COVID-19 Conversations

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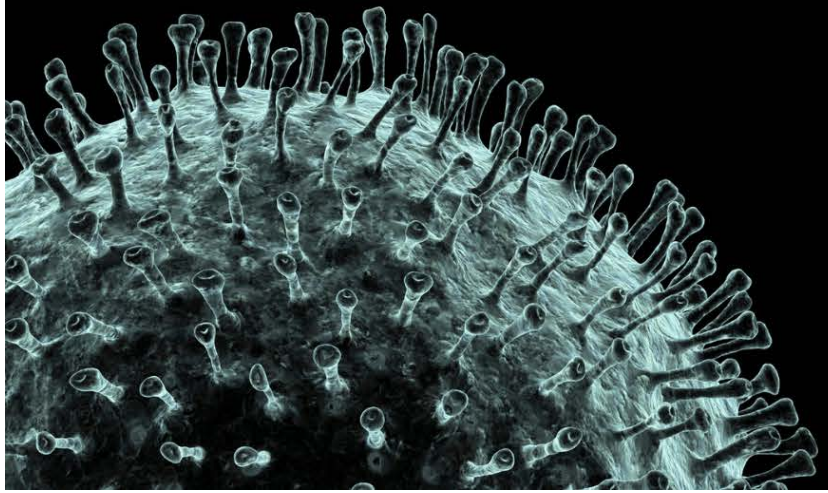

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Research and Care During a Public Health Emergency: Using Unapproved Indications or Products

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Background: Usual Rules for Therapeutics

- Unapproved drug gets permission to begin clinical trials under an IND
  - Trials conducted with control arm (placebo or standard intervention)
  - Phase 1 very small population; safety data
  - Phase 2 somewhat larger population; safety and efficacy
  - Phase 3 larger population; safety and efficacy

- FDA gives approval for product in conjunction with its intended use (population, dosage, contraindications…)

- No marketing for unappoved uses but physicians may prescribe “off label” for unapproved uses

Special Rules for Therapeutics During an Emergency

- **Emergency Use Authorization**: unapproved uses or unapproved medical products may be used in an emergency, and offers liability protection to those who use them

- **Procedure**:
  - DHS, DoD, or HHS Determination related to a CBRN threat or DHS makes Material Threat Determination (MTD).
  - HHS EUA Declaration. HHS Secretary declares that circumstances exist to justify an EUA
  - After HHS declaration, FDA can issue an EUA

EUA: Hydroxychloroquine sulfate & chloroquine phosphate

- March 28: FDA issues EUA to allow hydroxychloroquine sulfate and chloroquine phosphate products to be used for certain hospitalized patients with COVID-19.

- EUA fact sheets must be made available to health care providers and patients, including the known risks and drug interactions.

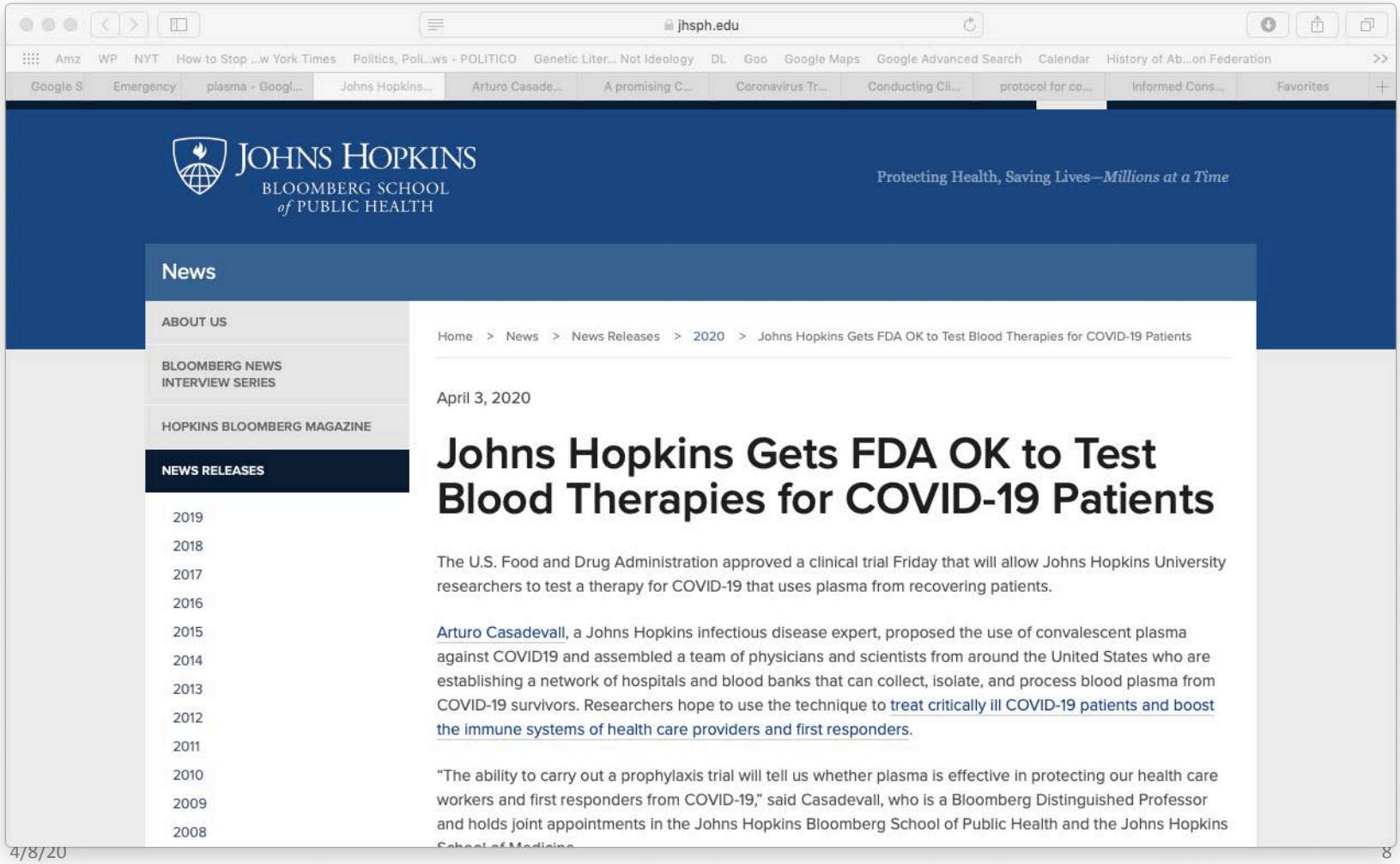
- Drugs will be distributed from the Strategic National Stockpile for adolescent and adult patients hospitalized with COVID-19, as appropriate, *when a clinical trial is not available or feasible.*

Conducting Clinical Trials During this Pandemic: Ethical Challenges

- Ethical Challenges
- risk/benefit ratio for the sickest (but most complex) vs for mildest (but less informative?)
- consent from sickest complicated by cognitive incompetence; surrogate decisionmakers not on the spot (but is this same as unreachable?)
  - Use of emergency consent procedures
  - Patient in life-threatening circumstances
  - Implied consent
  - Community notification

Conducting Clinical Trials During this Pandemic: Additional Challenges

- IRB approval process
- Site for trial
- Perception when placebo is the control arm but there are not good therapies
- Perception of clinical trial as chance to get newest/best vs being made into a guinea pig
- FDA expanded access program (undermining clinical trial?)
- Maintaining clinical equipoise: when to halt trial (and effect of supply)
- Managing public expectations/controlling fraudulent offers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April 3, 2020
Johns Hopkins Gets FDA OK to Test Blood Therapies for COVID-19 Patients
The U.S. Food and Drug Administration approved a clinical trial Friday that will allow Johns Hopkins University researchers to test a therapy for COVID-19 that uses plasma from recovering patients.
Arturo Casadevall, a Johns Hopkins infectious disease expert, proposed the use of convalescent plasma against COVID19 and assembled a team of physicians and scientists from around the United States who are establishing a network of hospitals and blood banks that can collect, isolate, and process blood plasma from COVID-19 survivors. Researchers hope to use the technique to treat critically ill COVID-19 patients and boost the immune systems of health care providers and first responders.
"The ability to carry out a prophylaxis trial will tell us whether plasma is effective in protecting our health care workers and first responders from COVID-19," said Casadevall, who is a Bloomberg Distinguished Professor and holds joint appointments in the Johns Hopkins Bloomberg School of Public Health and the Johns Hopkins

Recommendations for Investigational COVID-19 Convalescent Plasma

April 8, 2020

FDA has issued guidance to provide recommendations to health care providers and investigators on the administration and study of investigational convalescent plasma collected from individuals who have recovered from COVID-19 (COVID-19 convalescent plasma) during the public health emergency.

The guidance provides recommendations on the following:

- pathways for use of investigational COVID-19 convalescent plasma
- patient eligibility
- collection of COVID-19 convalescent plasma, including donor eligibility and donor qualifications
- labeling, and
- record keeping

Because COVID-19 convalescent plasma has not yet been approved for use by FDA, it is regulated as an investigational product. A health care provider must participate in one of the pathways described below. FDA does not collect COVID-19 convalescent plasma or provide COVID-19 convalescent plasma. Health care providers or acute care facilities would instead obtain COVID-19 convalescent plasma from an FDA-registered blood establishment.

Content current as of:
04/08/2020

Health Topic(s)
Infectious Disease
Coronavirus

Time Permitting: Additional Considerations for Testing Prophylaxis

- Subject population healthy; risk tolerance lower
- Need to maintain all standard precautions in control group
- Need to select population from high-risk region or lifestyle group
- Need to decide if first responders must be given priority
- Need to decide if first responders can be required to consent as condition of current employment