Are we close to a treatment for preterm preeclampsia?
Researchers of a new study published in *BMJ* say that extended-release metformin could prolong gestation in women with preterm preeclampsia.

According to results of the study, pregnancies were prolonged by a week in the metformin treatment group compared with the no treatment group. Authors note, however, that the results were not statistically significant and therefore point to the need for further study.

Preterm preeclampsia often leads to preterm delivery, putting infants at risk of disability and death.

The trial involved 180 pregnant women undergoing monitoring for preterm preeclampsia at a large hospital in Cape Town, South Africa, between February 2018 and March 2020. Women were split into 2 arms: 90 received extended-release metformin and the other 90 received placebo. At the start of the trial, the women were 29 weeks pregnant on average and received either metformin or placebo until delivery.

The average time from the beginning of treatment to delivery was 17.7 days in the metformin arm, and 10.1 days in the placebo arm, an average difference of 7.6 days. This difference was not statistically significant. However, additional analyses proved statistically significant. The first—in women who continued to take metformin at any dose—showed an average 9.6-day longer gestation, and the second—in women who took the full dose of metformin—showed an average 11.5-day longer gestation.

There were no differences between the 2 arms in terms of serious birth complications or death among both mothers and babies. No severe adverse events were observed either, although diarrhea was more common in the metformin arm.
NIH: Methamphetamine-involved overdose deaths nearly tripled between 2015 and 2019

A study conducted by the National Institute on Drug Abuse (NIDA) found that overdose deaths in the United States involving methamphetamine nearly tripled from 2015 to 2019 among people 18 to 64 years old.

The number of people who reported using methamphetamine during this time did not increase as sharply, but the study revealed that populations with methamphetamine use disorder have become more diverse.

The study, published in *JAMA Psychiatry*, cited such factors as rising methamphetamine use disorder, frequent use, and concurrent use of other drugs as contributing to the rise in overdose deaths.

“Public health approaches must be tailored to address methamphetamine use across the diverse communities at risk, and particularly for American Indian and Alaska Native communities, who have the highest risk for methamphetamine misuse and are too often underserved,” said Nora Volkow, MD, NIDA director and one of the study authors.

More than 93,000 Americans died from drug overdoses in 2020, making it the largest 1-year increase in overdose deaths ever recorded, according to provisional CDC data.

“What makes these data even more devastating is that currently, there are no approved medications to treat methamphetamine use disorder,” said Emily Einstein, PhD, chief of NIDA’s Science Policy Branch and a co-author of the study. “NIDA is working to develop new treatment approaches, including safe and effective medications urgently needed to slow the increase in methamphetamine use, overdoses, and related deaths.”

Disparities in opioid overdose deaths continue to worsen for Black people, suggests study

Non-Hispanic Black individuals in 4 U.S. states experienced a 38% increase in the rate of opioid overdose deaths from 2018 to 2019, while the rates for other race and ethnicity groups held steady or decreased, according to a new NIH study.

The research emphasizes the need for equitable, data-driven, community-based interventions that address these disparities.

The research was conducted as part of the HEALing Communities Study, which aims to reduce opioid-related overdose deaths by helping communities put in place evidence-based practices to treat opioid use disorder and reduce other harms associated with opioid use in New York, Massachusetts, Kentucky, and Ohio.

For this study, data were collected from death certificates for 2018 and 2019 across 67 communities with a total population of more than 8.3 million people in the 4 states. The researchers calculated rates and trends of opioid overdose deaths overall and for each state, and then further analyzed trends by race and ethnicity. Overall, the investigators observed no change in the opioid overdose death rate in these states from 2018. However, the researchers observed a 38% overall increase in the opioid overdose death rate for non-Hispanic Black individuals from 2018 to 2019 across these 4 states. There were no changes overall among the other racial and ethnic groups. The study authors note that these data add to the evidence of increasing disparities in opioid overdose deaths by race and ethnicity and highlight the importance of access to timely, local data to inform effective community-tailored strategies to reduce these deaths.

FDA takes steps to improve quality, safety of sunscreens

FDA is working to improve the quality, safety, and efficacy of sunscreens as part of its new authorities for certain OTC drugs.

In the short-term, these new authorities preserve status quo marketing conditions for these sunscreens. However, the agency recently proposed revisions and updates to those requirements that are related to maximum SPF values, active ingredients, broad spectrum requirements, and product labeling, among other provisions.

“Sun safety is important for everyone, regardless of your skin tone. Americans can reduce risks from sun exposure with continued use of Sun protection measures including broad spectrum sunscreen with SPF values of at least 15,” said acting FDA Commissioner Janet Woodcock, MD.

“[This] represents a key milestone in our implementation of transformative new authorities related to OTC drugs that will allow us to continue ensuring that sunscreens are safe and effective for frequent, life-long use and provide consumers with the protection they expect from these products.”

This order regarding sunscreen includes certain requirements about active ingredients from the 1999 final monograph regulation for OTC sunscreen products, which never took effect. It also includes labeling and effectiveness requirements from a final 2011 labeling and effectiveness testing rule and proposes updates to how products are labeled to make it easier for consumers to identify important product information. The agency will consider comments on the proposed order submitted during a 45-day public comment period before issuing a revised final order.
Drug combo has potential to reduce COVID-19 hospitalization and death

New research published in the New England Journal of Medicine found that a combination of the monoclonal antibodies casirivimab and imdevimab, REGEN-COV, significantly reduced the risk of COVID-19–related hospitalizations and death in patients. The study results were part of the phase 3 portion of an adaptive trial.

In the cohort receiving the REGEN-COV antibody combination, 18 out of 1,355 patients (1.3%) experienced COVID-19–related hospitalization or death from any cause over a period of 28 days after treatment. In the placebo group, 62 out of 1,341 patients (4.6%) were reported to have COVID-19–related hospitalization or death.

Researchers said the antibody drug combination also resolved symptoms and reduced COVID-19 viral load more rapidly than a placebo. The median time to resolution of symptoms was 4 days shorter with each REGEN-COV dose than with placebo. Additionally, the antibody combination was efficacious across various subgroups, including patients who were SARS-CoV-2 serum antibody-positive at baseline.

The study authors write: “Previous data from the phase 1-2 portion of this trial showed that in outpatients with COVID-19, REGEN-COV lowered the viral load, reduced the need for medical attention related to COVID-19, and may have reduced the risk of hospitalization. The phase 3 clinical outcomes data presented here are consistent with and strengthen these findings showing that early use of REGEN-COV in outpatients with risk factors for severe COVID-19 can lower the risk of hospitalization or death from any cause.”

The trial was funded by Regeneron Pharmaceuticals, the maker of the medication.

Federal drug pricing plan includes PBM transparency, other APhA recommendations

On September 9, 2021, HHS Secretary Xavier Becerra released his much-anticipated comprehensive plan to lower drug prices, which he was tasked with developing in a July 2021 executive order. The secretary solicited APhA’s input on potential strategies to reduce drug prices during the creation of the plan, and the organization released a statement thanking him for taking several of the recommendations they made.

Secretary Becerra’s plan included measures that require PBMs to operate in a more transparent manner, such as submitting data to CMS. The plan also supports legislation to ban spread pricing, in which PBMs pocket more money for drugs than they pay the pharmacies that dispense them, in Medicaid contracts.

Pharmacy has long decried secrecy that allows PBMs to profit “at the expense of patients, pharmacies, and the health care system,” APhA wrote in its September 10, 2021, statement. In its work with HHS, APhA shared several examples of PBMs engaging in business practices that “generate revenue for themselves without passing most of these savings along to patients at the pharmacy counter.”

The statement calls the plan’s inclusion of PBM transparency a positive step forward for pharmacies, pharmacists, and patients. “[APhA applauds] Secretary Becerra for taking the next steps to … shine the light on PBMs’ deceptive and anticompetitive business practices,” it reads.

HHS also took an APhA recommendation that the federal government speed the entry of interchangeable biosimilars and generic drugs into the marketplace. The plan encourages the passage of legislation that would make it happen. The HHS plan also indicated support for the 340B Drug Pricing Program, which provides access to affordable medications for many of the nation’s most vulnerable and underserved individuals. “We appreciate [Becerra’s] endorsement.”

The drug pricing plan includes a strategy to which APhA is strongly opposed, however. Its statement expressed disappointment that HHS will pursue drug importation in its efforts. APhA maintains that drug importation threatens patient safety and drug supply chain integrity without effectively reducing prices. “[We] will continue to work with Secretary Becerra and others at HHS to provide education about the pitfalls of [drug importation].”

Despite that, APhA is unequivocal in its appreciation for the opportunity to participate in the plan’s development and HHS’s “[recognition of] the value of the pharmacist perspective and the insights gleaned from our experience and expertise.”

“Today we reiterate our thanks for a seat at the table and reaffirm our willingness to advise and support the federal government as it pursues much needed drug-price solutions.”