Introducing Virtuality - Virtual Care Process Simulator: A Concept Utilizing Synthetic Data and a Digital Health Sandbox for Care Process Simulations

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Abstract: To design effective and safe IT systems for healthcare is a significant technical and societal challenge, and it is of highest importance to confirm safety of patients when implementing new innovations. It would be beneficial if new innovations could be verified and validated in a realistic and safe digital environment using data that preserve patient integrity and safety, before going into real clinical trials and market release. In this article we introduce and describe *Virtuality* - Virtual Care Process Simulator, a concept for realistic simulation of healthcare scenarios in a digital sandbox environment using synthetic health data. The concept represents a safe environment to develop, test and prepare systems and digital tools for usage in healthcare.

1 INTRODUCTION

To design effective and safe IT systems for healthcare is a major challenge, and there is plenty of examples of systems that have not fulfilled the goal of facilitating provision of high-quality care (Campion-Awwad et al., 2014; Hertzum et al., 2022). For example, The National Programme for IT in the NHS (NPfIT) in the UK, a large IT programme for the public sector, was cancelled after delays, stakeholder opposition and implementation issues (Campion-Awwad et al., 2014). Some of the highlighted problems with NPfIT was confidentiality and security of patients, unreliable software and lack of engagement with end-users (Campion-Awwad et al., 2014). In Sweden, IT system functionality deficiencies and lack of a standardized infrastructure are reported to cause technostress leading to critical incidents (Stadin et al., 2020), and to be a barrier to innovation such as precision medicine and developing Clinical Decision Support Systems (CDSS) (Fioretos et al., 2022; Frisinger & Papachristou, 2023). These are all issues that urge the importance to prepare systems for implementation, through sufficient testing and thought-through requirement specifications.

In the healthcare industry, safety of patients is of highest importance. Regulations put high demands on devices, digital tools and systems being safe to use and free of bugs. One important step for new innovations before entering the market is passing clinical trials, which requires confirmed effectiveness and safety for the patients and users. This necessitates extensive verification and validation and access to high quality data. There is a need to boost innovation and speed up the development process of new technologies and systems for healthcare, enabling promising research to reach the market earlier, while ensuring regulatory compliance. A new complementary method to traditional product development is virtual tests with simulated healthcare processes and synthetic data. Early research shows

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high potential for usage of synthetic data (Chan et al., 2022; Dahmen & Cook, 2019; Walonoski et al., 2018) and digital sandboxes (Leckenby et al., 2021) for simulations in healthcare. These technologies are suggested as important building blocks for virtual testing environments.

In the Care@Distance group at Chalmers University of Technology in Sweden, a concept and solution for simulation and testing of digital tools for healthcare is under development. The concept, called *Virtuality* - Virtual Care Process Simulator, has been a stepwise process over the past 10 years, as a result of insights from several projects and practical experiences (Andersson Hagiwara et al., 2019; Bakidou et al., 2023; Candefjord et al., 2024; Fhager et al., 2018; Lee et al., 2023; Maurin Söderholm et al., 2019). It consists of several different parts that together build a virtual simulation environment: synthetic health data, Digital Health Sandbox (DHS) and third-party applications. Through Virtuality, digital systems and tools can be tested in a safe environment, before going into real clinical trials, implementing systems and entering the market.

The Care@Distance group performs research on digital solutions for healthcare, with focus on improving the care process by introducing new CDSS based on innovative methods and Artificial Intelligence (AI).

By using virtual care process simulations, we could prepare systems and tools for the clinical environment and avoid iterating clinical trials again when potential problems and bugs in the systems arise. An important part of virtual care process simulations is usage of digital health sandbox environments, i.e. environments in which developers can test and modify innovations in collaboration with clinicians, adding and removing features or combining them with other related innovations (Ribiere & Tuggle, 2010). DHS acts as a safe-space in which algorithms and tools for healthcare can be tested and further developed iteratively, before tested in the real-world clinical settings (Leckenby et al., 2021).

For Virtuality to be useful in performing realistic simulations, it needs to have access to relevant and high-quality data. The demand of high-quality data for medical and healthcare research are increasing and the challenges with accessing those data are highlighted by many (Kokosi & Harron, 2022; Moniz et al., 2009; Tsao et al., 2023; Walonoski et al., 2018). The information kept in Electronic Health Records (EHR) is highly sensitive and usage of real data should respect integrity, confidentiality and security for the patients.

To avoid unnecessary use of sensitive data, simulations on artificially generated versions of patient health data, so-called synthetic health data, is a suggested solution (Kokosi & Harron, 2022). Synthetic data mimics the statistical properties of real-world data and leaves minimal traces to the real data (Gonzales et al., 2023). Thereby, the possibility to link the data to individuals is low and the integrity and safety of individuals is kept.

By connecting synthetic data with DHS and running simulations enabled by a scenario engine used for mimicking selected care processes, Virtuality is a promising concept to solve above mentioned challenges and needs. Our vision with Virtuality is to get as close to reality as possible without involving real patients in testing, and to validate and simulate new IT-tools improving care processes. In this article, we will present Virtuality, describe its parts and motivate the usage of it by exemplifying two different scenarios of healthcare processes simulated in the virtual environment. Our initial target scenarios are for time-critical patient conditions, i.e. trauma represented by fall at home and motor vehicle crash, and stroke, which are important societal problems representing significant morbidity and mortality.

2 RELATED WORK

In recent years the interest in using digital sandboxes, synthetic data and simulation environments in the healthcare sector have increased (Leckenby et al., 2021; Pezoulas et al., 2024).

The approach of using a sandbox environment can be divided into two main categories; the sandbox as a testing environment and the sandbox as regulatory sandbox approach (Leckenby et al., 2021). Both categories are often focused on trial of products, services and business models to confirm their compliance with existing regulations before they are implemented in real-world settings.

The concept introduced in this article, Virtuality, is more focused on development and testing of new services and systems in a simulated realistic setting. It is unique in the sense that few similar technologies that combine a digital sandbox with synthetic health data are currently in use in a healthcare setting. One closely related technology in use is the Blue Button Sandbox, which uses synthetic claims data from U.S. Centers for Medicare & Medicaid Services (CMS), to develop and test applications and information systems that will need to interact with CMS data systems and Medicare services (Gonzales et al., 2023). The Blue Button

Sandbox is oriented towards development of services that benefits Medicare enrolees, rather than being applicable to a wider range of data, systems and services.

There are several different main testing environments used for product innovation and development of systems and tools for healthcare (Leckenby et al., 2021). In Figure 1, we have positioned Virtuality in relation to other testing environments. Compared to sandboxes currently used, Virtuality aims for a broader scope and to be useful during a broader extent of the development process, from idea generation to implementation.

The number of studies on synthetic health data generation shows an increasing trend between the years of 2015–2024 (Pezoulas et al., 2024). Synthetic health datasets are created and used for a broad range of use cases. Gonzales et al. (2023) summarized current use cases as a) simulation and prediction research, b) hypothesis, methods, and algorithm testing, c) epidemiology/public health research, d) health IT development, e) education and training, f) public release of datasets, and g) linking data. The past years, several public synthetic health datasets have been published. Some examples of published, publicly available synthetic health datasets and tools for synthetic health data generation are: 1) *Synthea*, generates synthetic EHRs through statistical modelling and usage of publicly available health statistics, clinical guidelines and protocols (Walonoski et al., 2018), 2) *SynSys, a* Machine Learning (ML)-based synthetic data generation method for generating synthetic time series sensor data for healthcare application (Dahmen & Cook, 2019), *3) Medkit-Learn(ing) Environment,* a ML-based synthetic data generation method for generating synthetic medical datasets (Chan et al., 2022). All three above synthetic health data generation methods and datasets are open source, allowing developers to contribute to further development.

The importance of conducting full-scale simulations and their potential in prehospital care was highlighted by Maurin Söderholm and colleagues (Maurin Söderholm et al., 2019). By providing an isolated and controlled environment, stakeholders can test, validate and confirm their ideas based on synthetic data, in order to better prepare systems for wider implementations (Leckenby et al., 2021). This can guide decision making and allow stakeholders to draw conclusions comparable to those from real clinical settings, without the immediate need to address legal barriers.

3 CONCEPT

The Care@Distance group and collaborators are now developing a virtual testing environment, called Virtuality. Virtuality provides all the tools needed to set up, configure and run realistic healthcare simulations in isolated environments, facilitating performing the first two steps in the Verified

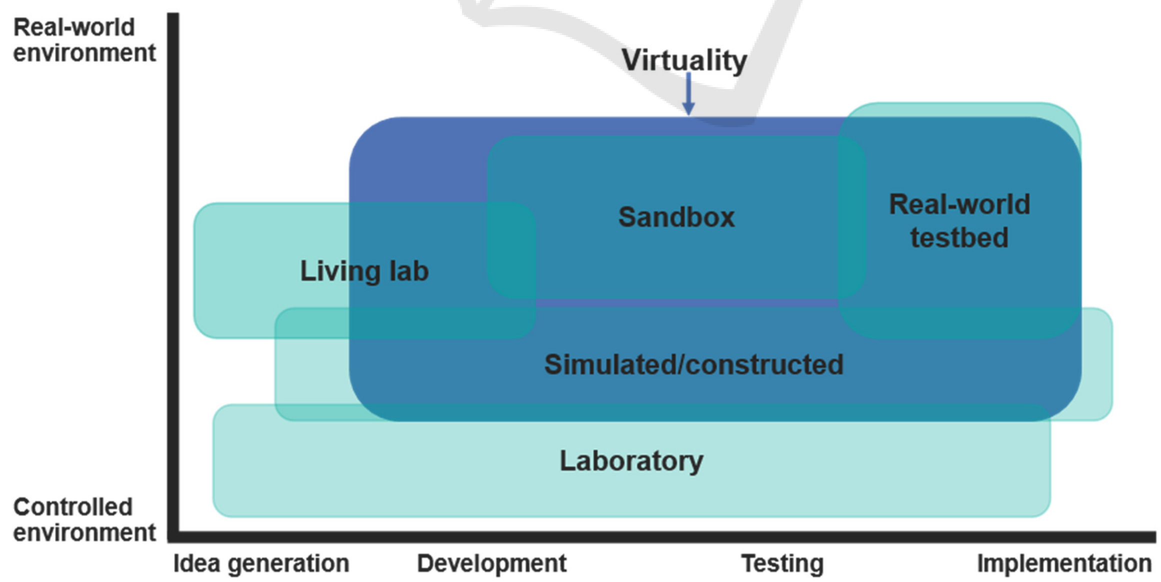

Figure 1: Positioning of Virtuality concept in relation to the main testing environments used in product innovation (adapted from (Leckenby et al., 2021) and (Arntzen et al., 2019)).

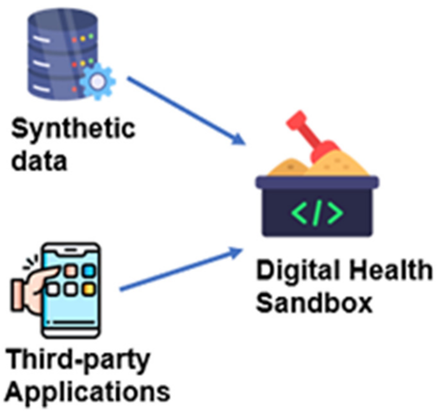

Figure 2: Virtuality consists of 1) synthetic data, 2) third-party applications, 3) Digital Health Sandbox.

Innovation Process for Healthcare Solutions (VIPHS) model, which corresponds to defining a prototype (Lee et al., 2023). This includes synthetic data generation mechanisms, access to third-party applications and DHS, see Figure 2.

Virtuality is based on the Acute Support Assessment and Prioritizing (ASAP) Concept. This concept emphasizes the importance of aggregating data from multiple sources to increase decision precision, streamline workflows and improve patient safety. By building the Virtuality environment around the ASAP Concept, it ensures that interoperability remains the central focus and foundation of all activities within this environment.

3.1 Digital Health Sandbox

The DHS will be one of the main parts within Virtuality, enabling effective utilization of synthetic data and digital technologies to test and validate the clinical utility of digital innovations, refer to Figure 2 and 3. Regardless of applications, whether it is a fall detection system, stroke detection or trauma severity prediction (Bakidou et al., 2023), the goal is to bridge the gap between stakeholders, enabling clinicians, engineers and researchers to actively participate in the design, execution and evaluation of advanced and realistic simulations (Maurin Söderholm et al., 2019).

The DHS is based around four core building blocks: ASAP Providers, Services, Consumers and the Scenario Engine. Each of these blocks, along with their associated functionality can be seen in Table 1. Depending on the scope and objective of the simulation, different number of components within each building block can be used, and various levels of complex interaction patterns can be applied. This means that the Graphical User Interface (GUI) also adapts to the specific simulation scenario. For example, in a traffic safety scenario, a user may want to simulate how AI-algorithms and vehicle sensors can be utilized to assess the likelihood of injuries in a motor vehicle crash (Maurin Söderholm, 2023). In this case, the GUI should adapt to that specific scenario, meaning that the user should be able to select the number of cars, car model, car occupants, crash type, type of AI-model and type of sensor data.

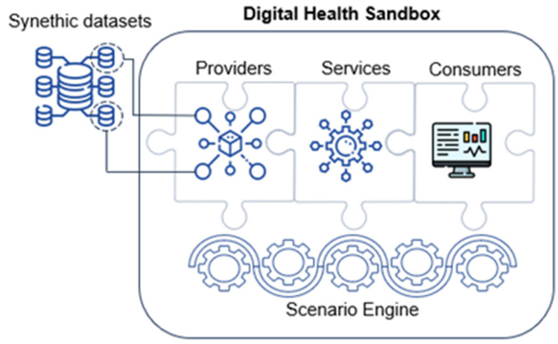

Figure 3: In Virtuality, DHS can be combined with synthetic datasets to enable realistic simulations and get full control of the simulation scenario.

Together, the ASAP Building Blocks constitute a comprehensive and fully customable testing arena where any combination of devices, algorithms and platforms can be put together to allow for realistic simulations. The ASAP Concept supports this, by promoting open – and standardized interoperability interfaces, as well as synthetic data to avoid dependencies on third-party vendors, see Figure 3.

Table 1: The DHS is composed of four building blocks: Providers, Services, Consumers and Scenario Engine.

ASAP Building Block	Functionality
Providers	Devices or information providers responsible for initiating a simulation by sending data to ASAP Services for further processing.
Services	Software modules responsible for processing information coming from ASAP Providers.
Consumers	GUI (Graphical User Interface) responsible for displaying information from ASAP Services to end users.
Scenario Engine	Orchestrator that enables the user to determine what to simulate and how it should be conducted, ie., decide on the simulation scenario, what components to be used and how they should fit together.

For instance, the synthetic data generator within Virtuality could be used to create a fictious smartwatch to be used within the DHS (the ASAP Provider Building Block in Table 1). This approach would provide immediate access to realistic data, refer to Figure 3, eliminating delays typically caused by dependency on third-party vendors and applications. The Provider Building block (smartwatch) could be integrated with an AI-based trauma algorithm (Bakidou et al., 2023) and a third-party EHR, represented by the ASAP Service Building Block and Consumer Building Block, respectively. The ASAP Concept would guide this integration process, by specifying open – and standardized interfaces between and within each building block.

3.2 Synthetic Data

For the DHS to be effective and useful, data that can act as ASAP Provider is needed. To get qualitative real health data can be challenging and requires going through often extensive data access applications (Kokosi & Harron, 2022). An alternative data source to use as ASAP Provider is synthetic data. Synthetic data is an interesting complement to real data and has several advantages that motivates why it is useful: a) accelerate development processes, b) secure patient anonymity, privacy, integrity and safety, c) improve data accessibility, d) increase data volume and diversity, e) account for underrepresented data and scenarios, f) testing of not yet existing solutions, g) address regulatory challenges in early development without using patient data and h) decrease dependency of data providers.

Synthetic health data can be divided into five main categories; tabular data, image and video data, time-series data, radionics data and multimodal data (Pezoulas et al., 2024). The Care@Distance group aims to create a database of synthetic data, which can be used to run simulations on different scenarios in the DHS. With their primary focus on improving the prehospital care, synthetic versions of data accessible in prehospital healthcare settings will be the primary focus. In a prehospital setting tabular data like EHR, image and video data of a patient or accident site and timeseries sensor data are some of the most interesting categories.

In addition, new data sources with the potential to improve prehospital care are of high interest. A broad range of parameters and different kind of data should be available and possible to use for simulations in Virtuality. Synthetic data can be used alone or in combination with real data. The purpose with the synthetic data is not to completely replace real data, but rather to enable early verification and validation of tools and systems before accessing real data (Kokosi & Harron, 2022).

In a prehospital setting, for example in a motor vehicle crash, ambulance or smart home, video data are a promising data source. Video data in ambulances could enable automated assessment and informed decision-making during emergencies (Jalo et al., 2023). To explore the use of synthetic data and video analysis in the early characterization of stroke-related eye movements, we generated 69 videos simulating typical eye movements seen in stroke patients (Ollila et al., 2024). These videos were reviewed and deemed clinically relevant by a stroke neurologist, making them suitable for developing CDSS. The synthetic videos were combined with real recordings of healthy individuals mimicking stroke-related eye movements. The use of synthetic data resulted in creating a larger dataset, which was crucial for models training and evaluation to ensure strong performance.

3.3 Simulation Scenarios

In Sweden, senior citizens have been wearing social alarms since early 1980s (Lydahl, 2024). These alarms, consisting of a manual alarm button which usually looks like a clock or a pendant, are frequently used in Home Care Services (HCS) and in nursing homes. Although these social alarms are the most common welfare technology in the Nordic Countries (Lydahl, 2024), an alarm from this device might be difficult to interpret. Does the patient need acute medical attention, or do they just need to refill a glass of water? Since these alarms are used in both acute and non-acute scenarios, it becomes stressful for the personnel and can pose a danger to the patient if critical alarms are overlooked or delayed.

Therefore, it could be valuable for the HCS to investigate alternative setups. Perhaps combining the social alarm with complementary information from other sources, as in Figure 4, or analyzing the data with AI, could give meaningful insights. For example, if the social alarm data were accompanied by the patient's heart rate, angular velocities, gait patterns and medical history, it could potentially reveal a frail individual with a history of osteoporosis who has experienced a fall.

This setup could potentially provide more valuable insights, allowing the nurse to plan appropriate interventions in a timely manner and help in prioritizing among multiple occurring alarms. Such simulations could be carried out within Virtuality by utilizing the DHS and synthetic data, see Figure 4. The results from the simulation could potentially lead to an extension of current social alarm services, enhance patient safety, and optimize care delivery.

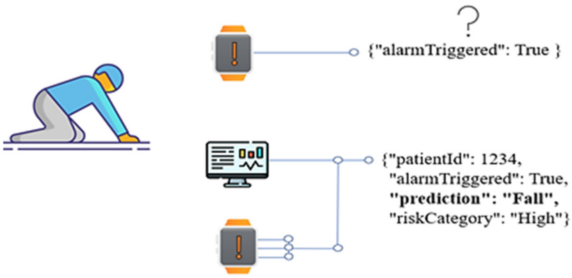

Figure 4: By aggregating data from multiple sources, decision precision can be increased. By utilizing synthetic data, more valuable insight could potentially be provided to end-users during system development and tests.

Two different simulation scenarios, and how they could be set up in Virtuality, will be described below.

Let us first assume that a user wants to investigate new technologies and workflows to detect falls, as alternatives or complements to the current social alarm systems used in nursing homes. This could be done as a realistic simulation within Virtuality, utilizing standardized synthetic datasets together with interoperable health applications.

The first step is to define the scope and objective of the simulation in the DHS using the Scenario Engine. This step is essential, as all subsequent actions are tailored to the specific scenario. In the case of fall detection simulations in nursing homes, the user can start by defining a patient persona in the Scenario Engine (step 1 in Figure 5). With just a few clicks, a realistic but fictious elderly patient is generated. This will create a synthetic patient profile, including information about the patient's age, sex, residential address, living situation, medications and medical history.

In the next step (step 2 in Figure 5), the user decides what sensors to be included in the simulation. In this scenario, the user might want to add a smartwatch together with the social alarm as two components in the ASAP Provider Building Block. Based on the previously defined patient profile, the synthetic sensor data will be dynamically generated to ensure realistic data that accurately reflects the patient's characteristics.

In step 3, the user specifies how the data received from the ASAP Providers should be processed and managed. This step includes options for data processing as well as data storage. For example, the user could choose to include an AI-algorithm for binary classification that predicts the probability of a fall, given that the elderly have pressed the social alarm button. This AI algorithm will be represented as the ASAP Service Building Block in Figure 5.

In step 4, the user chooses how the output from the algorithm will be presented to the nurses. Maybe the nurse should be notified in a mobile app? This can be achieved by adding the mobile app as an ASAP Consumer Building Block. This building block represents how and when information should be available and presented to end users. Aspects such as user-friendliness of the GUI can be practically tested.

Once step 1–4 in Figure 5 has been completed, corresponding to step 1 in the VIPHS model (Lee et al., 2023), an ASAP Pipeline has been created. The ASAP Pipeline represents a selection of ASAP Building Blocks which can be used for simulating the effectiveness of the specific setup. For example, the pipeline created in Figure 5, could be used to examine the effectiveness of combining real-time smartwatch data with social alarms, using a binary classification model to predict falls among elderly at nursing homes. A summary of the simulation process, including a detailed description of the integration process and its components, could be summarized in a downloadable pdf-report. This report could act as a recommendation or recipe for how to move this simulation closer to clinical practice.

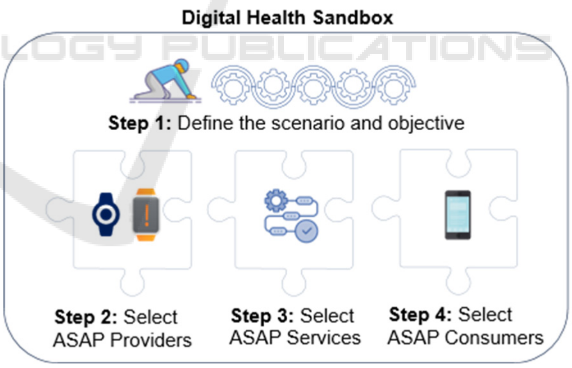

Figure 5: Example of a fall simulation conducted within DHS.

In the case of stroke, timely and accurate assessment is critical, with subtypes like large vessel occlusion (LVO) requiring specialized interventions (Jalo et al., 2023). Stroke mimics, such as seizures or migraines, can complicate the assessment, making prehospital triage more challenging. If a user wants to simulate how AI models and video analysis can identify whether a patient has a stroke and characterize the type (e.g., ischemic, hemorrhagic or LVO) in an ambulance setting, the GUI in the DHS could adapt to support this scenario.

In step 1 in Figure 6, the user could select the patient population to simulate, which in this case is generating a synthetic patient exhibiting stroke symptoms, such as facial asymmetry, abnormal eye movements and limb paralysis.

In step 2, the user decides on which data sources to include in the simulations such as cameras installed in the ambulances, smartwatch, etc. as well as configuring parameters for the prehospital environment. In step 3, the user selects the AI models to test their ability to identify stroke patients based on the provided data. These models could provide probability scores for stroke presence, subtype classification and a recommendation for transportation destination. In step 4, the simulation results are tailored for end-user presentation. For ambulance clinicians, results could be displayed on devices commonly used in ambulances. For example, the AI model might generate alerts indicating a high probability of stroke, with a prediction of an LVO and recommending transport to a comprehensive stroke center.

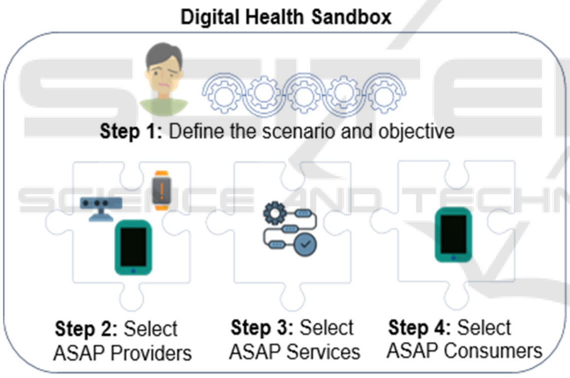

Figure 6: Example of stroke simulation conducted within DHS.

4 DISCUSSION

Virtuality connects existing tools where research has been ongoing for several years, like digital sandboxes and synthetic data (Chan et al., 2022; Dahmen & Cook, 2019; Leckenby et al., 2021; Walonoski et al., 2018), and build upon them to create an easily accessible environment with potential to boost healthcare innovations. The development of Virtuality within the Care@Distance group is a result of successful projects and observations of a rising need for this type of solution.

As standalone tools, sandboxes and synthetic data often require the users to do much programming themselves to implement the available tools and solutions. By requiring high programming competence, we may exclude the users that possibly would benefit the most from doing the simulations. For example, clinicians could strongly benefit from trying out new systems and tools in a simulated and safe environment. Instead, by connecting the tools to an environment that is easy to use even for non-programmers, such as clinicians and care givers, we introduce the possibility for a broader group to test new systems as integrated with the current clinical setup of systems. This can be an important step before procurement of new systems are done, where challenges in specifying requirements for interoperability are common (Seth et al., 2024). The aim with Virtuality is that a broad group of practitioners working in the healthcare industry should be able to use and benefit from simulating healthcare scenarios.

Since 2016, regulatory sandboxes have been used in the financial sector and later expanded to other sectors including the healthcare sector (Leckenby et al., 2021). The introduction of Medical Device Regulation (MDR) in Europe is welcomed to further strengthen the safety of patients, but it has introduced further challenges in development of new innovative products and systems. By using sandbox environments, exploration of processes that may violate current rules and regulations but have potentially large benefits if introduced into standard practice are possible (Leckenby et al., 2021). This enables taking one step further with innovations, preparing them for clinical trials, motivating their need on the market and showing the benefits they bring. By implementing virtual testing environments in healthcare innovation development processes, a shortening of clinical trials is possible, resulting in a reduction of associated costs.

There are several drawbacks with creating testing and simulation environments that should be used by a broad target group. First is a potential lack of complexity in the environment. It is certainly easier to build an environment with high complexity and flexibility if the targeted user group has a higher technical knowledge. The challenge will be to balance a high complexity and flexibility of the environment and keep it easy enough to use for users with lower technical knowledge and skills.

Another challenge will be how to confidently show that the created scenarios and synthetic data used within the DHS are sufficiently realistic. Achieving this requires a close collaboration with clinicians, both when developing tools and concepts, and while running simulations and tests in the system (Leckenby et al., 2021). One way to confirm realism is to run Virtuality for scenarios where the outcome is known and compare the results.

To confirm quality and realism of the data used is important, especially when working with synthetic data (Chen et al., 2021). Therefore, verification and validation of the data is an important step in the creation process. The quality of the synthetic data is strongly related to the methods, models and underlying data used to create it (Gonzales et al., 2023). We also need to be aware of the potential risk of traces from the original data left in the synthetic dataset, which possibly could be a risk for the integrity and privacy of patients (Vallevik et al., 2024). Synthetic data shows high potential to keep the integrity, privacy and anonymity, but still the data should be treated with respect and carefully used. Effort needs to be put in on choosing appropriate methods and datasets to work with, showing the realism of the created data and ensure that the data is disconnected from the patients in the original dataset.

We want to emphasize that the concept described in this article is currently on a conceptual and early-stage level. Further work is needed before Virtuality is ready to run at full strength and its parts sufficiently developed and connected. This article has shown the potential of Virtuality and its building blocks. Now the building blocks need to be connected, and the process simulator tried out on realistic scenarios. Future work includes developing the DHS further and generating synthetic datasets. The first use cases in Virtuality will be related to the scenarios exemplified in this article; trauma represented by fall at home and motor vehicle crash and stroke. Later, the scenarios used will be expanded to include other interesting healthcare scenarios.

5 CONCLUSIONS

In this article we have described Virtuality, a concept for simulation of care processes in a safe digital sandbox environment using synthetic health data. We see a need and possibility to introduce this concept in healthcare. By exemplifying two scenarios, we have shown how Virtuality is intended to work and motivated its potential to speed up development processes in healthcare.

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