

CHAPTER IV

RESULTS



This present study was designed with the purpose to investigate the contamination rate of PN solutions prepared from a traditional separated room compared with a cleanroom in Ramathibodi Hospital. Cost analysis was also compared.

4.1 The Validation of Sterile Area

Six TSA plates were placed in LAFH. Five plates were exposed to air in the hood and one plate was exposed to room air. In both separated room and cleanroom, settling plate method was performed every other day, 8 weeks at each site. The results are presented in Appendix B. The results showed that most of TSA plates placed in the separated room were contaminated, particularly at position 4 and position 7. Most contaminated organisms were gram-positive aerobic cocci and rods. Gram negative microorganisms and fungi were found in some extent. In contrast, no microorganism growth was found in most TSA plates placed in the cleanroom. Almost contaminated TSA plates in the cleanroom were gram-positive microorganisms. Figure 6 shows types and number of microorganisms found during the study.

Eventually, the comparison of two sites was made by frequencies of microorganism growth on TSA plates (Table 9). The Chi-Square test was used to evaluate the difference. The result showed that TSA plates from the separated room

were more contaminated than those from the cleanroom in every position of TSA plates. The significant difference ($p < 0.05$) was found in position 2, 4, 5 and 7, resulting in significantly difference in the sum of all plates.

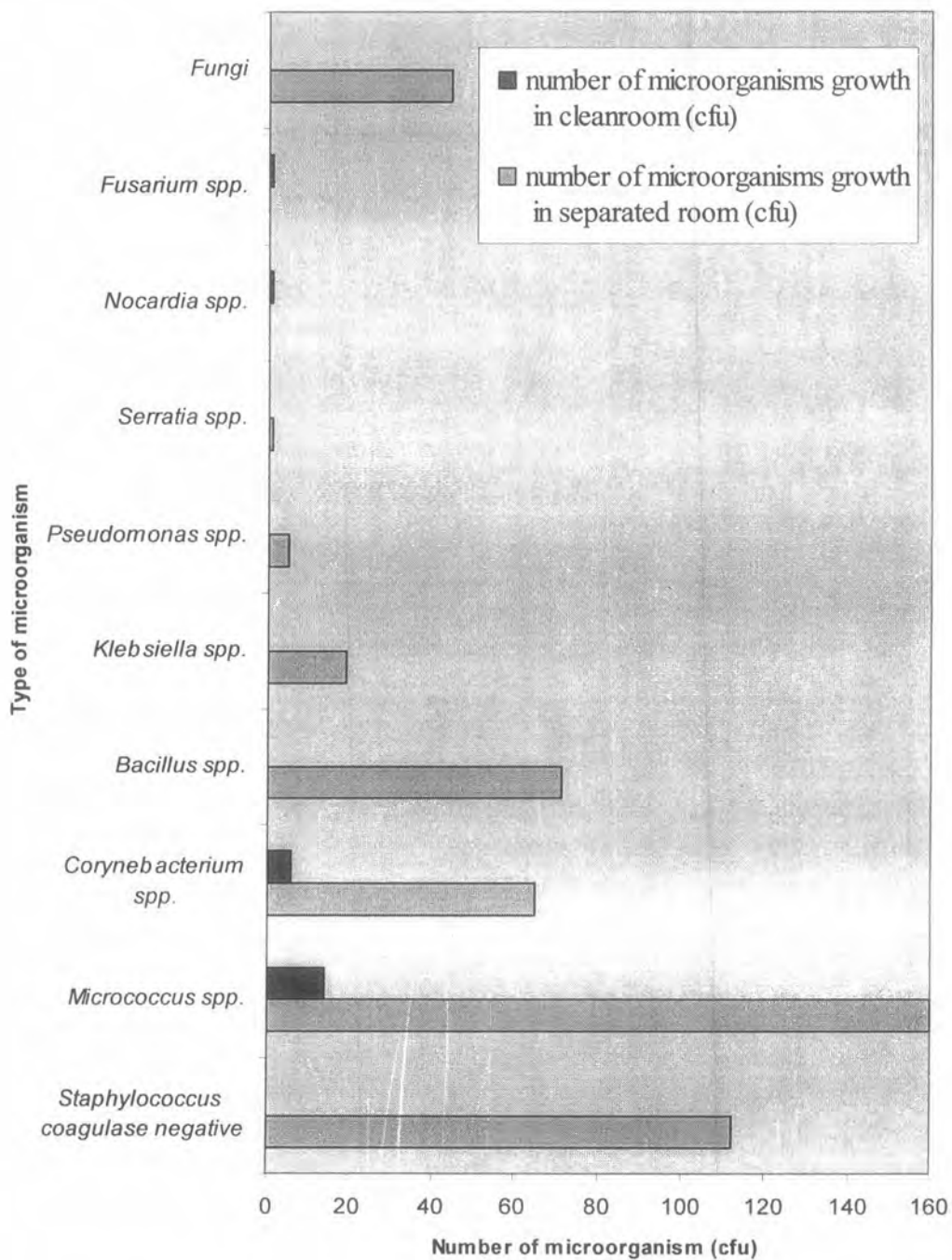


Figure 6 Type and number of microorganisms found in the separated room and cleanroom

Table 9 The number of contaminated TSA plates and TSB bottles in the separated room and cleanroom

Media form and position	Separated room* Frequency (%)	Cleanroom** Frequency (%)	p-value (χ^2 , df)
TSA plates			
position 1	4 (16.67)	2 (8.33)	0.333 (0.762,1)
position 2	7 (29.17)	1 (4.17)	0.024 (5.400,1)
position 3	7 (29.17)	3 (12.50)	0.143 (2.021,1)
position 4	21 (87.50)	0 (0.00)	<0.001 (37.333,1)
position 5	9 (37.50)	0 (0.00)	0.001 (11.077,1)
position 7	22 (91.67)	8 (33.33)	<0.001 (17.422,1)
total	70 (48.61)	14 (9.72)	<0.001 (52.706,1)
TSB bottles	7 (0.94)	0 (0.00)	0.008 (6.845,1)

* October 22nd, 2007 - December 16th, 2007

** November 3rd, 2008 – December 28th, 2008

4.2 Sterility Test of Parenteral Nutrition

Numbers and types of PN prepared from the separated room and cleanroom were presented in Table 10 and Table 11 respectively. Numbers of PN prepared in both sites were slightly different. Seven hundred and forty-eight of PN prepared in the separated room were tested for sterility. It was found that 7 samples were contaminated (Table 12). In cleanroom, 728 samples were tested for sterility and no microorganism was found. The positive control could support microbial growth while the negative control was found no microorganism in every test. It revealed that there was statistical difference ($p < 0.05$) in sterility of PN prepared between both sites (Table 9).

Table 10 Numbers of various types of PN prepared in the separated room*

Time	Ped. PN (bottles)	Adult PPN (bottles)	Adult TPN (bottles)	Number/week (bottles)
week 1	149	167	159	475
week 2	150	153	143	446
week 3	199	196	72	467
week 4	188	182	124	494
week 5	181	186	127	494
week 6	149	186	177	512
week 7	146	111	194	451
week 8	124	92	144	360
total	1,286	1,273	1,140	3,699

* October 22nd, 2007 - December 16th, 2007**Table 11** Numbers of various types of PN prepared in the cleanroom*

Time	Ped. PN (bottles)	Adult PPN (bottles)	Adult TPN (bottles)	Number/week (bottles)
week 1	129	132	127	388
week 2	136	100	149	385
week 3	187	82	132	401
week 4	165	140	126	431
week 5	178	121	187	486
week 6	175	106	191	472
week 7	197	127	173	497
week 8	184	177	211	572
total	1,351	985	1,296	3,632

* November 3rd, 2008 - December 28th, 2008

Table 12 Result of microorganism culture on TSB medium from the separated room

Date	Code	Formula	Microorganism
27-Oct-07	B57	Adult TPN	<i>Staph. coag neg.</i>
	B103	Adult TPN	<i>Corynebacterium spp.</i>
3-Nov-07	B106	Adult TPN	<i>Micrococcus spp.</i>
11-Nov-07	B38	Pediatric PN	<i>Staph. coag neg.</i>
14-Nov-07	B02	Adult TPN	<i>Bacillus spp.</i>
17-Nov-07	B48	Adult TPN	<i>Staph. coag neg.</i>
4-Dec-07	B25	Adult TPN	<i>Micrococcus spp.</i>

Abbreviations: Oct = October, Nov = November, Dec = December, *Staph coag neg* = *Staphylococcus coagulase negative*

4.3 Cost and Unit Cost Analyses of Parenteral Nutrition

In this study, total direct cost of PN preparation were the sum of 3 main costs that comprised of capital cost, material cost and labor cost. Unit cost of PN pediatric PN, adult PPN and adult TPN were also calculated.

4.3.1 Cost and Unit Cost of PN Prepared from the Separated Room

Total volume of PN prepared in the separated room during October 22, 2007 - December 16, 2007 was 2,999,033.39 ml. Three types of PN, pediatrics PN (661,327.19 ml), PPN (1,274,823.70 ml) and TPN (1,062,882.50 ml) were prepared. Thus, various cost of production that were shared by 3 formulas, such as capital cost, labor cost, cost of other materials, were multiplied by a cost allocation factor of 0.2205, 0.4251 and 0.3544 for pediatrics PN, adult PPN and adult TPN respectively. Total cost of PN prepared during this period is shown in Table 13. Most of overall cost was material cost, followed by labor cost and capital cost respectively.

The labor cost was analyzed from number of personnel, wages and working hours for PN processing. In the separated room period, 2 pharmacists, 3

pharmacist assistants, 1 worker and 1 messenger were analyzed. Total labor cost was 137,400 Baht per 8 weeks. The capital cost included all equipment cost used in PN processing, in which lifetime of each equipment was estimated for depreciation rate per year. Capital cost of this period was 37,891.51 Baht. The material cost comprised of nutrient cost, chemical cost, medical devices cost, office and household supplies cost, and water supply and electricity cost estimation. Nutrient cost was directly calculated in each formula preparation, 201,723.37 Baht for pediatrics PN, 311,884.51 Baht for adult PPN and 389,217.87 Baht for adult TPN. Details of cost for PN preparations are shown in Appendix C.

Although the 3 main costs were shared by 3 PN formulas, except nutrient cost that was calculated separately, cost allocation was used for determining the preparation ratio for each formula. Cost per milliliter of the preparation for each formula was then calculated by dividing the total cost of each formula by total volume of each preparation. Table 14 shows unit cost analysis of PN prepared in the separated room. Unit cost per milliliter of pediatrics PN, adult PPN and adult TPN was 0.40, 0.34, and 0.46 Baht respectively.

4.3.2 Cost and Unit Cost of PN Prepared in the Cleanroom

In the cleanroom period, volume of PN preparations had slightly differ from the separated room period, that 618,582.17 ml (21.49%), 975,297.40 ml (33.88%) and 1,284,785.20 ml (44.63%) of pediatric PN, adult PPN and adult TPN respectively were prepared, which could allocated them respectively into 0.2149, 0.3388, and 0.4463 for each formula. Surprisingly, nutrient cost of pediatric PN formula in the cleanroom period was higher than the separated room period even lesser volume were prepared, attributed to the higher use of 10% Aminoven infant[®] above 2 times (Appendix C). Total cost of PN prepared in the cleanroom during

November 3, 2008-December 28, 2008 is shown in Table 13. Proportion of labor cost, capital cost and material cost was 9.51%, 4.05% and 86.44% respectively.

The labor cost of this period was 129,400 Baht quoted from 2 pharmacists, 2 pharmacist assistants, 1 worker and 1 messenger. The labor cost was reduced when compared with the separated room period. This was due to the decreasing of a pharmacist assistant. Capital cost of this period was 55,047.42 Baht, which arose chiefly from construction cost. The material cost was slightly increased from the previous period, due to the chemical cost in which benzalkonium chloride was introduced (Appendix C). Finally, unit cost of each formula was calculated, and the results showed 0.49, 0.36, and 0.55 Baht per milliliter for pediatric PN, adult PPN and adult TPN respectively (Table 14).

Unit cost of PN prepared from 2 sites was compared. The result showed that the cost of PN prepared from the cleanroom was higher than those from the separated room (Table 14).

Table 13 The cost of PN prepared in the separated room and the cleanroom

Cost (Baht)	Separated room		Cleanroom	
	Baht	%	Baht	%
Labor cost	137,400.00	11.91	129,400.00	9.51
Capital cost	37,891.51	3.28	55,047.42	4.05
Material cost	978,898.41	84.81	1,176,138.84	86.44
Total cost	1,154,189.92	100.00	1,360,586.26	100.00

Table 14 The unit cost of PN prepared in the separated room and cleanroom

Cost	Separated room			Cleanroom		
	Pediatric PN	Adult PPN	Adult TPN	Pediatric PN	Adult PPN	Adult TPN
Labor cost (Baht)	30,402.54	58,612.79	48,864.67	27,911.21	44,003.35	57,965.44
Capital cost (Baht)	8,355.08	16,107.68	13,428.75	11,829.69	18,650.07	24,567.66
Material cost (Baht)	224,712.29	356,204.65	426,166.95	262,108.36	289,373.56	624,656.92
Volume (ml)	661,327.19	1,274,823.70	1,062,882.50	618,582.17	975,297.40	1,284,785.20
Preparation ratio	0.2205	0.4251	0.3544	0.2149	0.3388	0.4463
Unit cost (Baht/ml)	0.40	0.34	0.46	0.49	0.36	0.55
Unit cost difference (%)				+22.50	+5.88	+19.57