Status of Medical Disputes in Hospitals in Tokyo Prefecture, Japan, and the Role of Medical Safety Support Centers in Resolving Disputes: Primary survey

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### **Abstract**

Purpose Medical Safety Support Centers are organizations established by prefectures and other bodies to handle citizens' complaints about medical practice and related issues. The Tokyo Medical Safety Support Center (hereinafter cited as the Center) conducted a survey of hospitals in Tokyo Prefecture as a step to consider how

hospitals in Tokyo Prefecture as a step to consider how the Center should be operated as an organization trusted by both citizens and medical institutions.

Methods Among the hospitals in Tokyo, the survey targeted 344 members of Tokyo Metropolitan Hospitals Association. A questionnaire asking about the past records of patient relations service and the opinions toward the Center was sent to each target hospital.

Results Responses were obtained form 210 hospitals (recovery rate: 61.0%). In Fiscal Year 2006, they experienced at least 2,674 cases of physical violence, 273 cases of resignation of personnel due to violence or similar reasons, 727 cases of refused medical fee payments by patients who filed complaints, and 175 lawsuits. The numbers of these incidents were correlated with the number of complaints. Although the expectations towards the Center were high (67.3%), the data also suggested disappointments of the hospitals that have actually used the Center's services. Additionally, the data indicated that lawsuits were undermining the relationship between hospitals and administrative bodies.

**Conclusion** The results suggest that early intervention in complaint cases may prevent and reduce lawsuits and other problems over medical practice. The Center should nurture human resources with expertise in order to meet the needs of both citizens and medical institutions through actions.

Key words Medical Safety Support Center, Medical safety, Complaint, Hospital violence, Lawsuit

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### Introduction

The amendment to the Medical Act Law (also known as Medical Care Act) of Japan, enforced in April 2007, stipulates that all prefectures, the cities with public health centers, and special wards must endeavor to establish Medical Safety Support Centers. The legally functions of these centers include responding to patient's concerns and complaints, giving advices to relevant hospitals, providing information, and conducting medical safety training. However, the centers are not endowed with the legal authority to investigate the cause of problems in medical practice or to judge any causality.<sup>1</sup>

Tokyo Metropolitan Government established its Medical Safety Support Center (herein after cited as the Center) in May 2001 to address the concerns and anxieties of citizens about medical care. According to the authorities of Tokyo Metropolitan Government, while many hospitals desire that the Center to have the authority to investigate causes and make judgments, a number of hospitals dissatisfied with the present services is also increasing.<sup>2</sup>

We conducted a survey to grasp the status of problems in medical practice at hospitals in Tokyo to aid us in evaluating the Center as it ought to be hereafter.

### **Methods**

### **Survey methods**

### **Survey targets**

Of the 658 hospital facilities in Tokyo Prefecture (as of October 2006), we targeted the 344 hospitals that were the members of Tokyo Metropolitan Hospitals Association, which have agreed to cooperate in the survey in advance.

### Questionnaire

We prepared a questionnaire covering eight subjects: 1) status of the patient relations service (the number of available staff and the number of cases handled in Fiscal Year (FY) 2006), 2) the capacity of the patient relations service at present and expected trend in the number of complaints, 3) probable causes of the increase in complaints against medical institutions, 4) whether the hospital has experienced intervention of the Center in the past, 5) the effectiveness of the Center in resolving disputes, 6) whether the hospital would accept or refuse interventions of the Cen-

ter, 7) who should be held responsible for the efforts to reduce the burdens of responding to complaints against the hospital, and 8) any requests for the administrative bodies. The questionnaire was sent in November 2007, and the hospitals completed the form based on the situations at the time of the survey.

In this survey, the terms are defined as follows. "General consultations" refers to the handling of patient's concerns and anxiety by a hospital about medical care that do not meet the definition of "complaints," whereas "complaints" refer to the cases of dissatisfaction and demands filed with the patient relations services of a hospital by patients. "Physical violence" is the use of physical power by a patient on hospital personnel to cause physical harm as defined by Japanese Nursing Association. The "interventions by the Center" are defined as the actions of the Center on the relevant hospital in the form of noncompulsory investigation or advice based on the information from filed complaints.

### Methods of analysis

Statistical tests were performed using SPSS® 15.0J for Windows® with  $\alpha$  level of 0.05 (two-tailed). Spearman's rank correlation coefficient  $\rho$  was calculated for the correlation analyses between the number of complaint cases and the number of licensed beds, number of cases involving hospital violence, incidences of resignation of personnel due to violence or similar reasons, number of refused medical fee payments by patients among filed complains, and the number of damage suits, respectively. In the regression analysis between the number of complaints and the number of licensed beds, the equation was determined using the forced entry method.

The relationship between the expectations for the Center and the past experience from the interventions by the Center was analyzed using a  $2\times2$  contingency table, in which the dichotomy between "effectiveness is expected" and "not expected" was related to the dichotomy between "the hospital has experienced interventions by the Center" and "has not experienced"; a Pearson's  $\chi^2$  test was performed for significance of proportions. The effect of lawsuits on the hospital's willingness to cooperate with the Center was assessed using the stratified  $2\times2$  contingency table with the Mantel-Haenszel method to test for statistical significance, by assigning 4-point

Table 1 Present status of problems in medical practice at hospitals in Tokyo Prefecture, Japan

Type of problem	Number of hospitals that answered the question (a)	Number of hospitals with one or more cases	Total number of cases (b)	Average (b/a)	Coefficient of correlation $[\rho]$ with the number of complaints	Statistical significance [P]
Hospital violence	201	133	2,674	13.30	0.53	0.00**
Resignation of personnel due to violence or similar reasons	202	64	273	1.35	0.38	0.00**
Refused medical fee payments from patients who filed complains	202	123	727	3.60	0.53	0.00**
Damage suits	199	72	175	0.88	0.35	0.00**

The total number of cases (b) is the summation of records in Fiscal Year 2006. Hospitals in Tokyo experienced at least 2,674 cases of hospital violence, 727 cases of refused medical fee payments from patients who filed complains, 273 cases of resignation of hospital personnel due to violence or similar reasons, and 175 medical suites involving 72 facilities. The correlation between the number of problems over medical practice and the number of complaints at the respective hospitals was analyzed using Spearman's rank correlation coefficient  $\rho$ . Significant correlation was found between the number of cases in each category and the number of complaints at respective hospitals (\*\*P<0.01).

rank orders to the increasing degree of reluctance ("cooperate willingly," "cooperate only when necessary," "cooperate only in trivial cases," and "refuse to cooperate") and by evaluating the effect of "there have been lawsuits" in relative risks.

### **Ethical consideration**

This survey was approved by the Ethics Board of the National Institute of Public Health according to the Ethics Guidelines Concerning Epidemiological Study (as amended on December 28, 2004) of the Ministry of Education, Culture, Sports, Science and Technology (MEXT) and the Ministry of Health, Labour and Welfare (MHLW) of Japan.

In obtaining information including the name and address of hospitals from Tokyo Metropolitan Hospitals Association, we obtained a consent in advance from its Board of Trustees regarding cooperation in the survey and disclosure of hospital information to a third party. In addition, the handling of hospital information was explained to respective hospitals in writing beforehand, and an explicit written consent was obtained from each hospital. Data were processed to prevent retracing to secure anonymity, and the questionnaire sheets were shredded upon completion of the survey.

### Results

### **Attributes of hospitals**

Answers were obtained from 210 hospitals, with

the recovery rate of 61.0%. In terms of the type of operating entity, 4 facilities (1.9%) were operated by the national government and independent administrative corporations, 16 (7.6%) by public bodies (metropolitan government, municipalities, Japan Red Cross, Saiseikai), 8 (3.8%) by social insurance organizations, 21 (10.0%) by publicservice corporations, 119 (56.7%) by incorporated medical institutions, 4 (1.9%) by incorporated educational institutions, 13 (6.2%) by social welfare corporations, 2 (1.0%) by Health Cooperative Association, 3 (1.4%) by private companies, 4(1.9%) by other corporations, and 16(7.6%) by individuals. In terms of the hospital function, 3 were in specific functions (1.4%), 5 in community medicine support (2.4%), 174 in general practice (82.9%), and 28 in psychiatry (13.3%). The median number of licensed beds was 234.6, with the standard deviation of 228.2.

## Number of personnel for patient complaint reception and number of cases handled in FY 2006

The number of facilities with staff assigned to patient relations services was 187, representing 90.3% of the surveyed hospitals. The number of general consulting cases was 162,053 in total, with 822.6 per facility in average. The number of complaint was 7,641 cases in total, with 38.4 per facility in average. When the number of complaint cases was used as the target variable [y] and the number of licensed beds was used as the predictor [x], the regression equation was

Table 2 The contingency table relating the expected future trend in the number of complaints and the perceived capacity of patient relations service to handle more complains

Future trend in the number of complaints	Status of patient relations se	T 1.1	
	There is no reserve capacity	There is a margin to spare	— Total
Expect an increase	127	19	146
Expect a decrease	1	0	1
Expect no change	33	30	63
Total	161	49	210

Of the 146 facilities that expected an "increase" in the number of complaints in the future, 127 facilities (87.0%) had "no reserve capacity" to handle more complaints. The data suggest many hospitals may not be able to bear further increase in burdens and fail to handle the rising number of complaints.

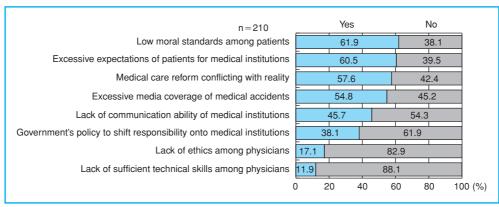


Fig. 1 Probable causes for the recent increase in complaints (multiple answers allowed)

The most frequent answer was "low moral standards among patients" (61.9%), followed by "excessive expectations of patients for medical institutions" (60.5%), and "medical care reform conflicting with reality" (57.6%). These answers suggest that hospitals consider it difficult to reduce complaints against them through their own efforts alone.

[ $y \times 1.83 + 0.15x$ ], and the correlation (0.63) was statistically significant (P < 0.01).

# Correlation between the number of problems over medical practice and the number of complaint filed

The correlation coefficient between the number of problems over medical practice and the number of complaint filed in FY 2006 are shown in **Table 1**. The data included 2,674 cases (13.30 per facility) of hospital violence, 273 cases (1.35 per facility) of resignation of personnel due to violence or similar reasons, 727 cases (3.60 per facility) of refused medical fee payments among filed complaints, and 175 cases of damage suits involving 72 facilities (0.88 per facility). The

correlation coefficients between these items and the number of complaint filed at surveyed hospitals were 0.53 for hospital violence, 0.38 for resignation, 0.53 for refused payments, and 0.35 for the number of damage suits; all of which were statistically significant (P<0.01).

## Trend in the number of complaints and the handling capacity of the patient relations service

Of the 210 hospitals in the survey, 146 (69.5%) expected "an increase" in the number of complaints against their own hospital, greatly outnumbering 1 (0.5%) that expected "a decrease" and 63 (30.0%) that expected "no change" (**Table 2**). Regarding the handling capacity of the patient

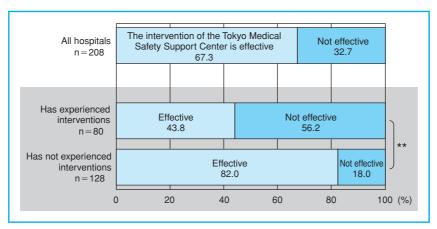


Fig. 2 Effect of past intervention on the expectations for the intervention of the Tokyo Medical Safety Support Center

The difference between proportions was tested using Pearson's  $\chi^2$  test. Of all hospitals that are in this survey, 67.3% considered that the interventions of the Tokyo Medical Safety Support Center were "effective" for early resolution of disputes. However, among the hospitals that had actually experienced intervention, as compared with those without, the percentage of the answers choosing "effective" was significantly low at 43.8%. This result suggests that the interventions of the Center were disappointing to the hospitals that have actually experienced them (\*\*P<0.01).

relations service, 161 facilities (76.7%) had a reserve capacity to handle more complains and 49 (23.3%) did not. Of the 146 facilities expecting "an increase" in the number of complaints, 127 (87.0%) had no extra margin to handle any increase.

## Probable causes of the increase in complaints against medical institutions

Figure 1 summarizes the answers to this multiple-choice question. The most frequent answer was "low moral standards among patients" from 130 facilities (61.9%), followed by "excessive expectations of patients for medical institutions" from 127 (60.5%), "medical care reform conflicting with reality" from 121 (57.6%), "excessive media coverage of medical accidents" from 115 (54.8%), "the lack of communication ability of medical institutions" from 96 (45.7%), and "the government's policy to shift responsibility onto medical institutions" from 80 (38.1%). Only 36 facilities (17.1%) blamed "the lack of ethics among physicians" and 25 (11.9%) noted "the lack of sufficient technical skills among physicians."

### Expectations for the effectiveness of intervention of the Center

Figure 2 shows the expectations towards the

Center by with or without the previous experience of the Center's interventions. Of the 208 hospitals that answered the question, 140 hospitals (67.3%) considered the intervention of the Center to be "effective" in early resolution of disputes. In the comparison between the hospitals with experience and those without, only 43.8% of hospitals with experience answered that the interventions were actually "effective," which is significantly falling short of the 82.0% (128 facilities) that have not experienced any interventions but expect results from the interventions (P<0.01).

### Effect of lawsuits on the level of cooperation with the Center

**Table 3** shows the comparison of the hospital's willingness to cooperate with the Center between those that experienced lawsuits in FY 2006 and those that did not. When compared to those that would "cooperate willingly," other answers were more strongly affected by the experience of lawsuits; "cooperate only when necessary" (relative risk 4.10), "cooperate only in trivial cases that does not involve lawsuits" (7.36), and "refuse to cooperate in noncompulsory investigation" (12.63) (P<0.01).

Table 3 Effect of past lawsuits on the cooperativeness to the investigation of the Tokyo Medical Safety Support Center

Rank order	Number of lawsuits filed by patients (In Fiscal Year 2006)		Relative risk	95% confidence
	One or more	None		interval
Degree of willingness to cooperate in investigation by the Center				
1. Cooperate willingly	11	93	1.00	Baseline
2. Cooperate only when necessary	23	30	4.10**	1.41–11.94
<ol><li>Cooperate only in trivial cases that does not involve lawsuits</li></ol>	18	2	7.36**	1.63–33.36
Refuse to cooperate in noncompulsory investigation	19	1	12.63**	1.85–86.09
Total	71	126		

For each level of willingness to cooperate, stratified comparison was made between hospitals with and without lawsuits for damage in Fiscal Year 2006. The degree of reluctance was assigned in rank orders, and the effect of "one or more lawsuits" on the degree of reluctance was evaluated in terms of relative risk. Statistical significance was tested using the Mantel-Haenszel method on the stratified  $2 \times 2$  contingency table. The effect of "one or more lawsuits" increased with the increasing degree of reluctance from "cooperate willingly" to "cooperate only when necessity," "cooperate only in trivial cases," and "refuse to corporate" and the increase in relative risk was significant (n = 197, \*\*P<0.01).

## Requests to administrative bodies (including the Center) for dispute resolution support

The most frequent request to the Center was "investigation and judgment concerning problems over medical care contracts and safety issues" from 139 facilities (66.2%), followed by "education of citizens on the uncertainty inherent to medical care" from 128 facilities (61.0%), and "disclosure of the collected information in terms of specific details and actions taken" from 113 facilities (53.8%). Finally, 66 facilities (31.4%) answered "administrative bodies should directly accept complaints and act for dispute resolution," and 37 facilities (17.6%) answered that "administrative bodies should have an internal organization for alternative dispute resolution (ADR) to make out-of-the-court arbitration and conciliation."

### Discussion

Based the amended Medical Service Law of Japan (Article 6 Item 11), Medical Safety Support Centers are established by prefectures, cities with public health centers, and special wards for the purpose of building the confidence of citizens in medical care by responding to the concerns and complaints of patients and citizens related to medical care, giving advice to medical care

providers and patients, and educating citizens and promoting medical safety in the community.<sup>1</sup> The operation of these centers is based on the MHLW Operation Guide of Medical Safety Support Centers.<sup>1</sup> This Guide states the basic policy including the commitment "to provide consultation from a neutral standpoint between citizens and medical institutions and strive to earn the trust of both sides." It also explains that, among others, centers are not to judge or decide the presence or absence of causality in medical practice or the location of responsibility.

There were various reasons that we chose to sample from the members of Tokyo Metropolitan Hospitals Association in this survey. Concerns and complaints involving hospitals represented a majority of the cases filed with the Center.4 In 2006 when this survey was conducted, medical institutions other than hospitals were not legally obliged to have medical safety management systems.<sup>5</sup> Tokyo Metropolitan Hospitals Association with the membership covering 51.6% of hospitals in Tokyo Prefecture was the largest organization of hospitals in Tokyo.6 Also, we had obtained the consent from the Association regarding cooperation in this survey, provision of hospital information, and disclosure of the results of analysis. The hospitals that cooperated with this survey were distributed widely in terms

of the type of operating entity, hospital function, and hospital size (number of licensed beds). Although the effect of selection bias needs to be considered, we believe these samples reasonably reflect the current status of hospitals in Tokyo.

Tada et al.8 asserted that complaints against medical care providers serve as a starter for corrective actions at the relevant medical facilities and contribute to the betterment of medical care quality and promotion of medical safety. Kikuchi<sup>9</sup> suggested the need of organizational approaches including posting of designated department and setting up a reporting system because employees tend to hesitate to report incidences of complaints and violence. An encouraging finding of our survey was that most of the hospitals in the survey had implemented organizational measures such as assigning personnel to patient relations (concurrently with other assignments in some cases) and collecting information on complaints. However, many hospitals were expecting increases in the number of complaints in the future, and a great majority of them were not prepared to handle such increases. Consequently, some hospitals might cut corners on patient relations, which may cause a delay in improving the quality of medical care and medical safety.

The interview survey of 8 hospitals conducted by Ibe et al.<sup>10</sup> in March 2006 revealed that violence, intimidation, and sexual harassment in hospitals are increasing in number and worsening in maliciousness. The authors also pointed out that the real problems in medical practice tend to be concealed from outsiders because hospitals are concerned about their reputation. In this context, our survey was valuable as it clarified the actual number of problems over medical practice like hospital violence and revealed the reality of the problems. This trend of disclosure among hospitals may be the effect of the MHLW notification in September 2006, which, in response to a series of hospital violence cases, instructed medical institutions to attempt to grasp the situation of hospital violence at each facility and to strengthen the liaison with administrative bodies.<sup>11</sup>

According to International Labour Organization (ILO), healthcare workers are frequent victims of violence in workplaces.<sup>12</sup> The survey by the U.S. Bureau of Labor Statistics (2005)<sup>13</sup> showed that the percentage of employees of private healthcare and welfare facilities who experienced violence from patients and clients

during the past one year was higher at facilities with more employees: 20% at facilities with 50–249 employees, 40% at facilities with 250–999 employees, and 69% at facilities with 1,000 or more employees. It also revealed that staff specialized in mental health suffered violence more frequently than other healthcare workers. Our survey identified that, in Tokyo in FY 2006 alone, at least 2,674 cases of hospital violence and 273 employees resigning because of violence or similar reasons, and that the number of violence cases was higher at the facilities with more complaint cases or with more licensed beds. A comparison between psychiatric hospitals and other hospitals detected no significant difference in the number of violence cases.

According to Ohwaki et al.<sup>14</sup> the number of medical lawsuits compiled by the Supreme Court<sup>15</sup> increased remarkably during the past 10 years. Our survey also highlighted the profusion of patient-hospital disputes, revealing the occurrence of at least 727 cases of refused medical fee payments by patients with complains and 175 cases of damage suits involving 72 facilities. As many healthcare providers suspect the number of complaints will increase, the concern for further increase in disputes calls for prompt measures. We hope the results of this survey would bring more discussions in future.

MHLW considers that direct exchange of allegations between the patient and its family members and the relevant medical institution is not a good way to resolve a dispute, as it may strengthen distrust in medical practice on the patient/family side and aggravate confrontation.<sup>16</sup> On the other hand, intervention of the police and judiciary authorities may discourage medical institutions form performing high-risk procedures and lead to the spread of overly cautious medical practice. MHLW therefore intends to discuss out-of-court measures to handle medical disputes, while considering a possibility of amending laws and rules in the future at the same time. MHLW is also considering the promotion of internal mediators at hospitals.<sup>17</sup>

This survey found that many hospitals are not well prepared to handle the increase in a number of complaints. Additionally, many attribute the increase in complaints to the factors on the patient side, find difficult to improve situations through their own efforts only, and expect government agencies to play a bridging role between medical institutions and citizens. The survey also revealed that the experience of being involved in lawsuit affects adversely on not only the relationship between the relevant hospital and patients but also the relationship with the administration (the Center). In view of these facts, we consider important that local public bodies support medical institutions and work actively toward the resolution of problems over medical practice.

On the other hand, considerably less proportion of those that have experienced interventions of the Center feel that such actions were in fact "effective" for early resolution of disputes compared with those that have not actually experienced interventions. This discrepancy suggests there is a room for improvement in this respect.

The MHLW Operation Guide to the Medical Safety Support Centers¹ stipulates that the Centers "do not judge or determine the presence or absence of causality in medical practice or the location of responsibility." This clearly separate the operations of Medical Safety Support Centers from the procedures in the medical version of ADR, which are now under deliberation by the government, and the accident investigation committee, which deals with fatal and other serious incidents. Yet, many of the hospitals in our survey demanded the Center to perform "investigation and judgment concerning problems over medical care contracts and safety issues," "education of citizens on the uncertainty inherent to medical care," and "disclosure of the collected information in terms of specific details and actions taken." This result demonstrates Medical Safety Support Centers are expected to function like a medical version of Consumer Affair Centers in Japan, to collect information, conduct survey and research, and distribute information from a neutral standpoint within the administrative system.

According to Tokyo Metropolitan Government, 17-19 many of the hospitals who sought investigation, judgment, and guidance from the Center were unsatisfied with its services. This fact should be considered seriously in the redefining of the Center as the organization to be trusted by both citizens and medical institutions. Increased efforts to improve the quality and safety of community medical care would hopefully ensure the sense of safety and security and raise the level of trust by citizens towards medical practice.

#### Conclusion

This survey revealed the status of problems over medical practice that occurred in Tokyo, Japan, in FY 2006. Our data suggest that problems may be prevented and reduced by appropriate responses to complaints. Many hospitals expect Medical Safety Support Centers to perform investigation and judgment concerning safety, as well as the distribution of information. Considering these demands, Medical Safety Support Centers should address the needs of both citizens and medical institutions through various actions, including the training of human resources with expertise in healthcare systems and medical safety.

### Acknowledgement

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