Methods

This study was a retrospective study using data from gastric cancer patients admitted to four Japanese hospitals for the purpose of gastrectomy. This study was approved by the Kyoto University Graduate School and Faculty of Medicine Ethics Committee (Registration Number E553).

The reliability of our HAI identification method was assessed using sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) relative to a contemporaneous chart review conducted on the same sample. Additionally, we have included Cohen's kappa coefficient[13] and prevalence-adjusted and bias-adjusted kappa (PABAK) [14] to analyze inter-rater agreement between the two different methods.

Sample size selection

The number of subjects required for this study to detect a statistically-significant kappa of 0.70 ($P \leq 0.05$) at 0.10 proportion of positive ratings, a 2-tailed test null value of 0.50, and 90% power was calculated to be 509[15-16].

Sample:

Our study originally comprised of 590 patients who underwent scheduled gastrectomies (both total and partial) due to gastric cancer from four Japanese hospitals from 2005 to 2009. After employing the exclusion criteria as described below, the actual number of patients used in analysis was 584. Candidate hospitals were recruited from participating hospitals enrolled in the Quality Indicator/Improvement Project (QIP); a program administrated by the Department of Healthcare Economics and Quality Management, Kyoto University, in which participant hospitals voluntarily provide clinical and claims data for analyses. The four hospitals used in this study were designated A to D.

Exclusion Criteria

Patients were excluded from analysis if they were minors below 20 years of age, had other surgical procedures before gastrectomy was performed, or were given antibiotics within 48 hours of admission (indicating possible community-acquired infections).

HAI Identification based on Chart Review

Both electronic and paper-based records from each of the four hospitals were analyzed. Using criteria developed by the Centers for Disease Control and Prevention (CDC)[17], HAIs were identified and categorized into infections of the urinary tract, surgical site, bloodstream, bone and joint, central nervous system, cardiovascular system, eye, ear, nose, throat or mouth, gastrointestinal system, lower respiratory tract, reproductive tract, skin and soft tissue, systemic infections and pneumonia. The CDC criteria for HAI identification were compiled into a standardized data collection and evaluation form that was used by all analysts involved in this chart review. Cases with uncertainties were discussed prior to decision-making.

HAI Identification based on Antibiotic Utilization

In addition to the clinical information obtained from the chart review, we recorded the daily antibiotic utilization and ICD-10 codes for each patient. Patients were then identified as having HAIs if the reported ICD codes indicated that an infection had occurred[8]. Patients were also identified if they fell into any of the following categories: (1) Antibiotic utilization episodes beginning from the day of gastrectomy that had durations longer than the modal duration for the hospital where the case was based; (2) Three or more antibiotic types used within a single episode of antibiotic utilization; (3) Antibiotic types changed or a 2nd antibiotic type added midway during a single antibiotic utilization episode; and (4) Antibiotic utilization episodes unrelated to surgical procedures with durations greater than 4 days.

Criteria (1) to (3) were designed to provide a certain degree of flexibility with respect to variations in prophylactic antibiotic utilization patterns, while criterion (4) was designed to allow for cases where the prescribing physician ordered antibiotics for a suspected but unconfirmed infection.

Accuracy Analysis of New HAI Identification Method

The accuracy of our HAI identification method was then analyzed using sensitivity, specificity, PPV and NPV.

Furthermore, while the detailed clinical information available in patient charts would theoretically provide an infallible HAI identification method, the accuracy of identification is completely dependent on the quality of data in the patient charts. Therefore, although a chart review may represent a gold standard for HAI identification, its status as such is based on a clinical, and not a statistical, judgment. We have thus included estimates of Cohen's kappa coefficient as well as PABAK in this analysis. Kappa coefficients are conventionally used to analyze the inter-rater agreement between two unreliable raters, and as such the inclusion of these indicators provides insight into the comparative agreement between both methodologies. We calculated these based on the methods as stipulated by Cohen (1960) [13] and Byrt et al (1993) [14].

Results

Hospital and Patient Characteristics

The four hospitals used in this study included two public hospitals and two private hospitals from the Kansai region in Japan, and had a mean capacity of 620 acute care beds (range 380 ~ 902 beds). The mean age of the patients in our sample was 68.2 years at the point of admission, and ranged from 26 to 94 years. Males formed the majority of the patients, comprising 69.3% of the sample.

Infection Incidence

[Figure 1 should be placed here]

As shown in Figure 1, HAI incidence as identified by chart review under CDC-based criteria was 21.6% in total, with an inter-hospital range of 15.0% to 29.1%. The majority of these infections were surgical site infections (comprising 41.6% of the total), followed by bloodstream infections (22.0%). Urinary tract infections, gastrointestinal tract infections and pneumonia had similar incidences at approximately 11.4%~13.6% of HAIs. Other HAIs identified were skin infections, infectious hepatitis, and respiratory tract infections.

[Table I should be placed here]

Table I shows the details of HAI statuses as identified by both methods at the hospital levels and in total. Of 584 patients, 117 were identified by both methods as having had an infection, and 419 patients who had no infections during their hospitalization. It was observed that there was a tendency for more patients to be identified as infected by the administrative data method alone ("false positives") than by the chart review method alone ("false negatives"). The observed agreement between HAIs identified using our method and those identified by chart review was 91% (hospital range: 90% to 93%).

[Table II should be placed here]

An example of a case in which both methods have independently identified the presence of an infection (true positive) is provided in Table II. In this patient, our method of HAI identification showed that the antibiotic utilization patterns obtained from administrative data fulfilled two of the four infection identification criteria as outlined above. As fulfillment of a single criteria would constitute a positive infection status, this patient was flagged as infected. This evaluation proved to be correct as the patient was also positively identified as having a surgical site infection due to methicillin-resistant *Staphylococcus aureus* (MRSA), as revealed in laboratory cultures of the central venous catheter tip and drainage from the surgical site occurring within 30 days of the surgical procedure.

Sensitivity, Specificity, PPV and NPV

[Table III should be placed here]

Table III shows the sensitivity, specificity, PPV and NPV of our method of HAI identification when compared to using chart reviews for identification. The overall sensitivity and specificity of our method of HAI identification were 0.93 (95% CI: 0.87~0.96) and 0.91 (95% CI: 0.89~0.94), respectively. The overall NPV was 0.98 (95% CI: 0.96~0.99), while the overall PPV were slightly lower at 0.75 (95% CI: 0.68~0.81).

Cohen's Kappa coefficient and PABAK

The overall Cohen's kappa coefficient was calculated to be 0.78 (95% CI: 0.72~0.84; hospital range from 0.74 to 0.80). The overall bias index was low at 0.05 and prevalence index moderate at 0.51. After adjusting for prevalence and bias, PABAK was calculated to be 0.84 (95% CI: 0.78~0.90).

Discussion

In this study, we utilized chart review analysis as well as a method based on administrative data to contemporaneously identify HAIs in patients who underwent gastrectomy from four Japanese hospitals. In order to test the validity of our administrative data method, we calculated the sensitivity, specificity, PPV and NPV of the method relative to that of chart review analysis. Additionally, we analyzed the degree of non-random agreement between both methods through the use of Cohen's Kappa coefficient and PABAK.

We designed this identification method using antibiotic utilization data in response to a need for a more accurate method of identifying HAIs from administrative data[7-8]. As further proof of the inadequacy of using only hospital-reported ICD codes to identify HAIs, our current sample of hospitals reported 2 out of a possible 126 chart review-identified HAIs, or only 1.6% of the infections (authors' unpublished data).

The calculated sensitivity, specificity, PPV and NPV of our method of HAI were high, with particularly high values observed for sensitivity, specificity and NPV. The sensitivity and specificity values showed that our series of criteria using administrative data have a high probability of correctly identifying both cases and non-infected patients. The NPV was observed to be markedly higher than the PPV, at 0.98 compared to 0.75. It is possible that in addition to the presence of false positives, the relatively lower prevalence of HAI incidence may have influenced the lower PPV.

The relatively low PPV may preclude the use of our HAI identification method at the individual patient level. It should, however be noted, that the purpose of our method was not to identify infections at this level, but instead to elucidate HAI incidences and proportions in large groups of patients. As such, this method would not be likely to have any applications in prospective infection surveillance, nor would it

influence the clinical treatment of a single patient. It would instead be more useful in retrospective analyses, in which the risk-adjusted economic or clinical impact of infections or the effects of infection control measures can be evaluated. Furthermore, as greater efforts to reduce unnecessary antibiotic utilization in Japan are made, these utilization patterns would become more standardized, thereby resulting in fewer false positives and increasing the PPV of our identification method.

Prior to accounting for random agreement between the two methods, the observed agreement was high at 0.91. Using the scale of interpretation provided by Landis & Koch, the overall kappa coefficient of 0.78 implies a "substantial" agreement, and in fact close to the "almost perfect" range[18]. According to Fleiss' method of interpretation, a kappa coefficient above 0.75 may be interpreted as having "excellent agreement beyond chance"[19]. After adjusting for prevalence and bias, PABAK was found to be 0.84. According to Byrt, this PABAK score indicates "very good agreement"[20]. We had included PABAK in order to address the possible difficulties associated with the interpretation of Cohen's Kappa by itself[14, 21-25]. However, care should also be taken in the interpretation of PABAK as a realistic indicator of the situation[26], as PABAK essentially assumes no bias and a prevalence of 50%, which would be extremely rare in any disease condition. Despite this, we found that Cohen's Kappa coefficient and PABAK for our study were not drastically different, suggesting that the former was relatively robust.

While Cohen's kappa coefficient and PABAK may not be direct indicators of the accuracy of our HAI identification method, they provide an alternate perspective into the degree of non-random agreement between the two methods. Our major indicators of accuracy (sensitivity, specificity, PPV and NPV) are based on the assumption that chart reviews are a comprehensive database, and that the CDC criteria are able to identify all infections. While there is no pressing evidence to suggest otherwise, the inclusion of these coefficients shows that even in a situation where chart reviews may misidentify the infection status of some patients, the high level of non-random inter-rater agreement between both methodologies supports the relative accuracy of our method.

As our criteria were based on antibiotic utilization patterns, inappropriate utilization in non-infected patients that extends beyond the parameters in our criteria would result in a false positive. While our HAI

identification method has been designed to take into account a certain degree of inappropriate utilization, the presence of false positives again highlights the need for interventions to reduce the overuse and improve the standardization of antibiotics in Japan[12].

The applications of this validated method of HAI identification include large-scale HAI identification at the hospital level and above, as well as providing a context of multi-institutional data in which the performance of individual hospitals in HAI control and antibiotic utilization may be gauged. Additionally, this indicator may also be useful in cost-of-illness analyses where the additional costs associated with identified HAIs are calculated, and further used in downstream analyses such as cost-effectiveness studies of infection control interventions.

A possible limitation of this study concerns the interpretation of Cohen's kappa coefficient: The various methods of interpretation have no empirical foundation and are therefore arbitrary[14, 18-19]. However, as there is no universally accepted interpretation standard for kappa, the abovementioned methods of interpretation are generally used in studies that present kappa coefficients.

Conclusion

We have developed a screening method to identify HAIs in large groups of patients using administrative data with a far higher accuracy than previously available. The validation of our novel method of HAI identification based on antibiotic utilization patterns from administrative data shows that this is an accurate indicator for large-scale studies, and is ready to be used for this purpose.

Footnotes:

The authors declare no commercial or other associations that pose a conflict of interest with this research. This study was supported in part by a Health Sciences Research Grant from the Ministry of Health, Labour and Welfare of Japan, and a Grant-in-aid for Scientific Research from the Japan Society for the Promotion of Science.

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Figure Legend

Figure: Healthcare-Associated Infection incidence by hospital and in total as identified by chart review based on CDC criteria.

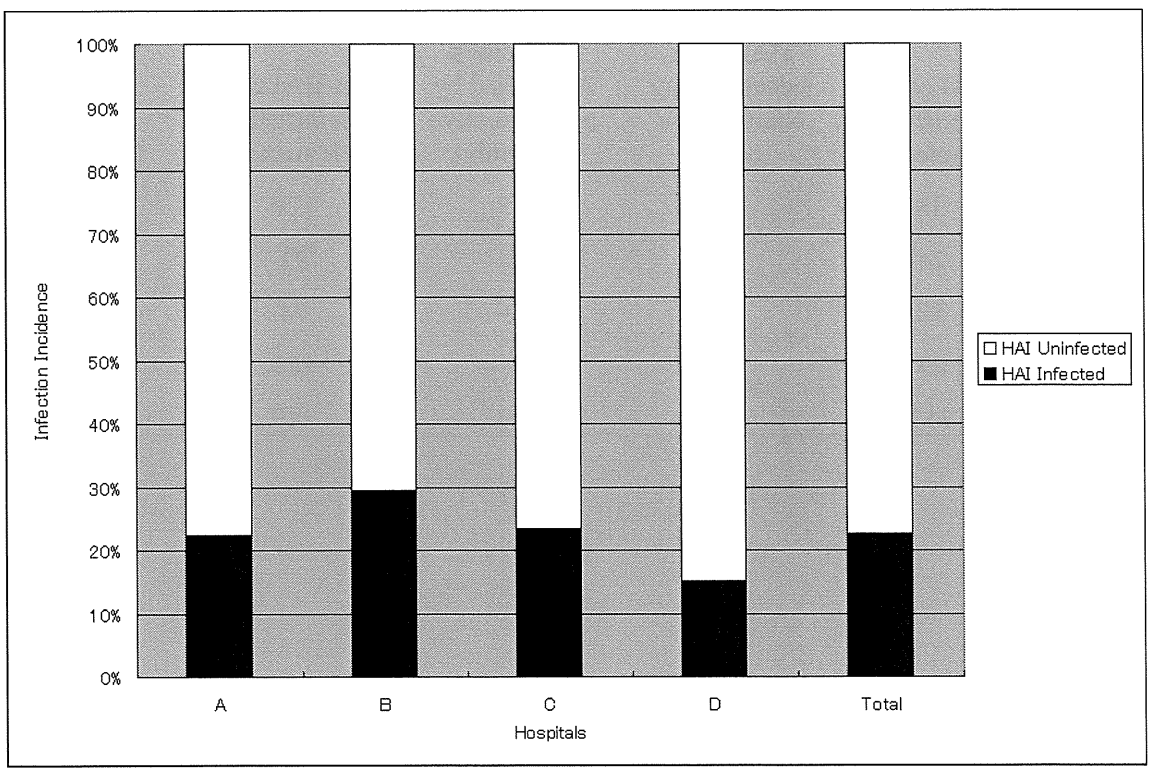

Table I
Healthcare-Associated Infection cases and non-cases as identified by chart review and administrative data

Hospitals	HAI cases (identified by both methods	HAI cases (identified by chart review only)	HAI cases (identified by administrative data only)	Non-HAI cases (identified by both methods)	Overall
A	38	3	15	127	183
B	24	3	6	91	124
C	32	2	9	74	117
D	23	1	9	127	160
Total	117	9	39	419	584

Table 2
Healthcare-Associated Infection cases and non-cases as identified by chart review and administrative data

Hospitals	HAI cases (identified by both methods	HAI cases (identified by chart review only)	HAI cases (identified by administrative data only)	Non-HAI cases (identified by both methods)	Overall
A	38	3	15	127	183
B	24	3	6	91	124
C	32	2	9	74	117
D	23	1	9	127	160
Total	117	9	39	419	584

Table III

Sensitivities, specificities, positive predictive values and negative predictive values of our method of Healthcare-Associated Infection identification by hospital and in total

Hospitals	A	B	C	D	Overall
Sensitivity	0.93 (0.81~0.98)	0.89 (0.72~0.96)	0.94 (0.81~0.99)	0.96 (0.80~0.99)	0.93 (0.87~0.96)
Specificity	0.89 (0.83~0.94)	0.94 (0.87~0.97)	0.89 (0.81~0.94)	0.93 (0.88~0.97)	0.91 (0.89~0.94)
Positive Predictive Value	0.72 (0.58~0.82)	0.8 (0.63~0.91)	0.78 (0.63~0.88)	0.72 (0.55~0.84)	0.75 (0.68~0.81)
Negative Predictive Value	0.98 (0.93~0.99)	0.97 (0.91~0.99)	0.97 (0.91~0.99)	0.99 (0.96~0.99)	0.98 (0.96~0.99)

Values are presented as [Mean (95% Confidence Interval)]

1．　演題名：臨床指標の公表・非公表に関する病院特性の検討

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3．　共著者：猪飼 宏、今中 雄一

4．　所属機関：京都大学大学院医学研究科医療経済学分野

5．　抄録

【背景】近年のDPCデータの整備によって臨床指標を多施設で横断的に算出することが可能になった。そして診療の質の改善や標準化、透明化を目的として病院団体等で多施設を対象にした臨床指標の公表事業が行われ始めている。Quality Indicator/Improvement Project（QIP）においてもDPCデータを用いた臨床指標について、2010年10月には公表の了承を得た病院の臨床指標の匿名公表を、12月には同じく了承を得た病院の臨床指標の実名公表を行った。しかし、本邦においてこうした臨床指標の公表を行う病院とそうでない病院の病院特性の違いについては明らかになっていない。

【目的】臨床指標を実名公表した病院とそうでない病院で設立主体、病床規模、症例数、指標の値を比較する。

【方法】QIP参加病院のうち臨床指標公表プロジェクトの対象となった257病院を対象とした。まず対象病院について、17指標のうち少なくとも1つの指標を実名で公表している病院を公表病院（n=111）、実名を行わなかった病院を非公表病院（146）として比較した。つづいて、公表の対象となった3分野17指標（心筋梗塞・心不全患者への対象薬剤投与割合5指標、脳梗塞患者へのリハビリ実施割合1指標、周術期の抗菌薬投与日数11指標）それぞれについて、指標を実名で公表した病院と匿名で公表した病院について対象指標の値と症例数、病床数を全体と設立主体別（公立、公的、民間）で比較した。各指標で公表の対象とならない対象症例数10ケース以下の病院については解析から除外した。

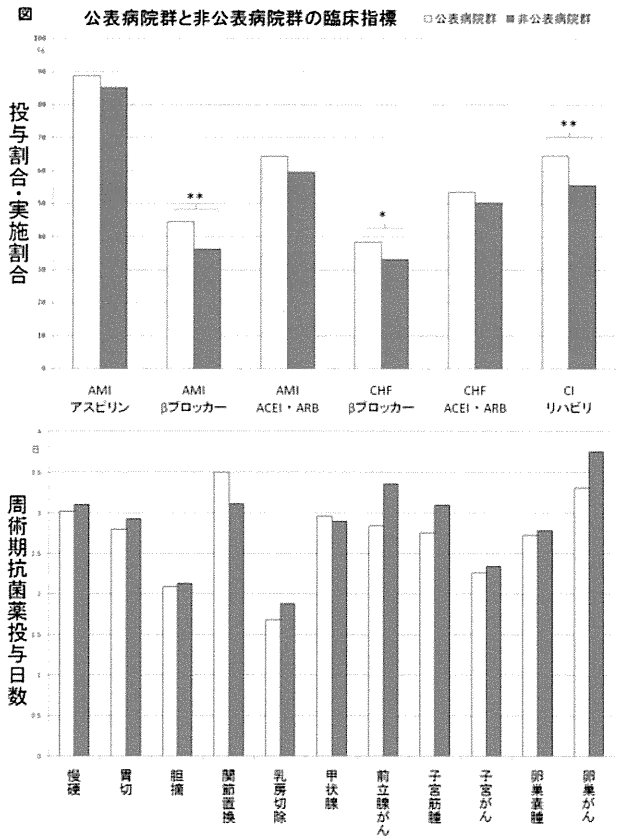
【結果】全体では公表病院の方が非公表病院よりも有意に症例数及び病床数が多かった（$p<0.05$）が、設立主体についての違いは有意ではなかった。指標毎に見ると、公表病院のうちすべての指標を公表している病院が88病院、部分的に公表している病院が23病院であった。心筋梗塞へのβブロッカー投与割合（公表病院：n＝84，非公表病院：90，$p<0.01$）、心不全患者へβブロッカー投与割合（100，136，<0.05）、脳梗塞患者へのリハビリ実施割合（102，134，<0.01）において、公表病院の指標の方が非公表病院よりも有意に指標の値が良かった。統計的に有意ではないものを含めると全17指標のうち15指標において公表病院の方が非公表病院よりも指標の値が良かったが、両者の比の四分位は1.03、1.08（中央値）、1.13となっており、全体的に大きな差はなかった。

【考察】海外では指標の値が良かった場合にその指標を公表するとしている先行研究があるが、今回の研究ではいくつかの指標で統計的な有意差が出たものの逆転している指標もあり、実質上の違いは大きくなかった。また、指標の良し悪しに関わらず臨床指標を公表することを選んだ病院や、指標を選ばず全指標を一律に公表することを選んだ病院が少なくなく、診療の質の改善や標準化、透明化などの動きに積極的に関わっていく傾向が示唆

された。

キーワード： 臨床評価指標、公表、DPC

図



臨床指標の公表・非公表に関する病院特性の検討

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背景

- 近年、診療の質の改善や標準化、透明化を目的として病院団体等で多施設を対象にした臨床指標の公表事業が行われ始めており、厚生労働省でも昨年度より医療の質の評価・公表等推進事業として政策的な後押しが行われている。

- 当分野のQuality Indicator/Improvement Project（QIP）においてもDPCデータを用いた臨床指標について、2010年12月に了承を得た病院の臨床指標の実名公表を行った。

↓

本邦においてこうした臨床指標の公表を行う病院とそうでない病院の特性の違いについては明らかになっていない。

- 臨床指標が悪い病院では指標自体に批判的であり、データの収集を始めて間もない病院では臨床指標に消極的である。

（Marshall 2000）

- 臨床指標の公表は金銭的なインセンティブではなく、名声や職務満足度に対して影響を与えている。
- 患者や医師、保険者が公表されたデータを認識しているか、また、それらをどの程度理解しているかや、病院自体のキャラクターによって影響が変わる。

（ Frølich 2007）

仮説1

臨床指標を公表している病院はそうでない病院に比べて指標の値が良い。

仮説2

病院特性によって、臨床指標の公表に対する態度が違う。

目的

臨床指標を実名公表した病院とそうでない病院で設立主体、病床規模、症例数、指標の値を比較する。

方法

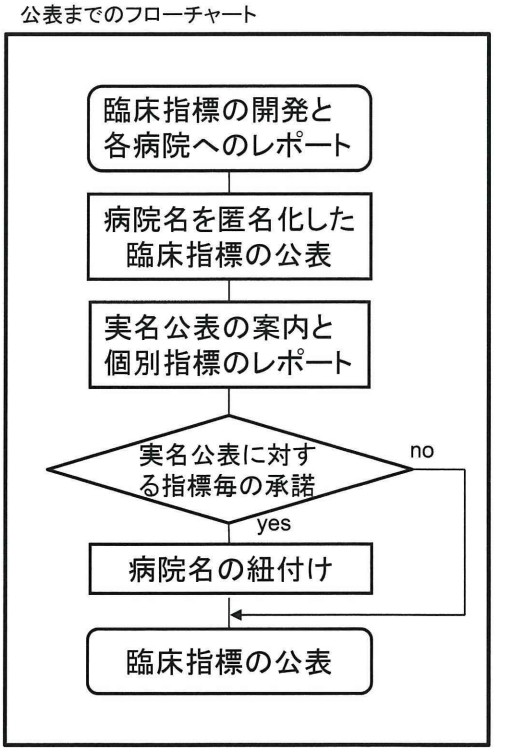
- 使用データベース：Quality Indicator/Improvement Project（以下QIP）
- デザイン：クロスセクショナル
- 対象病院：2010年度指標公開の対象となった**237**病院
- 対象臨床指標：2010年度指標公開の対象となった3分野**17**指標
- 除外条件：各病院各指標毎にケース数が10未満のもの

- 対象患者：**2009年4月−2010年3月**に退院した患者
- 公表の場所：**QIPホームページ上**
- 公表の条件
  - 指標毎に公表の対象となる値と患者データを病院側に返し、承諾を頂いた指標のみ公表。
  - 承諾がなかった指標については匿名で公表。
  - 匿名公表の拒否は該当なし。
- 対象病院

	設立主体		
病床規模	公立	公的	民間
300床未満	14	26	65
300床以上	37	59	36

病院所在地					
北海道・東北	関東	中部	近畿	中国・四国	九州
19	45	40	62	35	36

公表までのフローチャート



対象指標

- 循環器疾患患者への薬剤投与割合5指標
  - 心筋梗塞（以下AMI）：①アスピリン、②βブロッカー、③ACE阻害剤orアンギオテンシンⅡ受容体阻害剤（以下ACEI・ARB)
  - 心不全（以下CHF）：④βブロッカー、⑤ACEI・ARB

- 脳梗塞患者へのリハビリ実施割合1指標
  - ⑥入院期間内実施割合

- 周術期予防的抗菌薬投与日数11指標
  - 清潔手術：⑦慢性硬膜下血腫，⑧人工股・膝関節置換，⑨乳房切除，⑩甲状腺手術
  - 準清潔手術：⑪胃切除，⑫胆嚢摘出，⑬前立腺がん，⑭卵巣嚢腫，⑮卵巣がん,⑯ 子宮筋腫，⑰子宮がん

今回の指標はすべてプロセス指標である

ドナベディアン・モデル

- ストラクチャー：医療が行われる環境特性。
  （例）地域環境、病院設備、人員配置・・・

- プロセス：実際にどういった行為がなされたか。
  （例）手術の種類、薬剤の投与量・・・

- アウトカム：患者や地域住民の健康状態への影響。
  （例）死亡率、再入院率、平均寿命・・・

(Donabedian 1966)

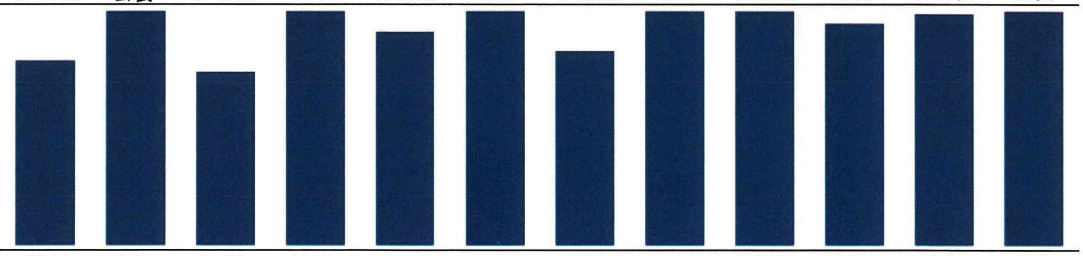
結果

全体の結果 （1／2）

病床規模	設立主体	臨床指標公表の有無 非公表病院	公表病院 部分	公表病院 全部	計	カイ2乗検定 p値
300床未満	公立	8 (57%)	1 (7%)	5 (36%)	14 (100%)	
	公的	15 (58%)	3 (12%)	8 (31%)	26 (100%)	0.93
	民間	42 (65%)	6 (9%)	17 (26%)	65 (100%)	
300床以上	公立	16 (43%)	4 (11%)	17 (46%)	37 (100%)	
	公的	30 (51%)	5 (8%)	24 (41%)	59 (100%)	0.91
	民間	15 (42%)	4 (11%)	17 (47%)	36 (100%)	
計		126 (53%)	23 (10%)	88 (37%)	237 (100%)	0.61

公表の有無に設立主体は関係あるとはいえない

全体の結果 （2／2）



指標公表の有無	病床数 非公表	病床数 公表[2]	全症例数 非公表	全症例数 公表	HHI(病床数)[1] 非公表	HHI(病床数)[1] 公表	HHI(全症例数) 非公表	HHI(全症例数) 公表	人口密度 非公表	人口密度 公表	高齢化率 非公表	高齢化率 公表
平均値	299	380	5049	6797	–	–	–	–	15919	15041	20%	21%
中央値	–	–	–	–	688	753	1533	1852	–	–	–	–
p-value[3]	＜0.01		＜0.01		0.28		0.16		0.72		0.59	

[1] ハーフィンダール・ハーシュマン・インデックス（病床数については2次医療圏内全病院の一般病床、症例数については2次医療圏内DPC病院のデータを用いた）
[2] ここでは少なくとも1つの指標について公表している病院を公表としている。
[3] HHIについてはMann-Whitney検定、その他についてはT検定

公表病院の方が有意に病院規模が大きい

指標別の結果 （1／3）

指標公開の有無別病院数

	除外[1]	指標公開の有無 公表	指標公開の有無 非公表	解析病院数
① AMI－アスピリン	83	78 (50%)	76 (49%)	154
② AMI－βブロッカー	83	79 (51%)	75 (48%)	154
③ AMI－ACEI・ARB	83	78 (50%)	76 (49%)	154
④ CHF－βブロッカー	25	98 (46%)	114 (53%)	212
⑤ CHF－ACEI・ARB	25	98 (46%)	114 (53%)	212
⑥ 脳梗塞リハビリ	39	99 (50%)	99 (50%)	198
⑦ 抗菌薬－慢硬	173	43 (67%)	21 (32%)	64
⑧ 抗菌薬－人工関節置換	121	64 (55%)	52 (44%)	116
⑨ 抗菌薬－乳房切除	90	80 (54%)	67 (45%)	147
⑩ 抗菌薬－甲状腺	175	37 (59%)	25 (40%)	62
⑪ 抗菌薬－胃切	115	67 (54%)	55 (45%)	122
⑫ 抗菌薬－胆摘	51	92 (49%)	94 (50%)	186
⑬ 抗菌薬－前立腺がん	203	20 (58%)	14 (41%)	34
⑭ 抗菌薬－子宮筋腫	152	31 (36%)	54 (63%)	85
⑮ 抗菌薬－子宮がん	114	68 (55%)	55 (44%)	123
⑯ 抗菌薬－卵巣嚢腫	121	65 (56%)	51 (43%)	116
⑰ 抗菌薬－卵巣がん	208	18 (62%)	11 (37%)	29

[1]該当症例が10ケース未満による除外