SUMMARY MINUTES

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

PATIENT ENGAGEMENT ADVISORY COMMITTEE

July 12, 2022

Via Video Conference

Attendees:

Chairperson

Paul T. Conway
Chair, Policy & Global Affairs
American Association of Kidney Patients

Voting Members

Amye L. Leong, M.B.A.
Healthy Motivation
Patient Engagement in Care & Translational Research

Bennet R. Dunlap, M.S.
President, Your Diabetes May Vary Consulting
Diabetes Patient Advocacy

Monica L. Willis Parker, M.D.
Assistant Professor, Dept. of Neurology
Director, Minority Engagement Core
Goizueta Alzheimer's Disease Research Center
Emory University School of Medicine

Rita T. Roy, M.D.
CEO
National Spine Health Foundation

Phillip X. Rutherford
Chief Operating Officer
Faces & Voices of Recovery

Mary (Suzanne) Schrandt, J.D.
Founder, CEO & Chief Patient Advocate
ExPPECT, LLC

Temporary Non-Voting Members

Heather R. Adams, Ph.D.
Associate Professor
Departments of Pediatric & Neurology
University of Rochester School of Medicine & Dentistry

Colleen M. Gallagher, Ph.D, LSW, FACHE
Executive Director, Clinical Ethics, Chief
Section of Integrated Ethics in Cancer Care, Medical Executive
The University of Texas MD Anderson Cancer Center

Grace Levy-Clarke, M.D.
Director
Uveitis Services, Department of Ophthalmology
West Virginia University

Omer Liran, M.D.
Assistant Professor of Psychiatry
Department of Psychiatry & Behavioral Neurosciences
Cedars-Sinai Medical Center

Naiem Nassiri, M.D.
Associate Professor
Department of Surgery, Division of Vascular & Endovascular Surgery
Clinician Educator Track
Yale University

Stephen B. Wilcox, Ph.D., FIDSA
Founder & Chairman, Board of Designed Science

Industry Representative

Diane M. Johnson, M.S.
Senior Director, North American Policy
Global Digital Health Policy Lead
Johnson & Johnson

Consumer Representative

Teresa Diaz
Co-Founder
Global Patient Advocacy Coalition (GPAC)

Food and Drug Administration

Letise Williams, Designated Federal Officer

Kathryn Capanna
Deputy Director, Division of All Hazards Response, Science & Strategic Partnerships, Office of Strategic Partnerships Technology Innovation (OST)

Brendan O'Leary
Acting Director, Digital Health Center of Excellence (DHCoE), OST

Anindita Saha
Assistant Director, DHCoE, OST

Angela Krueger
Deputy Director for Regulatory Policy, Office of Product Evaluation and Quality

CALL TO ORDER

Panel Chairperson Paul T. Conway called the meeting to order at 10:00 a.m. He asserted the purpose of the FDA's Patient Engagement Advisory Committee (PEAC) and highlighted outcomes of its operations to date. He noted the presence of a quorum and affirmed that Committee members had received training in FDA law and regulations. He announced that the Committee would be discussing and providing advice on the benefits, risks, and uncertainties of augmented reality (AR) and virtual reality (VR) medical devices, and ways to integrate patient perspectives into FDA and industry decision-making.

He then asked the Committee members and the FDA staff to introduce themselves.

CONFLICT OF INTEREST STATEMENT
TEMPORARY-NONVOTING MEMBER STATUS STATEMENT
GENERAL ANNOUNCEMENTS

Letise Williams, Designated Federal Officer, reported that Dr. Omer Liran was issued a conflict of interest waiver. She announced that Ms. Diane M. Johnson would serve as the Industry Representative and that Dr. Heather R. Adams would serve as a temporary non-voting member.

She then made general announcements regarding speaker identification and disclosures, transcript availability, and breakout session procedures. She introduced Lauren Jei-McCarthy as the FDA press contact.

WELCOME AND OPENING REMARKS

Jeff Shuren, M.D., J.D., Director, CDRH, FDA, provided updates of CDRH's purpose and recent work in patient science and engagement and digital health technology. He highlighted outcomes of previous PEAC meetings, and he apprised the Committee of recent events, workshops, programs, and partner organizations. He emphasized the role of the PEAC in incorporating patient input into regulatory processes and noted this meeting will showcase perspectives on AR/VR medical devices from patients, industry representatives, academics, and healthcare providers.

PRESENTATIONS

Augmented Reality and Virtual Reality Medical Devices: An Overview

Leeda Rashid, M.D., M.P.H., A.B.F.M., Physician, DHCoE, CDRH, FDA, clarified working definitions and provided current uses of AR/VR technology. She discussed technological and regulatory challenges and provided examples of benefits and risks of AR/VR

technologies. She emphasized the agency's commitment to meeting patient needs in a safe, effective, and equitable manner by facilitating informed decisions of patients.

A General Overview- AR/VR in Healthcare- What is it? How is it Used? What's the Difference?

Walter Greenleaf, Ph.D., Neuroscientist, Virtual Reality, and Digital Health Expert Stanford University, defined terminologies (AR, VR, MR, XR) and outlined how these technologies fit into the digital health ecosystem and shared examples of current clinical uses, including medical student training. He addressed the improved affordability and availability of devices and acknowledged the decades of research that have moved AR/VR/MR/XR technologies into their recent clinical applications.

Industry Perspective – Developing AR Medical Devices for the Surgical Field

Jennifer N Avari Silva, M.D., CCEP-PC, FHRS, FAHA, FACC, Co-Founder & Co-Inventor, SentiAR, Co-Founder & Co-Inventor Excera, recounted developing AR to meet unmet medical diagnostic needs, including use of holograms to enhance protocols in real-time and three-dimensional space. She expounded upon her SentiAR technology, which compounds data from multiple sources for collaborative diagnostics and procedural improvements. She identified problems during development, such as optimizing digital space, user interface, noise levels, and technical specifications. She then provided examples of patient outcomes and emphasized the importance of achieving measurable patient-facing outcomes through patient-provider dialogue.

Industry Perspective – Designing Immersive Therapeutics (ITx) for Self-Directed, At-Home Use

Josh Sackman, Co-Founder & President, AppliedVR, presented on his experience designing immersive VR therapeutics for self-administered, at-home use. He highlighted healthcare inequities in the chronic pain epidemic, including provider shortages, stigmas, and treatment autonomy. He recounted the research conducted that informed his product design requirements: efficacious, easy-to-use, and engaging. He then shared examples of measurably improved patient outcomes and addressed policymakers' role in driving awareness, acceptance, and adoption of new medical technologies, and concluded with his vision for in-home VR pharmacies.

Healthcare Provider Perspective – Pediatric User as Special Populations for VR Considerations

Jeffery I. Gold, Ph.D., Prof. of Anesthesiology, Pediatrics, and Psychiatry & Behavioral Sciences, Keck School of Medicine, University of Southern Californio **and Juan Espinoza,**

M.D., FAAP, Assistant Prof. of Clinical Pediatrics, Children's Hospital Los Angeles, Keck School of Medicine, University of Southern California, expounded upon the terms "extended reality" and "mixed reality" and regulatory difficulties on the wide spectrum of uses for VR. They discussed education, training, and preparation for device usage in training, diagnostic, and therapeutic applications before moving to pediatric-specific considerations, such as: data and privacy protections under HIPAA, physical/mechanical customizations, eye health, developmental appropriateness, and screen time.

Healthcare Researcher Perspective – The Use of VR in other vulnerable populations and health equity considerations

Courtney Lyles, Ph.D., Associate Prof., Center for Vulnerable Populations, University of Southern California, San Francisco, discussed the use of VR to manage chronic pain as a means to increase health equity in the country. She shared research that shows high interest and high usability of VR and discussed fitting digital health platforms to community preferences and privileges. She mentioned dialogue with co-design with stakeholders and patients to improve accessibility of digital health platforms and called for multi-sectional and multi-factorial collaboration with policymakers.

Patient Perspective- The experience of using VR in a healthcare journey

Sharif Razzaque, Vision Therapy Patient, disclosed his affiliations and spoke exclusively from the perspective as a patient with double vision. He detailed his prognosis and obstacles to his vision therapy, including VR therapies not being covered by insurance and technological illiteracy amongst doctors limiting his VR therapy in-office. He shared his excitement for at-home VR therapy along with his concern for his and other patients' data privacy.

Open Committee Discussion

Mary Schrandt, J.D., inquired about specific trainings or processes for the use of VR for clinical training on conscious patients. **Walter Greenleaf, Ph.D.,** explained that developers prioritize understanding the patient's journey and design to optimize diversity and inclusiveness.

Bennett Dunlap, M.S., requested clarity on how data privacy is handled in de novo evaluations of medical devices and on how research results can be communicated to patients. **Angela Kreuger from the FDA** answered that these processes are unique to each individual study and that FDA does take cybersecurity considerations into account.

BREAKOUT SESSION

A virtual breakout session for the discussion of scenario questions was held from 12:30 to 1:00 p.m.

BREAKOUT SESSION SUMMATIONS

Breakout Room Number 1:

Fraser Bocell, Ph.D., recapped his group's discussion of the question, "What would you expect a healthcare provider to communicate to you about the device?" He listed conflicts of interest, time on market, safety and efficacy, patient experiences, contraindications, and safety checks as primary concerns of the group. This raised the question from another group, "Is the provider expected to proactively communicate?"

Breakout Room Number 2:

Chris Harner, M.D., addressed his group's discussion of whether healthcare providers should be the main point of contact to educate parents about a device for themselves or their child. The group concluded the physician should be the primary point of contact, supplemented by input from family and friends, the internet, the manufacturer, and patient groups.

Breakout Room Number 3:

Bart Sachs, M.D., summarized the group's dialogue on the question, "Would you expect or want to receive training and information about the device from anyone else besides your healthcare provider?" The group agreed that this depends on device and its usage, but in general, groups like providers, industry, and FDA should share information on patient outcomes, the manufacturer should share technical information, and lived experiences should come from peer-to-peer feedback. The group expressed concerns about release of information and HIPAA and generated the idea of educational apps from manufacturers/providers.

Breakout Room Number 4:

Jessica Weinberg, M.A., recounted her group's contributions to the question, "How do you weigh the risk and benefit trade-off in device deciding whether your daughter would use the device?" Group members said open communication with a trusted physician that knows the daughter's history, needs, and potential drug interactions. Also of concern were cost and the accessibility to specific populations.

Specific concerns from this discussion include:

- Video trainings done by individual groups may not be as accurate as obtaining information directly from the manufacturer that includes real patients.
- Patient ability to parse through information can be limited, so trusting the doctor is important.
- AR/VR devices may exacerbate dizziness caused by certain medications.

- Benefit and risk assessment depends on the child's usual activities and preferences.
- AR/VR devices with video games may create a desire for more screen time fora child.
- Software updates and hardware coverage over the long term is of concern.

Breakout Room Number 5:

Caiyan Zhang, Ph.D., summarized her group's contributions to the question, "What additional information can help you make a decision about a need to use a device to supplement medication use?" Along with the common themes from other groups, the group mentioned that healthcare providers should directly provide literature on the device/therapy. They would also want to know when to stop treatment in the event of complications and potential repercussions of stopping it.

Breakout Room Number 6:

Anil Kochhar, M.Sc., M.B.A., summarized his group's contributions to the question, "Since you can't see what your child is watching, what would you like to feel confident that the device is doing what it is supposed to do?" The group mentioned: pretests to ensure children can follow the machine's directions, an external indicator that the patient passed a safety checkpoint, and an automatic system that stops the device if the patient is distraught. They also noted the importance of educating the child.

Additional suggestions include:

- Physician and parents initiating discussions with the child about their experience
- Child-centered focus groups
- Headset sensors to convey biological information
- Making headset content available to view remotely on an app
- Ensuring less tech-savvy guardians know what to do if the device malfunctions

Breakout Room Number 7:

Allen Chen, Ph.D., reported his group's ideas on the question of whether manual or automatic shutoff of the device is better. The group noted that this depends on the course of treatment. For example, some devices require acclimation, some have levels to advance through as treatment continues, some have prescribed times, and some are as-needed. In general, the group agreed that there should be an external signal that the desired time has been completed.

Group seven was also asked if they had concerns about altering a child's perception of reality as a result of routine use of the AR/VR technology and/or concerns about overuse and underuse. The group had mixed ideas: some found this a non-issue due to the existing prevalence of reality-distorting screen time activities, and some suggested working with a child psychiatrist to prevent overuse. Many agreed parents should see the environment firsthand to

anticipate biases, and they should have the ability to monitor progress. The concern was raised that a child may begin to see the medical device as a game if there are no automatic shutoffs.

OPEN PUBLIC HEARING

Joe Morgan, M.D., president of WAYA Health, addressed how AR and VR address patient needs. He spoke on high patient engagement, immersive learning, and remote care that surpasses telehealth. He noted that safety considerations are largely handled by clinical subject domain experts and emphasized the crucial role of patient-reported outcomes in determining efficacy and the importance of provider awareness. He also highlighted the need for clinical experts to be involved in all stages of the design process. He closed by commenting that efficacy depends on 3D model accuracy, and accessibility features must be incorporated into the technology.

Theodora Scarato, M.S.W., raised concerns about radio frequency absorption into tissue. She cited legal precedents and peer reviewed research on this subject and raised concerns about medical vulnerabilities of exposed children. She questioned the FDA on aspects of radio frequency absorption including developmental risk analysis, potential adverse health effects in pediatrics, levels of exposure in VR, monitoring protocols, data collection and analysis, FDA transparency, and long-term safety. She cited examples of other countries with policies that are intended to protect children against radio frequency exposure.

Kavya Pearlman, founder and CEO of XR Safety Initiative, described her nonprofit and spoke on AR/VR safety on behalf of the company's Medical XR Advisory Council. She underscored the importance of patient privacy, mentioning concerns with Meta. She highlighted challenges of monitoring AR/VR's unique data types and proposed three recommendations to the FDA: improve medical standards to incorporate AR/VR, educate stakeholders on risks and opportunities, and enable standardized enforcement across geopolitical boundaries.

Emmy Schwab expressed their excitement at utilizing AR/VR for mental health treatment and urged the FDA to expedite regulatory processes to keep treatments off of informal marketplaces such as app stores.

Shweta Daga, Director of Regulatory Affairs for Align Technology, underscored the importance of user-centered design, early patient engagement for pre-market evaluations, and post-market patient perspectives. She also noted that the design process should consider family members and environment.

Roger Holzberg of Reimagine Well described his company's development of immersive patient experiences. **Debbie Wagers** detailed their experiential education model; A video of a patient detailed the patient's EEG exam and an MRI stillness game, providing relevant patient stories.

John Tawfik, DPT, GCS, Director of Clinical Services with Accelerated Care Plus (ACP), commented on the use of VR as rehabilitation for use by physical and occupational therapists and language pathologists. He presented evidence for effective VR for rehabilitation in neurological, cardiopulmonary, and dysphasia cases.

Open Committee Discussion

Amye Leong urged any relevant individuals to speak on any difficulties in engaging patients to aid in product development. **Dr. Morgan** replied that his initial subjects were family and friends. **Dr. Tawfik** described acquiring patient feedback from clinical settings and assisted living facilities during physical, occupational, and speech therapy sessions. **Mr. Holzberg** mentioned constant collaboration with clinicians to develop solutions. **Bennet Dunlap** urged participants to delve deeper into the meaning of patient engagement.

Dr. Omer Liran asked for specific obstacles faced by pediatric patients. **Ms. Wagers** describes challenges in the areas of patient consent, comprehension, acclimation, supervision, and fear of immersion.

Suz Schrandt inquired whether, during the development of tools for clinicians, the end user is the clinician or the patient? She asserted her belief that the patient is the end user and solicited thoughts on obtaining patient perspectives and creating patient engagement with diagnostic tools. **Dr. Joe Morgan** stressed the role of providers and catering devices to providers even though patients are the end users.

Dr. Monica Willis Parker inquired when developers expect private and governmental insurance companies would cover cost and development of AR/VR medical devices. **Ms. Pearlman** described a collaboration with British Health Services to establish shared responsibility between healthcare providers, manufacturers, and insurance providers. She concluded that the answer depends on context and commented on cyberspace's lack of geopolitical boundaries.

Ms. Scarato addressed the prior question of children's vulnerability and reiterated her concerns about the safety of children's developing eyeballs. In response to an inquiry from Dr. **Heather Adams**, **Ms. Pearlman** asserted that lack of data prevents assessment of many safety concerns, but the CAMERA Act was put forth to allocate funding to research into AR/VR child safety. **Mx. Schwab** stated they are concerned about lack of data given that commercial headsets are not recommended for children. **Mr. Holzberg** addressed **Dr. Adams'** inquiry into his company's flying game, stating that graphically similar 2D experiences help prepare children for the counterpart 3D experience.

Philip Rutherford asked if there is any research to support a correlation between substance use disorders and a predisposition towards addiction to altered reality experiences. **Mx. Schwab** spoke from personal experience and affirmed that this phenomenon may occur in certain individuals. **Mr. Tawfik** brought up generational differences in technology use and pointed out that geriatric patients experience positive outcomes.

Ms. Pearlman, in response to **Teresa Diaz's** question on long-term data regarding adverse effects of VR use with pediatric patients, mentioned the Collingridge Dilemma and reiterated a lack of research into the subject. **Ms. Scarato** alluded to research showing nonionizing radiation enhances the effects of drug exposures and said that metal on/in the body could be harmful to a child in a clinic when electrical devices are present. **Mr. Tawfik** noted that, for geriatrics, screen-based extended reality reduces motion sickness and ionization exposure as compared to use of head-mounted devices. **Dr. Morgan** stressed the incorporation of parental feedback to evaluate long-term effects, and commented on accessibility features, the use of 'end session' buttons, AI, and data privacy.

Chairperson Paul Conway directly addressed **Mx. Schwab** regarding their patient journey and inquired towards what promise they see in AR/VR technology to improve mental health, and challenges for patients beginning a similar journey to theirs. **Mx. Schwab** answered that VR is only useful for healing if a patient's real-world setting is also conducive to healing, raising more concerns for disadvantaged populations that cannot escape situational trauma, creating institutional and legacy issues that prevent productive conversations about benefits of the technology. They offered the advice that before beginning a VR treatment journey, one should establish a sense of removal from themselves. **Mx. Schwab** also noted that within the panel, both a patient and industry representative work for the same company that received a federal grant in 2018 and stated that benefits of medical VR cannot be accurately assessed within a privatized healthcare system.

To **Mr. Tawfik, Mr. Dunlap** asked if the competitive nature of one of his VR programs could establish unhealthy dynamics between children and what kind of protections against security lapses he incorporates into his VR technology. **Mr. Tawfik** responded that the game uses exclusively positive feedback and affirmations and the software adjusts to account for physical disabilities.

CLOSING REMARKS AND ADJOURNMENT

Chairperson Conway announced the conclusion of day one of the two-day PEAC meeting. He thanked the participants, prompted the Committee to reconvene the next day, on July 13th, 2020, at 10:00 a.m. Eastern time, and adjourned the meeting.

I certify that I attended this meeting on July 12, 2022 and that these minutes accurately reflect what transpired.

Letise W. Williams -S

Digitally signed by Letise W. Williams -S
Date: 2022.09.02 13:51:54 -04'00'

Letise Williams
Designated Federal Officer

I approve the minutes of this meeting as recorded in this summary.

Paul T. Conway
Chairperson 9/6/2022

Summary prepared by:

Debbie Dellacroce

Translation Excellence

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