FDA Approves Artificial Intelligence Device for Guiding Regional Anesthesia

The FDA authorized a software medical device intended to help anesthetists and other health professionals identify important anatomical structures in ultrasound images before inserting needles to deliver regional anesthesia.

Marketed as the ScanNav Anatomy Peripheral Nerve Block by Intelligent Ultrasound Group, the device uses deep learning artificial intelligence technology to create color overlays of key anatomical structures on live ultrasound images. It’s intended to support health care professionals who perform ultrasound-guided regional anesthesia less frequently, and to help increase use of regional anesthesia when appropriate, according to a company statement.

A stand-alone device that can be used with compatible general-purpose diagnostic ultrasound systems, the ScanNav device highlights anatomy associated with 9 common peripheral nerve blocks, the statement noted. Users may also refamiliarize themselves with scanning for specific blocks using the device’s integrated 3-dimensional animation reference materials, the company said.

In a study involving 15 anesthesiologist experts in ultrasound-guided regional anesthesia and 15 nonexpert anesthesiologist trainees, experts most often identified teaching and supervising as device benefits, though some reported that the device decreased supervising confidence. Nonexperts were more likely to see training, learning scans, identifying anatomic structures, and increasing confidence in scanning as device benefits, though some nonexperts and experts thought it decreased scanning confidence.

The device is already licensed for clinical use in the UK and Europe and is scheduled for US market launch shortly, according to the company statement. The company also seeks to license the device to major ultrasound manufacturers for integration with diagnostic products.

Novavax COVID-19 Vaccine Booster Authorized

The Novavax COVID-19 vaccine, adjuvanted received FDA Emergency Use Authorization for use as a first booster dose.

The Novavax booster dose is intended for individuals aged 18 years or older for whom an FDA-authorized messenger RNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate and for individuals aged 18 years or older who would otherwise not receive a COVID-19 vaccine booster. The 0.5-mL booster dose may be administered intramuscularly at least 6 months after completion of primary vaccination with an authorized or approved COVID-19 vaccine.

The vaccine previously received Emergency Use Authorization for a 2-dose primary series for individuals aged 12 years or older. The two 0.5-mL intramuscular doses are given 3 weeks apart.

Cooling Device to Prevent Chemotherapy Oral Mucositis Gains Authorization

A device that cools the inside of the mouth during chemotherapy cancer treatment, reducing the likelihood and severity of oral mucositis, gained FDA marketing authorization.

Marketed as the Cooral System by BrainCool, the device consists of an automated portable cooling system attached to a disposable thermostatically controlled mouthpiece that cools the oral cavity to 8 °C using sterile water. The cooling extends from 30 minutes before chemotherapy infusion begins, through infusion times of up to several hours, and 30 minutes after.

The treatment is designed to cool major arteries entering the oral cavity, BrainCool Chief Executive Officer Martin Waleij wrote in an email to JAMA. The artery cooling is thought to reduce oral blood flow, reducing oral tissue exposure to chemotherapy agents. This in turn prevents soreness, erythema, and ulcerative lesions, Waleij explained.

The FDA authorization was granted in part based on a study presented at the European Society for Medical Oncology Virtual Congress 2020, according to Waleij. The study involving 182 patients with multiple myeloma or lymphoma who were undergoing high-dose chemotherapy found the Cooral device was as effective as ice chips for preventing severe oral mucositis, with rates below 10% for both methods in both disease groups.

However, in the lymphoma group, oral mucositis severity scores were significantly lower among patients treated with the Cooral device. This is important because patients with lymphoma undergoing chemotherapy typically receive chemotherapy for longer periods—sometimes 6 hours or more—making severe oral mucositis a potentially life-threatening complication, according to a company statement. Both disease groups found the device significantly more tolerable than ice chips, which can cause significant discomfort including chills, nausea, and tooth pain, according to the study.

Oral mucositis is a common, debilitating complication of cancer treatment, the FDA said. Cooral was approved as a De Novo device, meaning no similar previously approved device addresses the indication, and was previously designated a Breakthrough Device, meaning it potentially provides more effective treatment for a life-threatening or irreversibly debilitating condition.

Final Results for Study of Transvaginal Mesh for Pelvic Organ Prolapse

A 36-month follow-up study showed that Coloplast transvaginal mesh for pelvic organ prolapse repair had similar effectiveness and safety outcomes as native tissue repair.
However, the FDA said it continues to believe that devices of this type present potential additional risks compared with native tissue repair, including mesh exposure and erosion, and therefore maintains that they do not have a favorable benefit-risk profile. Premarket applications were rejected for 3 such devices in April 2019.

The current finding is the last in a series of postmarket surveillance studies of surgical mesh for transvaginal repair of pelvic organ prolapse ordered by the FDA that have failed to reach the end point of superiority to native tissue repair that an FDA advisory committee recommended in February 2019. Previously, 36-month postmarket studies of 2 such devices manufactured by Boston Scientific also showed similar efficacy and safety as natural tissue repair, according to the FDA.

The agency’s concerns about mesh for pelvic organ prolapse repair date back to at least 2008, when it issued a safety warning based on more than 1000 reports. Erosion through vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and incontinence were most frequently reported. In 2011 the warning was updated to state that such complications were not rare.

This led to the FDA reclassifying mesh for pelvic organ prolapse as a high-risk class III medical device in January 2016, requiring substantial evidence of efficacy and safety for market approval. As a result, all such products were eventually removed from the market. The FDA continues to monitor urogynecological surgical mesh for adverse events including low-frequency but life-altering events that may occur. — Howard D. Larkin

Note: Source references are available through embedded hyperlinks in the article text online.