

Navigating *The Playbook*: Digital Healthcare Edition

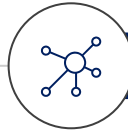
- Your user guide to *The Playbook*: Digital Healthcare Edition
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- The **opportunities** digital health solutions bring to deliver high-value healthcare.
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- **Industry definitions, classification and regulation** of digital health solutions.
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Your micro-playbooks to digital health solutions



AI/ML



AR/VR/MR



Connected
Sensor
Technology



Digital
Therapeutics



Electronic
health
records



Mobile
health
applications



Engagement
and Social
Media



Virtual care



PRO TIP

Throughout the slides you will see *'TL;DR'*. This is a common acronym for *'Too Long; Didn't Read.'*

We are acknowledging how busy you are and that a **small chunk of text is easier to digest** than a large portion of text on a slide.

Augmented Reality(AR), Mixed Reality(MR), Virtual Reality(VR)



TL;DR

XR = {AR/MR/VR}

Extended reality (ER) encapsulates current and future developments in augmented reality, mixed reality and virtual reality

What is **AR/MR/VR**?

- ▶ **Extended reality (XR)** is a collective term for real-and-virtual combined environments and human-machine interactions generated by computer technology and wearables. XR includes:
 - **Augmented reality (AR)**
 - **Mixed reality (MR)**
 - **Virtual reality (VR)**
- ▶ **Deployed throughout the continuum of care delivery** for a range of purposes including, but not limited to, diagnosis or prediction of anxiety, depression, schizophrenia, addiction, ADHD, autism spectrum disorder and about a person's cognitive and physical function.

Applications



What is the difference between AR <> MR <> VR?

XR = {AR/MR/VR}

- **Augmented reality (AR)** is an interactive experience of a real-world environment where the objects that reside in the real world are enhanced by computer-generated perceptual information, sometimes across multiple sensory modalities, including visual, auditory, haptic, somatosensory and olfactory.
- **Mixed reality (MR)** is the merging of real and virtual worlds to produce new environments and visualizations, where physical and digital objects co-exist and interact in real time. Mixed reality does not exclusively take place in either the physical world or virtual world, but is a hybrid of augmented reality and virtual reality.
- **Virtual reality (VR)** is a simulated experience that can be similar to or completely different from the real world. Applications of virtual reality include entertainment (video games), education (medical or military training) and business (virtual meetings).



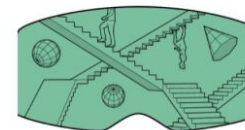
Augmented Reality

In augmented reality—like Google Glass or the Yelp app's Monocle feature on mobile devices—the visible natural world is overlaid with a layer of digital content.



Mixed Reality

In technologies like Magic Leap's, virtual objects are integrated into—and responsive to—the natural world. A virtual ball under your desk, for example, would be blocked from view unless you bent down to look at it. In theory, MR could become VR in a dark room.



Virtual Reality

VR places the user in another location entirely. Whether that location is - computer-generated or captured by video, it entirely occludes the user's natural surroundings.

The promise of immersive digital tools for care delivery

Opportunities to create value for patients, providers and healthcare systems



Large amount of biometric tracking data collected from micro-movements of head, torso, hands, and eyes



Create safe **experiential learning** environment



Facilitate analyzation and **application of real world evidence** and/or product performance data



Provides learners with **hard skills** (motor functioning) and **soft skills** (empathy) through virtual interactions



Convenient to **scale and reuse** of equipment can support product sharing



Support diagnoses or prediction of various **cognitive and physical function**



Collects **metrics to track** individual progress and knowledge of the skills



20 min in a XR session can record 2 million data points about an individual's body movement!

XR solutions are being used to improve key areas of patient care including mental health, elder-care, physiotherapy, and pain management. Experts estimate the market for XR in healthcare could reach [\\$7B by 2026](#).

Risk

Reliability, validity, and accuracy of data may vary greatly based on various factors

Challenge

High upfront unit cost have limited widespread use of AR tools

Risk

Non-transparent **privacy policies** for the purpose and use of user-generated data has discouraged progress

Risk

Intellectual property (IP) infringement is seen as a prime legal risk for stakeholders

Risk

Sprawling psychographic profiles coupled with medical inputs could leave people vulnerable

Risk

Lack in anonymity tracking data is serious concern due to individual's unique movement patterns



The challenges of applying real-world regulations to XR

- XR technologies are evolving fast – and our **legal systems are unprepared.**
- Despite the multitude of opportunities, some real **risks and regulatory challenges exist** like:
 - Questions about [privacy](#) and [copyright](#)
 - Disputes over the [speech rights](#) and [physiological tracking](#)
 - Threat to [geolocation of individuals](#)
 - Risks of [property damage](#) and destructions and more
- **Currently**, there are **no regulations** or guidance on AR/VR/MR usage. However, **FDA is taking steps to identify critical gaps** that may impede medical XR products **development**, innovation, and to advance the **evaluation** of medical XR products and **applications**, thus accelerating the development of safe and effective medical XR products benefiting patients and healthcare. View recordings: [1](#), [2](#), [3](#), [4](#)

The screenshot shows the FDA website interface. At the top left is the FDA logo. To the right are search and menu buttons. Below the navigation bar is a section titled "IN THIS SECTION" with a dropdown arrow. Underneath, there is a link for "Workshops & Conferences (Medical Devices)". The main content area features a "WORKSHOP" announcement for a "Public Workshop - Medical Extended Reality: Toward Best Evaluation Practices for Virtual and Augmented Reality in Medicine" scheduled for "MARCH 5, 2020".

Case study: VR for orthopedic surgical training



The Challenge:

Video learning before surgery is common practice for surgical trainees and surgeons. This study is designed to evaluate whether **Immersive virtual reality (IVR)** improves **learning** effectiveness for **surgical** trainees and to validate a VR rating scale through **correlation to real-world performance**.



The Approach:

An **IVR training platform** providing a case-based module for reverse shoulder arthroplasty (RSA) for advanced rotator cuff tear arthropathy. Participants were permitted to repeat the module indefinitely. The **primary outcome measure was a validated performance metric (Objective Structured Assessment of Technical Skills [OSATS])**. Secondary measures included transfer of training (ToT), transfer effectiveness ratio (TER), and cost-effectiveness (CER) ratios of IVR training compared with control.

RCT: Effectiveness of Immersive Virtual Reality on Orthopedic Surgical Skills Among Senior Surgical Residents

POPULATION

14 Men, 4 Women



Orthopedic postgraduate residents in years 4 and 5

Mean (SD), age 31 (27-36) y

INTERVENTION

18 Participants randomized and analyzed



9 Immersive virtual reality (IVR) simulation

Precision orthopedic surgery virtual reality simulator with reverse shoulder arthroplasty training module



9 Technical instructional video

Technical instructional video of reverse shoulder arthroplasty

SETTINGS / LOCATIONS



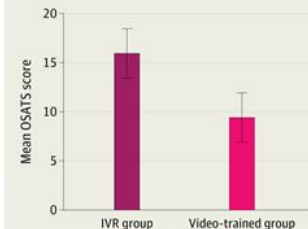
Single-site simulation center in Ottawa, Ontario, Canada, with participants from 9 training institutions

PRIMARY OUTCOME

Objective Structured Assessment of Technical Skills (OSATS) score (range 0-21) during masked cadaveric evaluation in performing reverse shoulder arthroplasty

FINDINGS

Participants trained with IVR had significantly higher OSATS scores than participants trained with video



Difference, 6.9; 95% CI, 3.3-9.7; P < .001



The Result:

Surgical training with IVR demonstrated **superior learning efficiency, knowledge, and skill transfer**. The control group with receiving only technical instructional video missed a mean of 67% of the key steps while the IVR group outperformed. The IVR training is at minimum **34.1 times more cost-effective** than our control.



SPOTLIGHT

ADVISORY COMMITTEE MEETING

July 12-13, 2022: Patient Engagement Advisory Committee Meeting Announcement

JULY 12 - 13, 2022

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On This Page

- [Meeting Information](#)
- [Event Materials](#)

Date: July 12 - 13, 2022
Day1: Tue, Jul 12 10:00 AM - 4:00 PM ET
Day2: Wed, Jul 13 10:00 AM - 2:00 PM ET

“AR/VR devices are increasingly applied to healthcare settings across the patients’ care continuum. From diagnostics to clinical decision making, to surgical support, and to directly treating patients, AR/VR devices are used across multiple medical specialties.”




On July 12 and 13, 2022, the CDRH Patient Engagement Advisory committee met to discuss and make recommendations on the topic of “Augmented Reality (AR) and Virtual Reality (VR) Medical Devices.”




LEARN FROM THE EXPERTS


AR / VR Technology
*Converging with Machine Learning, Biosensing, and Telemedicine
 To Transform Healthcare*

Walter Greenleaf PhD

 National Mental Health Innovation Center
UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS

Click on the image below to launch



Walter Greenleaf, PhD