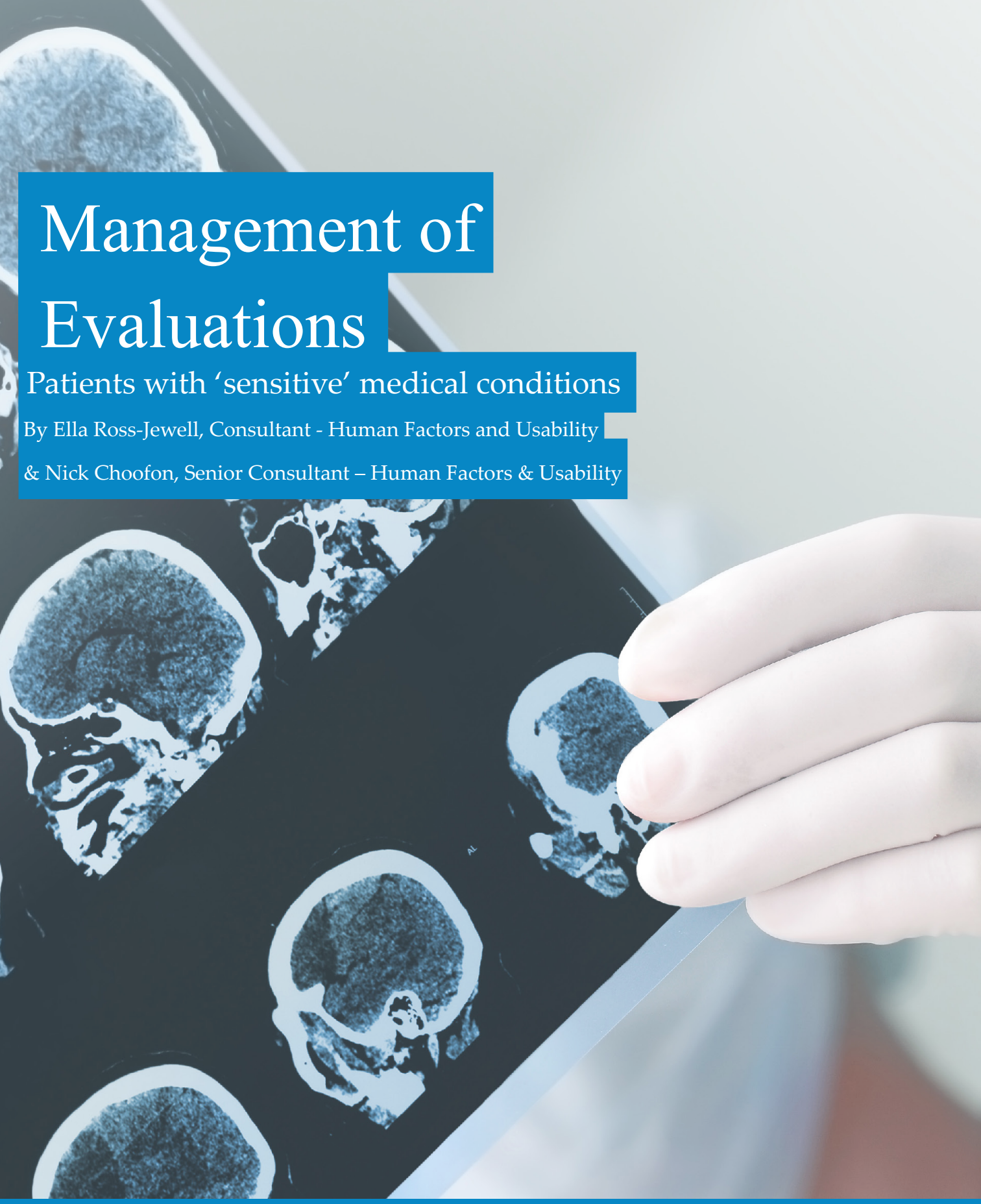

Management of Evaluations

Patients with 'sensitive' medical conditions

By Ella Ross-Jewell, Consultant - Human Factors and Usability

& Nick Choofon, Senior Consultant – Human Factors & Usability

Healthcare

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An insight into human factors evaluations with patients suffering with 'sensitive' medical conditions and the difficulties associated with conducting these types of evaluations.

Conducting any kind of patient-centric evaluations can present numerous challenges;preparing for and conducting evaluation sessions with patients suffering from sensitive and changeable conditions (such as Alzheimer's) can present even more complex challenges, as we found out on a study we conducted in the past year. The aim of this particular evaluation was to determine patient's ability to carry out simulated injections using a patch worn injector device. When recruiting for this study the intended end users were patients with 'mild to moderate' Alzheimer's, as it was expected that these users would maintain an element of ownership over their treatment delivery (whereas family members or caregivers may intervene more, at a more advanced stage of the condition). Taken from the ***Alzheimer's Society*** information website, the table below shows common symptoms experienced by patients who are diagnosed with different severities of Alzheimer's.

Even though the table shows guideline symptoms for each severity, these symptoms can vary considerably, not only from person to person but also on a day to day basis for each

individual sufferer. Therefore, it is hard to distinguish with confidence what severity an Alzheimer patient's condition is,making a definitive diagnosis challenging.

In addition, and specifically for cognitive conditions such as Alzheimer's, putting the patient in a position of unfamiliarity or additional stress can exacerbate the condition. This fact is especially pertinent for the prospect of the research described here, as we were not only introducing new faces and equipment to the participant, but we were asking them to perform tasks under observation.

It was obvious, as the study progressed, that this particular group of 'mild to moderate' varied broadly. This presented a new challenge. For example, during the evaluation sessions, it was made apparent to the moderation team that, on the day of evaluation, two of the 12 participants recruited were exhibiting symptoms more in line with 'moderate to severe' Alzheimer's, rather than 'mild to moderate'. The reasons for this may have been threefold:

1. Normal fluctuations in the condition may have caused a short-term increase in observed severity; 2. The introduction of the moderation team and tasks may have exacerbated the condition and observed symptoms;

3. Families of Alzheimer's patients may have difficulty accepting that their family member has a more severe case of Alzheimer's than they would like to think (due to the degenerative nature of the condition) and therefore underestimate the severity of the condition during recruitment.

Whatever the cause, this observation further highlighted the issue surrounding recruitment of a specific severity of Alzheimer's and created a particularly sensitive situation with respect to the moderation team and the interaction with the recruited participants.

At ***PDD***, we carefully consider the approach to each research activity to be undertaken in order to ensure it is fit for requirements and, in this example, in order to mitigate any potential influence the evaluation may have on the patient's condition. Emotional, physical and cognitive ergonomics are considered, not only to ensure that the correct elements of the system are tested, but to ensure

Severity	Symptoms
Mild	• Memory loss for recent events • Difficulty with problem-solving, complex tasks and sound judgements • Difficulty organising and expressing thoughts
Moderate	• Show increasingly poor judgement and deepening confusion • Experience even greater memory loss • Need help with some daily activities
Severe	• Lose the ability to communicate coherently • Require daily assistance with personal care • Experience a decline in physical abilities

that the design of the evaluation does not negatively affect the participants recruited (and therefore the results received). With this in mind, we implemented the following measures for this evaluation. Conducting these sessions in the patient's home was beneficial to ensure comfort and familiarity, and provided a more realistic environment for participants to conduct tasks. This therefore allowed PDD and our client to gain a better insight into the intended final use and the performance of the device in a real world setting; including the influence of various external variables

Image credit: Pexels

impacting upon the participant's ability to stay focused on the task at hand. Reporting such findings to the client is imperative to ensure the device is used safely and effectively for a specific intended user group and use environments. Overall, the study successfully provided sufficient data to aid the development of the patch injector device.

Regardless of the issues faced during the study, we met a group of incredible people (patients and caregivers) who all welcomed us in to their homes, allowing us to gather valuable insights into their life and condition. Most of all, participants were determined to provide the most honest feedback they possibly could; they understood that the data we gathered could enhance the device development process, and contribute towards the provision of a future device-drug combination that could improve their lives and the lives of their loved ones.

With the occurrence of Alzheimer's disease increasing yearly, with an estimated 75 million people worldwide living with the condition by 2030, it is easy to see why this kind of research is so imperative.

Ella Ross-Jewell
Consultant - Human Factors & Usability
ellarossjewell@pddinnovation.com

Nick Choofon
Senior Consultant - Human Factors & Usability
nickchoofon@pddinnovation.com

Measures used for evaluations

- All sessions were conducted in the participants' home to ensure familiar surroundings
- A family member or caregiver was present for all sessions for support and familiarity
- All members of the PDD moderation team were introduced to the participant prior to execution of the evaluations
- Evaluation sessions were not started immediately upon arrival at the participants home; a period of familiarization was provided
- The time allowed for the study sessions was longer than average to allow participants a break if required, or to mitigate any periods of confusion where the session needed to be paused
- The number of over-recruits was increased (compared to a standard evaluation) to ensure a minimum number of mild to moderate Alzheimer's sufferers were evaluated