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*	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†	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‡	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

*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.

†Presented is average length of stay limited acute beds.

‡Presented is the total number of co-medicals without pharmacists.

Ⅱ. 説明と同意および記録作成に要する資源の推定　（つづき：英文報告）

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

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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 healthcare 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, healthcare 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-beds 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 seven 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.

Table 3. The Volume and Proportion of Manpower Activities for Patient Safety and Infection Control

	A	B	C	D	E	F	G	Avg.
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 & 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.

Ⅱ．説明と同意および記録作成に要する資源の推定

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

要約

インフォームド・コンセントの取得は、適切な治療情報の提供や、医師と患者の両者が互いの知識や背景および価値観を共有することを通じ患者にとって最良の選択を実施する shared decision making に実施において極めて重要な要件である。患者からインフォームド・コンセントを得ることは、今日の医療従事者の責務となっていることに疑いの余地はない。しかしながら、その一方で、医療従事者の疲労の増加もまた深刻な問題として表面化されつつある。仮にインフォームド・コンセント取得に要する活動が医療従事者に対して多くの負担を強いているのであれば、理論的には医師・患者関係を改善させ、医療の質向上に便益をもたらすものであったとしても、そのような活動は究極的には医療システムを改悪させることにもなりかねない。以上の問題意識にたち、本研究では、インフォームド・コンセントの取得およびそれに必然的に付随する記録作成に要する人的資源投入量を明らかにしたい。さらに、医療安全に対する社会的な関心が高まる契機となった 1999 年に比べたこれら活動の増分の推定を試みたい。

2006 年 2 月、西日本に位置する 6 つの公的病院における全常勤職員（総計 3,304 人）を対象に質問票を送付した。質問票は以下の設問から構成される。(1) この 1 週間のインフォームド・コンセントの取得時間、(2) 1999 年時における 1 週間のインフォームド・コンセントの取得時間、(3) この 1 週間の文書作成の取得時間、(4) 1999 年時における 1 週間の文書作成の取得時間。施設あたりの必要資源を推定するために、本研究では、調査協力を得られた職員における推定値を、調査協力の得られなかった職員にも外挿した。

インフォームド・コンセントの取得のための、全職種平均の 1 週間あたり所要時間は 3.89（95%信頼区間：3.71～4.07）時間であった。施設別平均の 1 週間あたり所要時間は 3.45～4.21 時間であった。一方、記録作成に要する 1 週間あたり所要時間は、全職種平均で 6.64（95%信頼区間：6.40～6.88）時間であり、施設別の範囲は 5.88～9.04 時間であった。

インフォームド・コンセントおよび記録作成のための資源の施設別年間増分量は、4,968～5,349 千人・時間（100 床規模換算：5,080～10,776 千人・時間）であった。1999 年から 2006 年にかけて増加した資源をコストに換算すれば、インフォームド・コンセントのための活動（100 床規模換算）に-47～21,414 千円、記録作成に要する活動（100 床規模換算）に 6,628～33,226 千円が増加していた。これら増分コストは、インフォームド・コンセントや記録作成のためだけの活動のために常勤職員を 100 床規模の施設で雇うとすれば、2.0～7.5 人もの職員を新たに雇用するのに匹敵する額である。

本研究により、インフォームド・コンセントやそれに付随する記録作成に要する活動時間およびコストがここ数年で大幅に増加していることが明らかとなった。患者の

自立性や自己決定権を確保するという観点からは、インフォームド・コンセントの取得プロセスにより大きな注意を払うべきではあるものの、医療費が総体的に縮小される経営環境に鑑みれば、これら活動に要する医療者の負担の増大という視点もまた同時に考慮すべきであるといえよう。

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 healthcare 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 healthcare 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 (2,219, response rate: 67.7%) Japanese doctors suffered from increased burdens compared to the situation three 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 healthcare 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 healthcare 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 (3,304 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 95th 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 ten years (excluded only when

comparing the amount of activity time between 1999 and 2006).

Because the incremental analysis compared situations with a seven-year span and because most healthcare staff spend much of the beginning portions of their careers in training programs, we focused on individuals who had more than ten years of experience. In addition to this "direct comparison", we conducted an "indirect comparison" by targeting individuals who had less than ten 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; co-medicals, 26.3 and 33.0; others, 25.7 and 32.3. In addition, since 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 non-parametric 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 3,304 questionnaires sent, we received 2,924 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 to 9 years, 21%; 10 to 19 years, 21%; 20 years and over, 23%. Data was similar in each hospital.

Volume of Manpower Resources

Excluding the outliers and the responses with missing data, we analysed 2,172 responders for informed consent and 2,079 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 to 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 to 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 to 6.98). The average time taken weekly to write documentation per staff was 6.64 hours (95% CI 6.40 to 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 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 to 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 to 0.97; $P < 0.001$). In five of the hospitals, this value was found to be significantly different from the time spent seven years ago ($P < 0.05$). Overall, doctors showed the highest increase in time consumption from activities for informed consent (1.18 hours/week), followed by co-medicals (0.72 hours/week), others (0.64 hours/week), and nurses (0.55 hours/week).

Hospitals' increased volume of activities and costs

For the individuals with less than ten 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, chi-squared 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, chi-squared test). Since the distribution of years in practice for both the eligible and ineligible groups was almost identical, we concluded that the missing data was 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 amongst 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 4,968 and 5,349 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 5,080 to 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 to 181,478 US dollars and 56,172 to 281,574 US dollars, respectively. These incremental costs were equivalent to employing 2.0 to 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

healthcare 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 healthcare 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 honored. 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 to 7.5 full-time staff members with the dedicated purpose of obtaining informed consent and providing documentation in a 100-beds hospital.

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 healthcare 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, due to the decreased average length of stay over these seven 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 seven years the time used to obtain informed consent and to document medical information increased an average of 8,257 thousand person-hours in a bed-size of one hundred.

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 to 1.26 person-years higher, see **Table 3**). The same holds true for data in 2006 (0.12 to 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 [6].

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 that is currently under submission, 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 to 2.5 million US dollars per hospital between 1999 and 2004. This amount was equivalent to the employment of 17 to 33 full-time staff dedicated to patient safety and infection control.

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 [16]. 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 honored. It is a patient right. In practice, there is some indication that these activities contribute to the quality of healthcare services. For example, good adherence to drug therapy is associated with positive health outcomes [17, 18]. Thus, efforts to improve patients' adherence is a critical activity in providing healthcare. 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 [19-22]. 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 healthcare staff, since obtaining informed consent requires the consumption of great amounts of time as revealed in this study. While controversial [23, 24], considering the current research that suggests a relationship between extended work duration and medical errors [25, 26], 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 seven years between 1999 and 2006. These processes involve substantial activities and resources. To ensure the notions of patient autonomy and self-determination, healthcare staff should pay greater attention to the informed consent process. Unfortunately, however, these activities might increase the fatigue of healthcare 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 healthcare employee is necessary.

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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,I29-I33.
3. Mazur, D.J. (2003) Influence of the law on risk and informed consent. *British Medical Journal*, 327(7417),731-4.
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. *Kanpo (Public Newsletter)*,Supple 251,S53-S55. [in Japanese]
7. Ministry of Health, Labour and Welfare. Kongo no iryo anzen taisaku ni tsuite. [A report on future action for patient safety] 2005. 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? There are probably many causes, some of them deep. *British Medical Journal*, 322(7294),1073-4.
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. 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.
17. 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),177-86.
18. 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),15-8.
19. Lidz, C.W., Appelbaum, P.S., Meisel, A. (1988) Two models of implementing informed consent. *Archives of Internal Medicine*, 148(6),1385-9.
20. 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),553-9.

21. Kraman, S.S., Hamm, G. (1999) Risk management: Extreme honesty may be the best policy. *Annals of Internal Medicine*, 131(12),963-7.
22. Smith, M.L., Forster, H.P. (2000) Morally managing medical mistakes. *Cambridge Quarterly of Healthcare Ethics*, 9(1),38-53.
23. 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),851-7.
24. Gaba, D.M., Howard, S.K. (2002) Patient safety: Fatigue among clinicians and the safety of patients. *New England Journal of Medicine*, 347(16),1249-55.
25. 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),1838-48.
26. 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),1055-62.

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 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/week)								
Doctors	Mean (95% CI)	7.65 (6.15 to 9.15)	6.72 (4.82 to 8.62)	5.71 (4.65 to 6.77)	6.26 (4.96 to 7.56)	5.62 (4.38 to 6.86)	6.45 (4.37 to 8.53)	6.38 (5.78 to 6.98)
	n	46	33	57	70	33	22	261
Nurses	Mean (95% CI)	3.89 (3.39 to 4.39)	3.61 (3.09 to 4.13)	3.15 (2.55 to 3.75)	4.03 (3.57 to 4.49)	3.91 (3.41 to 4.41)	2.92 (2.34 to 3.5)	3.73 (3.51 to 3.95)
	n	304	212	180	361	244	93	1394
Co-medicals	Mean (95% CI)	3.94 (2.76 to 5.12)	3.50 (2.20 to 4.80)	2.80 (2.04 to 3.56)	2.14 (1.52 to 2.76)	3.50 (2.16 to 4.84)	4.58 (2.62 to 6.54)	3.21 (2.75 to 3.67)
	n	68	48	54	73	33	19	295
Others	Mean (95% CI)	2.40 (0.36 to 4.44)	4.73 (2.75 to 6.71)	2.83 (1.73 to 3.93)	2.54 (1.48 to 3.60)	1.86 (-0.14 to 3.86)	2.75 (0.07 to 5.43)	2.88 (2.24 to 3.52)
	n	24	32	62	68	20	16	222
All	Mean (95% CI)	4.21 (3.75 to 4.67)	4.02 (3.54 to 4.50)	3.45 (3.03 to 3.87)	3.89 (3.51 to 4.27)	3.91 (3.47 to 4.35)	3.63 (2.99 to 4.27)	3.89 (3.71 to 4.07)
	n	442	325	353	572	330	150	2172
Documentation (person-hours/week)								
Doctors	Mean (95% CI)	9.53 (7.81 to 11.25)	7.83 (5.33 to 10.33)	8.46 (6.98 to 9.94)	7.50 (5.90 to 9.10)	7.25 (5.19 to 9.31)	7.93 (5.61 to 10.25)	8.12 (7.36 to 8.88)
	n	43	27	54	68	30	20	242
Nurses	Mean (95% CI)	7.05 (6.47 to 7.63)	6.02 (5.34 to 6.70)	6.90 (6.04 to 7.76)	6.79 (6.25 to 7.33)	5.79 (5.21 to 6.37)	9.14 (7.76 to 10.52)	6.73 (6.45 to 7.01)
	n	290	203	176	373	239	92	1373
Co-medicals	Mean (95% CI)	5.36 (4.08 to 6.64)	6.50 (4.88 to 8.12)	3.39 (2.43 to 4.35)	4.63 (3.45 to 5.81)	4.57 (2.83 to 6.31)	7.47 (4.57 to 10.37)	5.05 (4.45 to 5.65)
	n	63	47	53	71	31	19	284
Others	Mean (95% CI)	3.67 (1.03 to 6.31)	7.09 (4.49 to 9.69)	5.52 (3.74 to 7.30)	6.29 (3.89 to 8.69)	7.06 (3.34 to 10.78)	12.31 (6.69 to 17.93)	6.41 (5.27 to 7.55)
	n	21	29	49	51	17	13	180
All	Mean (95% CI)	6.88 (6.38 to 7.38)	6.35 (5.75 to 6.95)	6.39 (5.77 to 7.01)	6.56 (6.08 to 7.04)	5.88 (5.32 to 6.44)	9.04 (7.90 to 10.18)	6.64 (6.40 to 6.88)
	n	417	306	332	563	317	144	2079