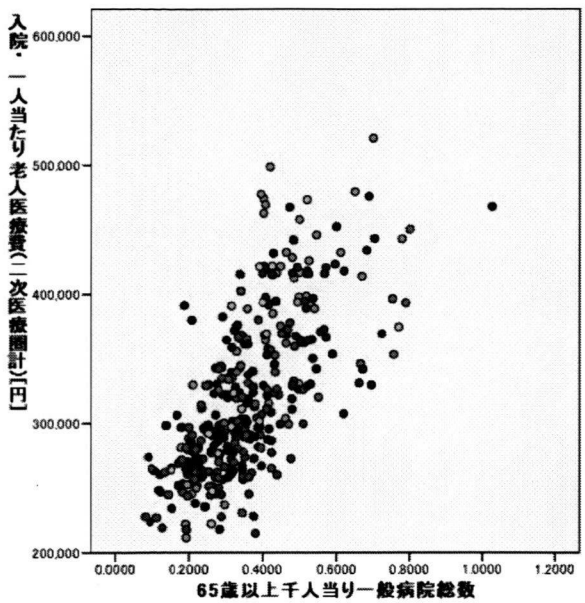
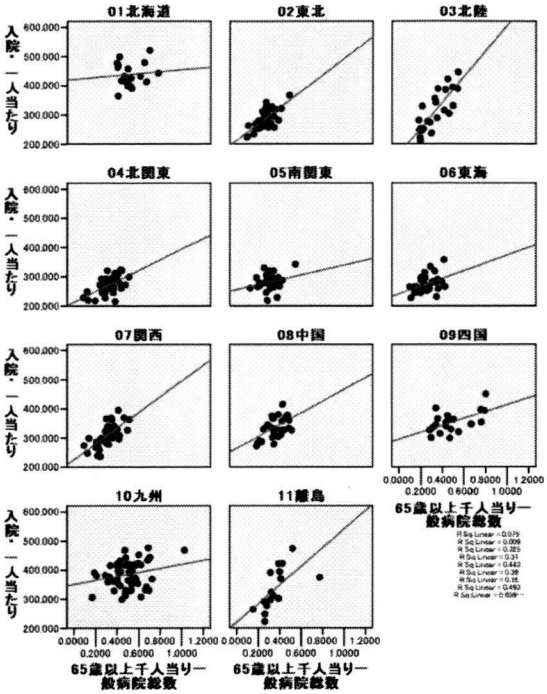
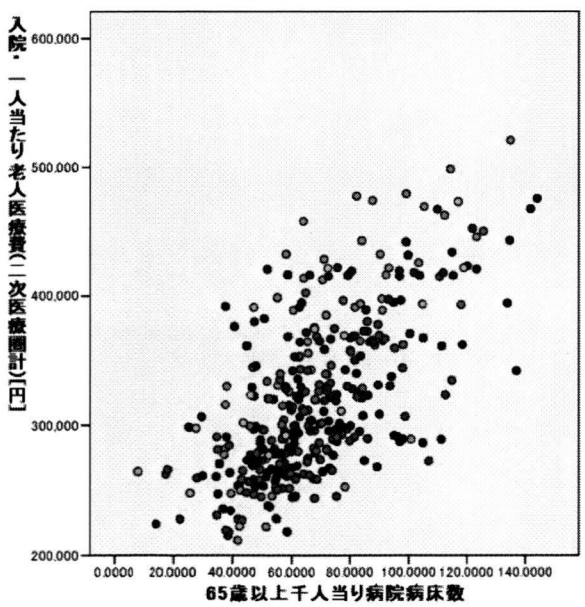
図表28 65歳以上千人当り一般病院総数

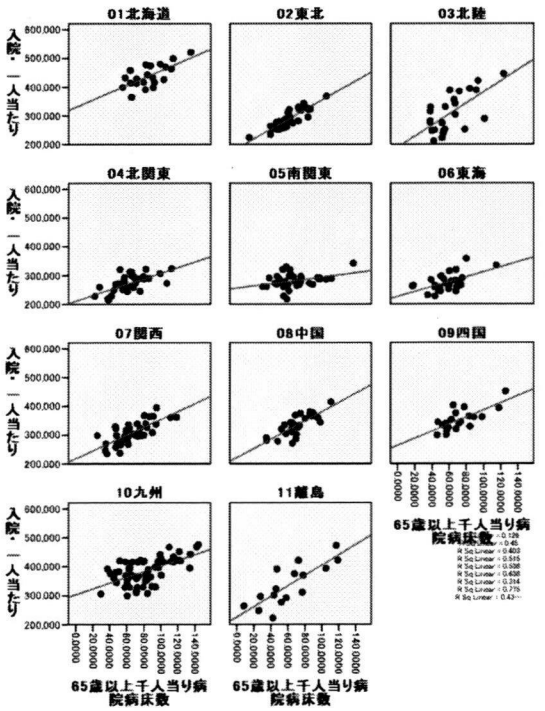




地域	01北海道	02東北	03北陸	04北関東	05南関東	06東海	07関西	08中国	09四国	10九州	11離島	全国
R^2 (n)	0.009 (21)	0.493 (39)	0.659 (24)	0.325 (43)	0.075 (39)	0.160 (30)	0.443 (40)	0.273 (30)	0.310 (21)	0.051 (60)	0.390 (16)	0.463 (363)

図表29 65歳以上千人当り病院病床数





地域	01北海道	02東北	03北陸	04北関東	05南関東	06東海	07関西	08中国	09四国	10九州	11離島	全国
R^2 (n)	0.450 (21)	0.775 (39)	0.430 (24)	0.403 (43)	0.126 (39)	0.314 (30)	0.538 (40)	0.621 (30)	0.515 (21)	0.362 (60)	0.638 (16)	0.420 (363)

医療安全活動、説明と同意、
記録・書類作成が
医療のコストに及ぼす影響

医療安全活動、説明と同意、記録・書類作成が医療のコストに及ぼす影響

Ⅰ．医療安全対策の必要資源の推定

Cost of hospital-wide activities to improve patient safety and infection control: A multi-centre study in Japan

要約

医療の質と安全の確保へ医療界ならびにより広く社会における要望は益々高まってきており、質と安全の確保のために、医療機関は体制を充実し活動を強化してきている。そのための人的および物的負担は益々大きくなってきている。本研究では、医療の質と安全の確保に関して先進的な取り組みを行っている医療機関の内、比較的大規模の病床（300 床以上等）を対象に、医療の質と安全を保証し向上させるための組織体制づくりや活動状況等の実態を把握し、その必要資源を明らかにしコスト計算を行い、今後の医療の質・安全への取り組み方を検討するための基礎資料を得ることを目的とする。

医療安全の確保に向けて精力的に取り組みを行っていると思われる医療機関の内、300 床以上の施設に、地域、開設者を幅広く選定することを考慮した上で、調査協力を求めた。2005 年中に同意の得られた 7 施設を対象に、質問票調査および複数回の聞き取り調査を、2005 年 8 月から実施した。調査協力施設の所在地域は北海道、東北、関東、東海、中国の各地域へと全国にばらついており、開設者は、自治体、公的医療機関、医療法人、会社である。当該施設における、調査対象者は、医療安全管理および感染制御の担当者、あるいはそれらに相当する者を中心に、看護部、薬剤部、事務部門等の担当者等についても状況に応じて対象に含め、調査を行った。

医療の質と安全の確保に関する活動要素を、コスト計算の対象範囲とする。ここで問題となるのは、医療の質と安全を確保するために実施されている活動と、医療活動が本来満たすべき質を維持するために実施されている活動とを峻別することが極めて困難であることである。しかしながら、本研究では、およそ 1999 年頃より医療の質と安全の確保への取り組みへの強化が進んできた社会背景を活用することで、そのころの一般的な水準に比しての“増分”費用を把握することで、医療の質と安全の確保に関する活動要素を抽出するフレームワークを用いることとした。

人的資源を貨幣価値に換算する際の人件費の単価は、国家公務員の水準を基に、1 時間当たり単価として算出した。この時間給は、月例基本給ならびに、それぞれ月額換算された賞与、法定福利費の事業主負担部分（国家公務員共済組合）、退職給付金[4)]の総和を実労働時間で割ることにより算出した。ただし、退職給付金と事務職員以外の職種における実労働時間は民間医療機関における統計値を使用している。なお、全ての職種は、経験年数 10 年未満、経験年数 10 年以上、経験年数考慮なし、の各カテゴリー別に算出し、医師については、さらに診療科長以上のカテゴリーを設定した。

それぞれの各カテゴリーの月例基本給は、統計データにおける経験年数別の基本給とサンプル数の分布を使用した人数重み付け平均値である。人件費単価を国家公務員の水準に基づき、経験年数別に算出することの根拠は、本邦における近年の医療の原価計算に関する調査研究において、同様の方式により算出していることによる。

材料および設備費は、調査施設の提供による市場流通価格に基づき、法定耐用年数あるいは利用予定年数を用いた年間費用として推計した。印刷費用は 1 枚 10 円としている。また、会議や研修の実施や安全管理室等の設置に要するスペース費用は、東京における貸会議室の市場相場から基本料金（利用可能時間：2～4 時間）を推計し、その上で、東京の平均路線価に対する調査対象施設の平成 16 年度路線価により重み付けし算出した。なお、安全管理室等の常駐場所は貸オフィスの市場相場から、1 坪当たり 10,000 円とした。また、研修費用、受審費用は実費とし、外部評価の受審費用は、その更新間隔により年間費用に換算した。

今回の対象範囲における安全管理および感染制御に係る活動の“増分”として、年間で総計 19,414～78,540 人・時間、100 床規模換算で 14,171～56,870 人・時間が投じられていた。職種・経験年数別の活動時間を各カテゴリーにおける 1 時間当たりの人件費単価を乗じた結果、本研究が定義した医療安全に係る活動に限定した場合、年間 129,108～295,447 千円（100 床規模換算：15,988～49,962 千円）が医療安全対策の増分として費用を要していることが推計された。この値は、医業収益の 0.55～2.57%を占めている。また、医療者の平均給与を用い、常勤人数の雇用可能人数として換算すれば、17～40 人に相当する。さらに、病床規模の小さな施設ほど、医療安全活動の実施により大きな負担を強いられる現状が明らかとなった。

本研究は、病院横断的な医療安全対策の実施に要するコストを測定するフレームワークを提示した。当該フレームワークに基づき、実際のコストを推定した結果、医療機関が医療安全対策を実施するには膨大なコストを要するために、医療安全活動を持続的に継続するためには、科学的エビデンスに基づいた医療政策の支援が不可欠であることが示唆される。本研究は、医療安全方策の実施に要するコストに関する知見を生み出すものである。

c.f.　Health Policy 2008, in press.

Cost of hospital-wide activities to improve patient safety and infection control: A multi-centre study in Japan

Fukuda H, Imanaka Y, Hayashida K.

Abstract

Objective: The aim of this study was to assess the financial costs to hospitals for the implementation of hospital-wide patient safety and infection control programs.

Methods: We conducted questionnaire surveys and structured interviews in seven acute care teaching hospitals with an established reputation for their efforts towards improving patient safety. We defined the scope of patient safety activities by use of an incremental activity measure between 1999 and 2004. Hospital-wide incremental manpower, material, and financial resources to implement patient safety programs were measured.

Results: The total incremental activities were 19,414 to 78,540 person-hours per year. The estimated incremental costs of activities for patient safety and infection control were calculated as US$1.100 million to US$2.335 million per year, equivalent to the employment of 17 to 40 full-time healthcare staff. The ratio of estimated costs to total medical revenue ranged from 0.55% to 2.57%. Smaller hospitals tend to shoulder a higher burden compared to larger hospitals.

Conclusions: Our study provides a framework for measuring hospital-wide activities for patient safety. Study findings suggest that the total amount of resources is so great that cost-effective and evidence-based health policy is needed to assure the sustainability of hospital safety programs.

1. Introduction

Adverse events including hospital-acquired infections enact heavy disease tolls on patients and place large financial burdens on healthcare institutions. According to the Institute of Medicine [1], preventable adverse events in the United States (US) cause 44,000 to 98,000 deaths annually and represent a cost of US$17 to US$29 billion. In the United Kingdom (UK), between 0.3 - 1.4 million patients in the National Health Service hospital

sectors are affected by adverse events each year, resulting in £2 billion in inpatient costs. The costs attributable to hospital-acquired infections were estimated at nearly £1 billion a year, which was regarded as preventable in about 15% of cases [2].

Over the past ten years, the Japanese government has taken measures against adverse events in healthcare institutions. The first measures were conducted in 1996 for the prevention and control of hospital-acquired infection [3]. These measures included new medical regulations requiring hospitals to implement several infection control policies, including establishing infection control committees, reporting comprehensive infection data, and developing hand hygiene activities. By implementing these programs, hospitals received additional payments of US$0.43 (JPN¥50) per patient day as an incentive. Later, in 2000, following growing concerns for patient safety, the reimbursement system was changed to a punitive approach whereby hospitals failing to implement these programs were charged a decreased hospital reimbursement US$0.43 (JPN¥50) per patient day [4].

After a devastating medical error at a university hospital in 1999, concerns over patient safety in Japan further increased. The government responded by issuing a new series of patient safety regulations for healthcare institutions. These measures were enacted in 2000, requiring all university hospitals and two large medical centers to 1) establish institutional guidelines for patient safety, 2) develop reporting systems of adverse events, 3) organize patient safety committees, and 4) provide continuous staff education and training about patient safety [5]. In 2002 these measures were extended to all hospitals in Japan [6]. Additionally, the government took a punitive approach in providing a decreased hospital reimbursement of US$0.85 (JPN¥100) per patient-day for those hospitals that did not implement these programs [7].

In 2006, regulations for infection control and for patient safety did not reflect national fee schedules. Instead, as long as hospitals employed full-time staff who had professional training for patient safety, hospitals could receive additional payment of about US$4.26 (JPN¥500) per patient [8]. In contrast, in the US, the Centers for Medicare and Medicaid Services will stop reimbursing hospitals for clearly preventable adverse events from 2008 [9].

Contrary to the policies encouraging hospitals to implement these programs for patient safety, there are few financial incentives in Japan's payment system to invest in such programs. Under the existing fee-for-service reimbursement system or new per-diem payment system, even the costs incurred by treatment of complications resulting in additional length of stay are compensated by the payment systems. In such systems, there is a conflict

of interest between society and hospitals; decreases in healthcare resources benefit society and patients, but increases in resources are financially beneficial for hospitals. Moreover, increasing pressure to contain the growth of healthcare expenditures has made safety program implementation extremely difficult, since there are limited resources, and the challenge of balancing the hospital budget is great. If studies demonstrate that safety programs can improve patient outcomes, the information could be used to support the financial worth of patient safety activities. However, patient safety is difficult to measure and there is a limited number of validated measures to use [10-12]. Therefore, the formulation or use of such outcomes remains highly unlikely.

Despite these formidable barriers, the healthcare system should be well poised to increase the pace of improving patient safety. The first step is to assess the costs of activities related to patient safety. Detailed cost information is valuable for the following reasons. First, cost information can help hospital administrators make decisions that contribute to the front-line practitioners who work to promote patient safety. Cost analysis is an essential tool for visualizing actual activity conditions in a quantitative context. Second, cost information can help in the budgeting of safety improvement activities [13]. The sustainability of hospital safety programs is a potential threat to the medical delivery system due to constrained finances and limited staff time to implement safety-related activities. A potential way to deal with this problem is clear budgeting, for which cost information is imperative. Finally, from a societal perspective, cost information can provide a guide for how to supply health services at a patient safety level that the community agrees to. The main driving force for patient safety regulations has been an increased demand from the community. Although the community has good reasons to ensure their own safety in hospitals, the underlying and inevitable increase in associated costs has received little attention in the claim. However, in order for patient safety levels to increase, the community must also be prepared to bear an equitable share of these costs. Successive improvements in safety are generally associated with progressively higher costs for each increment of improvements gained [14]. Without knowing the actual costs of safety programs, it can be impossible to decide what measure is feasible within a constrained financial environment. At present, however, past estimates of the costs associated with programs for patient safety have had serious limitations; they have either mainly focused only on single programs for infection control such as education [15] and surveillance [16], or targeted material interventions [17]. Therefore there is scant data regarding the resources necessary to implement hospital-wide activities involving patient safety and infection control. To address this lack of data, this study aimed to perform a

multi-center cost analysis to assess the amount of financial resources that Japanese hospitals invest for patient safety activities. The main outcome measures were the volume and the monetary value of activities for patient safety and hospital infection control.

2. **Methods**

2.1. Study Setting

Seven acute care teaching hospitals in Japan participated in this study. We recruited hospitals located across distinct geographic regions in Japan, under various kinds of ownership (public sector, healthcare corporations, and company). All were hospitals with an established reputation for their efforts to improve patient safety and infection control. In most cases, the individuals interviewed were department managers of patient safety and infection control. When necessary, we also interviewed the directors of nursing, pharmacy and administrative staff. We conducted questionnaire surveys and structured interviews between August 2005 and March 2006.

2.2. The Concept of Incremental Activity

To measure activities and financial costs of patient safety, we focused on the scope of patient safety activities through the incremental activities concept. We assessed all the activities which were aimed at enhancing patient safety systems and were introduced between 1999 and 2004. Within this scope, we estimated the annual volume of activities conducted in 2004. It is typically difficult to distinguish the activities for patient safety and the activities for quality that healthcare inherently sustains. In this case, however, there was a dramatic rise in social concern and health policy, sparked by the media coverage of a wave of medical accidents in Japan since 1999. This time thus marked a major turning point that allowed us to better assess the incremental activities changes. Therefore, we retrospectively assessed the additional patient safety activities provided in hospitals in 2004 compared to typical activity levels in 1999 (the base case).

2.3. Development of Scope of Patient Safety and Questionnaire

The incremental concept was reified in the form of questionnaire. The draft of the questionnaire was developed through a review of the findings from previous studies that demonstrated the effectiveness and/or significance of patient safety programs [1,17-21], and

from a review of the items of the Japan Council for Quality Health Care (JCQHC) [22] hospital accreditation standards. We also collected activity items through a web-based interface, and public relations magazines from a variety of hospitals. We modified questionnaires through interviews conducted with several managers of patient safety practices and hospital infection control, and through panel discussions with experts. The scope of the questionnaire included the following domains: staff assignment, meetings and conferences, materials and equipments, prevention of occupational infection, internal audit activities, internal education and training, external education and training, incident report system and its related activities, infection surveillance, standardized processes and their manuals, external audits, management of medical equipment, and management of medication (**Table 1**).

To assess the volume of activities annually, we surveyed the following four items: (1) type of activity component, (2) number of staff by type of profession, (3) volume of time required, and (4) frequency of activities conducted in 2004. For example, in the domain of meetings and conferences, we asked what type of conferences were conducted, which specialists the members belonged to, how many hours were allotted for the functioning of each committee (such as a supreme decision-making board committee or a regular meeting in patient safety division), and how many times the committee met in 2004. We surveyed the same questions across all activity domains. We also elicited from interview respondents information regarding non-personnel expenses such as space, handouts and participation fees within each activity component, as well as materials or equipments designed for patient safety and infection control. **Table 1** shows the possible activity components within each activity domain. Categories for type of profession included doctor, nurse, pharmacist, other medical staff, and administrative staff. Additionally, all staff were categorized by whether they had ten years in practice or not.

2.4. Data

We first sent the questionnaire to each participant and, using the collected data from the questionnaire, we then conducted individual face-to-face interviews to examine costs incurred in 2004. In each hospital, we interviewed around five to ten staff members who belonged to either patient safety division, infection control teams, nursing sections, pharmaceutical sections and administrative sections. HF participated in all interviews. Interviews were supplemented by e-mail, phone or additional interviews. To reduce institutional differences in definitions of activities, we also sent feedback of the whole lists of

activity components collected through these interviews to participant hospitals. Components in the list that participants did not respond to were also included in the definition and added to estimates of activities volume. Such feedback was continued until discrepancy between the actual activities and reporting activities in each hospital was resolved. When there were intra-institutional discrepancies, all authors met to discuss and reach a consensus about activity inclusion. There were no instances of disagreement in which consensus could not be reached. This study was approved by the Institutional Review Board at the Graduate School of Medicine of Kyoto University.

2.5. Cost Analysis

We converted the annual volume of activities into monetary values through the use of conversion rates of activity per hour to cost from national statistical data [23-26]. The annual volume within each activity component was calculated by multiplying the number of staff by the annual time spent by the frequency of activities within each component. The conversion rates by type of profession were computed by taking a weighted average of annual income divided by annual labor hours. The rates of activity per hour to cost (US$) by years in practice for under 10 years, for 10+ years and for not adjusted by years in practice were, respectively: doctors, 38.5, 51.5 and 49.1; nurses, 21.0, 30.4 and 26.3; pharmacists, 21.3, 31.1 and 28.7; other medical staff, 21.3, 30.6 and 28.5; administrative staff, 18.6, 29.4 and 26.8; and other staff, 19.5, 26.5 and 26.3. The estimates were converted to 2007 dollars using the Japanese consumer price index (adjusting to the 2007 Yen value) and the Purchasing Power Parities (JPN¥100 = US$0.85; April 2007) [27].

In addition to manpower resources, we estimated the costs of material resources such as spaces for conference or training, handouts, participation fees for training sessions, and materials or equipment designed for patient safety and infection control. The costs of spaces were calculated by adjusting the cost of a rental conference room in Tokyo by the value of land in each locality of the participant hospital. The costs for training, and materials or equipments were actual costs. All estimates were converted into the 2007 US dollar value. Throughout the study, the cost perspective was that of the hospital. All cost estimates are presented in values equivalent to the 2007 US dollar value.

Since the annual amount of resources consumed depended on the hospital size, we estimated incremental costs adjusted to 100 beds, incremental costs per bed, incremental costs per patient-day, and ratio to medical revenue. We also calculated the number of full-time

healthcare staff that could be hired from the total costs by dividing total incremental costs by the average annual revenue of healthcare staff.

3. **Results**

Of eight hospitals referred, seven hospitals were included in this study. All sites were tertiary referral centers with bed numbers ranging from 300 to 1,100 and more than 100,000 inpatient-days per year (**Table 2**).

3.1. Activity Volume

The cumulative volumes for each activity component within each domain of hospital preventive measures are summarized in **Table 3**. The total volume of activities in each domain was 19,414 to 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 million to US$2.206 million and that of material resources ranged from US$0.297 million to US$0.691 million. The total cost of activities for patient safety and infection control were calculated to range from US$1.094 million to US$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 to 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% to 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$2,969 per bed or US$9.68 per patient-day on average.

4. Discussion

To the best of our knowledge, this is the first multi-center 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 million to US$2.504 million per hospital, which is equivalent to the cost of employing 17 to 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 the 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 and colleagues, 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.

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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) 1996; Gogai 50:3-27. [in Japanese]

[4] Kouseishou Kokuji 66th. (66th Announcement by Ministry of Welfare) Kanpo (Public Newsletter) 2000; Gogai 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 (111st 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) 2002; Gogai 42:2-104. [in Japanese]

[8] Kouseiroudoushou Kokuji 92nd (92nd Announcement by Ministry of Health, Labour and Welfare). Kanpo (Public Newsletter) 2006; Gogai 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 eds. 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.