Federal Public Health Policymaking in an Epidemic: Access to Care for Pregnant Women, Newborns, & Children

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The Alliance for Patient Access (allianceforpatientaccess.org), founded in 2006, is a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care. AfPA accomplishes this mission by recruiting, training and mobilizing policy-minded physicians to be effective advocates for patient access. AfPA is organized as a non-profit 501(c)(4) corporation and headed by an independent board of directors. Its physician leadership is supported by policy advocacy management and public affairs consultants. In 2012, AfPA established the Institute for Patient Access (IfPA), a related 501(c)(3) non-profit corporation. In keeping with its mission to promote a better understanding of the benefits of the physician-patient relationship in the provision of quality healthcare, IfPA sponsors policy research and educational programming.

During the first full week of March 2020, Congress passed, and President Donald Trump signed into law $8.3 billion in emergency funding to address a growing number of coronavirus (COVID-19) cases in the United States. The funding will ensure a coordinated federal and state response to minimize and treat future outbreaks.

The legislation, Coronavirus Preparedness, and Response Supplemental Appropriations Act, 2020, Public Law No: 116-123 "will bolster vaccine development, research, and equipment stockpiles, as well as boost state and local health budgets," as government officials and health workers fight to contain the outbreak. (1) More than $400 million will be disbursed to states within the first 30 days of the bill's enactment, with each state receiving no less than $4 million," according to Politico. (2) Provisions of the bill also include an "Economic Support Fund" and "International Disaster Assistance."

With any rapid response and an epidemic that has reached a global scale, one has to ask which populations stand to benefit the most from this funding, and which are likely to be left on the outskirts or underrepresented in the distribution?

Two key demographics come to mind: young children and pregnant women.

Is coronavirus infection less prevalent in children?

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In late February, Business Insider described a study of nine infants in China infected with the virus between December 8, 2020, to February 6, 2020 - all under one year old. (3,4) The study acknowledged in all nine cases, and each baby had become sick after exposure to at least one infected family member, "with the infant's infection occurring after the family members' infection." Of interest, none of the nine infants "required intensive care or mechanical ventilation or had any severe complications."

This is too small a sample size of infants with the infection to predict future infant health outcomes. Policymakers have difficult decisions to make: How should they, as lawmakers react during an infectious outbreak amid an early lack of impact reports? Should research and data collection for infants and children with the virus be less of a priority for government funding and outreach?

Babies under one year old cannot put on/wear masks, as the study notes. They do not sterilize their own toys or items in their environment, or voluntarily wash their own hands, or even make their own bottles/feed themselves. They are completely reliant on a caregiver to take precautionary measures when it comes to their health and protection of their developing immune systems. So it does not make logical sense, absent scientific proof or under-

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standing; otherwise, that infants are going to be more "immune" to coronavirus.

Yet to the contrary, based on early studies of coronavirus outbreak, children are reported to have milder symptoms with the coronavirus. As the article above says, "there are two possible explanations for why so few children have gotten sick: They've either been less likely to be exposed in the first place, or there's something different about how their bodies respond to the virus."

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Policymakers should consider that perhaps symptoms of the virus in babies and children are less likely to be reported by hospitals and individuals - or articulated by a small child, who may just be feeling feverish or may be unable to verbalize their symptoms.

But, maybe caregivers and adults are taking meticulous precautions around the pediatric population to keep them safe from infection and the spread of the virus.

Either way, current data and reports do not seem comprehensive; and so final decisions on the allocation of emergency funding to pediatric populations in the U.S. should be allowed to continue to take shape as we learn more about transmission and demographic impacts of COVID-19. Arguably, it is not yet known how coronavirus will impact the pediatric population across the U.S., or how living with infected adults can increase the risk of transmission of the coronavirus to children.

Vaccine Development

In a related occurrence, on March 5, 2020, in the same week, as the emergency funding was working its way through Congress, Politico reported, "Scientists have been amazed at the speed with which government health agencies and vaccine makers are assembling possible coronavirus vaccines. (5) Even so, top infectious disease scientist [and Director of the National Institute of Allergy and Infectious Diseases] Anthony Fauci MD has warned — repeatedly, and with the president nearby — that it will be at least a year before a vaccine could be launched."

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While policy and health experts applaud global developments for a COVID-19 vaccine, researchers and academics in the United States are less enthusiastic and optimistic about the possibility of the benefits of such a vaccine for pregnant women and their infants.

- Ensuring there's a vaccine that can be offered to pregnant women is critical to health equity.

"Historically, the interests of pregnant women have not adequately featured in global responses to outbreaks and epidemics," wrote bioethics and immunization research experts, all affiliated with John Hopkins University. (6)

Their article cautions vaccine funders and researchers that scientific responses to global health outbreaks typically ignore the interests of pregnant women, who are not tested nor included in drug trials. As a result, scientific data collected on the outcomes of administered vaccines are woefully lacking for pregnant women and the child(ren) they carry. Lack of data also thereby blocks access to the vaccine for pregnant women and their children.

To combat this incongruity, the authors recommend that data collection and health surveillance collection systems include "data relevant to maternal, obstetric, and newborn health outcomes … to inform scientific and public health responses."

Additional suggested policies for drug developers and investors include:

- Ensure one or more of the vaccine candidates in the pipeline will be suitable for use in pregnancy;
- Determine what types of reproductive and developmental toxicology studies will be needed prior to enrollment of pregnant women in later-stage trials;
- Large-scale efficacy trials for promising vaccines should assume that pregnant women are eligible to be enrolled unless the risks outweigh the benefits.

The aim of these recommendations is a body of evidence tailored towards pregnant women - so that they may, in turn, base their decisions and response during their pregnancy and a health crisis on the information most relevant to their current circumstances.

More Information

The coronavirus emergency funding bill, Public Law No: 116-123, is likely the first in a series of emergency funds requested by the Administration and executed by Congress. (7) If coronavirus amounts to the broad scale of a global epidemic - as is the current narrative in the U.S. news media - more funding will be needed to address prevention, treatment, care, and cure.

Watch for where and to whom the money gets directed.

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