Manufacturer Training Impact in Heuristic Analysis: Usability Evaluation Applied on Health Devices

V.H.B. Tsukahara, F.N. Bezerra, R.H. Almeida, F.S. Borges, E. Pantarotto, R.V. Martins, M. Iglesias, P. Trbovich, S. Pinkney, and S.J. Calil

[1] Unicamp/Biomedical Engineering Department (DEB), Campinas, São Paulo, Brazil
[2] HCor, São Paulo, São Paulo, Brazil
[3] University Health Network, Toronto, Ontario, Canada

Abstract—**The adoption of new technologies into hospitals has been improved diagnosis and patient care, and it has been also increased the effectiveness of the services concerned. Despite all the benefits of using medical devices, however, this new reality has brought a new kind of problem: errors caused by misuse. Errors which may result in adverse events and usually are credited to health professionals' mistakes, often solved through actions like training and institute protocols that sometimes are inefficient. The study of interaction between man and machine may help to understand this new misuse issue and the causes that may lead to use errors. Aiming to improve equipment usability, the use of tools from Human Factors Engineering like Heuristic Analysis can contribute to usability problems identification. The objective of this paper is to verify the influence of equipment training on its usability problems by means of comparing the results from applying Heuristic Analysis technique on a traditional infusion pump before and after manufacturer training.**

Keywords—**Human Factors Engineering, Usability, Heuristic Analysis, Infusion Pump, Usability Problem.**

I. INTRODUCTION

The introduction of new technologies into the healthcare system significantly improved diagnosis and diseases treatments, as well the effectiveness of the services concerned [1]. However, even with all the benefits derived from this improvement, such as better work conditions for health professionals and better patient assistance, the use of medical devices introduced a new kind of problem: device use errors. Operating errors or device misuses represent 60-80% percent of the total hospital adverse events in Brazilian's Health System (SUS) [2]. ECRI Top Ten Hazards 2012 [3] states that errors on the administration of medications using infusion pumps are the third most important concern related with use of health technologies by professionals. The same publication [4] moved up its concern to the second position in 2013.

Related to use errors, it is verified that lack of operator training, stress and equipment interface project are factors that must be considered on this scenario [5].

One way to analyze this human-machine interaction could be through device usability evaluation, which allows the identification of problems that may lead to human errors [6]. A practical tool that can be used for error identification is Heuristic Analysis.

This paper presents the outcome of the application of Heuristic Analysis technique, by a multidisciplinary team on a commonly used infusion pump model. The technique was applied twice: once before the team received training on the pump by the manufacturer, and once after the training.

II. BACKGROUND

Initially developed in Usability Engineering (related to Computer Science, Ergonomics area), Heuristic Analysis was later adapted to medical devices evaluation [6].

This tool consists in a practical technique, in which at least three evaluators apply a set of heuristic rules to identify usability problems in a medical device.

To apply the technique, a total of 14 rules are used as a reference by the evaluator to better explain the usability problems identified during device's Heuristic Analysis, the Nielsen-Schneiderman heuristics[7]. After identifying a problem, the heuristics violations are associated, and then the severity levels of each violation are defined, that represents the gravity level associated to the usability problem that can lead to an adverse event.

To apply the Heuristic Analysis technique, the evaluator doesn't necessarily need to be an expert on heuristics (the minimum requirement is to have a basic knowledge on Heuristic Analysis technique), and neither to have a deep knowledge about the studied device, like a medical device for example. The adoption of a multidisciplinary evaluation team also influences positively the analysis. The observation of a medical device by professionals with different backgrounds allows the identification of a larger number of problems, because of the different viewpoints applied in the evaluation.

L.M. Roa Romero (ed.), *XIII Mediterranean Conference on Medical and Biological Engineering and Computing 2013*, IFMBE Proceedings 41,
DOI: 10.1007/978-3-319-00846-2_293, © Springer International Publishing Switzerland 2014

III. Methodology

To apply Heuristic Analysis it is necessary for the evaluator to explore the object under evaluation, purposing to investigate its usability. With this experience the evaluator could point out usability problems and determine corresponding heuristic violations and severity level.

A "heuristic violation" means that some characteristic (physical, software, use, hardware) violates one of the fourteen heuristic rules described below.

The study was based on the 14 Nielsen-Schneiderman heuristic rules [7]. Although rules definitions were presented in this literature, the team had to discuss them to ensure evaluators the same understanding over all the fourteen rules, because it was the first team contact with the technique. The following interpretation was achieved from this discussion:

1. Consistency and patterns: aspect that must be followed and observed on product interface, through layout and positioning, color patterns, action sequences, language;
2. Visibility of system state: the system must present information to user in order to provide a clear current state;
3. Match between system and world: interface must be intuitive. The operator perception about the system must correlate to user vision about the system;
4. Minimalist: information must be summarized. However, caution is necessary to not transform it in abstract information for the user;
5. Memory: memory load must be minimized. User doesn't have to memorize a lot of information to use the product;
6. Feedback: user needs confirmation of their system actions;
7. Flexibility and efficiency: operators have different modes of interaction with the system. Therefore, the system must provide a flexible interface in such a way as to consider users preferences and variability to ensure maximum efficiency;
8. Messages: during system problems, the user must be informed to understand, learn and solve the presented error;
9. Error preventions: system interface must be developed to prevent misuse;
10. Closure: executed tasks must have well defined starting and ending points;
11. Reversible actions: the operator must be capable to recover from errors;
12. Language: the language used must be clear to the user profile;
13. Control: the system must allow at least minimum control over the user actions;
14. Help and documentation: operator must have easy access to help when necessary.

Still according to [7], severity levels for equipment problems can be assessed using a severity scale:

0, when it does not cause a misuse problem, but it's an opportunity for future improvements;
1, only when it is a cosmetic problem, and correction must be done only when there is free time;
2, small usability problem. It may have a small priority to correct;
3, major usability problem. High priority must be given to solve the problem, because it is important to be fixed;
4, catastrophic error. It is essential to solve. If the object under evaluation has not been released, it is mandatory previous correction.

The Heuristic Analysis of the device is realized individually by evaluators, to avoid bias. Each heuristic violation is associated to one of the fourteen rules and subjectively assigned a severity level.

After identification and rating processes, individual evaluations are compiled and discussed with team, to generate a combined analysis. The comparison of results contributes to reach consensus on the heuristic violations as well as on the severity levels of each problem.

IV. Applied Methodology

A traditional infusion pump model was selected for the case study, because of its wide use in healthcare and medium complexity of operation.

In this study, evaluators executed an initial Heuristic Analysis without any training on that specific infusion pump model. After receiving training from the manufacturer (company instructor providing details about programming, cassette priming and troubleshooting), evaluators performed the technique again.

Heuristic Analyses were done by a multidisciplinary team, composed of: one pharmacist, two nurses, six engineers and two psychologists specialized in cognitive analysis.

Each Heuristic Analysis (before and after manufacturer training) was developed simulating the processes of preparation and programming of intravenous medication infusion. The usability problems identified were analyzed according to the fourteen Nielsen-Schneiderman heuristic rules and then the severity level for each of those violations was assigned through team discussion. Based on discussion, a chart with problems and respective heuristic violations and severities was elaborated.

V. Results

A. Heuristic Analysis Before Manufacturer Training

The team found 22 usability problems, resulting in 88 heuristic violations, separated in 13 heuristic rules. Seven of the problems were rated as severity level 3 – it means a major usability problem, as described above – and one problem was rated as severity level 4 – catastrophic problem. Most of the problems identified were related with aspects about patterns adopted for infusion pump (i.e. programming sequence, alarm), difficulties for user to understand the current state of system (i.e. discerning whether primary or secondary infusion is running), icons and messages, and user memory load. The final histogram of the Heuristic Analysis is presented in Figure 1. The number of problems for each severity level is showed in Figure 3.

B. Heuristic Analysis Done After Manufacturer Training

The team found 26 usability problems (18 of them were new), resulting in 94 heuristic violations, separated in 13 heuristic rules. Eight of the problems were rated as severity level 3 and one problem was rated as severity level 4. In this analysis, the main rules violated remain similar to first Heuristic Analysis with problems regarding to patterns adopted, visibility of system state, icons and messages, and memory load. For better visualization of violated heuristic rules, the resulting histogram of Heuristic Analysis is presented in Figure 2 and the number of problems for each severity level is showed in Figure 3.

C. Comparative Results from Heuristic Analyses

From both analyses, some information can be extracted. The number of total problems identified was 40, with 14 exclusively identified in the first evaluation, 18 discovered only during the second analysis, and 8 identified in both Heuristic Analyses (four of them were rated as severity level 3). Figure 2 show percentages representing those data.

After manufacturer training, some problems identified on first analysis were redefined, and some of them were not considered a usability problem. For example, the activities to turn the pump on and the configuration of the parameter “Keep Vein Open” (KVO) were considered a usability problem on first analysis, but after training they were not considered a problem anymore. Also three of the eight problems found in both analyses were modified. The reason to change them was due some unclear activities during first analysis that became more intuitive, or because of the interpretation after training that brought up new usability issues.

The first analysis showed mainly problems related with intuitive aspects, because none of the evaluators had experience in handling the device. The second analysis allowed the evaluation according to manufacturer guide. So it made possible to observe a slight difference about violated heuristics (some of them were less violated and contrariwise) and the number of problems (more grasp of equipment revealed new problems).

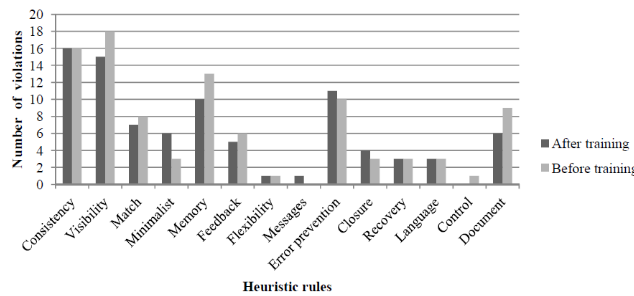

Fig. 1 Heuristic Analysis results on traditional infusion pump after and before manufacturer training

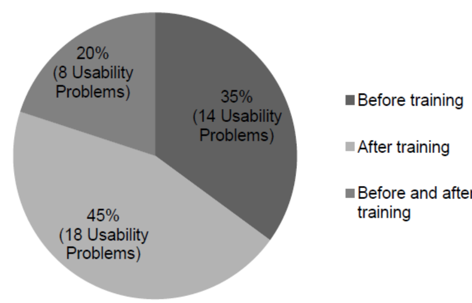

Fig. 2 Percentages of usability problems identified on Heuristic Analyses

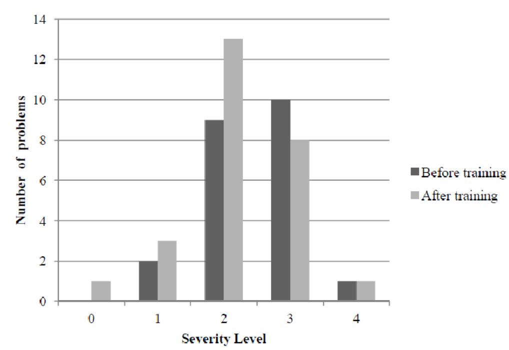

Fig. 3 Number of usability problems related with their severity levels for Heuristic Analysis before and after manufacturer training

VI. Discussion

Observing the histogram on Figure 1 (Heuristic Analysis before training), it’s possible to conclude that “Consistency” rule have the larger incidence among all of the problems identified (16 violations), followed by “Visibility”, “Error Prevention” and “Memory” respectively. Considering only the two more incident rule violations, they represent 35% of all violations, and changing this analysis up to 4 most incident heuristic violations, the percentage represents 59%, an expressive result. Nine usability problems were identified as severity level 3 or 4, which mean that approximately 41% of all pump problems are considered a serious or catastrophic, requiring urgent solutions. It is a expressive and worrying data.

On Figure 1 about Heuristic Analysis results after training, it is possible to verify that "Visibility" rule is the most violated heuristic rule (18 violations), followed by "Consistency", "Memory" and "Error Prevention" respectively. Comparing the results obtained from first Heuristic Analysis, the same top 4 rule violations represent 60% of total in this second analysis. This suggests consistency between analyses. Considering problems severity levels, it's verified that 11 of 22 represent a serious or catastrophic issue. In other words, 42% of all usability problems need urgency to solve. Thus, this data represents consistency between analysis and it is a expressive and worrying data.

Another important issue observed after applying again the technique, refers that 8 problems remained on results (Figure 2), which represents 20% of total pump problems identified. Thinking about training aspect, even acquiring more knowledge about the infusion pump, it wasn't enough to finish up the problem. It suggests that it might be a device usability problem that could only be solved performing infusion pump redesigning. Four of those eight problems were rated as severity level 3. It means that 50% of them are major usability problems that need high priority to solve. Sometimes, when a near miss or an adverse event occurs during a drug administration process, in which health professionals are using technology, there's a common reasoning that misuse is caused usually due to the user's lack of training. This result could contribute to indicate that usability problems that exist in product design may lead to operator misuses.

Furthermore, there was better understanding about product usability after training. It changed three of the eight problems identified during both analyses. The problem about how to reset an alarm may clarify it: without training, evaluators didn't discover what the right procedure was, they were turning the pump off and switching on again to reset the alarm. This was pointed out as a usability problem. After the manufacturer training, the team learned how to proceed in this activity. However it did not completely solve the problem, and from the right way to execute the procedure new problems were revealed, like icons that weren't intuitive about their functions, and the lack of a user guide sequence in the pump. This changed the focus about analyzed problems, influencing on violated heuristics and severity level on second Heuristic Analysis, indicated by the identification of 45% percent of all pump usability issues and a higher number of problems with severity level 3.

VII. Conclusions

The use of Heuristic Analysis proved to be useful in identifying usability problems. By applying this technique before and after manufacturer training, it was possible to recognize a higher number of usability problems that represent serious or catastrophic issues. In addition it was identified problems that cannot be solved through training, suggesting that they could be eliminated only by infusion pump redesigning. The multidisciplinary approach allowed a better understanding about user interaction with device, providing a comprehensive analysis. Ultimately, as the fact that Heuristic Analysis is a practical technique, it could be a good alternative for health devices usability inspections.

Acknowledgment

This project has financial support from São Paulo State Research and Support Funds (FAPESP).

References

1. C. Koutsojannis, J. Prentzas, I. Hatzilygeroudis (2001), A web-based intelligent tutoring system teaching nursing students fundamental aspects of biomedical technology, Proceedings of the 23th Annual EMBS International Conference, Istanbul, Turkey, 2001, pp 4024-4027.
2. M.V. Lucatelli (2002), Proposta de Aplicação da Manutenção Centrada em Confiabilidade em Equipamentos Médico-Hospitalares. Thesis – (Doctorate), Biomedical Engineering Institute, Santa Catarina Federal University – UFSC. Florianópolis, Brazil, 286p.
3. ECRI Institute, Top 10 technology hazards for 2012: the risks that should be at the top of your prevention list (2011), Health Devices 40: 358-369.
4. ECRI Institute, Top 10 health technology hazards for 2013: key patient safety risks, and how to keep them in check [guidance article] (2012), Health Devices 41: 342-365.
5. L. Lin, R. Isla, K. Doniz et al. (1998), Applying human factors to the design of medical equipment: patient-controlled analgesia, Journal of Clinical and Monitoring Computing 14: 253—263.
6. M. J. Graham, T.K. Kubose, D. Jordan et al. (2004), Heuristic evaluation of infusion pumps: implications for patient safety in Intensive Care Units, International Journal of Medical Informatics 73: 771-779.
7. J. Zhang, T.R. Johnson, V.L. Patel et al. (2003), Using usability heuristics to evaluate patient safety of medical devices, Journal of Biomedical Informatics 36: 23-30.

Author: Victor Hugo Batista Tsukahara
Institute: Campinas State University (Unicamp)
Street: Cidade Universitária Zeferino Vaz
City: Campinas, São Paulo
Country: Brazil
e-mail: vhbtsukahara@gmail.com