平成25年度厚生労働科学研究費補助金(地域医療基盤開発推進研究事業)
分担研究報告書
救急外来に特化した電子カルテシステムと臨床診断意思支援システムの開発による
医療安全の向上に関する研究

臨床診断意思決定支援システムの開発

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研究要旨
救急外来における電子カルテシステムに搭載する機能の一つである臨床診断意思決定支援システムを開発する。開発するに当たり、主訴から取るべき身体所見に関する文献を収集し整理した。

A.研究目的

本研究の目的は、救急医療現場における医療関係者の負担を軽減し、かつ救急医療における診療の質を担保することで医療の安全性を高める電子カルテシステムを開発することである。

この電子カルテの中に搭載する機能の一つとして臨床診断意思決定支援システム(CDSS)がある。

本研究では、多数の教科書や文献から主訴から取るべき身体所見を網羅するという作業を行った。

B. 研究方法

救急外来で使いやすい電子カルテ(EDIS)の開発には以下のことを注意し行っている。

①タイムリーに、正確なデータの収集や分析が出来る
②使用方法が容易であり、ユーザーが使用したいと思えるシステム
③明確、かつ直感的なデータの表示
④容易に目的の情報が見つけることが出来る
⑤簡単な作業は自動化し、作業負荷を増やさずに仕事の流れを良くする
⑥救急医療 業務の流れに合わせて設計されている。

また EDIS の中で医療安全の向上や, 臨床上の判断根拠の共有を図ることでより良い医療を提供するシステム(CDSS)として以下に関して多数の教科書から作成を行った。

Ⅰ. 患者の主訴からの取るべき身体所見の作成

これは、多数の和本や洋書で書かれているが、疫学データに基づくものは存在しない。

救急外来で見られる主訴に対して、救急専門医5人の意見を取り入れて作成した。

(倫理面への配慮)
情報の漏洩等については防止に努めた。

C.研究結果

66個の主訴に対して、取るべき身体所見の表を作成した。

D.考察

救急外来は同時に多数の患者を見なければならず、ともすると血液検査や画像検査を優先させてしまうことが多い。しかし身体所見や問診で必要な検査は絞られることが多い。我々は取るべき身体所見を画面に表示させることで、診療効率の改善、医療費削減を期待し作成した。

E.結論

我々が作成した主訴から取るべき身体所見の

一覧は、疫学データやEBMに基づいているものでは、なく専門医の意見による鑑別疾患表が限界である。

開発した電子カルテシステムにおいて、主訴と疾患の関係性が疫学研究から明らかとなった際、より良い身体所見の一覧が作成されるであろう。

F.研究発表

1. 論文発表

特になし

2. 学会発表

特になし

G.知的財産権の出願・登録状況（予定を含む）

1. 特許取得

特になし

2. 実用新案登録

特になし

3. その他

特になし

Ⅲ　研究成果報告

研究成果の刊行に関する一覧表

雑誌

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Ⅳ　参考資料

American Journal of Emergency Medicine xxx (2014) xxx–xxx

Contents lists available at ScienceDirect

American Journal of Emergency Medicine

journal homepage: www.elsevier.com/locate/ajem

Original Contribution

Motivations and barriers to implementing electronic health records and ED information systems in Japan☆,☆☆,★

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ARTICLE INFO

Article history:
Received 4 February 2014
Received in revised form 20 March 2014
Accepted 20 March 2014
Available online xxxx

ABSTRACT

Background: Although electronic health record systems (EHRs) and emergency department information systems (EDISs) enable safe, efficient, and high-quality care, these systems have not yet been studied well. Here, we assessed (1) the prevalence of EHRs and EDISs, (2) changes in efficiency in emergency medical practices after introducing EHR and EDIS, and (3) barriers to and expectations from the EHR-EDIS transition in EDs of medical facilities with EHRs in Japan.

Materials and methods: A survey regarding EHR (basic or comprehensive) and EDIS implementation was mailed to 466 hospitals. We examined the efficiency after EHR implementation and perceived barriers and expectations regarding the use of EDIS with existing EHRs. The survey was completed anonymously.

Results: Totally, 215 hospitals completed the survey (response rate, 46.1%), of which, 72.1% had basic EHRs, 4.2% had comprehensive EHRs, and 1.9% had EDISs. After introducing EHRs and EDISs, a reduction in the time required to access previous patient information and share patient information was noted, but no change was observed in the time required to produce medical records and the overall time for each medical care. For hospitals with EHRs, the most commonly cited barriers to EDIS implementation were inadequate funding for adoption and maintenance and potential adverse effects on workflow. The most desired function in the EHR-EDIS transition was establishing appropriate clinical guidelines for residents within their system.

Conclusion: To attract EDs to EDIS from EHR, systems focusing on decreasing the time required to produce medical records and establishing appropriate clinical guidelines for residents are required.

1. Introduction

Developed primarily for use in general inpatient and outpatient care, electronic health record systems (EHRs) have improved patient care worldwide [1-3]. However, extending EHRs to the emergency department (ED) setting has been a challenge due to differences between the requirements of general medical practice and those of an ED. Specifically, EDs must routinely treat several patients simultaneously, and many patients do not schedule their visits [4-6]. Therefore, EDs require customized emergency department information systems (EDISs) that reflect the unique procedures and treatments performed in emergency care settings [4,7].

First proposed in 1975 [8], EDISs are now defined broadly as "EHRs designed specifically to manage data and workflow in support of ED patient care and operations [9]." Cumulative evidence indicates that EDISs have improved workflow and patient care in the ED [10]. However, to the best of our knowledge, although there has been only one report on the prevalence of EDIS from the United States [11], the prevalence of EDISs in Japan is not known.

In Japan, EHR adoption started in the 1990s [12,13], but it is assumed that the prevalence of EDISs remains low [14,15]. Considering the shortage of medical staff and the increasing number of patients visiting EDs, widespread adoption of user-friendly EDISs is urgently needed to improve workflow and the quality of patient care

☆ Grant: This work was funded by a grant-in-aid for Young Scientists (C) (127100000424) to HS, MG, NY, and SN and a Health Labour Sciences Research Grant to HS, NY, and SN.

☆☆ Author contribution: RI conceived the study. RI, HS, YK, and SN designed the analysis plan. RI and HS performed the statistical analyses. RI wrote the first draft of the study. KN and YA contributed to draft of the study. RI, KN, MG, TM, YK, NY, and SN obtained the data. YA, KS, and NY critically reviewed the manuscript. All authors contributed to the design, interpretation of results, and critical revision of the article for intellectually important content.

★ Conflicts of interest statement: The authors declare that they do not have any conflicts of interest.

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http://dx.doi.org/10.1016/j.ajem.2014.03.035
0735-6757/

[13]. To facilitate hospitals' adoption of such systems (thereby supporting prompt, safe medical treatment in the ED), it is particularly important to determine why hospitals with EHRs hesitate to introduce EDISs. The aim of this multicenter survey was to identify current problems with EHR and the barriers to EDIS adoption in Japan. To this end, we conducted a questionnaire survey on (1) the prevalence of EHR and EDIS adoption, (2) the changes made after EHR introduction, and (3) the barriers to and expectations for EHR-EDIS transitions in Japanese emergency medical facilities with existing EHRs.

2. Method

2.1. Setting: emergency medical facilities in Japan

In Japan, emergency medical facilities are designated as primary, secondary, or tertiary care facilities [16], and paramedics choose the appropriate health care facilities depending on the patient's condition. Primary care facilities do not have beds, as they are designed for walk-in patients who do not require in-hospital care. Secondary care facilities provide inpatient care to both walk-in patients and those transported by ambulance; these facilities are used to examine and treat patients with moderately severe conditions. Tertiary care facilities offer intensive treatment to critically ill or injured patients in all medical specialties [17].

2.2. Sample

The questionnaire was sent to the ED directors of 466 hospitals listed as accredited training institutions by the Japanese Association for Acute Medicine in 2012 [18]. The survey was initially mailed in February 2013; all hospitals received reminder letters, and responses were accepted until the end of April 2013. The survey was completed anonymously.

2.3. Survey content

Electronic health record systems interact with clinical documentation, computerized provider-order entry (CPOE) [19], and clinical decision-support system (CDSS) [20]. The CPOE is communicated over a computer network to the medical staff or to the departments (eg, prescription, laboratory, or radiology) responsible for fulfilling the order. A CDSS is an interactive decision-support system designed to assist physicians with decisions such as patient diagnosis. Thus, we divided EHR functions into 4 categories: "clinical documentation," "test and imaging results," "CPOE," and "CDSS."

Respondents were first asked whether their hospital (1) had EHR for all departments, (2) had an EHR only for general inpatient and outpatient use but not in the ED, or (3) had no EHR for any hospital department. If they reported having an EHR in place for the ED, they were asked to specify the type of EHR according to the classification system of Jha et al [21]: "basic EHR" (demographic information, CPOE, and laboratory and imaging results) or "comprehensive EHR" (the functions listed for the basic system as well as electronic prescribing, radiographic image display, and CDSS). Detailed information regarding the classifications is presented in Table 1. Accordingly, we divided the hospitals into 4 categories: hospitals with comprehensive EHR, those with basic EHR, those with EHR for inpatient or outpatient departments but not for the ED, and those with no EHR in the hospital. Respondents with EHR were further asked to specify whether (1) their EHR had been developed exclusively for use in an ED or (2) their EHR was designed for general inpatient and outpatient care and was partially customized for use in an ED. We defined the former as EDIS because there are no standardized definitions or required functions in EDIS [22].

Second, respondents with EHR and EDIS were asked whether they thought that introducing the EHR had improved the efficiency of their emergency practices. Items in this section were rated as "improved," "no change," or "worsened."

Third, respondents with EHR were asked to identify factors that they considered to be (1) major barriers, (2) minor barriers, or (3) no barriers regarding "cost," "ED practice," "introducing an EDIS," and "data privacy." Items in this section were rated as "major barrier," "minor barrier," and "not a barrier."

Finally, respondents with and without EHR were asked to rate their expectations for EDIS as "essential," "very desirable," "desirable," or "no need." The questions and response categories used are listed in the Supplementary file A and B.

Table 1
Requirements for the 2 types of EHR systems

Requirements	Comprehensive EHR	Basic EHR
Clinical documentation		
Demographic characteristics of patients	✓	✓
Physician notes	✓	✓
Nursing assessments	✓	✓
Problem lists	✓	✓
Medication lists	✓	✓
Discharge summaries	✓	✓
Advance directives[a]	✓	
CPOE		
Laboratory tests	✓	
Radiology tests	✓	
Medications	✓	✓
Consultation requests	✓	
Nursing orders	✓	
Test and imaging results		
Laboratory reports	✓	✓
Radiology reports	✓	✓
Radiology images	✓	
Diagnostic test results	✓	✓
Diagnostic test images	✓	
Consultant reports	✓	
CDSS		
Clinical guidelines	✓	
Clinical reminders	✓	
Drug allergy alerts	✓	
Drug-drug interaction alerts	✓	
Drug-laboratory interaction alerts[b]	✓	
Drug-dose support[c]	✓	

[a] That is, do not resuscitate.
[b] For example, digoxin and low level of serum potassium.
[c] For example, renal dose guidelines.

2.4. Statistical analysis

2.4.1. Difference in hospital size between respondent and nonrespondent hospitals

First, we conducted Pearson χ^2 test to investigate differences between respondent and nonrespondent hospitals in terms of hospital size.

2.4.2. Adoption of EHRs and EDISs

We then calculated the percentage of respondent hospitals with and without EHRs. The former was further divided into the 2 types of EHRs (basic or comprehensive EHR), and the latter was divided into 2 types (EHR in the inpatient or outpatient departments but not in the ED and no EHR in the hospital). Next, we explored bivariate relationships among key hospital characteristics (hospital size, ownership, teaching status, and medical facility classification) and adoption of basic or comprehensive EHR using Pearson χ^2 or Fisher exact tests, as appropriate.

2.4.3. Impact of introduction of EHRs and EDISs

Second, we carried out Kruskal-Wallis tests to compare the effects of introducing EHR on the respondent hospital emergency practices, as measured by 7 questions.

Please cite this article as: Inokuchi R, et al, Motivations and barriers to implementing electronic health records and ED information systems in Japan, Am J Emerg Med (2014), http://dx.doi.org/10.1016/j.ajem.2014.03.035

Table 2
Characteristics of survey respondents and all survey hospitals

	Respondents, n = 215 (%)
Size	
Small (<100 beds)	5 (2.3)
Medium (100-399 beds)	48 (22.3)
Large (≥400 beds)	149 (69.3)
Unknown/no response	13 (6.0)
Ownership	
National	38 (17.7)
Municipal	49 (22.8)
Public	47 (21.9)
Private	72 (33.5)
Unknown/no response	9 (4.2)
Teaching status	
Teaching	185 (86.0)
Nonteaching	10 (4.7)
Unknown/no response	15 (7.0)
Total hospital beds (mean ± SD)	551 ± 248
Total observation beds (mean ± SD)	5.4 ± 3.1
Total ambulance admissions per year (mean ± SD)	4007 ± 2074
Medical facility classification	
Tertiary care	117 (54.4)
Secondary care	94 (43.7)
Primary care	0 (0)
Unknown/no response	4 (1.9)

2.4.4. Barriers to EHR-EDIS transition

Third, we analyzed the scores of 11 questions regarding barriers, rated as 2 ("major barrier"), 1 ("minor barrier"), or 0 ("no barrier"). We divided these questions into 4 categories and compared the difference in categories by using the Kruskal-Wallis test.

2.4.5. Expectations regarding the functionality of EDISs

Finally, we compared the characteristics of hospitals with and without EHR by using univariate comparisons of reported expectation scores, with either Student *t* test or the Wilcoxon-Mann-Whitney *U* test, as appropriate.

We compared the characteristics of respondents with all survey hospitals using STATA software, version 13 (Stata Corp, College Station, TX). For all analyses, statistical significance was set as 2-tailed $P < .05$.

3. Results

Among the 466 hospitals contacted, 215 completed the survey (46.1% response rate) (Table 2). There were no significant differences in hospital size between respondent and nonrespondent hospitals.

3.1. Adoption of EHRs and EDISs

Among the 215 respondent hospitals, ~~155 (72.1%)~~ had EHRs in their EDs. Only 9 hospitals (4.2%) had comprehensive EHRs, but ~~160 (74.4%)~~ had basic EHRs in their EDs (Table 3). Teaching hospitals were more likely to use EHRs. We found no relationship between hospital size, ownership status, or medical facility classification and level of adoption of EHRs. With regard to EDISs, 4 hospitals (1.9%) had EDISs; all were large teaching hospitals with basic EHRs.

3.2. Adoption of CPOE and CDSS functionality

As shown in Table 4, all EHRs (>95%) included all the expected functions in the categories of "clinical documentation," "CPOE," and "test and imaging results;" a smaller percentage of hospitals reported that they already had "advanced directives" (73%) and "nursing orders" (88%) functions. The lowest scores belonged to the CDSS category. Most hospitals had alerts for "drug-allergies" (77%), "drug-drug interactions" (60%), and "drug-dose support" (59%); however, a minority of hospitals had functionality related to "drug-laboratory interactions" (28%), "clinical guidelines" (18%), or "clinical reminders" (11%).

3.3. Impact of introduction of EHRs and EDISs

Respondents were asked to describe how EHR or EDIS implementation had affected patient care (improved, no change, or worsened). As presented in Table 5, the survey shows that the directors felt that EHRs and EDISs improved information sharing (95.1% ± 1.7%; mean ± SD), providing explanations (82.7% ± 3.0%), access to previous patient information (81.6% ± 3.4%), and medical safety (73.4% ± 3.7%), but that time spent on medical records (36.9% ± 3.9%) and overall medical care (31.4% ± 3.7%) were worsening.

Table 3
Use of comprehensive and basic EHR according to hospital characteristics

	Total respondents (n = 215)				
	EHR in ED (n = ~~171~~)		No EHR in ED (n = 40)		*P*
	Comprehensive EHR (n = 9)	Basic EHR (n = ~~155~~)	EHR for inpatient/outpatient departments (n = 12)	No EHR within hospital (n = 28)	
	% ~~Of~~ hospitals				
Size					.507
Small (<100 beds)	0	50.0 ± 28.9	0	50.0 ± 28.9	
Medium (100-399 beds)	4.5 ± 3.2	75.0 ± 6.6	4.5 ± 3.2	15.9 ± 5.6	
Large (≥400 beds)	4.9 ± 1.8	76.3 ± 3.6	6.9 ± 2.1	11.8 ± 2.7	
Ownership					.541
National	3.1 ± 3.1	68.8 ± 8.3	12.5 ± 5.9	15.6 ± 6.5	
Municipal	2.1 ± 2.1	80.9 ± 5.8	6.4 ± 3.6	10.6 ± 4.5	
Public	4.2 ± 2.9	85.4 ± 5.1	2.1 ± 2.1	8.3 ± 4.0	
Private	4.4 ± 2.5	70.6 ± 5.6	5.9 ± 2.9	19.1 ± 4.8	
Teaching status					<.001
Teaching	5.0 ± 1.6	77.7 ± 3.1	5.6 ± 1.7	11.7 ± 2.4	
Nonteaching	0	30.0 ± 15.3	0	70.0 ± 15.2	
Medical facility classification					.581
Tertiary care	4.5 ± 2.0	72.3 ± 42.4	6.3 ± 2.3	17.0 ± 3.6	
Secondary care	4.5 ± 2.2	79.5 ± 4.3	5.7 ± 2.5	10.2 ± 3.2	

Please cite this article as: Inokuchi R, et al, Motivations and barriers to implementing electronic health records and ED information systems in Japan, Am J Emerg Med (2014), http://dx.doi.org/10.1016/j.ajem.2014.03.035

Table 4
Functionality of EHR system in the ED

	Fully implemented in ED	Implementation within 1 y	Implementation under consideration	No implementation, with no specific plans for ED
	% of hospitals			
Clinical documentation				
Patient information[a]	97.7			
Physician notes	97.1			0.6
Nursing assessments	96.6	0.6		0.6
Problem lists	97.1			0.6
Medication lists	97.7			
Summary	97.7			
Advance directives[b]	73.1	0.6	1.1	21.7
CPOE				
Blood test order	97.7			
X-ray order	97.7			
CT, MRI order	97.7			0.0
ECG order	96.0		0.6	0.6
Echocardigram order	97.7			
Prescribed medication	97.7			
Consultation requests	95.4		0.6	1.1
Nursing orders[c]	88.0		1.7	6.9
Test and imaging results				
Laboratory reports	97.7			
X-ray images	97.1			
CT, MRI images	97.1			
ECG images	93.1	0.6	1.1	2.9
Echocardigram images	94.3	0.6	1.1	1.1
Radiology reports	97.1			
Echocardigram reports[d]	94.9	0.6	1.1	0.6
Consultant reports	95.4			1.7
CDSS				
Clinical guidelines[e]	17.7	1.1	8.0	66.3
Clinical reminders[f]	11.4	1.1	8.0	68.6
Drug-allergy alerts	76.6		7.4	12.0
Drug-drug interaction alerts	60.0	0.6	6.9	25.7
Drug-laboratory interaction alerts[g]	28.0		8.0	56.6
Drug-dose support[h]	59.4		5.1	30.3

Abbreviations: *CT*, computed tomography; *MRI*, magnetic resonance imaging; *ECG*, electrocardiogram.

[a] Age, sex, address, etc.
[b] Do not resuscitate.
[c] For example, call order.
[d] For example, echocardiogram.
[e] For example, β blockers after myocardial infarction.
[f] For example, pneumococcal vaccine.
[g] For example, digoxin and low level of serum potassium.
[h] For example, renal dose guidance.

3.4. Barriers to EHR-EDIS transition

Among hospitals with EHRs, the most commonly cited barriers to transitioning to EDIS from EHR were inadequate capital for purchasing the system, concerns about maintenance costs, and future support from the providers (Table 6). Among ED practices, the most cited barrier to implementation was potential adverse effects on workflow ($P < .0001$).

Table 5
Impact of introduction of EHR system

	EHR in ED (n = 171)				EDIS in ED (n = 4)			
	Improved	No change	Worsened	*P*	Improved	No change	Worsened	*P*
	% of hospitals				% of hospitals			
Effects on medical care in ED				<.001				.0045
Clinical documentation								
Shortened time for clinical documentation	36.9 ± 3.9	29.2 ± 3.6	33.8 ± 3.8		0	66.7 ± 33.3	33.3 ± 33.3	
CPOE								
Shortened time for imaging and laboratory orders	57.2 ± 3.9	28.9 ± 3.6	13.8 ± 2.7		66.7 ± 33.3	33.3 ± 33.3	0	
CDSS								
Improved medical safety	73.4 ± 3.7	25.9 ± 3.6	0.7 ± 0.7		100	0	0	
Others								
Shortened time for overall medical care	31.4 ± 3.7	48.1 ± 4.0	20.5 ± 3.2		0	66.7 ± 33.3	33.3 ± 33.3	
Improved access to previous patient information	81.6 ± 3.4	7.3 ± 2.1	11.0 ± 2.5		100	0	0	
Improved providing explanations to patients	82.7 ± 3.0	16.0 ± 2.9	1.2 ± 0.9		100	0	0	
Improved sharing patient information with staff	95.1 ± 1.7	3.7 ± 1.5	1.2 ± 0.9		100	0	0	

Please cite this article as: Inokuchi R, et al, Motivations and barriers to implementing electronic health records and ED information systems in Japan, Am J Emerg Med (2014), http://dx.doi.org/10.1016/j.ajem.2014.03.035

Table 6
Perceived barriers regarding the adoption of EDIS for hospitals with and without EHR

	EHR in ED	P
	Score (mean ± SD)	
Barriers[a]		
Cost		.145
The amount of capital needed to purchase and implement an EDIS	1.8 ± 0.4	
Concerns about the ongoing cost of maintaining an EDIS	1.7 ± 0.5	
Concerns about a lack of future support from vendors in upgrading	1.7 ± 0.5	
ED practice		<.0001
Resistance to implementation from ED physicians	0.6 ± 0.7	
Resistance to implementation from other staff (eg, RNs, NPs, PAs)	0.8 ± 0.7	
Concerns about adverse effects on workflow	1.1 ± 0.7	
Introducing EDIS		.589
Lack of interoperable IT systems on the market	1.3 ± 0.7	
Lack of adequate IT staff when trouble occurs	1.6 ± 0.6	
Finding an EHR that meets hospital needs	1.2 ± 0.7	
Data privacy		.956
Concerns about inappropriate disclosure of patient information	1.2 ± 0.8	
Concerns about illegal record tampering or "hacking"	1.2 ± 0.8	

Abbreviations: *RNs*, registered nurses; *NPs*, nurse practitioners; *PAs*, physician assistants; *IT*, information technology.
[a] In hospitals with EHR, we asked the extent to which these items were a barrier in adopting EDIS. Possible multiple-choice responses to each item were 2, "major barrier; 1, "minor barrier;" and 0, "not a barrier."

3.5. Expectations regarding EDIS functionality

As shown in Table 7, hospitals without EHRs in the ED had significantly higher expectations than those with EHR for a system developed exclusively for use in the ED setting ($P = .0018$). In addition, hospitals with EHR in their EDs had higher expectations for showing appropriate clinical guidelines for residents ($P = .033$).

4. Discussion

To the best of our knowledge, this is the first comprehensive national survey of EHRs and EDISs in Japanese hospitals to explore barriers to and expectations for EDISs implementation in hospitals with existing EHRs. First, the current survey identified that only 9 hospitals (4.2%) had comprehensive EHR, and only 4 hospitals (1.9%) had EDIS. Second, ED directors reported that the introduction of EHR did not change the time required to create medical records and did not reduce overall clinic hours. Finally, the survey also revealed that the most common barriers against transitioning to EDIS from EHR were cost and potential adverse effects on workflow. However, ED physicians expect that EHR-EDIS transition will provide clinical guidelines for resident physicians.

4.1. Adoption of EHRs and EDISs in Japan

Although most hospitals surveyed had EHR, very few had comprehensive EHR. Our analysis also revealed that most hospitals in Japan with a fully implemented EHR in the ED do not have efficient CDSS. This low prevalence may be the result of a previous ban on selling separate CDSS software and that CDSS functionality such as flagging drug-laboratory interactions, providing clinical guidelines, and clinical reminders were seldom present. Although most nonparticipating hospitals have no plans to adopt these features in the near future, the Ministry of Health, Labour and Welfare lifted the ban on the sale of separate CDSS software in February 2013; this may boost the development of CDSS software and increase its use. In contrast, the advantages of CPOE were well understood early on in Japan, spurring the adoption of this function [23]. Today, CPOE has a higher rate of adoption in Japan [24]. Consequently, comprehensive EHR should increase in Japan.

4.2. Impact of introducing EHRs

According to the present survey, hospitals recognized that although CPOE shortened time for imaging and laboratory orders and CDSS improved medical safety in emergency care, it did not lead to a noticeable change in the time required to create medical records or overall clinic hours after the introduction of EHR. A previous study showed that physicians did not expect that EHR would decrease documentation time in ED settings [25], but emergency physicians would expect this function [26]. Our study showed that hospitals without EHR in the ED had significantly higher expectations for a system developed exclusively for use in ED than hospitals with EHR, suggesting that they have more expectations for this function. Thus, emergency physicians and providers should match the expectation by specifically focusing on systems that decrease the time required to create medical records.

4.3. Barriers to the EHR-EDIS transition

The survey identified that, among hospitals with EHR, the most commonly cited barriers to introducing an EDIS system were

Table 7
Expectations regarding the adoption of EDIS for hospitals with and without EHR

Expected functions[a]	EHR	No EHR	P
	Score (mean ± SD)	Score (mean ± SD)	
Allows for cooperation with other facilities	2.3 ± 0.9	2.2 ± 0.9	.55
EHR was developed exclusively for EDs	1.5 ± 1.1	2.1 ± 1.0	.0018
Provides explanation sheets to patients (eg, exercise caution after head trauma)	2.0 ± 0.9	2.0 ± 0.9	.95
Clinical decision support system (eg, drug-overdose alerts)	2.3 ± 0.8	2.4 ± 0.8	.65
Provides clinical guidelines for resident physicians	2.2 ± 0.9	1.9 ± 0.9	.033

[a] Hospitals were asked to identify desired functions in EDIS. Possible multiple-choice responses to each item were 3, "essential;" 2, "very desirable;" 1, "desirable;" and 0, "not needed."

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inadequate funding for the initial purchase and maintenance costs. Importantly, we also found that they believed that the transition of EHR to EDIS would have a negative effect on workflow. These negative findings may indicate a failure to attend to workflow changes created by the system, which may have severe consequences in an ED [27]. For example, Han et al [28] reported an increase in mortality after the introduction of EHR, and an Australian study found a significant increase in patient waiting times, treatment time, and total time to discharge patients after the implementation of an EDIS created in the United States [29]. Thus, it is important to develop EDISs to match each ED, including country.

4.4. Expectations regarding the functions of EDISs

Hospitals without EHR in the ED had significantly higher expectations for a system developed exclusively for use in the ED setting. This is important to note because it suggests that these hospitals would not implement their present EHRs in their EDs. In addition, hospitals with EHRs in their EDs have higher expectations for showing appropriate clinical guidelines for residents to make better use of their systems. Thus, for an EDIS to be successfully adopted in a hospital without EHR, its integration into routine clinical workflow within the ED must require no extra work on the part of clinicians [30,31]; providing appropriate clinical guidelines for residents would strongly stimulate EDIS adoption by hospitals with EHRs.

5. Limitations

The present study has several limitations. First, we achieved only a 46.1% response rate, and the hospitals that did not respond to our survey were somewhat different from those that did respond. We found no significant hospital size difference between the hospitals that did and did not respond to our survey. However, because this survey was completed anonymously, it was difficult for us to follow the nonrespondents. According to the supplemental small-scale phone interviews after the survey, we have an impression that nonresponder hospitals tended not to have EHR systems, compared with those responding; therefore, we cannot deny the presence of some selection bias. Namely, the true prevalence of EHRs and EDISs might be lower than our results. Second, we did not ascertain whether EHR users were satisfied with them. Finally, few hospitals in our sample had EDISs in place that had been developed exclusively for ED use. There may not be enough information on the characteristics that predict EDIS adoption. We recommend that this portion of the study be repeated again with hospitals having EDIS in place, to gain a better understanding of the ED characteristics associated with EDIS adoption.

6. Conclusion

We found that very few hospitals have comprehensive EHR systems or EDIS in Japan. As EHR-EDIS transitions become faster, providers and emergency physicians together should focus on developments that decrease cost, shorten the time to create medical records, and incorporate clinical guidelines.

Acknowledgments

We thank the physicians who participated in the survey and Ms Takako Sakamaki, who assisted with data collection. Finally, we thank the Japanese Association of Healthcare Information Systems for providing data.

Appendix. Supplementary data

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.ajem.2014.03.035.

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Supplemental file A

Supplemental file B

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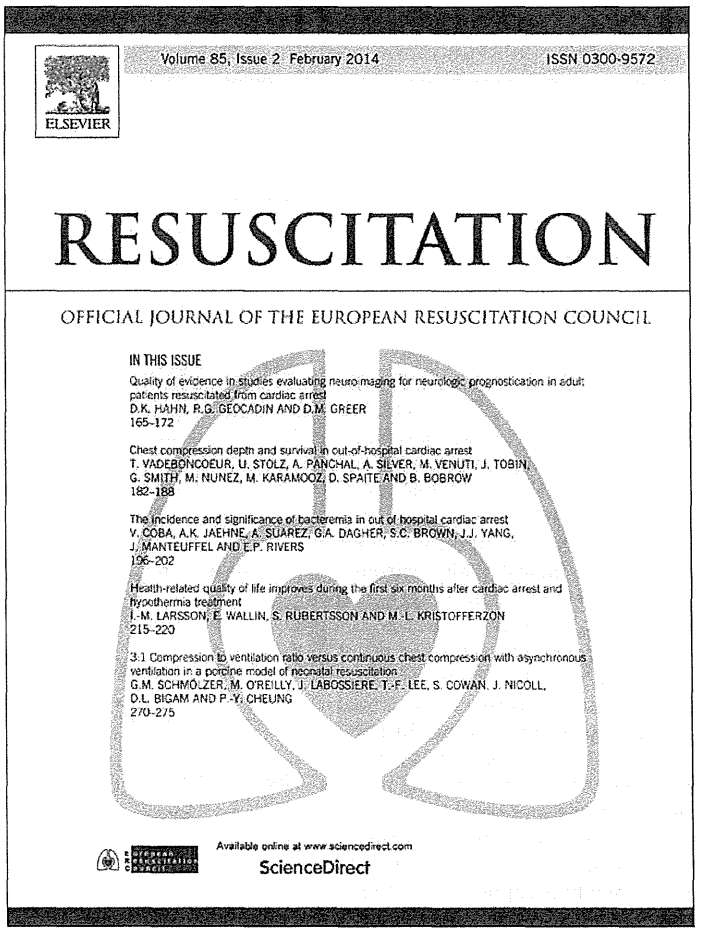

Resuscitation 85 (2014) e27

Contents lists available at ScienceDirect

Resuscitation

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Letter to the Editor

Current policies on informed consent in Japan constitute a formidable barrier to emergency research

Sir,

Emergency medicine research is mired in an ethical dilemma: Do researchers discontinue valuable research when unable to obtain informed consent or include patients in clinical trials without their informed consent?[1] During emergency treatments (e.g., resuscitative care), patients are unable to sign informed consent forms when admitted. The United States has had guidelines since 1996 concerning the steps researchers can take when prior informed consent cannot be obtained in clinical trials.[2] Furthermore, the European Commission introduced rules regarding clinical research for European countries in 2001, although consensus was not reached then on how researchers should act when prior informed consent cannot be obtained[3]; in 2010, however, new regulations were established, and it was hoped that these would stimulate clinical research in emergency medicine across Europe.[4]

In Japan, no reported emergency clinical studies with interventions have been conducted without first obtaining informed consent. This may be because ethical guidelines regarding clinical studies in Japan differ from those in Europe and the United States, where clinical studies are reviewed by institutional review boards (IRBs) in accordance with internationally accepted good clinical practice (GCP) guidelines. In Japan, clinical studies can be broadly classified into "clinical trials" and "clinical studies."

Clinical trials are conducted to gain regulatory approval to manufacture and sell new medicines, or to expand indications and additional or altered dosages or amounts of established medicines. Clinical trials are reviewed by the Ministry of Health, Labour and Welfare (MHLW), and are conducted in accordance with GCP guidelines.

Conversely, clinical studies involve prospective research and interventions, and are conducted to improve diagnoses and treatments by using confirmed diagnostic techniques or medicines. Additionally, clinical studies are conducted in accordance with governmental ethical guidelines and do not follow GCP guidelines, thus differing from clinical trials. Clinical studies can further be classified into two types: with and without interventions. Confusion has arisen in researchers because of the subtle differences in the ethical guidelines between study types. In addition, despite having ethics committees in relevant institutions, there is still a lack of legal regulation and government monitoring of clinical studies. Thus, in the future, it is anticipated that all clinical studies in Japan will be subject to the GCP guidelines and be reviewed by IRBs, just as in Europe and the United States.

Nevertheless, it is currently impossible in Japan to conduct clinical trials and clinical studies with interventions in emergency medicine when informed consent cannot be obtained; researchers may only proceed with trials by obtaining consent from a legal representative of the patient. The Japanese Association for Acute Medicine proposed revision of these ethical guidelines to the MHLW on 12 December 2012; discussions regarding these revisions are currently underway.

If these guidelines are revised, it would be particularly important to gain the trust of the general public so that clinical studies in emergency medicine can be conducted even when informed consent cannot be obtained.[5] Accordingly, it would be necessary to conduct information sessions and awareness campaigns for the general public regarding their participation in clinical studies.

Conflict of interest statement

The authors declare no conflicts of interest.

Funding

This work was supported by a Grant-in-Aid for Young Scientists (C) (127100000424), and a Health Labour Sciences Research Grant to SN, NY, and HS.

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5 September 2013

http://dx.doi.org/10.1016/j.resuscitation.2013.09.026

BMJ open

The proportion of clinically relevant alarms decreases as patient clinical severity decreases in intensive care units: a pilot study

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To cite: Inokuchi R, Sato H, Nanjo Y, *et al*. The proportion of clinically relevant alarms decreases as patient clinical severity decreases in intensive care units: a pilot study. *BMJ Open* 2013;**3**: e003354. doi:10.1136/bmjopen-2013-003354

► Prepublication history for this paper is available online. To view these files please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2013-003354).

Received 7 June 2013
Revised 24 July 2013
Accepted 30 July 2013

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ABSTRACT

Objectives: To determine (1) the proportion and number of clinically relevant alarms based on the type of monitoring device; (2) whether patient clinical severity, based on the sequential organ failure assessment (SOFA) score, affects the proportion of clinically relevant alarms and to suggest; (3) methods for reducing clinically irrelevant alarms in an intensive care unit (ICU).

Design: A prospective, observational clinical study.

Setting: A medical ICU at the University of Tokyo Hospital in Tokyo, Japan.

Participants: All patients who were admitted directly to the ICU, aged ≥18 years, and not refused active treatment were registered between January and February 2012.

Methods: The alarms, alarm settings, alarm messages, waveforms and video recordings were acquired in real time and saved continuously. All alarms were annotated with respect to technical and clinical validity.

Results: 18 ICU patients were monitored. During 2697 patient-monitored hours, 11 591 alarms were annotated. Only 740 (6.4%) alarms were considered to be clinically relevant. The monitoring devices that triggered alarms the most often were the direct measurement of arterial pressure (33.5%), oxygen saturation (24.2%), and electrocardiogram (22.9%). The numbers of relevant alarms were 12.4% (direct measurement of arterial pressure), 2.4% (oxygen saturation) and 5.3% (electrocardiogram). Positive correlations were established between patient clinical severities and the proportion of relevant alarms. The total number of irrelevant alarms could be reduced by 21.4% by evaluating their technical relevance.

Conclusions: We demonstrated that (1) the types of devices that alarm the most frequently were direct measurements of arterial pressure, oxygen saturation and ECG, and most of those alarms were not clinically relevant; (2) the proportion of clinically relevant alarms decreased as the patients' status improved and (3) the irrelevance alarms can be considerably reduced by evaluating their technical relevance.

ARTICLE SUMMARY

Strengths and limitations of this study

- We evaluated the technical and clinical relevance of each alarm by using 24 h video monitoring. This technique reduced bias introduced by bedside evaluations.
- This study was limited by the small sample size (18 patients, total).

BACKGROUND

In an intensive care unit (ICU) setting, a large number of medical devices are attached to patients, generating numerous alarm signals every day. Several studies have demonstrated that most of these alarms are not clinically relevant[1–3] and tend to lower the attentiveness of the medical staff and, in turn, lower patient safety.[4 5] In addition, alarm sounds are associated not only with patient delirium,[6–10] which increases mortality,[11] but also with medical staff memory and judgement disturbances, decreased sensitivity and exhaustion.[6 7] Many attempts have been made to reduce the number of clinically meaningless alarms by using statistical methods and artificial intelligence systems.[5 12] Some examples include extending the time between the incident and the sounding of the alarm, shutting off alarms prior to performing procedures on patients, and calibrating machines to detect gradual changes in the patient condition. However, alarm devices having high sensitivity and specificity have not been developed because discrepancies remain between the priorities of equipment manufacturers, who are seeking devices with high sensitivity, and those of medical professionals, who desire machines with high specificity.

Previous studies have demonstrated that of the three types of alarms—threshold alarms, arrhythmia alarms and technical alarms—clinical relevance is the lowest for threshold alarms.[13] However, the impact of patient clinical severity on the proportion of clinically relevant alarms remains unknown. Our objectives were (1) to determine if the number and proportion of clinically relevant alarms differ based on the type of monitoring device; (2) to determine whether patient clinical severity, based on the sequential organ failure assessment (SOFA) score, affects the proportion of clinically relevant alarms and (3) to suggest methods for reducing clinically irrelevant alarms. To answer these questions, we used video monitors to collect 24 h continuous data from ICU patients.

MATERIALS AND METHODS

Study setting and patient population

This study was conducted in a 6-bed, mixed ICU at the University of Tokyo Hospital, where patients are mainly admitted following ambulance transport. The study ICU is organised in an 'I' shape, with two individual patient rooms on the west side and two double patient rooms on the east side, with a central monitoring station. The doors to the patient rooms are left open unless procedures are being performed or privacy is required. The unit is staffed with one nurse for every two patients. Most patients monitored during the study had sepsis, respiratory failure, acute respiratory distress syndrome, multisystem organ failure, renal failure, heart failure or trauma.

The following inclusion criteria were used to enrol patients in the study: (1) admitted directly to the University of Tokyo Hospital mixed ICU, not stepped-down from other ICUs and (2) age ≥18 years. Patients were excluded if they were (1) already admitted to this ICU or (2) the patient refused active treatment. This study was approved by the Ethics Committee of the University of Tokyo Hospital, and all patients or their family provided signed informed consent before the beginning of the recordings.

Data collection

General patient information, such as age, gender and disease, was recorded. All patients were continuously videotaped using a network of cameras (JVC-Kenwood, V.NET@Web, Tokyo, Japan), attached to the ceiling above each bed, to record patient and/or system manipulations. Each patient was monitored for heart rate, invasive or closely monitored non-invasive arterial blood pressure, respiratory rate, oxygen saturation (SpO_2), end-tidal carbon dioxide ($ETCO_2$) and temperature. In addition, any changes in the equipment used for each patient were recorded throughout the study period. In addition, the acute physiology and chronic health evaluation (APACHE II) score[14] was calculated for each patient within 24 h of admission, and the SOFA score[15] was calculated every 8 h. Patient data were pseudonymised and the electronic files and videos were stored in locked, encrypted hard drives.

Alarm systems and settings

During the study period, all patients were monitored with a standard cardiovascular monitoring system (BSM-9101 & CNS-9701, Nihon Koden, Tokyo, Japan). The numerical measurements, waveforms, alarms, alarm settings and alarm messages were acquired in real time and saved continuously (CNS-9600 & CAP-2100, Nihon Koden). The alarm information consisted of the parameter causing the alarm and the alarm message (table 1). The alarm messages were divided into three types: threshold alarms, arrhythmia alarms and technical alarms. The technical alarms indicated technical problems, such as a disconnected probe.

The initial alarm limits and every modification of these during the observation period were registered with corresponding time stamps and automatically recorded (CNS-9600 & CAP-2100, Nihon Koden). Chambrin *et al*[1] determined the initial limits for heart rate and systolic arterial pressure by using the rule, 'initial value observed during a stable period ±30%'. This rule was used in this study as well. When the prehospital patient heart rates and arterial pressures were not obtained, the initial limits were 156/56 mm Hg (120/80±30%) for systolic arterial pressure/diastolic pressure and 78 and 43 bpm (60±30%) for upper and lower heart rate limits, respectively. In addition, the SpO_2 limit was 93%, except for patients with chronic obstructive pulmonary disease or acute respiratory distress syndrome, where the limit was 90%; a temperature limit of 38.3°C was also used. After these initial settings, the alarm limits could be modified; any changes were automatically recorded.

Technical annotations

After completion of the data collection for a particular patient, two nurses and two intensivists, with at least 6 years' experience in intensive care medicine, annotated the data. The two nurses first analysed the technical validity of the alarms, and divided the alarms into three categories, *technically true*, *technically false* and *indeterminable*. They referred to the multimonitoring wave shapes or pulse rate when the monitor described alarm messages, rather than using the video record. Alarms were classified as *technically false*, unnecessary alarms if the monitor referred to other waveforms or pulse rates at the same time.

The classifications were defined, in detail, according to the following criteria. For ECG, SpO_2, direct measurements of arterial pressure and $ETCO_2$, if the waveform was obviously an artefact produced by movements or procedures, the alarm was determined to be *technically false*. For waveforms in which the origin of the artefact(s) or arrhythmia(s) was uncertain, other waveforms or pulse rates (eg, a direct measurement of arterial pressure (ART) or SpO_2) at the time of alarm generation were also referenced. Alarms that did not meet any of