

## A STUDY ON THE HANDLING AND PREPARATION OF CYTOTOXIC DRUGS IN SOME HOSPITALS IN INDONESIA

By

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### INTRODUCTION

- A cytotoxic drug is a drug that possesses a specific destructive action on certain cells
- Has inherent mutagenicity, carcinogenicity, teratogenicity, may be risks for long-term, low level exposure to these drug by personnel who are responsible for their handling and preparation
- Healthcare providers who are responsible for the use of cytotoxic drugs are:
  - Doctors: in the selection and administration
  - Nurses: in the administration
  - Pharmacist: in the management of every aspect related to cytotoxic drugs : safety of stock, storage and distribution of drugs, information service in selection and determination of the regime according to the need of each individual patient
- Therefore, the appropriateness in the handling and preparation of cytotoxic drugs as done by the pharmacy departments were researched.

## METHODOLOGY

Methodology of this research covered :

- A reference study : Cancer disease and therapeutic, chemotherapy of cancer, Pharmacy function in preparation and handling of cytotoxic drugs, etc.
- Introduction study to determine the hospitals that were to be studied.
- A study using reference books were done to compile a standard , which would serve as a reference and be used to determine the appropriateness or non-appropriateness of handling and preparation of cytotoxic drugs.
- Designing and preparing the forms for collecting the data, based on the standard above.
- To organize and to analyze the data quantitatively and qualitatively

## DESIGN AND PROCEDURE OF THE RESEARCH

- Determination of hospitals that were to be studied, based on criteria of hospitals with more than 50 chemotherapy cases in December – February 2004.  
Hospitals in accordance with these criteria were:
  1. National Cancer Reference Hospital (NCRH)
  2. Government General Hospital (GGH)
  3. Private General Hospital (PGH)

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The standard of the handling and preparation of cytotoxic drugs covered the following policies and procedures on the handling of cytotoxic drugs :

- Policy and Procedure; Employment of personnel
- Orientation of new employees
- Occupational preventive medicine ( medical examinations)
- Training of personnel
- Evaluation of personal performance
- Information service
- Room and Room air equipment
- Personal protective equipment
- Technical equipment for production
- Infusion pump for the administration
- Evaluation of the prescription
- Preparation of injectable cytotoxics
- Preparation of non-injectable dosage forms of cytotoxic drugs
- Labels; Container and transport
- Validation of aseptic technique
- Waste disposal ; Pharmaceutical care the patient
- Administration ; Decontamination after inadvertent release
- Extravasation

- That standard would serve as a reference and be used to determine the appropriateness or non-appropriateness of handling and preparation of cytotoxic drugs.
- Data was collected at three hospitals by observation and interviews during January-February 2005.
- The data was organized in table form and compared using a scoring system 0 to 4 where the standard was always given a score of 4
- The three hospitals were scored as follows :
  - 0 = not done at all
  - 1 = small portion done according to standard (25%)
  - 2 = close to the standard (50%)
  - 3 = almost fulfilling the standard (75%)
  - 4 = according to the standard (100%)

### Analyzed the data

- The scores of every parameter and sub-parameter in the table comparing the three hospitals with the standard were separately counted and each given a total score.
- The total value of each parameter and sub-parameter of the relevant hospital were expressed as a percentage of the total score of the standard and analyzed as follows:
  - 0 = not done at all
  - 1 – 49% = a small portion close to the standard
  - 50 – 74% = close to the standard
  - 75 – 99% = almost fulfilling the standard
  - 100% = according to the standard

## RESULT AND DISCUSSION

Table 1: Comparison of data score of the policy and procedure

Paramater/sub-parameter	Score			
	Standard	NCRH	GGH	PGH
Policy and Procedure	108	78 (72%)	21 (19%)	23 (21%)
Existence, documentation, suitability with the regulation	12	12 (100%)	2 (17%)	2 (17%)
Scope	84	56 (67%)	18 (21%)	20 (24%)
Collaboration, availability, adherence	12	10 (83%)	1 (8%)	1 (8%)

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Table 2: Comparison of data score total of the personnel

Paramater/sub-parameter	Score			
	Standard	NCRH	GGH	PGH
Employment of personnel	52	34 (65%)	8 (15%)	7 (14%)
Interview	16	8 (50%)	2 (13%)	2 (13%)
Personnel will be employed	24	20 (83%)	6 (25%)	5 (21%)
Medical examination	12	6 (50%)	0	0
Orientation of new employees	24	12 (50%)	7 (29%)	7 (29%)
Scope of orientation	12	12 (100%)	7 (58%)	7 (58%)
Documentation	12	0	0	0
Occupational preventive	72	33 (46%)	0	32 (44%)
Availability	16	10 (63%)	0	6 (38%)
Scope	56	23 (41%)	0	26 (46%)
Training of personnel	96	78 (81%)	43 (45%)	53 (55%)
Existance	4	4 (100%)	3 (75%)	2 (50%)
Personnel will be trained	20	20 (100%)	5 (25%)	8 (40%)
Scope and procedure	72	54 (75%)	35 (49%)	43 (59%)

Table 2: Comparison of data score total of the personnel

Paramater/sub-parameter	Score			
	Standard	NCRH	GGH	PGH
Evaluation of personal performance	20	9 (45%)	3 (15%)	4 (20%)
Existance	12	5 (42%)	2 (17%)	4 (33%)
Scope	8	4 (50%)	1 (13%)	0

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Table 3: Comparison of data score of the Information Service

Paramater/sub-parameter	Score			
	Standard	NCRH	GGH	PGH
Information service	60	54 (90%)	41 (68%)	19 (32%)
Personnel	8	6 (75%)	2 (25%)	2 (25%)
Professional collaboration	12	10 (83%)	8 (67%)	2 (17%)
Scope of information	40	38 (95%)	31 (78%)	15 (38%)

Table 4: Comparison of data score of the room

Paramater/sub-parameter	Score			
	Standard	NCRH	GGH	PGH
Room	384	270 (70%)	16 (4%)	21 (6%)
Sterilization	4	4 (100%)	0	0
Production	108	95 (88%)	0	0
Air Lock	56	20 (36%)	0	0
Preparation	24	19 (79%)	0	0
Documentation	36	15 (42%)	0	0
Storage	44	23 (52%)	16 (36%)	21 (48%)
Access to the room	16	15 (94%)	0	0
Cleaning and disinfection	52	37 (71%)	0	0
Procedure of control in production room	44	42 (95%)	0	0

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Table 5: Comparison of data score of the room air equipment

Paramater/sub-parameter	Score			
	Standard	NCRH	GGH	PGH
Room air equipment	364	202 (55%)	0	0
Room air equipment- LAF	244	126 (52%)	0	0
Room air equipment - removal and supplying air system	68	24 (35%)	0	0
Room air equipment – certification and examination	52	52 (100%)	0	0

Table 6: Comparison of data score of the personal protective equipment

Paramater/sub-parameter	Score			
	Standard	NCRH	GGH	PGH
Personal protective equipment	312	283 (91%)	124 (40%)	153 (49%)
Obligated	4	4 (100%)	2 (50%)	4 (100%)
Scope	48	48 (100%)	8 (17%)	13 (27%)
Gown	56	56 (100%)	21 (38%)	25 (45%)
Gloves	120	97 (81%)	57 (48%)	68 (57%)
Respiratory protection	48	48 (100%)	29 (60%)	34 (71%)
Eyes protection	16	15 (94%)	7 (44%)	9 (56%)
Overshoes	20	15 (75%)	0	0

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Table 7: Comparison of data score of the technical equipment for production

Paramater/sub-parameter	Score			
	Standard	NCRH	GGH	PGH
Technical equipment for production	424	222 (52%)	142 (34%)	170 (40%)
Appropriateness with criteria, sterility, quality	16	16 (100%)	9 (56%)	9 (56%)
Storage	48	40 (83%)	29 (60%)	31 (65%)
Technical equipment scope	76	26 (34%)	19 (25%)	20 (26%)
Work cover 3 layers	32	29 (91%)	12 (38%)	25 (78%)
Towel and absorbent	20	20 (100%)	5 (25%)	10 (50%)
Syringes	40	30 (75%)	25 (63%)	30 (75%)
Needles	36	25 (69%)	25 (69%)	26 (72%)
Containers for disposal of needles	12	12 (100%)	6 (50%)	5 (42%)
Waste container	12	12 (100%)	4 (33%)	6 (50%)
Cover of disposable syringe	8	4 (50%)	0	0

Table 7: Comparison of data score of the technical equipment for production

Paramater/sub-parameter	Score			
	Standard	NCRH	GGH	PGH
Filter needle/filter absorbent	28	0	0	0
Closed system	68	0	0	0
Discharge pressure system	20	8 (40%)	8 (40%)	8 (40%)
Balance	8	0	0	0
Infusion pump for the administration	76	62 (82%)	22 (29%)	67 (88%)
Suitability with the regulation	16	13 (81%)	9 (56%)	13 (81%)
Using	4	4 (100%)	1 (25%)	2 (50%)
Purchasing	40	29 (73%)	0	36 (90%)
Filling up	16	16 (100%)	12 (75%)	16 (100%)

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Table 8: Comparison of data score of the prescription evaluation

Parameter /sub-parameter	Score			
	Standard	NCRH	GGH	PGH
Evaluation of the prescription	164	76 (46%)	81 (49%)	66 (40%)
Prescription acceptance	68	0	0	0
Information in prescription	20	8 (40%)	8 (40%)	8 (40%)
Adjustment doses	8	0	0	0

Table 9: Comparison of data score of the technique aseptic validation

Parameter/Sub-parameter	Score			
	Standard	NCRH	GGH	PGH
Validation of aseptic technique	80	74 (93)	0	0
Suitability with the monograph	16	16 (100%)	0	0
Validation	36	34 (94%)	0	0
Microbiologic status evaluation of the final product	28	24 (86%)	0	0

Table 10: Comparison of data score of the preparation, labels, container and transportation

Parameter/sub-parameter	Score			
	Standard	NCRH	GGH	PGH
Preparation of injectable drugs	432	327 (76%)	144 (33%)	174 (40%)
Work instruction	16	13 (81%)	4 (25%)	9 (56%)
Specification of the production	48	31 (65%)	10 (21%)	10 (21%)
Documentation	56	36 (64%)	0	6 (11%)
Work order	312	274 (79%)	130 (42%)	149 (48%)
Preparation of non-injectable dosage forms of cytotoxic drugs	72	61 (85%)	46 (64%)	61 (85%)
Calculation and pouring	40	30 (75%)	28 (70%)	38 (95%)
Mixing	32	31 (97%)	18 (56%)	23 (72%)
Labels, Container and transport	196	147 (75%)	15 (8%)	19 (10%)
Label	100	60 (60%)	11 (11%)	15 (15%)
Container and Transportation	96	87 (91%)	4 (4%)	4 (4%)

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Table 11: Comparison of data score of the waste disposal

Paramater/sub-parameter	Score			
	Standard	NCRH	GGH	PGH
Waste disposal	196	174 (89%)	60 (31%)	79 (40%)
Suitability with the requirment	20	20 (100%)	10 (50%)	11 (55%)
Centralization or decentralization of the waste	16	13 (81%)	9 (56%)	9 (56%)
Container	28	27 (96%)	13 (46%)	19 (68%)
Controlled waste	12	4 (33%)	4 (33%)	4 (33%)
Waste for patient homecare	28	28 (100%)	0	0
Biological waste	40	34 (85%)	11 (28%)	21 (53%)
Filter and LAF	20	20 (100%)	0	0
Transportation container of the waste	32	28 (88%)	13 (41%)	15 (47%)

Table 12: Comparison of data score of the Pharmaceutical care the patient

Paramater/sub-parameter	Score			
	Standard	NCRH	GGH	PGH
Pharmaceutical care the patient	140	51 (36%)	92 (66%)	0
Patient counseling	124	50 (40%)	84 (68%)	0
Documentation	16	1 (6%)	8 (50%)	0

Table 13: Comparison of data score of the administration

Parameter/Sub-parameter	Score			
	Standard	NCRH	GGH	PGH
Administration	148	133 (90%)	89 (60%)	113 (76%)
Selection of administration devices	8	7 (88%)	6 (75%)	7 (88%)
Preparation of final product	36	35 (97%)	21 (58%)	29 (81%)
Rinsing	36	33 (92%)	33 (92%)	32 (89%)
IV container	16	12 (75%)	5 (31%)	12 (75%)
Personal safety	52	46 (89%)	24 (46%)	33 (64%)

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Table 14: Comparison of data score of the decontamination and extravasation

Parameter/Sub-parameter	Score			
	Standard	NCRH	GGH	PGH
Decontamination after inadvertent release	236	136 (58%)	15 (6%)	47 (20%)
Work instruction	28	19 (68%)	2 (7%)	16 (57%)
Compliance with the regulation	32	29 (91%)	9 (28%)	24 (75%)
Decontamination kit and procedure	176	88 (50%)	4 (2%)	7 (4%)
Extravasation	340	166 (49%)	98 (29%)	64 (19%)
Pharmacy Installation service	44	8 (18%)	0	1 (2%)
Irritable agent	4	1 (25%)	0	0
Prevention of extravasation	64	64 (100%)	63 (98%)	63 (98%)
Handling instruction of extravasation	124	93 (75%)	35 (28%)	0
Emergency kit of extravasation	104	0	0	0

Table 15: Comparison of data score total for all parameter

Paramater/sub-parameter	Score			
	Standard	NCRH	GGH	PGH
Policy and Procedure	108	78 (72%)	21 (19%)	23 (21%)
Employment of personnel	52	34 (65%)	8 (15%)	7 (14%)
Orientation of new employees	24	12 (50%)	7 (29%)	7 (29%)
Occupational preventive	72	33 (46%)	0	32 (44%)
Training of personnel	96	78 (81%)	43 (45%)	53 (55%)
Evaluation of personal performance	20	9 (45%)	3 (15%)	4 (20%)
Information service	60	54 (90%)	41 (68%)	19 (32%)
Room	384	270 (70%)	16 (4%)	21 (6%)
Room air equipment	364	202 (55%)	0	0
Personal protective equipment	312	283 (91%)	124 (40%)	153 (49%)
Technical equipment for production	424	222 (52%)	142 (34%)	170 (40%)

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Table 15: Comparison of data score total for all parameter

Paramater	Score			
	Standard	NCRH	GGH	PGH
Infusion pump for the administration	76	62 (82%)	22 (29%)	67 (88%)
Evaluation of the prescription	164	76 (46%)	81 (49%)	66 (40%)
Preparation of injectable cytotoxics	432	327 (76%)	144 (33%)	174 (40%)
Preparation of non-injectable dosage forms of cytotoxic drugs	72	61 (85%)	46 (64%)	61 (85%)
Labels, Container and transport	196	147 (75%)	15 (8%)	19 (10%)
Validation of aseptic technique	80	74 (93)	0	0
Waste disposal	196	174 (89%)	60 (31%)	79 (40%)
Pharmaceutical care the patient	140	51 (36%)	92 (66%)	0
Administration	148	133 (90%)	89 (60%)	113 (76%)
Decontamination after inadvertent release	236	136 (58%)	15 (6%)	47 (20%)
Extravasation	340	166 (49%)	98 (29%)	64 (19%)
<b>Total value</b>	<b>3996</b>	<b>2682(67%)</b>	<b>1067 (27%)</b>	<b>1179 (30%)</b>

## CONCLUSION

### National Cancer Reference Hospital (NCRH)

- On the whole, this hospital was close to the standard with a percentage of 67%
- In detail :
  1. Almost fulfilling the standard (75-99%): Training of personnel; Information service; Personal protective equipment; Infusion pump for the administration; Preparation of injectable cytotoxics; Preparation of non-injectable dosage forms of cytotoxic drugs; Labels; Container and transport; Validation of aseptic technique; Waste disposal; Administration.
  2. Close to the standard (50-74%): Policy and procedure; Employment of personnel; Orientation of new employees; Room; Room air equipment-LAF; Technical equipment for production; Decontamination after inadvertent release.
  3. A small portion close to the standard (1-49%) : Occupational preventive medicine ( medical examinations); Evaluation of personal performance; Room air equipment- for removal and supplying system; Evaluation of the prescription; Pharmaceutical care the patient; Extravasation.

## CONCLUSION

### Government General Hospital (GGH)

- On the whole, this hospital with a small portion close to the standard with a percentage of 27%
- In detail :
  1. Close to the standard (50-74%): Information service; Preparation of non-injectable dosage forms of cytotoxic drugs; Pharmaceutical care the patient; Administration.
  2. A small portion close to the standard (1-49%) : Policy and procedure; Employment of personnel; Orientation of new employees; Training of personnel; Evaluation of personal performance; Room; Personal protective equipment; Technical equipment for production; Infusion pump for the administration; Evaluation of the prescription; Preparation of injectable cytotoxics; Labels; Container and transport; Waste disposal ; Decontamination after inadvertent release; Extravasation.
  3. Not done at all ( 0%) : Occupational preventive medicine ( medical examinations); Room air equipment-LAF; Room air equipment- for removal and supplying system; Room air equipment- for certification and examination; Validation of aseptic technique.

## CONCLUSION

### Private General Hospital (PGH)

- On the whole, this hospital with a small portion close to the standard with a percentage of 30%
- In detail :
  1. Almost fulfilling the standard (75-99%): Infusion pump for the administration; Preparation of non-injectable dosage forms of cytotoxic drugs; Administration.
  2. Close to the standard (50-74%): Training of personnel.
  3. A small portion close to the standard (1-49%) : Policy and procedure; Employment of personnel; Orientation of new employees; Occupational preventive medicine ( medical examinations); Evaluation of personal performance; Information service; Room; Personal protective equipment; Technical equipment for production; Evaluation of the prescription; Preparation of injectable cytotoxics; Labels; Container and transport; Waste disposal; Decontamination after inadvertent release.
  4. Not done at all ( 0%) : Room air equipment-LAF; Room air equipment- for removal and supplying system; Room air equipment- for certification and examination; Validation of aseptic technique. Pharmaceutical care the patient.

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