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Application of Current Risk Assessment Methods to Digital Health: Identification of High-Risk Events in a Digital Therapeutics App for Psoriasis

Master's thesis

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Riskihindamise Meetodite Rakendamine E-tervises: Kõrge Riskiga Juhtumite Tuvastamine Psoriaasi Digiravimi Puhul.

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Author’s declaration of originality

I hereby certify that I am the sole author of this thesis. All the used materials, references to the literature and the work of others have been referred to. This thesis has not been presented for examination anywhere else.

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Abstract

Background: Risk assessment is a critical component of the risk management plan. The evolving digital therapeutic sector has implemented several risk assessment methods to ensure the safety and performance of products, services, and organizations.

Aims: This master's thesis aims to identify and classify the high-risk events that are likely to occur in a digital therapeutic application for psoriasis patients by using the standardization document for the risk management of medical devices to select an appropriate risk assessment method.

Methods: The risk assessment tool, Failure Modes, and Effects Analysis, is used to analyse three different risk categories: process, design, and human factors (FMEA).

Results: The potential failure modes for each category are identified and classified into three different risk reduction activity classes based on a risk priority number (RPN). Risk-mitigation actions are proposed, with priority given to high-risk events. Six high-risk events were identified in the process FMEA (pFMEA), four in the design FMEA (dFMEA) and none in the human factors FMEA (hfFMEA).

Conclusion: While FMEA is useful in the early stages of a risk management process, it can be supplemented with other methods. Given the method's approach, this thesis proposes combining an assessment tool with a top-down approach. Another option is to use the risk management results of existing products to understand the knowledge gap and potentially identify pressing hazardous situations.

This thesis is written in English and is 66 pages long, including 6 chapters, 3 figures and 12 tables.

Annotatsioon

Riskihindamise Meetodite Rakendamine E-tervises: Kõrge Riskiga Juhtumite Tuvastamine Psoriaasi Digiravimi Puhul.

Taust: Riskihindamine on riski juhtimise kava oluline osa. Arenevas digiravimite ja digitaalse teraapia sektoris on kasutusele võetud mitmeid riskihindamismeetodeid, et tagada toodete, teenuste ja organisatsioonide ohutus ja toimivus.

Eesmärgid: Käesoleva magistritöö eesmärk on identifitseerida ja klassifitseerida kõrge riskiga sündmused arendatavas psoriaasi digitaalse teraapia rakenduses, rakendades sobivat riskihindamismeetodit meditsiiniseadmete riskijuhtimise standardist.

Meetodid: Riskihindamise tööriistana kasutati riskihalduse meetodit *Failure Modes and Effects Analysis (FMEA)*, et analüüsida kolme erinevat riskikategooriat: protsess, disain ja inimfaktorid.

Tulemused: Iga kategooria võimalikud tõrkeviisid tehti kindlaks ja liigitati riskiprioriteedi numbri (RPN) alusel kolme erinevasse riski vähendamise tegevusklassi. On pakutud riskide maandamise meetmeid, eelistades kõrge riskitasemega sündmusi.

Protsessis FMEA (pFMEA) tuvastati kuus kõrge riskiga sündmust, kavandatud FMEA (dFMEA) puhul neli ja inimtegurite FMEA (hfFMEA) puhul mitte ühtegi. **Kokkuvõte:** Kuigi FMEA on varajase riskijuhtimisprotsessi käigus kasulik saab seda täiendada teiste meetoditega. Käesoleva magistritöö autor soovitab hindamise tööriista ühendada ülalt-alla lähenemisviisidega. Samuti on võimalus kasutada olemasolevate toodete riskijuhtimise tulemusi, et katta teadmiste puudujääk ja potentsiaalselt tuvastada kriitilisi ohtlikke olukordi.

Lõputöö on kirjutatud inglise keeles ning sisaldab teksti 66 leheküljel, 6 peatükki, 3 joonist, 12 tabelit.