

Application of safety feature evaluation in single-use safety syringe design

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Received 09 May 2008; revised 27 May 2009; accepted 28 May 2009

Reuse and abuse of syringes has led to cross-infection of diseases. Usability evaluation of three of the most commonly used safety syringe types conducted in this study is through-push retract breakable safety syringe, rotary plunger retractable safety syringe and release-ring breakable safety syringe. By administering Safety Feature Evaluation Form (SFEF) and Focus Group Interviews on six professional nurses with an average professional experience over 11 years, usability problems with three types of safety syringe are found out. Six design principles have been ascertained and applied in development of a new safety syringe design, with input from a number of designers, nursing professionals and occupational safety technicians. New safety syringe significantly outperformed existing safety syringes on all evaluation indices.

Keywords: Focus group interviews, Needlestick injuries, Safety feature evaluation form (SFEF), Safety syringes

Introduction

Reuse of unsterilized and contaminated syringes causes transmission of many diseases. Also, studies recommend reduction of unsafe and unnecessary injections¹. Needlestick injury (23~71% each year) among nursing professionals² also causes infection in many healthcare workers. Nursing professionals (65%) had suffered needlestick injuries or cuts from injection needles, sewing needles and scalpels³. Intravenous catheter stylets, blood transfusions and blood drawing result in needlestick injuries⁴. For nursing professionals in Taiwan, general injection needle represent 55.3% of injuries, with another 21.3% caused by recapping a needle⁵.

In November 2000, the US adopted the Needle-Stick Safety and Prevention Act, and a full-scale program to use safety syringes for injection was launched in all hospitals in 2005. Nursing professionals are interested in purchasing safety syringes with combined automatic needle protection and syringe-locking features⁶. In 2000, contaminated injections caused an estimated 21 million HBV infections (32%), two million HCV infections (40%) and 260,000 HIV infections (5%) of new infections for a burden of 9,177,679 disability-adjusted

life years between 2000 and 2030 due to reuse of injection tools⁷. In practical use, there are two major types of manually operated safety syringes: i) Activated needle shielding design; and ii) Retracting design with needle retracted into the barrel after use.

This study presents designing of a new single use safety syringe incorporating features and discarding problems with X, Y, Z type of syringes by using a questionnaire (Table 1) based on working professionals in this area.

Methods

This study explores of single-use safety syringes with reuse prevention feature, which can be distinguished into three main types (Fig. 1): i) X, through-push retract breakable safety syringe; ii) Y, rotary plunger retractable safety syringe; and iii) Z, release-ring breakable safety syringe. These three types of syringes have needle destroying feature and used in the same way as traditional syringes. For X, push plunger to the end after injection and it will tie in with needle hub; pull back plunger and needle will retract into barrel. After needle retracts into barrel, plunger can be broken so that needle remains in barrel. For Y, rotate plunger by 30° so that plunger is tied in with needle hub; pull back plunger and needle will retract into barrel, and after needle retracts, it can be destroyed by pushing plunger, and needle remains in barrel. For Z,

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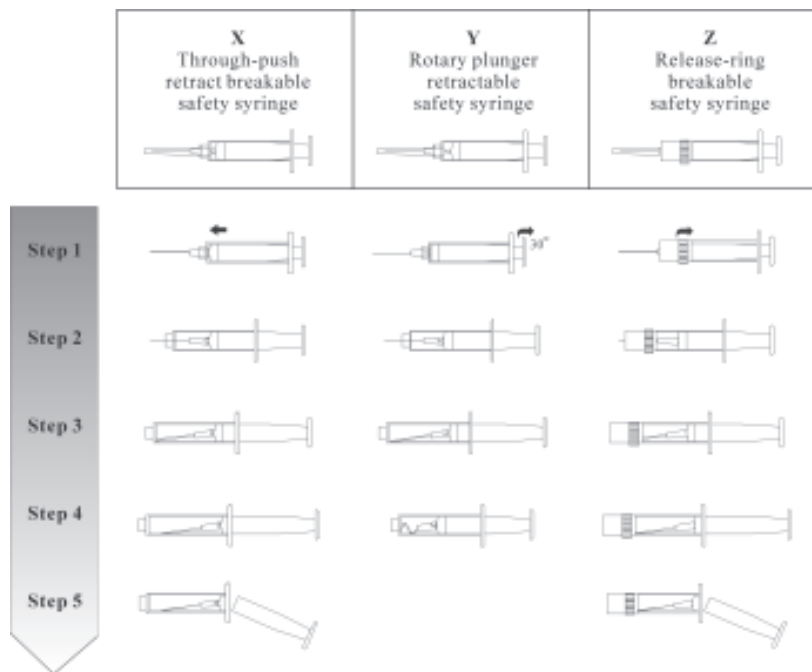


Fig. 1—Operational steps of X, Y and Z types of syringes

Table 1—Safety feature evaluation form (SFEF)

Steps Questions

During use

- 1 Safety feature can be activated using a one-handed technique
- 2 Safety feature does not obstruct vision of tip of the sharp
- 3 Use of this product requires you to use safety feature
- 4 This product does not require more time to use than a non-safety device
- 5 Safety feature works well with a wide variety of hand sizes
- 6 Device is easy to handle while wearing gloves
- 7 This device does not interfere with uses that do not require a needle
- 8 This device offers a good view of any aspirated fluid
- 9 This device will work with all required syringe and needle sizes
- 10 This device provides a better alternative to traditional recapping

After use

- 11 There is a clear and unmistakable change (audible or visible) that occurs when the safety feature is activated
- 12 Safety feature operates reliably
- 13 Exposed sharp is permanently blunted or covered after use and prior to disposal
- 14 This device is no more difficult to process after use than non-safety devices

Training

- 15 User does not need extensive training for correct operation
- 16 Design of device suggests proper use
- 17 It is not easy to skip a crucial step in proper use of device

rotate release ring so that plunger is tied in with needle hub; pull back plunger and needle will retract into barrel, and after needle retracts into barrel, plunger can be broken to leave needle inside barrel.

Focus Group Interviews (FGI) method evaluated advantages and disadvantages of X, Y and Z types of safety syringes. In FGI, a team is formed to collect data from a specific group of people and for a specific question.

FGI can be used to understand opinions of people in different groups or different levels, and to probe into potential views on such questions as a new proposal, service or product design, etc⁸. Objective of FGI is to find out perceived differences on the use of X, Y and Z types of safety syringes among interviewees, and set future directions for safety syringe design. Interviews are generally categorized into structured, semi-structured, and unstructured interview, in which semi-structured interview is most commonly used. This study combines structured interview with semi-structured interview, and is based on Safety Feature Evaluation Form (SFEF) designed by Training for Development of Innovative Control Technology Project (TDICT) on safety syringes as interview guide. Finally, an in-depth and open-ended semi-structured interview is conducted with interviewees. Six interviewees, having an average professional nursing experience of 11 years, were invited for FGI study, and interview lasted for 2 h in conference room at Tainan Hospital, Taiwan.

Results and Discussion

Interviewees (6) completed SFEF questionnaire on X, Y and Z types of safety syringes in first stage. Semi-structured FGI based on questionnaire was conducted in second stage.

Scores of SFEF Questionnaire

Interviewees rated level of satisfaction with X, Y and Z syringes according to SFEF questionnaire indicated 5 being most satisfactory and 1 being most unsatisfactory. Average scores of syringes on SFEF questionnaire (Table 2) was: X, 62.6; Y, 62.2; and Z, 52.2. All X, Y and Z syringes scored less than 4 in questions 1, 9, 11, 12, 13, 15, 16 and 17.

Results of FGI

After acquiring SFEF scores for syringes X, Y and Z, interview host began FGI. Interview was structured by three topics: A, advantages and disadvantages of X, Y and Z safety syringes; B, ideal safety syringe; and C, scores of SFEF questionnaire.

In terms of A, a preparatory pushing action is customary when nurses use a syringe, and so safety mechanism in X syringe may be easily triggered mistakenly. In Y syringe, although it can be confirmed that needle is destroyed, act of crushing needle easily causes mental pressure. When using a 1 cc syringe, it happened that needle ran out of barrel. In Z syringe, release ring is too close to needle, which easily causes

Table 2—Average scores of new safe syringe and X, Y and Z safety syringes on SFEF questionnaire

Question steps	X	Y	Z	X, Y, Z average	New average
<i>During use</i>					
1	3.8	3.7	2.0	3.2	2.2
2	4.0	4.0	3.7	3.9	4.2
3	3.8	4.0	3.7	3.8	4.2
4	3.2	4.0	2.8	3.3	4.2
5	4.3	3.8	3.3	3.8	4.2
6	4.0	4.0	3.0	3.7	4.2
7	4.0	4.0	3.7	3.9	4.0
8	4.0	4.0	3.7	3.9	4.0
9	2.7	2.7	2.7	2.7	4.0
10	4.0	3.2	3.0	3.4	4.8
Average during use	3.8	3.7	3.2	3.6	4.0
<i>After use</i>					
11	3.8	3.3	3.0	3.4	3.8
12	3.9	3.7	2.8	3.5	4.3
13	3.2	3.3	3.0	3.2	4.2
14	4.0	3.8	3.0	3.6	4.2
Average after use	3.7	3.5	3.0	3.4	4.1
<i>Training</i>					
15	3.3	3.7	3.0	3.3	4.0
16	3.3	3.3	2.8	3.2	4.2
17	3.3	3.7	3.0	3.3	4.0
Average after training	3.3	3.6	2.9	3.3	4.1
Sum	62.6	62.2	52.2	59.1	68.7

mental pressure on users. Despite these drawbacks, all interviewees agreed that X, Y and Z syringes are safer than traditional syringes. In terms of B in interviewees' view, ideal safety syringe is one that user need not worry about accidentally triggering safety mechanism, and one that does not require education and training in its use. Syringe should be similar to traditional syringes in operation as much as possible. In terms of C for 8 questions that X, Y and Z did not score over 4, interviewees stated that Question 1 was relatively unimportant, because both hands were used when doing injection. For questions 16 and 17, interviewees believed that score could be increased by simple learning.

Interviewees' Suggestion on Design of SFEF Questionnaire

Concluding interviewees' opinion on most important questions in SFEF questionnaire, more than three persons felt that questions 9, 11, 12, 13 and 15 were of more importance than other factors. Moreover, several

Table 3—Problem summary of existing safety syringes

S No.	More important questions in interviewees' opinion	Problem summary	Implication
1	This device will work with all required syringe and needle sizes	Safety syringes all come with their specific safety mechanism, and thus increase interviewees' suspicion of their compatibility.	Compatibility
2	There is a clear and unmistakable change (audible or visible) that occurs when safety feature is activated	When using safety syringes, many interviewees cannot confirm whether safety mechanism has started or completed. Interviewees generally think a clear feedback is lacking.	Clue
3	Safety feature operates reliably	Since interviewees are using X, Y and Z safety syringes for the first time, situations of accidental trigger or omission of safety mechanism are likely.	Correctness
4	Exposed sharp is permanently blunted or covered after use and prior to disposal	There have been incidents of a needle poking out of barrel when some users are using a 1 cc safety syringe, and an incident wherein a retracted needle came out of barrel.	Containment
5	User does not need extensive training for correct operation	Since interviewees have been using traditional syringes for a long time, they dread using safety syringes for the first time. Interviewees believe that additional training may help use syringe correctly.	Cognition

interviewees suggested addition of questions related to psychological factors (about “afraid of using it” and “mental pressure”).

Among X, Y and Z safety syringes, each has advantages and disadvantages. But in itemized evaluation, all X, Y and Z syringes scored less than 4 in questions 1, 9, 11, 12, 13, 15, 16 and 17. Interviewees also pointed out that questions 9, 11, 12, 13 and 15 require more attention. Therefore, this study tries to sort out design principles for a new safety syringe by focusing on three safety syringes problems as seen from questions 9, 11, 12, 13 and 15.

Design of New Safety Syringe

Problem Summary of Existing Safety Syringes

Since interviewees felt that questions 9, 11, 12, 13 and 15 in SFEF questionnaire scored <4 and require more attention, researcher identified problems with existing safety syringes. This study found that questions 9, 11, 12, 13 and 15 implied problems of compatibility, clue, correctness, containment and cognition respectively (Table 3). Then, average scores of five interviewees in

SFEF questionnaire were presented in radar graph (Fig. 2).

Designing Principles of New Safety Syringe

Applying method of Expert Opinion⁹, three experts working in fields related to product design conducted a comprehensive design review of five parameters (compatibility, clue, correctness, containment and cognition) and following points were concluded for new safety syringe design: 1) Design should be based on traditional syringes, and should not add too many new functions; 2) In terms of operation, it should be as similar to original mode of operation as possible, and avoid conflicting with original operation habit and gesture; 3) There should be confirmation and clear feedback for start and end of safety mechanism, and its status should be clear at a glance; 4) Possibility of accidental triggering of safety mechanism should be minimized; (5) Users' feelings of security should be considered in the shape and position of safety device of safety syringe; and (6) Any possibility that used needle would come out (poke out or fall out) of the barrel should be completely avoided.

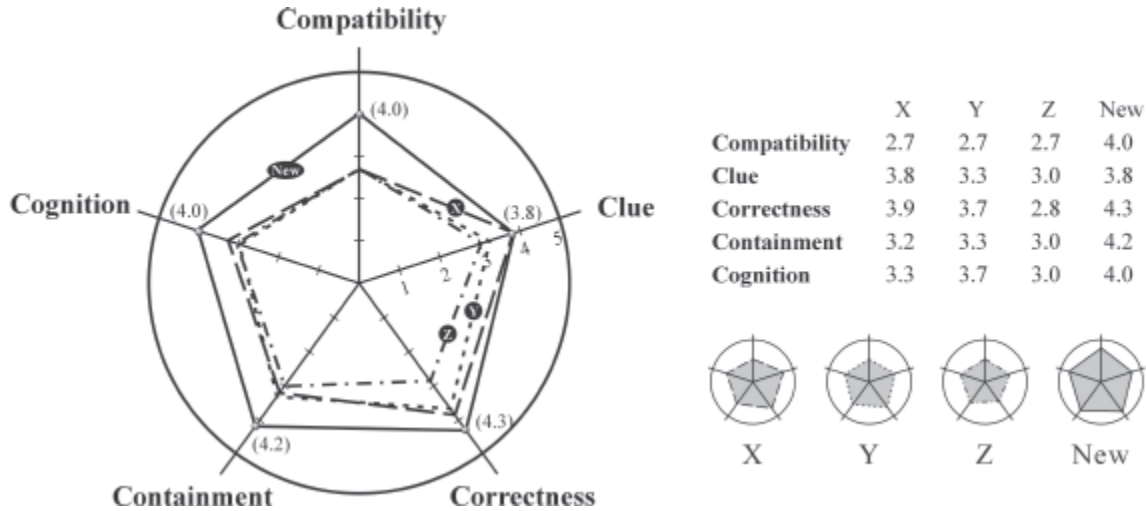


Fig. 2—Radar graph of new safety syringe and existing safety syringes

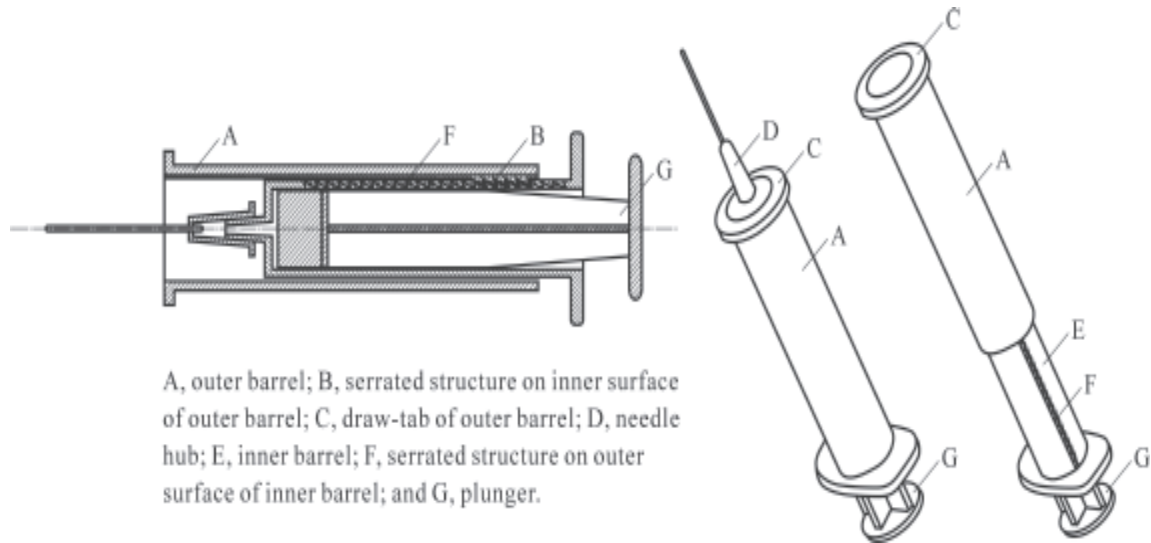


Fig. 3—New safety syringe design

Proposed Design of New Safety Syringe

New safety syringe consists of an outer barrel, a needle hub, an inner barrel, and a piston plunger (Fig. 3). Needle hub and piston plunger in new design are exactly the same as in a traditional syringe. Key feature of new design lies in serrated structure on outer surface of a traditional syringe’s barrel (referring to inner barrel here). Then, it is wrapped with an outer barrel, which has a similar structure on its inner surface that can be interlocked with outer surface of inner barrel. Such a structure ensures a unidirectional movement. User may pull out outer barrel of syringe to the end to totally contain

the needle. This meets WHO’s “reuse prevention” standard for design of safety injection syringe. Advantages of new design are: 1) With a simple structure, new design of safety syringe can be produced at a low cost, which meets cost requirement of disposable articles; 2) Serrated structure allows only unidirectional movement, ensuring that syringe can only be used once, and fully meets WHO’s regulation of “reuse prevention”; 3) Action of pulling out outer barrel ensures no need for recapping a needle, thus avoiding any possibility of needle stick injury to user; and 4) New safety syringe closely resembles traditional syringes, since users do not have to learn any new operating skill before use.

Evaluation of New Safety Syringe

To confirm feasibility of new safety syringe design, simple models were made from design sketch, and same six experts were invited to do SFEF questionnaire and FGI. Total score on SFEF was 68.7, which was higher than average score of existing safety syringes (Table 3).

On SFEF, new safety syringe only fails to score more than 4 on question 1 and question 11. In follow-up in-depth interview, all interviewees felt that new safety syringe presented a highly satisfactory design, because its shape and operation are almost same as traditional syringe. Users only required to do a pulling out action after use, and although new design does not support single-hand operation, it is still quite convenient for use. Moreover, score on question 11 was relatively low because only simple models were provided during examination. This problem can be improved by using precise molds when syringe is formally put to production..

Intellectual Property Right (IPR) Issue for New Safety Syringe

To ensure a great benefit of new safety syringe, Adaptive Design Process (ADP) was introduced. From “Problem” to “Patent protection”, ADP includes 14 key steps¹⁰. With implementation of ADP, new safety syringe has successfully obtained a Taiwan Patent¹¹, making new safety syringe more competitive.

Conclusions

Six professionals conducted an SFEF questionnaire survey and FGI on three safety syringes (X, Y and Z), to find out their advantages and disadvantages. Experts rated satisfaction level of three safety syringes (X, Y and Z) on SFEF questionnaire. X safety syringe scored highest, followed by Y, and Z. Safety mechanism in X is easily triggered by mistake. For Y, even though it can be confirmed that needle is destroyed, pushing it back forward easily causes mental pressure. In Z, release ring is too close to the needle, also easily creating mental pressure. Summarizing problems with X, Y and Z, six designing principles (compatibility, clue, correctness,

containment and cognition features) were utilized in creating a new safety syringe. Subsequent to experts’ evaluation, new safety syringe was proven to be able to significantly increase their level of satisfaction. New safety syringe prevailed over X, Y and Z in terms of usage, but due to its large size after use, it is unfavorable in terms of waste reduction. Hence, new design needs further study in hope of resolving this drawback. Thus provision of a safer and more usable safety syringe design gives significant and obvious benefits for safety of needle use and prevention of spread of infectious diseases.

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