Requirements Catalogue

on hospital-specific Framework Conditions for VR Applications in Therapeutic Use

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Preliminary results from the BGI project (Output 4.2)

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This document is the output 4.2 of the Interreg BSR project “Baltic Game Industry” showing preliminary results. It includes a collection of single requirements for the effective implementation of VR application in the context of an everyday clinical routine, covering aspects such as technical, personnel, spatial resources as well as aspects of law and ethics.

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1. Introduction

Within the scope of the “Baltic Game Industry - Empowering a Booster for Regional Development“-project, one major aim is to further investigate general framework conditions that have to be met in order to implement virtual reality (VR) applications in non-game sectors. In the present interim report, we comment on basic framework conditions for implementing VR application in clinical settings in therapeutic use.

The project is set up as a multinational cooperation of different partners in the EU. Concerning the VR implementation in a clinical setting and therapeutic use, the University Medical Center Hamburg-Eppendorf (UKE) in Hamburg, Germany, the Institute of Psychiatry and Neurology (IPiN) in Warsaw, Poland, and the Unit of Clinical Alcohol Research, Clinical Institute (UCAR) in Odense, Denmark, are partners and conduct research on feasibility, collect information and acquire experience on necessary framework conditions. We have now gained insight into basic prerequisites that need to be addressed in this specific context. Although on a basic level, there are differences between sites concerning experience with VR application, the situation concerning framework conditions is similar at all three sites (UKE, IPiN, and UCAR).

In the following we will briefly describe achievements, challenges, and obstacles that are specific for the implementation of VR applications in a clinical setting for therapeutic use.

2. Requirements

Technical requirements and resources

VR applications are considered as rather new, evolving technology. Traditionally applied in the game-sector, implementation in non-game sectors is unusual. Generally, there are no VR applications in hospitals implemented and in use yet. At UKE, VR applications have been applied on some wards in pilot studies, however, not comprehensively. UCAR has tested some VR applications, however, to a lesser extent. IPiN has no experience with VR applications whatsoever.

As a result, powerful technical equipment to readily implement VR application is lacking. This is true for VR application itself, but also for the technical equipment needed to run the application and to create a VR environment. Hardware and software that is needed must be purchased. Besides the fact that technical equipment is lacking completely, a lack of knowledge about possible applications within the clinical setting and its benefits poses another hurdle. Without raising awareness about the usefulness of VR applications for the clinical settings, no effort will be made to implement this technology as hospitals may find the costs daunting whilst doubting their usefulness.

Taken together, up to date, all three sites are lacking the technical equipment necessary in order to easily implement VR applications in therapeutic use. The IT-infrastructure still has to be built at all sites cross-nationally. As accruing costs always impose an obstacle on hospitals due to difficult financing conditions, convincing (scientific) evidence that VR applications are beneficial and powerful in patient treatment is needed in order to facilitate the comprehensive implementation of basic technical prerequisites within the hospital setting.

Spatial resources

Here, again, the situation is similar for all three sites. Generally, spatial resources are very limited. No separate room will be available for the use of VR applications. At present, use of VR applications would take place in therapy rooms. This, however, has two major disadvantages.

First, time for VR use directly competes with time for other therapeutic interventions. This is problematic, as an additional intervention must be fitted into an already existing schedule. Although this is not so problematic for the individual patient, it is challenging on general level on ward. Shortage of space must necessarily lead to a suboptimal use of potential benefits of the application. Be it either in a less intensive use per patient or in non-treatment of eligible patients. Second, equipment must be movable. As long as no separate facility is available for the use of VR applications, all equipment must be easily movable in order to be stowed away safely and to not take up to much space in a multifunctional room.

At present, the spatial constraints pose a considerable obstacle on the implementation of VR application in therapeutic use. However, if in the course of a pilot-implementation evidence becomes obvious that VR use within patient treatment is an intervention that is powerful, beneficial, and easy to apply and accepted by the patient, spatial obstacles might be overcome within the general distribution of spatial resources on wards.

Staff

A lack of expertise with respect to the handling of VR applications in a clinical setting is a concern that needs to be faced at all three sites. Up to date, there is no staff trained in the correct and safe use of VR applications. As an important prerequisite for successful implementation and use of VR applications in clinical setting, staff would need to attend training sessions. However, training sessions are time- and cost-intensive, which, against the background of personnel shortages that are present in the everyday hospital routine, is a serious obstacle. Although this does not concern the technical side of implementing VR applications in a non-game sector, it is a major point that needs to be addressed. Without thorough training of staff with respect to the correct application of the equipment, careful handling of personal data, and aspects of hygiene, VR application cannot be successfully implemented.

Although this poses an important limitation on the quick implementation of VR use in a clinical setting, one major resource concerning this matter is the staff`s eagerness to be trained. Especially nursing staff is open to new technology and the necessity of comprehensive training before use. As nursing staff spends most of their working hours around patients, they would be the professional group best suited for the routinely application of VR in a hospital setting anyway.

Sanitation requirements

Sanitation and infection control is a major concern. With respect to VR-goggles, especially bacterial and viral agents concerning eye infection are critical, as devices are used in different patients.

In a UKE pilot study, a smear was taken to take tests concerning possible bacterial and viral agents. Findings were inconspicuous, however, a significant concern from the point of sanitation and infection control is the foam material used for cushioning. This is difficult to clean and disinfect. Two possible solutions exist to resolve this issue: First, disposable covers for VR goggles exist that would be in accordance with hygiene regulations. The covers can easily be affixed on the outer rim of the foam material and replaced after every patient. Second, goggles using synthetic leather for cushioning can be applied. Synthetic leather can be wiped off with a disinfectant-cleaning wipe. Both possibilities are in accordance with hygiene regulations and are considered sufficient as the VR application is a non-invasive, external device, used with superficial dermal contact only. However, in the course of a study, further experiences should be acquired, for example, ensuring that the VR devices can withstand the effects of disinfectant cleaning solutions between each patient's use. Although those hygiene requirements are relatively straightforward, compliance here is crucial. Hence, informing about hygiene regulations should be part of the staff training before implementation of the VR application.

Statutory regulations

Data protection regulations are a central concern when it comes to the implementation of VR applications in a hospital setting.

It cannot be drawn on specific data protection regulations concerning VR application as experience is lacking. Data protection officers were contacted to ask for their advice. In Denmark, one is referred to the Danish Personal Data Act. No specific rules for the automatic collection of personal data for instance by VR or other health care technologies exist so far. The same is true for Germany and Poland. However, the German data protection officer raised some questions that he thought would probably be important to address within this context. Core aspect is the question of which and how data are stored and transmitted to whom. In order to gather information on which and how personal data are stored and/or transmitted

during VR application use, a short questionnaire was developed and sent to main VR-manufacturers. Of interest is if data about physical characteristics of users (e.g., movement profiles), data from active sensors (e.g., facial recognition), location related data (e.g., GPS), time related data (e.g., length of device use), or system environment data (e.g., network connectivity) are stored and/or transmitted (see Appendix 1 for the questionnaire in detail). For harmless use from the point of data protection, it would be critical that storage and transmission options of those data would be turned off, so that VR-manufactures do not gain any access to personal data of patients. Unfortunately none of the contacted manufactures replied to the enquiry (see Appendix 2 for a list of contacted VR manufacturers). Hence, to date, no information is available about how and if and which personal data are stored and/or transmitted. Once it is known which data are stored, another crucial aspect is to inform patients in detail before use about which and how data are stored and/or transmitted. As long as patients are informed and aware of the information they reveal, this should be no reason to prevent VR application in a hospital setting.

Non-response to the questions mentioned above, constitutes a major obstacle in the implementation process of VR application in a hospital setting. We will, hence, continue trying to obtain this crucial information from the manufacturers.

Ethical aspects

For all three sites applies that ethical approval will not be problematic as long as it is clearly known and stated which data are collected by the manufacturers and how/if storage and transmission are handled. However, as to date no company has replied to our enquiry concerning this issue, a study protocol would probably not be approved by the ethics committee. Collecting information about data protection, hence, remains a central prerequisite in order to describe a detailed study protocol, which could then be submitted to the ethics committee, including potential side effects, concerns, benefits etc.

Patients have to be educated before use about which and how personal data are stored and/or transmitted. Use of VR applications must remain voluntary for patients at all times and consent to participate can be withdrawn at any time without giving any reasons.

3. Conclusions

Generally, successful and comprehensive use of VR application in therapeutic use is still at the very beginning at all three participating sites. Few differences exist so far as UKE has some experience with the use of VR applications in a pilot setting concerning patients with addiction. The same is true for UCAR, however, to a lesser extent. IPiN does currently not have any experience with VR application in patient treatment. Although differences concerning experience exist between sites, no effort has been made to comprehensively implement VR applications on a routine level and to comprehensively address the abovementioned obstacles at any site.

As an important prerequisite and to provide a basis to motivate hospital leaders to take effort in order to address obstacles with VR application implementation, evidence-based results showing positive effects of the use of VR applications within therapeutic use are needed. Concerning data protection, there might even be a basic need for data regulation experts to look at specific aspects arising in a hospital setting. As the use of VR applications in data sensitive areas, such as hospitals, is just evolving, no generally binding arrangements exist yet.

Needed requirements for the comprehensive implementation of VR application at the three sites are:

- (entire) equipment is lacking and needs to be purchased
- Spatial resources are scarce, finding adequate premises is and will remain challenging
- Comprehensive training off staff is needed (however, nursing staff would be motivated to participate in training sessions)
- As devices are only used non-invasively and externally, hygiene regulations will be sufficiently met by either wiping off the synthetic leather cushioning with disinfectant-cleaning wipes after every patient or affixing disposable covers at the outer rim of the goggles.
- Aspects of data protection regulations are not yet resolved as VR manufacturers do not reveal if and which and how personal data are stored and/or transmitted.
- Ethical regulations and the approval of a study by the ethics committee will presumably be unproblematic as long as the data protection issue is resolved and appropriately addressed in a study protocol.

Appendix

Appendix 1 - Questionnaire with detailed questions concerning possible storage and/or transmission of sensitive personal data during VR application use.

When asking about data transmission and storage in this survey, the question refers to transmission to, and storage of, data on any device other than the local PC/ Smartphone/ Standalone VR device. E.g. transmission of data via Internet connection to a cloud server. If you answer one of the questions with yes, please specify the kind of data that is being transmitted and/or stored.

Questions for VR hardware manufacturers

- Do you transmit and/or store data about physical characteristics of the user?

  This may include data the user entered, such as gender, or data that can be derived from device usage patterns. For example: Body height, movement profiles, single or two handed usage, dominant hand, eye pictures taken via eye tracking, eyesight derived from usage of corrective add-on lenses or focal point adjustable optics.

- Do you transmit and/or store data from active sensors?

  This may include direct transmission of life data, such as a camera video stream or microphone audio stream. It may also include recordings, such as pictures, video and audio files, as well as data derived from processing the sensor information, such as facial recognition, object recognition, speech recognition and 3D environment reconstruction.

- Can active sensors be disabled via hardware interfaces, e.g. physical buttons?
- Can the user tell if a sensor is active via hardware based feedback, e.g. a glowing LED?
- Can active sensors be disabled via software interfaces, e.g. a setting menu?

- Do you transmit and/or store location related data?

  This may include GPS data, mobile phone signal derived location data, network identifications or 3D environment reconstruction of device position inside a building.

- Do you transmit and/or store time related data?

  This may include start/end/length of device usage sessions, as well as timestamped events such as turning on/off of auxiliary devices like motion controllers.

- Do you transmit and/or store usage related data?

  This may include the use of VR software applications and any data derived from their use.

- Do you transmit and/or store system environment data?

  This may include information about system hardware, operation system, network connectivity, system user and installed software.

- Do you transmit and/or store other data that might be relevant in the context of professional use of VR hardware in areas where sensitive data may be generated?

  Some examples to consider when answering the question would be the use of the VR device in hospitals, in research & development departments of high tech companies, in government agencies or in operation centres for critical infrastructure.

- If you transmit and/or store any kind of data of the kind asked in the previous questions, please describe who in your company has access to the data.
- Does your VR device / do your VR devices require an Internet connection in order to be used?
- Does your VR device / do your VR devices automatically create a connection and/or login to some kind of user account when it is in use?
- What options does a user of your VR device / devices have to control the kind of data transmitted and/or stored?

When asking about data transmission and storage in this survey, the question refers to transmission to, and storage of, data on any device other than the local PC/ Smartphone/ Standalone VR device. E.g. transmission of data via Internet connection to a cloud server. If you answer one of the questions with yes, please specify the kind of data that is being transmitted and/or stored.

Questions for VR platform software developers & operators

For this survey, VR platform software refers to all types of software required to run individual VR applications. E.g. VR drivers, SDKs, VR software stores, launchers, digital distribution platforms and such.

- Do you transmit and/or store data about physical characteristics of the user?

  This may include data the user entered, such as gender, or data that can be derived from device usage patterns. For example: Body height, movement profiles, single or two handed usage, dominant hand, eye pictures taken via eye tracking, eyesight derived from usage of corrective add-on lenses or focal point adjustable optics.

- Do you transmit and/or store personally identifiable information?

  This may include name, address, email or social media account information, payment information and more.

- Do you transmit and/or store data from active sensors?

  This may include direct transmission of life data, such as a camera video stream or microphone audio stream. It may also include recordings, such as pictures, video and audio files, as well as data derived from processing the sensor information, such as facial recognition, object recognition, speech recognition and 3D environment reconstruction.

- Do you transmit and/or store location related data?

  This may include GPS data, mobile phone signal derived location data, network identifications or 3D environment reconstruction of device position inside a building.

- Do you transmit and/or store time related data?

  This may include start/end/length of device/VR software/VR experience usage, as well as timestamped events such as turning on/off of auxiliary devices like motion controllers. It may also include time spent in different menus/scenes, time spent with different types of content, local time of day when using the VR platform software and more.

- Do you transmit and/or store usage related data?

  This may include the use of VR software applications and any data derived from their use. It may also include interaction events such as button presses, picking up and using virtual objects, using menus and interacting with system-generated content such as advertisements. It may include general usage patterns, eye-tracking derived information on what the user is looking at, search histories and more.

- Do you transmit and/or store communication between multiple users of your VR platform software?

  This may include text chat, voice chat, video chat, virtual and mixed reality meetings, direct messages or messages posted to some common message board.

- Do you transmit and/or store system environment data?

  This may include information about system hardware, operation system, network connectivity, system user and installed software.

- Do you transmit and/or store other data that might be relevant in the context of professional use of VR platform software in areas where sensitive data may be generated?

  Some examples to consider when answering the question would be the use of the VR platform software in hospitals, in research & development departments of high-tech companies, in government agencies or in operation centres for critical infrastructure.

- If you transmit and/or store any kind of data of the kind asked in the previous questions, please describe who in your company has access to the data.
- Does your VR platform software require an Internet connection in order to be used?
- Does your VR platform software automatically create a connection and/or login to some kind of user account when it is in use?
- What options does a user of your VR platform software have to control the kind of data transmitted and/or stored?

Appendix 2 - List of manufacturers that were contacted to answer the questionnaire.

1. HTC Vive (HTC in cooperation with Vive)
2. Oculus Rift (Facebook)
3. Windows Mixed Reality (e.g., lenovo)
4. Dell Visor (Microsoft)
5. Dongguan Shinecon Industrial Co
6. Playstation VR (Sony)

THE PROJECT

The project 'Baltic Game Industry' (BGI) aims to foster the game industry in the Baltic Sea region - turning an ambitious game developer scene into a competitive and attractive business sector with sound innovation potential and thus making the region a game hotspot with worldwide competitiveness.

The partnership works together on framework condition improvements, on making business support services fit for the special needs of game start-ups and finally on new business opportunities for game developers in other industry sectors, such as health care. The core element is the installation of durable game incubators, programmes and schemes for game start-ups across the region.

BGI effectively combines policy and business development. Tailor-made game business support fosters a durable economic growth of this innovative industry in the whole region. The introduction of VR technologies in non-game industries contributes to boosting innovation beyond games. The common branding of the Baltic Sea region as game innovation hotspot will attract international clients, investors, creative entrepreneurs and qualified workforce.

Read more at www.baltic-games.eu

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