A CASE STUDY APPLYING HUMAN FACTORS ANALYSIS FOR PATIENT-CENTERED SMART PUMP PROCUREMENT

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INTRODUCTION

As treatments and the design of medical devices become increasingly complex, the possibility of patient injury due to mistakes made by clinicians also increases [1]. Infusion pumps errors are no exception to this phenomenon and are strongly associated with adverse drug events causing patient harm [7]. A 2007 report by the ISMP states that 51% of drug administration errors result in harm [8]. A contributing factor to user error may be improper device design, which can be amplified by human factors such as fatigue and high cognitive load in a stressful environment [1]. Substantial improvements in patient safety by reducing errors can be achieved by evaluating the usability of analgesic infusion devices to mitigate adverse drug events [3, 9, 11, and 13]. New generation "smart pumps" focus on user-centered design and can provide a valuable medication safety check at the point of care when used in conjunction with standardized drug libraries [8].

Research performed at Canadian healthcare institutions has validated medical device evaluation using a human factors approach [2, 4, 5, 9, 10 and 13]. However, this case study represents the first project in a healthcare institution in Vancouver, British Columbia to incorporate human factors into a procurement process to enhance the standard technical and clinical device evaluation and implementation. The application of human factors principles to the procurement process guided the selection of safer epidural pumps. Heuristic analysis, cognitive walkthroughs and usability evaluations were conducted to understand user needs as they relate to safety and seamless implementation of each product. This study does not intend to provide a repeat approach for subsequent procurement projects but rather represents one method of analysis for this instance.

This fast-paced ten month project was predominantly driven by the obsolescence of the existing Abbott Laboratories (Hospira) APM I & APM II ambulatory infusion pumps. The purpose of the project was to evaluate 4 submitted responses to a regional request for proposals (RFP) and to replace the existing fleet of infusion pumps with 'smart pump' technology. To achieve an economy of scale for best pricing, the scope of this project spanned two health authorities and four hospitals.

BACKGROUND

A multidisciplinary evaluation team comprising of members from Vancouver Coastal Health, Providence Health Care, and Fraser Health led the partnership between stakeholder groups and drove device evaluations lead by the Healthcare Technology Management/Biomedical Engineering; Human Factors and Quality and Patient Safety with clinical input from Anaesthesiology, Nursing and Pharmacy. To ensure a patient centered focus, the ratio between clinical and financial components of the RFP favored a clinical approach. This evaluation was supported by the Shared Services Organization (SSO) for British Columbia and the Purchasing representatives.

Table 1: RFP Evaluation Weighting Factors and Breakdown

Clinical 50% • Heuristics & Technical Evaluation 20% • Usability Study 10% • Real-time Clinical Evaluation 20%
Financial 25%
Value Adds 25% • Academic Excellence 5% • Supply Chain Management 10% • Corporate Strength 10%
Total: 100%

A comprehensive medical evaluation team was assembled to provide a combined clinical and technical approach to procurement. The team engaged all key stakeholders at the outset of the project and although resource intensive, ensured an optimal outcome for patient safety by considering all

aspects of the system of drug delivery, from logistics through to the patient bedside.

The primary function of the ambulatory pump for purchase was epidural therapy; however it was important that the new 'smart pump' technology could accommodate other drug delivery routes such as subcutaneous, intravenous and intrathecal, as well as other modalities including: labour and delivery, peri-neural blocks, patient controlled analgesia and end-of-life palliative care.

METHODS OF HUMAN FACTORS EVALUATION

The procurement process for acquiring a new infusion device included a comprehensive Human Factors analysis as well as technical and real-time clinical evaluations. The Human Factors principles used included a Heuristic Analysis with clinical and technical experts, Cognitive Walkthroughs incorporating clinical perspectives, task specification, and workflow and Usability Evaluations with representative clinical users. It was imperative that a trained human factors specialist lead the human factors component of the analysis [6]. A multi-disciplinary review of the pre-printed physician orders (PPO) and pharmacy preparation was also undertaken in order to simplify the drug protocols, standardize the nomenclature and streamline the clinical workflow with the workflow of the pump.

The evaluation took place in two phases with a sample of evaluators from various backgrounds to provide a holistic response to the investigation. The *first phase* consisted of a technical evaluation and heuristic analysis to evaluate all four devices. The two proponents' devices with the lowest scores were eliminated and removed from further consideration in the RFP. The remaining two devices progressed to the *second phase* to assess how the device performed in a controlled and simulated clinical setting. This phase combined the safety and clinical evaluation with cognitive walkthroughs, real-time clinical evaluations, and simulated usability evaluations. All of this work was documented and recorded on video to formalize the clinical evaluation of the RFP. A brief explanation of each method follows.

Heuristic Evaluation

The Heuristic Evaluation is a discount usability engineering technique that uses objective criteria to systematically identify usability violations of technology and interfaces [12]. Presentation of epidural pumps was counter-balanced for each evaluator. Evaluators received no training on the epidural pumps in order to prevent bias from vendors and were looking for "discoverability" and ease of use features, as well as heuristic violations. Sufficient usability information was obtained to evaluate this step without the need for the programmed drug libraries.

Each evaluator examined each device against the set of heuristic principles related to cognitive and physical human factors needs. The Heuristic Evaluation facilitated the identification of design flaws that posed potential safety and usability problems and identified design elements that might pose difficulties for users. This knowledge was helpful in eliminating products that posed clear safety risks early in the process before other human factors methods were utilized.

A modified Heuristic Evaluation technique originally developed by Nielsen [12] was used. Two heuristic examples have been provided below. The user assessed each heuristic criterion to capture both positive and negative information about the pump. A heuristic violation can be any failure to meet the criteria as deemed by the evaluator. Each violation was assigned a severity score rating on a 5-point rating scale. A score of 0 captured distinguishing comments and likeable features about the pump whereas, a severity rating of 4 demonstrated a severe usability issue that represented an increased potential for critical adverse events. The pumps were then compared among evaluators to determine those deemed 'high risk'. Severity scores of 3-4 were debriefed with the vendor to see if they could change their device to mitigate the perceived risks and incompatible design identified by the evaluators.

Examples of Two Usability Heuristics and Associated Criteria from Nielsen [12]:

1. Visibility of System Status: *The system should keep users informed with timely and appropriate feedback*
   - Feedback keeps the user informed about what goes on
   - Interface provides status info
   - Feedback shows that user input has been received
   - Feedback is timely and accurate
   - Interface indicates progress made in task performance
   - Interface contains visible objects and results
   - Interface allows identification of system response cues
2. Match between System and Real World– *The system should use concepts familiar to the user, following real world convention*
   - Interface contains familiar terms and natural language
   - Interface uses metaphors from the real world
   - Interface makes use of user's background knowledge
   - Interface follows real world conventions
   - Interface allows identification of cues for action

Cognitive Walkthrough

A cognitive walkthrough was performed using the two pumps selected for clinical trials. A video analysis in which representative clinicians performed a series of simulated tasks using familiar hospital PPOs created a fidelic clinical scenario to assess the cognitive workload and determine pitfalls in the process of the device. The use of lifelike scenarios identified user frustrations and cognitive challenges.

Video analysis allowed the human factors specialist to replay the scenario to determine where subtle workflow disruptions might arise and compare and contrast different users. The study also provided an estimate of the time taken to perform the following tasks: set up the device for infusion on a new patient, replace medications mid-therapy using the same patient, and change drug protocols using the same patient.

Usability Evaluation

A usability evaluation is an observational research technique where representative end users (i.e. nurses) are recruited to participate in realistic scenarios in a simulated environment. A usability evaluation was used in this procurement process to exhibit product deficiencies that could affect its overall usability. The evaluation assessed the appropriateness and ease of use of the product in the user's environment prior to its introduction into the clinical setting.

Deficiencies that were identified were used as qualitative data representing user performance. This included user-errors, inability to complete tasks, and increased task time.

Twenty-one nurses from the wards that would eventually be using the purchased pumps participated in this component of the project. They were asked to complete 3 use cases, with sufficient steps to expose the majority of functions on the pump. The nurses were asked to "think aloud" as they completed the use cases so that the human factors specialist could better understand their thought process. This usability evaluation was conducted in parallel with the clinical evaluations on the unit. A questionnaire was designed using a 7-point Likert Scale (0 – 6, strongly disagree to strongly agree) that included 31 questions on the pump display, keypad, lockbox, alarms, setup, and operation. It was used in both the real-time clinical and controlled usability studies.

RESULTS

Phase 1 - Heuristic Outcome

The results of 5 heuristic evaluators produced a combined total of over 450 identified heuristic violations for all four pumps. Every pump had a heuristic violation with a maximum severity rating of 4, each of which was addressed with the vendor.

Table 2: Summary of Heuristic Comments

Device	***Heuristic Violations***	***Evaluator Comments***
Pump A	28	• Difficulty loading the tubing set • No ability to store drug protocols into the software • No review capability of programmed amounts
Pump B	17	• Non-traditional numeric layout and dual key usage was confusing • Tubing can be pinched during loading compromising flow – no alarm during operation! • ECRI alert if pump dropped with loading mechanism open pump can run incorrectly even if visual ok • Severe usability heuristic, pump does not save changes when made or provide feedback to user leading to drug dosing error
Pump C	3	• Pump has a consistent interface with other devices in the environment • Flimsy lockbox design • Pump does not say ``Epidural`` on the body or screen anywhere • Further clinical and usability evaluations were required
Pump D	2	• Font size and wording was small • Screen size and clarity of visual feedback was large • Constantly entering the unlock code was annoying • Further clinical and usability evaluations were required

Phase 1 - Technical Evaluation

Any noted discrepancies in the RFP between the preferred response and the response provided by the proponent was earmarked. Each discrepancy deducted points from a starting total of 100 points, to determine the final score. Tables 3&4 show the values of deducted points and the final scoring for each pump in the technical evaluation, respectively.

Table 3: Points Removed for Technical Evaluation

Points	***Explanation***
0	Little or no significance on operation
-1	Negligible impact on operation
-3	Low impact on operation
-5	Considerable impact on operation
-10	Severe impact on operation

Table 4: Results of the Technical Evaluation

Rank	*Pump*	*Score*	*Primary Concern(s)*
4	Pump A	46 pts	Tiny screen – scroll for information Events stored per patient, new patients clear past events
3	Pump B	57 pts	Damage to metal arm can cause flow inaccuracies Cannot run 15 minutes after low-battery alarm
2	Pump C	77 pts	Not designed with repairs in mind
1	Pump D	82 pts	Few Canadian installations

After combining the results of the *first phase* of the evaluation (Heuristic and the Technical evaluation), Pumps A&B ranked lowest and were removed from the RFP.

Phase 2 - Usability Evaluation

The quantitative metric was based on user preference from the common questionnaire used in the formal usability evaluation and the real-time clinical evaluations. Issues of concern exhibited by the actions of the users and identified by the human factors specialist were noted in the usability evaluation.

Table 5: Sample Usability Evaluation Comments for Pump C and Pump D

Pump C	*Pump D*
Poor medication abbreviations and acronym use in pump settings, and lack of informative double checks	PCA dose on front of machine confusing
Difficulties: 1) Lock sequence and speed to enter pass-code, 2) Replacing batteries, 3) Loading the cassette	Screen blanking out too often
Mixing up medication routes (e.g. Epidural and PICRA)	Tubing caught in upstream occlusion
Pump alarm sounds are similar to ambent sounds in the environment. A mistake could cause incredible confusion	Lockbox is too big

Video analysis verified that the existing PPOs used nomenclature and language that was not consistent with the logic and workflow of the pump. This evidence supported recommendations to have the PPOs changed to match the workflow of the pump prior to the clinical go-live date.

Phase 2 – Real Time Clinical Evaluation

The user questionnaire generated over 100 participant responses. The results obtained from the *second phase* supported the findings from the heuristic evaluation, cognitive walkthroughs, technical evaluation, and usability evaluation.

The table below identifies three key pieces of information. The Average Score shows the average value per questions given to the pump on a 0-6 scale. The order in which the pumps were trialed (i.e. 1st or 2nd) at each hospital helps the reader better understand the differential between the totals for each facility. The total clearly indicates that Pump D is the preferred choice for both hospitals.

Table 6: Qualitative Results of the Clinical Trial Surveys

Facility	*Pump C*	*Pump D*
Average Score	**4.36**	**5.59**
SPH	(2nd) 102.6	(1st) 169.6
VGH	(1st) 167.9	(2nd) 177.2
Total	270.5	346.8

CONCLUSIONS

The collaborative approach integrating a variety of different institutions and disciplines was crucial to the success of this selection and acquisition process. This project presented new opportunities to work with colleagues and staff across different facilities and health authorities in an aggressive ten month timeframe. Through the collaborative approach, one device was accepted by all stakeholders as the most safe and most appropriate device. This decision was fully supported by the SSO for British Columbia and the Purchasing representatives.

This case study documents the first steps taken to formalize human factors analysis into the purchasing process for medical devices for health institutions in Vancouver, British Columbia. The end-result of this collaborative, multi-disciplinary approach was the selection of a smart pump that includes safety features at multiple steps in the system for the delivery of medical care to the patient. It is hoped that the rigorous front-end evaluation will drastically reduce the potential for adverse drug events and improve the overall safety of drug delivery.

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