Table 2
Characteristics of participant hospitals (approximate figures)

	Hospital A	Hospital B	Hospital C	Hospital D	Hospital E	Hospital F	Hospital G
No. of beds	300	390	510	520	690	880	1100
Intensive care unit[a]	10	5	10	10	10	25	50
No. of inpatient-days	101,000	114,000	153,000	142,000	299,000	262,000	397,000
Average LOS[b]	12	14	14	12	15	16	15
No. of doctors	80	110	120	100	130	240	290
No. of nurses	240	370	450	470	510	570	960
No. of pharmacists	20	20	20	30	20	50	60
No. of other medical staff[c]	90	270	110	160	90	310	290
No. of administrative staff	80	100	50	160	40	330	410
No. of others	50	30	40	180	80	190	160

[a] Presented is the total number including intensive care unit, coronary care unit, high care unit, neonatal intensive care unit, and maternal-fetal intensive care unit.
[b] Presented is average length of stay limited acute beds.
[c] Presented is the total number of co-medicals without pharmacists.

measures are summarized in Table 3. The total volume of activities in each domain was 19,414–78,540 person-hours per year. The volume of activities for management of medications, meetings and conferences, and internal education and training formed the majority of total activities. The proportion of the total volume for patient safety and for infection control was respectively: doctors, 5.8% and 16.6%; nurses, 34.5% and 53.5%; pharmacists, 31.3% and 4.1%; other medical staff, 16.8% and 16.9%; administrative staff, 11.2% and 7.4%; other staff, 0.5% and 1.5%.

3.2. Cost

The average cost of materials implemented for patient safety and infection control – including the prevention of patient misidentification, falls, pressure ulcers, retained surgical sponges, venous thromboembolism, hospital infection and adverse drug events – at the seven hospitals was estimated to be US$ 0.475 million (Table 4), with a median cost of US$ 0.456 million. Materials used for infection control included gloves, gowns, hand hygiene, safety needles, and antimicrobial catheters, while patient safety was ensured through the use of identification bracelets, bed alarms, barcode patient identification systems, unit-dose drug distribution systems, automated medication dispensing devices. (Data describing materials for infection control used in hospitals F and G were not available.)

The estimated total incremental cost of manpower resources ranged US$ 0.591–2.206 million and that of material resources ranged from US$ 0.297 to 0.691

Table 3
The volume and proportion of manpower activities for patient safety and infection control

	Hospital A	Hospital B	Hospital C	Hospital D	Hospital E	Hospital F	Hospital G	Average
Total activities (person-hour/year)	27,787	44,472	43,685	48,247	19,414	26,753	78,540	41,271
Activity domain (%)								
Meetings and conferences	4.5	8.9	8.6	25.0	14.4	10.1	7.8	11.3
Internal audit	60.9	0.8	2.3	1.5	14.8	12.1	4.7	10.0
Internal education	4.2	9.8	14.5	5.8	8.0	28.3	7.9	10.4
External education	0.7	7.6	0.9	3.0	4.3	6.6	1.1	3.1
Incident reporting	5.0	24.5	2.0	5.4	19.0	8.4	11.3	10.6
Infection surveillance	2.7	0.5	1.8	4.9	1.6	8.5	0.9	2.5
Development of standardized manuals	4.8	1.2	2.9	0.6	3.6	2.0	0.4	1.7
External audit	0.0	3.8	0.4	0.3	0.0	3.2	0.0	1.0
Maintenance of medical equipments	12.3	4.7	13.7	12.8	12.9	0.0	9.9	9.7
Management of medications	0.0	31.7	33.4	34.4	20.3	0.0	52.8	31.4
Other activities	4.8	6.6	19.5	6.3	1.0	20.7	3.2	0.0

Table 4
One-year incremental costs of hospital-wide activities for patient safety and infection control

Activity domain	A	B	C	D	E	F	G	Average
Material and other costs								
Sub total (US million $)[a]	0.456	0.336	0.635	0.691	0.503	0.406	0.297	0.475
Materials for patient safety	4.0%	19.2%	16.8%	3.5%	12.3%	3.3%	0.0%	8.7%
Materials for infection control	79.4%	37.2%	26.6%	39.6%	31.7%	N/A	N/A	45.8%
Equipments for patient safety	4.9%	12.0%	14.2%	2.1%	4.7%	0.6%	1.2%	5.9%
Vaccination	1.8%	0.5%	10.9%	3.5%	0.0%	4.4%	19.7%	5.4%
Spaces for conference or training	4.8%	9.7%	7.4%	15.9%	13.1%	11.6%	23.7%	11.9%
Handouts	0.9%	3.3%	0.5%	3.5%	1.3%	2.5%	6.6%	2.4%
Disposal cost	2.4%	7.4%	21.6%	26.5%	32.3%	57.0%	42.7%	26.4%
Others[b]	1.9%	10.7%	2.0%	5.3%	4.6%	20.7%	6.1%	6.6%
Human resource costs								
Sub total (US million $)[a]	0.823	1.144	1.168	1.409	0.591	0.783	2.206	1.161
Meetings and conferences	5.0%	11.2%	11.1%	28.8%	18.8%	11.7%	11.1%	14.2%
Internal audits	62.5%	0.9%	2.7%	1.7%	14.3%	12.2%	5.9%	11.0%
Internal education	4.2%	10.8%	15.7%	6.0%	7.4%	34.8%	9.6%	11.7%
External education	0.7%	4.2%	1.2%	2.8%	3.8%	5.0%	1.2%	2.4%
Incident reporting	5.0%	29.9%	2.7%	5.4%	20.3%	8.4%	11.3%	11.4%
Infection surveillance	2.8%	0.9%	2.1%	4.7%	1.6%	7.9%	1.2%	2.7%
Development of standardized manual	5.8%	1.2%	4.0%	0.5%	4.3%	2.1%	0.5%	2.1%
External audits	0.0%	3.6%	0.5%	0.1%	0.0%	3.3%	0.0%	0.9%
Maintenance of medical equipment	8.6%	5.1%	14.4%	12.3%	12.0%	0.0%	9.9%	9.4%
Management of medications	0.0%	28.5%	21.0%	30.9%	16.0%	0.0%	46.0%	26.0%
Other activities	5.6%	3.7%	24.6%	6.8%	1.4%	14.7%	3.2%	8.2%
Total costs (US million $)[a]								
For patient safety	0.793	1.109	1.175	1.341	0.615	0.550	2.104	1.098
For infection control	0.486	0.371	0.629	0.759	0.479	0.638	0.400	0.538
Total	1.279	1.480	1.804	2.101	1.094	1.188	2.504	1.636

N/A, not available.
[a] JPN¥ 100 = US$ 0.85 (April 2007).
[b] Includes fees for participation in each training session and external reviews.

Table 5
Indicators based on total incremental cost for patient safety and infection control

Indicators	Hospital A	Hospital B	Hospital C	Hospital D	Hospital E	Hospital F	Hospital G	Average
Total cost								
Adjusted to 100 beds (US million $)[a]	423	378	352	403	160	135	226	297
Equivalent number of staff that could be employed[b]	20	24	29	33	17	19	40	26
Ratio of costs to total medical revenue[c] (%)	2.18	1.53	2.01	2.57	0.94	0.55	N/A	1.62
Total cost per unit								
Per bed (US$)[a]	4,234	3,785	3,516	4,032	1,597	1,355	2,264	2,969
Per patient-day (US$)[a]	12.61	12.94	11.80	14.79	4.78	4.53	6.31	9.68

N/A, not available.
[a] JPN¥ 100 = US$ 0.85 (April 2007).
[b] Based on the average total income of all healthcare staff.
[c] Since we could not obtain the data of total revenue in hospital G, we did not indicate the value.

million. The total cost of activities for patient safety and infection control was calculated to range from US$ 1.094 to 2.504 million per year; the proportion of material costs ranged from 11.9% to 46.0%. The costs were not discounted because estimates were focused only on the year 2004.

Smaller hospitals (under 500 beds) tend to shoulder a higher burden compared to larger hospitals. As shown in the costs adjusted number of bed to 100 in Table 5, the costs of hospital E (690 beds), F (880 beds) and G (1100 beds) were much smaller than those of hospital A (300 beds) and B (390 beds).

Table 5 summarizes the indicators based on total incremental costs for patient safety and infection control. Converted to number of staff, these incremental costs were equivalent to employing 17–40 full-time staff only for patient safety and infection control. The ratio of costs for patient safety to total medical revenue ranged 0.55–2.57%. Since we could not obtain the data of total revenues in hospital G, we did not compute the value. To sustain the existing activities for both activities, it cost US$ 2969 per bed or US$ 9.68 per patient-day on average.

4. Discussion

To the best of our knowledge, this is the first multicentre study to provide a descriptive account of what hospitals are spending on hospital-wide programs for patient safety and infection control. One reason for the lack of previous literature on the subject is the difficulty in defining the scope and estimating the costs of hospital-wide activities for patient safety. By using the incremental concept, we were able to estimate the costs of patient safety. Because a major turning point in patient safety practices and policies occurred in 1999 in Japan, we were able to define the scope of activities for patient safety as activities since that time, and thereby estimate incremental activities.

Our estimates provide significant information due to the following advantages: First, we estimated the cost for patient safety plus infection control by parceling each activity domain into components, estimating the labor and material costs for each component, and then summing the total cost. This formula was applied to each activity domain and all seven hospitals to ensure a higher quality of cost estimation.

Second, our study scope covered hospital-wide activities for patient safety and infection control. Previous cost studies that have estimated prevention costs for patient safety or infection control tended to focus only on specific programs. Therefore, no data accurately reflects the cumulative resources burden incurred by a hospital as a whole. In contrast, our comprehensive estimate of the cost required to maintain hospital-wide patient safety and infection control activities.

Third, in an environment of constantly increasing pressure to contain healthcare costs, we demonstrated for the first time a dramatic increase in the cost to run patient safety systems. In Japan, since healthcare is increasingly affected by government policy and societal pressures, doctors feel overworked and under compensated [28]. This phenomenon closely resembles the situation in the United Kingdom [29]. In such an environment, we found that the overall annual incremental costs ranged from US$ 1.094 to 2.504 million per hospital, which is equivalent to the cost of employing 17–40 full-time healthcare staff. From the patient's perspective, the safety levels of health services are intangible. Patients are unable to identify whether the hospital maintains adequate safety systems, except in cases where patients suffer personal damage from adverse events during their hospital stay. However, from the hospital's point of view, huge amounts of money are spent to maintain safety systems. Hence, quantification and evaluation of the costs for patient safety systems are important to enhance public regard for the costs of patient safety, and the need to allocate additional resources.

Lastly, we also found that the economic burden of activities for patient safety was heavier in relatively smaller hospitals. We reasoned that most activities were invested for the development and maintenance of safety systems rather than for each individual inpatient measure. It might therefore be wise for hospitals to take advantage of scale economies in the activities for patient safety.

The high proportion of patient safety activities was accounted for by management of medications and monitor of medical equipment. The activities of by clinical pharmacists in Japan have been expanding recently. In 1994, management of medication conducted by deploying clinical pharmacists was reimbursed by Japan's payment system. These reimbursements were justified by several international studies demonstrating the efficacy of pharmacy services in enhancing patient safety [30–33]. Of the seven participant hospitals, though one hospital (Hospital F) had sufficiently delivered clinical pharmacy services before 1999, several of them started to deploy clinical pharmacists after 1999, which resulted in increased incremental costs.

On the other hand, health device inspection and preventive maintenance by clinical engineering departments were expected to improve patient safety by reducing equipment failure [17]. Although these activities have historically been conducted by nurses in each clinical unit, there is a growing trend towards management of medical equipment by clinical engineers located in a central department. Several healthcare institutions have adopted this strategy over the past several years.

Our cost estimates may be conservative because we excluded the following activities. First, we did not estimate the costs of activities implemented before 1999, even if they could be rightfully regarded as patient safety activities. Indeed, it has been recognized that some programs for infection control and prevention have been studied and implemented since 1980s [18]. As a result, we may have underestimated the amount of infection control activities. This is one possible reason explaining why the costs of hospital infection were smaller than that of patient safety (Table 4).

Second, we did not include the costs for installing and operating computerized physician order entry (CPOE) systems. There are two reasons for this decision. Firstly, most Japanese teaching hospitals installed and have operated order entry systems in 1999 (the base year of this study). Since we defined the scope of patient safety activities as being those introduced between 1999 and 2004, the implementation of CPOE before 1999 did not fulfill this definition. Although it is true that a portion of participant hospitals did not yet introduce the information systems in 1999, we decided to exclude the CPOE to reduce intra-institutional discrepancies regarding study focus. Secondly, previous studies have not provided evidence regarding the degree of contribution of CPOE on patient safety and on other effects such as business efficiencies. Although CPOE could be expected to reduce medication errors [34,35] and is one of the leading patient safety interventions recommended by experts in the US, it involves a variety of efficiencies for the hospital above and beyond its effects of safety [36,37]. Hence, calculating the total costs of these systems may result in overestimating the costs of CPOE as an investment for patient safety intervention. Because of the difficulty in separating the contribution of CPOE on patient safety from the overall contribution of CPOE adequately, we could not estimate the costs of CPOE.

Third, we also excluded the costs of informed consent, which may impact patient safety [17]. It is said that an increasing volume of activities to ensure informed consent have been implemented in recent years [38]. Better informed consent may improve the patient–physician relationship, establish trust, increase patient compliance, and provide information that could reduce medical error [39]. However, we did not estimate these costs because of the difficulty in identifying the amount of contribution for patient safety.

Since this study focused on acute tertiary care hospitals, findings cannot be generalized to other settings. The type of hospital may influence the nature and incidence of medical errors; the necessary investments for patient safety will thus be different. For example, in chronic or long-term care facilities, the major errors are distinct from those of acute-care hospitals and include those related to falling, aspiration, and pressure ulcers.

Although this study demonstrated that participant hospitals are spending an average of US$ 9.68 per patient-day on hospital-wide programs for patient safety, is it appropriate for hospitals to fully shoulder the burden of costs for patient safety? Stated differently, is there a business case for patient safety? If hospital administrators who invest in programs to reduce adverse events reap financial benefits, then hospital administrators have incentive to invest patient safety programs [40]. To apply a business case to patient safety, it is essential for hospital administrators to understand the amount of the anticipated investment in the patient safety programs, the magnitude of effectiveness of the programs in reducing the rates of adverse events, and the gross cost savings by subtracting the cost of adverse events without the programs from the cost of adverse events with the programs. However, to evaluate the effectiveness of safety programs on patient safety ranges from extremely difficult to impossible, due to the lack of evaluation tools, and the difficulty in measuring rare outcomes in small samples over a short period of time among patients with progression of diseases [10–12].

In addition, if the effectiveness of patient safety programs could be evaluated, hospital administrators were still not able to decide whether patient safety programs are cost saving "business case" or not, because the interpretation of the cost of adverse events which is imperative to estimate the gross cost savings depends on the type of reimbursement payment method and the viewpoint of stakeholders. Firstly, under fee-for-service payment systems, prevention of the costs attributable to adverse events was regarded as the potential savings from the viewpoint of society but was also equal to the reduced revenue from the hospital standpoint. Secondly, most of the direct costs of adverse events fall on patients and their families, their health insurers, their employers, state disability and income-support programs, rather than on hospitals [41]. Although the costs of poor safety are largely externalized to other parties, the costs of implementing safety programs fall squarely on hospitals. Therefore, even if the payment method is prospective payment systems, there is a conflict of interest between society and hospitals. To make matters more complicated, Marshall et al. empirically demonstrated that even when data on quality are available, neither consumers nor managed care companies use them to guide their healthcare purchases [42]. For these reasons, hospital administrators are to be difficult to find economic incentives for patient safety programs.

Despite the lack of incentive schemes to invest in patient safety programs for hospitals, many hospitals have actually invested huge amounts of resources for patient safety. The reason for this decision might be due to meeting ethical imperatives to minimize patient injuries as part of professionalism, and not as part of a financial gain plan. However healthcare resources are limited and healthcare staff are overworked [28,29]. It is extremely difficult to sustain safety and quality of the healthcare delivery system by relying solely on professionalism. There is a certain unfairness in demanding that the party which does not tangibly benefit from the process invest the most. Furthermore, together with the uncertainty of the size of effectiveness of patient safety programs due to the difficulty of measurement, it would be rational to conclude that the public should support a widespread movement towards a safer environment that rewards organizations willing to invest in patient safety.

As shown in this study, to provide a descriptive account of what hospitals are spending on the programs regardless of their effectiveness on patient safety systems was the first step in building a safe environment. Using public support to further promote a sustainable and safe environment for patients in practice, we should also consider what amount of dollar to maintain patient safety systems at a national level was incurred, and how patient safety measures would actually be implemented.

There is the question of what amount of costs public sector should pay. Knowledge of the distribution of hospital resources for patient safety activities is critical to long-term sustainability of these services. Our study demonstrated that an average of US$ 9.68 per patient-day is needed to implement patient safety systems (Table 5). However, hospitals may not take adequate measures across all domains. If all hospitals were to implement previously inadequate measures, the question of the cumulative financial resources required for the whole nation arises. To promote a sustainable and safe environment for patients in an era of healthcare cost containment, it is imperative that we consider the financial impact of implementing safety measures on a national level. Such data, along with our results, would provide an estimate of the incremental costs needed for all hospitals in Japan to implement similar safety measures used by hospitals in this study. Such research could also enhance public regard for the costs of patient safety and the need to allocate additional resources in order to improve safety measures on a national scale.

Next, how should public support be conducted? Performance-based payment programs impact professional practice [43–45]. These payment systems are also promising for patient safety [12]. However, it is extremely difficult to select performance measures in accordance with evidence-based approaches. Therefore, the demonstrated success of systematic quality improvement in other industries should be used, even if they may not have been built on evidence that certain measures reduced the frequency of adverse events [20]. Based on this new approach, the development of indicators to evaluate whether hospitals can theoretically conduct continuous improvement for their quality and safety systems is necessary. As suggested by Pronovost et al., incident reports may serve as proxies of identified opportunities for improvement [10]. Since the number of incident reports is dependent on the reporting system design, number of patients, number of staff, and other factors, development of this concept into a valid indicator of patient safety still remains a crucial task.

5. Conclusions

This study provides critical insights into the amount of financial resources used by hospitals for patient safety. To estimate the cost of patient safety and infection control activities, we developed a framework to survey hospital-wide activities by use of an incremental activity measure between 1999 and 2004. Although there are currently few financial incentives for prevention for patient safety within Japan's current reimbursement system, our study findings suggest that the total amount of resources are so large that public supports for patient safety activities are critical to assure the sustainability of safety and quality of the healthcare delivery system.

Acknowledgements

The authors are grateful to the staff at the seven hospitals that participated in this study. This study was supported in part by a Grant-in-aid for Scientific Research A from the Ministry of Education, Culture, Sports, Scientific and Technology of Japan and the Health Sciences Research Grants for the Research on Policy Planning and Evaluation from the Ministry of Health, Labor and Welfare of Japan.

References

[1] Institute of Medicine. To err is human: building a safer health system. Washington, DC: National Academy Press; 2000.

[2] U.K. Department of Health. An organization with a memory. London: Stationery Office; 2000.

[3] Kouseishou Kokuji 21st (21st Announcement by Ministry of Welfare). Kanpo (Public Newsletter). Gogai 1996;50:3–27 [in Japanese].

[4] Kouseishou Kokuji 66th (66th Announcement by Ministry of Welfare). Kanpo (Public Newsletter). Gogai 2000;51:1–105 [in Japanese].

[5] Kouseishou Shorei 7th (7th Ministerial Ordinance by Ministry of Welfare). Kanpo (Public Newsletter). 2000;2798:2–3 [in Japanese].

[6] Kouseiroudoushou Shorei 111th (111th Ministerial Ordinance by Ministry of Health, Labour and Welfare). Kanpo (Public Newsletter). 2002;3437:2 [in Japanese].

[7] Kouseiroudoushou Kokuji 71st (71st Announcement by Ministry of Health, Labour and Welfare). Kanpo (Public Newsletter). Gogai 2002;42:2–104 [in Japanese].

[8] Kouseiroudoushou Kokuji 92nd (92nd Announcement by Ministry of Health, Labour and Welfare). Kanpo (Public Newsletter). Gogai 2006;46:3–117 [in Japanese].

[9] Medicare program: changes to the hospital inpatient prospective payment systems and fiscal year 2008 rates. Federal Register 2007;72:47379–428.

[10] Pronovost PJ, Miller MR, Wachter RM. Tracking progress in patient safety: an elusive target. Journal of the American Medical Association 2006;296:696–9.

[11] Brennan TA, Gawande A, Thomas E, Studdert D. Accidental deaths, saved lives, and improved quality. New England Journal of Medicine 2005;353:1405–9.

[12] Leape LL, Berwick DM. Five years after to err is human: what have we learned? Journal of the American Medical Association 2005;293:2384–90.

[13] Morse WJ, Roth HP, Poston KM, Measuring. Planning, and controlling quality costs. New Jersey: National Association of Accountants; 1987.

[14] Warburton RN. Patient safety: how much is enough? Health Policy 2005;71:223–32.

[15] Zack JE, Garrison T, Trovillion E, Clinkscale D, Coopersmith CM, Fraser VJ, et al. Effect of an education program aimed at reducing the occurrence of ventilator-associated pneumonia. Critical Care Medicine 2002;30:2407–12.

[16] Karchmer TB, Durbin LJ, Simonton BM, Farr BM. Cost-effectiveness of active surveillance cultures and contact/droplet precautions for control of methicillin-resistant Staphylococcus aureus. Journal of Hospital Infection 2002;51:126–32.

[17] Shojania KG, Duncan BW, McDonald BW, Wachter RM, editors. Making health care safer: a critical analysis of patient safety practices. Evidence Report/Technology Assessment no. 43. Rockville, MD: Agency for Healthcare Research and Quality; 2001. AHRQ publication 01-E058. Available at: http://www.ahrq.gov/clinic/ptsafety/pdf/ptsafety.pdf. Accessed February 8, 2008.

[18] Haley RW, Culver DH, White JW, Morgan WM, Emori TG, Munn VP, et al. The efficiency of infection surveillance and control programs in preventing nosocomial infections in United States hospitals. American Journal of Epidemiology 1985;121:182–205.

[19] Bolyard EA, Tablan OC, Williams WW, Pearson ML, Shapiro CN, Deitchman SD. Guideline for infection control in healthcare personnel, 1998. Infection Control and Hospital Epidemiology 1998;19:407–63.

[20] Leape LL, Berwick DM, Bates DW. What practices will most improve safety? Evidence-based medicine meets patient safety. Journal of the American Medical Association 2002;288:501–7.

[21] Pittet D, Allegranzi B, Sax H, Bertinato L, Concia E, Cookson B, et al. Considerations for a WHO European strategy on health-care-associated infection, surveillance, and control. Lancet Infectious Diseases 2005;5:242–50.

[22] Hirose M, Imanaka Y, Ishizaki T, Evans E. How can we improve the quality of health care in Japan? Learning from JCQHC Hospital accreditation. Health Policy 2003;66:29–49.

[23] National Personnel Authority. Report on fact-finding survey of remuneration of national public employees; 2004. Available at: http://www.jinji.go.jp/kyuuyo/f_kyuuyo.htm. Accessed February 8, 2008 [in Japanese].

[24] Ministry of Health, Labour and Welfare. Iryo Keizai Zittai Chousa Houkoku; 2003 (a status report of economics in health care 2003). Available at: http://www.mhlw.go.jp/shingi/2005/01/s0126-8.html. Accessed February 8, 2008 [in Japanese].

[25] Ministry of Health, Labour and Welfare. Basic survey of wage structure; 2004. Available at: http://wwwdbtk.mhlw.go.jp/toukei/kouhyo/data-rou4/data16/30501.xls. Accessed February 8, 2008 [in Japanese].

[26] Ministry of Internal Affairs and Communication. Annual report on the labour force survey; 2004. Available at: http://www.stat.go.jp/data/roudou/2004n/ft/zuhyou/201420.xls. Accessed February 8, 2008 [in Japanese].

[27] OECD statistics on Purchasing Power Parities (PPP): comparative price levels. Available at: http://www.oecd.org/dataoecd/48/18/18598721.pdf. Accessed February 8, 2008.

[28] Ministry of Health, Labour and Welfare. Ishi no jukyu ni kansuru kentoukai houkokusho (a panel report on doctor supply and demand); 2006. Available at: http://www.mhlw.go.jp/shingi/2006/07/dl/s0728-9c.pdf. Accessed February 8, 2008 [in Japanese].

[29] Smith R. Why are doctors so unhappy? There are probably many causes, some of them deep. British Medical Journal 2001;322:1073–4.

[30] Leape LL, Cullen DJ, Clapp MD, Burdick E, Demonaco HJ, Erickson JI, et al. Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. Journal of the American Medical Association 1999;282:267–70.

[31] Bond CA, Raehl CL, Franke T. Clinical pharmacy services and hospital mortality rates. Pharmacotherapy 1999;19:556–64.

[32] Lee AJ, Boro MS, Knapp KK, Meier JL, Korman NE. Clinical and economic outcomes of pharmacist recommendations in a Veterans Affairs medical center. American Journal of Health-System Pharmacy 2002;59:2070–7.

[33] Nesbit TW, Shermock KM, Bobek MB, Capozzi DL, Flores PA, Leonard MC, et al. Implementation and pharmacoeconomic analysis of a clinical staff pharmacist practice model. American Journal of Health-System Pharmacy 2001;58:784–90.

[34] Bates DW, Leape LL, Cullen DJ, Laird N, Petersen LA, Teich JM, et al. Effect of computerized physician order entry and a team intervention on prevention of serious medication errors. Journal of the American Medical Association 1998;280:1311–6.

[35] Teich JM, Merchia PR, Schmiz JL, Kuperman GJ, Spurr CD, Bates DW. Effects of computerized physician order entry on prescribing practices. Archives of Internal Medicine 2000;160:2741–7.

[36] Birkmeyer CM, Lee J, Bates DW, Birkmeyer JD. Will electronic order entry reduce health care costs? Effective Clinical Practice 2002;5:67–74.

[37] Chaudhry B, Wang J, Wu SY, Maglione M, Mojica W, Roth E, et al. Systematic review: impact of health information technology on quality, efficiency, and costs of medical care. Annals of Internal Medicine 2006;144:742–52.

[38] Fukuda H, Imanaka Y, Kobuse H, Hayashida K, Murakami G. The subjective incremental cost of informed consent and documentation in hospital care: a multi-centre questionnaire survey in Japan. Journal of Evaluation in Clinical Practice, in press.

[39] Lidz CW, Appelbaum PS, Meisel A. Two models of implementing informed consent. Archives of Internal Medicine 1988;148:1385–9.

[40] Weeks WB, Bagian JP. Making the business case for patient safety. Joint Commission Journal on Quality and Safety 2003;29:51–4.

[41] Mello MM, Kelly CN, Brennan TA. Fostering rational regulation of patient safety. Journal of Health Politics Policy and Law 2005;30:375–426.

[42] Marshall MN, Shekelle PG, Leatherman S, Brook RH. The public release of performance data: what do we expect to gain? A review of the evidence. Journal of American Medical Association 2000;283:1866–74.

[43] Petersen LA, Woodard LD, Urech T, Daw C, Sookanan S. Does pay-for-performance improve the quality of health care? Annals of Internal Medicine 2006;145:265–72.

[44] Doran T, Fullwood C, Gravelle H, Reeves D, Kontopantelis E, Hiroeh U, et al. Pay-for-performance programs in family practices in the United Kingdom. New England Journal of Medicine 2006;355:375–84.

[45] Lindenauer PK, Remus D, Roman S, Rothberg MB, Benjamin EM, Ma A, et al. Public reporting and pay for performance in hospital quality improvement. New England Journal of Medicine 2007;356:486–96.

Journal of Evaluation in Clinical Practice ISSN 1356-1294

The subjective incremental cost of informed consent and documentation in hospital care: a multicentre questionnaire survey in Japan

Haruhisa Fukuda MPH,[1] Yuichi Imanaka MD MPH PhD,[2] Hiroe Kobuse MPH,[3] Kenshi Hayashida PhD[4] and Genki Murakami MEng[5]

[1]Graduate Student & Research Fellow, Japan Society for the Promotion of Science, Tokyo, Japan
[2]Professor, [3]Graduate Student, [4]Lecturer, [5]Graduate Student, Department of Healthcare Economics and Quality Management, School of Public Health, Kyoto University Graduate School of Medicine, Kyoto, Japan

Keywords
costs and cost analysis, health resources, informed consent, safety management

Correspondence
Yuichi Imanaka
Department of Healthcare Economics and Quality Management
School of Public Health, Kyoto University Graduate School of Medicine
Yoshida Konoe-cho
Sakyo-ku
Kyoto 606 8501
Japan
E-mail: imanaka@pbh.med.kyoto-u.ac.jp

Accepted for publication: 28 January 2008

doi:10.1111/j.1365-2753.2008.00987.x

Abstract

Objective To reveal the amount of time and financial cost required to obtain informed consent and to preserve documentation.

Methods The questionnaire was delivered to all staff in six acute care public hospitals in Japan. We examined health care staff perceptions of the time they spent obtaining informed consent and documenting information. All data were collected in 2006 and estimates in the past week in 2006 were compared to estimates of time spent in a week in 1999. We also calculated the economic costs of incremental amounts of time spent in these procedures.

Results In 2006, health care staff took about 3.89 hours [95% Confidence Interval (CI) 3.71–4.07] per week to obtain informed consent and 6.64 hours (95% CI 6.40–6.88) per week to write documentation on average. Between 1999 and 2006, the average amount of time for conducting informed consent was increased to 0.67 ($P < 0.001$) hours per person-week, and the average amount of time for documentation was increased to 0.70 ($P < 0.001$) hours per person-week. The annual economic cost of activities for informed consent and documentation in a 100-bed hospital increased from 117 755 to 449 402 US dollars.

Conclusions We found a considerable increase in time spent on informed consent and documentation, and associated cost over a 7-year time period. Although greater attention to the informed consent process should be paid to ensure the notions of patient autonomy and self-determination, the increased resources devoted to these practices must be considered in light of current cost containment policies.

Introduction

Informed consent is a critical element in the provision of appropriate treatment information and shared decision making [1]. There is no doubt that obtaining a patient's informed consent is now widely accepted as one of the key duties of any good health professional [2,3]. The importance of informed consent has been asserted by the American Medical Association and the British Medical Association [4,5]. In Japan, all health care staff were encouraged to obtain informed consent after the revision of the 1997 Medical Service Law [6]. The Japanese Ministry of Health, Labour and Welfare declared that the establishment of patient-centred medicine is one of the most important issues in delivering health care services [7]. Because of this, they began to encourage the enhancement of clinical informed consent.

With an increased drive to provide informed consent among hospitals, the resulting increased burden on health care workers has been acknowledged as a problem. Doctors were unhappy because they feel overworked and undersupported [8]. However, this phenomenon was not limited to hospitals in the UK. A recent questionnaire found that most (2219, response rate: 67.7%) Japanese doctors suffered from increased burdens compared with the situation 3 years ago because of four major reasons: increased time consumption from non-medical practices such as committees and conferences, increased time required to spend with patients, the enforcement of increased time and attention needed for informed consent and patient safety, and increased documentation [9]. If the activity involved in obtaining informed consent causes heavy burdens on health workers, such activities, even if theoretically expected to improve patient–physician relationships and therefore to have a beneficial impact on health outcomes, could instead ultimately contribute to the deterioration of the health care system. Despite these concerns, there has been little evidence to quantitatively associate resource consumption with obtaining informed consent.

Given the purpose of informed consent, it seems to be an outrageous idea to lump together the process of getting patient consent and the cost issue attributable to the practice. Health care staff may question the necessity of demonstrating a cost of informed consent, arguing that the imperative for consent is a matter of professional ethics, not burden. Unfortunately, however, it is true that health care staff suffered from increased burdens, and the burdens could cause the issue of sustainability of desirable health care delivery. Therefore, this study was conducted to reveal the amount of time (in terms of manpower hours) required to obtain clinical informed consent and its associated documentation, and to investigate the increase in time consumption for these activities since 1999, when medical accidents were not yet as widely covered by the media. In addition, using conversion rates to monetary value by type of profession and years in practice, we also estimated the resulting increase in economic cost, for use in formulating sustainable health delivery systems.

Methods

Subject

In February 2006, we sent a questionnaire to all full-time staff (3304 in total) in six public hospitals in western Japan. With assistance from supportive staff members in each hospital, the questionnaires were distributed, answered and returned. This study was approved by the Institutional Review Board at the Graduate School of Medicine of Kyoto University.

Questionnaire

The questionnaire consisted of the following questions:

- How much time did you spend obtaining informed consent from patients and their families in the past week? ('Informed consent' includes all associated activities.)
- How much time did you spend obtaining informed consent from patients and their families in a week in 1999, when the media coverage of medical accidents was not yet as intense?
- How much time did you spend preserving medical records and writing documents in the past week?
- How much time did you spend preserving medical records and writing documents in a week in 1999?

In addition, we also included questions about the specific type of profession and years in practice in order to obtain the characteristics of the responders.

Data analysis

There were three exclusion criteria in this study: responders whose answers involved amounts of time that were over the ninety-fifth percentile (outliers), data where either the type of profession or years in practice was missing (excluded only when performing subgroup analysis), and responders who had practiced for less than 10 years (excluded only when comparing the amount of activity time between 1999 and 2006).

Because the incremental analysis compared situations with a 7-year span and because most health care staff spend much of the beginning portions of their careers in training programmes, we focused on individuals who had more than 10 years of experience. In addition to this 'direct comparison', we conducted an 'indirect comparison' by targeting individuals who had less than 10 years in practice, who did not assess the amount of time spent (missing data), who were judged as outliers, and who did not respond to the questionnaire. To predict their incremental hours of activity for informed consent and documentation, we investigated the relationship between the amount of time spent and years in practice. We also examined whether the reasons for the missing data were random or not.

We converted the volume of activities into monetary values through the use of conversion rates based on national statistical data [10–12]. The estimates were also converted to US dollars using the Purchasing Power Parities of JPN¥100 = US$0.85 (April 2007) [13]. The conversion rates of 1-hour activity (in US dollars) by years in practice for 10–19 years and for 20+ years were, respectively, doctors, 46.5 and 55.8; nurses, 27.4 and 32.3; comedicals, 26.3 and 33.0; others, 25.7 and 32.3. In addition, as the annual amount of resources consumed per hospital depended on the number of beds, we adjusted each hospital to a bed-size of one hundred.

Differences in activities for informed consent and documentation between 1999 and 2006 were compared using the nonparametric Wilcoxon matched-pairs signed-test. Subgroup analyses were also calculated using suitable tests. SPSS version 14.0 (released 14.0.1; SPSS, Chicago) was used to perform the statistical analysis.

Results

Of the 3304 questionnaires sent, we received 2924 replies (response rate of 88.5%, range 74.1–97.4%) (Table 1). The overall distribution of years in practice in the six hospitals was as follows: less than 5 years, 33%; 5–9 years, 21%; 10–19 years, 21%; 20 years and over, 23%. Data were similar in each hospital.

Volume of Manpower Resources

Excluding the outliers and the responses with missing data, we analysed 2172 responders for informed consent and 2079 responders for documentation. Overall, in 2006, the distribution of weekly time consumed to obtain informed consent by type of profession in each hospital was similar when compared with the other hospitals ($P = 0.130$, Kruskal–Wallis rank test) (Table 2). All staff took about 3.89 hours per week [95% confidence interval (CI) 3.71–4.07] on average to obtain informed consent. The average time in each hospital ranged from 3.45 to 4.21 hours per week. The greatest amount of time for informed consent was reported as 6.38 hours per week (95% CI 5.78–6.98). The average time taken weekly to write documentation per staff was 6.64 hours (95% CI 6.40–6.88) with a range from 5.88 to 9.04 hours.

Table 3 shows the average amounts of time in 1999 and 2006 with respect to years in practice in 2006. Though the activity for informed consent and documentation increased from 1999 to 2006 as a general trend, a Kruskal–Wallis rank test indicated that the amount of time did not significantly change with years in practice.

Incremental analysis

A total of 830 responders for informed consent and 810 responders for documentation were eligible for our incremental analysis.

Table 1 Characteristics of hospitals and questionnaire responses

Characteristics	Hospital A	Hospital B	Hospital C	Hospital D	Hospital E	Hospital F
Participant hospital						
No. of beds (2006)	560	410	470	680	540	220
Response						
No. of questionnaires sent	640	521	549	823	582	189
No. of questionnaires returned (response rate)	570 (89.1%)	465 (89.3%)	491 (89.4%)	783 (95.1%)	431 (74.1%)	184 (97.4%)
No. of responders with less than 10 years in practice	296 (51.9%)	230 (49.5%)	254 (51.7%)	537 (68.6%)	167 (38.7%)	104 (56.5%)
No. of missing data regarding incremental time spent for informed consent in responders with more than 10 years in practice	84 (14.7%)	97 (20.9%)	81 (16.5%)	84 (10.7%)	75 (17.4%)	11 (6.0%)
No. of missing data regarding incremental time spent for documentation in responders with more than 10 years in practice	80 (14.0%)	98 (21.1%)	79 (16.1%)	80 (10.2%)	77 (17.9%)	13 (7.1%)

Table 4 compares the averages and 95% CI for informed consent and documentation between 1999 and 2006. Overall, the mean amount of time consumed to obtain informed consent was significantly increased to 0.67 hours per week (95% CI 0.47–0.88; $P < 0.001$, Wilcoxon matched-pairs signed-test). In each hospital, the activities associated with obtaining informed consent resulted in a significant increase in time consumption except for hospital B ($P \leq 0.001$). In addition to the activities associated with informed consent, time consumption associated with documentation was increased to an average of 0.70 hours (95% CI 0.42–0.97; $P < 0.001$). In five of the hospitals, this value was found to be significantly different from the time spent 7 years ago ($P < 0.05$). Overall, doctors showed the highest increase in time consumption from activities for informed consent (1.18 hours per week), followed by comedicals (0.72 hours per week), others (0.64 hours per week), and nurses (0.55 hours per week).

Hospitals' increased volume of activities and costs

For the individuals with less than 10 years in practice, missing data, outliers and non-responders, we estimated the incremental hours using estimates of direct comparison derived from the eligible group in the incremental analysis. There was no observed association between increased years in practice and the amount of time needed to obtain informed consent and complete documentation procedures (Table 3). In addition, there was no statistically significant difference in years in practice between eligible and ineligible (because of missing data) responders (47.5% vs. 48.9% had practiced 10–19 years; $P = 0.637$, χ^2-test). There was also no significant difference between eligible and ineligible responders in terms of time spent performing documentation (45.7% vs. 49.8%; $P = 0.174$, χ^2-test). As the distribution of years in practice for both the eligible and ineligible groups was almost identical, we concluded that the missing data were due to random effects. The outlier responses were also independent of the type of profession and years in practice. Thus, despite not having information regarding the distribution of years in practice in all subjects to which we sent questionnaires, we assumed the distribution to be similar to that of the missing data.

Table 5 depicts the adjustment index used to apply the direct estimate to the indirect estimate groups. In an analysis of the amount of activity volume, the index was set as a rate of samples in the eligible group to samples in the ineligible group. For cost analysis, the index was based on the distribution of profession type and years in practice in order to reflect the difference in opportunity cost among them.

The annual total increase in the volume of resources used for informed consent and documentation are summarized in Table 6. In a direct estimation analysis, the incremental amount of time to obtain informed consent and to preserve documentation increased to an average of 4968 and 5349 thousand person-hours per year, respectively. With the inclusion of indirect analyses estimates, the annual total amount of increased resources in each hospital ranged from 18 361 to 72 843 thousand person-hours. After a bed-size adjustment to 100, the total amount of increased resources amounted to 5080–10 776 thousand person-hours per year. The incremental cost estimates between 1999 and 2006 are shown in Table 6. The annual economic cost of activities related to informed consent and documentation in a hospital with a bed-size of one hundred were calculated as –400–181 478 US dollars and 56 172–281 574 US dollars, respectively. These incremental costs were equivalent to employing 2.0–7.5 full-time staff dedicated to informed consent and documentation in a 100-beds hospital.

Discussion

This study provides new information about the differences in time and economic cost health care staff spent obtaining informed consent and documenting medical data between 1999 and 2006. Although hospital employees have suffered from increasingly heavy burdens in the recent health care environment, little to no attention has been paid to measuring these burdens empirically. In practice, informed consent is intended to ensure that the ethical principle 'respect for persons', which includes the notions of patient autonomy and self-determination, is honoured. It is a patient right. Nonetheless, the activities related to and the cost for obtaining informed consent and providing documentation between 1999 and 2006 were a considerable increase. Degrees of increase were the equivalent of the employment of an extra 2.0–7.5 full-time staff members with the dedicated purpose of obtaining informed consent and providing documentation in a 100-bed hospital.

Table 2 The amount of person-hours per week required to conduct informed consent and provide documentation in 2006

Type of Profession		Hospital A	Hospital B	Hospital C	Hospital D	Hospital E	Hospital F	Overall
Informed consent (person-hours per week)								
Doctors	Mean (95% CI)	7.65 (6.15–9.15)	6.72 (4.82–8.62)	5.71 (4.65–6.77)	6.26 (4.96–7.56)	5.62 (4.38–6.86)	6.45 (4.37–8.53)	6.38 (5.78–6.98)
	n	46	33	57	70	33	22	261
Nurses	Mean (95% CI)	3.89 (3.39–4.39)	3.61 (3.09–4.13)	3.15 (2.55–3.75)	4.03 (3.57–4.49)	3.91 (3.41–4.41)	2.92 (2.34–3.50)	3.73 (3.51–3.95)
	n	304	212	180	361	244	93	1394
Co-medicals	Mean (95% CI)	3.94 (2.76–5.12)	3.50 (2.20–4.80)	2.80 (2.04–3.56)	2.14 (1.52–2.76)	3.50 (2.16–4.84)	4.58 (2.62–6.54)	3.21 (2.75–3.67)
	n	68	48	54	73	33	19	295
Others	Mean (95% CI)	2.40 (0.36–4.44)	4.73 (2.75–6.71)	2.83 (1.73–3.93)	2.54 (1.48–3.60)	1.86 (−0.14–3.86)	2.75 (0.07–5.43)	2.88 (2.24–3.52)
	n	24	32	62	68	20	16	222
All	Mean (95% CI)	4.21 (3.75–4.67)	4.02 (3.54–4.50)	3.45 (3.03–3.87)	3.89 (3.51–4.27)	3.91 (3.47–4.35)	3.63 (2.99–4.27)	3.89 (3.71–4.07)
	n	442	325	353	572	330	150	2172
Documentation (person-hours per week)								
Doctors	Mean (95% CI)	9.53 (7.81–11.25)	7.83 (5.33–10.33)	8.46 (6.98–9.94)	7.50 (5.90–9.10)	7.25 (5.19–9.31)	7.93 (5.61–10.25)	8.12 (7.36–8.88)
	n	43	27	54	68	30	20	242
Nurses	Mean (95% CI)	7.05 (6.47–7.63)	6.02 (5.34–6.70)	6.90 (6.04–7.76)	6.79 (6.25–7.33)	5.79 (5.21–6.37)	9.14 (7.76–10.52)	6.73 (6.45–7.01)
	n	290	203	176	373	239	92	1373
Co-medicals	Mean (95% CI)	5.36 (4.08–6.64)	6.50 (4.88–8.12)	3.39 (2.43–4.35)	4.63 (3.45–5.81)	4.57 (2.83–6.31)	7.47 (4.57–10.37)	5.05 (4.45–5.65)
	n	63	47	53	71	31	19	284
Others	Mean (95% CI)	3.67 (1.03–6.31)	7.09 (4.49–9.69)	5.52 (3.74–7.30)	6.29 (3.89–8.69)	7.06 (3.34–10.78)	12.31 (6.69–17.93)	6.41 (5.27–7.55)
	n	21	29	49	51	17	13	180
All	Mean (95% CI)	6.88 (6.38–7.38)	6.35 (5.75–6.95)	6.39 (5.77–7.01)	6.56 (6.08–7.04)	5.88 (5.32–6.44)	9.04 (7.90–10.18)	6.64 (6.40–6.88)
	n	417	306	332	563	317	144	2079

CI, confidence interval.

Table 3 The effect of years in practice on average person-hours per week to conduct informed consent and documentation

	Hospital A		Hospital B		Hospital C		Hospital D		Hospital E		Hospital F		Overall	
Years in practice in 2006	1999	2006	1999	2006	1999	2006	1999	2006	1999	2006	1999	2006	1999	2006
Informed consent (person-hours per week)														
Less than 10 years	NA	3.96	NA	3.86	NA	3.18	NA	3.85	NA	3.90	NA	3.38	NA	3.74
10–19 years	3.17	3.93	3.96	4.07	3.52	3.98	3.96	3.88	3.67	3.84	2.73	3.51	3.56	3.91
20+ years	3.76	5.17	4.71	4.34	2.67	3.51	3.49	4.07	3.59	3.98	4.16	4.34	3.64	4.21
Overall	3.43	4.21	4.33	4.02	3.07	3.45	3.75	3.89	3.62	3.91	3.51	3.63	3.60	3.89
P-value (years in practice)*	0.386	0.089	0.851	0.965	0.126	0.827	0.972	0.755	0.695	0.907	0.875	0.175	0.820	0.115
Documentation (person-hours per week)														
Less than 10 years	NA	7.18	NA	6.71	NA	6.68	NA	6.51	NA	6.00	NA	8.93	NA	6.80
10–19 years	7.05	6.47	4.47	5.20	6.50	7.13	5.18	5.61	5.22	5.49	8.06	8.16	5.93	6.14
20+ years	5.60	6.69	5.80	6.78	4.96	5.16	6.64	8.00	4.93	5.97	8.54	9.96	5.76	6.71
Overall	6.42	6.88	5.08	6.35	5.68	6.39	5.82	6.56	5.05	5.88	8.33	9.04	5.84	6.64
P-value (years in practice)*	0.306	0.545	0.356	0.069	0.026	0.008	0.108	0.102	0.731	0.466	0.797	0.996	0.494	0.167

*Kruskal–Wallis rank test.
NA, not available.

Table 4 Increased person-hours per week to conduct informed consent and provide documentation between 1999 and 2006

	Informed consent			Documentation		
Direct Estimation	*n*	Person-hours per week (95% CI)	*P*-value*	*n*	Person-hours per week (95% CI)	*P*-value*
Hospital A	177	1.28 (0.81–1.75)	<0.001	178	0.26 (−0.29–0.82)	0.468
Hospital B	120	0.00 (−0.57–0.58)	0.312	115	0.70 (0.04–1.35)	0.048
Hospital C	147	0.58 (0.19–0.97)	<0.001	140	0.59 (0.02–1.15)	0.035
Hospital D	149	0.60 (0.05–1.15)	0.001	145	0.91 (0.13–1.69)	0.019
Hospital E	175	0.61 (0.18–1.03)	<0.001	173	0.95 (0.36–1.53)	0.001
Hospital F	62	0.85 (0.33–1.36)	<0.001	59	1.04 (−0.22–2.30)	0.028
Overall	830	0.67 (0.47–0.88)	<0.001	810	0.70 (0.42–0.97)	<0.001

*P-values were calculated by nonparametric Wilcoxon matched-pairs signed-test.

Table 5 Adjustment index for indirect estimations of activity volume and cost compared with direct estimations

	Informed consent					Documentation				
	Direct estimation	Indirect estimation				Direct estimation	Indirect estimation			
	Eligible data* (n = 847)	<10 years† (n = 1588)	Missing data‡ (n = 461)	Outlier§ (n = 28)	Non-response (n = 380)	Eligible data* (n = 826)	<10 years† (n = 1588)	Missing data‡ (n = 456)	Outlier§ (n = 54)	Non-response (n = 380)
Adjustment index for activity volume										
Hospital A	1.00	1.64	0.50	0.02	0.39	1.00	1.63	0.47	0.03	0.38
Hospital B	1.00	1.85	0.81	0.08	0.45	1.00	1.95	0.86	0.13	0.47
Hospital C	1.00	1.73	0.59	0.02	0.39	1.00	1.81	0.61	0.09	0.41
Hospital D	1.00	3.56	0.60	0.03	0.26	1.00	3.65	0.59	0.08	0.27
Hospital E	1.00	0.92	0.44	0.02	0.83	1.00	0.93	0.45	0.02	0.84
Hospital F	1.00	1.65	0.21	0.06	0.08	1.00	1.73	0.25	0.08	0.08
Adjustment index for cost estimates										
Hospital A	1.00	0.69	0.94	0.93	1.00	1.00	0.70	0.95	1.03	1.00
Hospital B	1.00	0.68	0.94	0.97	1.00	1.00	0.70	0.97	1.14	1.00
Hospital C	1.00	0.71	0.92	0.99	1.00	1.00	0.70	0.92	0.96	1.00
Hospital D	1.00	0.66	0.88	0.80	1.00	1.00	0.68	0.90	1.12	1.00
Hospital E	1.00	0.67	0.96	1.17	1.00	1.00	0.67	0.98	1.14	1.00
Hospital F	1.00	0.67	0.92	0.92	1.00	1.00	0.67	0.92	0.86	1.00

*Responders who assessed the amount of time spent and have more than 10 years in practice.
†Responders who have less than 10 years in practice.
‡Responders who did not assess the amount of time spent and had more than 10 years in practice.
§Responders whose answers involved amounts of time that were over the 95 percentile of whole answers.

There are many advantages to this study's methodology in terms of reliability and validity. First, the high response rate (88.5%) suggests a high internal validity. Second, this study was conducted by targeting all staff in six hospitals. The results show that the distribution of the amounts of time per week by type of profession in each hospital was similar. This finding suggests that this study has a relatively high external validity. With these in mind, this is the first study to offer critical insights into the neglected cost issues associated with obtaining informed consent.

Study findings suggest that activities related to obtaining informed consent and providing documentation are associated with an increased burden on the health care staff. According to *accounting* (not economic cost) reports of each hospital [14,15], adjusted personnel expenses per person-year (weighted average of number of type of profession, their annual income and Japanese consumer price index) decreased between the two periods examined in this study (109 610 US dollars in 1999 compared with 106 932 US dollars in 2006). Furthermore, owing to the decreased average length of stay over these 7 years among all hospitals, the total amount of work time seems to have increased substantially. This is because as the average length of patient stay decreases, the total patient volume per year (along with accompanying informed consent and documentation activities) increases. Furthermore, the growth of national health spending in Japan slowed with figures in the fiscal years of 2002 and 2006 estimated at 1.30% and 1.36%, respectively. In such an environment, our results show that over these 7 years the time used to obtain informed consent and to document medical information increased an average of 8257 thousand person-hours in a bed-size of one hundred.

Table 6 Increased volume and cost for informed consent and documentation in each hospital per year

	Informed consent				Documentation				Total
Hospital	Direct estimation ($n = 847$)*	Indirect estimation ($n = 2457$)	Total ($n = 3304$)	Adjusted Total† ($n = 3304$)	Direct estimation ($n = 826$)*	Indirect estimation ($n = 2478$)	Total ($n = 3304$)	Adjusted Total† ($n = 3304$)	Adjusted Total† ($n = 3304$)
Person-hours									
Hospital A	11 857	30 070	41 927	7 460	2 378	5 984	8 362	1 488	8 948
Hospital B	99	318	417	102	4 589	15 671	20 260	4 978	5 080
Hospital C	4 458	12 192	16 650	3 565	4 271	12 476	16 747	3 586	7 151
Hospital D	5 272	23 460	28 732	4 250	7 879	36 232	44 111	6 525	10 776
Hospital E	5 694	12 615	18 309	3 391	9 459	21 295	30 754	5 695	9 086
Hospital F	2 425	4 849	7 274	3 368	3 520	7 567	11 087	5 133	8 500
Average	4 968	13 917	18 885	3 689	5 349	16 538	21 887	4 568	8 257
Cost (US$)‡									
Hospital A	418 169	801 737	1019 907	181 478	124 347	191 339	315 686	56 172	237 650
Hospital B	−542	−1 085	−1 627	−400	160 195	320 695	480 890	118 155	117 755
Hospital C	161 051	411 737	572 788	122 653	140 161	394 508	534 669	114 490	237 143
Hospital D	179 864	391 686	571 551	84 549	251 500	586 119	837 619	123 908	208 457
Hospital E	216 754	689 517	906 271	167 828	348 483	1172 017	1520 500	281 574	449 402
Hospital F	80 949	153 661	234 610	108 616	94 356	183 136	277 492	128 468	237 084
Average	176 041	374 542	550 583	110 787	186 507	474 636	661 143	137 128	247 915

*Because we included data that was eligible for time spent but was missing information regarding either job type or years in practice ($n = 17$, overall), the samples were different from the value in Table 4.

†Adjusted the number of hospital beds to 100.

‡JPN¥100 = US$0.85 (April 2007).

One exception to this trend was in hospital B. The incremental amount of activity volume for informed consent in hospital B was extremely small. Furthermore, the incremental cost estimates indicated a negative value for this hospital. However, this was likely due to the fact that their activity for informed consent in 1999 was already high compared with other hospitals in that year (0.58–1.26 person-years higher, see Table 3). The same holds true for data in 2006 (0.12–0.88 person-years higher, see Table 3). Therefore, our results are consistent with research suggesting that the demand on doctors' time is reaching a breaking point [9].

As shown in Table 3, our results are in accordance with societal change. Japanese hospitals have shunted resources into patient safety-related activities since 1999, when there was a dramatic rise in social concern and health policy. In a separate study, we targeted seven hospitals that invested incremental resources into patient safety and infection control. In these hospitals, the annual increased economic cost reached 1.1–2.5 million US dollars per hospital between 1999 and 2004. This amount was equivalent to the employment of 17–33 full-time staff dedicated to patient safety and infection control [16].

Although self-reports are often used in time measurement, long intervals can have a substantial impact on responders' report of time used for a task [17]. While this type of hindsight bias does present a study limitation, there are many reasons which support the accuracy and validity of our data. In 1999, a wave of devastating medical errors appeared in the media. This led to growing social concerns for patient safety in Japan, prompting a series of changes in professional behaviour. These changes included increased documentation and information provision for patients. The year 1999 marked a turning point in the struggle for patient safety in Japan. Therefore, the specific citation of the year 1999 in a phrase of the questionnaire was expected to work as a memory anchor and arouse the responders' memory of the situation. Also, when assessing data, the amount of time spent for informed consent and for documentation significantly differed among the various profession types. This time significantly increased for each profession type from 1999 to 2006. However, the time spent for each profession type was not significantly different across the hospitals (data not shown). In addition, the amount of time spent between activities for informed consent and for documentation in each hospital was significantly different (using the Wilcoxon matched-pairs signed-test; data not shown). These discriminant and convergent characteristics of the results match theoretical expectations and can be regarded as supporting evidence for acceptable accuracy and validity of the estimated time based on the self-reports of groups of people.

Further studies are needed to verify the sustainability of activities for informed consent. The issue we suggested in this article is fraught with serious problem. Obtaining a patient's informed consent is widely accepted as one of the key duties of any good health professional [2,3]. Informed consent is intended to ensure that the ethical principle 'respect for persons', which includes the notions of patient autonomy and self-determination, is honoured. It is a patient right. In practice, there is some indication that these activities contribute to the quality of health care services. For example, good adherence to drug therapy is associated with positive health outcomes [18,19]. Thus, efforts to improve patients' adherence is a critical activity in providing health care. We consider obtaining informed consent a key element of such efforts. Also, treating patients with respect and communicating in an honest, forthright and empathetic attitude is thought to improve the physician–patient relationship and thereby reduce legal risk

[20–23]. Therefore, it seems to be an outrageous idea to lump together the process of getting patient consent and the cost issue attributable to the practice.

Notwithstanding the purpose of the informed consent, in fact, activities for informed consent may also increase fatigue in health care staff, as obtaining informed consent requires the consumption of great amounts of time as revealed in this study. While controversial [24,25], considering the current research that suggests a relationship between extended work duration and medical errors [26,27], there is some concern that work quality may spiral downward. Hence, a study designed to reveal the impact of cost and benefits of obtaining informed consent and to evaluate the extent to which patients are willing to pay for their informed consent is necessary. Based on these points, further consideration is needed to develop a sustainable health system.

Conclusion

We have shown for the first time that the amount of time to obtain informed consent and to preserve proper documentation has increased significantly over the 7 years between 1999 and 2006. These processes involve substantial activities and resources. To ensure the notions of patient autonomy and self-determination, health care staff should pay greater attention to the informed consent process. Unfortunately, however, these activities might increase the fatigue of health care employees under current cost containment policies. Together with the results of this study, policy discussions on how to delivery patient-centred health care services without overworking health care employee is necessary.

Acknowledgements

The authors are grateful to the hospitals that participated in this study by answering our questionnaire: Otsu Municipal Hospital (Otsu, Shiga), Omihachiman Community Medical Center (Omihachiman, Shiga), Kohka Public Hospital (Kohka, Shiga), Nagahama City Hospital (Nagahama, Shiga), Tokushima Central Hospital (Tokushima, Tokushima) and Sakaide City Hospital (Sakaide, Kagawa).

This study was supported in part by the Health Sciences Research Grants for the Research on Policy Planning and Evaluation from the Ministry of Health, Labor and Welfare of Japan and the Grant-in-aid for Scientific Research A from the Ministry of Education, Culture, Sports, Science and Technology of Japan.

References

1. President's Commission for Ethical Issues in Biomedical and Clinical Research. (1982) Making Health Care Decisions, Vol. 1. Washington, DC: US Government Printing Office.
2. Doyal, L. (2001) Informed consent: moral necessity or illusion? *Quality in Health Care*, 10, 129–133.
3. Mazur, D. J. (2003) Influence of the law on risk and informed consent. *British Medical Journal*, 327 (7417), 731–734.
4. American Medical Association (2006) Code of Medical Ethics. Chicago: American Medical Association.
5. British Medical Association (2000) The Impact of the Human Rights Act 1998 on Medical Decision Making. London: British Medical Association.
6. Houritsu 125th. (1997) The third revision of the medical service law. *Kampo (Public Newsletter) Gogai*. 251 53–55. [in Japanese].
7. Ministry of Health, Labour and Welfare. (2005) *Kongo no iryo anzen taisaku ni tsuite. [A report on future action for patient safety]*. Available at: http://www.mhlw.go.jp/topics/bukyoku/isei/i-anzen/3/kongo/02.html (last accessed 14 January 2008). [in Japanese].
8. Smith, R. (2001) Why are doctors so unhappy? *British Medical Journal*, 322 (7294), 1073–1074.
9. Ministry of Health, Labour and Welfare. (2006) *Ishi No Jukyu Ni Kansuru Kentoukai Houkokusho. [A Panel Report on Doctor Supply and Demand] 2006*. Available at: http://www.mhlw.go.jp/shingi/2006/07/dl/s0728 –9c.pdf (last accessed 14 January 2008. [in Japanese].
10. Ministry of Health, Labour and Welfare. (2003) *Iryo Keizai Zittai Chousa Houkoku [A Research Report on Healthcare Institution's Economic Situations]*. Available at: http://www.mhlw.go.jp/shingi/2005/01/s0126 –8.html (last accessed 14 January 2008). [in Japanese].
11. Ministry of Health, Labour and Welfare (2005) *Basic Survey of Wage Structure*. Available at: http://wwwdbtk.mhlw.go.jp/toukei/kouhyo/data-rou4/data17/30501.xls (last accessed 14 January 2008). [in Japanese].
12. National Personnel Authority. (2004) *Report on Fact-finding Survey of Remuneration of National Public Employees*. Available at: http://www.jinji.go.jp/kyuuyo/f_kyuuyo.htm. last accessed. 14 January 2008). [in Japanese].
13. OECD (2007) *Statistics on Purchasing Power Parities: Comparative Price Levels*. Available at: http://www.oecd.org/dataoecd/48/18/18598721.pdf (last accessed 14 January, 2008).
14. Ministry of Internal Affairs and Communication. (1998) Annual Report on Local Public Enterprise. Tokyo: Ministry of Internal Affairs and Communication. [in Japanese].
15. Ministry of Internal Affairs and Communication. (2005) *Annual Report on Local Public Enterprise*. Available at: http://www.soumu.go.jp/c-zaisei/kouei17/index.html (last accessed 14 January 2008). [in Japanese].
16. Fukuda, H., Imanaka, Y. & Hayashida, K. (2008) Cost of hospital-wide activities to improve patient safety and infection control: a multi-centre study in Japan. *Health Policy*, 87 (1), 100–111.
17. Stewart, W. F., Ricci, J. A. & Leotta, C. (2004) Health-related lost productive time (LPT): recall interval and bias in LPT estimates. *Journal of Occupational and Environmental Medicine*, 46 (6), S12–S22.
18. Rasmussen, J. N., Chong, A. & Alter, D. A. (2007) Relationship between adherence to evidence-based pharmacotherapy and long-term mortality after acute myocardial infarction. *Journal of the American Medical Association*, 297 (2), 177–186.
19. Simpson, S. H., Eurich, D. T., Majumdar, S. R., Padwal, R. S., Tsuyuki, R. T., Varney, J. & Johnson, J. A. (2006) A meta-analysis of the association between adherence to drug therapy and mortality. *British Medical Journal*, 333 (7557), 15–18.
20. Lidz, C. W., Appelbaum, P. S. & Meisel, A. (1988) Two models of implementing informed consent. *Archives of Internal Medicine*, 148 (6), 1385–1389.
21. Levinson, W., Roter, D. L., Mullooly, J. P., Dull, V. T. & Frankel, R. M. (1997) Physician-patient communication – The relationship with malpractice claims among primary care physicians and surgeons. *Journal of the American Medical Association*, 277 (7), 553–559.
22. Kraman, S. S. & Hamm, G. (1999) Risk management: extreme honesty may be the best policy. *Annals of Internal Medicine*, 131 (12), 963–967.
23. Smith, M. L. & Forster, H. P. (2000) Morally managing medical mistakes. *Cambridge Quarterly of Healthcare Ethics*, 9 (1), 38–53.
24. Fletcher, K. E., Davis, S. Q., Underwood, W., Mangrulkar, R. S., McMahon, L. F. & Saint, S. (2004) Systematic review: effects of

resident work hours on patient safety. *Annals of Internal Medicine*, 141 (11), 851–857.

25. Gaba, D. M. & Howard, S. K. (2002) Patient safety: fatigue among clinicians and the safety of patients. *New England Journal of Medicine*, 347 (16), 1249–1255.
26. Landrigan, C. P., Rothschild, J. M., Cronin, J. W. *et al.* (2004) Effect of reducing interns' work hours on serious medical errors in intensive care units. *New England Journal of Medicine*, 351 (18), 1838–1848.
27. Ayas, N. T., Barger, L. K., Cade, B. E., Hashimoto, D. M., Rosner, B., Cronin, J. W., Speizer, F. E. & Czeisler, C. A. (2006) Extended work duration and the risk of self-reported percutaneous injuries in interns. *Journal of the American Medical Association*, 296 (9), 1055–1062.

自治体病院の医業収支推移に関する規模別要因分析

大坪（オオツボ） 徹也（テツヤ）*　今中（イマナカ） 雄一（ユウイチ）*

目的　一般会計負担金を除外した医業収支比率の変化と関連する要因の把握。

方法　主に急性期医療を提供する自治体病院を選定し（n＝436），病床数による規模別（100床未満，100–299床，300床以上）に重回帰分析を行った。従属変数は一般会計負担金除外医業収支比率の変化とし，独立変数は患者数の変化，患者単価の変化，費用の変化，期首資産状況とした。また，人口増加率などの外部環境要因を調整変数とした。病院財務データを2003および2004年度の地方公営企業年鑑から参照した。また，地域関連データは，住民基本台帳人口要覧，国勢調査報告，市町村税課税状況等調から市町村別に参照した。

結果　病床規模により収支の変化との関連要因が異なることが確認された。収支の変化に対して外来患者数の変化と入院患者単価の変化はいずれの病床規模群においても共通に有意な項目であり，病床規模が小さいほど関連が強くなる傾向が示された。費用の変化に関する項目のうち，収支の変化と有意な関連を示した項目は病床規模群により異なり，職員給与費の変化と収支の変化との関連は必ずしも有意ではなかった。また，300床以上群では研究研修費の変化が収支の変化と有意な正の関連を示した。

結論　収支の改善に向けての病床規模別検討課題は，以下のように考えられる。

100床未満群では，外来患者数と外来患者単価の増加が強く収支の改善と関連し，とくに，総じて減少傾向にある外来患者数の確保が重要な検討課題となろう。したがって，外来機能の縮小や分離については，持続可能な経営に向けて慎重な議論を要すると思われる。

100–299床群では，入院外来患者数の確保および入院患者単価の増加が収支の改善と強く正に関連し，財務改善のためにはこれらを中心とした収益強化が検討対象となろう。すなわち，限られた経営資源の中で如何に外来機能と入院機能を維持し調整するかが問われる。

300床以上群では，減価償却費の増加と収支の改善に強い負の関連がみられ，設備投資の大きさやその時期の適切性の判断が収支に大きく関連することが確認された。また，研究研修活動への投資の増加と収支の改善において正の関連がみられたが，因果の方向性については更なる研究が望まれる。

Key words：財務分析，医業収支，自治体病院，縦断分析

I　緒　言

本邦の医療提供体制の整備計画において，自治体病院は地域医療の担い手として期待されてきた。医療提供機能の階層構造を意図した量的整備が達成されるにつれ，機能の重複が生じ，医療機関の競合のために経営の健全性を損なう自治体病院が出てきた。これに対し，財政再建の制度が設けられ，経営の健全化に向けた措置が実施されてきた。近年では，社会保障の見直しや地方財政の危機の煽りを受け，自治体病院の財務管理はますます重要視されるようになり[1~10]，厚生労働省による「医療制度改革試案」，総務省の「公立病院改革懇談会」などにおいても議論されてきた。

わが国の病院を対象とし，収益性と資源の利用状況との関連性について論じた先行研究は報告されている。医業活動の収益性に対する評価指標のひとつとして，一般会計負担金を除外した医業収支比率（以下，負担金除外医業収支比率）が取扱われてきた[4~6]。この指標が財務評価に用いられてきた理由として，自治体病院の過半数は赤字であり，非営利性という側面からも利益ではなく費用に対する収益の比率が，より適切に活動状況を把握しうる指標で

* 京都大学大学院医学研究科社会健康医学系専攻医療経済学教室
連絡先：〒606-8501 京都市左京区吉田近衛町
京都大学大学院医学研究科社会健康医学系専攻医療経済学教室　今中雄一

あるためである。

しかし，これらの先行研究には，研究デザインによる限界がある。先行研究はいずれも横断研究によるものであり，時間的前後関係について言及することが困難である。具体的には，医業収支の改善に向けて職員給与費の管理が最も重要であるとされてきたが，縦断分析による支持は得られていない。

そこで本研究では，病院の立地する市場特性や施設特性を考慮した上で，個々の病院における負担金除外医業収支比率の縦断変化と，患者数，患者1人1日当り収益，費用の縦断変化との関連性を明らかにする。これにより，各自治体病院が財務リスクに関するマネジメントを実践するにあたって，収支改善への行動基準についての手がかりを提供することを目的とする。

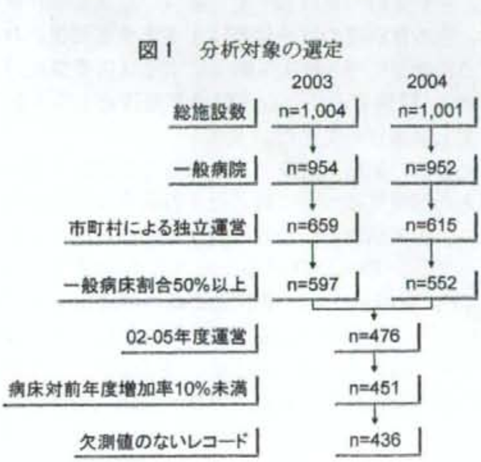
II　研究方法

1.　データ

病院別財務データについては，2003および2004年度の地方公営企業年鑑を参照した。参照期間には診療報酬改定が施行された2004年を含むものの，本体改定率は0%であることから，結果に大きな影響を与えないものとして扱う。また，ベースライン時の住民基本台帳人口要覧，国勢調査報告，市町村税課税状況等の調の市町村別データを参照した。分析対象は図1に示すとおり，全国の自治体病院から，比較可能性を確保するための選択基準を設け，436施設を選択した。

分析対象の選択基準を以下に示す。まず，ある開設者が複数の病院を運営する場合，財務リスクのヘッジが可能であることが考えられるため[2,11,12]，開設者と被開設病院が一対一である病院であることを選択条件とした。第二に，急性期医療を重点的に提供する病院を対象とした。ただし，経営比較をする際の急性期病院に関する明確な定義はなく[13]，一般病院のうち病床区分により療養病院との区別を行うため，一般病床割合が50%以上であることを選択条件とした。第三に，対象年度の次年度に運営が確認された病院を分析対象とした。なぜならば閉鎖，経営移譲，診療所への移行といった病院存続に変化が起こる直前の経営状況は，継続する病院の経営状況とは異なる可能性があるためである[14]。第四に，急激な病床数の変化は，収支状況に影響することが想定されるため，2003年度から2004年度にかけて病床増減数が前年度病床数の10%未満であることを選択条件とした。なお，公設民営である病院は，職員給与費や材料費がデータとして登録されていない状況が確認されたため，使用するデータに欠測値を含むレコードを除外した。

図1　分析対象の選定



2.　重回帰分析

財務状況に関する要因分析において提示されてきたフレームワークに基づき，本研究では独自に，関連要因を外部環境と内部環境からなるとした[2,15,16]。内部環境はさらに患者数の変化，患者単価の変化，費用の変化，期首資産状況からなるとした。

「患者数の変化」には，一般病床における入院患者数の増加率および外来患者数の増加率を含めた。一般病床における入院患者数は，一般病床利用率を一般病床在院日数で除して暦日数を乗算することにより算出した[17]。増加率は，基準年度と翌年度の値の差を基準年度の値で除することにより算出した。「患者単価の変化」として，入院，外来別の患者1人1日当り収益の増加率を用いた。「費用の変化」には，職種別職員給与費，材料費，減価償却費，委託料，委託料以外の経費，研究研修費，資産減耗費の増加率を含めた。「期首資産状況」には，基準年度の期首における設備寿命比率，1床当り建物資産額，1床当り器械・備品資産額を含めた。設備寿命比率は，減価償却累計額を減価償却費で除すことにより算出した[18]。また「外部環境」として，病院が立地する市町村における人口増加率，高齢者割合，就業者割合，一人当たり所得を含めた。

病床規模は財務状況に関連すると考えられてきたため[10,19]，病床数に基づき分析対象群を3群に分類した上で，群別に重回帰分析を行った。従属変数は負担金除外医業収支比率差とし，独立変数は内部環境に関する19変数および交絡調整変数としての外部環境に関する4変数とした。変数選択法は，いずれの従属変数のモデルにおいても強制投入法とした。出力として，標準偏回帰係数とP値を算出した。統計分析には，SPSS version 12.0を用いた。

Ⅲ 研究結果

病床規模別に集計した従属変数と独立変数の概要を表1に示す。負担金除外医業収支比率差はいずれの病床規模群においても平均値は負の値であり，最大値16.0%から最小値－42.0%の範囲であった。患者数は，いずれの病床規模群においても入院外来共に減少傾向にあり，とくに外来患者数は病床規模が小さいほど減少傾向にある。患者単価は，100–299床群の入院単価を除き，増加傾向にある。患者単価は概ね増加傾向にあるものの，患者数の減少に伴い，負担金除外医業収益はいずれの病床規模群においても減少傾向にあった。

各費目の平均値について記述する。事務職員，准看護師の給与費はいずれの病床規模群においても減少傾向にあった。看護師および医療技術員の給与費はいずれの病床規模群においても増加傾向にあった。医師の給与費は，300床未満群では減少傾向にあるものの，300床以上群では増加傾向にあった。薬品費はいずれの病床規模群においても減少傾向にあった。医療材料費は100–299床群においてのみ減少傾向にあった。減価償却費，委託料，経費，資産減耗費はいずれの病床規模群においても増加傾向にあった。

負担金除外医業収支比率差を従属変数とした重回帰分析結果を表2に示す。患者数の増加および患者単価の増加は，いずれの病床規模群においても収支の改善と有意な関連を示した。100床未満群では，収支の改善に対して，入院では患者数よりも患者単価の増加が強く関連しており，外来では患者単価よりも患者数の増加が強く関連していた。100–299床群では，入院および外来のいずれも患者単価よりも患者数の増加が収支の改善とより強く関連していた。一方，300床以上群では，入院および外来のい

表1　病床規模群別変数の概要

カテゴリー	変数	単位	100床未満 n＝133		100–299床 n＝162		300床以上 n＝141	
			Mean	SD	Mean	SD	Mean	SD
収支の変化	負担金除外医業収支比率*1	%	−1.0	6.4	−1.2	4.4	−0.5	3.0
患者数の変化	一般病床年間退院患者数*2	%	−2.4	19.4	−2.5	13.1	−0.3	5.1
	外来患者数*2	%	−3.4	9.5	−2.9	6.4	−1.7	4.3
患者単価の変化	患者1人1日当たり入院収益*2	%	0.1	5.8	−1.2	3.5	0.7	3.0
	患者1人1日当たり外来収益*2	%	0.1	11.9	1.1	9.6	2.0	7.2
費用の変化	事務職員給与費*2	%	−2.0	12.4	−1.1	11.1	−0.9	6.9
	医師給与費*2	%	−2.4	19.3	−2.2	10.0	1.1	5.3
	看護師給与費*2	%	1.2	12.0	1.5	6.5	1.6	4.0
	准看護師給与費*2	%	−6.8	17.8	−8.3	14.8	−9.9	11.9
	医療技術員給与費*2	%	0.2	10.9	0.5	7.5	1.4	5.0
	薬品費*2	%	−9.0	23.5	−6.3	15.4	−4.2	10.8
	医療材料費*2	%	0.5	32.0	−2.7	13.8	0.2	9.8
	減価償却費*2	%	9.8	93.7	0.5	22.8	9.0	96.7
	委託料*2	%	0.0	14.5	2.5	8.3	4.5	16.8
	経費*2	%	3.3	18.8	4.3	17.7	2.6	10.2
	研究研修費*2	%	−9.2	30.3	2.2	28.5	4.4	14.4
	資産減耗費*2	%	535.3	2,866.1	448.5	2,940.6	147.5	569.3
期首資産状況	設備寿命比率		14.8	8.2	13.6	7.7	12.2	6.4
	1床当たり建物資産額	百万円/床	12.3	10.1	13.0	9.2	16.1	11.5
	1床当たり器械・備品資産額	百万円/床	2.8	2.4	2.7	1.7	3.4	2.0
外部環境	人口増加率*2	%	−0.7	1.3	−0.4	0.9	0.1	0.7
	高齢者割合	%	25.8	6.1	22.8	5.4	18.0	3.9
	就業者割合	%	58.2	5.2	56.9	5.0	59.2	4.2
	一人当たり所得	百万円/人	1.1	0.3	1.2	0.3	1.4	0.2

*1：対前年度差

*2：対前年度増加率

ずれも患者数よりも患者単価の増加が収支の改善とより強く関連していた。

費用の変化や期首資産状況においては，病床規模により有意となった変数が異なった。100床未満群で有意となった変数は，薬品費増加率（$P=0.001$），減価償却費増加率（$P=0.001$）であった。100–299床群で有意となった変数は，看護師給与費増加率（$P=0.014$），医療材料費増加率（$P=0.028$）であった。300床以上群で有意となった変数は，減価償却費増加率（$P<0.000$），研究研修費増加率（$P=0.001$），設備寿命比率（$P=0.021$），1床当たり建物資産額（$P<0.000$）であった。

調整変数で有意となった変数は，100床未満群において，高齢者割合（$P=0.019$）と人口増加率（$P=0.012$）であった。100–299床群ではいずれの調整変数も有意ではなかった。300床以上群において，高齢者割合（$P<0.000$）であった。なお，有意であった変数のいずれの標準偏回帰係数も非負であった。

病床規模群により有意となった変数は異なるものの，決定係数（R^2）は病床規模群間で大きな差異は認められなかった。なお，多重共線性を判断する指標である VIF（Variance Inflation Factor）は，概ね1を上回る程度であったが，300床以上群の分析で7を超える2変数が確認された。しかし，いずれの VIF も10未満であるため，モデルの線形性は満たされているとした。また残差分析の結果，モデルの前提条件となる等分散性，正規性を全て満たすものであった。

Ⅳ 考 察

患者数の変化，患者単価の変化，費用の変化および期首資産状況が収支の変化とどのような関連にあるのかを，外部環境変数により交絡を調整したうえで病床規模別の重回帰分析により検討した。その結

表2 病床群別負担金除外医業収支比率差との関連要因

カテゴリ	変数	100床未満 n=133		100–299床 n=162		300床以上 n=141	
		β	p-value	β	p-value	β	p-value
患者数の変化	一般病床年間退院患者数	0.109	0.140	0.271	0.000	0.097	0.120
	外来患者数	0.858	0.000	0.339	0.000	0.180	0.024
患者単価の変化	患者1人1日当たり入院収益	0.198	0.017	0.179	0.012	0.141	0.047
	患者1人1日当たり外来収益	0.488	0.004	0.034	0.770	0.374	0.002
費用の変化	事務職員給与費	0.127	0.062	−0.124	0.091	−0.137	0.038
	医師給与費	−0.071	0.324	−0.008	0.915	−0.091	0.172
	看護師給与費	−0.072	0.284	−0.185	0.014	−0.091	0.193
	准看護師給与費	−0.048	0.498	−0.130	0.061	0.010	0.878
	医療技術員給与費	−0.070	0.368	0.033	0.644	−0.094	0.174
	薬品費	−0.564	0.001	0.050	0.665	−0.148	0.174
	医療材料費	−0.078	0.325	0.172	0.028	0.032	0.637
	減価償却費	−0.279	0.001	−0.069	0.320	−0.811	0.000
	委託料	−0.040	0.601	−0.027	0.702	0.167	0.279
	経費	−0.085	0.270	−0.075	0.275	−0.103	0.098
	研究研修費	−0.027	0.714	−0.028	0.680	0.208	0.001
	資産減耗費	−0.049	0.481	−0.019	0.785	0.022	0.743
期首資産状況	設備寿命比率	0.117	0.198	0.020	0.806	0.205	0.021
	1床当たり建物資産額	0.059	0.503	0.023	0.790	0.358	0.000
	1床当たり器械・備品資産額	−0.044	0.573	0.082	0.340	0.007	0.930
外部環境	人口増加率	0.215	0.012	0.209	0.052	0.019	0.824
	高齢者割合	0.227	0.019	0.159	0.146	0.318	0.003
	就業者割合	0.055	0.488	−0.134	0.085	0.027	0.702
	一人当たり所得	−0.001	0.990	−0.105	0.255	0.154	0.116
	R^2	0.555		0.469		0.624	

従属変数：負担金除外医業収支比率差
独立変数：患者数，患者単価，費用の対前年度増加率，期首資産状況（2003）および外部環境

果，病床規模により収支構造が異なることが示唆された。山本[20]は，外来患者の増加は財務リスクのひとつである倒産の抑制効果を持たないとしているものの，いずれの病床規模群においても，外来患者数の増加は収支の改善との関連が強いことが確認された。また，外来患者数の増加は病床規模が小さくなるほど，収支の改善との関連が強い傾向がみられた。患者調査によれば，病院を対象とした入院外来別推計患者数の年次推移において，入院患者数は年次変動が小さく，一定の需要が発生しているものの，外来患者数は1996年以降継続して減少傾向にある。したがって，全体的な傾向として患者数の増加を見込むことは現実に即さず，病床規模が小さい病院ほど患者数の減少による財務的困難に直面する可能性が高くなる。

患者単価の増加と収支の改善に正の関連が認められた。これは，患者数が同数でも患者単価の増加に伴い収支が改善するという基本的な構造が反映された結果であろう。とくに，入院患者単価の増加は病床規模が小さくなるほど，収支の改善との関連が強い傾向がみられた。また患者数の変化と患者単価の変化において有意となる項目と関連の強さが病床規模群により異なることから，病床規模群により受療する患者像が異なると考えられる。

職員給与費については，100–299床群で看護師職員給与費増加率，300床以上群で事務職員給与費増加率が収支の変化と有意な負の関連を示した。横断研究では，医業収益や医業費用に対する全職員給与費の比が医業収支と強い関連を示していたが[6,10]，職種別の給与費の増加率を用いた縦断分析の結果，各職種において必ずしも有意な強い関連は認められなかった。この結果は，横断研究で給与費が収支と強く関連することが報告されているものの，多くの病院において人材確保が困難な中，職種別の給与費を削減して収支を改善することが困難であることの表れであろう。

研究研修費には，研究材料費，図書費からなる研究費ならびに，謝金，旅費交通費，研究雑費からなる研修費が含まれる。すなわち，研究研修活動は直接的な診療活動ではないため，直接収益に係わる業務の削減となる可能性があり，短期間においては財務の悪化を招く恐れがある。また，研究研修活動への投資が組織の発展につながり，患者数の増加や費用の節約による経済効果が期待されるものの，効果が表れるまでに一定の期間を要する可能性がある。つまり，経営環境の悪化は収支の確保を困難にし，研究研修活動への投資が抑制されている可能性があり，分析結果からも経営が厳しいといわれている小規模病院において研究研修費は減少傾向にあった。

一方，300床以上群においてのみ，研究研修費の増加と収支の改善に有意な正の関連が認められた。研究研修活動の増加と収支改善の因果関係のメカニズムに関して，McSherry, Pearce and Tingle[21]によれば，研究研修活動は，職員の専門性を高め，質改善活動への動機付けとなるとしており，Alexander, Weiner and Griffith[22]は，質改善活動の普及が財務を改善する可能性を示唆している。今後，研究研修活動への投資と収支の改善の因果関係とその方向性について慎重に議論する必要がある。

建物への投資が財務を圧迫している可能性が自治体病院において注目されており，本研究の結果から，減価償却費や期首資産状況と収支の変化との関連において規模により異なる特徴をもつことが明らかとなった。減価償却費の変化は，100床未満群および300床以上群で有意な負の関連が認められ，300床以上群では，全ての独立変数の中で最も関連が強いことが認められた。100–299床群では，平均値および標準偏差ともに他の群と比較して小さかった。つまり，100–299床群は，対象期間において設備投資が他の群と比較して少額であったため，収支の変化とは統計学的に有意な関連が認められなかったと考えられる。

期首資産状況については，期待される結果とは異なっていた。McCue[2]は，設備寿命比率が低いほど，設備が新しく，収支の改善が期待できるとしている。そこで収支とは負の関連が期待されたが，本研究において収支の変化との関係を分析した結果，300床以上群でのみ有意な正の関連が認められた。また，大内，坂本[10]は，医業収支の横断状況と１床当たり固定資産額に負の関連を示唆している。本研究では，300床以上群においてのみ１床当たり建物資産額と収支の変化に有意な正の関連性が認められた。300床以上群では収支の変化と特定の期首資産状況とは有意な正の関連があり，減価償却費の変化とは有意な負の関連があるため，適正な設備投資戦略が望まれる。

調整変数のうち，100床未満群において人口増加率と収支の変化に有意な正の関連が認められた。人口増加率は地域の需要を反映する尺度であるため，需要が増加傾向にあるほど収支改善が認められた結果は支持される。また，100床未満群および300床以上群において高齢者割合と収支の変化に有意な正の関連が認められた。Harrison and Sexton[23]は高齢者割合が高いほど財務状況が悪化するとしている。しかし，本邦における診療報酬は必ずしも費用に基づいて決定されていないことから，高齢者割合は地域