



Trends & Technology

Trends

FDA rescinds emergency use authorization for some respirators as N95 supply issues end

Early in the pandemic, emergency use authorizations (EUs) of certain respirators, and decontamination and bioburden reduction systems needed to disinfect disposable

cilizumab) as a treatment for COVID-19. The drug is authorized to treat hospitalized adults and children age 2 years and older receiving systemic corticosteroids and who require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation. The drug is not authorized for patients with COVID-19 outside of the hospital.



respirators, which were not yet approved by the National Institute for Occupational Safety and Health (NIOSH), were required to expand health care worker access to these devices. Now, since the national supply of NIOSH-approved N95s is no longer in jeopardy, EUs are not as crucial to maintaining needed supply levels.

On June 30, 2021, the U.S. FDA announced it would be revoking the EUs for all non-NIOSH-approved disposable respirators, as well as decontamination and bioburden reduction systems. From the beginning of the coronavirus pandemic, NIOSH approved over 875 new respirator models. Today, there are more than 6,400 respirator models or configurations included on the NIOSH-certified equipment list.

The FDA recommends that health care institutions transition back to single-use of disposable respirators, as is possible and appropriate.

Source: asahq.org/pub/3hRyNh5

FDA issues EUA for new COVID-19 treatment from Genentech Inc.

On June 24, 2021, the U.S. FDA granted emergency use authorization for Genentech Inc.'s new drug Actemra (to-

Data from four clinical trials conducted on hospitalized patients with COVID-19 showed that tocilizumab in combination with routine COVID-19 treatment, including corticosteroid therapy, reduced the risk of mortality for 28 days and shortened the patients' hospital stays. Tocilizumab is a monoclonal antibody designed to reduce inflammation by blocking the interleukin-6 receptor.

Although the number of patients with COVID-19 who require hospitalization has significantly decreased due to vaccination, additional effective therapies will be needed to combat COVID-19 in unvaccinated patients, especially as the SARS-CoV-2 variants continue to spread.

Source: asahq.org/pub/3hvy5Hn

Dozens of medical advocacy groups call for COVID-19 vaccination mandate among health care workers

Over summer 2021, several health care professional organizations, such as the American Hospital Association, America's Essential Hospitals, and the Association of American Medical Colleges, published joint or individual statements supporting the implementation of mandatory

COVID-19 vaccination policies for health care staff.

In July, 57 professional groups representing the interests of hospitals, clinicians, nurses, long-term care facilities, infectious disease specialists, pharmacists, and others issued a joint statement calling for mandatory COVID-19 vaccination among health care personnel.

The statement cited rising COVID-19 cases, as well as increased availability of vaccines, as justification for a vaccination mandate. It also called vaccination an "ethical commitment" for all health care professionals.

Another noteworthy aspect of the joint statement is its acknowledgment of the community's "historical mistrust of healthcare institutions" and recognition that even many workers in the health care landscape may share such hesitation toward vaccination.

Source: asahq.org/pub/2UOKnCa

House bill pursues higher Medicare reimbursements for rural hospitals

A new bill introduced in the U.S. House of Representatives in June 2021 aims to assist rural hospitals undergoing financial hardship due to the effects of the COVID-19 pandemic. The new legislation, headed by Reps. Terri Sewell (D-AL) and Drew Ferguson (R-GA) raises Medicare reimbursement levels for rural hospitals.

Hospital inpatient Medicare payments are determined according to the hospital wage index, which is a ratio of a region's average hourly wage compared with the national wage. The proposed legislation would establish a national minimum of 0.85 for the Medicare Area Wage index.

The lawmakers assert that Medicare reimbursements for services in rural hos-

pitals already lagged behind their urban counterparts and the pandemic only exacerbated this health disparity when patient volume declined during this global health crisis.

Last year, the Centers for Medicare & Medicaid Services did boost reimbursement payments for rural hospitals falling below the 25th percentile of the wage index, but lawmakers argue that more intervention is needed to establish fairness in payment.

Source: asahq.org/pub/3hvYIkV

Technology

FDA clears Micromate surgical robot for U.S. market entry

The Austrian devicemaker Interventional Systems has been granted FDA clearance for its Micromate surgical robot, paving the way for entry into the U.S. market. Micromate is a small, boxlike motorized robot that allows surgeons to conduct image-guided, percutaneous procedures remotely. The robot attaches to the operating table and is controlled by the surgeon using a joystick. It can perform almost any procedure requiring a straight needle through the skin, e.g., biopsies and ablations.

The remote control of Micromate keeps surgeons at a safe distance from the radiations associated with real-time fluoroscopy or CT scans. From outside of the OR, a surgeon can use Micromate to line up and guide a needle. The machine's small size means it can fit between the patient and the surrounding imaging tools.

Interventional Systems plans to launch the device in the U.S. over the remainder of 2021 using centers of excellence and third-party commercial partnerships. ■

DON'T MISS! PSH Learning Collaborative: Roadmap to Success

The PSH Learning Collaborative: Roadmap to Success is available for download by members at asahq.org/psl. Learn how the ASA's Perioperative Surgical Home (PSH) Learning Collaborative participants launched successful PSH programs at their institutions. This resource is free to ASA members and discusses challenges faced and lessons learned. For any questions regarding the PSH paper and other resources, contact psl@asahq.org.

