Patient Perspectives on AR-based Surgery

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Key takeaways from the FDA Patient Engagement Advisory Committee July 2022 meeting

The FDA's Center for Devices and Radiologic Health (CDRH) recently hosted the Patient Engagement Advisory Committee (PEAC) Meeting, to discuss augmented reality (AR) and virtual reality (VR) medical devices.[1] The PEAC was established in 2017 to solicit input from patients, caregivers, and patient advocates, relating to the regulation and use of medical devices, and to promote a culture of patient-centered care.

The convening of the PEAC comes at an important time, as AR- and VR-enabled platforms are rapidly being developed, tested, and adopted for an increasing number of healthcare applications across the continuum of care.[2][3][4]

Over the course of the two-day meeting, patients, providers, researchers, industry leaders, and policy makers presented and discussed topics of high importance about the continued evolution of AR and VR in healthcare.

One particularly informative discussion focused on the use of AR devices for surgical procedures. A subset of the PEAC Committee (12 members, including patients, physicians, researchers, and patient advocates) were asked to address two questions.

The first question the Committee was asked to address was, ***"What information would you want your surgeon to share with you during the informed consent process prior to a surgery that will involve an AR device?"***

Here, the Committee members stressed the need for safety and efficacy data from clinical studies. Specifically, the Committee members said they would want to know, for example, rates of complications and adverse events associated with AR-enabled surgery. They would also want to be made aware of the advantages of employing AR compared with usual care (e.g., how AR could help to mitigate potentially harmful techniques that have long been used in practice, such as reliance on contrast infusion and radiation). Additionally, they would want to be made aware of details of clinical trials to assess the generalizability of the results (i.e., did the patients in these studies share my baseline characteristics such as demographics, clinical comorbidities, and undergo the very same operation that I am considering?).

With regard to making safety and efficacy data accessible and digestible to patients, Committee members suggested that the FDA might consider overseeing and maintaining a repository for up-to-date objective data related to the use of AR in surgery. Specific steps might include building registries of patient outcome data, and potentially identifying and monitoring "Centers of Excellence"[5] for AR use in surgery.

In this context of sharing information about safety and efficacy data, Committee members suggested various approaches for patient education and patient engagement. With regard to approaches to educating patients during the consent phase, it was suggested that the learnings from the shared decision making[6] literature could be applied in the context of AR devices to aid discussions between surgeons and patients. One member noted that, if a surgeon could show a patient a joint in their wrist, what surrounds the joint, and how the technology will enable more precision during the procedure, the patient could then visualize the benefits and feel more comfortable about the surgeon's decision to use this new technology. This highlights the need for patient engagement tools specific to pre-surgical consultations.

The second question the Committee was asked to address was, ***"What would assure you that the surgeon is appropriately trained to use a specific AR device?"***

Committee members stated that they would want to know details about the training programs surgeons and the entire surgical team had completed, including:
Who provides the oversight for training?

- How many hours of training has the surgeon had with this technology?
- How many procedures the surgeon completed using this technology?
- How does this surgeon's performance compare with other surgeons as measured by patient outcomes?

The Committee members emphasized the importance of the surgeon's ability to describe their own AR education and training, as well as that of the entire surgical team. Additionally, they recommended that training be regulated by an independent body like the American Medical Association or other specialty boards.

Committee members also thought it would be important for surgeons to explain the training, and have a plan if something unexpected related to the AR device occurred during the surgery. Here, they would want assurance that the surgeon would have the ability and know-how to override the technology should it malfunction.

Lastly, this question brought to light considerations around equity and access to novel technology. For example, how will information and training spread systematically across institutions? And what will the process be for ensuring that smaller, rural hospitals have the same access to, and training for, this technology as better funded institutions?

Acting on these insights

These insights from the PEAC highlight the need for: 1) continued efforts around rigorous clinical studies to understand short- and long-term outcomes across diverse patient populations, 2) careful consideration and oversight of training programs for surgeons and surgical teams, and 3) new approaches to patient engagement and patient education to help them understand the motivation for using AR during surgery, as well as the benefits and potential risks.

References

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