Design Blindspots: User testing clinical IT systems

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SUMMARY

In early 2021, the MHRA launched its guidance on applying human factors and usability engineering to medical devices including drug-device combination products in Great Britain (MHRA, 2021). In its guidance it states: A usability engineering process can, and should, be applied by device manufacturers in the identification, assessment and mitigation of potential patient and user safety risks; also in the analysis of incidents that have occurred, in order to identify learning and put into place corrective actions to improve device design

However, experience in hospital healthcare is that many devices and IT systems are often poorly designed and continue to contribute to patient safety risks. A seminar Harvard Business Review paper stated: "to fix physician burnout, we must first fix the electronic patient record". In everyday work in our hospitals we see examples where poor device and IT design is making clinicians lives harder, and decreasing patient safety as a consequence. We have a workforce cataclysm, of which the state of hospital devices and IT is possibly contributing to rather than helping to fix. We explore a simplified multi-method approach to user testing to identify patient safety and usability risks. We present evaluations of 3 clinical IT systems, showing how user testing conducted correctly easily identifies these safety risks. The MHRA guidance as currently stands is not being used fully by suppliers, we need to consider how to strengthen its impact.

KEYWORDS

Maternity, Clinical, IT, design, usability

Introduction

In healthcare, the model most widely accepted to describe the system of work is the Systems Engineering in Patient Safety (SEIPS) model (Carayon et al., 2006). In that model, one of the 6 main components is tools and technology, which signifies the importance of considering the impact of tools and technologies on patient outcomes. This is a long acknowledged fact in human factors/ergonomics (Grandjean, 1988).

In healthcare, there is a fraught relationship with technology. The National Programme for IT (NPfIT) was one of the largest publicly funded IT project failure. Most people outside healthcare would reasonably be surprised at the lack of digitisation, and lack of design in the technology that is available. Many had been calling for a significant time for engagement of HF in the design of clinical devices (Waterson, 2014). In Jan 2019, the much awaited guidance from the MHRA was launched, largely based on the guidance from the US Food and Drug Administration (FDA) (FDA, 2016). This guidance requires manufacturers of devices to follow a usability engineering process. What is considered a device in healthcare is complex, some IT systems are included, some are not. However, there is nothing preventing those not strictly covered by the guidance from taking its advice.

Informal conversations with manufacturers shows that they believe meeting the guidance is easy to fake. That they have had to change very little in their processes. We sought to explore what the reality of this is

through the testing of some devices in the healthcare setting. Could we identify risks to patient safety that could, and should have been picked up if the suppliers had followed a usability engineering process.

Methods

We tested different devices and IT systems currently being implemented/offered for sale to the Trust. We used a mixed methods approach, based on the ISO 9241 standard for usability. For satisfaction we used the system usability scale, a validated tool. We also present an updated version for use in healthcare.

Results

The testing revealed that even the devices and systems felt to be the most useful, still had usability issues. Perhaps most alarmingly, during testing significant risks to patient safety were easily identified. Users verbalised “this is the first time anyone has allowed us to talk about IT as if it is making us less safe, which we all know, but can’t say”.

Discussion

The impact of poor design of clinical devices and IT systems is vast in terms of patient safety outcomes and staff experience. This will only increase as the push for paperless healthcare increases. We must put pressure on designers of these systems to fully embrace the MHRA guidance and deliver real benefits to healthcare as a result.

References

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