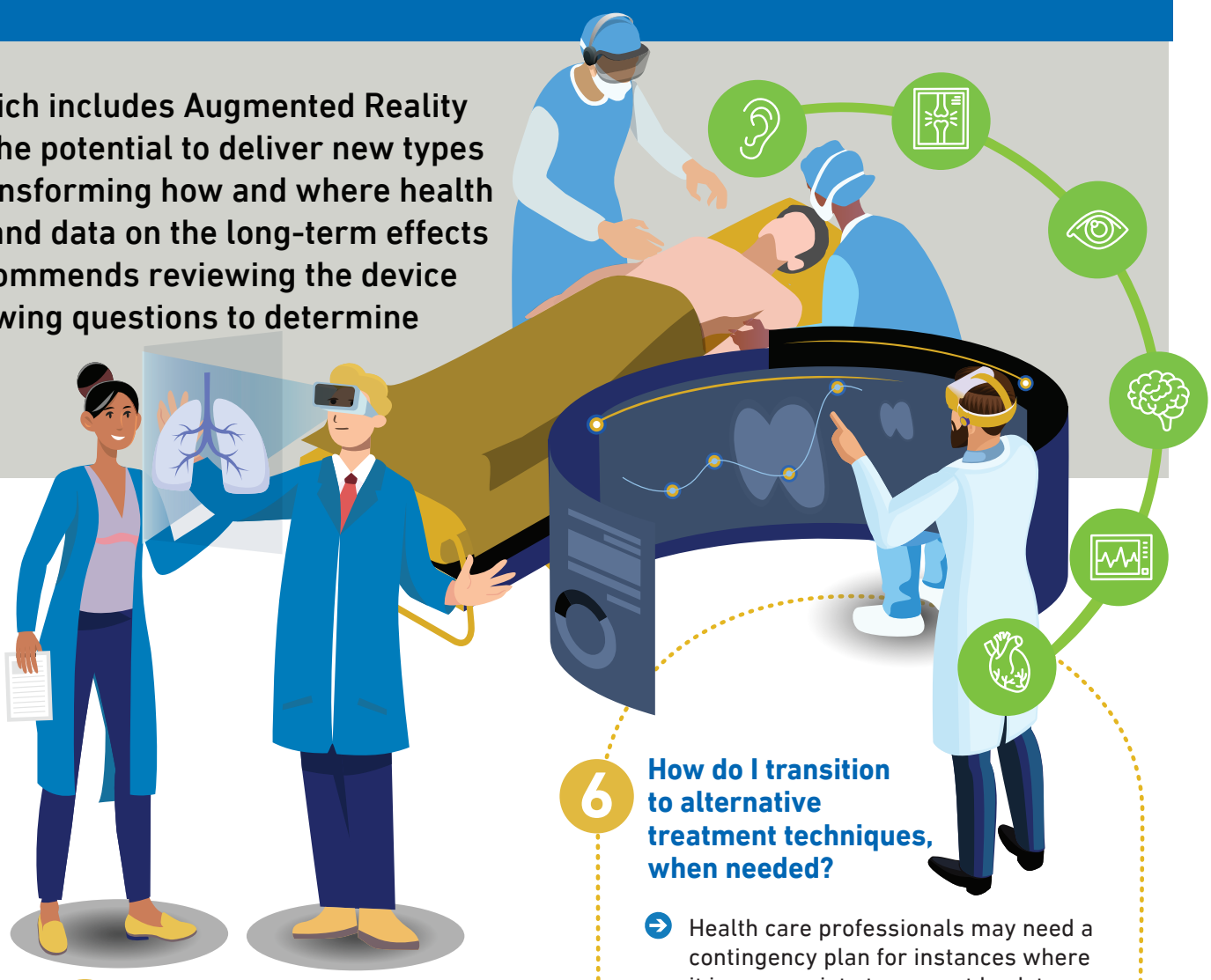
AUGMENTED REALITY & VIRTUAL REALITY IN MEDICAL DEVICES

7 Questions to Consider When Deciding Whether to Use Augmented Reality and Virtual Reality Devices in Your Practice

Medical Extended Reality (XR), which includes Augmented Reality (AR) and Virtual Reality (VR), has the potential to deliver new types of treatments and diagnostics, transforming how and where health care is delivered. As information and data on the long-term effects of medical XR evolve, the FDA recommends reviewing the device labeling and considering the following questions to determine whether an XR technology is right for use in your practice.



1 Is there clinical evidence for using XR in health care?

- The FDA has published a list of XR devices that incorporate AR or VR and that have been authorized for marketing based on data and information that demonstrate their safety and effectiveness.

2 Are there benefits to using XR?

- XR devices may be more portable, convenient, and accessible to diverse populations.
- XR devices may help increase patient compliance and adherence to therapy.
- XR may provide benefits for training health care professionals.

3 Are there limitations to who can use XR?

- XR may be used by health care professionals and some XR types may be appropriate for use by patients.
- XR devices vary in size and weight and may not be comfortable for all body types.
- Some XR devices are intended for specific health care professionals (for example, surgeons or therapists).

4 What training and education are needed to safely and effectively use XR?

- To be used safely and effectively, XR devices are typically intended to be used by individuals with specialized training, and in some cases certifications.
- Like other tools, it may take time to become familiar with the controls. Typically, XR devices include tools and programs to enable health care professionals to build experience.
- Occasionally, the device can malfunction due to various factors. It is important to understand these factors and what to do in such cases.

5 How will XR change a procedure or workflow?

- Technology used in XR may change the operative environment, including but not limited to set-up procedures and intervention performance. These changes could impact the safety of the operating room, so it is important to identify such changes before each procedure. For example, an overlay from the device could obscure the user's view and impact the operative approach to the patient.
- XR hardware needs to be adjusted for each user and requires verification of the personalized set up for each health care professional.
- XR may also require ongoing tech support to help with set up, bandwidth, and personalized adjustments for each patient and health care professional.

6 How do I transition to alternative treatment techniques, when needed?

- Health care professionals may need a contingency plan for instances where it is appropriate to convert back to a different procedural approach or a different diagnostic or treatment modality.
- Post-procedure or therapy debriefing documentation is recommended to help standardize best practices, and for reporting any adverse events that were experienced, including increased treatment time, to the FDA's Medical Device Reporting tool, MedWatch.

7 Does XR pose any physical risks to health care professionals?

- Risks may include, but are not limited to headaches, neck pain, eye strain, motion sickness, fatigue, and distraction in the operating room.
- Manufacturers, device user facilities, and importers are required to submit to the FDA certain types of reports for adverse events. The FDA encourages health care professionals and patients to submit voluntary reports about harms or other adverse events that may be associated with the use of AR/VR devices to the FDA's Medical Device Reporting tool, MedWatch.

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