FDA Drug Topics:

CURE ID:

Capturing Clinician’s Experiences Repurposing Drugs to Inform Future Studies in the Era of COVID-19

Heather A. Stone, MPH
Disclaimers

Heather Stone reports no financial disclaimers.

Discussion of Unapproved use

This presentation will contain significant discussion of the use of medical products for diseases and conditions that are not included in the FDA approved labeling. The discussion should not be construed as promoting unapproved uses of approved drugs, or that the data should be used for anything more than hypothesis-generation.

Intent and Limitations of Data

CURE ID is not intended to be used by pharmaceutical companies or manufacturers to advertise or promote unapproved uses of approved drugs

Individual case reports are insufficient to establish the safety or effectiveness of a new use of an approved product

Inclusion of data in the CURE ID repository also does not indicate that FDA, NIH, or other CURE ID partners endorse its validity, reliability, or usefulness in making individual patient treatment decisions
Learning Objectives

Discuss the intent behind CURE ID.

Demonstrate the mobile app and its features.

Explain the potential uses of CURE ID.

Summarize the limitations of CURE ID.
Outline

Overview and Context
  Diseases
  Drug Development
  Drug Repurposing

CURE ID Platform
  Background
  Demo
  Case Study: Nontuberculous Mycobacteria
  Data and FAQ
  Use for COVID-19
  CURE Drug Repurposing Collaboratory
Context of the Problem
What do these diseases have in common?

**Parasites/protozoa**
- Sarcocystis
- Anasikiasis
- Dracunculiasis
- Dirofilariasis
- Fascioliasis
- Paragonimiasis
- Clonorchis
- Babesiosis
- Anaplasmosis
- Balantidium
- Sparganosis
- Microsporidiosis
- Loa loa
- Plasmodium knowlesi
- Enterophthoromykosis
- Toxoplasmosis in pregnancy

**Bacteria**
- Trichinellosis
- Myiasis
- Balamuthia mandrillaris
- Acanthamoeba
- Naegleria
- Melioidosis
- Nocardia
- Whipples disease
- Oroya fever
- Atypical mycobacteria
- Buruli ulcer

**Fungi**
- Penicillium marneffii
- Mycetoma
- Exerohilum rostratus

**Viruses**
- Dengue
- Japanese encephalitis
- Rabies
- CCHF
- Marburg/Lassa/Ebola
- Zika/Chikungunya
- West Nile
- Western/Eastern encephalitis
- Powassan
- California encephalitis
- Rift valley fever
- Yellow fever
- Creutzfeldt-Jacobs
- MERS
- SARS
- COVID-19
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- Rift valley fever
- Yellow fever
- Creutzfeldt-Jacobs
- MERS
- SARS
- COVID-19

They all lack sufficient approved treatments.
Current State....

For FDA drug approval and marketing, a sponsor must submit a new drug application.

When there is no commercial incentive, diseases are often neglected, trials are not funded and drug discovery ceases.

A significant percentage of the world’s population suffers from an infectious disease with no approved therapy; many others suffer from infectious diseases which have one or more approved therapies, but from which they are unable to benefit.
Upon approval, drugs are labeled for those indications or diseases sought by the drug sponsor for which there is substantial evidence of effectiveness.

Once a drug is approved, based on knowledge and professional judgement, physicians may take the responsibility for prescribing drugs for different populations, doses and diseases not listed in the approved label.
Q: So why aren’t there any approved treatments for some infectious diseases or sufficient therapies for many others?

A: Because the commercial incentives for drug development may not work for all diseases and in all places...
Some of the challenges

Insufficient funding of research and development directed towards identifying effective therapies for diseases with high public health need, but low commercial value.

Even where there is anecdotal evidence of drug activity for a new indication, a commercial sponsor is unlikely to conduct formal clinical trials if the investment needed for a new indication will not be recouped through sales.

Academic or non-commercial institutions may perform studies demonstrating the value of a drug in a new indication, but they don’t have the capacity to sponsor a drug application that can be reviewed by FDA.
Additional Challenges

Companies with an approved drug are unlikely to seek additional indications if market dynamics do not support the investment.

Companies are unlikely to pursue additional indications for older drugs that are no longer patent-protected, because a generic drug can be substituted.

For certain infectious diseases that are found in lower resource countries, the market incentives may not favor investment.

It may also prove very difficult to identify effective therapies for some infectious diseases.

For all of these reasons, there remain many tropical infectious diseases, parasitic diseases, drug-resistant infections and emerging infections that lack sufficient approved treatment.
What is Drug Repurposing?

Drug repurposing is the identification of potential novel uses of existing drugs.
What kinds of new information can be gleaned from looking at existing drugs?

Doctors may discover new ways of treating diseases.

Doctors may discover new combinations of drugs that are useful.

Doctors may discover new dosing regimens and durations of therapy.

Doctors may discover new populations that can benefit from existing treatments.

Doctors may discover that unapproved uses do not work or are harming patients.
What can be done for diseases lacking adequate approved treatments?

Clinical experience on how existing drugs are being used can be collected, so that promising candidates, drug combinations, and treatment regimens are quickly identified, and clinical trials are conducted to investigate these new uses.
### Examples of approved drugs repurposed for infectious diseases

<table>
<thead>
<tr>
<th>Drug</th>
<th>FDA approved indications</th>
<th>Uses documented in Literature/Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imipenem</td>
<td>Lower respiratory tract, Urinary tract, Intraabdominal, Gynecologic, Bacterial septicemia, Bone and Joint, Skin and skin structure, Endocarditis, Polymicrobial infections</td>
<td>Nocardia</td>
</tr>
<tr>
<td>Azithromycin</td>
<td>Bacterial exacerbation of chronic bronchitis, Bacterial sinusitis, Pharyngitis/tonsillitis, Skin infections, urethritis/cervicitis, Genital ulcers, Pneumonia (CAP),</td>
<td>Trachoma</td>
</tr>
<tr>
<td>Levofloxacin</td>
<td>Pneumonia (CAP), Skin infections, Prostatitis, Plague, Anthrax, Urinary tract infections, Bacterial exacerbation of chronic bronchitis, Bacterial sinusitis</td>
<td>Tuberculosis, Oroya fever</td>
</tr>
<tr>
<td>Pentamidine</td>
<td>Pneumocysits Jiroveci</td>
<td>Trypanosomiasis</td>
</tr>
<tr>
<td>Ambisome</td>
<td>Aspergillus, candida, Cryptococcus, febrile neutropenia, visceral leishmaniasis,</td>
<td>Acanthamoeba</td>
</tr>
<tr>
<td>Ivermectin</td>
<td>Strongyloides, Onchocerciasis</td>
<td>Lymphatic filariasis, Scabies, Lice</td>
</tr>
<tr>
<td>Atovaquone</td>
<td>Pneumocystis</td>
<td>Babesiosis</td>
</tr>
<tr>
<td>Ceftriaxone</td>
<td>Lower Respiratory Tract Infections, Skin Infections, Urinary Tract Infections Pelvic Inflammatory Disease Bacterial Septicemia, Bone and Joint Infections, Intra-abdominal Infections, Meningitis, Surgical Prophylaxis</td>
<td>Whipple’s disease, Lyme disease</td>
</tr>
<tr>
<td>Rifampicin</td>
<td>Tuberculosis, Meningococcal prophylaxis</td>
<td>Brucellosis</td>
</tr>
</tbody>
</table>
Advantages of repurposing existing drugs

Time and cost to develop a new indication for an existing drug may be significantly less compared to developing a new drug from scratch because:

Most of the non-clinical drug development has already been done including chemistry, manufacturing and control, animal toxicology and clinical pharmacology.

There is clinical data on safety in a population that may be relevant to the novel use.
Drug Repurposing vs. De Novo Drug Development

Why repurposing?

<table>
<thead>
<tr>
<th>Drug Repurposing</th>
<th>New Drug Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Success Rate</td>
<td>Success Rate</td>
</tr>
<tr>
<td>1/10</td>
<td>1/10,000</td>
</tr>
<tr>
<td>Known Safety</td>
<td>Unknown Safety</td>
</tr>
<tr>
<td>VS</td>
<td>VS</td>
</tr>
<tr>
<td>1-3</td>
<td>12-19</td>
</tr>
<tr>
<td>Costs &lt;$500,000</td>
<td>Costs &gt;$1,500,000,000</td>
</tr>
</tbody>
</table>

Source: [https://www.cureswithinreach.org/](https://www.cureswithinreach.org/)
A Platform to Capture Novel Uses of Existing Drugs

Challenging Cases... Innovative Treatments

**CONTRIBUTE**
Contribute your knowledge and expertise

**EXPLORE**
Explore experiences of clinicians globally

**DISCUSS**
Discuss and share your most challenging clinical cases and treatment questions
What is CURE ID?

It is an internet-based data repository developed as a collaboration between the U.S. Food and Drug Administration (FDA) and the National Center for Advancing Translational Sciences, a part of the National Institutes of Health (NCATS/NIH).

It was developed with support from the Infectious Diseases Society of America (IDSA), the Centers for Disease Control and Prevention (CDC), and the World Health Organization (WHO).

It gives the global clinical community the opportunity to report novel uses of existing drugs for patients with difficult-to-treat infectious diseases through a website, a smartphone or other mobile device.
CURE ID Goals

To enhance the understanding of new uses of approved medical products.

To facilitate clinical trials and drug development.

To serve as a resource for physicians to share information where no FDA approved product (which has been proven to be safe and effective) exists for the new use.
Where can CURE ID be found?

Visit:
https://cure.ncats.io

OR

Download from the App or Play store as “CURE ID”
CURE ID – A mobile app to help clinicians, regulators and drug developers

Share cases - report your own cases and read cases from other clinicians around the world of neglected infectious diseases with no sufficient approved therapies

Communicate – engage directly with communities of disease experts around the world

Access information – view information on approved therapies for each disease and on active clinical trials for each disease
Potential uses of CURE ID

Serve as a rapid communication platform for healthcare providers during an outbreak, providing for systematic case-sharing, discussions, and the latest literature.

Facilitate the sharing of information on potential therapies for diseases which lack available, approved treatments and inform current and future clinical trials, serving as an important bridge between unstructured anecdotal reports and robust randomized trials ultimately required for drug approval.

Enable the exchange of opinions from global communities of experts.

Help to identify potential new uses for existing drugs, and limit unhelpful or harmful uses.
How can the global Infectious Disease community participate?

Neglected infectious diseases
Antimicrobial resistant organisms
Emerging threats

Initial Pilot Priority Diseases:

COVID-19
Mycetoma
Atypical mycobacteria
Drug-Resistant Gonorrhea
Rare and Resistant Fungal Infections
Multi-drug resistant gram negatives (MDRGNB)

Insufficient or No Approved Therapies
Platform Features

**EXPLORE**
View reported case reports (from individual clinicians and the published literature) individually and in aggregate, as well as discussions and clinical trials.

**CREATE**
Create your own case report or discussion post using an easy electronic/mobile platform.

**COMMENT**
Join the conversation by commenting on case reports and discussion posts from other users.

**NEWSFEED**
Stay up to date on the latest infectious disease news, journal articles, events, and submissions to CURE ID.
EXPLORE
Search by disease
View clinical trials
Look up published cases
Review user-submitted cases

CONTRIBUTE
Enter or update a case
Participate as a curator
Get involved in the initiative

DISCUSS
Ask your questions and get replies
View others’ discussion posts
Comment on others’ cases
Consult with colleagues
EXPLORE

CASE REPORTS

CURE ID

COVID-19

Drug Used

Lopinavir-Ritonavir

Hydroxychloroquine

Interferon Alfa

Tocilizumab

Combination Therapy (6)

Tocilizumab + Azithromycin + Hydroxychloroquine

Outcomes

Improved

Undeteriorated

Deteriorated

User-Submitted (1)

Case ID # 6402

Deteriorated

COVID-19

90+ years | Male | 12/2021 | United States

Created By: Adam Klein | Medical Director

Date: 02:00 PM, Apr 30 2020

Dosage: 800 mg, once
Cheng-Hsun Chiu

We switched to oral amoxicillin + rifampin after 3 months of combination treatment with amikacin + imipenem + azithromycin. Erythromycin was given for 2 weeks in this period. Clinically, he improved and a CT showed 'limited' resolution of the subcutaneous abscess and cellulitis. Then we shifted the treatment to maintenance with azithromycin and rifampin (oral). He started to have intermittent mild fever 3-4 days afterwards. Blood test showed normal WBC and CRP. The intermittent fever persisted for 4-5 days until we decided to add IV imipenem and amikacin back.

Leonard Sacks

Could the fever have been an adverse effect of the rifampin? Was the rifampin stopped at the time you resumed the imipenem?

Cheng-Hsun Chiu

Yes we stopped it when imipenem and amikacin added again. Fever was gone in 1-2 days. Rifampin common to cause drug fever?

Parvesh Paul

Yes, rifampin can cause fever and this was picked up in the post marketing reports for this drug.

07:16 AM, Oct 05 2019

Cheng-Hsun Chiu

So we back to IV imipenem + amikacin plus oral azithromycin, and the fever well controlled. We plan to give probably 6 months with such regimen and then follow-up MRI for the subcutaneous "milk abscesses" (5.8 cm estimated). We have a problem the causes confirmed resistant to FQ and linezolid. Our hands are short, if useful oral agents and we are unable to move a Pyrex to shift to QMx.
EXPLORE CLINICAL TRIALS

- **Title**: Impact of Plasma Levels of Colistin in Patients With Carbapenem-Resistant Acinetobacter Baumannii Infection
- **Sponsor**: DongGuk University
- **Status**: Unknown status
- **Phase**: N/A
- **Participants**: 50 patients
- **Start Year**: 2015

**Title**: Pharmacodynamics Modeling to Optimize Therapy Strategies of Colistin

[Image of CURE ID app with clinical trial information]

**Logos**: FDA, U.S. Food & Drug Administration, NIH, National Center for Advancing Translational Sciences
CREATE CASE REPORTS

- Share your experience with an infection that was difficult to treat
- Create Case Report
- Create Discussion Post
Case ID # 5452

**Disease**: COVID-19

**Diagnosis**
- Clinical assessment
- PCR
- Imaging

**Challenge**: There is no standard/approved therapy for this disease

**Drug(s)**: Tocilizumab

**Outcome**: Patient deteriorated

**Adverse Events**: stroke

**Patient Characteristics**
- **Age**: 90+ years
- **Sex**: Male
- **Country Contracted**: United States
- **Country Treated**: United States
- **Treatment Began**: 2020

**Co-Morbidities**:
- Co-Morbidities: atrial fibrillation, hypertension

**Diagnosis**
- **Organism**: Sars-cov-2

**Treatment Details**
- **Tocilizumab**: 400mg once IV X 1 day

**How new way**: To treat a disease other than the one for which the drug is approved

**Treatment setting**: ICU/Critical Care

**Surgery**: No

**Outcome**
- **Method(s) of outcome determination are**:
  - Clinical assessment
  - Imaging
- **Outcome assessed**: At the time the treatment was completed
- **Relapse**: No

**Comments**

- **09:38 PM, Apr 28 2020**
  - Rita Abbud (Medical Doctor)
  - Had similar experience in my practice

- **09:31 AM, Apr 27 2020**
  - CURE ID Admin (Medical Doctor)
  - Dr. Abbud, please consider sharing your experiences as case reports as well. Thanks for adding your comment!

  Add a comment...
CREATE
DISCUSSIONS

Share your experience with an infection that was difficult to treat

Create Discussion Post

By Judy Stone | Medical Doctor | 2 years ago

Empiric Rx Or Immunocompromised Patient With Sepsis, Shock Liver 3/N

Post anonymously

Submit a new discussion
“The CURE ID application focuses on drugs for infectious diseases lacking adequate treatments, including neglected tropical diseases, emerging infectious threats and infections caused by antimicrobial-resistant organisms. When health care professionals directly input their clinical cases into the app, CURE ID allows these real-world experiences to be organized and analyzed much faster, making it easier to spot promising new uses for existing drugs,” said Amy Abernethy, M.D., Ph.D., FDA Principal Deputy Commissioner. “Our hope is that this app will serve as a connector among major treatment centers, academics, private practitioners, government facilities and other health care professionals from around the world and ultimately get treatments to patients faster.”

- Amy Abernethy, M.D., Ph.D., FDA Principal Deputy Commissioner

“The potential importance of new therapeutic opportunities from repurposing drugs can’t be understated,” said NCATS Director Christopher P. Austin, M.D. “The CURE ID platform exemplifies how collaborative efforts can spark innovations that benefit patients. This new platform harnesses the power of crowdsourcing to help gather medical observations in the field and help identify potentially effective treatments for diseases.”

- Christopher Austin, M.D., NCATS/NIH Director
Case Study:

Repurposing for Nontuberculous Mycobacteria
Examples from the Published Literature:


**Improvement of Mycobacterium abscessus Pulmonary Disease after Nivolumab Administration in a Patient with Advanced Non-small Cell Lung Cancer.**

Ishii S¹, Tamiya A¹, Taniguchi Y¹, Tanaka T¹, Abe Y¹, Isa S², Tsuyuguchi K³, Suzuki K¹, Atagi S².


Combinations of avibactam and carbapenems exhibit enhanced potencies against drug-resistant *Mycobacterium abscessus*

Amit Kaushik, Chhavi Gupta, Stefanie Fisher, Elizabeth Story-Roller, Christos Galanis, Nicole Parrish, and Gyanu Lamichhane.


**Preliminary Results of Bedaquiline as Salvage Therapy for Patients With Nontuberculous Mycobacterial Lung Disease.**

Philley JV¹, Wallace RJ Jr², Benwill JL³, Taskar V⁴, Brown-Elliott BA⁵, Thakkar F⁴, Aksamit TR⁶, Griffith DE⁴.
FDA Approved Drugs with any Nontuberculous Mycobacteria Indication

Amikacin
Azithromycin
Clarithromycin
Minocycline
Rifabutin
<table>
<thead>
<tr>
<th>Drug Used</th>
<th># of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clarithromycin</td>
<td>38</td>
</tr>
<tr>
<td>Ethambutol</td>
<td>36</td>
</tr>
<tr>
<td>Rifampicin</td>
<td>20</td>
</tr>
<tr>
<td>Moxifloxacin</td>
<td>19</td>
</tr>
<tr>
<td>Amikacin</td>
<td>14</td>
</tr>
<tr>
<td>Rifabutin</td>
<td>13</td>
</tr>
<tr>
<td>Ciprofloxacin</td>
<td>7</td>
</tr>
<tr>
<td><strong>Levofloxacin</strong></td>
<td><strong>4</strong></td>
</tr>
</tbody>
</table>
### Nontuberculous Mycobacterium

<table>
<thead>
<tr>
<th>Monotherapy (0)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combination Therapy (4)</td>
</tr>
<tr>
<td><strong>Levofloxacin</strong> + <strong>Amikacin</strong></td>
</tr>
<tr>
<td><strong>Levofloxacin</strong> + <strong>Azithromycin</strong> + <strong>Clarithromycin</strong> + <strong>Ethambutol</strong></td>
</tr>
<tr>
<td><strong>Levofloxacin</strong> + <strong>Rifabutin</strong></td>
</tr>
</tbody>
</table>

#### Case Reports
- **66** Reports

#### Discussion Posts
- **0** Posts

#### Clinical Trials
- **82** Trials

*FDA: This drug is approved by the FDA for this disease/indication.*
Nontuberculous Mycobacterium > Case Reports > Case ID # 5060

Case ID # 5060

Disease: Nontuberculous Mycobacterium

Challenge:
- Other - Patient refused IV of PICC lines
- Patient failed previous therapy

Drug(s):
- Levofloxacin
- Rifabutin

Outcome: Patient's condition was unchanged

Patient Characteristics:
- Age: 51-60 years
- Sex: Male
- Country Contracted: United States
- Country Treated: United States

Co-Morbidities and Concomitant Treatments:
- Co-Morbidities: COPD

Presentation:
- Site(s) of disease: Cavitary
- Clinical syndrome: MAC

Diagnosis:
- Diagnosis made by:
  - Smear
  - PCR
  - Culture
  - Clinical assessment
- Etiology:
  - Mycobacterium avium complex (mac)

Previous drugs:
- Azithromycin
- Ethambutol

Treatment Details:

Levofloxacin
750 mg QD Oral X 12 months

How new way:
In a novel combination with another drug
To treat a disease other than the one for which the drug is approved

Rifabutin
300 mg QD Oral X 12 months

How new way:
In a novel combination with another drug
To treat a disease other than the one for which the drug is approved

Method(s) of outcome determination are:
- Serology
- Smear
- Culture
- Clinical assessment

Surgery: No

Outcome assessed: While the patient was still on treatment

Relapse: No

Other: My case was a middle aged male smoker with cavitary MAC to which received 18-months of standard MAC therapy (azithromycin, rifampin and ethambutol) per ATS guidelines; however, the patient did not improved despite therapy. His monthly respiratory samples continued to demonstrate growth of MAC. Multiple sensitivities revealed no resistance. Serum levels demonstrated adequate absorption and antimicrobial levels too. As a salvage method I tried oral rifabutin and levofloxacin (the patient refused IV and PICC) but still no resolution. He was referred to CT surgery but due to his COPD classification he is unable to have a surgical resection.

Comments

Add a comment...
App Development Process

The group has focused on an agile, user-centered design approach to ensure that the CURE ID platform will be useful for healthcare providers.

This has involved extensive user-testing of the platform (including internationally – India, Peru, and South Africa), as well as continuous improvements based on this user feedback.
How does the data platform work?

A healthcare provider submits a case report form via the app or website with completely de-identified data and largely standardized terminology.

Once a case is posted, it is rapidly reviewed (typically within 12 hours) by CURE ID moderators to ensure quality. The moderators may contact the user for additional details or clarification.

The data from the case reports is then aggregated to show the total number of cases using each drug as either monotherapy or specific combination therapies.

It is then further broken down by treatment outcome.

Users can also download the entire de-identified dataset to conduct their own research.
Data Curation

Data quality check

COVID report

Data Contributor

Data Curator

Curation

Source: Critical Path Institute
Who can participate?

CURE ID is open to licensed healthcare professionals to report their clinical experience.

Healthcare Professionals Include:

- Physicians
- Nurse Practitioners
- Physician Assistants
- Nurses
- Pharmacists
Other Key Features - Platform

Free, Open-source, Globally-accessible Platform (including offline capabilities for access in resource-limited settings)

De-identified case information; Curation; Ability to anonymize individual submissions

Emphasis on both successful and unsuccessful treatments (what doesn’t work is as important as what does), as well as adverse events

Ability to connect clinicians from around the world and provide a “one-stop shop” of information
Total Numbers To Date:

- **325** Infectious Diseases
- **1,580** Case Reports
- **4,736** Activated Users
- **18,907** Clinical Trials
CURE ID Updates for COVID-19

Facilitates clinicians reporting their real-world experiences treating COVID-19 patients, when patients are unable to be enrolled in a clinical trial.

Includes an updated case report form tailored to COVID-19 and data fields that have been harmonized with other RWD and clinical trial platforms.

Enables data to be entered and adverse events to be automatically shared with the FDA’s Medwatch Adverse Reporting System.

Voluntary submission of cases to CURE ID is not a substitute for filing information with regulatory and public health authorities, where required.

Includes almost all clinical trials for COVID-19 treatments submitted to clinicaltrials.gov; updated nearly daily.

Includes relevant COVID-19 journal articles, news articles, and events; updated nearly daily.

Includes more than 150 case reports of COVID-19 treatments that have been extracted from the published literature or entered by clinician users, with the data displayed in an aggregated format.
COVID-19 Data in CURE ID

<table>
<thead>
<tr>
<th>Case Reports</th>
<th>Discussion Posts</th>
<th>Clinical Trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>151</td>
<td>80</td>
<td>694</td>
</tr>
<tr>
<td>Journal Articles</td>
<td>212 News Articles</td>
<td>Events</td>
</tr>
<tr>
<td>303</td>
<td></td>
<td>34</td>
</tr>
</tbody>
</table>
COVID-19 Cases

150+ cases reported
65 repurposed drugs identified
15 drugs with 10 or more cases

<table>
<thead>
<tr>
<th>Drug Used</th>
<th># of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lopinavir-Ritonavir</td>
<td>50</td>
</tr>
<tr>
<td>Hydroxychloroquine</td>
<td>31</td>
</tr>
<tr>
<td>Azithromycin</td>
<td>27</td>
</tr>
<tr>
<td>Arbidol</td>
<td>22</td>
</tr>
<tr>
<td>Interferon alfa-2B</td>
<td>18</td>
</tr>
<tr>
<td>Moxifloxacin</td>
<td>17</td>
</tr>
<tr>
<td>Methylprednisolone</td>
<td>16</td>
</tr>
<tr>
<td>Ivermectin</td>
<td>12</td>
</tr>
<tr>
<td>Lopinavir</td>
<td>12</td>
</tr>
<tr>
<td>Oseltamivir</td>
<td>12</td>
</tr>
<tr>
<td>Danoprevir-Ritonavir</td>
<td>11</td>
</tr>
<tr>
<td>Immunoglobulins, IV</td>
<td>11</td>
</tr>
<tr>
<td>Interferon</td>
<td>11</td>
</tr>
<tr>
<td>Interferon alfa</td>
<td>11</td>
</tr>
<tr>
<td>Tocilizumab</td>
<td>10</td>
</tr>
</tbody>
</table>
Current CURE ID Goals

Get cases submitted to CURE ID from as many clinicians as possible, if they choose to use approved drugs for unapproved uses.

Provide a platform for discussion amongst healthcare providers globally.

Responsibly share the limited data that is available.

Use anecdotal reports (captured systematically and then aggregated) to inform randomized clinical trials, as rapidly as possible.
Use of CURE ID for COVID-19 Case Collection

FDA, NIH (NIAID and NCATS), CDC, C-Path, and IDSA are now collaborating to promote the use of CURE ID as a tool to collect cases on the treatment of patients with COVID-19, in conjunction with ongoing clinical trial efforts.

Activities are also being coordinated with WHO through the existing FDA-WHO CURE ID partnership.

Healthcare providers around the world are encouraged to share their COVID-19 treatment experiences via the CURE ID platform.

Voluntary submission of cases to CURE ID is not a substitute for filing information with regulatory and public health authorities, where required.
Do you have COVID-19 cases to share?

FDA encourages patients to be enrolled in clinical trials of potential COVID-19 treatments.

If that is not possible:

Have you used an existing drug approved for another indication to treat a patient infected with SARS-CoV-2?

Did you use a combination of approved products?

Did you find any safety concerns with the approved products being used in a new way?

Please share these cases on CURE ID!

www.fda.gov
Utility Now and in the Future

By utilizing the CURE ID platform now for COVID-19 case collection - in conjunction with data gathered from other registries, EHR systems, and clinical trials - data collected during an outbreak can be improved and coordinated.

This may allow us to find possible treatments to help ease this pandemic, and prepare us better to fight the next one.
How can the scientific community move from the collection of anecdotal reports to informing clinical trials, and potentially drug labeling?

The CURE ID Partners believe it is important to establish a consortium, made up of all of the relevant stakeholders.

Next, the partners hope to identify a clear pathway forward, both for generating adequate evidence from RCTs, and submitting that evidence to the FDA for review.
Announcing the Launch of the CURE Drug Repurposing Collaboratory

CURE ID was initiated in 2013 by FDA and NCATS/NIH with support from WHO, IDSA, CDC, and NIAID, and promises to be a long-term initiative.

To this end, the Critical Path Institute (C-Path) has announced that it is convening a public-private partnership in collaboration with FDA and NCATS/NIH called the CURE Drug Repurposing Collaboratory.

It will begin with a pilot focused on furthering drug development for COVID-19 through use of the CURE ID platform.

The Collaboratory will demonstrate how data shared from clinicians in real-time can be used to inform ongoing and future clinical trials, and potentially drug labeling.
CURE Drug Repurposing Collaboratory

CDRC is designed to capture real-world clinical outcome data to advance drug repurposing and inform future clinical trials for diseases of high unmet medical need.

The CURE Drug Repurposing Collaboratory (CDRC) is a public-private partnership initiated in June 2020 by C-Path and the U.S. Food and Drug Administration (FDA) in partnership with the National Center for Advancing Translational Sciences (NCATS), part of the National Institutes of Health (NIH).

CDRC, in partnership with the FDA-NCATS CURE ID* platform, is a dedicated initiative designed to capture real-world clinical outcome data to advance drug repurposing and inform future clinical trials for diseases of high unmet medical need. The initiative includes emerging/reemerging diseases, anti-microbial drug resistant infections, neglected infectious diseases as well as rare oncology diseases where there are limited treatment options. The Collaboratory is strongly interested in capturing data from diverse populations including pediatric and pregnant women. C-Path leads CDRC, with participation from a diverse set of global stakeholders including, but not limited to, clinicians, scientists, U.S. Health and Human Services (HHS) agencies, non-government organizations, foundations and societies in order to:

- Promote the CURE ID platform to enable the global health community to openly share patient treatment outcomes
- Evaluate drug leads through advanced analytics to identify candidates for repurposing as new treatments in a transparent open forum
- Inform the design of clinical trials of existing marketed drugs for new indications
- Generate real-world evidence for expanding drug labels
- Provide a regulatory roadmap to advance drug repurposing and expedite the availability of safe and efficacious treatments for diseases with limited or no treatment options
Get involved with the CDRC

Join as an Institutional Partner
Serve on the Advisory or Coordinating Committees
Become a CURE ID Curator
Contribute your dataset to the CURE ID database
Participate as a CURE ID Clinical Champion

Visit the Consortium’s Website:
https://c-path.org/programs/cdrc/

Or email:
cdrc@c-path.org
Participate and Get in Touch!

The app is available for free as “CURE ID” in the Google Play store and iTunes App Store.

Visit us at: https://cure.ncats.io/

If you have comments or suggestions or are interested in other ways to be involved, please email us at cureadmin@mail.nih.gov.
Thanks to the CURE ID Team!

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**Funders/In Kind Support:**
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- FDA Oncology Center of Excellence
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- FDA Office of Women’s Health
- FDA Office of Translational Sciences
- FDA Medical Countermeasures Initiative
- HHS IDEA LAB
- NCATS/NIH
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