Science and Clinical Potpourri for Your Life and Your Practice

Research Involves Very Dangerous Organisms
National Institutes of Health press release, Nov. 2017

A 2014 National Institutes of Health moratorium on select studies associated with dangerous viruses has been somewhat softened. The studies primarily focused on influenza and Middle East respiratory syndrome (MERS) and were put on hold in October 2014, but other deadly avian influenza viruses were targeted as well. Given the considerable risks associated with the viruses, a new process has been implemented that will help to facilitate the “safe, secure, and responsible conduct of this type of research.”

What is known as gain-of-function (GOF) studies are designed to make pathogens even more virulent and, as a result, enhance the potential for inadvertent spread. Such a concern was realized in 2011, when a lab in the Netherlands announced that it had modified the H5N1 bird flu virus to enable it to spread between ferrets. While the potential for such research may help us prepare for pandemics, there is a considerable risk if the amped-up pathogens were to escape the lab.

Monitoring officials were also uneasy after several accidents in U.S. biocontainment labs. The 2014 “pause” in funding such research targeted studies of influenza and severe acute respiratory syndrome viruses. Recently White House science administrators informed the Department of Health and Human Services, to craft policies using the criteria for what officials now call “enhanced potential pandemic pathogens.”

New proposals involving GOF that pass early scientific review will be reviewed by Health and Human Services experts in biosafety, security, ethics, and law. The panel will weigh the benefits and risks and may recommend that the proposed study be rejected, allowed to move forward, or permitted with modifications.

The goal of course is to allow high-quality, relevant research to move forward, all the while helping to ensure public health and safety.

Who Should Take Statins? An Update
J Amer Coll Cardiology. Sept. 2017

Given that cardiovascular disease (CVD) is the leading cause of U.S. morbidity and mortality (it accounts for 1 of every 3 deaths among adults), it was time for an update of the 2008 U.S. Preventive Services Task Force (USPSTF) recommendation on screening for lipid disorders in adults. The USPSTF reviewed a wide range of high-quality evidence on the benefits and harms of screening for and treatment of dyslipidemia in adults 21 years and older; the benefits and harms of statin use in reducing CVD events and mortality in adults without a history of CVD events; whether the benefits of statin use vary by subgroup, clinical characteristics, or dosage; and the benefits of various treatment strategies in adults 40 years and older without a history of CVD events.

The newly composed USPSTF recommendations urge initiating the use of low- to moderate-dose statins in adults aged 40 to 75 years without a history of CVD who have one or more of the well-appreciated CVD risk factors. These include dyslipidemia, diabetes, hypertension, or smoking, and a calculated 10-year CVD event risk of 10% or greater. The recommendations further urge that clinicians selectively offer low-to-moderate-dose statins to adults aged 40 to 75 years without a history of CVD who have one or more CVD risk factors and a calculated 10-year CVD event risk of 7.5% to 10%. The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of initiating statin use in adults 76 years and older.

Blood Donation by Gay Men Under Reconsideration
NEJM. 2017;376:174-177.

A concern about allowing men who have sex with men to donate blood stems from the fact that in the United States, this population has a higher prevalence of HIV than heterosexuals. With near-perfect sensitivity of fourth-generation HIV testing after the window period, prevalence has minimal, if any, effect on the predictive value of a negative
test result. Therefore, the risk of HIV in the blood supply comes mainly from the risk of donation during the first few weeks after infection.

In June 2016, one week after the Pulse nightclub shooting in Orlando, 24 U.S. senators wrote to the FDA Commissioner asking the agency to revisit this ban. This prohibition was, of course, not the tragedy the day of the shooting, but the added insult that gay and bisexual men were unable to offer this measure of help to their community was deeply felt. Each day in the United States, 36,000 units of red blood cells, 7,000 units of platelets, and 10,000 units of plasma are transfused into patients throughout the country. With excellent screening technologies in place, the risk of transmitting HIV through a blood transfusion is 1 in 1.5 million; the risk for hepatitis C virus (HCV) is 1 in 1.1 million; and the risk for hepatitis B virus (HBV) is 1 in 282,000.

While scientific progress has since revolutionized HIV testing, the deferral strategy with respect to men who have sex with men has changed little. In 2015, a policy revision recommended that blood banks ban donations only from any man who has had sex with a man in the previous year, rather than at any time since 1977. Some, though not all, blood banks have adopted this updated recommendation, which some see as a positive incremental step. Still, the 1-year deferral is misaligned with the current science of HIV test characteristics and viral transmission.

Transfusion of blood from one person to another will never be without risk, and it may not be possible to predict future bloodborne pathogens or the communities that will be most directly affected. The next big infectious culprit may well be vector borne. Today, the Zika virus, looms as a potential threat, and the FDA now recommends universal testing of all blood donations for Zika virus. *Babesia microti*, a parasite carried by ticks in New England where the infection is endemic, has been transmitted through the blood supply, yet donated blood is not universally screened for this infection. The FDA confronts a constant challenge as it seeks to maximize safety, assuage public fear, and prevent stigma—a complex mission indeed.

The ban on donations from men who have sex with men was instituted at a time of public health panic and vast uncertainty, but now more than 3 decades later, scientific advances in testing and in understanding of disease transmission offer new tools and better ways than a sweeping ban to minimize the risk of transfusion-related HIV. Perhaps it is time to more thoughtfully consider who might be added to the donor pool.

**What Birds Do For Us**

*National Geographic Magazine, Jan. 2018*

Ever since Rachel Carlson’s opus, *Silent Spring*, birds have captured our attention as a kind of general barometer for the health of the planet. In this compelling article—one generously enhanced by beautiful photographs—their role as essential environmental elements and their role and impact on our general sense of well being is explored. There are some 10,000 species of birds with a diversity that is startling, which speaks to their ability to inhabit and thrive in so many different locales. While some are hugely social, others are literally anti-social. Among the many environmental services they perform are the pollination of plants, dispersal of seeds, control of insects, and even disposal/removal of the rotting flesh of animals. We should all pay a bit more attention skyward and pay homage to these marvelous creatures.

**Breastfeeding and Epidural Analgesia with Fentanyl**

*Anesthesiology. 2017;127:614-624.*

Breastfeeding is a universal phenomenon with major public health implications. Is breastfeeding success adversely affected by epidural fentanyl administered for labor analgesia? More than 300 women were studied in this randomized study that compared bupivacaine 1mg/mL; bupivacaine 0.8 mg/mL + fentanyl 1 µg/mL; or bupivacaine 0.625 mg/mL + fentanyl 2 µg/mL. In this population of women with a history of previous successful breastfeeding, the use of an analgesia solution containing fentanyl, administered via the epidural route for labor analgesia, did not have adverse effects on breastfeeding outcomes.

**Fires in the OR**

*J Am Coll Surg. 2017;225:160-165*

Intraoperative fires continue to occur despite large-scale education programs and surveys that indicate that those of us working in the OR are familiar with the relevant risk factors. A study was performed on a porcine skin model involving 5 different prep solutions, 3 being alcohol based and 2 non-alcohol based. A Bovie was activated immediately after application and 3 minutes after application of the skin-prep solutions. Although it seems obvious, the bottom line was that the use of non-alcohol based solutions can substantially reduce the risk of an intraoperative fire. Even a 3-minute wait in the alcohol-based solutions was found to be of substantial concern for fire genesis. The research and practical experience is there; we all need to be extremely mindful of the risk of intraoperative fires and how those risk factors can be “extinguished.”