 1.12-1.49, P<0.001). There was no mortality benefit. Further analysis revealed that the benefit was in patients on oxygen but NOT requiring O2 via HFNC, NIV, mechanical ventilation or ECMO. See:
   e. A phase 3, open label study of 5 versus 10 days of remdesivir revealed no significant differences in terms of clinical status at day 14, time to clinical improvement and death from any cause-the authors of the manuscript raised concern about extrapolating these findings to patients receiving mechanical ventilation based on post-hoc subgroup analysis: https://www.nejm.org/doi/full/10.1056/NEJMo2015301.
   f. A study by Olender et al was published on 7/24/2020; this compared patients with COVID-19 who received remdesivir from the phase 3 RCT GS-US-540-5773 to a retrospective cohort who did not. The authors noted a significant time to clinical improvement in the RDV treated group and also noted a 62% reduced odds of death compared to standard of care treatment. **Of note, this study was of inferior methodologic quality to the RCT results that had already been released that DID NOT show a mortality benefit with RDV.** See:
Table 4a. Clinical Trial Criteria

If you would like your patient screened for possible COVID-19 clinical trial enrollment, please place an order in CERNER for this (type in “Clinical Trials Referral”) and select “COVID-19 (CRC)” under “Area Requested.” You can identify the specific trial you are interested in having the patient screened for or just indicate you would like the patient screened for all COVID-19 clinical trials. See Addendum 4.

<table>
<thead>
<tr>
<th>Study</th>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
<th>Inclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>CM4620-204 (Auxora); a calcium release-activated calcium channel inhibitor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PI: Dr. Paula Ferrada</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PassItOn (Passive Immunity Trial for Our Nation); convalescent plasma</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PI: Dr. Marjolein de Wit</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
VCU Adult ABX Guide

Monthly

• Content accessed 5,000-6,000 times
Figure 1. VCU Health COVID-19 Treatment Options Flow Map
Updated 4/19/21

This figure depicts where various potential therapeutic options can be considered.
Treatment decisions are at the discretion of the clinical service with input from Infectious Diseases and Pulmonary & Critical Care Medicine as needed.

Clinical Trials are in RED boxes; drugs available under FDA emergency use authorization (EUA) criteria are in PURPLE boxes; other (non-trial) options are in GREEN boxes; boxes with double lines = agents that are available to patients who are incarcerated.

Gray shading = targeting immune response.
Yellow shading = targeting virus directly.

*If dexamethasone/other corticosteroids are contraindicated EUA baricitinib can be substituted (in combination with remdesivir).

**Would give a one time dose of tocilizumab (8 mg/kg, up to 800 mg) for patients within 48 hours of the development of rapid progressive hypoxic respiratory failure requiring NIV or MV or high-flow O2 (>0.4 FiO2/30L/min oxygen flow) who also have a CRP of ≥ 7.5 mg/dL.

^The clinical trials teams are screening patients and will reach out to primary providers about potential enrollment. Primary teams can also put a clinical trial referral in CERNER (type in "Clinical Trials Referral").
Antimicrobial Stewardship & COVID-19 Preparation/Response

- Anticipate & manage drug shortages
- Assist in completing eIND and local IRB paperwork for emergency use agents (such as remdesivir)
- Monitor/enhance compliance w/ local treatment guidelines

Diagnostic Stewardship

- Assist in creating treatment guidelines

Collaboration w/ Epidemiology/Infection Prevention

- Can assist w/ early case identification
- Assist with communication
- Opportunity to longitudinally link programs

Coordinate w/ microbiology and Hospital Epidemiology for real-time interpretation of PCR test results
Antimicrobial Restriction

- Restricted:
  - Hydroxychloroquine, chloroquine, darunavir/cobicistat and lopinavir/ritonavir: 3/11/2020
  - Remdesivir when released under Emergency Use Authorization
  - Monoclonal antibodies (involved w/ outpatient screening)
- Helped guide:
  - Convalescent plasma use
Antimicrobial Restriction

• Our antimicrobial stewardship pharmacists took on expanded antimicrobial restriction pager coverage
  • Usually 8 AM to 5 PM M-Fr, then ID fellows take call 5 PM to 9 PM and on weekends/holidays
  • Hours expanded to 8 AM to 9 PM
    • Hospital provided additional pay for expanded coverage hours
Expanded AS Restriction Pager Coverage

- March 30-July 3rd pharmacy paid ASP pharmacists to take call from 5 PM-9 PM
Critical Drug Monitoring

- Working with Drug Information Services have helped monitor critical drug supplies
## Critical Drug Monitoring

**9/9/2020**

<table>
<thead>
<tr>
<th>Medication</th>
<th>Total</th>
<th>Target patients able to treat</th>
<th>Patients able to treat</th>
<th>Change of patients able to treat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cefepime</td>
<td>75</td>
<td>75</td>
<td>75</td>
<td>15%</td>
</tr>
<tr>
<td>Ciprofloxacin</td>
<td>75</td>
<td>16</td>
<td>16</td>
<td>1%</td>
</tr>
<tr>
<td>Levofloxacin</td>
<td>75</td>
<td>47</td>
<td>47</td>
<td>3%</td>
</tr>
<tr>
<td>Meropenem</td>
<td>75</td>
<td>38</td>
<td>38</td>
<td>10%</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>75</td>
<td>57</td>
<td>57</td>
<td>-6%</td>
</tr>
<tr>
<td>Micafungin</td>
<td>50</td>
<td>14</td>
<td>14</td>
<td>-13%</td>
</tr>
<tr>
<td>Piperacillin/tazobactam</td>
<td>75</td>
<td>137</td>
<td>137</td>
<td>0%</td>
</tr>
<tr>
<td>Azithromycin</td>
<td>75</td>
<td>670</td>
<td>670</td>
<td>0%</td>
</tr>
<tr>
<td>Ceftaroline</td>
<td>25</td>
<td>6</td>
<td>6</td>
<td>24%</td>
</tr>
<tr>
<td>Ceftazidime/avibactam</td>
<td>15</td>
<td>0</td>
<td>0</td>
<td>-100%</td>
</tr>
<tr>
<td>Ceftriaxone</td>
<td>75</td>
<td>98</td>
<td>98</td>
<td>0%</td>
</tr>
<tr>
<td>Ceftolozane/tazobactam</td>
<td>15</td>
<td>1</td>
<td>1</td>
<td>0%</td>
</tr>
<tr>
<td>Doxycycline</td>
<td>75</td>
<td>64</td>
<td>64</td>
<td>6%</td>
</tr>
<tr>
<td>Ertapenem</td>
<td>20</td>
<td>2</td>
<td>2</td>
<td>50%</td>
</tr>
<tr>
<td>Meropenem/vaborbactam</td>
<td>75</td>
<td>1</td>
<td>1</td>
<td>17%</td>
</tr>
</tbody>
</table>

* total based on dosage form (vial, premix, tablet)

† target to treat established with ID input

§ updated weekly on Wednesdays

C/o Kyle Hoelting, PharmD
# Critical Drug Monitoring

<table>
<thead>
<tr>
<th>Medication</th>
<th>Total(\ast)</th>
<th>Total mg per course</th>
<th>Target patients able to treat(\dagger)</th>
<th>Patients able to treat(\dagger)</th>
<th>Change of patients able to treat(\ddagger)</th>
<th>Alternative medication for use available</th>
<th>Supplier status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Etomidate</td>
<td>400</td>
<td>400</td>
<td>410</td>
<td>634</td>
<td>9%</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Rocuronium</td>
<td>400</td>
<td>400</td>
<td>845</td>
<td>32</td>
<td>12%</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Succinylcholine</td>
<td>400</td>
<td>400</td>
<td>57</td>
<td>32</td>
<td>2%</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Cisatracurium</td>
<td>400</td>
<td>400</td>
<td>24</td>
<td>32</td>
<td>-11%</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Vecuronium</td>
<td>400</td>
<td>400</td>
<td>57</td>
<td>32</td>
<td>2%</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Dexmedetomidine</td>
<td>400</td>
<td>400</td>
<td>24</td>
<td>32</td>
<td>-11%</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Fentanyl(\ddagger)</td>
<td>400</td>
<td>400</td>
<td>2625</td>
<td>32</td>
<td>1%</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Hydromorphone(\ddagger)</td>
<td>400</td>
<td>400</td>
<td>144</td>
<td>32</td>
<td>-1%</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Ketamine(\ddagger)</td>
<td>400</td>
<td>400</td>
<td>46</td>
<td>32</td>
<td>-2%</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Lidocaine</td>
<td>400</td>
<td>400</td>
<td>39577</td>
<td>32</td>
<td>1%</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Midazolam(\ddagger)</td>
<td>400</td>
<td>400</td>
<td>43</td>
<td>32</td>
<td>-33%</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Propofol</td>
<td>400</td>
<td>400</td>
<td>49</td>
<td>32</td>
<td>-85%</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Norepinephrine</td>
<td>400</td>
<td>400</td>
<td>112</td>
<td>32</td>
<td>13%</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Epinephrine</td>
<td>400</td>
<td>400</td>
<td>37</td>
<td>32</td>
<td>0%</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Dopamine</td>
<td>400</td>
<td>400</td>
<td>46</td>
<td>32</td>
<td>-2%</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Vasopressin(\ddagger)</td>
<td>400</td>
<td>400</td>
<td>18</td>
<td>32</td>
<td>6%</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Albuterol MDI</td>
<td>400</td>
<td>400</td>
<td>2380</td>
<td>32</td>
<td>9%</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Albuterol Nebs</td>
<td>400</td>
<td>400</td>
<td>127</td>
<td>32</td>
<td>3%</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Albuterol-iratropium Nebs</td>
<td>400</td>
<td>400</td>
<td>45</td>
<td>32</td>
<td>0%</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

\(\ast\) total based on dosage forms available
\(\dagger\) target to treat 400 patients (derived from 20% of estimated 2000 patients)
\(\ddagger\) 7-day adult dosing estimate for intubated patient (85 kg)
\(\ddagger\) updated weekly on Wednesdays
\(\ddagger\) based on formulations used to make CADDs and IV bags
\(\ddagger\) dose expressed in units

C/o Kyle Hoelting, PharmD
ASP Involvement in COVID-19 Response Efforts

• Major ways Antimicrobial Stewardship Programs (ASPs) have been involved (not exhaustive):
  • Case identification and diagnostic stewardship of SARS-CoV-2 testing
  • COVID-19 treatment
    – Guidelines
    – Facilitating access to potential therapeutics
  • Outpatient pandemic stewardship
    – Preauthorization for potential therapeutics
    – Managing access process for monoclonal antibodies
  • Vaccine Planning
Remdesivir

- ASP prepared to take on paperwork/assist with process for compassionate use

Email the “Remdesivir Clinical History Intake Form” to:
CompassionateAccess@gilead.com;
COPY: adam.dezure@gilead.com;
Huyen.Cao@gilead.com;
Jason.Hindman@gilead.com;
susanna.tan3@gilead.com;
Marisa.Alvarez@gilead.com;
Ioannis.Katsarolis@gilead.com;
USRegulatoryCOVIDCU@gilead.com

Gilead determines if eligible; if yes will ask us to send “FDA Form 3926” (goes to FDA directly, not Gilead)

Remdesivir Application (VCU Health)

Notify VCU Health Investigational Drug Service Pharmacy

Notify: Christine Davison (cmdaviso@vcu.edu); Susan Kimbrough (sdkimbrough@vcu.edu); John Horigan (jhorigan@vcu.edu)

VCU IRB

Coordinate w/ investigational pharmacy

Complete IRB submission (HM20019004)

Updated 3/9/2020
"VCU is one of only a handful of institutions in the United States to make these clinical trials available to patients who meet the criteria for this investigational drug."  bit.ly/3aghZeF  #COVID-19  @VCUHealth

We are proud to share that #VCU researchers have started two clinical trials on a potential, experimental treatment for COVID-19.  @VCUHealth  @VCU_CCTR  @NIH  #COVID-19  #SARS—Cov2
Integration with Clinical Trial Teams

- Early enrollment in two remdesivir trials in March
- ASP personnel and ID physicians involved in screening positive patients
- Daily (all patients) through mid-May for remdesivir trials
- As content experts available via consultation from May onward
- Clinical trials included in COVID-19 guidelines
- ASP and ID physicians on newly created COVID-19 Clinical Trials Oversight Committee
Clinical Trials are in RED boxes; drugs available under FDA emergency use authorization (EUA) criteria are in PURPLE boxes; other (non-trial) options are in GREEN boxes; boxes with double lines = agents that are available to patients who are incarcerated.

Gray shading = targeting immune response.
Yellow shading = targeting virus directly.

*If dexamethasone/other corticosteroids are contraindicated EUA baricitinib can be substituted (in combination with remdesivir).

**Would give a one time dose of tocilizumab (8 mg/kg, up to 800 mg) for patients within 48 hours of the development of rapid progressive hypoxic respiratory failure requiring NIV or manual vent (high-flow O2 (>0.4 FiO2/30L/min oxygen flow) who also have a CRP of ≥ 7.5 mg/dL.

The clinical trials teams are screening patients and will reach out to primary providers about potential enrollment. Primary teams can also put a clinical trial referral in CERNER (type in "Clinical Trials Referral").
Integration with Clinical Trial Teams

![Clinical Trial Team Integration](image-url)

<table>
<thead>
<tr>
<th>Bed</th>
<th>ST</th>
<th>Name</th>
<th>Age</th>
<th>Proj Discharge</th>
<th>Trial Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>C4</td>
<td>54</td>
<td></td>
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<td></td>
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<td>C4</td>
<td>63</td>
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<td>74</td>
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<td></td>
<td></td>
<td>C4</td>
<td>81</td>
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<tr>
<td></td>
<td></td>
<td>C4</td>
<td>62</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

New COVID-19 icon is controlled solely by the One Call Center. Do not add or remove.

Patient removed from remdesivir trial on 5/8 to receive tocilizumab.

Evaluating CrCl.

May 10, 2020
Center for clinical and translational research COVID-19 clinical trial committee: The development of a review and prioritization matrix during a pandemic

Published online by Cambridge University Press: 25 January 2021

Leslie Bobb, Lisa Richman Ballance, Antonio Abbate, Jesse C. Bain, Patricia J. Sime, F. Gerard Moeller, Margaret K. Lessard, Alisson J. Montpetit, Mary P. Harmon, Michael P. Stevens and Deborah DiazGranados

Abstract

The rate at which the coronavirus disease (COVID-19) spread required a rapid, structured approach for prioritizing interventions to prevent infection and improve clinical outcomes. The Center for Clinical and Translational Research COVID-19 Clinical Trial Committee, in partnership with the Clinical Research Office at the University of Michigan, was established to facilitate coordination, accelerate research, and streamline the conduct of clinical milestones. A two-tiered prioritization algorithm was developed to systematically identify areas of greatest need for clinical trials. The first tier prioritizes treatments that target use in severely ill patients, whereas the second tier prioritizes interventions for use in the general population. This prioritization framework is designed to guide decision-making during the early months of the pandemic. Future efforts will continue to expand on these approaches, including the development of a tiered prioritization approach to guide clinical research during the pandemic.
Remdesivir Under EUA Process

- Hospitals required to complete time-consuming patient monitoring and documentation with reporting to the Virginia Department of Health
- Our ASP took this on
- From 5/16/20-9/10/20 helped facilitate treatment with and monitored 114 patients

<table>
<thead>
<tr>
<th>Subject number</th>
<th>Treating Hospital Name</th>
<th>Age</th>
<th>Gender</th>
<th>Race</th>
<th>Ethnicity</th>
<th>Date of First Symptom Onset, if known</th>
<th>Date of Hospital Admission</th>
<th>Date of Remdesivir Initiation</th>
<th>Patient Location During Date of Initiation</th>
<th>Total Duration of Remdesivir Therapy, days</th>
<th>Patient Disposition</th>
<th>Date of Patient Disposition</th>
<th>Was the patient ever mechanically ventilated during duration of remdesivir therapy</th>
<th>Was the patient ever placed on ECMO during duration of remdesivir therapy</th>
<th>Payer Source for Hospitalization</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>VCUHS</td>
<td>51</td>
<td>Female</td>
<td>White</td>
<td>Not Hispanic or L</td>
<td>05/06/2020</td>
<td>5/13/2020</td>
<td>5/18/2020 ICU</td>
<td>6</td>
<td>Discharged</td>
<td>5/26/2020</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Private/Commercial</td>
</tr>
<tr>
<td>2</td>
<td>VCUHS</td>
<td>70</td>
<td>Male</td>
<td>Black/African-A</td>
<td>Not Hispanic or L</td>
<td>5/16/2020</td>
<td>5/15/2020</td>
<td>5/17/2020 ICU</td>
<td>5</td>
<td>Discharged</td>
<td>6/1/2020 Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Medicare</td>
</tr>
<tr>
<td>3</td>
<td>VCUHS</td>
<td>71</td>
<td>Male</td>
<td>Other</td>
<td>Not Hispanic or L</td>
<td>5/16/2020</td>
<td>5/18/2020</td>
<td>5/20/2020 Non-ICU</td>
<td>6</td>
<td>Discharged</td>
<td>6/1/2020 Yes</td>
<td>No</td>
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<tr>
<td>4</td>
<td>VCUHS</td>
<td>57</td>
<td>Female</td>
<td>White</td>
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<td>5/19/2020</td>
<td>5/19/2020</td>
<td>5/20/2020 Non-ICU</td>
<td>6</td>
<td>Discharged</td>
<td>5/26/2020 No</td>
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<td>No</td>
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</tr>
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<td>VCUHS</td>
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<td>Male</td>
<td>Black/African-A</td>
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<td>5/21/2020 Non-ICU</td>
<td>5</td>
<td>Discharged</td>
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<td>5/21/2020</td>
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<td>Discharged</td>
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<td>Self-pay</td>
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<tr>
<td>7</td>
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<td>Not Hispanic or L</td>
<td>04/19/2019</td>
<td>4/19/2019</td>
<td>4/19/2019 Non-FU</td>
<td>4</td>
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<td>6/26/2020 Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Medicare</td>
</tr>
</tbody>
</table>
Antimicrobial Stewardship Programs and Convalescent Plasma for COVID-19: A New Paradigm for Pre-Authorization?

Michael P. Stevens (1), Payal K. Patel (2) and Priya Nori (1)

DOI: https://doi.org/10.1017/ice.2020.459  Published online by Cambridge University Press: 09 September 2020
Table 1. Considerations for and Against Antimicrobial Stewardship Program (ASP) Involvement in COVID-19 Convalescent Plasma Pre-authorization

<table>
<thead>
<tr>
<th>Pro-ASP involvement</th>
<th>Against ASP Involvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>• ASPs already have pre-authorization infrastructure in-place</td>
<td>• ASPs have no direct involvement with Transfusion Medicine programs or authority to restrict access to blood products</td>
</tr>
<tr>
<td>○ Transfusion Medicine programs likely would need to create pre-authorization processes de novo and identify how to staff these</td>
<td>• ASP personnel are not experts in Transfusion Medicine</td>
</tr>
<tr>
<td>• ASP personnel are experts at creating and applying algorithm-based pre-authorization criteria</td>
<td>• ASP involvement will divert time away from other important stewardship activities, such as antibiotic use monitoring</td>
</tr>
<tr>
<td>• ASPs that are already responsible for local COVID-19 guidelines can help contextualize CP use relative to other potential therapies</td>
<td>• ASPs are put in the difficult position of brokering CP access against scientific community recommendations to use only in the context of randomized, clinical trials</td>
</tr>
<tr>
<td>• ASP personnel are experts at cooperative integration with non-Infectious Diseases or pharmacy-based service lines</td>
<td></td>
</tr>
</tbody>
</table>
Practical implementation of COVID–19 patient flags into an antimicrobial stewardship program's prospective review

Ryan W Stevens ¹, Lynn Estes ¹, Christina Rivera ¹

Affiliations  + expand

PMID: 32290883  PMCID: PMC7184145  DOI: 10.1017/ice.2020.133

Free PMC article
Prospective Audit and Feedback

• Stevens and colleagues described the creation of custom EMR-based flags for patients with possible COVID-19 that were utilized by their ASP as a part of prospective audit and feedback activities
• Identified patients with negative PCR tests on potential COVID-19 therapeutics
• Identified patients with positive PCR tests for ASP review
  • To verify appropriate ID team involvement
  • To consider candidacy for clinical trial involvement
  • To assess for eligibility for potential therapeutics
Antimicrobial Stewardship & COVID-19 Preparation/Response

Collaboration w/ Epidemiology/Infection Prevention
- Can assist w/ early case identification
- Assist with communication
- Opportunity to longitudinally link programs

Diagnostic Stewardship
- Coordinate w/ microbiology and Hospital Epidemiology for real-time interpretation of PCR test results

Treatment
- Assist in creating treatment guidelines
- Anticipate & manage drug shortages
- Assist in completing eIND and local IRB paperwork for emergency use agents (such as remdesivir)
- Monitor/enhance compliance w/ local treatment guidelines
Addendum 3. Possible Bacterial Superinfection in Patients Admitted with COVID-19
Authors: Cathy Grossman, MD, Kimberly Lee, PharmD, Jihye Kim PharmD, Michael P. Stevens, MD, MPH
Last Updated: April 13, 2021

Background:

- This guidance document is focused on patients hospitalized with a NEW diagnosis of COVID-19 in the past 14 days. Recommendations are broken down by time frame of hospitalization (≤ 48 hours and > 48 hours), and by risk factors for infection with drug-resistant bacteria (e.g., MRSA and Pseudomonas aeruginosa/other MDR Gram negative organisms).

- Patients with COVID-19 who develop worsening respiratory disease later than 14 days after symptom onset, especially who received potentially immunosuppressing medications (like steroids, tocilizumab, et cetera), have increased risk for bacterial superinfection as well as fungal infections (e.g., invasive aspergillosis). Would consider consultation with Infectious Diseases as needed.

- Patients with baseline immunosuppression (from things like neutropenia, transplant-related medications, et cetera) are at risk for infection with a broader array of possible organisms. Would consider consultation with Infectious Diseases as needed.

Evaluation:

- We acknowledge that time from COVID-19 testing to result return varies, and that many patients with COVID-19 may present similarly to severe community-acquired pneumonia (CAP)
  - Patients hospitalized with COVID-19 can develop hypoxic respiratory failure, viral pneumonia and can also develop ARDS. Diagnosing concomitant bacterial superinfection in these patients can be challenging.
  - The following diagnostic findings may indicate increased risk for bacterial superinfection:
    - Leukocytosis; lobar consolidation; evidence of necrotizing pneumonia on imaging; new fever after defervescence WITH new consolidation on chest imaging

- We do not recommend routinely administering empiric therapy for bacterial pneumonia in patients with COVID-19; the best available data suggests 3-14% of hospitalized patients with COVID-19 may have bacterial superinfection (either presenting with this or developing it during their hospitalization)

- If empiric antibiotics are going to be initiated based on clinical/radiographic evaluation, the following diagnostic testing should be considered

<table>
<thead>
<tr>
<th>Diagnostic Test</th>
<th>Duration of hospitalization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood cultures x 2 sets (if risk factors present for MRSA or P. aeruginosa¹)</td>
<td>≤ 48 hours</td>
</tr>
</tbody>
</table>

¹ MRSA: Methicillin-resistant Staphylococcus aureus; P. aeruginosa: Pseudomonas aeruginosa
Impact of COVID-19 on Pneumonia-Focused Antibiotic Use at an Academic Medical Center

Matthew Nestler (a1), Emily Godbout (a1) (a2), Kimberly Lee (a3), Jihye Kim (a3), Andrew J. Noda (a3), Perry Taylor (a3), Rachel Pryor (a2), J. Daniel Markley (a3) (a4), Michelle Doll (a1) (a2), Gonzalo Bearman (a1) (a2) and Michael P. Stevens (a1) (a2)

1: Virginia Commonwealth University School of Medicine, Richmond, VA, USA
2: Healthcare Infection Prevention Program. Virginia Commonwealth University Health System, Richmond, VA, USA
3: Virginia Commonwealth University Health System, Richmond, VA, USA
4: Hunter Holmes McGuire VA Medical Center, Richmond, VA, USA

DOI: https://doi.org/10.1017/ice.2020.362 Published online by Cambridge University Press: 23 July 2020
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<tbody>
<tr>
<td>MICU</td>
<td>156 (28% of total PD)</td>
<td>212 (30% of total PD)</td>
<td>Cefepime</td>
<td>134</td>
<td>117</td>
<td>0.61</td>
<td>184</td>
<td>0.16</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Pip-Tazo</td>
<td>341</td>
<td>385</td>
<td>0.42</td>
<td>324</td>
<td>0.75</td>
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<td></td>
<td></td>
<td></td>
<td>Meropenem</td>
<td>72</td>
<td>78</td>
<td>0.81</td>
<td>56</td>
<td>0.49</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Vancomycin</td>
<td>281</td>
<td>262</td>
<td>0.55</td>
<td>271</td>
<td>0.76</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Ceftriaxone</td>
<td>55</td>
<td>193</td>
<td><strong>0.00</strong></td>
<td>81</td>
<td>0.10</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Azithromycin</td>
<td>50</td>
<td>109</td>
<td><strong>0.03</strong></td>
<td>49</td>
<td>0.95</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Levofoxacin</td>
<td>56</td>
<td>24</td>
<td>0.07</td>
<td>3</td>
<td>0.01</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Doxycycline</td>
<td>15</td>
<td>12</td>
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<td>0</td>
<td>0.23</td>
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<tr>
<td>CICU</td>
<td>6 (3% of total PD)</td>
<td>14 (5% of total PD)</td>
<td>Cefepime</td>
<td>53</td>
<td>72</td>
<td>0.56</td>
<td>46</td>
<td>0.84</td>
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<td></td>
<td></td>
<td></td>
<td>Pip-Tazo</td>
<td>210</td>
<td>216</td>
<td>0.89</td>
<td>268</td>
<td>0.25</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Meropenem</td>
<td>25</td>
<td>38</td>
<td>0.42</td>
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<td>Vancomycin</td>
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<tr>
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<td>Doxycycline</td>
<td>18</td>
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## Impact on Normal ASP Activities

<table>
<thead>
<tr>
<th>Activity</th>
<th>Projected # of hours invested (as of April 22, 2021)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Updating COVID-19 treatment guidelines (including mobile app updating)</td>
<td>&gt; 300</td>
</tr>
<tr>
<td>Nighttime antimicrobial restriction pager coverage</td>
<td>~ 372</td>
</tr>
<tr>
<td>Remdesivir monitoring under EUA distribution</td>
<td>~ 200</td>
</tr>
<tr>
<td>Remdesivir and other COVID-19 focused therapeutic restriction</td>
<td>~ 195 (call volume up 40-60%)</td>
</tr>
<tr>
<td>Monoclonal Ab outpatient screening (including meetings and planning)</td>
<td>~ 35</td>
</tr>
<tr>
<td>Meetings (including clinical trial committee meetings)</td>
<td>&gt; 100</td>
</tr>
<tr>
<td>Research (not included in hour total)</td>
<td>~ 150</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>~ 1,200 + hours</strong></td>
</tr>
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</table>
ASP Involvement in COVID-19 Response Efforts

- Major ways Antimicrobial Stewardship Programs (ASPs) have been involved (not exhaustive):
  - Case identification and diagnostic stewardship of SARS-CoV-2 testing
  - COVID-19 treatment
    - Guidelines
    - Facilitating access to potential therapeutics
  - Outpatient pandemic stewardship
    - Preauthorization for potential therapeutics
    - Managing access process for monoclonal antibodies
  - Vaccine planning

Letter to the Editor

Antimicrobial stewardship and bamlanivimab: Opportunities for outpatient preauthorization?

Payal K. Patel MD, MPH1, Priya Nori MD2 and Michael P. Stevens MD, MPH3

1Infectious Diseases Section, Ann Arbor Veterans’ Affairs Medical Center, Ann Arbor, Michigan, 2Division of Infectious Diseases, Department of Medicine, Montefiore Medical Center, Albert Einstein College of Medicine, Bronx, New York and 3Healthcare Infection Prevention Department, Virginia Commonwealth University Health System, North Hospital, Richmond, Virginia

To the Editor—Preauthorization is a fundamental action of antimicrobial stewardship programs (ASPs).1 ASPs have played essential roles in coronavirus disease 2019 (COVID-19) response efforts since the onset of the pandemic. For instance, ASPs have implemented the preauthorization of remdesivir throughout its path from an experimental antiviral obtained via compassionate use or expanded access, to Food and Drug Administration (FDA) Emergency Use Authorization (EUA), to ultimate FDA approval.2,3 On November 8, 2020, the FDA released an EUA for bamlanivimab, a monoclonal antibody that was halted due to unfavorable data,6-8 it may be prudent to await further data and/or guidance from professional organizations (eg, the Infectious Diseases Society of America). See Figure 1 for additional considerations.

The bamlanivimab EUA may present ASPs with a golden opportunity to enhance their outpatient stewardship impact. As of January 1, 2020, the Joint Commission has mandated that health systems deploy active antimicrobial stewardship interventions in
Figure 1. ASPs and Bamlanivimab preauthorization

ASPs and Bamlanivimab Preauthorization

Reasons for Involving ASPs
- Have experience with preauthorization
- Can chart review patients to make sure they meet criteria for use
- Can help maintain compliance with local equitable distribution processes
- May help ASPs develop infrastructure for outpatient and ER-based preauthorization
- Outpatient antimicrobial stewardship is now mandated

Reasons Against Involving ASPs
- ASPs likely do not have 24/7 preauthorization coverage; this limits equitable and consistent restriction of a limited resource
- ASP involvement in this work will siphon time away from other ASP work

Important Additional Considerations
- Who will be responsible for state-level monitoring and reporting requirements?
- What will be the impact on clinical trials?
- How to assure equity in access?
- Given the limited data available incorporating into local treatment guidelines will be challenging
- Opportunity for ASPs to enhance their business case for program building
- Will patients be followed to assess if desired outcomes were achieved? If yes, who will do this work?
ASP Role in Process:
* Screen for eligibility
* Connect providers to correct person in CDU if patient eligible
ASP does NOT put in orders, documentation in CERNER and is not involved in any other specific parts of the process (but is available as an expert resource)

At any point in the process ASP pharmacist can discuss with Mike Stevens

ASP Pharmacist calls CDU provider at 919-216-8649 and gives her/him the patient's MRN and confirms they are okay with the referral.

CDU APP agrees with referral

ASP pharmacist calls the referring provider back and:
1) Emails her/him the FDA EUA Fact Sheet for providers as well as sample CERNER documentation verbiage
2) Gives the referring provider the APP number to discuss the ER referral process (if patient is in agreement—see #3)
3) It is the responsibility of the referring provider to discuss with their patient & if the patient is in agreement with referral to document this in CERNER

Patient eligible

This is communicated to the primary provider and she/he is notified that the next step is for ASP to discuss with the CDU APP

Patient not eligible

This is communicated to the referring provider

CDU disagrees with referral

Call Mike Stevens to discuss

ASP pharmacist documents in Sentri7 (AMS ASP Consult = "yes")

Contact Information:
Mike Stevens = 919-216-8649
Dr. Taruna Aurora = 919-216-8649

VCU Health provider pages ASP (3144) for patient eligibility assessment

ASP Pharmacist reviews eligibility criteria in Table 1a of the Adult COVID-19 guidelines & determines eligibility
ASP Involvement in COVID-19 Response Efforts

- Major ways Antimicrobial Stewardship Programs (ASPs) have been involved (not exhaustive):
  - Case identification and diagnostic stewardship of SARS-CoV-2 testing
  - COVID-19 treatment
    - Guidelines
    - Facilitating access to potential therapeutics
  - Outpatient pandemic stewardship
    - Monoclonal antibodies
  - Vaccine planning

Rational allocation of COVID-19 vaccines to healthcare personnel and patients: a role for antimicrobial stewardship programs?

Published online by Cambridge University Press: 16 December 2020

Priya Nori, Payal K. Patel and Michael P. Stevens

Abstract
Figure 1. Antimicrobial Stewardship (AS) and SARS-CoV-2 Vaccination
Overview

• Describe novel activities that Antimicrobial Stewardship Programs (ASPs) have taken on during the COVID-19 pandemic
• Describe ASP collaboration with infection prevention programs (IPP) during the pandemic
• Discuss implications from the pandemic on future ASP activities and program building
Similarities and Differences Between ASPs and Infection Prevention Programs

**ASPs**

**Focus:** Improve antimicrobial use, ↓ resistance

**Strategies:** Antimicrobial Restriction a major strategy

**Personnel:** *Pharmacists*

Report through Pharmacy

**Infrastructures:** Use of 3rd party software platforms

Need for leadership commitment

**Focus:** Patient outcomes & MDROs

**Strategies:** Audit & feedback

Education

**Personnel:** *ID Physician*

IT Specialist

Microbiologist

Nursing

**Metrics:** Focus on CDI

Use process & outcome metrics

NHSN reporting

**IPPss**

**Focus:** ↓ HAIs

**Personnel:** *Infection Preventionists*

(IPs; often RNs)

Director and IPs report through nursing

**Focus:** Improve antimicrobial use, ↓ resistance

**Strategies:** Audit & feedback

Education

**Personnel:** *ID Physician*

IT Specialist

Microbiologist

Nursing

**Metrics:** Focus on CDI

Use process & outcome metrics

NHSN reporting
## ASP and IPP Key Activities During the COVID-19 Pandemic

<table>
<thead>
<tr>
<th>IPPs</th>
<th>ASPs</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Identification and isolation of potentially infected patients; including test stewardship</td>
<td>• Creation and maintenance of treatment guidelines</td>
<td>• ASPs can play a role in test stewardship, case identification and can alert IPPs about possible cases</td>
</tr>
<tr>
<td>• Managing evolving PPE strategies based on access</td>
<td>• Restriction of potential therapeutics</td>
<td>As part of guidelines dissemination ASPs can reinforce key IP messaging</td>
</tr>
<tr>
<td>• Communication with leadership, staff and patients</td>
<td>• Managing access process for key therapeutics</td>
<td>New mechanisms for data acquisition and reporting have been important to both IPPs and ASPs</td>
</tr>
<tr>
<td>• Outbreak investigation and mitigation</td>
<td>• Monitoring and reporting on key drug stock/shortages</td>
<td></td>
</tr>
</tbody>
</table>

ASP and IPP Collaboration During the Pandemic

• Playing a key role in managing guidelines and potential therapeutics provided ASPs a “seat at the table” and reinforced program value to key stakeholders
• The COVID-19 pandemic created new real-time data needs; IPPs and ASPs have collaborated w/ other groups to create new reports and mechanisms for reporting
• Enhancement in communication infrastructure was developed during the pandemic
• An emphasis on social distancing and telework has led to the adoption of new technologies for real-time collaboration
• The pandemic has highlighted the critical need for real-time IT support
• Some ASPs and IPPs enhanced telehealth services to other hospitals during the pandemic
# ASPs and IPPs: Future Activities

## Low Hanging Fruit
- ASPs can utilize IPP structures to solidify regular C-suite access
- Technology for remote communication will facilitate ASP/IPP collaboration
- Infrastructure created for data access, reporting and collaboration can facilitate collaboration

## Moderate Fruit
- ASPs can work with IPPs to refine/enhance data tracking and reporting
  - Includes NHSN reporting
  - ASPs and IPPs can create business plans for collaborative access to IT infrastructure and specialists
  - ASPs and IPPs can collaborate on staff and patient education

## High Fruit
- Enhanced models for ID physician and pharmacist recruitment, training and certification can be developed
- ASPs and IPPs can consider new combined program models
- ASPs and IPPs can collaborate on bundled telehealth services to other hospitals

Post-Pandemic Collaboration: A Model

Advantages:

- Utilize same cadre of trained ID physicians; pull on data expertise
- Streamlined organizational structure
- Enhanced leadership access
- Synergy with software use and IT specialist access
- Synergy with data reporting
- Synergy with patient and staff education
- Enhanced patient outcomes
Thank You

• The VCU Health Antimicrobial Stewardship Program
  • Dr. Kim, Dr. Deja, Dr. Lee, Dr. Cooksey, Dr. Noda, Dr. Godbout
• The VCU Health Hospital Infection Prevention Program
• Dr. Priya Nori and Dr. Payal Patel
References


References

References
