e3iVR: Conference on ethics in investigational and interventional uses of immersive VR

Final Report

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Abstract

Purpose: Applications of virtual reality technologies as an investigational and clinical research tool are promising; however, this emerging technology also presents new ethical issues. The objective of the e3iVR conference was to produce a set of standard ethical guidelines to support the safe use of virtual reality technologies for research and clinical purposes. This conference was unique in that it brought together the communities who *create* the technology, *use* the technology, and *experience* the technology as patients or research subjects.

The use of this technology in a clinical and research setting raises ethical issues such as (1) informed consent, (2) clarification of risk, and (3) estimation of benefit. Consistent to the mission of AHRQ, the guidelines created at e3iVR advocate for improved quality of the healthcare system through sound research methods.

Scope: The scope of the conference was to convene stakeholders and experts in the VR research and interventional domains, provide foundational knowledge to the general public and workgroup participants, and provide the framework and resources to support the development of a list of initial guidelines for dissemination. The intent of the guidelines is to serve as an initial list for further discussion and refinement as the technology evolves and as more data becomes available.

The conference centered on immersive experiences with virtual reality (VR) technologies (e.g. Oculus Rift™, Samsung Gear VR™, Google Cardboard™, HTC VIVE™, and CAVE environments). Discussions focused exclusively on the applications of VR technology that seek to answer research questions or provide clinical care, and on uses that are supported by a clinician or researcher, in a clinical or research setting. Of greatest consideration was the impact on the direct participants, not on society as a whole. The advisory panel and workgroup participants agreed that the overarching goal of the guidelines is to help individuals exercise their freedom to participate in novel scientific research and clinical interventions in an informed way.

Methods: We engaged an advisory panel to assist us with conference planning. The advisory panel nominated individuals to participate in the conference workgroup, provided guidance on the framework for the workgroup discussions, and advised on the dissemination plan for the guidelines developed during the conference. The advisory panel met three times leading up to the conference.

With respect to the structure of the conference, the event was held over a two-day timeframe. The morning and afternoon of the first day of the conference was open to the public. The evening and following day were invitation-only, attended by thirty representatives of the different stakeholder groups impacted by this topic.

The goal of Day 1 was to provide tours, technology demonstrations, and talks to ensure a base level of knowledge across the different stakeholder groups. In the evening, an invite-only talk for workgroup participants offered over dinner discussed the relationship between virtual reality technologies and underserved communities. On Day 2, the thirty workgroup members spent the morning in facilitated deliberations over specific ethical issues associated with the use of virtual reality technologies. The group spent the afternoon reviewing and debating the guidelines generated in the morning session.

Results: By the end of Day 2, the group of stakeholder representatives and subject matter experts produced a list of guidelines addressing the following four topics: data tracking, informed consent, reporting guidelines, and patient and subject protections. Dissenting opinions and areas for further

discussion were also captured. The project team drafted a paper summarizing the guidelines, which is currently under peer review. A summary, companion article is under discussion for submittal in 2018.

Key Words
Virtual reality, ethics, emerging technologies, healthcare research

Purpose

Immersive virtual reality (VR) technologies (e.g. Oculus Rift™) provide an opportunity for researchers and clinicians to study health issues and treat patients in new ways. The promising research methodology raises ethical issues such as (1) informed consent, (2) clarification of risk, and (3) estimation of benefit which need to be considered when utilizing this technology with human subjects and patients. The e3iVR conference included a half-day of public lectures followed by an invitation-only workgroup that focused on identifying ethical issues and drafting guidelines to address them. These guidelines for the investigational and interventional use of immersive virtual reality will be widely disseminated for discussion and adoption.

Currently, there are no formal ethical guidelines for the use of VR technology in healthcare research and clinical interventions. As the nation seeks to advance innovation in health care delivery to improve quality while reducing costs, this was the opportune time to posit guidelines for ethical use of this emerging technology. This conference helped build consensus on a challenging topic in healthcare research methodology.

As commercial use of these technologies grows, these principles are going to govern access and use in the engagement of underserved groups in research and clinical care. Issues regarding the use of VR with priority populations were addressed through lectures on utilization of VR research methods to improve child safety and considerations for vulnerable populations when utilizing VR methodology. These talks set the stage for development of guidelines that address the needs of these priority populations.

Stakeholder representatives were nominations by our Advisory Panel. This conference was unique in that it brought together the communities who *create* the technology, *use* the technology, and *experience* the technology as patients or research subjects.

Scope

Immersive 3D virtual realty (VR) – a visualization experience in which participants are exposed to vivid, color images by wearing head-mounted devices (HMD) or stand in special rooms (CAVES) provide the experience of being in any environment – from underground caves to starry galaxies. Health applications of VR are growing, and include such things as distraction interventions for pain management, high performance training, phobia treatment, and design of home care technologies. There are very few guidelines for ensuring safe exposure for patient and fair treatment of human subjects. Thus, the goal of the e3iVR conference is to develop and disseminate guidelines for the investigational and interventional use of immersive virtual reality. We sought to deliver a conference and dissemination strategy that:

1. Provided experts, scholars and lay people with informative lectures to ensure a baseline understanding.
2. Engaged an invited subset of these participants in a thoughtful discussion in which each stakeholder group (patients, researchers and clinicians) was provided space to articulate their ideas and consider varying viewpoints.
3. Achieved consensus amongst representatives from the healthcare IT, VR research, and patient communities on a baseline set of formal guidelines for the investigational and interventional use of virtual reality technologies in healthcare.
4. Disseminated the guidelines for debate, discussion and adoption by the clinical care and scientific research community.

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Methods

The Living Environments Laboratory (LEL) at the University of Wisconsin-Madison hosted the conference. The LEL is a multidisciplinary lab with space in the lower level and third floor of the Wisconsin Institute for Discovery (WID) that uses advanced and 3D visualizations to explore scientific, clinical and aesthetic research questions and applications including perception and visualization, human decision making and behavior as well as natural interfaces in virtual reality environments.

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We implemented a two-part approach to this work, a day and one-half meeting and a dissemination strategy. In the first afternoon, we held general lectures open to the public to provide foundational information about immersive virtual reality, behavioral effects, and general ethics. Day 2 was invitation-only with experts and stakeholders who deliberated in facilitated small groups and then reported to a larger group. A detailed discussion of the meeting follows.

Optional Tour/Demonstrations. An optional tour of the virtual reality environments in the LEL was offered the morning prior to the talks. Participants of e3iVR and members of the public were eligible to sign up for one of three tour times prior to the conference date. Attendees who chose to sign up for a tour were able to experience the CAVE, a fully immersive room with four 9’6” x 9’6” walls, a ceiling and a floor – all of which are projection screens, except the floor, which is a clear plexi-glass surface. Two projectors are found behind each screen which form 3D rear projected images. Conference attendees also had the opportunity to use a head-mounted display. This opportunity was recommended for anyone with minimal exposure to

Figure 1 - Optional Virtual Reality Demonstrations

virtual reality to broaden his or her understanding of how the technology works.

Day 1 Presentations. General lectures were open to the public to provide foundational information about immersive virtual reality, behavioral effects, general ethics, and illusions. Talks started in the afternoon of Day 1 after the optional tours. A fifth lecture on *VR and the Underserved by Health Care* was available to experts and stakeholders who were scheduled to participate in Day 2's Breakout Sessions. Workgroup participants gained a common understanding for various issues in VR together before proposing ethical guidelines on the second day of e3iVR.

Day 1 of e3iVR had four speaker events open to the public with an additional invite-only presentation during dinner for workgroup participants specifically. A summary of each presenter and their talk is given below. *For video recordings, the talks are accessible to watch at this address:* https://conferences.discovery.wisc.edu/e3ivr/talks/

Figure 2: Day 1 Public Talks

Kevin Ponto, PhD - A Retrospective on the Field of Virtual Reality

Kevin Ponto is an Assistant Professor at the University of Wisconsin-Madison with a rich history of interdisciplinary research. Dr. Ponto has worked on previous projects aimed to rediscover a lost Leonardo da Vinci painting, monitor pollution levels through the development of smart backpacks for homing pigeons and build next generation theater productions through augmented projected environments. Currently, Dr. Ponto leads multiple funded research projects that utilize VR to better understand the context of the home environment for the purposes of health in the home, generate new methodologies for crime scene investigation, create new systems to support informal learning for scientific research projects, and develop new interaction techniques to support next generation consumer marketplaces.

Dr. Ponto presented *A Retrospective on the Field of Virtual Reality,* which provided a brief history as to how the field has evolved from its foundational roots to the state of art of today. Affordances and deficiencies of various VR technologies were discussed for a variety of use cases. To conclude, the talk provided context around current issues in the field as well as visions for future applications of virtual reality technologies.

Jodie Plumert, PhD - Virtual Environments as Laboratories for Studying Human Behavior

Jodie Plumert is Professor and Chair of Psychological and Brain Sciences at the University of Iowa. Her research interests include cognitive development, perceptual-motor development, and unintentional childhood injuries. She is an expert in using virtual environment technology to study the development of perception-action skills such as how children and adolescents make gap decisions and time their movement when crossing roads with traffic.

Dr. Plumert spoke on *Virtual Environments as Laboratories for Studying Human Behavior.* An overview of research findings were discussed from the Hank Virtual Environments Laboratory on how child (and adult) pedestrians and cyclists cross virtual roads, with a special focus on the problems encountered when conducting VR research with vulnerable populations. The talk concluded with a discussion of potential

ethical dilemmas raised by studying risk taking in virtual environments, and potential safeguards for protecting vulnerable research participants after they leave the lab.

Mar Gonzalez-Franco, PhD - Illusions and Virtual Reality
Dr. Mar Gonzalez-Franco is a Researcher at Microsoft Research and an Honorary Research Fellow at the Experimental Virtual Environments for Neuroscience and Technology Lab (EVENT-Lab) in University of Barcelona. In her research, she tries to achieve strong immersive experiences using different disciplines: Virtual Reality, computer graphics, computer vision and haptics. All while studying human behavior, perception and neuroscience to better understand human perception.

In her presentation on *Illusions and Virtual Reality*, a wide set of illusory experiences that take place in VR were reviewed and the underlying perceptual and cognitive mechanisms that enable the set of illusions were described. Dr. Gonzalez Franco explained that in VR it is possible to induce illusions that make people feel they have entered an alternate reality (place illusion), that the events happening are real (plausibility illusion), and even that their bodies have been substituted by an avatar (embodiment illusion).

Kenneth Goodman, PhD - Ethical Considerations in the Use of Virtual Reality
Dr. Kenneth Goodman is Professor of Medicine at University of Miami School of Medicine, with secondary appointments in Philosophy, Nursing and Health Studies, Epidemiology and Public Health and Anesthesiology. Dr. Goodman is a leading bioethicist in the United States who focuses on biomedical informatics. His initial background in computational linguistics and machine translation, and in journalism, has fostered his understanding of, and interest in, ethical issues in informatics.

Dr. Goodman's presentation on *Ethical Considerations in the Use of Virtual Reality* explained that new technologies are often a source of ethical challenges, the study, adoption, and use of virtual reality tools should be accompanied by comprehensive ethical and policy analyses. The ethical issues raised by the use of virtual reality include but are not limited to (i) the training of health professionals (e.g., percutaneous renal access, ultrasound-guided neuraxial anesthesia, responding to inappropriate patient requests), which raises concerns about the risk of clinical skill degradation; (ii) appropriate uses and users, or the challenges imposed when a new tool might be used without adequate research or training, when the uses themselves might be illicit or inappropriate, or when VR devices are used for recreational and other non-professional purposes; and (iii) alterations in the clinician-patient relationship with potentially adverse consequences, as might occur when VR modifications or enhancements of the treatment setting emerge as atherapeutic.

Chris Gibbons, MD, MPH - VR and the Needs and Capacities of Those Underserved by Health Care
Dr. Chris Gibbons is the Chief Health Innovation Advisor at the Federal Communications Commission and Associate Director of the Urban Health Institute at The Johns Hopkins University. Prior to his position at the FCC, Dr. Gibbons founded a multicultural digital health innovation company. He is passionate about digital health, the underserved, and health innovation.

Figure 3: Dr. Chris Gibbons and e3iVR guest chat after lecture

Dr. Gibbons' presentation on *VR and the Needs and Capacities of Those Underserved by Health Care* gave a brief overview of the FCC health activities was discussed before delving into the intersection between VR and the underserved population. During the talk, a possible bias in VR was investigated. Consumers controlling the boundaries of virtual reality was a topic of discussion when determining the scope to which the realities presented in VR are the perceptions of the privileged scientists producing the technology. The biases society holds are also proven to be displayed within VR. If recognition of biases and defective perceptions in VR does not occur, we could end up increasing disparities—one population should not benefit while the other is forgotten. Dr. Gibbons concluded his lecture by recognizing the need for an increase in minority researchers, and a more representative research portfolio that includes minorities.

Day 2 Breakout Sessions. A group of 30 individuals convened on Day 2 to create a set of recommended instructions for use of virtual reality technology. The individuals were nominated by the conference Advisory Panel. Each workgroup member was asked to contribute to two, 90-minute breakout sessions. The participants were assigned to two topics based on their self-reported interest and expertise: (1) Patient and Subject Protections, (2) Informed Consent, (3) Data Tracking, and (4) Reporting Guidelines. Each topic discussion group was comprised of six workgroup participants, one professional facilitator, and one scribe.

Each breakout group was charged to distill their discussion into 2 – 3 draft guidelines that would be reviewed in the afternoon as a large group. In the afternoon, ideas that were discussed within each breakout group of six were presented to the entirety of participants. The lead facilitator initiated conversation per topic to create a consensus among proposed guidelines and ideas.

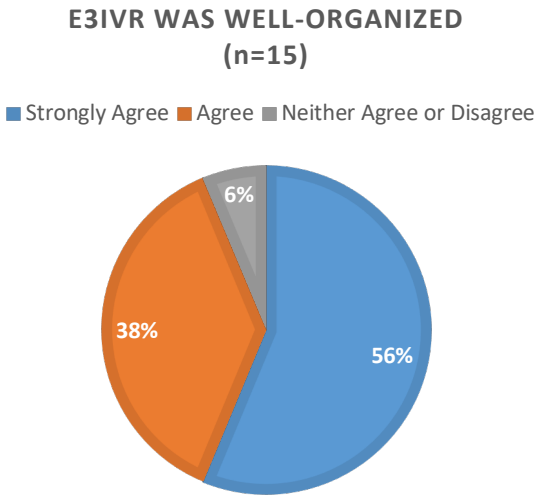
Figure 4 & 5 - Day 2 Breakout Sessions

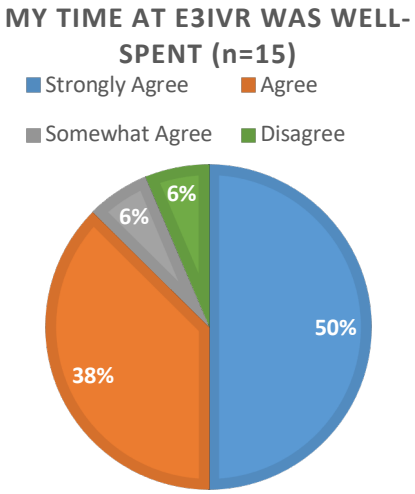
Workgroup Composition. The 30 workgroup participants were from both local and non-local locations. The following stakeholder groups were represented in the discussions: clinical (5), ethics/IRB (6), healthcare consumers (4), industry (2), research (9), and technical experts (4).

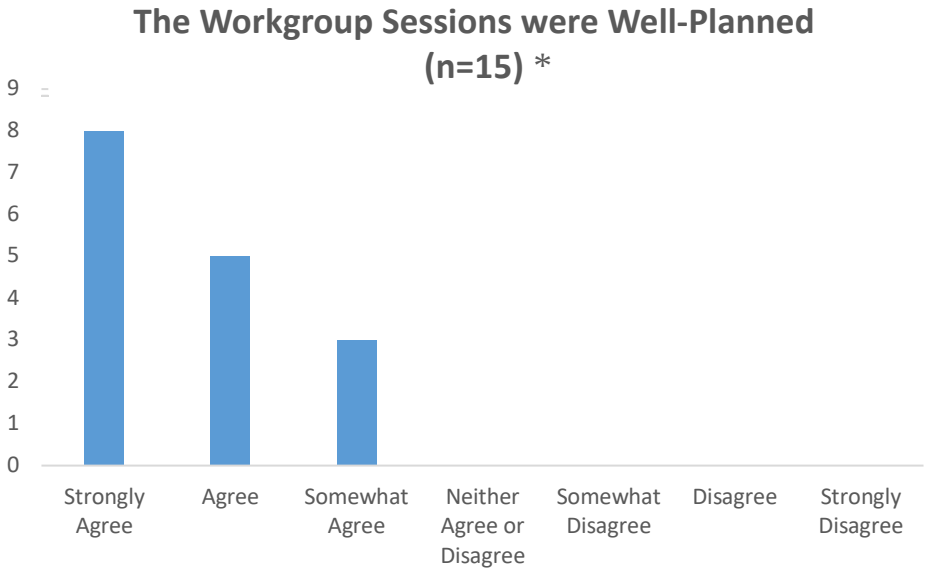
Media Presence. Before e3iVR took place, a community of individuals interested in the ethics of VR were brought together through the conference's social media presence, workgroup-only blog, and website (https://conferences.discovery.wisc.edu/e3ivr/). The communications office at the Wisconsin Institute for Discovery produced a news story prior to the conference (Appendix A). Relevant articles were shared through the workgroup blog to support a baseline level of knowledge prior to the conference. Post-conference, videos were posted on the website of the public talks, and Storify was used to share highlights from the conference.

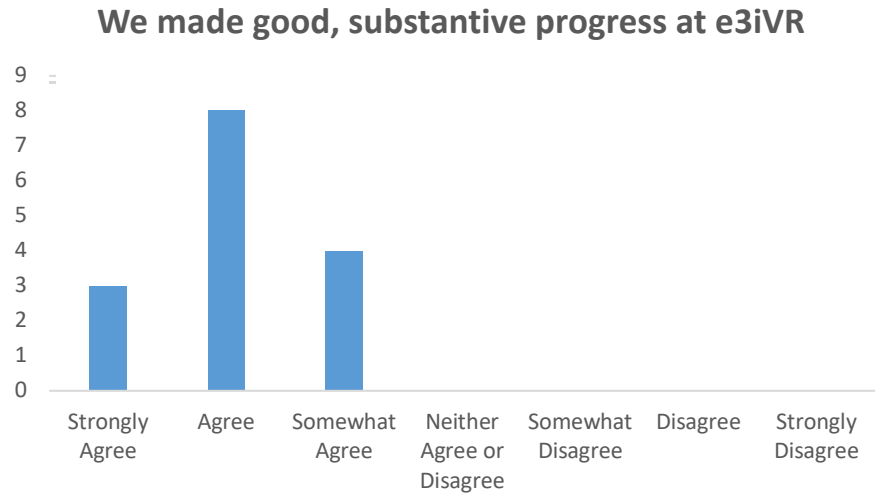
Results

A survey was administered to the conference workgroup participants one week after the event. Fifty percent of the workgroup participants responded to the survey. Summary statistics are below.









Items to retain. Based on the comments submitted in the conference evaluation forms, the opportunity to come together with a diverse group of stakeholders was the most valuable aspect of the conference. The feedback from the post-conference survey indicates that the participants appreciated the opportunity to discuss real-world applications of virtual reality, and the ability to contribute to thoughtful and collaborative discussions on the ethical issues associated with this emerging technology. Several respondents commented on the value of having a public talk on the social and racial context to the work done in this field.

Items to change. Our ideal composition of workgroup participants would have included more representation from industry; this was noted by several of the survey respondents. Several of the VR hardware manufacturers declined the invitation to participate. In the future, we would allocate more resources to enlisting a member of industry to serve on the advisory panel. This would likely help in generating a more balanced workgroup composition. One respondent suggested that case studies be woven in throughout the conference. This suggestion should be discussed prior to implementation; one of the challenges we faced in structuring a conference on ethics is to keep the discussions balanced --- appropriately sensitive to potential harms, while avoiding overly alarmist anecdotes.

We achieved the overall goal of the conference – generating a list of draft ethical guidelines for the investigational and interventional uses of immersive virtual reality from a multidisciplinary perspective. The dissemination efforts are underway. The project team is eager to disseminate the balanced, well-thought list of guidelines developed during the conference.