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Clinician engagement and Training on an Electronically Controlled Gravity Feed Infusion set as a precursor for clinical studies

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Abstract—**User training is an important aspect in the implementation of medical technology to facilitate the safe use of new medical devices yet it is an ignored field in many settings especially resource limited settings. Carrying out clinical studies on new medical technology without end user training could compromise patients' and clinicians' safety, take up a lot of clinicians' time learning on the job and negatively affect study results. The purpose of this paper is to present results of the training, clinician engagement and usability tests on the ECGF device. Clinician and hospital technician training on the Electronically Controlled Gravity Feed (ECGF) infusion set device was carried out at Mulago National Referral Hospital as a precursor to clinical validation. 19 clinicians were trained and their feedback was collected through group discussions and structured questionnaires. Training improved user understanding and set-up of the ECGF, most clinicians found the ECGF to be user friendly, safe for use with the potential to simplify their work, to save time and improve on patient safety. It also provided in-valuable feedback for re-design specifically color and alarm audibility.**

Keywords— **Clinician training, user feedback, usability, ECGF.**

I. Introduction

Medical device end users are one of the principal medical device technology stakeholders [1]. Their involvement in medical technology development and assessment is central to meet their needs and also enables the development of safer and more usable medical devices that are better suited to users' needs [2]. Training offers access to experiences, ideas and improvements in the medical device design process, in particular usability, functionality and quality [3]. Influence of the operator on the effective and safe application of a medical device is generally underestimated yet the majority of hospital incidents are correlated to incorrect operation and maintenance [4]. As such, clinicians and biomedical technicians were trained on the Electronically Controlled Gravity Feed Infusion Set (ECGF) device as a precursor to its clinical validation.

The ECGF is a low-cost, automated, non-invasive fluid infusion system that utilizes a standard fluid giving set (IV tubing and drip chamber) to convey fluids with additional means for sensing and controlling the rate of fluid flow [5]. It incorporates a sensor housing containing a reference light source located a fixed distance from a photocell to define a fixed optical sensing gap there between, with the reference light beam normally impinging upon the photocell. A falling drop of fluid within the drip chamber interrupts the reference beam, and the corresponding variation in the electrical response of the photocell is electronically communicated, indicating the presence of a drop. A non-invasive drop controller (actuator) attached to the IV tubing controls the rate of fluid flow by constriction based on feedback from the drop detector module. The ECGF has been designed to address challenges with access to infusion pumps in low resource settings such as; unreliable power supply, limited supply due to the costs involved and lack of trained personnel.

The purpose of this paper is to present results and impact of the training, clinician engagement and usability test results on the ECGF device as a precursor to the first in-human clinical studies.

II. METHODOLOGY

A total of 19 clinicians including 3 hospital technicians, 13 nurses and 3 doctors from Mulago National Regional Referral Hospital were trained for one day on the ECGF device. The tools used in this training included: questionnaires, device manuals, posters, 5 device prototypes for hands-on workshops, user manuals, usability tests. At the start of the user training, the device was setup by the instrumentation team and user training manuals provided to all participants. Questionnaires were then given to participants to assess initial unbiased perceptions of the ECGF, this was followed by hands on user training which included: installation, therapy set up via the user interface, identification and rectification of alarms. This was followed by usability testing in which participants were allowed to set up the device individually, errors were simulated to assess users' ability to troubleshoot errors. After training semi-structured questionnaires and group discussions captured feedback on perceptions after training, questionnaires were structured to capture information about functionality, usability, device attributes and their relevance to the clinical settings. Feedback was then grouped, coded and analyzed and interpreted using the Likert

Scale Weightage, the median and mean percentage were calculated and graphs plotted in MATLAB. The Likert Scale used ranged from 1 (strongly disagree) to 5 (strongly agree).

III. RESULTS AND DISCUSSION

Generally training improved participants' understanding and usability of the ECGF device as shown in Table 1 and the median and weightage bar graphs shown in Figures 1 and 2. Table 1 shows the summary of the median and mean percentage scores of the Likert scale responses before and after training.

Table 1: Summary showing the mean percentage score and median of the Likert scale responses from the 19 participants 5 main parameters

Features		Before		After	
		% Score	Med	% Score	Med
Functionality	Audibility	66.67	3.00	57.78	2.50
	Indicators	67.50	3.50	82.22	4.00
	Response	61.54	3.00	82.86	4.50
Instruction Manual	Usability	80.00	4.00	88.89	5.00
	Device	72.73	4.00	83.53	4.00
	Therapy	72.73	4.00	86.67	4.00
	Follow up	75.56	4.00	89.33	5.00
Attributes	Color	85.33	4.00	67.78	3.50
	Size	82.50	4.00	72.22	4.00
Relevance	Impact	68.24	3.00	88.89	4.00
	Setup	56.67	3.00	91.43	5.00
Usability	Keys	85.88	4.00	90.00	4.50
	Wording	85.88	4.00	93.33	5.00
	Alarms	68.33	4.00	77.65	4.00

Figure 1 comparisons of the median scores of the before and after user training responses and Figure 2 shows an analysis of the same data using mean percentage.

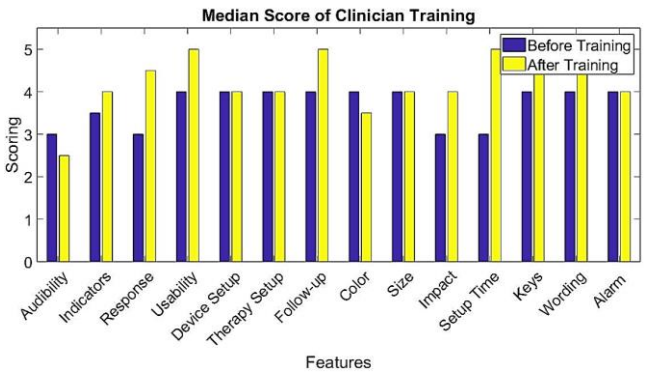

Fig. 1 Comparison of user responses before and after user training on the ECGF device using the median range of the Likert scale.

Usability and setup time in particular improved greatly, users noted that the ECGF user interface is intuitive and simple to understand, and could improve the workflow in the wards

Participants also got better understanding of the functionality and use of the safety features such as alarms, as they were able to independently troubleshoot most of the simulated errors with the aid of the instruction manual. Positive responses on the features increased after the training. Important to note is that most participants were neutral prior to the training.

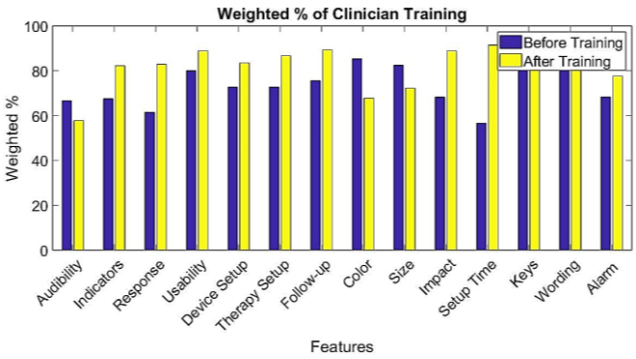

Fig. 2 Comparison of before and after user training responses using the Weightage range of the Likert Scale.

This training raised confidence levels of the design team as it prepared for its first inhuman trials since users found the device relevant and quite easy to use

The user manual was very key in the training and most, users often referred to it when setting up or even troubleshooting the device. The clinicians expressed the importance of user manuals, but mentioned that they were rarely provided when new devices were implemented in the hospitals.

Participants provided invaluable feedback on physical attributes that needed revision. In particular, they were dissatisfied with the alarm audibility (median of 2.5) citing low decibel levels for the very busy settings, user interface color (3.5) as it increased chances of cross contamination due to inability to sight blood and other contaminants. It was also noted that the device was bulky and the drop monitor which was difficult to setup. Users also suggested incorporation of air bubble detection especially for pediatric care.

IV. CONCLUSION

User training and engagement improved participants' understanding of the ECGF device as evidenced by their improved device set-up time, understanding of the alarm indicators, troubleshooting and correcting errors. The change in responses from 'neutral' to 'agree' or 'strongly agree' proved

the relevance of user training and engagement before conducting the clinical study.

The training was a resource on the features of the ECGF that needed improvement which included user interface color, alarm audibility and design of the drop detector module.

Based on the responses, alarm audibility was increased to cater for the busy clinical settings in Ugandan hospitals, air bubble detection was also incorporated. Future developments will focus on modification of the drop monitor, changing user interface colors and designing all components into a single unit.

Clinician engagement and Training on an ECGF was paramount in the preparation for the first in-human clinical studies on the ECGF device as it equipped study clinicians with the necessary skills to independently and correctly operate the ECGF, this in turn will minimize errors associated with incorrect use of the device as a precursor for clinical studies.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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