Application of Usability Engineering to the Development of a Personalised Decision Support System for Type 1 Diabetes Self-Management

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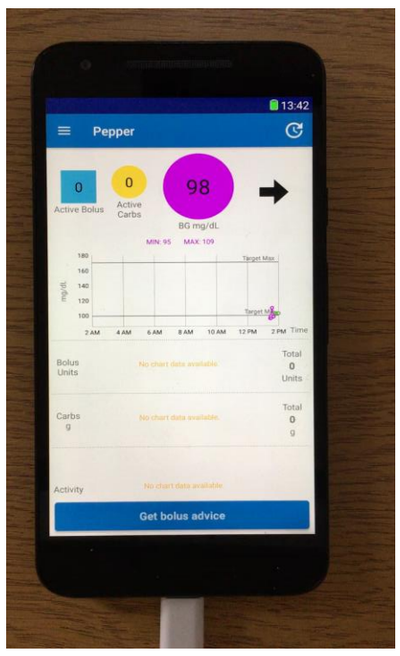
Background and Aims

PEPPER (Patient Empowerment through Predictive PERsonalised decision support) is an EU-funded research project which aims to improve the self-management behaviour of adults with type 1 diabetes (T1D). Human factors and ergonomics play a key role in the development of this system.

Image 1: Clinical Study



Video 1: PEPPER App

Method

The usability engineering process for PEPPER adheres to the international standard IEC 62366-1:2015 - Application of usability engineering to medical devices [1]. The iterative methodology includes multiple stages of formative evaluation and redevelopment involving both patients and clinicians. The first stage is an analytical study using heuristic evaluation and the keystroke-level model (KLM). The second stage is a laboratory study with users to measure performance with regard to the usability goals of simplicity, effectiveness, efficiency, and satisfaction [2] using 13 use case scenarios (Table 1). Finally, a contextual diary study is undertaken to understand the day-to-day user experience with PEPPER during a clinical feasibility study.

Number	Scenario
1	Open the application on the smartphone (MDI) / Turn on the device (CSII).
2	Calibrate the continuous glucose meter using the Bluetooth capiliary meter.
3	Locate and state the most recent bolus in the last 12 hours.
4	Locate and state the most recent carbohydrate intake in the last 12 hours.
5	Request bolus advice, for the following situation: (a) 45 grams of carbohydrates. (b) Medium meal absorption. (c) Low intensity, nonaerobic past exercise. (d) No planned exercise. (e) No hormone cycle info. (f) Low alcohol consumption. (g) Not stressed, good mood.
6	Accept or reject the bolus advice.
7	Record 65 grams of carbohydrates without requesting bolus advice.
8	Record a 3 Insulin Unit bolus without requesting bolus advice.
9	Locate and state the current blood glucose level.
10	Locate and state the average blood glucose level for the past week.
11	Locate and state the percentage of time have you spent in a 'high' blood glucose state over the past week.
12	Locate and state the highest BG value in the last 12 hours.
13	Locate and state the total bolus over the last 12 hours.

Table 1: Use case Scenarios

Results

The results of the analytical study produced a series of redesign recommendations to improve usability prior to the user study. Video analysis of the latter showed that users made few errors and most tasks were completed, indicating high **simplicity** and **effectiveness** respectively. **Efficiency** was indicated by the time taken to complete a task and the number of touches needed. The latter was compared to the baseline KLM. Figure 1 shows time per task: it can be seen that tasks 2 and 5 were not efficient. Design recommendations for the subsequent prototype were suggested accordingly. Figure 2 shows that the average of the number of touches per task were close to the optimal KLM, indicating that users could see what to do. The SUS questionnaire was used to determine satisfaction, excellent scores for the handset (74.3%) and good for the server (66.3%). The diary study is not yet completed.

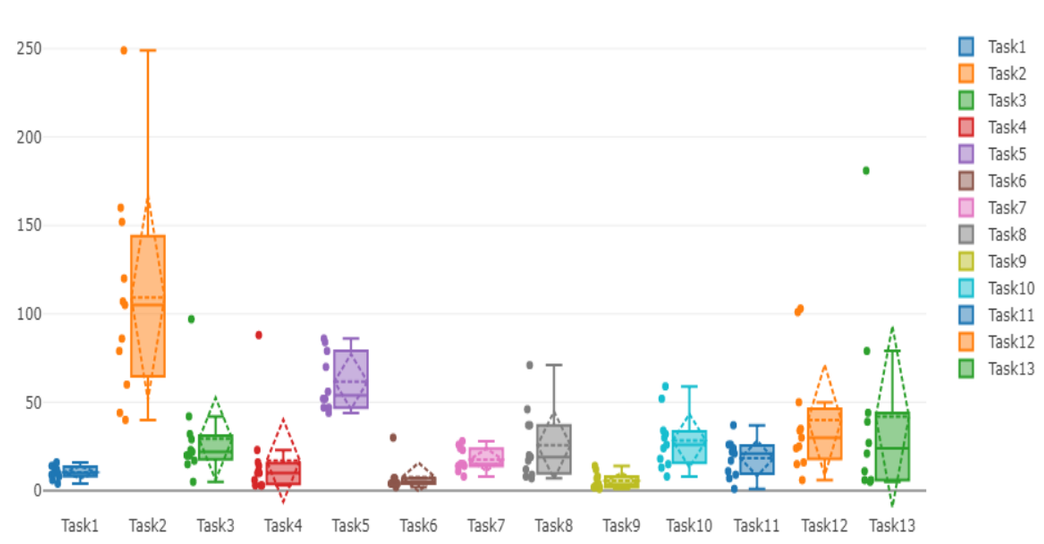


Figure 1: Time Per Task

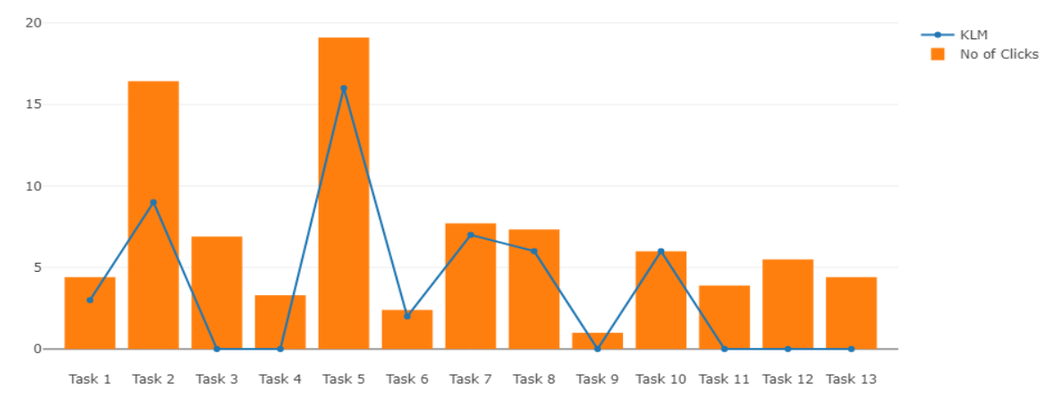


Figure 2: Clicks Per Task Compared To KLM

Conclusion

The usability evaluation protocol used in PEPPER adheres to international standards. The iterative development methodology has potential to improve patient acceptance and safety.

References

[1] International Electrotechnical Commission. (2015) IEC 62366-1:2015: Medical devices -- Part 1: Application of usability engineering to medical devices. Geneva, Switzerland: International Organization for Standardization.

[2] International Organization for Standardization (2018). ISO 9241-11:2018(en). Ergonomics of human-system interaction — Part 11: Usability: Definitions and concepts.

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