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Preliminary Safety Analysis of a Wearable Clinic for the Early Detection of Psychotic Relapse

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Abstract. We discuss the preliminary safety analysis of a smartphone-based intervention for early detection of psychotic relapse. We briefly describe how we identified patient safety hazards associated with the system and how measures were defined to mitigate these hazards.

Keywords. Safety, wearables, smartphones apps, serious mental illness

1. Introduction

We focus on a smartphone-based intervention, called the Wearable Clinic, which assists in remote monitoring of patients with chronic conditions, including serious mental illness. A key function of the Wearable Clinic is to detect relapse early by identifying sudden changes in activity and behaviour, particularly for patients with schizophrenia. Relapses often result in unscheduled hospital admissions, with substantial suffering of affected individuals and their families as well as high costs for mental health services. Despite the potential benefits of the Wearable Clinic, it is a complex digital intervention in a complex clinical and social setting. This increases the risk of new unintended hazardous events that can compromise patient safety [1]. The aim of this paper is to show how the consideration of these safety concerns was incorporated into the early design of the Wearable Clinic by proactively conducting a hazard analysis in order to generate safety requirements for mitigation of the identified safety hazards.

2. Methods

We modelled the intended use of the Wearable Clinic for an early detection of psychotic relapse in an explicit use case, clearly representing the flow of activities, decisions and data. This activity has been conducted with a multidisciplinary team comprising data scientists, engineers, economists, clinicians and public contributors. This use case provided a basis for scoping and conducting a hazard and risk analysis, which is a mandatory requirement for safety standards. The safety analysis of the

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Wearable Clinic, as scoped by our use case, was conducted using the Software Hazard Analysis and Resolution in Design (SHARD) technique [2]. SHARD is used in the safety-critical domain to assess the suitability of a proposed design of a data-intensive system and derive safety requirements for the detailed development of the design. SHARD is structured around data flows, considering inputs to the system, e.g. from sensors, and outputs, e.g. to alerting devices. SHARD uses a set of guide words (*omission*, *commission*, *early*, *late* and *value*) for identifying potential deviations from the intended behaviour of each data flow, prompting the analysts to determine plausible causes, hazardous effects and the safety requirements.

3. Results

SHARD was applied to all the data flows in the use case. Take the data flow between the decision 'Is *risk of relapse high?*' and the activity '*Inform care team*', considering three key deviations (*omission*, *commission* and *late*). Here, the omission and late reporting of high risks of relapse represent two potential hazardous failures that have to be mitigated. For example, a potential omission cause is a common smartphone notification option that can centrally disable all notifications. This could limit the ability of the Wearable Clinic to collect user data and thus to proactively predict relapse. A mitigation measure comprises user training and greater control over central OS functions. These form explicit safety requirements for the subsequent detailed design, and the potential deployment, of the app.

4. Discussion and Conclusions

An important feature of the Wearable Clinic is that its functions are interweaved into the care pathway. With this benefit comes the challenge of identifying the safety considerations that have to be mitigated specifically by the Wearable Clinic designers. For example, is the scope of the system limited to (1) alerting the care team, (2) automatically initiating an intervention or/and (3) guiding the intervention? The greater the scope, the more safety-critical the system becomes, with more stringent regulatory constraints. Further, the confidence with which the safety requirements have to be satisfied should be proportionate to the risks posed by the technology. However, neither the safety standards nor clinical guidelines state what would be deemed as acceptable risk targets. Without these targets, it is a significant challenge for the engineers to make transparent decisions concerning the reliability of the different system components, e.g. choice of accelerometers or mobile phone platforms, in the absence of any qualitative or quantitative notion of risk acceptance.

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