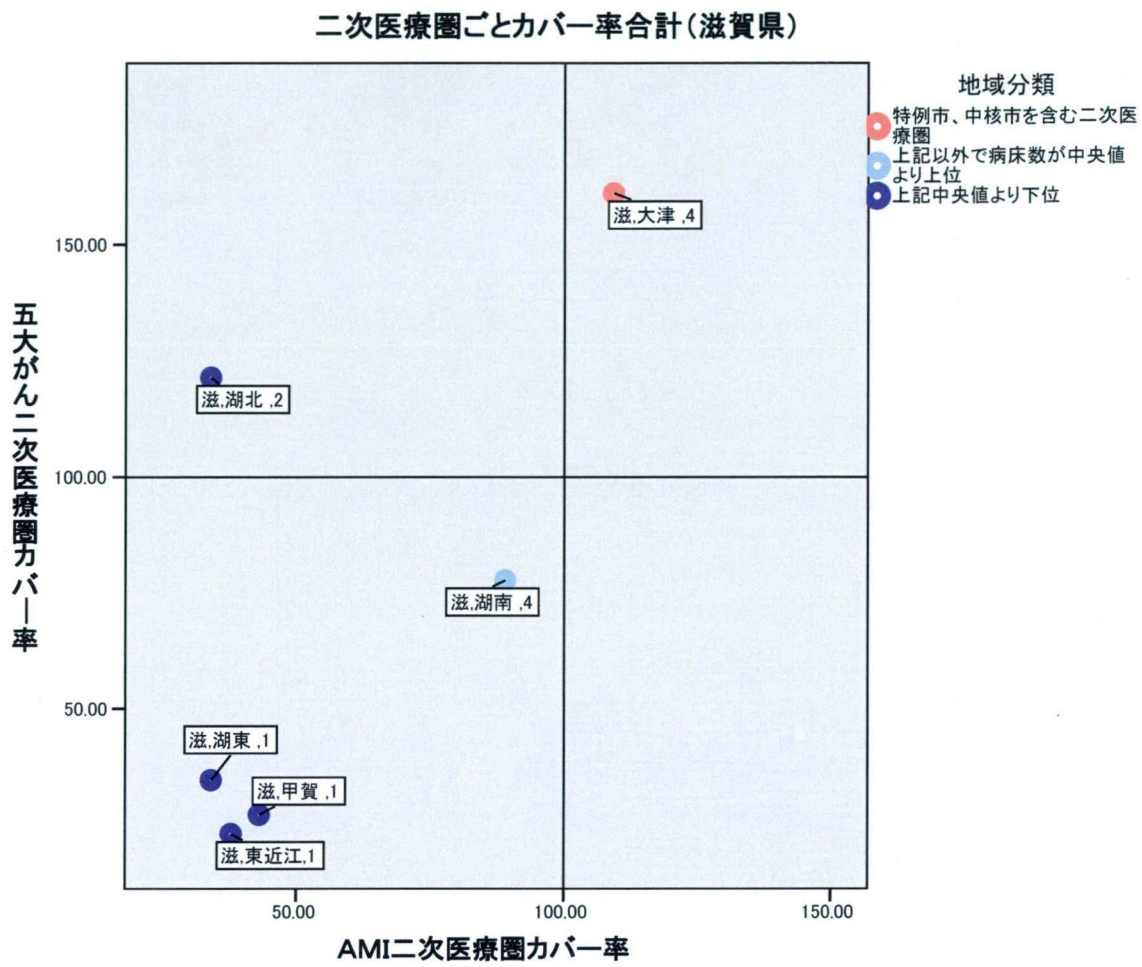
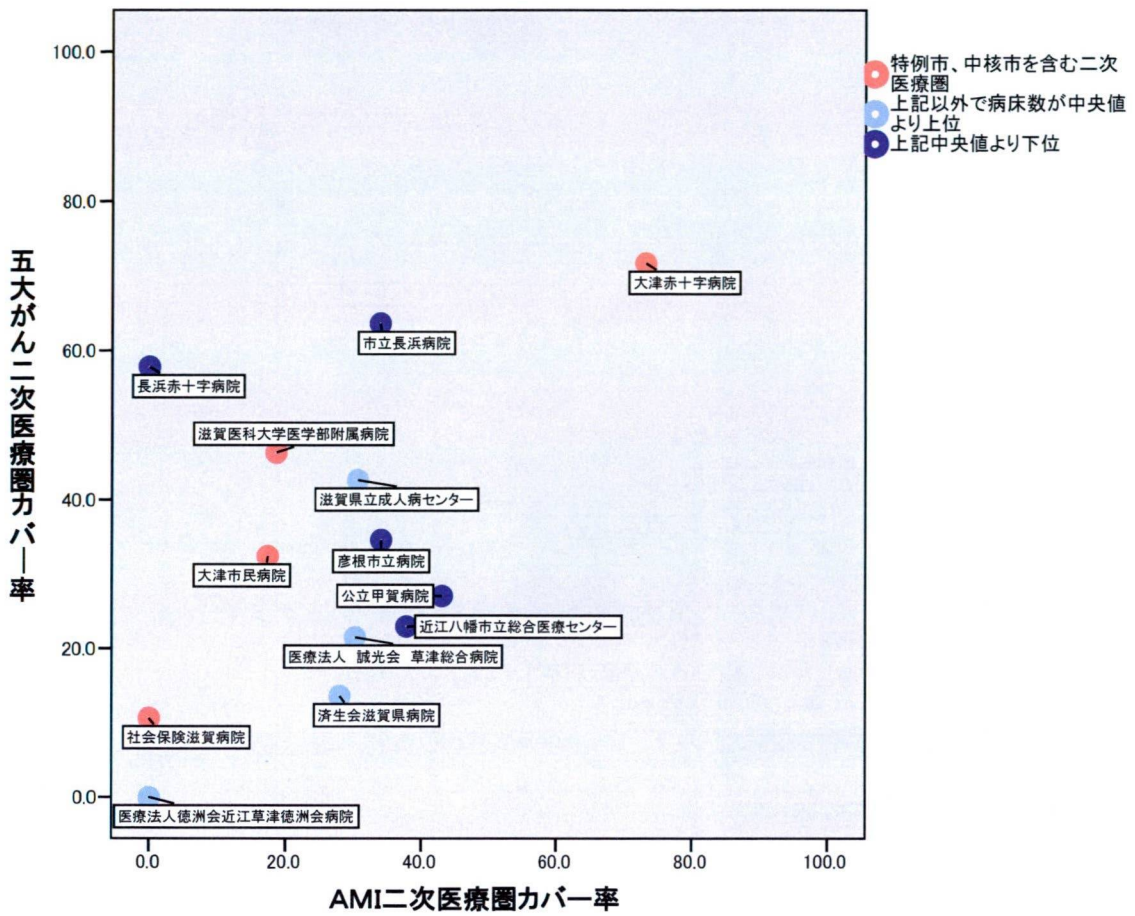
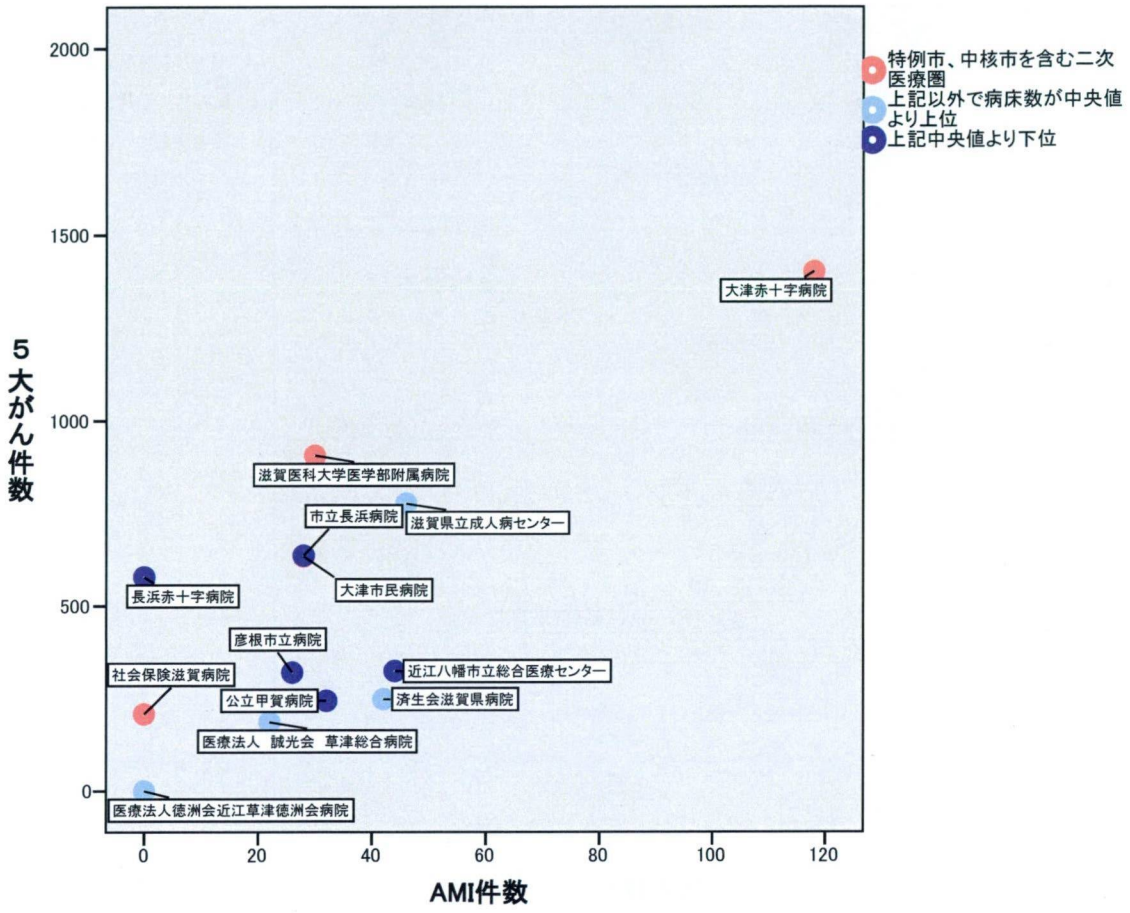

二次医療圏ごとカバー率合計（滋賀県）
地域分類
特例市、中核市を含む二次医療圏
上記以外で病床数が中央値より上位
上記中央値より下位
滋,大津 ,4
滋,湖北 ,2
滋,湖南 ,4
滋,湖東 ,1
滋,甲賀 ,1
滋,東近江,1
150.00
100.00
50.00
五大がん二次医療圏カバー率
50.00
100.00
150.00
AMI二次医療圏カバー率

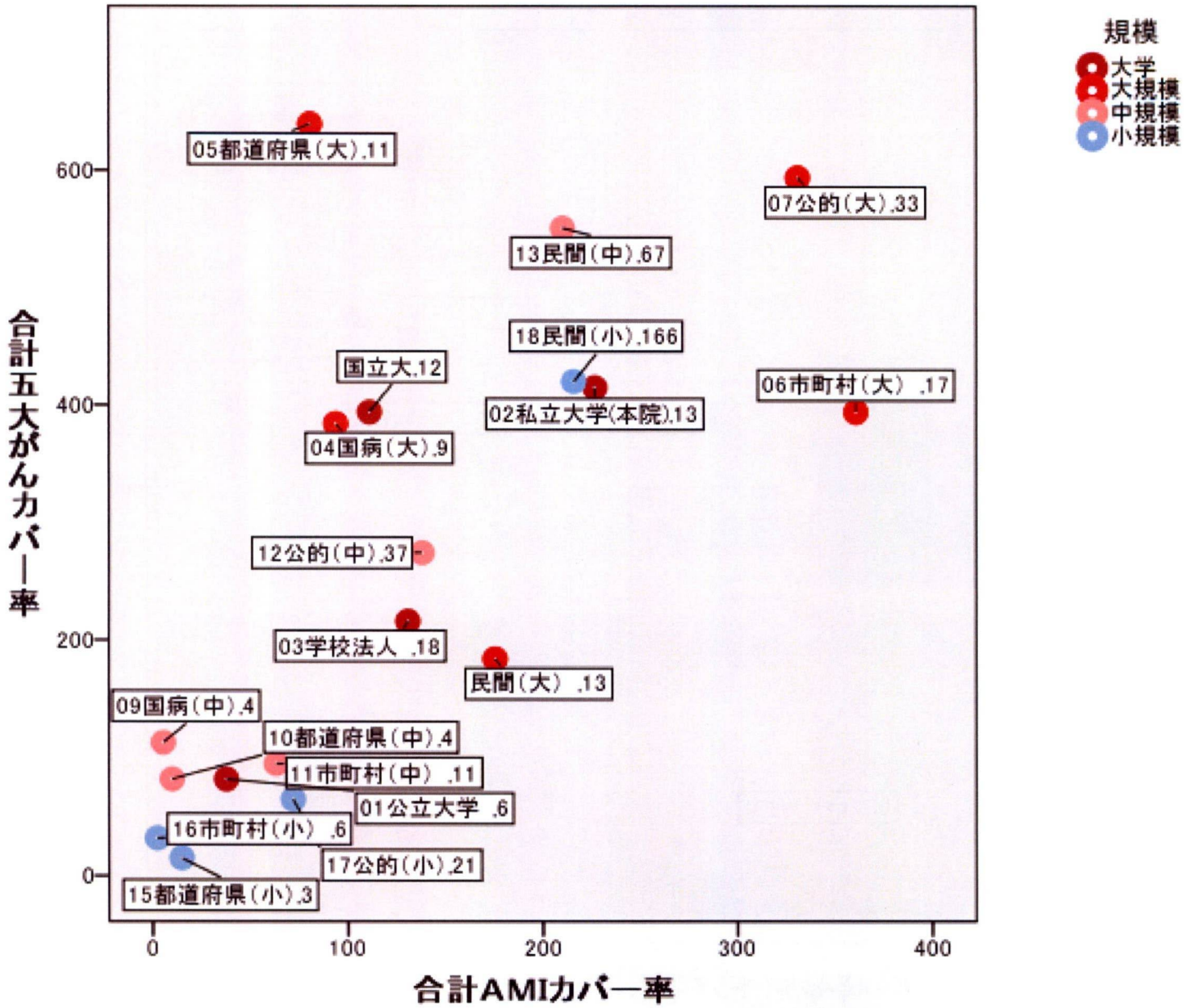
## 個別病院の二次医療圏カバー率(滋賀県)



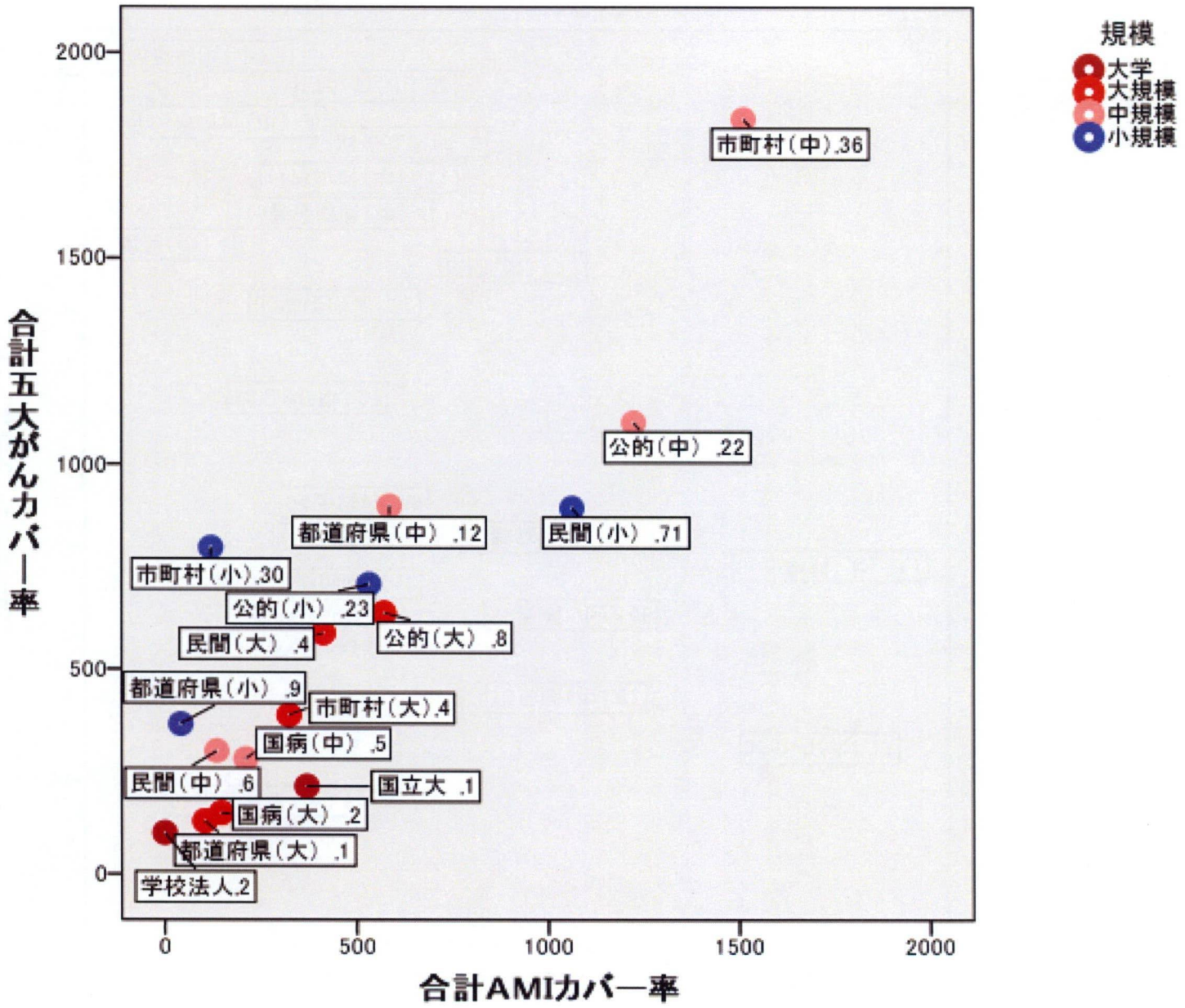
## 個別病院の件数(滋賀県)


特例市、中核市を含む二次医療圏
上記以外で病床数が中央値より上位
上記中央値より下位
5大がん件数
AMI件数
2000
1500
1000
500
0
0
20
40
60
80
100
120
大津赤十字病院
滋賀医科大学医学部附属病院
市立長浜病院
滋賀県立成人病センター
大津市民病院
長浜赤十字病院
彦根市立病院
社会保険滋賀病院
近江八幡市立総合医療センター
公立甲賀病院
済生会滋賀県病院
医療法人 誠光会 草津総合病院
医療法人徳洲会近江草津徳洲会病院

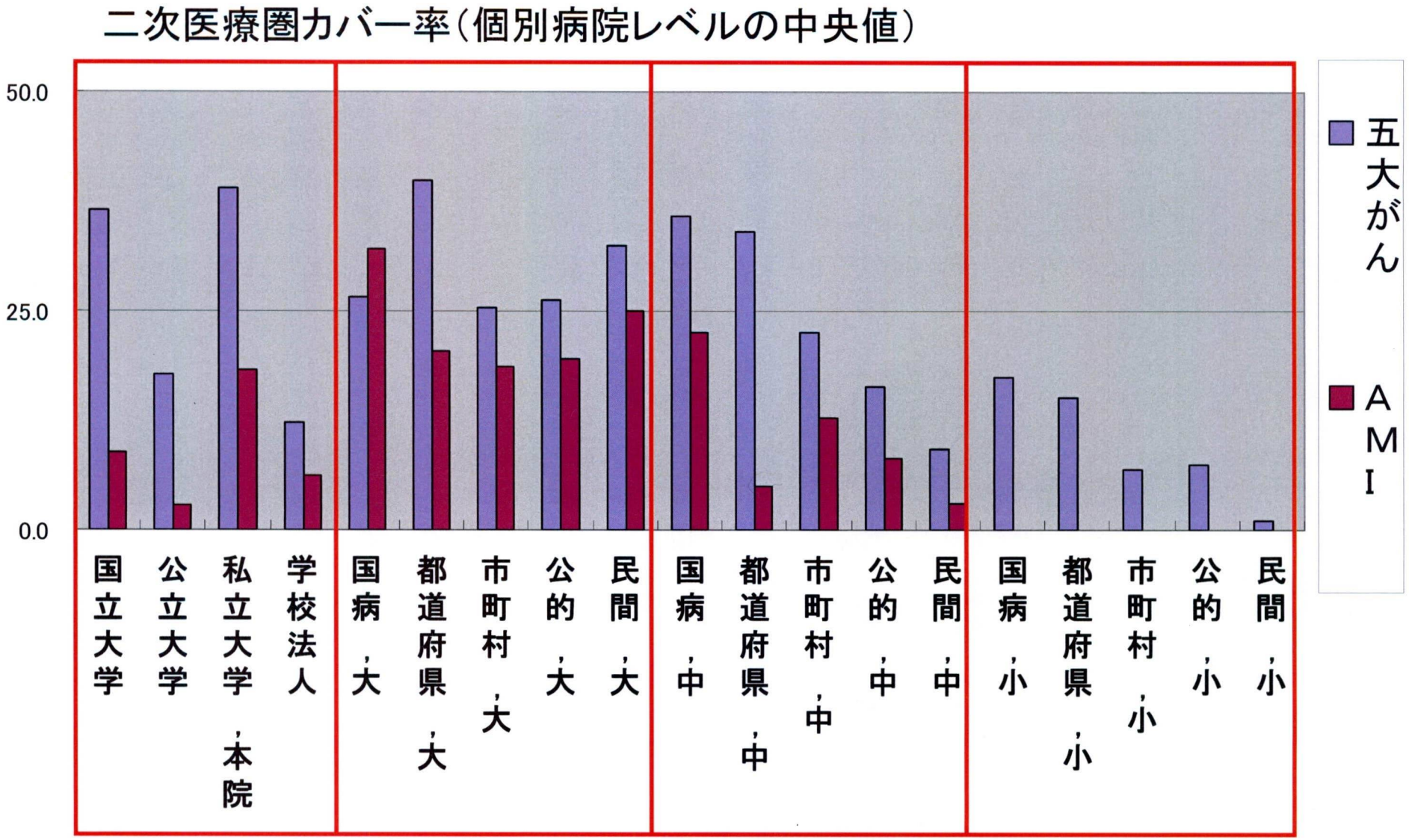
# 開設者ごと二次医療圏カバー率合計（地域①）



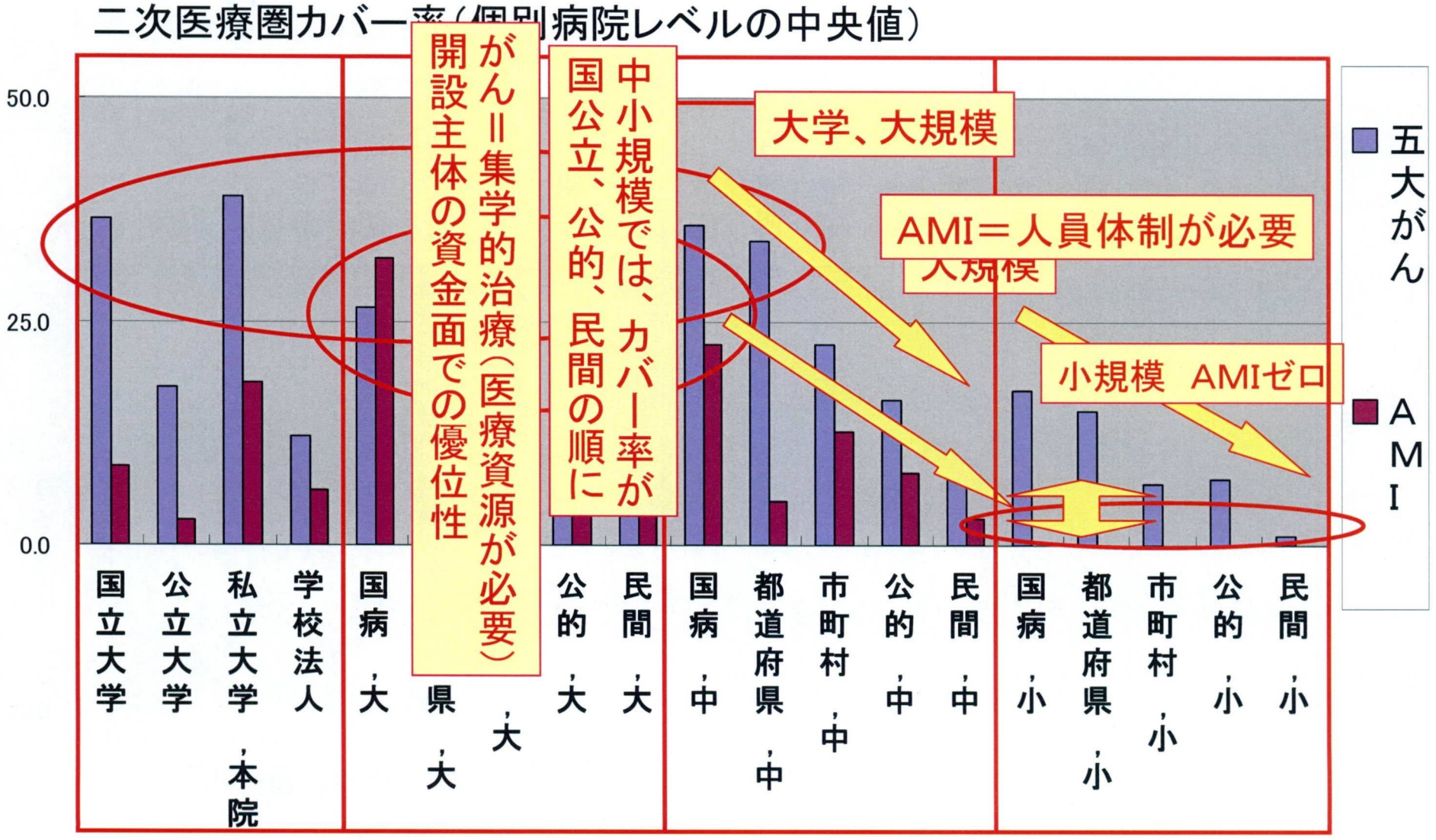
# 開設者ごと二次医療圏カバー率合計（地域④）



# 開設者別・規模別の診療分担状況



# 開設者別・規模別の診療分担状況



**Keywords:** Patient safety, incident reporting, reporting systems, national survey, teaching hospital, health professions education

**Topics:** xxx

Original research

# Impact of system-level activities and reporting design on the number of incident reports for patient safety

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## ABSTRACT

**Background** Incident reporting is a promising tool to enhance patient safety, but few empirical studies have been conducted to identify factors that increase the number of incident reports.

**Objective** To evaluate how the number of incident reports are related to system-level activities and reporting design.

**Methods** A questionnaire survey was administered to all 1039 teaching hospitals in Japan. Items on the survey included number of reported incidents; reporting design of incidents; and status for system-level activities, including assignment of safety managers, conferences, ward rounds by peers, and staff education. Staff education encompasses many aspects of patient safety and is not limited to incident reporting. Poisson regression models were used to determine whether these activities and design of reporting method increase incident reports filed by physicians and nurses.

**Results** Educational activities were significantly associated with reporting by physicians (53% increase, $p<0.001$) but had no significant effect on nurse-generated reports. More reports were submitted by physicians and nurses in hospitals where time involved with filing a report was short ($p<0.05$). The impact of online reporting was limited to a 26% increase in physicians' reports ($p<0.05$).

**Conclusion** In accordance with the suggestions by previous studies that examined staff perceptions and attitudes, this study empirically demonstrated that to decrease burden to reporting and to implement staff educations may improve incident reporting.

Despite emphasis by the Institute of Medicine on the importance of building a safer healthcare system,[1] study of effectiveness of safety programmes on patient safety has not yet accelerated. Because of lack of evaluation tools and difficulty in measuring rare outcomes over short periods for small samples of patients with progressive diseases,[2–4] trials based on adverse events as the outcome can be extraordinarily difficult.[5] Instead, using systematic quality improvement, which has demonstrated success in non-medical industries, is a promising approach.[5 6]

As quality and safety enhancement involves the ability to learn from errors, which have emphasised consequences in high-risk industries,[7–9] incident reporting is a leading initiative proposed to improve patient safety.[1 10–12] Having a systematic collection of reports enables organisational learning by identification of sources of failure and thereby allows implementation of corrective actions. Under-reporting, however, is inherently involved in incident reporting systems. Because under-reporting of incidents has been estimated to range from 50% to 96%,[13–19] the frequency of reports likely does not represent true incidence of errors. Therefore, in using numbers of incident reports as the indicator of capacity of organisational learning, we must adjust barriers to reporting.

In the present study, we identified factors that increase the number of incident reports based on aspects of system-level activities for patient safety and design of incident reporting method.

## METHODS

### Data and sampling

We conducted our cross-sectional survey between December 2006 and May 2007, using all 1039 teaching hospitals in Japan. Ownership structures of teaching hospitals vary widely in Japan, and our survey included university, national, municipal, public and corporate models of ownership. Number of acute care beds varied from 42 to 1505 per hospital.

This study was approved by the institutional review board at the Graduate School of Medicine of Kyoto University.

### Development of questionnaire

The questionnaire was designed to collect information about numbers of incident reports filed by physicians and nurses, system-level activities for patient safety and design of incident reporting method. Questionnaire content was developed based on a review of past literature on patient safety[20–24] and clinical experience of a multidisciplinary panel of healthcare professionals and patient safety experts. The questionnaire included factors addressed in previous studies, most of which examined staff perceptions of barriers to reporting incidents: a busy and fatigued workforce,[8 9 25–41] fear of reporting,[8 9 28–38 42] and lack of knowledge about reporting.[8 9 23 25–27 30–32 35–43]

Because each question in the questionnaire was designed to investigate the method of current incident reporting, and the system-level activity status of each hospital is stringently recorded, the reliability of the responses may be thought of as high. In addition, the questionnaire was validated through interviews with several managers of patient safety and discussions with panels of experts. Because our validation process involved literature reviews and expert consensus, we believe that the survey questions have at least face validity and are reliable markers of patient safety systems.

### Dependent variables: numbers of incident reports

We measured numbers of incidents by type of professionals (physicians and nurses) reporting incidents during the 6 months from April to September

2006. As the hospital accreditation authority in Japan has a voluntary incident reporting system using a three-level classification scheme based on severity of injury, most hospitals refer to any of the following criteria as an incident: (1) an event occurred, but was caught before reaching the patient; (2) an event occurred and reached the patient, but patient was unharmed; and (3) an event occurred and the patient was affected, but the treatment attributable to the event was minimal. Incidents that involve a degree of harm to patients that requires more than the minimal amount of treatment are categorised as *accident* and therefore were not included in our definition of incidents.

### Independent variables: predictors of numbers of incident reports

#### Hospital characteristics

We controlled for certain hospital characteristics that were suspected to be confounding factors in counting the number of incident reports submitted. These characteristics included ownership and the number of inpatient-days.

In addition, the length of time that the incident reporting was in place at each hospital was included because of the hypothesis that the longer an incident reporting system has been in place, the higher the chance that the individual staff members understand the importance and methods to report incidents. We used this factor as a binary variable: below and above the median of elapsed years from implementation.

#### Design of incident reporting method

To control some suggested barriers to reporting incidents, patient safety managers were asked to evaluate the following four qualitative measures of design of incident reporting method: (1) whether the incidents were reported electronically or via paper; (2) average length of time staff spent to fill out an incident report; (3) whether a policy of non-punitive reporting was guaranteed by written documentation and/or orally; (4) numbers of recommendations per bed that the hospital implemented to improve systems, processes or products resulting from incidents reported between April and September 2006.

The first question refers to the potential barrier of a cumbersome method of reporting, which may negatively affect staff perception of reporting.[25–30] The emphasis on the barrier of perceived staff busyness and fatigue is inherent in the second question. If the potential reporter is too busy and too tired to report incidents, decreasing extra work involved in reporting is important.[8 9 30–41] We required respondents to answer which of the following lengths of time was closest to the average for reporting: ≤15 min, ≤30 min, ≤45 min, ≤60 min or >60 min. Responses then were collapsed into two categories: ≤30 and >30 min.

Confidentiality or immunity from punishment may be essential for potential reporters to overcome the barrier of fear.[8 9 28–38 42] Therefore, we gave two options for the third aspect of reporting design—a policy of non-punitive reporting ensured by written documentation and/or oral description, or no policy. The fourth aspect—recommendations derived from reported incidents—was based on past findings that giving feedback on results of incident reporting is useful to enhance reporting.[25–33 41]

#### Amount of system-level activities for patient safety

Because lack of knowledge about the reporting method is one of the most important barriers to reporting incidents,[23 25–27 30–32 35–43] we evaluated the amount of staff education for physicians and nurses. Staff education encompasses many aspects of patient safety and is not limited to incident reporting. In addition, we assessed activities to advance the "plan-do-check-act" cycle and, thereby, to improve patient safety systems, including assignment of safety managers, conferences and ward rounds. The person-time spent on these practices was calculated for a specified 6-month window (table 1). To calculate the person-time for each patient safety activity, we surveyed number of staff, amount of time required per activity session and frequency of activity sessions conducted between April and September 2006. Then, we converted the time spent by personnel on patient safety programmes into 2007 US dollars, using the employee's hourly wage[44–46] and the Purchasing Power Parities.[47] Finally, by use of the number of beds and the distribution of amount of each system-level activities among respondent hospitals, we collapsed the cost per 100 beds into two categories: over and under the median.

### Statistical analysis

We excluded hospitals lacking data regarding incident reports, reporting design or institutional characteristics. In the remaining hospitals, the top 1% of hospitals in terms of numbers of incident reports was further excluded from analysis because we found that these hospitals showed inordinately high incident report numbers and would therefore act as outliers that substantially affect the estimates of regression analysis. Because numbers of incident reports conform to a Poisson distribution, Poisson regression with overdispersion was used to perform multivariable analysis. Standard errors were made heteroskedastically consistent via the Huber–White covariance matrix. Stata V.9.2 was used for all analyses.

## RESULTS

A total of 418 hospitals participated in the study (response rate, 40.2%). Hospitals that did not meet inclusion criteria were dropped from the statistical analysis, resulting in a final sample of 232 hospitals. No significant relationships were noted between response rates and hospital demographic information, including geographic location ($\chi^2$ test, p=0.24) and bed size ($\chi^2$ test, p=0.94).

The mean (SE) of incident reports per 10 000 inpatient-days by physicians and nurses was 2.62 (0.18) and 91.3 (4.42), respectively. Table 2 compares reporting design of incidents. Although 63.8% of hospitals surveyed required an average of ≤30 min to report incidents, approximately 80 hospitals (36.2%) took an average of >30 min to fill out a report. Significantly more hospitals used paper-based reporting than online reporting (65.5% vs 34.5%; p<0.001).

The median (interquartile range) dollars spent on system-level activities per 100 beds during a 6-month period for assigning patient safety managers, conferences, ward rounds by peers,

**Table 1** Contents of system-level activities for patient safety

| Activity domain | Activity component |
|---|---|
| Assignment of safety managers | Assignment of dedicated full-time and part-time staff to patient safety division |
| Conferences | Supreme decision-making board/committee |
| | Regular meetings in patient safety division |
| Ward rounds by peers | Regular assessment of ward environment conducted by patient safety division |
| | Additional internal audit conducted by a separate department, such as nursing |
| Staff education | Physicians' participation in educational seminars to promote patient safety. |
| | Nurses' participation in educational seminars to promote patient safety |

**Table 2** Design of incident reporting method in eligible hospitals (n=232)

| Reporting design | No. of hospitals (%)* | No. of hospitals (%)† |
|---|---|---|
| Time involved in documenting an incident | | |
| ≤5 min | 6 (2.6) | 148 (63.8) |
| ≤15 min | 69 (29.7) | |
| ≤30 min | 73 (31.5) | |
| ≤45 min | 41 (17.7) | 84 (36.2) |
| ≤60 min | 13 (5.6) | |
| >60 min | 30 (12.9) | |
| Reporting media and format of report | | |
| Online based: only structured questions | 1 (0.4) | 80 (34.5) |
| Online based: open-ended and structured questions | 76 (32.8) | |
| Online based: only open-ended questions | 3 (1.3) | |
| Paper based: only structured questions | 8 (3.5) | 152 (65.5) |
| Paper based: open-ended and structured questions | 129 (55.6) | |
| Paper based: only open-ended questions | 15 (6.5) | |
| Immunity policy | | |
| Both documentation and oral explanation | 167 (72.0) | 218 (94.0) |
| Only oral explanation | 51 (22.0) | |
| No policy | 14 (6.0) | 14 (6.0) |
| Rate of recommendations derived from the incidents | | |
| ≤First quartile (0.90 cases per 100 beds) | 59 (25.4) | 119 (51.3) |
| ≤Second quartile (2.00 cases per 100 beds) | 60 (25.9) | |
| ≤Third quartile (3.61 cases per 100 beds) | 55 (23.7) | 113 (48.7) |
| >Third quartile (3.61 cases per 100 beds) | 58 (25.0) | |

*Crude data on responses in accordance with the questionnaire.
†Converted data for use in multi-variable regression.

education for physicians and education for nurses was $9410 ($5729–$13 575), $1326 ($873–$1899), $204 ($79–$482), $992 ($50–$3440), and $488 ($63–$1128), respectively (table 3).

Results of regression analyses presented in table 4 demonstrate that incident reports filed by physicians could be increased by online reporting (26%, $p<0.05$) and shorter time required to file a report (27%, $p<0.05$). Moreover, hospitals that implemented more education for physicians significantly increased reporting by 53% ($p<0.001$). In hospitals with dedicated full-time staff for the purpose of patient safety, the number of incident reports by physicians significantly increased by 35% ($p<0.05$). However, immunity policy and rate of recommendations derived from reported incidents did not significantly influence the number of physician-generated incident reports.

However, results of predictor factors in numbers of nurse-reported incidents, compared to physician-reported incidents, showed different relationships. Nurse-reported incidents were encouraged only by decreased time for reporting (22% increase, $p<0.05$). Education for nurses was not a significant factor in reporting.

There was no significant relationship between the elapsed years of incident reporting system and the number of incidents reported by physicians and nurses.

## DISCUSSION

To our knowledge, this is the first empirical study that explores determinants associated with incident reporting and identifies the impact of system-level activities on numbers of incident reports that could increase capacity of organisational learning.

**Table 3** Status of system-level activities for patient safety (n=232)

| Activity component | Activity status, median (IQR) | Cost*, US$†, median (IQR) |
|---|---|---|
| Assignment of safety managers to patient safety division | | $9410 ($5729–$13 575) |
| Assignment of full-time staff | | |
| Physician (no. of staff per 100 beds) | 0.0 (0.0–0.0) | |
| Nurse (no. of staff per 100 beds) | 0.2 (0.1–0.3) | |
| Allied staff (no. of staff per 100 beds) | 0.0 (0.0–0.2) | |
| Assignment of part-time staff | | |
| Physician (person-hours per week per 100 beds) | 0.3 (0.0–0.7) | |
| Nurse (person-hours per week per 100 beds) | 0.0 (0.0–1.5) | |
| Allied staff (person-hours per week per 100 beds) | 0.2 (0.0–1.5) | |
| Conferences | | $1326 ($873–$1899) |
| Supreme decision-making board/committee | | |
| No. of staff (per session per 100 beds) | 2.6 (1.9–3.8) | |
| Time required (minutes per session) | 60 (60–75) | |
| Frequency (during a 6-month period) | 6.0 (6.0–6.0) | |
| Regular meeting in safety division | | |
| No. of staff (per session per 100 beds) | 4.1 (2.6–6.3) | |
| Time required (minutes per session) | 60 (60–80) | |
| Frequency (during a 6-month period) | 6.0 (5.0–6.0) | |
| Ward rounds | | $204 ($79–$482) |
| By patient safety division | | |
| No. of staff (per session per 100 beds) | 0.6 (0.1–1.1) | |
| Time required (min per session) | 60 (13–90) | |
| Frequency (during a 6-month period) | 3.0 (1.0–6.0) | |
| By other department | | |
| No. of staff (per session per 100 beds) | 0.6 (0.0–1.6) | |
| Time required (min per session) | 30 (0–60) | |
| Frequency (during a 6-month period) | 1.0 (0.0–4.8) | |
| Educational seminars | | |
| Physicians' participation (person-hours during a 6-month period) | 12.1 (5.6–25.7) | $992 ($50–$3440) |
| Nurses' participation (person-hours during a 6-month period) | 93.3 (51.4–171.0) | $488 ($63–$1128) |

IQR, interquartile range.
*Cost per 100 beds during a 6-month period in a hospital.
†2007 US$ (JPN¥=US$0.85).

Our results provide new evidence supporting most of the previous studies that examined staff perceptions regarding incident reporting.

Our rationale for the present study was an extension of other works hypothesising that system-level activities enable reporting of incidents by establishing a solid safety culture among employees. In the first outcome studies in patient safety, researchers focused on factors that contribute to improvement of safety culture. Ginsburg *et al*[21] and Thomas *et al*[22] found that an improved safety culture was associated with implementation of staff education and executive ward rounds, respectively. Next, Naveh *et al*[48] empirically demonstrated that enhanced safety culture was associated with increased reporting of incidents. Later, a randomised controlled study by Figueiras *et al*[23] showed that physician-generated reporting of adverse drug reactions was increased by implementing staff education. Recent studies revealed that implementation of a multifaceted intervention package comprising staff education and changes in reporting designs could improve incident reporting.[25 26 30] Because previous studies did not assess the effectiveness of each patient safety programme on incident reporting, we investigated these issues in the current study.

**Table 4** Results of Poisson regression for predictors of the number of incident reports in a hospital (n=232)

| Variable | Physician-generated reports | | Nurse-generated reports | |
|---|---|---|---|---|
| | IRR (95% CI) | p Value | IRR (95% CI) | p Value |
| Hospital size | | | | |
| No. of inpatient-days per 10 000 | 1.11 (1.08 to 1.14) | <0.001 | 1.10 (1.07 to 1.13) | <0.001 |
| Ownership | | | | |
| University hospital | 1.93 (1.47 to 2.55) | <0.001 | 1.00 (0.76 to 1.30) | 0.972 |
| National hospital | 1.20 (0.87 to 1.66) | 0.268 | 1.31 (1.03 to 1.67) | 0.028 |
| Municipal hospital | 0.78 (0.58 to 1.05) | 0.103 | 1.04 (0.84 to 1.29) | 0.713 |
| Public hospital | 0.92 (0.70 to 1.19) | 0.509 | 1.02 (0.84 to 1.24) | 0.817 |
| Healthcare corporation and others | 1.00 (1.00 to 1.00) | | 1.00 (1.00 to 1.00) | |
| Elapsed years of incident reporting system | | | | |
| −6 years (≤median) | 1.00 (1.00 to 1.00) | | 1.00 (1.00 to 1.00) | |
| +7 years (>median) | 1.19 (0.97 to 1.47) | 0.100 | 1.11 (0.95 to 1.30) | 0.177 |
| Design of incident reporting method | | | | |
| Reporting media | | | | |
| Paper-based reporting | 1.00 (1.00 to 1.00) | | 1.00 (1.00 to 1.00) | |
| Online reporting | 1.26 (1.05 to 1.52) | 0.012 | 0.95 (0.82 to 1.11) | 0.516 |
| Time involved with filing a report | | | | |
| >30 min | 1.00 (1.00 to 1.00) | | 1.00 (1.00 to 1.00) | |
| ≤30 min | 1.27 (1.05 to 1.53) | 0.014 | 1.22 (1.05 to 1.42) | 0.011 |
| Immunity policy in hospital | | | | |
| No policy | 1.00 (1.00 to 1.00) | | 1.00 (1.00 to 1.00) | |
| Non-punitive policy | 1.35 (0.88 to 2.06) | 0.172 | 0.99 (0.72 to 1.35) | 0.938 |
| Rate of recommendations to staff | | | | |
| Low (≤median) | 1.00 (1.00 to 1.00) | | 1.00 (1.00 to 1.00) | |
| High (>median) | 1.01 (0.82 to 1.24) | 0.939 | 1.01 (0.86 to 1.19) | 0.872 |
| System-level activities for patient safety | | | | |
| Assignment of safety managers | | | | |
| Low (≤median) | 1.00 (1.00 to 1.00) | | 1.00 (1.00 to 1.00) | |
| High (>median) | 1.35 (1.10 to 1.66) | 0.004 | 1.04 (0.89 to 1.21) | 0.650 |
| Conferences | | | | |
| Low (≤median) | 1.00 (1.00 to 1.00) | | 1.00 (1.00 to 1.00) | |
| High (>median) | 1.09 (0.89 to 1.33) | 0.414 | 1.02 (0.87 to 1.20) | 0.821 |
| Ward rounds by peers | | | | |
| Low (≤median) | 1.00 (1.00 to 1.00) | | 1.00 (1.00 to 1.00) | |
| High (>median) | 1.04 (0.87 to 1.25) | 0.661 | 1.02 (0.89 to 1.18) | 0.748 |
| Physicians' attendance at educational seminars | | | | |
| Low (≤median) | 1.00 (1.00 to 1.00) | | – | |
| High (>median) | 1.53 (1.24 to 1.89) | <0.001 | – | |
| Nurses' attendance at educational seminars | | | | |
| Low (≤median) | – | | 1.00 (1.00 to 1.00) | |
| High (>median) | – | | 1.08 (0.93 to 1.25) | 0.334 |

IRR, incidence–rate ratio.

In contrast to the physician-generated reports, there was no significant association between education for nurses and the number of nurse-initiated reports. A possible reason for this difference is a decreased marginal effect of education for nurses. Considering that the average number of nurse-generated reports was more than 30 times higher than that of physicians and that educational time for nurses was more than seven times greater than that for physicians, nurses' knowledge about incident reporting appears to be sufficient. According to previous studies,[31 36 37 41] staff perspectives regarding reporting show that lack of knowledge was not a major deterrent for reporting by nurses, although it may be a major barrier to reporting by physicians. In addition, other studies demonstrated that implementing physician education resulted in significant improvement in reporting by physicians.[23 38] Therefore, our results were partially consistent with previous qualitative findings. Furthermore, we shed light on the impact of assignment of safety manager on the number of incident reports filed by physicians for the first time. Although our survey focused on system-level activities for patient safety that were conducted organisationally, other daily detailed activities not specifically included in the survey were instead covered under the duties of full-time dedicated staff. For example, each dedicated staff member performs the activities involved in analysing reported incidents and giving feedback on results of incident reporting, and promotes awareness of patient safety throughout hospital via such routine activities. These activities might affect physicians' attitude to incident reporting.

In addition to a lack of knowledge as discussed above, our result that busyness and fatigue are barriers of incident reporting was consistent with past literature that examined the reasons of under-reporting of incidents.[31–41] By decreasing the time to fill out incident reports, the number of incidents by physicians and nurses could be significantly increased by 27% and 22%, respectively. Meanwhile, the influence of reporting method (online vs paper-based) was different depending on type of professions, and this was again in concordance with previous findings. For example, the finding that physician-generated online reports

significantly increased by 26% ($p<0.05$) is in accordance with previous studies that examined numbers of incidents reported via online systems.[28 29] Regarding reporting by nurses, in contrast, our results are also similar to previous studies.[29 30] Perceptions of usefulness versus the cumbersome nature of online reporting might depend on accessibility and a user-friendly interface. Because reducing the time required to fill out a report would obviously make reporting less burdensome, this reporting design could generate more reports by physicians and nurses.

Although fear of reporting has been previously found to be another barrier,[31–38 42] our studies did not observe this result. Willingness to report incidents could depend on the legislative system, such as presence of laws protecting patient safety whistle-blowers from retaliation. Japanese healthcare providers are susceptible to criminal prosecution for professional negligence.[49] Therefore, the impact of an immunity policy in hospitals might decrease the barrier of fear in reporting incidents.

Previous studies that evaluated staff perception suggested that giving feedback to staff was useful to enhance reporting.[27 31–33] A possible reason why our study did not confirm a significant relationship between these factors is that because our study was an observational study and therefore unable to standardise the definition of recommendation derived from reported incidents, there would be discrepancy of content of feedback among participant hospitals. Further study is needed to examine the true impact of feedback on incident reporting.

Previous studies have paid little attention to the impact of elapsed years since implementation of a reporting system, whereas it is likely that the longer an incident reporting system has been in existence in a particular hospital might correlate with a better maturation of the reporting system and therefore present an increased number of incidents. Although our model was unable to demonstrate this relationship, this result should be viewed with caution. Because the variable in our model used the elapsed years of the *first* adoption of incident reporting system, it did not reflect that of the *current* reporting system.

Our study has several limitations. First, questions on the amount of system-level activities were answered by patient safety managers. Therefore, even if activities to improve patient safety systems were conducted within other departments, all activities implemented in a hospital might not be reflected in our survey and thus might diminish the measurable effect of the activities. Second, many hospitals did not respond to our questionnaire, thus raising the existence of selection bias. Those that participated in our survey may systematically establish patient safety systems as compared to hospitals that did not respond our questionnaire because it is likely that hospitals that recorded daily activity status may tackle the issue of patient safety in an organised way. Therefore, our results might reflect the status of teaching hospitals with relatively high motivation to enhance patient safety. Last, our findings could be favourable within a stage in which the incident reporting system has not been fully matured. When the understanding of the incident reporting system increases among professions, and each staff member will report all incidences that he or she encounter, the next stage will be that the number of *true* incidents will gradually diminish. Although the influence of secular trends on our results is unclear, our findings may offer an effective way to attain such a desirable subsequent stage.

In conclusion, our results demonstrate empirically that the number of incident reports reflect the degree of staff education and have implications for initiatives to design better reporting methods. Further research is needed to develop successful educational content and to modify incident reporting formats. A challenge is to balance competing goals of ease of the reporting process and the need for more detailed information enabling prevention of recurrence of similar incidents.

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## REFERENCES

1. **Kohn LT,** Corrigan JM, Donaldson MS, eds. *To err is human: building a safer health system* Washington (DC): National Academy Press 2000.
2. **Brennan TA,** Gawande A, Thomas E, *et al*. Accidental deaths, saved lives, and improved quality. *N Engl J Med* 2005;**353**:1405–9.
3. **Leape LL,** Berwick DM. Five years after to err is human: what have we learned? *JAMA* 2005;**293**:2384–90.
4. **Pronovost PJ,** Miller MR, Wachter RM. Tracking progress in patient safety: an elusive target. *JAMA* 2006;**296**:696–9.
5. **Leape LL,** Berwick DM, Bates DW. What practices will most improve safety? Evidence-based medicine meets patient safety. *JAMA* 2002;**288**:501–7.
6. **Brennan TA,** Mello MM. Patient safety and medical malpractice: a case study. *Ann Intern Med* 2003;**139**:267–73.
7. **Reason J.** Human error: models and management. *BMJ* 2000;**320**:768–70.
8. **Barach P,** Small SD. Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems. *BMJ* 2000;**320**:759–63.
9. **Leape LL.** Reporting of adverse events. *N Engl J Med* 2002;**347**:1633–8.
10. **Leape LL.** Error in medicine. *JAMA* 1994;**272**:1851–7.
11. **Vincent C,** Taylor-Adams S, Stanhope N. Framework for analysing risk and safety in clinical medicine. *BMJ* 1998;**316**:1154–7.
12. **Cohen MR.** Why error reporting systems should be voluntary. *BMJ* 2000;**320**:728–9.
13. **Classen DC,** Pestotnik SL, Evans RS, *et al*. Computerized surveillance of adverse drug events in hospital patients. *JAMA* 1991;**266**:2847–51.
14. **Cullen DJ,** Bates DW, Small SD, *et al*. The incident reporting system does not detect adverse drug events: a problem for quality improvement. *Jt Comm J Qual Improv* 1995;**21**:541–8.
15. **Donchin Y,** Gopher D, Olin M, *et al*. A look into the nature and causes of human errors in the intensive care unit. *Crit Care Med* 1995;**23**:294–300.
16. **Jha AK,** Kuperman GJ, Teich JM, *et al*. Identifying adverse drug events: development of a computer-based monitor and comparison with chart review and stimulated voluntary report. *J Am Med Inform Assoc* 1998;**5**:305–14.
17. **Sanborn KV,** Castro J, Kuroda M, *et al*. Detection of intraoperative incidents by electronic scanning of computerized anesthesia records: comparison with voluntary reporting. *Anesthesiology* 1996;**85**:977–87.
18. **Sari AB,** Sheldon TA, Cracknell A, *et al*. Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review. *BMJ* 2007;**334**:79–81.
19. **Stanhope N,** Crowley-Murphy M, Vincent C, *et al*. An evaluation of adverse incident reporting. *J Eval Clin Pract* 1999;**5**:5–12.
20. **Corrigan J,** Eden J, Smith BM. *Leadership by example: coordinating government roles in improving healthcare quality* Washington (DC): National Academy Press, 2003.
21. **Ginsburg L,** Norton PG, Casebeer A, *et al*. An educational intervention to enhance nurse leaders' perceptions of patient safety culture. *Health Serv Res* 2005;**40**:997–1020.
22. **Thomas EJ,** Sexton JB, Neilands TB, *et al*. The effect of executive walk rounds on nurse safety climate attitudes: a randomized trial of clinical units. *BMC Health Serv Res* 2005;**5**:28.
23. **Figueiras A,** Herdeiro MT, Polónia J, *et al*. An educational intervention to improve physician reporting of adverse drug reactions: a cluster-randomized controlled trial. *JAMA* 2006;**296**:1086–93.
24. **Fukuda H,** Imanaka Y, Hayashida K. Cost of hospital-wide activities to improve patient safety and infection control: a multi-centre study in Japan. *Health Policy* 2008;**87**:100–11.
25. **Harris CB,** Krauss MJ, Coopersmith CM, *et al*. Patient safety event reporting in critical care: a study of three intensive care units. *Crit Care Med* 2007;**35**:1068–76.
26. **Tuttle D,** Holloway R, Baird T, *et al*. Electronic reporting to improve patient safety. *Qual Saf Health Care* 2004;**13**:281–6.
27. **Taylor JA,** Brownstein D, Christakis DA, *et al*. Use of incident reports by physicians and nurses to document medical errors in pediatric patients. *Pediatrics* 2004;**114**:729–35.
28. **Haller G,** Myles PS, Stoelwinder J, *et al*. Integrating incident reporting into an electronic patient record system. *J Am Med Inform Assoc* 2007;**14**:175–81.

29. **Kivlahan C,** Sangster W, Nelson K, *et al*. Developing a comprehensive electronic adverse event reporting system in an academic health center. *Jt Comm J Qual Improv* 2002;**28**:583–94.
30. **Evans SM,** Smith BJ, Esterman A, *et al*. Evaluation of an intervention aimed at improving voluntary incident reporting in hospitals. *Qual Saf Health Care* 2007;**16**:169–75.
31. **Jeffe DB,** Dunagan WC, Garbutt J, *et al*. Using focus groups to understand physicians' and nurses' perspectives on error reporting in hospitals. *Jt Comm J Qual Saf* 2004;**30**:471–9.
32. **Kingston MJ,** Evans SM, Smith BJ, *et al*. Attitudes of doctors and nurses towards incident reporting: a qualitative analysis. *Med J Aust* 2004;**181**:36–9.
33. **Karsh BT,** Escoto KH, Beasley JW, *et al*. Toward a theoretical approach to medical error reporting system research and design. *Appl Ergon* 2006;**37**:283–95.
34. **Katz RI,** Lagasse RS. Factors influencing the reporting of adverse perioperative outcomes to a quality management program. *Anesth Analg* 2000;**90**:344–50.
35. **Figueiras A,** Tato F, Fontaiñas J, *et al*. Physicians' attitudes towards voluntary reporting of adverse drug events. *J Eval Clin Pract* 2001;**7**:347–54.
36. **Uribe CL,** Schweikhart SB, Pathak DS, *et al*. Perceived barriers to medical-error reporting: an exploratory investigation. *J Healthc Manag* 2002;**47**:263–79.
37. **Vincent C,** Stanhope N, Crowley-Murphy M. Reasons for not reporting adverse incidents: an empirical study. *J Eval Clin Pract* 1999;**5**:13–21.
38. **Coyle YM,** Mercer SQ, Murphy-Cullen CL, *et al*. Effectiveness of a graduate medical education program for improving medical event reporting attitude and behavior. *Qual Saf Health Care* 2005;**14**:383–8.
39. **Eland IA,** Belton KJ, van Grootheest AC, *et al*. Attitudinal survey of voluntary reporting of adverse drug reactions. *Br J Clin Pharmacol* 1999;**48**:623–7.
40. **Elder NC,** Graham D, Brandt E, *et al*. Barriers and motivators for making error reports from family medicine offices: a report from the American Academy of Family Physicians National Research Network (AAFP NRN). *J Am Board Fam Med* 2007;**20**:115–23.
41. **Evans SM,** Berry JG, Smith BJ, *et al*. Attitudes and barriers to incident reporting: a collaborative hospital study. *Qual Saf Health Care* 2006;**15**:39–43.
42. **Robinson AR,** Hohmann KB, Rifkin JI, *et al*. Physician and public opinions on quality of health care and the problem of medical errors. *Arch Intern Med* 2002;**162**:2186–90.
43. **Kaldjian LC,** Jones EW, Wu BJ, *et al*. Reporting medical errors to improve patient safety: a survey of physicians in teaching hospitals. *Arch Intern Med* 2008;**168**:40–6.
44. **Ministry of Health Labour and Welfare.** Iryo Keizai Zittai Chousa Houkoku. 2005. http://www.mhlw.go.jp/shingi/2006/06/dl/s0621-6-05.pdf. (accessed 3 Mar 2008). [in Japanese]
45. **Ministry of Health Labour and Welfare.** [Basic survey of wage structure]. 2005. http://wwwdbtk.mhlw.go.jp/toukei/kouhyo/data-rou4/data17/30501.xls. (accessed 3 Mar 2008). [in Japanese]
46. **Ministry of Internal Affairs and Communication.** Annual report on the labour force survey. 2005. http://www.stat.go.jp/data/roudou/2005nft/zuhyou/201420.xls. (accessed 3 Mar 2008). [in Japanese]
47. OECD statistics on Purchasing Power Parities (PPP): comparative price levels. http://www.oecd.org/dataoecd/48/18/18598721.pdf. (accessed 3 Mar 2008).
48. **Naveh E,** Katz-Navon T, Stern Z. Readiness to report medical treatment errors: the effects of safety procedures, safety information, and priority of safety. *Med Care* 2006;**44**:117–23.
49. **Hirose M,** Regenbogen SE, Lipsitz S, *et al*. Lag time in an incident reporting system at a university hospital in Japan. *Qual Saf Health Care* 2007;**16**:101–4.

画像診断(CT,MRI)に関する実態調査 研究報告

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【背景と目的】

近年、画像診断機器及び処理装置の目覚ましい発達、また、病変の早期発見要望また治療の高度化による画像診断への要求高度化等により、膨大な件数の画像診断が施行されていると考えられる。また、日本にはCT,MRIといった画像診断装置が世界の中でも突出して導入されているのは既知の事実である。画像診断の高度化はそれ自体歓迎されるべきものではあるが、その解釈には専門性を要するのもまた事実である。医療の現場では、CT,MRIの撮像適応や撮像方法の決定、また撮像された画像を読影・文書化後担当医に伝達し医療に役立てる役割を担っているのが放射線科診断医であり、この過程が円滑に行われているとすれば画像診断の質を保証することもできていると判断できる。しかし、現在の画像診断機器稼働状況に比較し放射線診断医数は圧倒的に少数であり、画像診断の質が保証されているとは言い難い。また、昨今の都市部への医師集中は放射線科診断医でも例外ではなく、地域による業務量差も問題となる（通信手段の発達により遠隔画像診断という方法も既に導入されつつある)。

画像診断の質を保証するためには、診断機器・放射線科診断医の適正配置や診断医教育・養成など様々な要因について考慮しなければならないが、そのためには診断機器稼働状況及び診断医業務量等の現状を把握し、問題点を明らかにする必要があると考えられる。以上より、今回、日本における画像診断のあるべき姿を考察するため、CT,MRI検査数及び放射線診断医関与の現状把握目的に、病院による記入式の調査票に基づく調査を行った。

【方法】

全国の医療機関を対象として、アンケート調査を実施した。調査は、京都大学医学研究科・医療経済学分野と日本医学放射線学会の共催により実施された。同学会は、日本で唯一の放射線専門医の認定団体である。アンケート調査の内容および実施方法は同学会理事会で審議され、承認された。

放射線科診断業務の大部分は病院で行なわれるため、診療所は調査の対象から除外した。放射線診断の常勤医が存在する可能性の高い一般病床200床以上規模の病院はすべて調査対象とし、一般病床20-199床規模の病院は層別化サンプリングにより選択した。各都道府県ホームページ等で公表されている届出医療機関の一覧表から一般病床200床以上の病院を同定した。20-199床規模病院

は、以下の方法にてサンプリングを行った。すなわち、新医療 2008/2009(エムイー振興協会)の全国 CT,MRI 設置病院リストと届出医療機関の一覧表から、都道府県別に 100-199 床規模病院数の 1/10、20-99 床規模病院数の 1/20 をランダムサンプリングした。

調査票の質問項目は、1）施設の概要（一般病床数や患者数、設立主体など)、2）放射線科医数（常勤医師・非常勤医師・常勤技師・非常勤技師)、画像診断機器（CT・MRI の台数)、3）読影数などである。アンケート対象施設の中には回答するも件数等統計を実施していない施設もあり、解析の際、解析方針に合わせて使用可能なデータを利用した。

【結果と考察の概要】

1,998 施設にアンケートを送付し、855 施設より回答を得た。総回答割合は 43%であった。全回答 855 施設中、583 施設に画像診断常勤医が存在し、その割合は 68%であった。読影割合には病院種別に加え地域差が認められる。当調査により常勤医や遠隔診断の関与割合、常勤画像診断医年間平均パフォーマンス、常勤画像診断医と一人あたり CT/MRI 台数の分布が求められる。これらに基づき、台数や業務負担の不均衡を表すことができる。また、平均的なパフォーマンスや分布を参照した基準値の設定により、検査量から放射線科診断業務量や画像診断医の人員を求めて不足幅を明示することができるようになる。

# 二次医療圏単位で見た老人医療費の規定因子

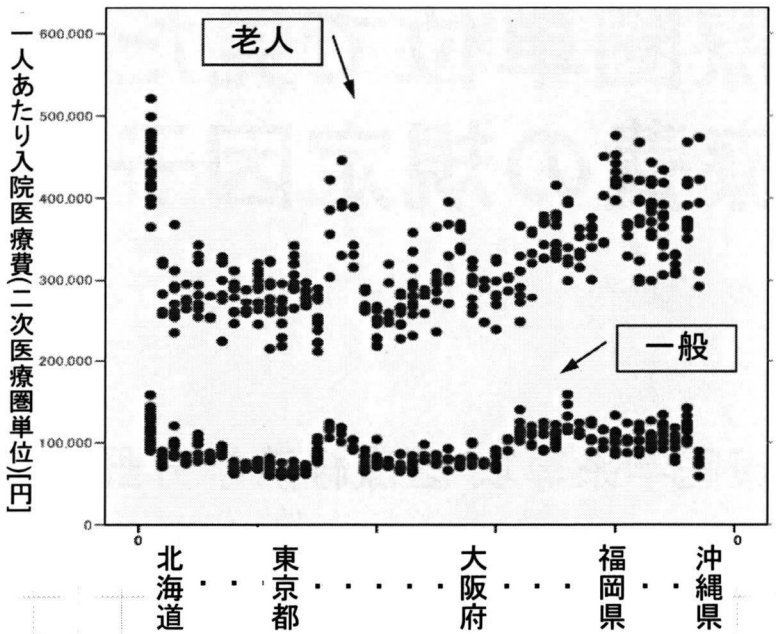
社会健康医学系専攻 医療経済学分野
後藤 悦

2

- 背景・目的
- 方法
- 結果
- 考察
- まとめ

3

# 老人医療費の地域差(2002年、国保データ)




- 老人医療費に地域差があることはかねてから指摘されている。[1][2]
- 医療費の地域差を、地域の疾病構造の差はほとんど説明しない。[3]

*[1]前田信雄. 1983　[2]藤原佳典,他. 1998*
*[3]府川哲夫　地域差研究会編. 地域差の研究. 第5章 2001*

4

背景

# 医療費の地域差の要因

- 先行研究(1)
  - 老人医療費の地域差は、主に病床数に拠る[4][5][6]
    - ➔病床数は医療費適正化計画の削減目標に[7]
  - 他の要因については十分に議論されていない
    - ➢病床数以外に地域差を説明する要因は？
    - 医療サービス供給側要因(診療所数[8]、…)
    - 医療サービス需要側要因(疾患構造[3]、大病院志向[9]、…)
    - 社会経済的要因(人口[8]、世帯人数[8][11]、経済力[10][11]、…)

*[4]今井博久,他　1998　[5]新村和哉,他　1999　[6]堀真奈美,他　2006*
*[7]医療費適正化に関する施策についての基本的な方針 平成20年　厚生労働省*
*[8]安西将也,他　1989　[9]青木研　地域差研究会編. 地域差の研究. 第10章 2001*
*[10]森満,他　1988　[11]印南一路　1997*

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背景

# 医療費の地域差の要因

- 先行研究(2)
  - 都道府県単位で分析を行った研究が多い
    - ■都道府県は、その内部での格差が大きい
    - ■地域に起因する諸要因を均してしまう可能性がある

都道府県を単位とした主な研究
- 1983 前田信雄
- 1987 安西将也、他
- 1988 森満、他
- 1989 安西将也、他
- 1989 二木立
- 1996 伏見恵文
- 1999 福田吉治、他
- 1999 新村和哉、他
- 2003 知野哲朗
- 2006 堀真奈美

市町村を単位とした主な研究
- 1990 多田羅浩三、他
- 1996 畝博
- 1997 印南一路
- 1998 山下真宏

二次医療圏を単位とした主な研究
- 1992 西村やよい、他
- 1998 今井博久、他

レセプトを単位とした主な研究
- 1995 府川哲夫
- 1999 府川哲夫

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目的

# 医療費の地域差の要因

- 本研究では
  - (病床数以外で)医療費の地域差には、何が関連するか？
  1. 医療サービス供給側、需要側、社会経済的因子
  2. 二次医療圏単位での分析
  3. 二次医療圏を可住地面積人口密度の高低で3グループに分ける
     - ■ 医療費と因子の関連は、地域の特性によって変わると考えられる[12][13][14]

*[12] Di Matteo L. 2005 [13] Thornton JA, et al. 2008 [14] Onwujekwe O, et al. 2005*

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- 背景・目的
- **方法**
- 結果
- 考察
- まとめ

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方法

## データ

- **医療費**
  - 資料：平成14年度国民医療費
  - 市区町村、国民保険被保険者のうち65歳以上
    - ■以降、65歳以上を「老人」とする
  - 入院医療費
- **分析単位**
  - 二次医療圏

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方法

# 可住地面積人口密度[人/Km²] ①

- 総人口÷可住地面積
- 高低による3サブグループ

| サブグループ | 範囲 | 二次医療圏数 |
|---|---|---|
| 低 | 下位20% | 72 |
| 中 | 中位60% | 219 |
| 高 | 上位20% | 72 |

■ 以降、人口密度とする

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# 可住地面積人口密度　度数分布