Evaluation of Engineered Phlebotomy Devices for Prevention of Percutaneous Injuries Associated with Phlebotomy Procedures

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Occupational exposure to bloodborne pathogens

- human immunodeficiency virus (HIV);
- hepatitis B virus (HBV);
- hepatitis C virus (HCV); and
- more…

Statistics in US

- annual number of needlestick injuries: 600,000[1,2]
- 15% of these injuries involve phlebotomy procedures[3]
- phlebotomy injuries caused by winged steel needles was as high as 88%.[4]

Needlestick Safety and Prevention Act

- It was introduced to the US in 2000
- It requires employers to devise engineering and work practice control to eliminate or minimize employee exposure to bloodborne pathogens.[5]

Sharps with Engineered Sharps Injury Protection (SESIP)

- defined as “a non-needle sharp or needle device used for withdrawing body fluids, accessing a vein or an artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.” [5]

Effectiveness of SESIP

- lowering the overall incidence of percutaneous injuries by more than 50%[6]
- resheathable winged steel needle by 23%[3]
- resheathable vacuum tube blood-collection needle by 66%[3]

Aims of the Study

- In view of the presence of residual risk in current blood taking methods in the DH, this study was aimed at:
  - investigating the effectiveness and staff acceptance to two safety devices
  - promoting use of engineered sharps in the department
  - raising the awareness of HCW on sharps injury in phlebotomy procedures

Methods

- The most common product evaluation is the informal evaluation or product trial that elicits subjective feedback from users and that has no sample-size requirements.[6]
- The evaluation of staff acceptances was conducted with the *Safety Device Evaluation Form* modified from the ‘Sample Device Evaluation Form’ of the S*harps Injury Prevention Workbook* adopted and validated by CDC.[7]

Targets

- The Elderly Health Services (EHS) and Tuberculosis and Chest Service (TB&CS) contributed the greatest portion of blood taking activities in the department (near 100,000 blood taking procedures in year 2005 at 15 Tuberculosis and Chest Clinics (TB&CCs) and 18 Elderly Health Centres (EHCs)

Project Design

- A pre-and-post intervention trial comparing half-year pre-intervention and half-year post-intervention period
- percutaneous injury data collected in all clinics under the EHS and TB&CS from January through December 2006

Phase 1

- baseline rates of percutaneous injury during the use of conventional devices (standard 2-way needles and ordinary butterfly needles)
- comments of staff on their use of the devices were collected

Phase 2

- effectiveness of engineered sharps injury prevention devices (resheathable 2-way needles and resheathable butterfly needles) was assessed by comparing results and data obtained in both phases
- Percutaneous injury monitoring and the evaluation of user acceptance to both conventional and improved new devices were conducted at the end of each phase

Devise Implementation

- skill enhancement workshops were conducted that included “hands-on” experience and practices with the new devices:
  - Resheathable Butterfly Needles
  - Resheathable 2-way Needles

Resheathable Butterfly Needles

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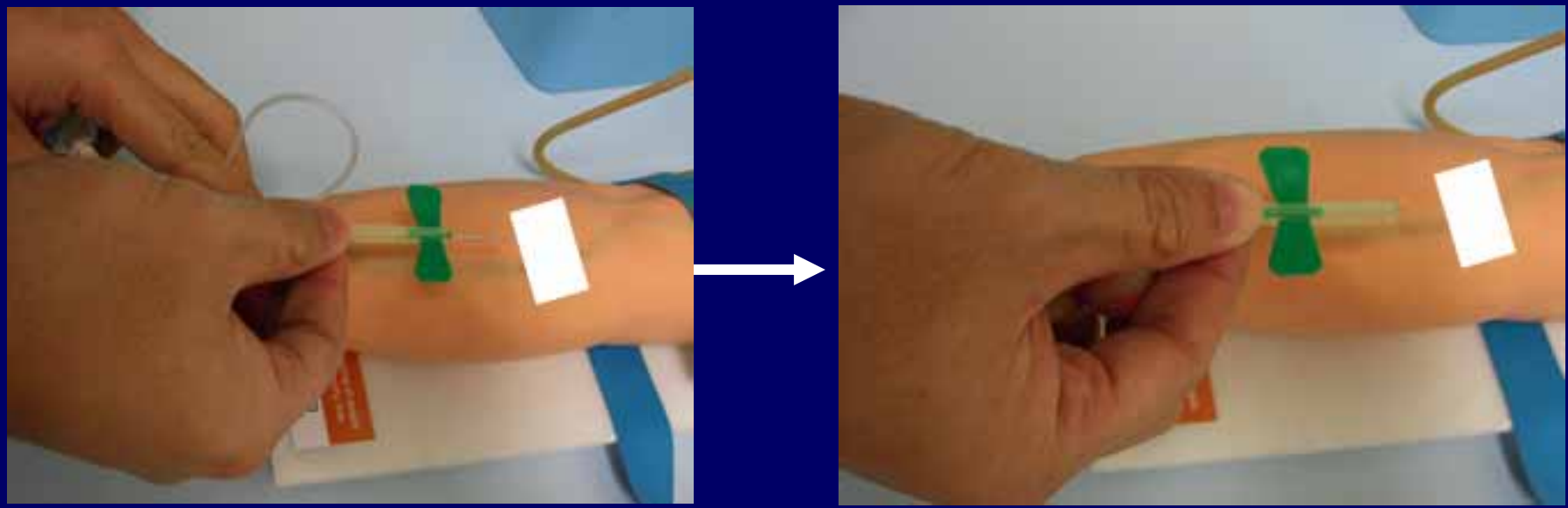
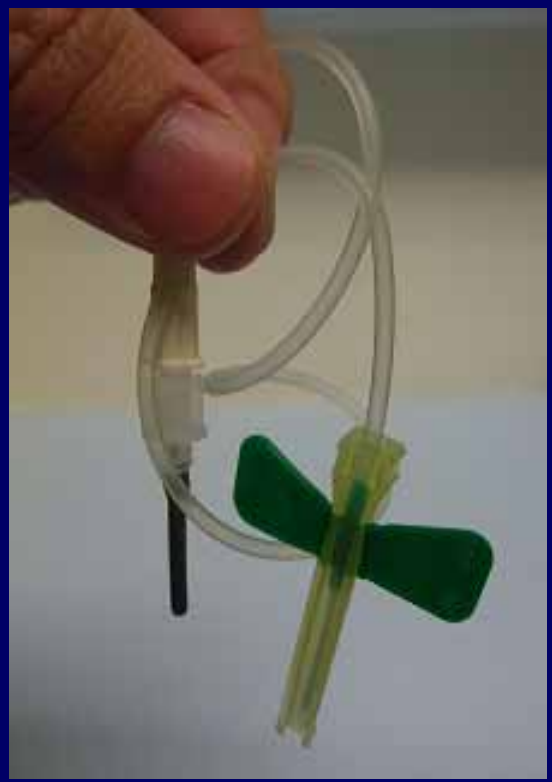
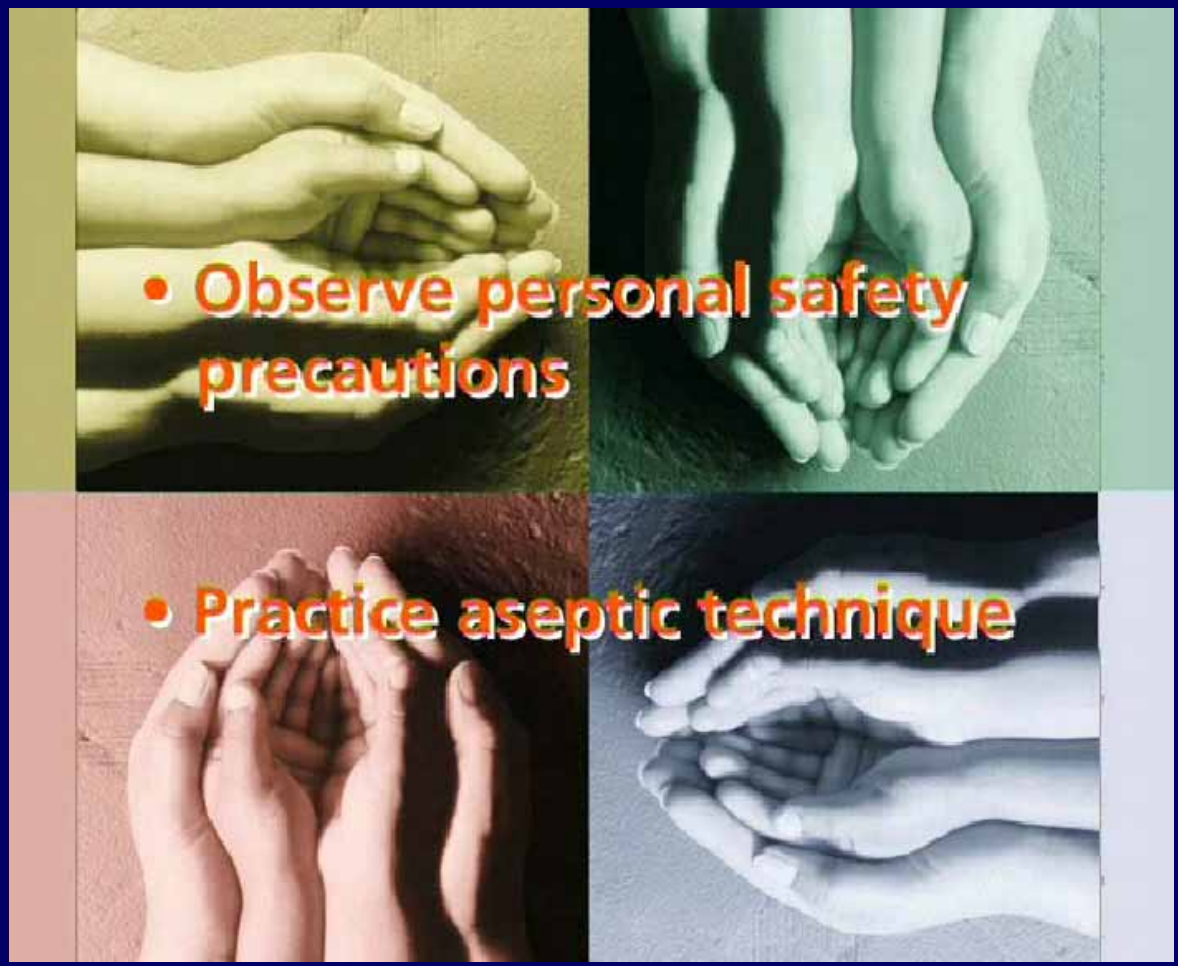
Resheathable Butterfly Needles



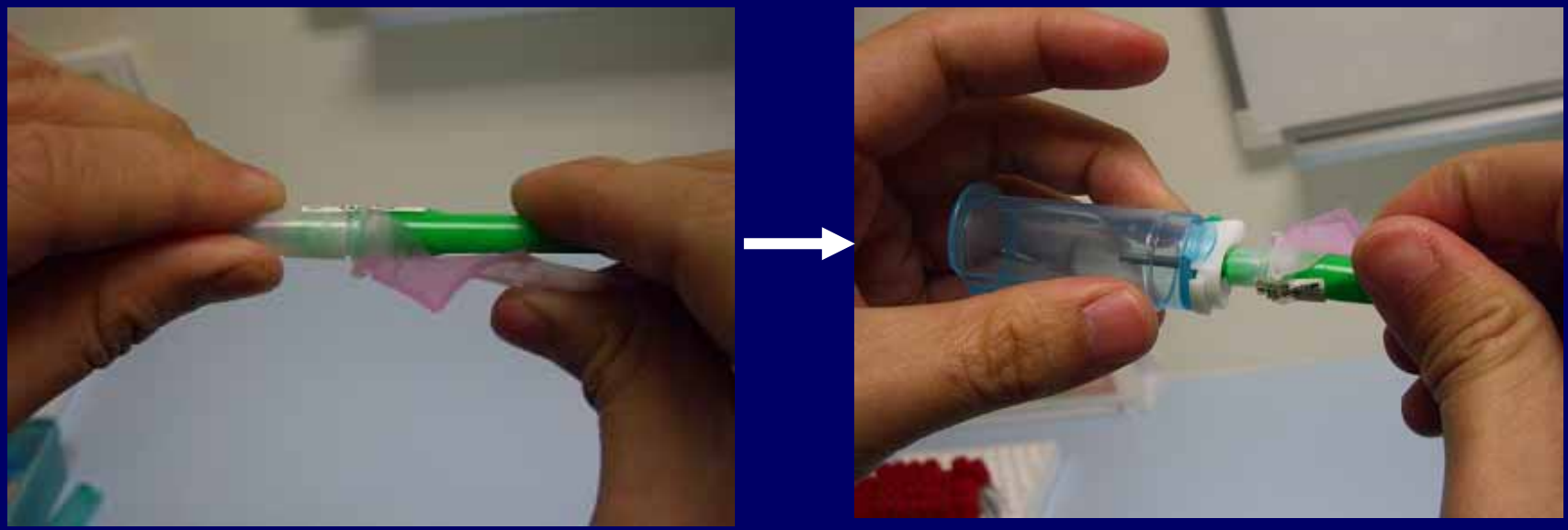
Resheathable Butterfly Needles



Resheathable 2-way Needles



Resheathable 2-way Needles



Resheathable 2-way Needles

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Resheathable 2-way Needles

Results

- Thirty-two skill-enhancement workshops were held at 14 TB&CCs and 18 EHCs
- One hundred and sixty-eight staff members from various professions and ranks, including Enrolled Nurse (EN), Registered Nurse (RN), Nursing Officer (NO), Senior Nursing Officer (SNO), Medical Officer (MO), and Senior Medical Officer (SMO) were trained in May and June 2006

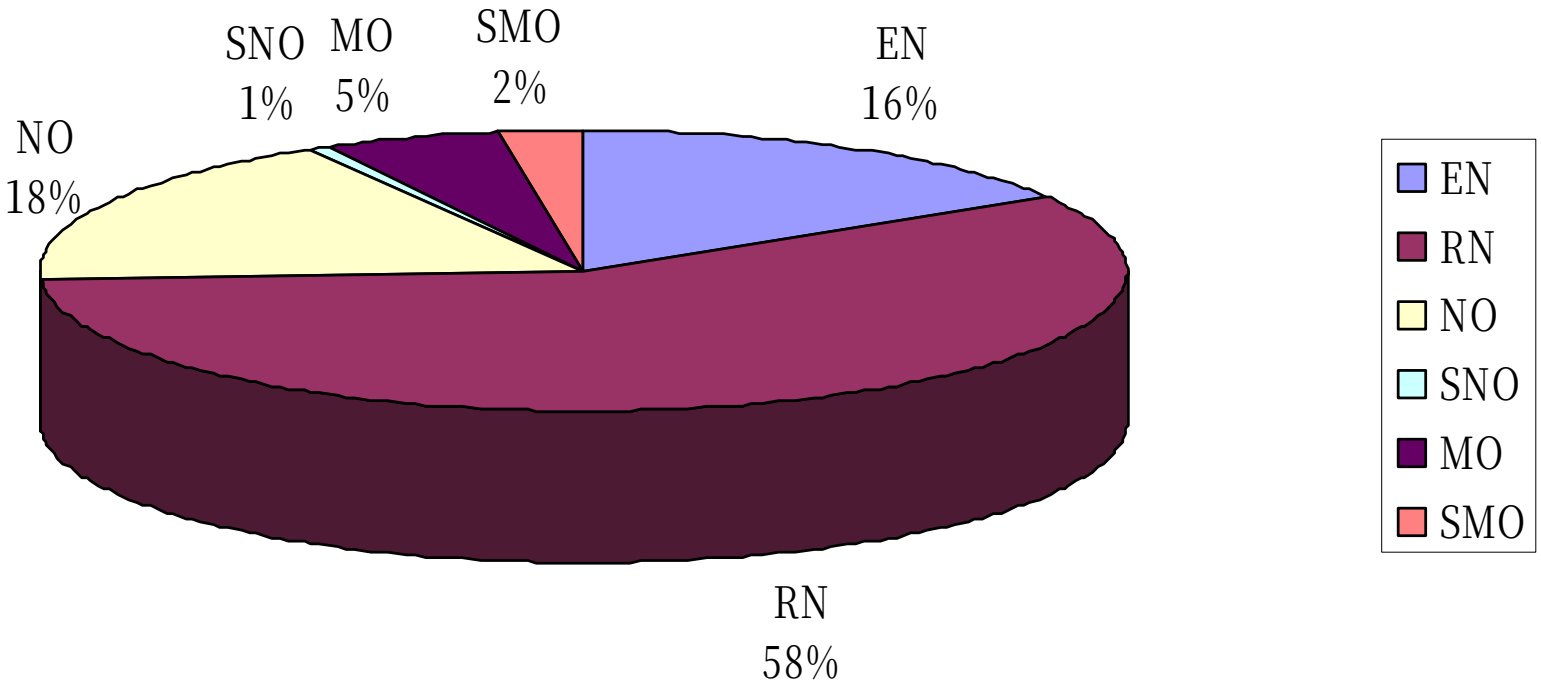


Figure 1.Distribution of Professions and Ranks of Staff Participating the Skill Enhancement Workshops before the Launch of Phase 2 of the Study.

Phase 1

- *Percutaneous Injuries*
  - *no percutaneous injury was reported by the service representatives from EHS and TB&CS*
  - 39,494 phlebotomy procedures were carried out (29,670 procedures were done with standard 2-way needles and 9,824 were done with conventional butterfly needles)

Phase 1

- *Administration of Product Evaluation Questionnaires*
  - *128 questionnaires in total were received. The response rate was roughly 76%.*
  - Likert-type scale (i.e., strongly disagree, agree, neither agree nor disagree, agree, and strongly agree) was used and assigned with a score for each of the above 5 choices from 1 to 5.
  - The mean and median of the scores given by all participants was calculated to get the overall picture or tendency of participants.

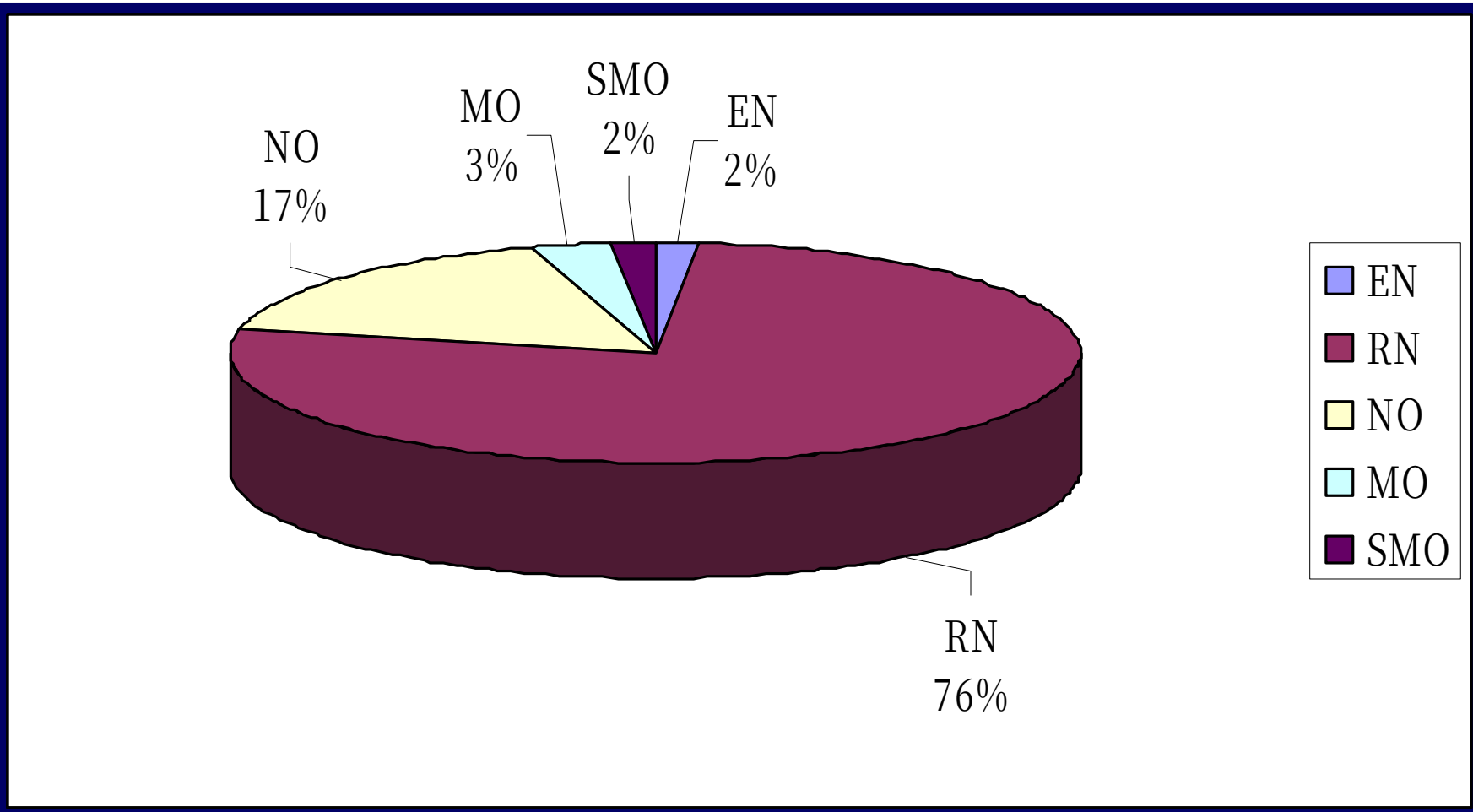
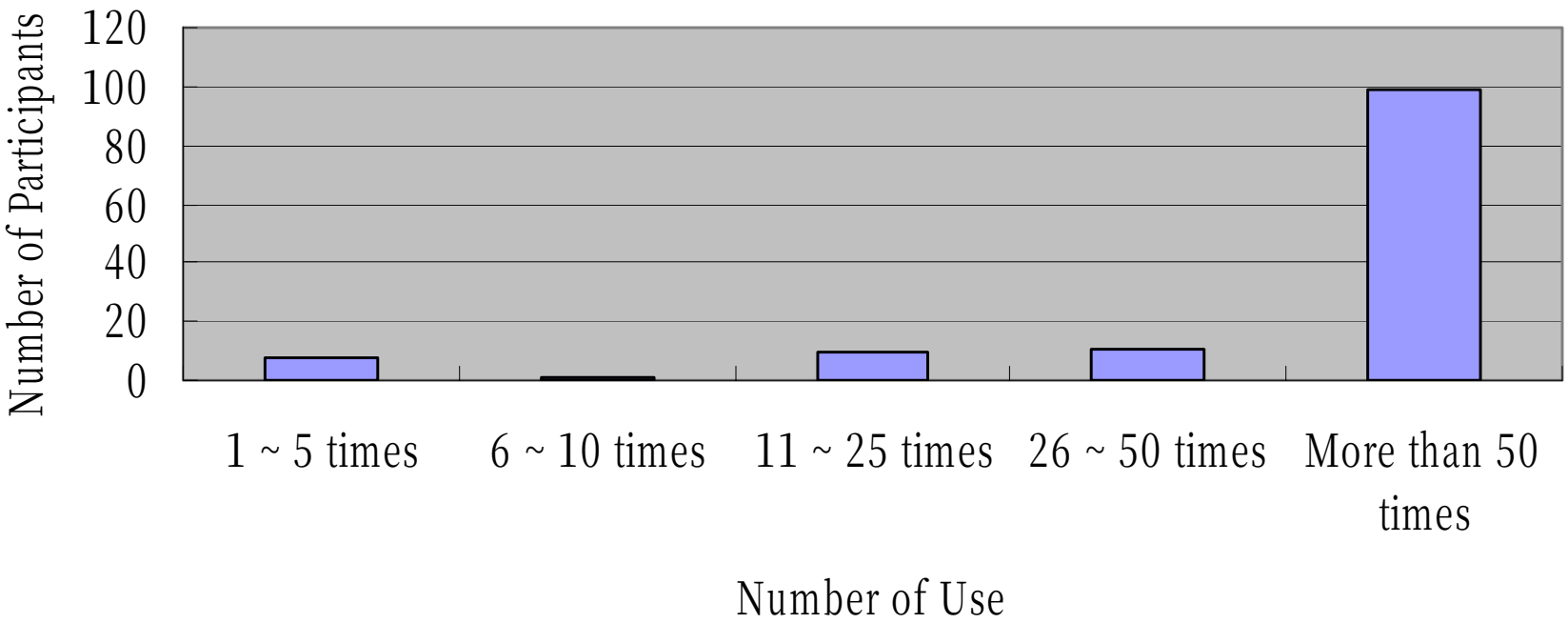


Figure 2. Distribution of Professions and Ranks of Staff Participating Phase 1 of the Study

Use of Standard 2-way Needles in Phase 1



Findings in Phase 1

Questions	Strongly Disagree (1)	Disagree (2)	Neither Agree Nor Disagree (3)	Agree (4)	Strongly Agree (5)
2a	0.0%	4.7%	23.3%	71.3%	0.8%
2b	1.6%	20.2%	36.4%	41.1%	0.8%
2c	0.8%	18.6%	16.3%	61.2%	3.1%
2d	0.8%	5.4%	21.7%	66.7%	4.7%
2e	5.4%	3.2%	23.3%	36.4%	3.1%
2f	2.3%	7.8%	20.9%	64.3%	3.9%
2g	0.8%	5.4%	17.0%	71.3%	4.7%
2h	0.8%	10.1%	26.4%	59.7%	1.6%
2i	0.0%	6.2%	24.8%	65.9%	2.3%
Overall Rating	0.8%	3.9%	20.2%	69.8%	1.6%

Table 1. Phase 1 – Comments and Overall Acceptance to the standard 2-way blood collection needles

Phase 2

- *Percutaneous Injuries*
  - *2 percutaneous injuries, caused by the use of resheathable butterfly needles, were reported*
  - 41,980 (30,859 with resheathable 2-way needles and 11,121 with resheathable butterfly steel needles) phlebotomy procedures were performed
  - The injury rates for resheathable 2-way needles and resheathable butterfly needles were 0 (95% exact CI = 0.0375%) and 1.8 (95% exact CI = 0.0649%) injuries per 10,000 phlebotomy procedures respectively

Circumstances Leading to the Accidents

- One of them happened when a nurse withdrew a resheathable butterfly needle from the vein of patient, she had her hand holding the needle bounced back inadvertently and had the needle stuck onto her hand holding the gauze for the patient.
- The other accident happened due to a nurse failing to fully activate the safety feature of resheathable butterfly needle and delaying in disposing the used needles immediately and properly into a sharps container.

Was the increase of sharps statistically significant?

Fisher's Exact Test

- p-value = 0.5019
- It is not statistically significant (p>0.05)

Administration of Product Evaluation Questionnaires (Resheathable 2-way Needle)

- 129 questionnaires were received, and the response rate was about 77%

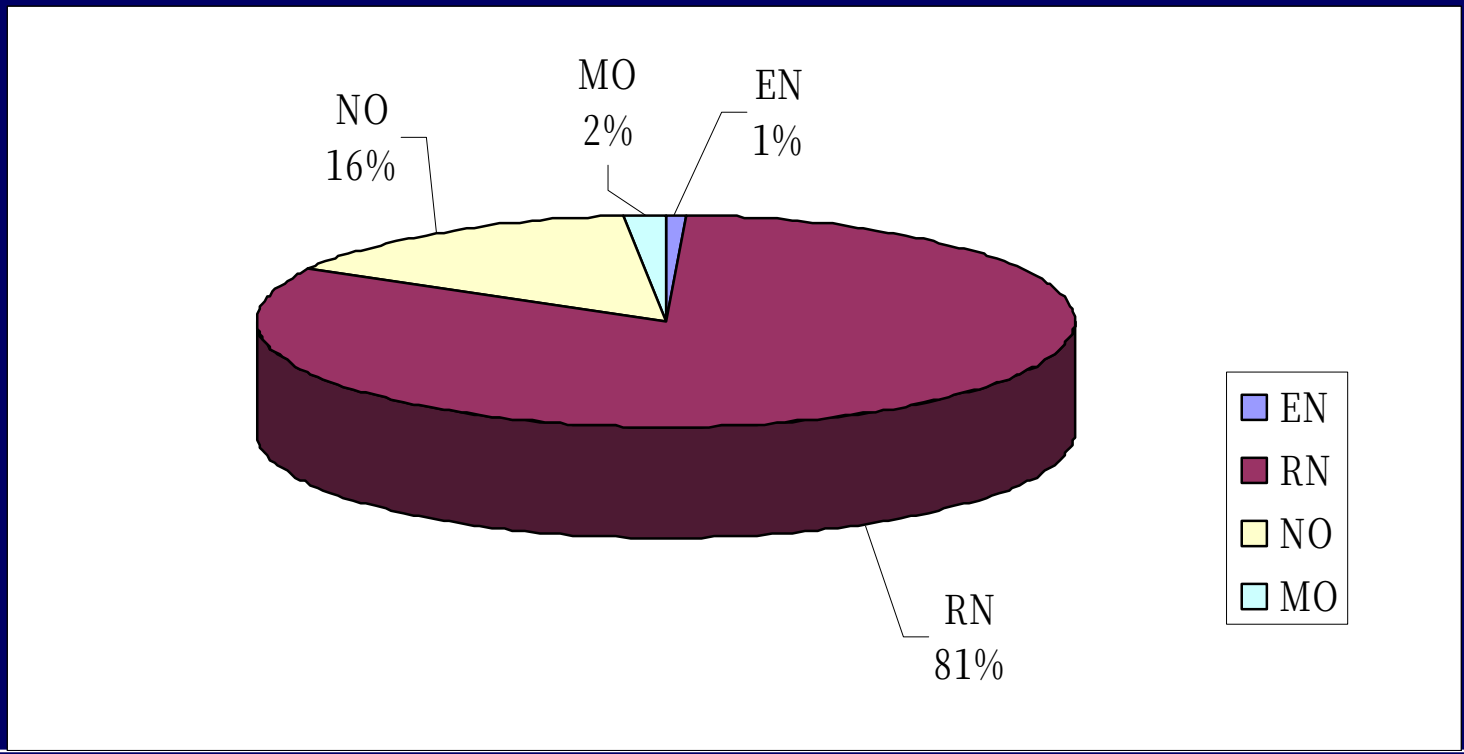


Figure 4. Distribution of Professions and Ranks of Staff Participating Phase 2 of the Study (Resheathable 2-way Needle)

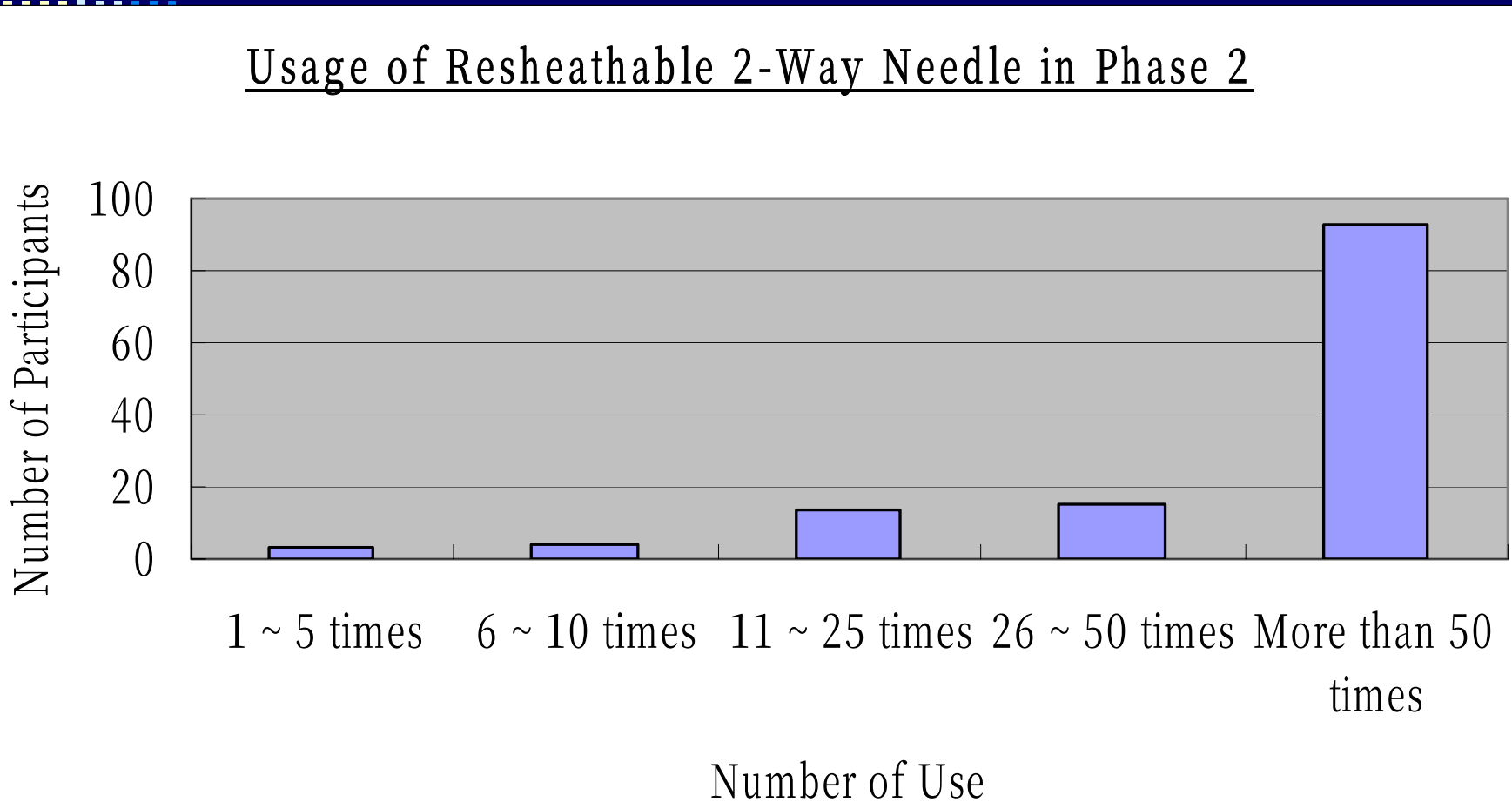


Figure 5. Frequency of Use of Resheathable 2-Way Needle in Phase 2

Findings from the Questionnaires for Resheathable 2-way Needles

- 65.9% participants agreed that the needle penetration is comparable to the old method (using syringe and needle)
- 68.2% participants agreed that the needle penetration is comparable to the standard method
- 68.2% agreed that patients do not receive more pain

- 71.3% found that the safety feature does not interfere the procedure
- 66.7% rated 4 and 16% rated 5 for the overall effectiveness
- Mean = 3.83
- Median = 3.91

Finding in Phase 2

Figure 3. Phase 2 - Resheathable 2-way					
Questions	Strongly Disagree (1)	Disagree (2)	Neither Agree Nor Disagree (3)	Agree (4)	Strongly Agree (5)
2a	0.0%	2.3%	23.3%	65.9%	8.5%
2a2	0.0%	0.0%	24.0%	68.2%	7.8%
2b	1.6%	11.6%	25.6%	54.3%	7.0%
2c	0.0%	3.1%	15.5%	68.2%	13.2%
2d	0.0%	2.3%	10.9%	70.5%	16.0%
2e	1.6%	14.7%	21.7%	54.3%	7.8%
2f	0.0%	6.2%	11.6%	71.3%	10.9%
2g	0.0%	5.4%	12.4%	68.2%	14.0%
2h	0.0%	3.9%	19.4%	66.7%	10.1%
2i	0.0%	3.9%	13.2%	68.2%	14.7%
Overall Rating	0.0%	3.0%	13.9%	66.7%	16.0%

Table 3. Phase 2 – Comments and Acceptance to Resheathable 2-way Needles

Administration of Product Evaluation Questionnaires (Resheathable Butterfly Needle

- 128 questionnaires were received. The response rate was 76%.

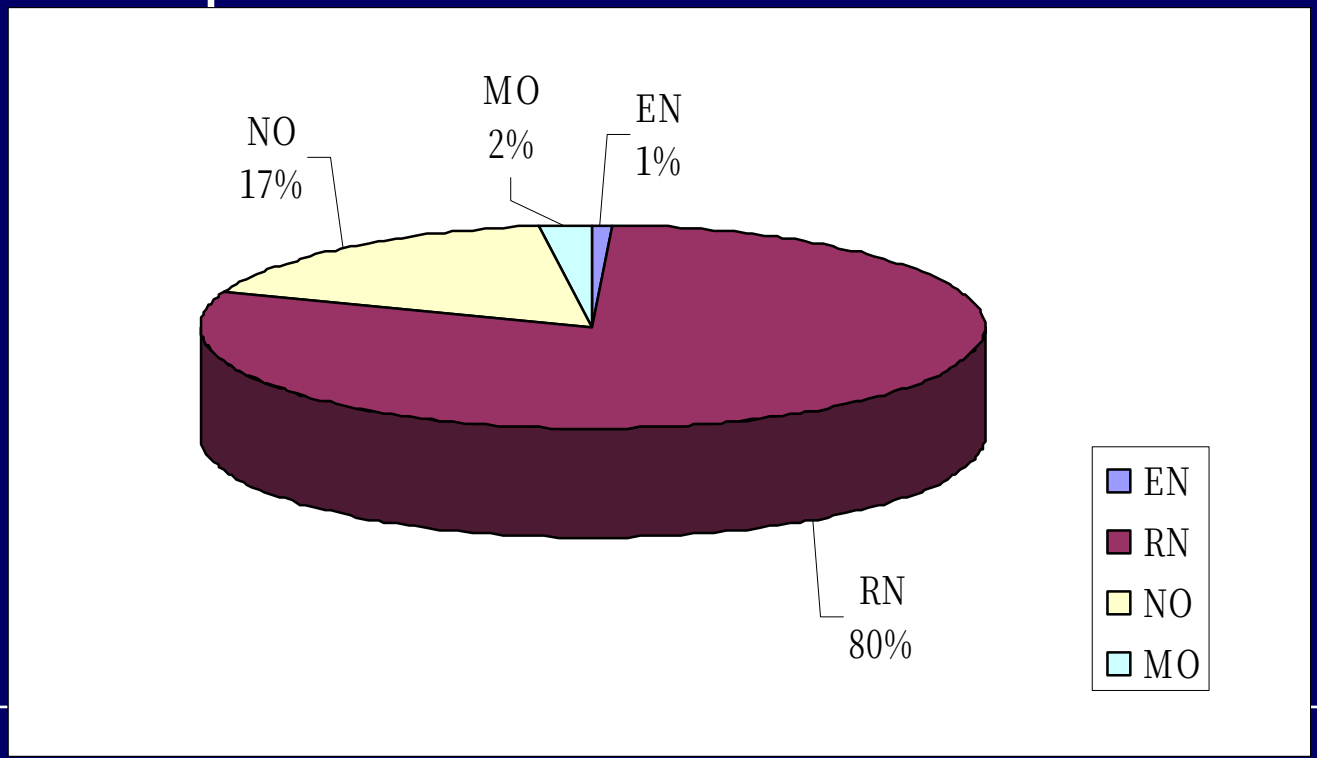


Figure 6. Distribution of Professions and Ranks of Staff Participating Phase 2 of the Study (Resheathable Butterfly Needle)

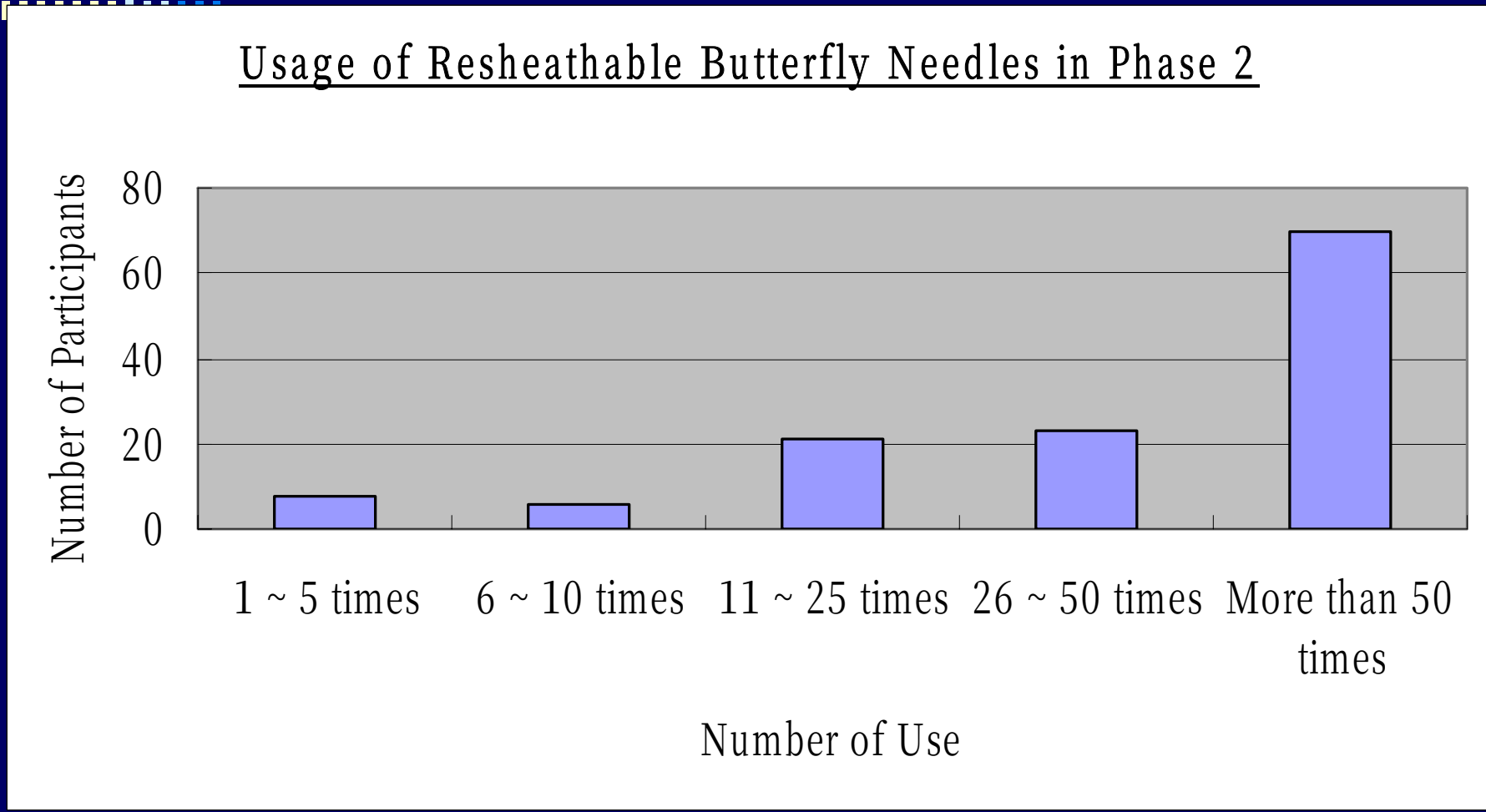


Figure 7. Frequency of Use of Resheathable Butterfly Needle in Phase 2

Findings from the Questionnaires for Resheathable Butterfly Needles

- Only 54.7% agreed that the needle penetration is comparable to ordinary butterfly needle
- 55.5% agreed that patients do not perceive more pain or discomfort
- 73.4% agreed that the device can be used for the same purpose as the original one
- Only 57% agreed that the safety feature does not interfere with procedural technique
- Only 50.82% agreed that the safety feature is easy to activate but 19.5% found it difficult

- 52% rated 4 for the overall effectiveness for both patient care and safety, 14.8% rated 5
- Mean = 3.72
- Median = 3.8

Finding in Phase 2

Questions	Strongly Disagree (1)	Disagree (2)	Neither Agree Nor Disagree (3)	Agree (4)	Strongly Agree (5)
2a	0.0%	7.0%	29.7%	54.7%	8.6%
2b	0.0%	3.9%	32.0%	55.5%	8.6%
2c	0.0%	5.5%	18.8%	64.1%	11.7%
2d	0.0%	1.6%	14.8%	73.4%	10.2%
2e	1.6%	9.4%	21.1%	58.6%	9.4%
2f	0.0%	14.1%	16.4%	57.0%	12.5%
2g	1.6%	18.0%	19.5%	50.8%	10.2%
2h	0.0%	7.8%	14.8%	64.8%	12.5%
2i	0.0%	4.7%	18.8%	63.3%	12.5%
Overall Rating	0.0%	10.9%	22.7%	52.0%	14.8%

Table 4. Phase 2 – Comments and Overall Acceptance to Resheathable Butterfly Needles

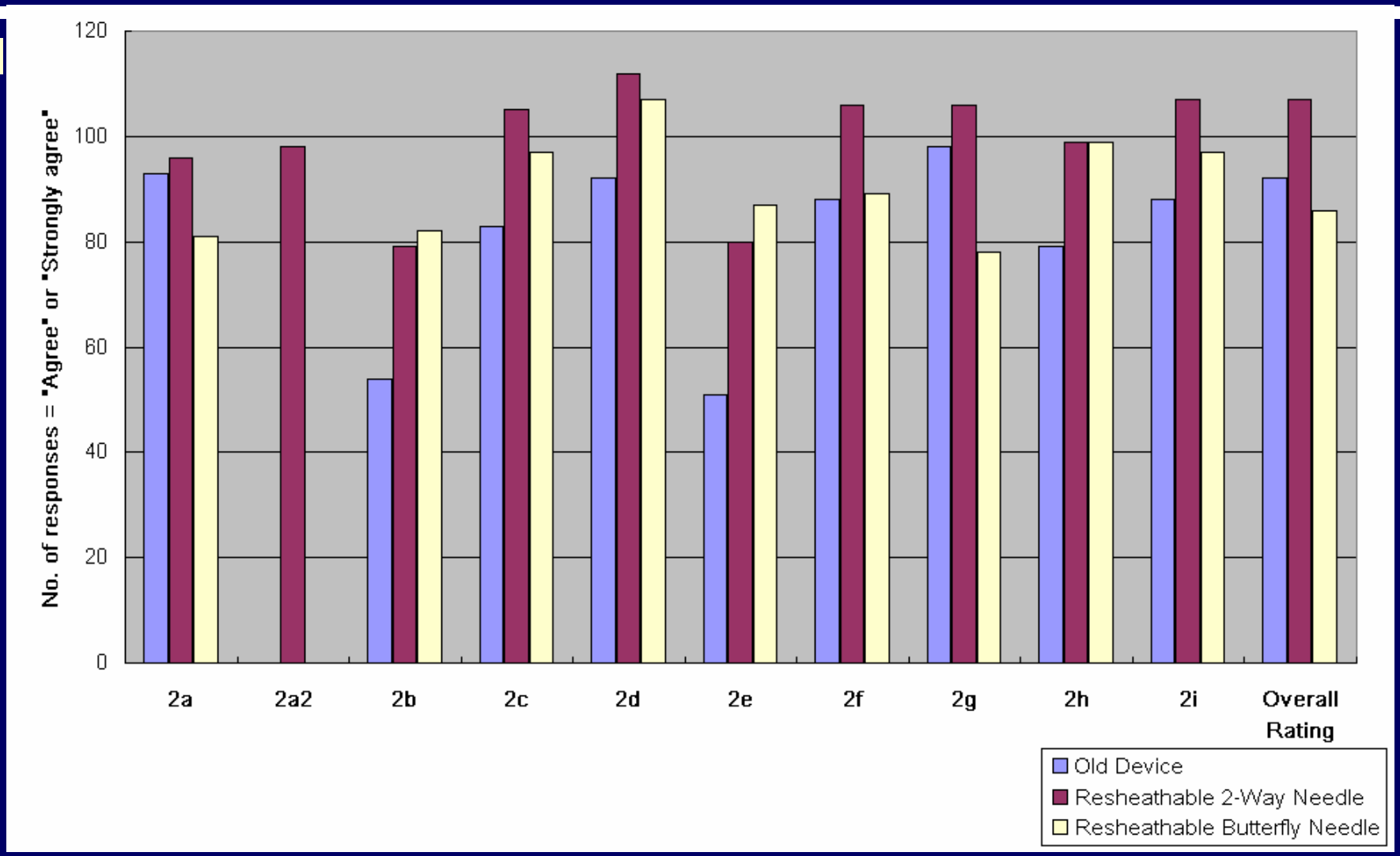


Figure 8. Comparison of Responses from Participants for All Three Device Uses

Questions

2a	Needle penetration is comparable to the standard device
2a2	The needle penetration of resheathable 2-way needle is comparable to conventional 2-way needle
2c	Patients/clients do not perceive more pain or discomfort with this device
2d	The device can be used for the safety purpose as the standard one
2e	Age or size of patient/resident does not affect use of this device
2f	The safety feature does not interfere with procedural technique.
2g	The safety feature is easy to activate
2h	The safety feature does not activate before the procedure is completed
2i	Once activated, the safety feature remains engaged
Overall rating	Overall, this device is effective for both patient/resident care and safety

Device in Evaluation	Mean of Scores	Median of Scores
Standard 2–way Needles	3.475	3.6
Resheathable 2-way Needles	3.816	3.91
Resheathable Butterfly Needles	3.727	3.8

Table 5. Comparison on Overall Level of Satisfaction on Devices Use

Statistical Analysis

- T-test used to test the significance of differences on level of satisfaction between phases and amongst different devices used
- Increase in satisfaction and acceptance to resheathable 2-way needles (p=0.000, 95% CI: -0.5164, -0.2640)
- Increase in satisfaction and acceptance to resheathable butterfly needles (p=0.000, 95% CI: -0.4952, -0.2358)

Statistical Analysis (Con't)

- Test for Association
  - Overall effectiveness of patient care and safety, and frequency of the use (week association)
  - Adequacy of training received for resheathable butterfly needles, they could use it for the same purpose as of the ordinary butterfly needle (Cramer's V=0.45, p=0.000)
  - Adequacy of training and ease of device operation (Cramer's V=0.63, p=0.000)
  - Overall level of satisfaction and perceived effectiveness and adequacy of training (Cramer's V=0.604, p=0.005)

Discussion

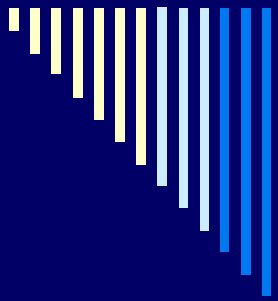
- Number of cases in Phase 2 is more than the one in Phase 1
- Device ineffective or even worse?
- Increase in number of case is not statistically significant
- Length of the study????
- Acceptance of new devices
- Improvement of the new devices

Limitation of the Study

- Length of post intervention period
- Recall bias
- Staff member too alert when being enrolled to the study at the first time?
- Skill enhancement workshop reminds staff to report injury??????

Further study

- Cost effectiveness of new device
- Cost-Benefit Analysis
- Contingent Valuation
- Effect on staff education and make use of territory-wide surveillance data



Thank you!

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