Systematic Innovation by User-centered Design: Case Study in Ampoule Opener Design

Ching-Wen Lien[1] and Po-Hsiang Liu[2]*

[1] Assistant Head Nurse, Department of Nursing, Taipei Veterans General Hospital, Taipei City, Taiwan
School of Nursing, National Taipei University of Nursing and Health Sciences, Taipei City, Taiwan

[2] Professor, Department of Industrial Engineering and Management, St. John's University, New Taipei City, Taiwan

*Corresponding author, E-mail: bsliu@mail.sju.edu.tw
(Received 14 August 2017; final version received 17 April 2018)

Abstract

About 90.3% of nurses reported to have experienced with sharp injuries and about 37.6% of nurses occurred more than one time of sharp injuries by opening the glass ampoules during recent 6 months. The sharp, jagged edges formed when the ampoule neck breaks incompletely pose a serious danger to medical professionals. Literatures reviewing showed that situation of sharps injuries by opening ampoule wasn't improved yet. Further, it needed to research and solve the problem. Thus, present study developed the new ampoule opener by systematic innovation of user-centered design to avoid painful and dangerous sharps injuries. User needs analysis have been conducted from district hospital, regional hospital and medical center medical center. A questionnaire was used to survey the behaviors (tasks of opening ampoule, types of ampoules, user requirements etc.) and sharp injuries while opening glass ampoules. After analyzing patents search, user needs analysis and results of questionnaire survey, present study designed and built the prototype of ampoule opener. Results of ergonomic evaluation showed that applied the ampoule opener had lower EMG activity of forearm and lower ulnar deviation on wrist. This easy-to-use multi-use ampoule opener avoids the unacceptable sharps injury rates seen when ampoules are opened by hand. The findings of this study could provide references to medical personnel in order to prevent and decrease sharp injuries as much as possible. In clinical effectiveness will be further assessed.

Keywords: Ampoule, Ergonomics, Sharp injuries, Systematic innovation

1. Introduction

The 2014 statistic data from the Taiwan EPINet (Exposure Prevention Information Network, Institute of Labor, Occupational Safety and Health) showed that the rate of needlestick and sharp injuries (NSIs) is 3.0%. However, first documented in 1983, up to 40% of all sharp injuries were not reported (Hamory, 1983). Subsequent studies have estimated the rate of under-reporting to be between 26% and 85% (Burke & Madan, 1997). Literatures review revealed that a total of 81.8% of sharp injuries were not reported, with job category significantly affecting reporting behavior. Shiao et al. (1999) surveyed 10,469 full-time medical, nursing, technical, and supporting personnel employed at 16 randomly selected hospitals from 132 available accredited teaching hospitals in Taiwan. Questionnaires were completed by 82.6% (8,645) of their samples, of whom 87.3% reported to have experienced a recent NSIs and medical staffs had the highest non-reporting rate. The epidemiology of NSIs was investigated among a complete cross-section of 1,162 nurses from a large hospital in southern Japan (Smith et al., 2006). Forty-six percent had experienced with NSIs in the previous year. Most NSIs were caused by ampoules or vials, which injured 32.3% of all nurses and accounted for 42.9% of all NSIs events. In addition, the 19,171 clinical nurses who came from 229 hospitals in 23 sites in China recalled the sharp injuries in past year. The 81.4% of nurses had sustained at least one sharp injury. The broken glass injuries accounted 38.3%. There are 49.7% of injuries occurred during "using the sharps" (Wang et al., 2009). Cheung et al. (2010) reported

that there were a total of 51 reported cases of NSIs from Hong Kong. The annual prevalence of NSIs in four academic years from 2002-2003 to 2005-2006 ranged from 0.6 to 1.6 cases while the incidence rate was one new case per 100 nursing students per academic year. Broken glass from opening ampoules (62.50%) was responsible for most sharp injuries. Further, Chiu et al. (2011) investigated sharp injuries from January 2007 to March 2009. The 165 cases revealed that 53.9% occurred mostly in ordinary ward. The main injury site is index finger (70.9%), and the depth located on superficial skin with bleeding (72.1%). Voide et al. (2012) also reported that about 9.7% of health workers had sustained at least one NSIs during the preceding twelve months. The NSIs were more frequent among nurses (49.2%) and doctors performing invasive procedures (36.9%). Yu et al. (2014) reported that the occurrence rate of sharp injuries was 70.4% among 189 nursing staffs and the nursing staffs with shorter working time, lower education had more sharps injuries (averaged 2-5 times) in Xinjiang. A study of nurse sharp injuries was conducted in the department of sterile supply in Chengdu. A total of 88 injuries cases found with an average of 2.7 times each person (Zhang et al., 2014). About 90.3% of nurses reported to have experienced the sharp injuries and about 37.6% of nurses occurred more than one time sharp injuries by opening the glass ampoules during recent 6 months (Lien et al., 2016). From the results of literatures reviewing indicates that the situation of sharps injuries by opening ampoule wasn't improved yet. It needed to research and solve the problem. Thus, present study want to develop the new ampoule opener by systematic innovation of user-centered design to avoid painful and dangerous sharps injuries.

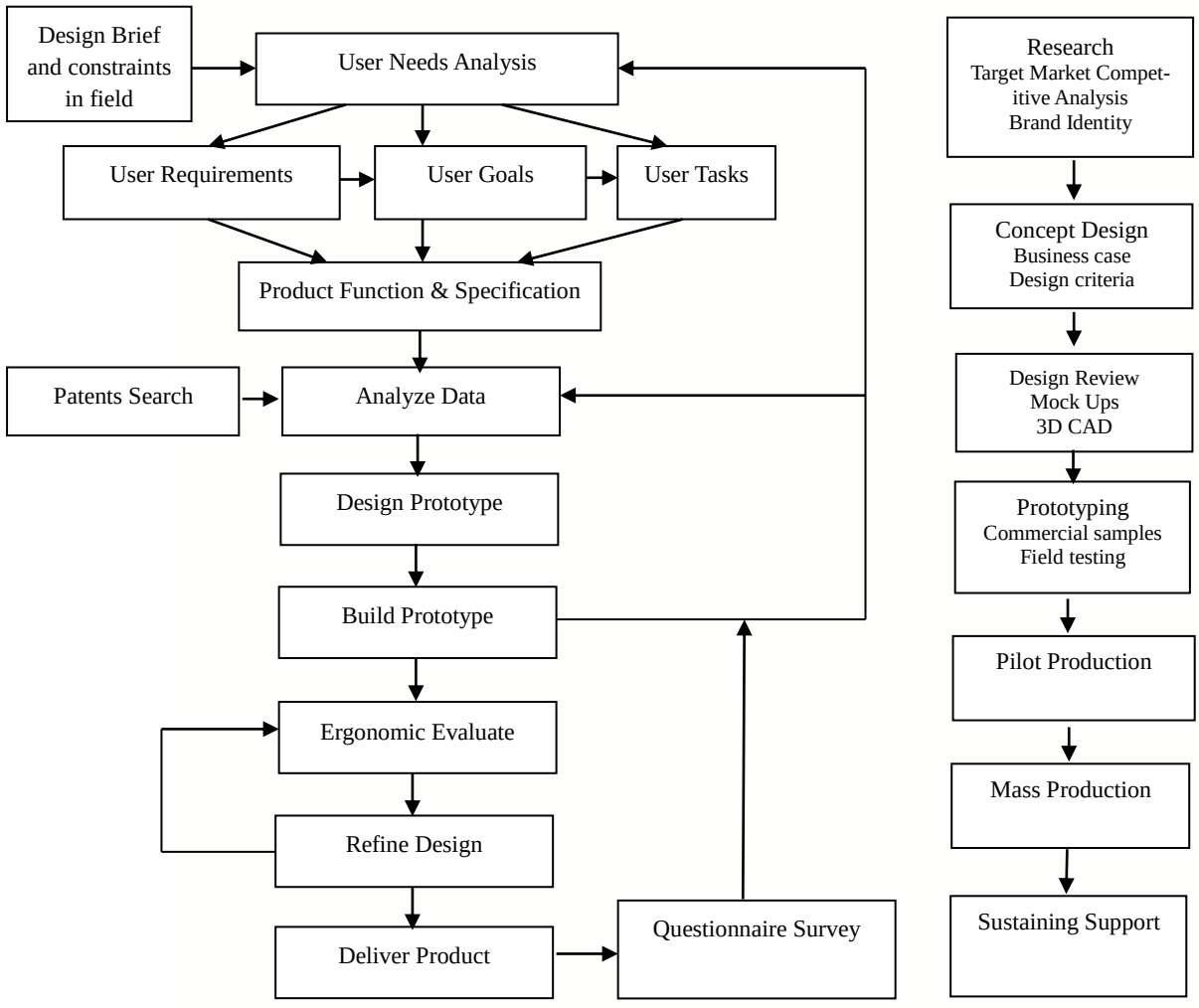
Engineering is concerned with improving products from the point of view of mechanical and electrical design, and human factors and ergonomics are concerned with adapting products to people, based upon their physiological and psychological capacities and limitations, the objective being to improve overall system performance (involving human and product elements). Present study integrated both engineering and human factors/ergonomics. New product development could be incorporation of the user requirements, user goals and user tasks into the design of a product and will only be realized through a user-centered design process in first time. In present study provided the systematic innovation by user-centered design: case study in ampoule opener design. An ampoule is a small sealed vial which is used to contain and preserve a sample Ampoules are most commonly used to contain pharmaceuticals and chemicals that must be protected from air and contaminants. Ampoules are commonly made of glass. Majority of nurses reported to have experienced the sharp injuries and about 37.6% of nurses occurred more than one time sharp injuries by opening the glass ampoules during recent 6 months. The sharp, jagged edges formed when the ampoule neck breaks incompletely pose a serious danger to medical professionals. Fingers and hands can be cut from the sharp jagged edge formed where the neck breaks. Ampoule related injuries are frequent and dangerous Thus, this project developed the new ampoule opener by systematic innovation by user-centered design to avoid painful and dangerous sharps injuries.

2. Methods

Incorporation of the user requirements, user goals and user tasks into the design of a product will only be realized through a user-centered design process as illustrated in Figure 1. Given that user activity is central to design, this information needs to be captured and incorporated into the design process. Design may start with a design brief specified by the client organization. The user-centered approach would start the design activities with methods aimed at capturing user needs. These needs, together with the functional specification and the constraints will be formulated into the system specification. Additional constraints might include the cost and weight of materials and the size of components. From this a prototype may be built and tested. The resultant data may be used to inform the design team. This could lead to a complete overhaul of the system specification (reversing the design process back to a re-analysis of the user needs), or modification of the prototype, or minor refinements in the design. After build prototype, ergonomic evaluation have been conducted for new ampoule opener. There may be many feedback loops around this process, or some stages may be omitted owing to resource constraints. Finally the product and associated materials (such as instructions, packaging and marketing) are delivered. Depending upon the life of the product, it may have to be supported by production of spares, maintenance contracts and helplines. Whilst this description represents a sanitized version of the design process, it does begin to touch on some of the complexity in-

volved in design. This complexity is exacerbated when one appreciates the number of people who have a stake in product design, including the designers, ergonomists, accountants, management, technicians and engineers. If this group is not working harmoniously, agreement on the design solution is not likely to be forthcoming. At the early stages of design there may be as many as ten concepts for the product. This may lead to, say, three proposals which are narrowed down to one product. The process of freezing a range of concepts into a single solution makes it clear why human factors needs to get into the process as early as possible, as this is when most change can be made at least cost to the design process (Stanton, 1998).

New product development of traditional researching system involved the research (target market analysis competitive analysis, brand identity, concept design (business case, design criteria), design review (mock up, 3D CAD), prototyping (commercial samples, field testing), pilot production, mass production and sustaining support. By contrast, present study applied the user-centered approach that would start the design activities with methods aimed at capturing user needs. Compared the two new product development stages presented in Figure 1. The research model focuses on user needs analysis, patents search and ergonomic evaluation.



(a) user-centered design approach (b) traditional researching system

Fig. 1 Systematic innovation by user-centered design (a) and traditional researching system (b)

3. Results

3.1 User needs analysis

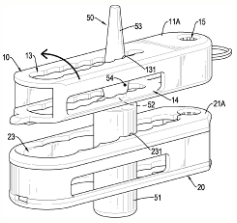
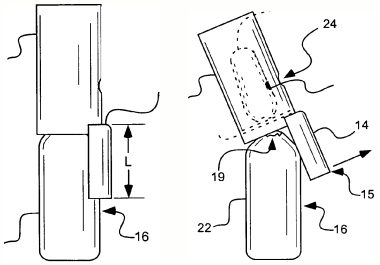
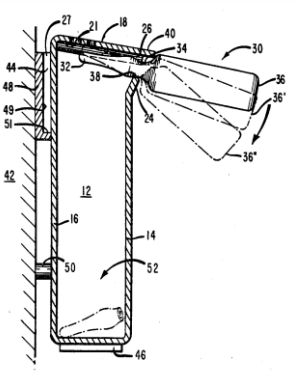
In present study the user needs analysis have been conducted from district hospital, regional hospital and medical center. A questionnaire was used to survey the behaviors (tasks of opening ampoule, types of ampoules, user requirements etc.) and sharp injuries while opening glass ampoules. A total of 300 questionnaires were dispatched to hospitals, with a response rate of 86% (n = 258). Nurses are sampling from district hospital (24%), regional hospital (14.3%) and medical center (61.6%). We collected the user needs analysis and design brief/constraints in field to develop the new product function and specification. A questionnaire was used to survey the behaviors and sharp injuries while opening glass ampoules. Results of analysis showed the socio-demographic characteristics of respondents by gender, age, education level, job category, hospital category and years of service. Majority of nurses are female (98.1%). Age distribution of the respondents is 36.4% (less than 29 years old), 44.2% (30-39 years old) and 19.4% (more than 39 years old). Majority of nurses (81.8%) had college degree. The years of service involved the 10.9% (< 1 year), 10.5% (1-2 years), 14.7% (3-5 years), 21.3% (6-9 years) and 42.6% (> 10 years). Among the 258 respondents are professional nurse (63.6%), followed by nurse (30.6%), and head nurse (5.8%). Nurses are sampling from district hospital (24%), regional hospital (14.3%) and medical center (61.6%). About 46.9%, 23.6% and 29.5% of respondents are in medicine department, surgery department and others, respectively.

Results of analysis showed that about 90.3% of nurses reported to have experienced the sharp injuries and about 37.6% of nurses occurred more than one time sharp injuries by opening the glass ampoules during recent 6 months. There are 43% nurses by hand, 40.3% nurses by hand with alcohol pad, and only 16.7% nurses by tools while opening glass ampoule. The main causes of sharp injuries are opening ampoule, drawing medication from an ampoule, and handling sharps collection. Further, main cause of sharp injuries is improper force to crush glass ampoule. Only 11.6% nurses could report to head nurse and about 63.6% nurses affected the work. About 88.8% of nurses want to use the ampoule opener and about 56.6% of nurses want to buy it while ampoule opener costs less than NT$100 (US$ 3).

3.2 Patents search and analysis

Patents search applied by Orbit Intelligence System (Questel, France). Totaled 1384 patent families had found for searching “ampoule opener or ampoule opening or ampoule breaking or ampule bottle opener or ampule opener”. Results of search patents showed that the main key technology concepts involved ampoules (22.4%), ampoule opening (12.6%), ampoule breaking (8.8%), ampoule neck (7.9%) and grinding wheel (7.2%). Main International Patent Classification (IPC) are B67B-007/92 (by breaking, e.g. for ampoules), B67B-007/46 (cutting devices, i.e. devices including at least one cutting element having one or more cutting edges for piercing through the wall of a closed container, e.g. can openers), B67B-007/54 (sweep cutter type, i.e. an opening device including means to establish a pivot point between the cutting element and the container and having means to move the cutting element about the pivot point), B67B-007/44 (combination tools, e.g. comprising cork-screws, can piercers, crown-cap removers), A61J-001/06 (ampoules or cartridges) and A61M-001/00 (Suction or pumping devices for medical purposes; Devices for carrying-off, for treatment of, or for carrying-over, body-liquids; Drainage systems). These data could be considered in further design of new ampoule opener. For example, three patents of ampoule opener showed in Table 1.

Table 1 Patents of ampoule opener.

Inventors, Patent name, Patent number and IPC codes	Abstract	Brief description of the drawings
Liu et al. (2015) Ampoule opener US8973800 B67B-007/92; B67B-007/44	An ampoule opener has an opening unit and a cover unit. The opening unit is a rigid frame and has two panels, two head-clamping holes and two pairs of wave-shaped flanges. The panels are respectively an upper panel and a lower panel. The head-clamping holes are elongated in length and tapered in width and are respectively formed through the panels. The pairs of wave-shaped flanges are formed between the panels and the head-clamping holes. The cover unit is flexible, is detachably mounted around the opening unit and has two covering boards, a mounting recess, two body-clamping holes and two pairs of wave-shaped edges. The body-clamping holes are elongated in length and tapered in width and are respectively formed through the mounting boards and communicate with the mounting recess. The pairs of wave-shaped edges are formed between the mounting boards and the body-clamping holes.	
Wiley & Halvorson (2011) Ampoule opener and associated methods US7,946,461 B67B-007/92; B62F-003/00	An ampoule opener comprises a receiving body sized to accommodate a cap portion of an ampoule and a shield extending from the receiving body and being configured to lie adjacent a medicament storing portion of the ampoule when the cap portion of the ampoule is accommodated within the receiving body. The shield is rigidly related to the receiving body so as to be more resistive to bending relative to the receiving body in a direction away from a longitudinal axis of the receiving body than toward the longitudinal axis of the receiving body.	
Caron (1983) Ampoule opener US4,405,067 B26F-003/00	An ampoule opener for safely and conveniently breaking the tips off elongated ampoules of varying sizes to make possible the extraction of the contents therefrom. The opener includes a housing having an opening formed on the front face thereof for insertion of an ampoule tip there through. A projection extending outwardly from the front face is disposed adjacent a lower edge of the opening and serves as a fulcrum upon which the ampoule neck is placed and about which torque is applied to snap off the ampoule tip at the neck when the end of the tip engages an internal bearing surface. A hood over the housing opening protects the user from any spray resulting from the breaking of the ampoule and an internal cavity collects the tips broken from the ampoules.	

3.3 Design Prototype

After analyzing patents search, user needs analysis and results of questionnaire survey, we are developing the prototype of ampoule opener. Furthermore, present study designed the new type ampoule opener with a clamping element and a cylindrical sleeve element (Taiwan Patent No. M489643; US Patent application No. US20160046474). An ampoule opener is provided. The ampoule opener includes a clamping element and a cylindrical sleeve element. The clamping element includes a plurality of clamping arms. Each one of the plurality of clamping arms includes a clamping terminal. The cylindrical sleeve element is disposed around the clamping element. The cylindrical sleeve element is adapted to move back and forth along the clamping arms thereby adjusting an interval of each two adjacent clamping terminals. The ampoule opener is capable of breaking off ampoules with various calibers due to that the interval between the clamping terminals can be adjusted by moving the cylindrical sleeve element. (Figure 2).

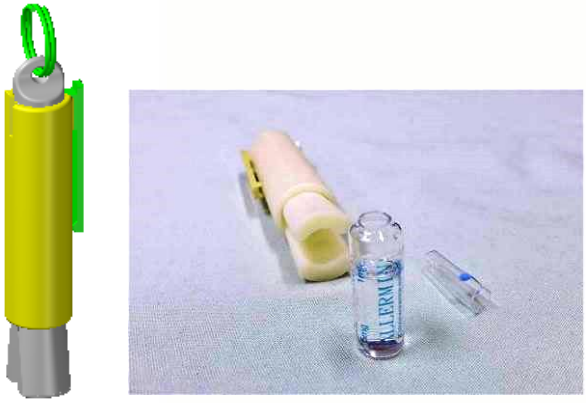


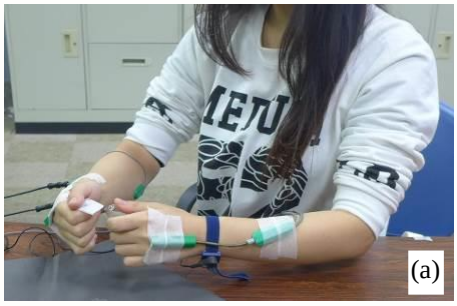
Fig. 2 The new ampoule opener design and prototype.

3.4 Ergonomic evaluation

An ergonomic evaluation was examined the forearm muscle activities, and wrist postures for the two methods of opening glass ampoule. Five nurses were recruited in present study. All subjects were healthy and reported no musculoskeletal problems that might influence performance detrimentally. Each participant performed the two methods of opening the glass ampoule for three repetitions, respectively (Figure 3). The experimental empty 5 ml ampoules made by GL Glass Company (Hsinchu, Taiwan). The Electromyography (EMG) activities of the pronator teres muscle groups and wrist postures were recorded by Biometric data acquisition system (DataLog MWX8, Biometric Ltd., UK).

All data were coded and summarized using SPSS 21.0 software for Windows. In ergonomic evaluation, the dependent variables were angles of wrist, and EMG (%) for Pronator Teres. Further, analysis of variance (ANOVA) was utilized to identify significant differences between conditions for dependent variables. Statistical significance was set at a probability level of 0.05.

Results of ergonomic evaluation showed that EMG of right hand was significant difference between opening methods (Figure 4). The right forearm muscle activities were significant lower while using the ampoule opener (44.14% MVC). However, the higher muscle activities were found while opening ampoule by hand (54.72% MVC). On the other hand, there were not significant differences in EMG of left hand between opening methods, because the main function of left hand is holding the ampoule bottle. Table 2 presented the wrist postures for dorsiflexion and ulnar deviation while opening the glass ampoule by hand and two types of ampoule opener. There are not significant differences in dorsiflexion and ulnar deviation of left hand between methods of opening ampoule. By contrast, lower mean dorsiflexion of right hand was found in applied the ampoule openers.



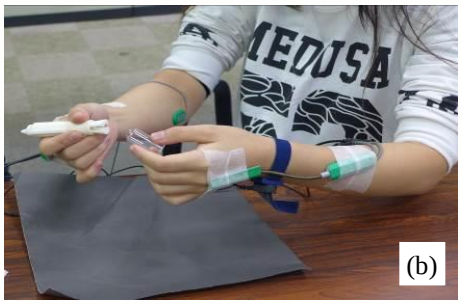


Fig. 3 Ergonomic evaluation for opening the glass ampoule by two methods ((a) by hand; (b) by ampoule opener)

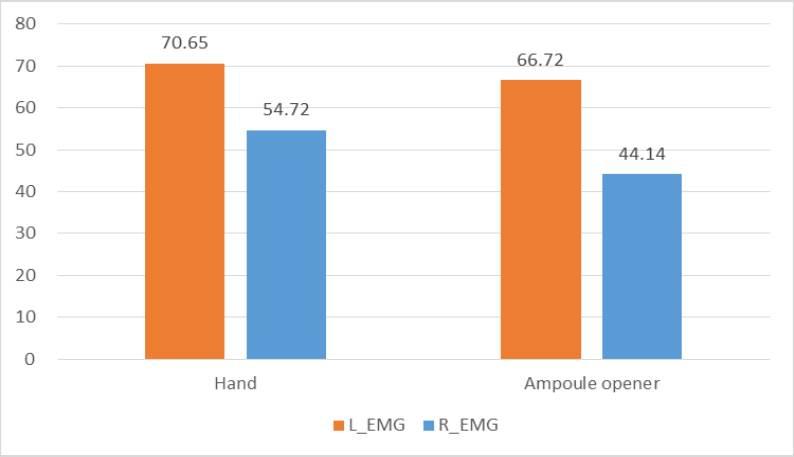


Fig. 4 Electromyography of the pronator teres for opening the glass ampoule by two methods

Table 2 The dorsiflexion and ulnar deviation between methods of opening ampoule

Methods of opening ampoule	Left hand		Right hand	
	Dorsiflexion	Ulnar deviation	Dorsiflexion	Ulnar deviation
Hand	25.52	19.61	24.26	17.71
Ampoule opener	23.21	17.15	19.42	19.46

4. Conclusion

The hospitals did not provide the appropriate tools to the nurses for opening the glass ampoule. Situation of sharps injuries by opening ampoule wasn't improved yet and needed to research and solve the problem. Thus, present study want to develop the new ampoule opener by systematic innovation of user-centered design to avoid painful and dangerous sharps injuries. Incorporation of the user requirements, user goals and user tasks into the design of a product will only be realized through a user-centered design process. Present study provided the new ampoule opener design with a clamping element and a cylindrical sleeve element. The new ampoule opener is capable of breaking off bottles with different calibers of ampoule. After ergonomic evaluation showed that the new ampoule opener had lower EMG activity of forearm and lower ulnar deviation and dorsiflexion on wrist. This ampoule opener can avoid painful and dangerous sharps injuries. For an example of existing tool (SnapIT™, Qlicksmart Ltd. Co., Australia) costs from AUD 33.3 to 41.9 (NTD 513 to 964). Further, users need to select the appropriate tool size for different ampoule sizes. e.g., Regular size is for 1ml to 15ml and large size is for 5ml to 25ml. It is not convenient for using. Thus, the new ampoule opener in this study could be compatible ampoule sizes from 1ml to 20ml and be more convenient, safer, cheaper avoiding the injury. This easy-to-use multi-use ampoule opener avoids the unacceptable sharps injury rates seen when ampoules are opened by hand. About 88.8% nurses want to use the ampoule opener. In clinical effectiveness will be further assessed.

Acknowledgement

This study was supported by a grant from the Ministry of Science and Technology, Taiwan, and Project No. MOST 104-2221-E-129-007. Researchers are very grateful for all participants in this study.

References

Burke, S. and Madan, I. (1997). Contamination incidents among doctors and midwives: reasons for non-reporting and knowledge of risks. *Occupational Medicine*, *47*, 357-360.

Caron, P. L. (1983). U.S. Patent No. 4,405,067. Washington, DC: U.S. Patent and Trademark Office.

Cheung, K., Ho, S. C., Ching, S. S. and Chang, K. K. (2010). Analysis of needlestick injuries among nursing students in Hong Kong. *Accident Analysis & Prevention*, *42*, 1744-1750.

Chiu, T. C., Wu, S. C. and Su, Y. L. (2011). Investigation of sharps injury incidences among nursing personnel in a medical center. *VGH Nursing*, *8*, 387-395.

Hamory, B. H. (1983). Underreporting of needlestick injuries in a university hospital. *American Journal of Infection Control*, *11*, 174-177.

Lien, C. W., Liu, B. S., Chen, Y. J. and Yu, C. H. (2016). *Ergonomic evaluation of new ampoule open design*, the 2016 International Conference on Applied System Innovation, Okinawa, Japan.

Liu, F., Huang, S., Huang, P. and Huang, U. (2015). U.S. Patent No. 8,973,800. Washington, DC: U.S. Patent and Trademark Office.

Liu, P. H., Lien, C. W. and Lin, Y. J. (2014). Taiwan Patent No. M489643. Ministry of Economic Affairs: Intellectual Property Office.

Shiao, J. S., McLaws, K. L., Huang, K. Y., Ko, W. C. and Guo, Y. L. (1999). Prevalence of nonreporting behavior of sharps injuries in Taiwanese health care workers. *American Journal of in Control*, *27*, 254-257.

Smith, D. R., Mihashi, M., Adachi, Y. Nakashima, Y. and Ishitake, T. (2006). Epidemiology of needlestick and sharps injuries among nurses in a Japanese teaching hospital. *Journal of Hospital Infection*, *64*, 44-49.

Stanton, N. (1998). *Human factors in consumer products*. London, UK: Taylor & Francis.

Voide, C., Darling, K. E., Kenfak-Foguena, A, Erard, V., Cavassini, M. and Lazor-Blanchet, C. (2012). Underreporting of needlestick and sharps injuries among healthcare workers in a Swiss University Hospital. *Swiss Medical Weekly*, 142: w13523.

Wang, H. Q., Zhang, M., Li, T. and Du, X. Y. (2009). A pooling analysis of occupational sharp injury on clinical nurses in China. *Chinese Journal of Industrial Hygiene and Occupational Diseases*, *27*, 65-70.

Wiley, J. L. and Halvorson, T. A. (2011). U.S. Patent No. 7,946,461. Washington, DC: U.S. Patent and Trademark Office.

Yu, S., Li, W., Zou, Y. and Zhang, C. (2014). An analysis on the relationship between medical sharp injuries and job satisfaction among nursing staff. *Journal of Xinjiang Medical University*, *37*, 635-639.

Zhang, X., Tang, Y., Zheng, D. and Liao, J. (2014). Investigation of risk factors of nurse sharps injury in the department of sterile supply. *Journal of Modern Clinical Medicine*, *40*, 379-381.

AUTHOR BIOGRAPHIES

Ching-Wen Lien received her B.S. and major the M.S. in Nursing from National Taipei University of Nursing and Health Sciences. She is an Assistant Head Nurse at Taipei Veterans General Hospital. She received the awards of clinical teaching teacher in 2011 and the 2010 Excellent Nurse in Veterans Affairs Council. She is members of Taiwan Nurses Association, Taiwan Oncology Nursing Society and Taiwan Society of Critical Care Nurses. Her areas of interests include women health care, health promotion, and clinical nursing.

Po-Hsiang Liu received his M.S. and Ph.D. in Human Factors and Ergonomics from National Taiwan University of Science and Technology. He is a Professor and Dean of Academic Affairs at St. John's University in Taiwan. His areas of interests include human factors in product design, workload assessment, and human-computer interaction. He has published a number of papers in Accident Analysis & Prevention, Applied Ergonomics, International Journal of Industrial Ergonomics, Industrial Health, Journal of Safety Research, Perceptual and Motor Skills, Transportation Research Part F etc.