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吉備国際大学 政策マネジメント学部研究紀要 第3号,69-77,2007

# Application of HACCP to the control of medical waste generated from endoscopy

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Keywords : HACCP, medical wastes, endoscopy, injection needle, manifest

## Introduction

Generally speaking, medical wastes in a hospital give rise to three problems; namely, increase of health hazards in the hospital<sup>5,15)</sup>, generation of environmental burden<sup>6)</sup> and high cost for disposal<sup>7)</sup>. To explore ways to solve these problems simultaneously, we attempted to apply the Hazard Analysis and Critical Control Points (HACCP)<sup>4,11)</sup> in medical waste control in a hospital. HACCP is a systematic approach to the identification, evaluation, and control of food safety hazards in food factories or restaurants<sup>11)</sup>.

Medical wastes from the whole hospital generally contain diverse objects that require complicated methods for disposal and transportation. In this study, we focused only on wastes generated from endoscopy, which involve multiple functions such as medical care, diagnostic test, and operation. endoscopists to the control of wastes generated from the endoscopy unit of Hospital X since December 2004. In food sanitation, HACCP is implemented according to twelve procedures<sup>11)</sup>. In this study, however, HACCP was applied following eleven procedures, excluding procedure 3 "Describe the intended use and consumers of the food", because wastes are generally disposed of without being used unless they are recycled. The eleven procedures were as follows.

**Procedure 1**: *Assemble the HACCP team*. The HACCP team consists of the director as the representative of the team, the chief officer, the endoscopist, and one nurse of this hospital.

**Procedure 2**: Describe the waste and its distribution.

**Procedure 3**: Draw up the flow diagrams of the waste management and the standard operating procedures (SOPs) that describe the prerequisite programs

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We applied HACCP based on the expertise of the

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*(PPs)*. PPs are defined as the conditions and practices that are considered to be prerequisite to the development and implementation of effective HACCP plans.

**Procedure 4**: Verify the flow diagrams and the SOPs in the hospital.

**Procedure 5**: *Conduct the hazard analyses (HAs)*. HA is the process of collecting and evaluating information on hazard associated with the wastes generated from endoscopy. A 'HA worksheet' describes the distribution of health hazards, the frequency of their occurrence and the degree of seriousness, and prevention of their occurrence.

**Procedure 6**: *Determine the critical control points (CCPs)*. A CCP is a step at which control can be applied and is essential to prevent or eliminate a hazard or to reduce it to an acceptable level. Two practices are identified as CCPs in this hospital: the management of injection needles and the management of the 'manifest' based on the 'Waste management and public cleansing law (Law No. 137 of 1970, Japan)'. The wastes segregated in each room are carried to the dump yard in the hospital. A hospital-designated transporter of industrial wastes vis-

its the hospital regularly and transports the wastes from the dump yard to the facility of final disposal, which has a contract with the hospital. The chief officer hands the transporter a manifest that lists the contents of the wastes to be disposed. When disposal of the wastes is finished, the manifest is sent back to the hospital.

**Procedure 7**: *Establish the critical limits (CLs)*. CL is a maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a health hazard.

**Procedure 8** : *Establish the monitoring procedures.* **Procedure 9** : *Establish the corrective actions.* 

**Procedure10**: *Establish the verification procedures.* 

**Procedure11**: Establish record-keeping and documentation procedures.

The specific items for Procedures 7 to 11 involved in this project are described in Table 1.

In this study, we first surveyed the wastes generated from endoscopy in three municipal hospitals with approximately 300 endoscopic procedures a

Table 1. Critical control point (CCP) Table

Procedure	ССР			
Procedure	Management of used needles	Confirmation of manifests		
Significant hazard	Needle stick injury	<ol> <li>Infection outside hospital</li> <li>Environmental pollution</li> </ol>		
Critical limit (CL) (procedure 7)	Consistency between number of needles and number of caps	Collection of the manifest and consistency with contents		
Monitoring (procedure 8 )	The nurse counts the numbers of needles and caps after a day's work.	The chief officer confirms the implemen- tation and the accuracy of the manifests.		
Corrective action (procedure 9)	The director guides the staff in managing the needles considering the cause of de- viation in CL.	The director changes the transporter or the disposer.		
Verification (procedure10)	The director confirms records.	The director confirms the manifests.		
<b>Record</b> (procedure11)	Form of the needles	File of the manifests		

year, in order to decide how the wastes should be segregated. HACCP was simultaneously implemented for the control of wastes generated from the endoscopy unit in Hospital X in which Procedure 1 was feasible.

#### Materials and methods

#### Waste analysis

We collected all the wastes generated from endoscopy in three hospitals; Hospitals X, Y and Z, during the month of November 2004. Each waste item was verified and the weight was measured. The number of waste items generated per case and the weight of waste per case were compared between the three hospitals using one-way analysis of variance (ANOVA) and post-hoc test. One case was defined as one panendoscopy or one colonoscopy for a patient.

From November 2004, we began to implement HACCP in the control of the wastes generated from endoscopy in Hospital X. Four decisive studies for the implementation of HACCP were conducted.

#### Study 1: Waste segregation

Wastes generated from 307 endoscopy cases in this hospital between December 2004 and November 2005 were segregated into the five categories based on the survey of three hospitals, which were "sharp infectious waste", "needle", "infectious waste", "non-infectious waste", and "non-infectious plastic waste". The weight of each of the 5 categories was measured. However, before implementing HACCP, the wastes in this hospital were segregated into two categories, which were "sharp infectious waste" (corresponding to "sharp infectious waste"), "needle" in the new segregation categories), and "infectious waste" (corresponding to "infectious waste" plus "non-infectious waste" plus "non-infectious plastic waste" in the new segregation categories). Therefore, the weights the wastes segregated into two old categories were also measured separately. This practice corresponded to an operation of HA in this HACCP.

#### Study 2: Needle count

For the used needles generated from endoscopy between December 2004 and November 2005 we counted the number of used needles discarded in the container for disposal and the number of needle caps everyday after work was finished.

Caps are separated from the needles just before use. Therefore, the number of caps should correspond to the real number of needles used. When there is a discrepancy between the number of the caps and that of the needles, the cause of the discrepancy was pursued. In this project, this practice corresponded to one of the CCP managements; management of needles. The CL of this CCP was the consistency between the numbers of needles and caps.

# Study 3: Bacterial count of disposal container for infectious waste

All "infectious wastes" generated from endoscopy are put in an appointed container in the endoscopy area. After the day's work is finished, the container is sealed by hand and carried to the dump yard. During 21 days between January and February 2005, we swabbed an area of approximate 100 cm<sup>2</sup> at the edge of the container before the container was sealed. Then, the whole edge area was sprayed with 70% ethyl alcohol (approximate 0.8 ml/100 cm<sup>2</sup>). After the edge was dried, we again swabbed an area of approximate 100 cm<sup>2</sup> of the edge, which was not sampled before spraying. Each cotton swab sample was suspended in 9.0 ml phosphate-buffered saline (PBS) and submitted for standard plate count (SPC), coliform count, and methicillin-resistant Staphylococcus aureus (MRSA) count. For SPC, 1.0 ml of the sample was inoculated on standard plate count agar (Kyokuto Pharmaceutical, Tokyo) and incubated at 35°C for 48 hours by standard methods. For coliform count, desoxycholate agar (Eiken Chemical, Tokyo) was used and similarly incubated for 20 hours. For MRSA count, 0.1 ml of the sample was inoculated on mannitol salt egg yolk agar (Eiken Chemical, Tokyo), incubated at 35℃ for 48 hours, and the number of suspected colonies was counted. The suspected colonies were suspended in PBS and inoculated on MDRS-K agar (Kyokuto Pharmaceutical, Tokyo) and modified Drigalski agar (Eiken Chemical, Tokyo). MRSA was identified when MDRS-K test was negative and modified Drigalski agar was positive. Spraying 70% ethyl alcohol corresponded to an operation of the PP and the bacterial examinations corresponded to verification of the PP.

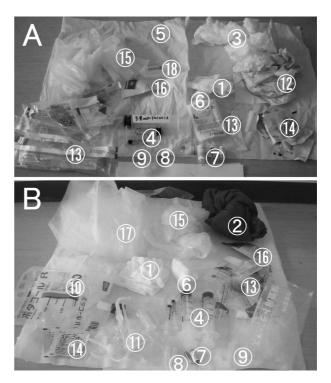
# Study 4: Verification of manifests

We verified the presence or absence and accuracy of the manifests once a month for the period between December 2004 and November 2005. In this project, this practice corresponded to verification of one of the CCPs; confirmation of manifest.

# Results

# Wastes of three hospitals

Figure 1 shows the waste generated from panen-



**Figure 1**. Photographs of the samples of the waste generated from endoscopy. A: the wastes generated from one case of panendoscopy, B: the wastes generated from one case of colonoscopy. They included (1) gauzes, (2) disposable underpants, (3) tissue papers, (4) syringes, (5) waterproof sheets, (6) alcoholic cottons, (7) ampoules and vials, (8) needles (including a winged needle), (9) caps of needles, (10) packs of continuous infusion, (11) lines of continuous infusion, (12) paper towels, (13) packages of ampoule and vial, (14) packages of alcoholic cotton, (15) plastic gloves, (16) film packs, (17) plastic aprons, and (18) plastic ampoules.

doscopy and colonoscopy performed in Hospital X on 1<sup>st</sup> December 2004.

Table 2 shows the number of items per case, the weight per case and the results of ANOVA and post -hoc test comparing the three hospitals. Significant differences(ANOVA, p<0.05)in the number of items per case were observed between Hospital Z and Hospital X. A significant difference(ANOVA, p<0.05) in the weight per case was observed between Hospital X and Hospital Y.

# Study 1: Waste segregation

Table 3 shows the weights of the wastes segre-

	Hospital		
	Х	Y	Z
No. of exermination (panendoscopy : colonoscopy)	21 (15:6)	24 (18:6)	19 (12:7)
Mean±SD of items/case	$13.4 \pm 2.1$	$10.6 \pm 5.0$	$7.9 \pm 2.9$
Range of items/case	9 - 18	3 - 24	2 -12
		*	
Mean $\pm$ SD of weight (g) /case	$179.8 \pm 103.0$	$110.2 \pm 75.2$	$116.9 \pm 86.0$
Range of weight (g) /case	70-400	53-405	31-311

	Table 2	Summary of the was	te generated from	endoscopy in th	e three hos	pitals in December.	, 2004.
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\*: *p* < 0.05, ANOVA

Table 3 Composition of the waste generated from endoscopy

	Segregation category	Weight(g)	percentage(%)
	Sharp infectious waste	6591	7.1
Category used before HACCP implementation	Infectious waste	86591	92.9
	Total	93182	100.0
	Sharp infectious waste	6377	6.8
	Needle	214	0.2
Cotomoral data HACCD in al montation	Infectious waste	64241	68.9
Category used after HACCP implementation	non-infectious waste	17739	19.0
	non-infectious plastic waste	4611	4.9
	Total	93182	100.0

307 examinations (220 panendoscopies and 87 colonoscopies) were performed in Hospital X between December, 2004 and November, 2005.

gated into different categories. The weight of the category "infectious waste" according to the pre-HACCP segregation method (2 categories) was 86591 g. Within this waste category, "non-infectious waste" and "non-infectious plastic waste" accounted for 25.8% (22350 / 86591).

# Study 2: Needle count

Table 4 shows the numbers of used needles and needle caps. The number of the needles did not cor-

respond to that of the caps only in December 2004 and March 2005. In both cases, the reason for the discrepancy was that the needle was discarded into a container outside the endoscopy unit.

# Study 3: Bacterial count of disposal container for infectious waste

For SPC, one pre-spray sample yielded a count of 37 colony-forming units (cfu)/cm<sup>2</sup>, while the other 20 pre-spray samples had 0 cfu/cm<sup>2</sup>. All the post-

Month	Used needles	Needle caps	Difference
December, 2004	72	73	1
January, 2005	42	42	0
February, 2005	41	41	0
March, 2005	37	38	1
April, 2005	39	39	0
May, 2005	32	32	0
June, 2005	29	29	0
July, 2005	39	39	0
August, 2005	17	17	0
September, 2005	71	71	0
October, 2005	31	31	0
November, 2005	20	20	0

Table 4 No. of the used needles and the caps every month

spray samples had 0 cfu/cm<sup>2</sup>. For coliform count, all the pre-spray and post-spray samples had 0 cfu/cm<sup>2</sup>. For MRSA count, all the pre-spray and post-spray samples had 0 cfu/cm<sup>2</sup>.

#### Study 4: Verification of manifests

Inspection confirmed that manifests were present for all the wastes transported from this hospital, and there was no error in the contents of the manifests.

#### Discussion

Many guidelines related to waste control in hospitals have been published by government administrations and specialist organizations<sup>8,9,10,12,13,14)</sup>. Manuals have been prepared based on these guidelines and used for the control of medical wastes in hospitals.

HACCP is a systematic approach to the control of food safety hazards in food factories or restaurants, and has also been applied to other settings such as water clarification<sup>2,3)</sup>, postoperative infection control<sup>1)</sup>, and pharmaceutical preparation<sup>16)</sup>. To the best of our knowledge, our report is the first on the application of HACCP to waste control in a hospital.

In this study, the wastes generated from the endoscopy units in Hospitals X, Y and Z were different although the numbers of endoscopies performed were similar. Therefore, the method of segregating the wastes generated from endoscopy should be decided considering the characters of the wastes in individual hospital.

By implementation of HACCP in Hospital X, the wastes generated from endoscopy were segregated into five categories, whereas they were segregated into two categories before HACCP implementation. Since "non-infectious plastic waste" is recycled in Japan, the present change in waste segregation method contributes to reduce the environmental load. On the other hand, the disposal of "non-infection waste" is free of charge for this hospital, because the municipality is responsible for disposal of wastes corresponding to "non-infection waste". Accordingly, we may anticipate a decrease in hospital cost for waste disposal for the endoscopy unit as a result of this change.

Management of injections needles was identified as one of the CCPs in this HACCP. In this hospital, recapping of needles was discontinued for the purpose of preventing needle stick injury. Through the procedure of this HACCP, deviation from the CL was detected. In response to this finding, the director guided the staff in managing the needles. The guidance had probably resulted in consistency of the numbers of needles and the caps from April, 2005, as shown in Table 4.

According to the results of the bacterial examination before the spray, it is possible that the edge of the container was contaminated with some microbes. The container could become a source of cross infection because the staff in the hospital always seals it up by hand. On the other hand, the bacterial examination after spraying suggests that spraying with alcohol disinfects the seal of the container and prevents the spread of bacterial contamination.

Verification of the management of manifests suggests that the safety has been secured inside and outside this hospital.

While HACCP is an approach that should be implemented systematically in the whole hospital, we attempted to adopt it to medical waste control in the endoscopy unit as an initial trial. Our results suggest that implementation of HACCP might simultaneously accomplish prevention of health hazards, reduction of environmental load, and containing the cost of waste disposal.

The present findings have several limitations. The reduction of environmental load and cost containment associated with the change in method of waste segregation were not substantial, since this study was limited to only wastes generated from endoscopy. Further expansion of HACCP to other areas in the hospital together with evaluation of its effectiveness should be continued, aiming at systematic adoption throughout the hospital.

# Conclusion

In this study, waste surveys in three hospitals suggest that an appropriate method of segregation of wastes generated from endoscopy should be decided for individual hospital. In Hospital X where implementation of HACCP was attempted, reduction of environmental load and cutting of disposal cost are anticipated by changing the categories of waste segregation based on hazard analysis. The results suggests that the endoscopy-related wastes should be managed more safely by setting the management of needles and manifests as critical control points, and setting the management of waste containers as a prerequisite program.

# Acknowledgements

We would like to express our thanks to the staff of three hospitals for cooperation in this study. We are extremely grateful to the late Professor Shohei Kira,Okayama University for his valuable instruction.

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#### Abstract

**Introduction** Wastes in a hospital increase health hazards, generates environmental load, and are costly to dispose. The Hazard Analysis and Critical Control Point system (HACCP) was applied to the control of wastes generated from endoscopy in a hospital to solve the above problems.

**Methods** The wastes in three hospitals were quantified. HACCP was applied to the endoscopy unit of Hospital X for a year. Wastes were segregated into five types and weighed. The number of used needles and needle caps were counted. Bacterial counts of the edge of waste container were determined before and after alcohol spraying. The manifests of waste were checked.

**Results** Differences in number and weight of waste per case were observed between the three hospitals. Within the category of "infectious waste" according to the segregation method before HACCP implementation, "non-infectious waste" and "non-infectious plastic waste" accounted for 25.8%. The numbers of needles and needle caps did not correspond in two occasions. A standard plate count of 37 cfu/cm<sup>2</sup> was obtained in one occasion before alcohol spraying of the waste container, but was 0 cfu/cm<sup>2</sup> in all other examinations. All the manifests were consistent with the wastes sent for disposal.

**Conclusion** An appropriate method of waste segregation should be decided for individual hospital. In Hospital X where implementation of HACCP was attempted, reduction of environmental load and cutting of disposal cost are anticipated by changing the categories of waste segregation. The results suggest that the wastes should be managed more safely by HACCP.