Development of information systems and clinical decision support systems for emergency departments: a long road ahead for Japan

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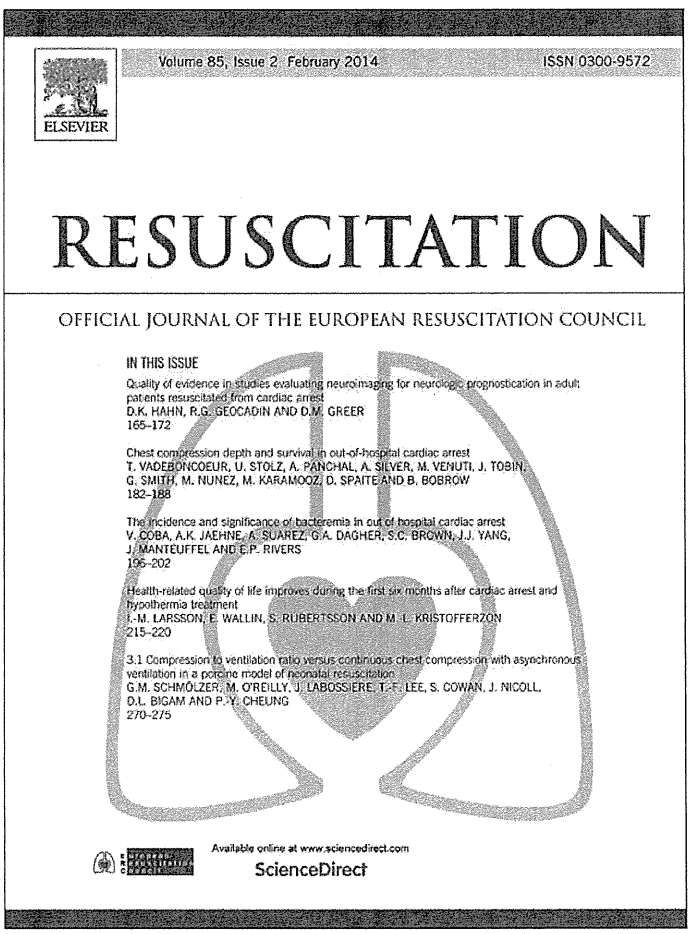
Emerg Med J published online January 8, 2013
doi: 10.1136/emermed-2012-201869



Resuscitation 85 (2014) e27

Contents lists available at ScienceDirect

Resuscitation

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

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

0300-9572/$ – see front matter
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

Table 1 The alarm information consisted of the parameter causing the alarm and the alarm message

Devices	Threshold alarm	Arrythmia alarm	Technical alarm
ECG	Bradycardia Tachycardia	Asystole ST(II) change Ventricular fibrillation Ventricular tachycardia Ventricular premature contraction run	Check electrodes cannot analyse
Oxygen saturation (SpO_2)	SpO_2		Not connected Check probe Check probe site Cannot detect pulse
Direct measurement of arterial pressure (ART)	ART (systolic) ART (diastolic) ART (mean)		Not connected Check sensor Check label
Non-invasive blood pressure (NIBP)	NIBP (systolic) NIBP (diastolic) NIBP (mean)		Cuff occlusion Not connected Module failure Mead time-out Cannot detect pulse
Capnometer	$ETCO_2$ CO_2 (APNEA)		Not connected Check sensor
Thermometer	Tblad T2		Not connected Check sensor
Central venous pressure monitor			Check sensor
Ventilator	VENT		Check sensor
Other			System failure

$ETCO_2$, end-tidal carbon dioxide; Tblad, bladder temperature.

the above criteria were considered *technically true*. All technical evaluations that could not be determined from the relevant monitor's waveform recording were defined as *indeterminable*. For temperature alarms, all upper and lower limits of the temperature alarms were defined as *technically true*. Finally, for non-invasive blood pressure (NIBP) determinations, if an apparently abnormal value was obtained for the NIBP measurement, the patient's movements and concurrent procedures were also considered. Other values, for example, ART or SpO_2 were also referenced as they may have triggered the upper and lower limit alarms. In such instances, these alarms were considered *technically false*.

Clinical annotations

After the technical analyses, the two physicians divided the alarms into three types. These types were relevant alarms, helpful alarms that were not relevant and irrelevant alarms; these were classified by referring to the video and medical records. In this study, an alarm was defined as relevant when an immediate clinical examination plus diagnostic or therapeutic decision (eg, ECG, echocardiography or drug administration) were necessary. When the situation required clinical examination but did not require a diagnostic or therapeutic decision, it was classified as a helpful alarm but not relevant. Intensivists determining the clinical relevance could see the result of technical validity.

Statistical analyses

All included patient characteristics were described using means and SDs for continuous variables, along with medians and ranges. After obtaining the descriptive statistics regarding the alarm counts and their proportions, the bivariate relationship of the alarms (the total number of alarms and the proportions of relevant alarms) to patient (SOFA) scores was examined by fitting cross-sectional, time-series models for panel data. Alarms from different monitoring devices were examined separately and together. In a preliminary analysis, the numbers and proportions of alarm types were regressed against SOFA scores by fitting either fixed-effects or random-effects models, using the Hausman test. The Hausman test indicated that the random-effects estimates were consistently more appropriate than the fixed-effects estimates.[16] Therefore, the results obtained by the random-effects model were adopted. The interpretation of the statistical significance of relationships was made following multiple comparisons using the Bonferroni method.[17] The NIBP data were not suited for univariate analysis because the amount of data and statistical power were inadequate.

Table 2 Study population baseline characteristics

Subject description (n=18)	Mean±SD	
Age	69.2±14.0	
Male/female	10/8 (55.6%/44.4%)	
	ICU admission	ICU discharge
APACHE score	18.5±8.3	
SOFA score	6.2±3.8	4.1±3.2
The equipment rate of monitoring devices		
Direct measurement of arterial pressure (%)	77.8	33.3
Electrocardiogram (%)	100	100
Oxygen saturation (%)	100	100
End-tidal CO_2 ($ETCO_2$) (%)	61.1	44.4
Bladder temperature (%)	100	94.4
Indirect blood pressure measurement (%)	100	100

APACHE, acute physiology and chronic health evaluation; SOFA, sequential organ failure assessment.

The intraobserver and interobserver variabilities between the two physicians performing the clinical annotations of alarms, and the two nurses performing the technical annotations of the alarms were judged by a κ test.[18] To evaluate the intraobserver variability, 300 alarm situations were reannotated by the same observer after a period of approximately 6 months. Statistical analyses were conducted using STATA Special Edition V.12.1 (StataCorp, College Station, Texas, USA).

RESULTS

Patient characteristics

Between January and February 2012, a total of 15 229 alarms were recorded for 20 patients. Two patients were excluded because of their poor clinical condition at the time of admission and of their families' lack of expected benefit from invasive treatment. Therefore, a total of 11 591 alarms for 18 patients were included in this study, corresponding to 2697 person-monitored hours. The observation time for the cases averaged 150±113 h. Table 2 describes patient characteristics on admission. During their treatment in the ICU, 66.7% of the patients improved (SOFA scores decreased), while 22.2% deteriorated (SOFA scores increased). The ECG, SpO_2 and NIBP devices were attached to all ICU patients throughout their time in the ICU.

The interobserver variabilities in the technical and clinical annotations, as estimated by the κ coefficient, were 0.98 and 0.68. Similarly, the intraobserver validities were 0.95 and 0.73. These values are within the range of substantial (0.61–0.80) or almost perfect (0.81–1.00) agreement.

In addition, false-negative situations were not recorded during the 2697 patient-monitored hours.

Alarm classifications

A total of 11 591 alarms were included in the analysis, classified as *technically true* (71%), *technically false* (21.4%) and *indeterminable* (7.7%) alarms (figure 1 and table 3). The overall contribution of each alarm type to the 11 591 alarms is shown in table 3. Only 6.4% of all alarms were relevant, whereas 32.8% were helpful alarms but not relevant, and 60.8% of all alarms were irrelevant. During an 8 h shift, on average, ICU nurses would hear a total of approximately 32 alarms, of which only two were relevant.

The monitoring devices that triggered alarms the most often were ART (33.5%), SpO_2 (24.2%) and ECG (22.9%; figure 2). The numbers of relevant alarms were 12.4% (ART), 2.4% (SpO_2) and 5.3% (ECG).

Effect of patient status on the alarms

The results of the cross-sectional time-series analysis are shown in table 4. ART demonstrated a positive correlation between the SOFA score and the proportion of relevant alarms, as well as between the SOFA score and the total number of alarms, and also between the SOFA score and the total number of relevant alarms. The SpO_2 and ECG monitors demonstrated positive

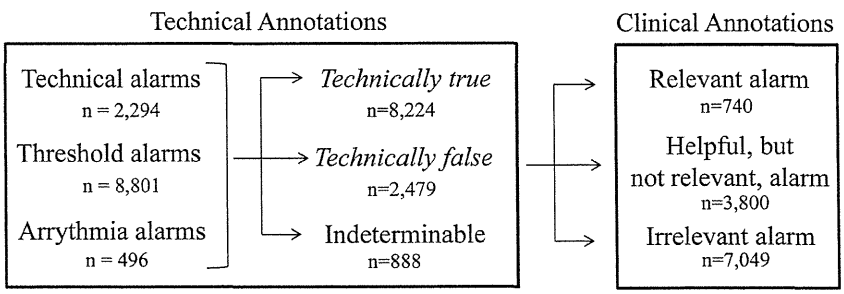

Figure 1 Technical and clinical annotations. After an evaluation of the technical relevance was made by two nurses, an evaluation of clinical relevance was made by two intensivists.

Table 3 The total number of all alarms and the number occurring every 8 h

Alarms (/overall period: 2697 patient-monitored hours)	n	Per cent of total
Total numbers	11 591	
Technical annotation		
Technically true	8224	71.0
Technically false	2479	21.4
Indeterminable	888	7.7
Clinical annotation		
Relevant alarm	740	6.4
Helpful, but not relevant, alarm	3800	32.8
Irrelevant alarm	7049	60.8
Indeterminable	2	0.02
Alarms (count/8 h)	Mean±SD	Median (ranges)
Total numbers	31.8±28.6	23.5 (1–200)
Relevant alarm	2.0±7.7	0 (0–60)
Helpful, but not relevant, alarm	10.4±13.3	6 (0–178)
Irrelevant alarm	19.4±20.9	13.5 (0–96)
Indeterminable	0.005±0.1	0 (0–2)

correlations only between the SOFA score and the proportion of relevant alarms.

All the devices demonstrated that the SOFA scores had statistically significant positive coefficients when regressed against the total number of relevant alarms ($p<0.0001$), as well as against the total number of alarms ($p=0.0061$) and the proportion of relevant alarms ($p<0.0001$). The results indicated that as the SOFA score decreased, the number of alarms, the number of relevant alarms and the proportion of relevant alarms decreased; the converse was also true.

The inclusion of a regression variable that indicated whether an event occurred during a day or night shift, in the time-series model, indicated that the time of the alarm did not demonstrate a statistically significant relationship with the SOFA score.

Technical validity

Relevant alarms comprised those that were *technically true* and those that were *indeterminable*, but did not include those that were *technically false*. Thus, the irrelevant alarms could be reduced by 21.4% by evaluating their technical relevance.

DISCUSSION

General statement

ICU patients are surrounded by medical devices that regularly sound alarms, but most of the alarms are not clinically relevant.[1–3] These irrelevant alarms cause a lower quality of patient care by distracting the medical staff[4–7] and contributing to patient delirium.[9 10] Thus, attempts to reduce the number of clinically irrelevant alarms are important as solutions for this national problem are sought.[19] The present study demonstrated that (1) the devices that alarm the most frequently are ART, SpO_2 and ECG; (2) the proportion of relevant alarms decreases as patient status improves and (3) the irrelevant alarms can be reduced by combining the data for the waveforms or pulse rates of each device.

Prior to this study, Siebig *et al*[13] were the first to record data with a 24 h video monitor, with the help of two physicians, to evaluate the clinical relevance of alarms. This technique reduced the possible bias introduced by bedside evaluations. The same method of evaluation was used in this study, with the added evaluation of alarm frequency for each device, and the determination of the fluctuations in alarm relevance and clinical severity for individual patients.

Alarm types and their relevance

The vast majority of alarms triggered in the ICU is either false alarms or are irrelevant for patient treatment. The present study shows that only 6.4% of all

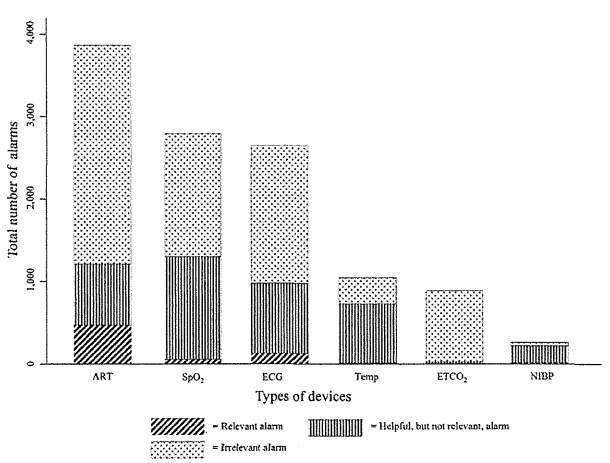

Figure 2 The numbers and types of different alarms. The monitoring devices that triggered alarms the most often were the ART, ECG and SpO_2 monitors. ART, direct measurement of arterial pressure; SpO_2, oxygen saturation; Temp; bladder temperature; $ETCO_2$, end-tidal carbon dioxide; NIBP, non-invasive blood pressure.

Table 4 Relationship of patient condition with alarm numbers and relevance

Alarm types	Regression coefficients of severity score (SOFA)†‡ Total number of alarms	p Value	Total number of relevant alarms	p Value	Percentage of relevant alarms	p Value
Direct measurement of arterial pressure	1.8±0.5	0.0001*	0.6±0.2	<0.0001*	2.2±0.6	0.0003*
Electrocardiogram	−0.4±0.4	0.3018	0.1±0.1	0.066	2.4±0.4	<0.0001*
Oxygen saturation	0.1±0.3	0.7191	0.05±0.03	0.167	0.7±0.2	0.0018*
Bladder temperature	0.4±0.2	0.0166	0.002±0.01	0.8704	−0.1±0.4	0.7307
End-tidal CO_2	−0.02±0.2	0.9363	0.004±0.004	0.4143	0.4±0.2	0.0726

*Attained statistical significance (p<0.05) after the adjustment for multiple comparisons by Bonferroni method.
†Only the regression coefficients of severity scores on the (numbers and proportions of) alarms are shown, which were obtained by the cross-sectional time-series analyses (analysis conducted for each kind of alarm).
‡Constant terms were included in the random effect models obtained, but they are not shown.
SOFA, sequential organ failure assessment.

alarms triggered in the ICU were relevant. These data are similar to the results of multiple prior studies from various institutions, which indicated that approximately 10% of alarms are relevant.[1–3 20] The number of alarms that were technically annotated as being *indeterminable* was 7.7%. When the amplitude of waveforms was small or when the arrhythmia indications and noises were mixed, the technical annotations were difficult.

The ART alarms had a positive correlation between the SOFA score and the number and proportion of relevant alarms. In contrast, the SpO_2 and ECG alarms only showed positive correlations between the SOFA score and the number of alarms. These findings indicate that the SpO_2 and ECG alarms sound regardless of the clinical severity. Therefore, the SpO_2 and ECG alarms are the primarily clinically irrelevant alarms, especially in patients with decreasing SOFA scores. However, this study revealed that the ECG and SpO_2 devices were attached to all ICU patients, for safety reasons, from the time of their ICU admission. Therefore, establishing criteria for removing these devices would be difficult.

How can we reduce the noise in the ICU?

We demonstrated that clinically irrelevant alarms were reduced by 21.4% by evaluating their theoretical technical relevance. When evaluating technical relevance, two nurses combined the data for waveforms or pulse rates for each device. After annotation, their intraobserver and interobserver correlations demonstrated almost perfect agreement and the relevant alarms comprised those that were *technically true* and *indeterminable*, but not those that were *technically false*. Thus, manufacturers can decrease the number of *technically false* alarms by combining the data from each device. In particular, the ART monitor is often used in the ICU setting, and a reduction in the number of clinically irrelevant alarms might be possible by combining the ART waveform with the data from the SpO_2 monitor and ECG.

The number of ART monitor alarms and the proportion of relevant alarms that were associated with the patient SOFA scores implied that there should be a criterion established to remove this device when the SOFA score has decreased to some appropriate level. We found that when the SOFA scores were ≤2, there were no relevant ART alarms. Thus, when the SOFA scores are ≤2 and the patient's condition is not likely to change suddenly, the ART device may be removed. As a general rule, if the sensitivity and specificity of a given test are constant, the positive predictive value (PPV) is assumed to increase as the (true) prevalence/incidence becomes higher. According to this rule, if alarms are being triggered constantly, then PPV is higher when the patient illness severity is higher. Thus, as the patient illness severity increases, the number of alarms increases, and these alarms include a large number of relevant alarms. In contrast, as the patient illness severity decreases, the number of alarms decreases, but these alarms include only a small number of relevant alarms. If the significance of medical treatment, measured by the alarms, is constant, the PPV would be more desirably held constant regardless of the patient's condition. Thus, when the patient illness severity is low, an increase in PPV is important, strictly according to the standards of sensitivity and specificity.

Why has this problem not resolved over the past decade?

The most serious problem encountered with these alarms was that although they provided PPVs (relevant alarms/all alarms), their sensitivity and specificity cannot be ascertained. These data cannot be ascertained because the evaluation of false negatives and true negatives are not possible in cases where the monitor does not alarm in clinical practice. Therefore, manufacturers need to produce alarmed devices that have higher sensitivities in order to avoid medical accidents. In this study, we did not detect false-negative situations. According to studies by Tsien[3] and Siebig *et al*[13] the sensitivity of the current alarms is close to 100%. However, their specificity, which is important for medical staff, could not be determined. Another reason for the failure to reduce the number of clinically irrelevant alarms is that physicians may be relatively insensitive to alarm problems because they do not stand by patient beds as often as nurses. Thus, physicians,

nurses, researchers and medical companies need to establish an evidence-based practice model and find a mutually acceptable solution to this matter.

Study limitations

his study has several limitations. The first is that the sample size was small, with only 18 patients. The second limitation is that although a determination could be made regarding whether an alarm was *technically true* or *false*, a strict definition of the clinical annotations was more difficult. There are relevant alarms that require clinical examination, plus diagnostic or therapeutic decision, but this annotation may differ from a definition considered by intensivists. Finally, we did not analyse ventilator and infusion pump alarms, because detailed ventilator alarm messages were not recorded by our system; thus, annotation of their clinical relevance could not be performed. In addition, infusion pump alarms could not connect our system. These irrelevant alarms also need to be decreased,[21] and should be the subject of a future study.

CONCLUSION

Excessive alarms in clinical settings are linked to lower medical attentiveness and poorer treatment environments. Manufacturers should work to decrease the number of *technically false* alarms by combining waveform data with the device measurement, especially for ART. Physicians should remove ART when patient conditions improve sufficiently and they are not likely to change suddenly.

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Acknowledgements The authors are deeply grateful to Yugo Tamura for collecting data, and would like to thank Yohei Hashimoto, Kikuo Furuta and Hiroko Hagiwara for their support. The authors would also like to thank all participating intensive care unit members at the University of Tokyo Hospital for their support.

Contributors RI conceived of the study, RI and HS designed the analysis plan and performed the statistical analyses. RI wrote the first draft of the study, RI, YN, ME, AT, TI, TM, KD, MG, TH, KN, YK, SN and NY contributed to patient management. KS, MU, 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.

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

Competing interests None.

Patient consent Obtained.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement The technical appendix, statistical code and dataset are available from the corresponding author at Dryad repository; a permanent, citable and open access home for the dataset will be provided.

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保健医療科学　2013　Vol.62 No.1 p.88－97

＜総説＞

米国の救急外来における電子カルテシステムと臨床診断意思決定支援システム

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Healthcare information systems and clinical decision support for emergency departments: History and development in the United States

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抄録

電子カルテは主に一般外来や病棟で開発されてきた．しかし，一般外来や病棟では数日から長期的に渡る治療に重点が置かれる傾向があることに対して，救急外来は短期的な治療や複雑な作業の効率を改善することに重点が置かれる．この救急外来の特殊性に対応した電子カルテシステムが，救急外来に特化した情報システム（EDIS）である．EDISの中には，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である，臨床診断意思決定支援システム（CDSS）が含まれており医療安全の向上に寄与していることが示されている．これらのシステムは，緊急疾患の見逃しといった医療過誤，標準的治療を逸脱した医療の質の低下，無駄な検査・画像偏重による医療費の増大，さらに救急医療に関する研修医教育の欠如等の問題を改善することが期待されている．これらを受けて米国では，EDISの構築ならびにCDSSの開発が2009年オバマ政権誕生以後加速している．

現在日本においては，EDISを開発している企業は無い．今後日本で開発し導入するに当たってEDIS，CDSS開発の歴史を鑑みると，EDISにおいては既存の病院システムとの互換性ならびに複数の医療機関との互換性や使いやすいインターフェースが必要となり，CDSSにおいては診療行為を妨げないように臨床医に注意喚起やアドバイスするデザインが必要であると考えられる．今後日本において，こうしたシステムが実地医療機関への導入が図られることで，日本人の救急疾患の特徴といった知見の蓄積や疫学研究の進展が望まれる．

キーワード：救急医療，医療情報，健康情報システム，電子カルテ，臨床診断

Abstract

Electronic health record systems were developed primarily for use in general outpatient care and in wards. The duration of both general outpatient and ward treatment can vary; in contrast, emergency care involves short-term treatment and requires the efficient performance of complex tasks. Therefore,

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［平成24年12月27日受理］

emergency departments require customized systems such as Emergency Department Information Systems (EDIS), which reflect the unique examinations and treatments required in emergency care. Clinical Decision Support Systems (CDSS) improve medical safety by reducing errors in judgment and enabling the information sharing that forms the clinical basis for decision making. These systems are expected to maintain the quality of medical care, decrease medical costs by avoiding unnecessary testing and overemphasis on imaging, and improve the level of medical education and training, which is currently inadequate. In the United States, improvements have been made to these systems to increase the efficiency and safety of emergency medical care, and efforts in this direction have been more pronounced during the Obama administration (since 2009).

Unfortunately, the concept of EDIS is not well known in Japan; as a result, no Japanese companies manufacture electronic medical record systems designed specifically for use in emergency departments. The history of EDIS and CDSS development in the United States. shows that they must be compatible with existing hospital systems, and standardization across medical facilities should be a major goal. In addition, a good interface design is required. CDSS should prevent clinicians from obstructing their course of medical treatment and advice and reminder with proper timing. We hope that such systems will increasingly be adopted by healthcare facilities, leading to an accumulation of knowledge and the advancement of epidemiological research in Japanese emergency medicine.

keywords: Emergency medicine, health information technology, healthcare information systems, electronic medical record, clinical decision

(accepted for publication, 27th December 2012)

I. はじめに

近年，一般外来や病棟において医療情報技術（Health Information Technology：以下HIT）の技術革新の速度は非常に速く，地域医療機関連携においてもHITが利用される機会が増えてきた．こうした医療情報電子化の導入，推進において診療記録の電子化（電子カルテ）が大きな推進力となっている．

救急外来における医療情報の電子化は，一般外来のそれとは区別して考えることが必要である．例えば，救急外来では一般外来や病棟と診療形態が異なることから，既存の電子カルテシステムを流用しても上手く機能しないことが指摘されている [1-3]．諸外国ではそれを踏まえて，救急外来に特化した救急情報システム（Emergency Department Information System：以下EDIS）の開発が進められている．さらにEDISの中に含まれる電子カルテシステムの中に，医療事故を減少させるための臨床診断意思決定支援システム（Clinical Decision Support System：以下CDSS）の開発が加速している [4]．

医療主導の大型予算でのHIT政策が行われるイギリス，カナダ，デンマークなどと異なり [5]，HIT政策が急には実現できず既存の電子カルテシステムにEDISシステムを導入する米国が参考になると考えられ，米国におけるEDISやCDSSの開発の経緯と現状，そして導入を阻む要因を吟味し，それを踏まえて日本の今後の課題を考察する．

II. 医療情報技術 (Health Information Technology: HIT)

1．HITとは何か？

HITの幕開けは1959年にLedleyとLustedが発表した“臨床診断推論の基礎”の論文であるとされている [6]．この論文は，Bayesの定理を用いた疫病診断の研究であり，後に心電図のコンピューター解析などに応用され医学研究に大きな影響を与えた．その後HITは医療者における意思決定だけでなく病院の業務処理にも用いられるようになった．

現在HITは，事務や医療機器管理のIT化，患者の医療情報を電子化し病院内外での利用，ITを介して患者へ情報提供・情報の双方向性の伝達（遠隔医療など）の3つに大別され，これらは医療コストの削減と，医療ミスの減少を目指した安全性の確保を大きな目的として導入が進められてきた [7, 8]．諸外国においては，オーストラリアでは1999年から“Health Connect”が，カナダは2001年から“Canada Health Infoway”が，イギリスは2002年から“NHS Connecting for Health”プロジェクトなどが国家施策としてHIT導入が進められている．さらに米国においては2009年になって，オバマ政権発足後の経済対策法（American Recovery and Reinvestment Act of 2009：ARRA）において，HIT導入促進に係る予算等が盛り込まれたこともあり，HITを巡る環境が大きく変りつつある．

HITの具体的な例として，電子カルテ，電子処方，個人健康記録，遠隔モニタリング（Remote Monitoring），保護された情報伝達（Secure Messaging），遠隔医療（Telehealth）などが挙げられる（表1）[9]．

表1　Health Information Technology Tools

電子診療記録 (Electronic Medical Record：EMR)	患者の診療履歴を電子媒体で記録・保存する． EMRの中に，臨床意思決定支援システム（CDSS）やオーダリングシステム（CPOE）などのアプリケーションが含まれる．
電子処方 (ePrescribing)	薬や点滴の選択・処方や投薬の効果などを，ソフトウェアやアプリケーションを通じて行う． EMRに組み入れられているものと，独立したシステムの双方を含む．
個人健康記録 (Personal Health Record：PHR)	個人が，自分の健康状況などの健康データを安全に管理できる電子アプリケーション．
遠隔監視 (Remote Monitoring)	患者や介護者から直接健康状態を，または医療装置を介してEMRやPHRを電送すること． 日々の測定値（体重，血圧，心拍数・リズム，パルスオキシメトリー，血糖値），薬の管理（輸液ポンプ，電子ピルボックス），活動（ADLを測定するバイオセンサー，歩数計，睡眠モニター）などを含む．
保護された情報伝達 (Secure Messaging)	電子メールと同様に，医師や介護者と患者との間で行われる，外部に情報が漏れないように保護された情報伝達のやり取り．
遠隔医療 (Telehealth)	通信技術を利用し，診療に対するアドバイスや教育を行う． ビデオ会議，画像転送システム，遠隔患者モニタリングなどを含む．

電子カルテはElectronic Medical Records（以下EMR）と記され，患者の診療履歴を電子媒体で即時に記録・保存するものである．この中には，CDSSやオーダリングシステムといったアプリケーションが含まれる．EMRは，Electronic Health Record（以下EHR）と記されることがあり，以下に述べる個人健康記録（Personal Health Record：以下PHR）とともに，EMR，HER，PHR間で言葉の混乱が生じていた．そこで，2008年米国HIT同盟は，EMRは“一つの医療機関内で共有される医療・健康記録”，EHRは“複数の医療機関の地域連携で共有される医療・健康記録”，PHRは“個人が自ら管理する医療・健康記録”と定義した [10]．

電子処方は，主に電子カルテを使用して点滴や薬の処方を行うものであり，多くの病院で取り入れられている．この電子処方は，安全面の向上や医療費削減など多くの利益をもたらした [11]．そして，電子処方された薬や病院の受診歴などの健康データを一元的に管理するように開発されたものがPHRである．このPHRを各人が広く提供することで，医療機関での長期に渡る個人の診療状況，健康保険の情報，公衆衛生管理などといったメリットがあることから現在開発が進んでいる [12, 13]．ただPHRは，患者が病院に来院できる状態である場合や救急車で搬送される際には有効であるが，頻繁に通院できない場合にはその有効性は低いことや患者状態をタイムリーに反映されないといった欠点がある [9]．その点を解決したのが，保護された情報伝達と遠隔医療である．保護された情報伝達は，電子メールと同様に医師や介護者と患者との間で行われるものであるが，外部に情報が漏れないように情報が保護されているのが特徴である．この方法により，患者は何か自分の異変に気付いた時にわざわざ病院に行かなくても，タイムリーな情報を医療者に提供することが出来る [14]．もう一つの遠隔医療は自宅にいながら自分の状態を自ら，もしくは介護者がポータブルの医療機器を介して医療機関に送信するものである．

個人と医療機関を繋ぐものとしては以上のものがあるが，医療機関を繋ぐ役割として遠隔医療がある．遠隔医療は通信技術を利用して，画像やデータを転送しそれに対するアドバイスや教育を行うために開発された．例として，遠隔地の患者に検査データや画像と音声を用いて，集中治療医がベッドサイドで行う場合と同様の診断や治療を行う目標としてelectronic intensive care unit（eICU）が開発されている．このシステムの導入により，死亡率の減少，平均滞在日数と平均入院日数の減少が報告されている [15]．

III. 救急情報システム（Emergency Department Information System: EDIS）

1．EDISとは何か？

HITは主に一般外来や病棟において主に開発されてきた．しかし一般外来や病棟で使用されていたシステムをそのまま救急外来に流用しようとしても，診療形態が異なることから今までのシステムとは異なるものが必要となった [1-3]．通常，一般外来や病棟では数日から長期的に渡る治療に重点が置かれる傾向がある．これに対して，救急外来では短い観察期間の間に緊急度の高い疾患を診断，治療しなければならないことや多くの患者が診察を待っている状況であっても緊急性の高い患者の受診により診療の中断を余儀なくされるといった特徴から短期的な治療や複雑な作業の効率を改善することに重点が置かれる．この救急外来の特殊性に対応したシステムがEDISであり，1975年に初めて提唱された [16]．現在，EDISは“救急患者の診療や対応を効率化させる電子カルテシステム”として広く定義されている [17]．この電子カルテシステムは診療記録だけでなく，オーダリングシステム，CDSS，トリアージシステム，また医療費請求といった事務的なシステム全てを包括したものを指す．その詳細は数百の項目からなるが [18]，EDISに必須の機能や標準的な定義といったものは現在定まっていない [19]．

2．EDISの有益性

米国においては，EDISは医療現場，病院経営，国家戦略の3つの立場から開発が推進されている [17]．救急外来では，その煩雑な環境から医療事故が発生しやすい [20, 21]．最近では医療事故が社会問題として取り上げられる機会が多くなったことにより，医療訴訟を恐れるあまりに消極的な医療が問題となっている [22, 23]．このような問題に対して，EDISを導入することで診療効率を改善させることや，患者情報を地域医療機関で共有させるシステムを使用することで安全性を向上させることが期待されている．

その他国家戦略として，救急外来のデータベースを電子化することでリサーチや疫学調査が容易に行える利点は，研究のしにくい救急医療分野では非常に大きい．電子化されたデータは即時に情報収集出来る為，新しい感染症やテロが起こった際の早期発見や集団マネジメントに非常に重要となる [24]．特に米国においては2001年炭疽菌によるバイオテロリズム [25]，重症急性呼吸器症候群（SARS）[26, 27] 発生以降，症候サーベイランス（Syndromic Surveillance）[28]やバイオサーベイランス（Biosurveillance）[29]と呼ばれるサーベイランスを目的とした取り組みが活発となっている [30]．これら患者の最初の入り口は救急外来であるため，アメリカ疫病管理予防センター（Centers for Disease Control and Prevention：CDC）は救急のシステムとの連携を強化している [31]．

3．EDIS導入を阻む原因

最近の研究では，米国において検査・画像データのオーダー・閲覧，電子診療記録，電子処方箋，CDSSなどの総合的な機能を備えた電子カルテシステムを導入している病院の割合は1.5%に留まり，一部機能を有する電子カルテシステムの導入率も7.6%しかなかったことが示された [32]．これを受けて，2010年Landmanらは米国の救急外来におけるEDISの普及率を調査した．オーダーシステム，情報相互運用機能，CDSSを有する包括的EDISを有する病院の割合は1.7%で，オーダーシステムや検査・画像表示機能といった一部の機能を有する基本的なEDISを有する病院は12.3%であった [19]．

HITやEDISの利点が関係者の間で広く認識されているにも関わらず，米国においてそれらの導入の動きは非常に遅かった．その原因としては，導入費用の問題，導入後の維持費，スタッフが現状からの変化を好まないこと，導入した後成功するか分からない不確実性，電子カルテの使用が難しい，システム自体の信頼性への不安感，直ぐにシステムが時代遅れになるのではという懸念や電子化される個人情報の取り扱いにまつわるプライバシー保護の問題が挙げられている [24, 32, 33]．

一方で，臨床現場で使いにくいシステムは仕事の効率を下げ，医療事故を増加させ，致死率をも上昇させることが指摘されている [7, 34, 35]．

4．米国におけるEDIS市場

米国においては，アメリカ復興・再投資法（ARRA）の成立と同法に基づく奨励策により，2013年までに大半の医療施設がEDISを導入すると見られている．EDISの市場規模（システム販売高）はその後2016年まで漸減するものの，2017年以後には古いEDISの更新のためまた市場規模が増大すると予測されている．2012年における米国EDISの市場規模は約2.12億ドルと評価されており，Cerner, Epic Systems, Allscriptsの3社で市場の55%以上を占めている [36]．これら企業の製品は，元々病院に導入されている電子カルテシステムにおける市場占有率が大きく，導入が図られるEDISとのシステム互換性が高いことも相まって，市場における高い製品競争力を確立していると考えられる．

IV. 臨床診断意思決定支援システム（Clinical Decision Support System: CDSS）

1．CDSSとは何か？

CDSSは医療従事者が診断や治療，点滴や処方などの指示といった意思決定を行う際に，判断ミスを抑制して医療安全の向上や，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のことである [4]．現在開発されているCDSSを表2に記す [37]．

フィードバックは，医療従事者がおこなった行為や入力したデータに関して警告をかけるものであり，例として薬剤アレルギーに対する警告，薬剤の併用禁忌に対する警告，薬剤と検査結果の相関関係に対する警告（例：ジゴキシンと血中カリウム低値），薬剤用量調節支援（例：オピオイドやインスリンの量，腎不全に対するガイダンス），培養結果において感受性の悪い抗生剤を選択した際の警告，高齢者の予後を悪くする薬剤の処方に対しての警告，ペースメーカー患者のMRI検査に対する警告などがある．その他，現在の病院における耐性菌の頻度をデータ編成して表示させる機能，疾患別に治療計画書を組み入れることでその後の治療や方針を明確にするもの，ルーチンな仕事では有るが忘れては重大な事故につながるものに対してアラームを出すもの（例：低血糖患者に対して，血糖値を図るように指示），異常値が出た時にメールを使って警告を促すもの，最新の治療ガイドラインを提示するもの，将来的に行う検査や注射の日付を知らせるものなどがある [8, 32, 38]．

救急外来に特化したものの一つとして自動トリアージシステムがある．自動トリアージシステムは，混雑する救急外来において，5段階で表すEmergency Severity Index：ESI）（図1）[39] による実行プロセスを救急外来で行うことにより，重症患者の早期発見やスタッフの人員配置やベッドコントロールを効率的に，すなわち適切な資源とマンパワーの配分を行うことが出来るものである．

この5段階のトリアージは成人のみならず小児領域でも，入院・ICU入室の必要性の評価ならびに入院期間と相関関係があることが示されている [40, 41]．評価者間においても，ずれが余りないことが証明されている [42]．

表2　Clinical decision support systemsの機能的分類と凡例

分類	機能	例
Feedback	医療従事者が行なった行為や入力したデータに関して，フィードバックをかける	- 薬剤アレルギーに対する警告 - 薬剤の併用禁忌に対する警告 - 薬剤と検査結果の相関関係に対する警告 （例：ジゴキシンと血中カリウム低値） - 薬剤用量調節支援（例：オピオイドやインスリンの量，腎不全に対するガイダンス） - 培養結果において感受性の悪い抗生剤を選択した際の警告 - 高齢者の予後を悪くする薬剤の処方に対しての警告 - ペースメーカー患者のMRI検査に対する警告
Data Organization	バラバラのデータを統合し，図として表示する	- 病院における耐性菌の頻度
Proactive Information	例として，肺炎で入院する患者に対しての診療計画書	- クリニカルパスやオーダーセット
Intelligent Actions	ルーチンな仕事や繰り返し作業に対して，決まった時間にデータ等を提供したり警告したりする	- 低血糖患者に対して，血糖測定の時間を警告 - ワーファリンを飲んだか，チェックするよう警告
Communication	検査値で異常があった際に，情報を提供する	- 診察している患者の検査値にパニック値があった際に自動的にメールを送る
Expert Advice	ガイドラインなどから診断や治療のアドバイスを行う	- 治療ガイドラインの提示 （例：心筋梗塞後にβブロッカーを内服させる） - 患者データから鑑別疾患や追加検査の提案 - 行なった検査に対して，不確実なことを減らす （例：肺塞栓に対して行なったシンチなど）
Reminder	予防注射など次にいつ注射をするか，画面に表示する	- リマインダー （例：肺炎球菌ワクチンを次回打つ日付が出てくる）

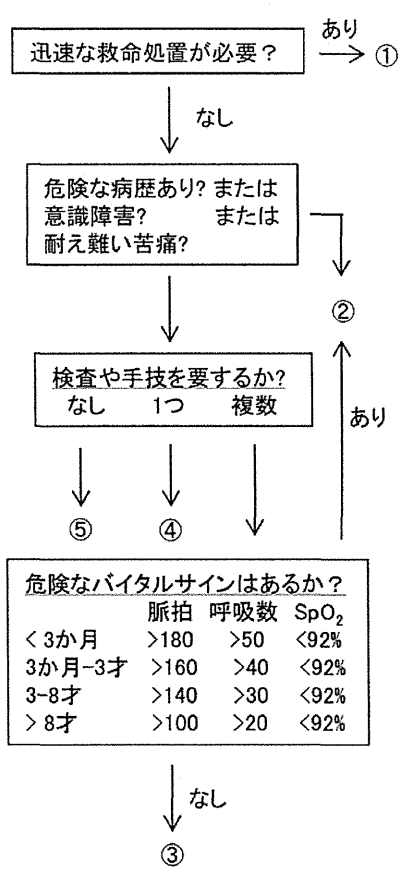


図1　Emergency Severity Index トリアージアルゴリズム，Version 4

ESI以外のトリアージシステムとして，アルバータ大学ではeTRIAGEシステム，カナダにおいてはCTAS（Canadian Triage Acuity Scale），英国・ヨーロッパ・オーストラリアではManchester triage systemを使用している．これらトリアージシステムは病院前システムにも取り入れられている．その他病院前システムでは，脳梗塞や心筋梗塞の早期判断補助にCDSSが取り入れられており研究の蓄積がある [43].

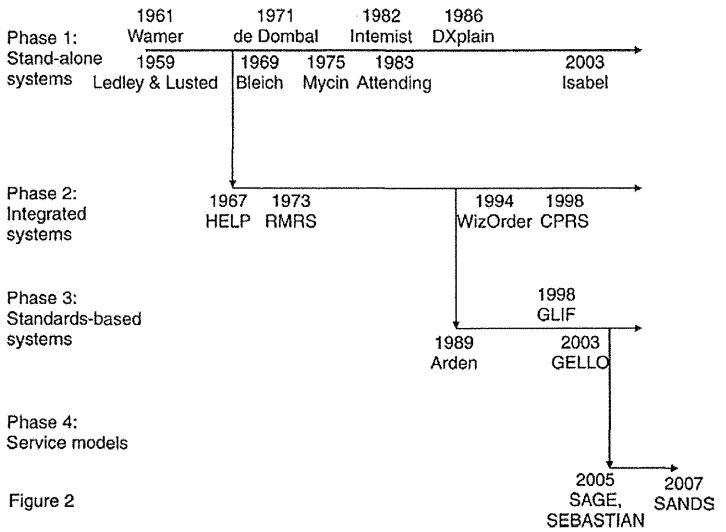
2．CDSS開発の歴史と種類

Nashは最初にCDSSの概念を提唱し，その応用可能性と有用性を論じ [44]，その後，様々なCDSSが開発された [6]．それらをWrightらは1959年から始まった独立した診断支援システム，1967年から始まった統合システム，1989年から始まった標準準拠システム，2005年から始まったサービスモデルの4つの種類に分類した（図2）[6, 45].

1）独立した診断支援システム

初期の診療支援システムは，病院内システムからは独立したものであった．他のシステムと独立していたため，誰でも容易に使えること，また標準化（専門用語，システムへの入力・出力方法，医療知識記述方法を相互運用するため統一すること）する必要がなかったため共有化は非常に容易であった．

問題点としては独立したシステムのため，患者データを直接入力しなければならず非常に手間がかかることや，その機能を使いたい人しか使用しない為，実際の医療現場において医療者に与える影響力は小さかった．



Excerpt from Wright A, Sittig DF. A four-phase model of the evolution of clinical decision support architectures. Int J Med Inform. Oct 2008;77(10):641-649.

図2　CDSS開発の歴史

2）統合されたシステム

次に診断支援システムを病院のシステムと統合する試みが始まった．患者データは病院システムから移行するだけで良いので入力する手間がなくなった．さらに薬剤の相互作用に対する警告や薬剤の用量に対する警告といったものが，データを入力することなく得られるようになった．

問題点は各医療機関で使用されている電子カルテシステムや薬剤システムが異なるため，他の医療機関とシステムを共有できないことと，臨床診断システムはガイドラインを基に作成されているが治療ガイドラインが更新された場合には，システム全体のソースコードを改定する必要が出てくることである．

3）標準準拠システム

一つの医療機関における医療情報システムは，オーダリングシステムや電子カルテシステムを機能的に使用するにあたり，多くの部門システム間で情報交換が必要となる．

さらに複数医療機関の地域連携では異なるシステムとの互換性と相互運用性が必要となってきた為に“標準化”が必要となった．

“標準化”は人間の会話と同様に，コンピューターの言語と文法を規定することである [46]．現在使用されているもので，言語に当たるものではICD-10 (International Statistical Classification of Diseases and Reated Health Problems 10th revision)，SNOMED CT (Systematized Nomenclature of Medicine-Clinical Terms) やLONIC (Logical Observation Identifier Names and Codes) であり，文法に当たるのものがHL7 (Health Level 7)，DICOM (Digital Image and Communication in Meidicine) やIHE (Integrating the Healthcare Enterprise) である．

1989年から始まった標準準拠システムは，この文法を標準化させる試みであった．問題点は数多くの規格が考案されているが，病院システムに採用され広く普及しているものがない [36]．

4）サービスモデル

最近では，膨大な数の診療ガイドラインからオントロジー工学を応用して信憑性が高いものを選択し提供するCDSSの開発が進められている．糖尿病に関しては，Duke大学で進められているSEBASTIAN (System for Evidence-Based Advice through Simultaneous Transaction with an Intelligent Agent across a Networkの頭文字を取ったもの) [47, 48]，高血圧に関してはスタンフォード大学とパロアルトの復員軍人病院と共同開発されたATHENA Hypertension Decision Support Systemがある [49]．

3．CDSSの有益性

2005年Gargらは1973年から2004年に行われた，CDSSに関する97の研究のうち62の研究（64%）で医療の質を改善させたと報告した [50]．主に医療の質を改善させたものとして，診断システム，リマインダーシステム，疾患（糖尿病，循環器疾患，その他）のマネジメントシステム，薬剤処方システムの4つを挙げている．

診断システムにおいては10の研究のうち4つ（40%），リマインダーシステムでは21のうち16（76%），疾患のマネジメントシステムは37のうち23（62%），薬剤処方システムは29のうち19（66%）で臨床における効率や安全性を高めたと述べている．さらにCDSSを導入したことで患者

の予後を13%向上させたことも示した [50].

同年出版された他のシステマティックレビューにおいても，KawamotoらはCDSSを導入したことにより医療の質を68%改善させたと報告した [51]．その中でCDSSが臨床における効率や安全性を高める重要な要因として，独立したシステムより病院のシステムに組み込まれているもの，紙媒体のものより電子化されているもの，CDSSが示した指示を行わなかった際にその理由を書かせるもの，患者の評価だけでなく推奨事項を示すもの （この患者は冠疾患のハイリスク群です，よりもこの患者は冠疾患のハイリスク群ですので，β遮断薬の投与を推奨しますというもの)，診察前後よりも診察中にその場で即座に使えるもの，の5つを挙げている．

また，救急医療においては特に教育，医療費の削減に大きな効果を持っていることが示されているが [24, 52-54]，これらに関しては後述する．

4．CDSS導入を阻む原因

CDSSを導入するに当たっては，電子カルテの導入が必須となる．しかし，電子カルテシステムが整備されていてもCDSSを導入するにあたって障害となっているのは，技術的に現在のシステムへ組み込むことが困難，導入費用，導入後の維持費，技術者の不足の他に臨床医がCDSSの存在を知らずその有効性を認識していないことが挙げられる [19, 32, 50, 55].

その他使いにくいシステムは仕事の効率を下げ，医療事故を増加させ，致死率も増加させることが報告されている [8, 34]．またあまりに警告が多すぎると“オオカミ少年”と同様に無視され効果がなくなることが報告されている [56].

5．米国EDISの中におけるCDSS市場

EDISは患者の医療・業務の円滑化を改善させることに重点を置かれているため，一般外来や入院システムと異なり，CDSSの開発には重点は置かれていない．いくつかの病院は教育ツールとしてCDSSを取り入れているが，作業を中断させるCDSSは臨床医から好まないことから，今後より使いやすいCDSSを開発することが希望されている [36].

V. 日本におけるEDISとCDSSの将来の展望

1．日本におけるEDIS

日本救急医学会によると2011年時点で救急医の数は3,219名であるが，いくつもの専門をとれる日本ではこれらの人数全てが救急医療に従事している訳ではなくさらに少ないと予想されている [57]．24時間救急業務を安全におこなう上では，一病院につき救急医が最低5人必要と言われているが [58]，全国には約4,500の救急告示医療施設があり救急医不在で診療を行っているところが多い．さらに近年，時間外外来の救急部門においても，応急処置にとどまらず診療時間内と同様の質を求める声があり，本来の救急医療の提供が十分に行われていない．

仕事の負担が大きいことで問題となってくるのは，緊急疾患の見逃しといった医療過誤，標準的治療を逸脱した医療の質の低下，無駄な検査・画像偏重による医療費の増大，緊急時を含めた研修医教育の欠如が挙げられる．それらを軽減させるために，諸外国では救急外来における電子カルテシステムの開発が行われているが [59]，残念ながら我が国においてはEDISという概念は未だ広がっていない．

特に我が国では過去，阪神・淡路大震災，東日本大震災 [60-62] や台風といった自然災害，地下鉄サリン事件といったテロ [63-66] の際に，病院外の状況を瞬時に病院電子カルテシステムに反映させる情報共有システムが有効であった可能性がある．現在，災害広域災害発生時には広域災害救急医療情報システム（Emergency Medical Information System：EMIS）が病院前システムとして使われている．

2．日本におけるCDSS

CDSSにおいても国内においていくつかの取り組みがなされている [67-69] が広く普及するには至っていない．今後日本においてCDSSをEDISと独立して開発することは比較的容易だが患者データの入力を別に行う必要がある為（図2 phase 1)，影響は小範囲に留まり全国的な普及は困難となる．よってCDSSの普及には患者データを直ぐに反映する電子カルテ，即ちEDISが必要となる（図2 phase 2)．さらに広範囲に普及させる為には，標準的な医療用語を使った，もしくはそれに変換が可能であるシステムと，さらに様々な電子カルテに対して標準的なデータ交換規約が整備させた状況が必要となる（図2 phase 3)．前述のⅣ章2.の中の3）標準準拠システムで述べたように，例として諸外国においてはコンピューター言語を標準化させる最も大きな用語集の一つであるSNOMED CT（Systematized Nomenclature of Medicine-Clinical Terms）があるが，言語形態の異なる日本においてそのシステムをそのまま適応する事は困難であり，日本独自のシステムの構築が必要でありその研究が現在進められている [70, 71].

救急外来においては症状や徴候から，低頻度でも考慮していないと重大な結果を生む疾患を否定することが求められているため，従来の診断をつけるようなアプローチとは異なった視点が必要となる．日本においては救急医以外の医師が救急医療を行っている現状から，CDSSを使用することで緊急度の高い疾患を見逃すことを減らす恩恵を与れることが期待できる．

将来的にCDSSで診療ガイドや治療ガイドラインを提示することが出来れば（図2 phase 4)，標準的な治療に沿って医療行為が行われることで医療の質の保証，無駄な検査を行わないことで医療費の削減，最新の情報による知識の獲得，さらには若手医師に対する救急医療の教育を行うことができ，今日の日本の救急医療の現状において非常に有効となると考えられる．

今後日本でCDSSを開発するに当たっては，4-2) CDSS開

発の歴史と種類で述べたように，各自の病院システムの中だけで使えるスタンドアロンのシステムではなく，標準化することで複数の病院のシステムに組み込めるよう互換性を持たせように作ることが重要となる．最も良い方法はCDSSを組み込むことを前提としてEDISを作製し，その後CDSSを開発するというアプローチと考えられる．さらに最近では，日本における病院前トリアージシステムとしてCTAS/JTASの導入が進められていることから [72]，その病院前システムとの互換性を持たせることでEDIS，CDSSはさらに良いものになると期待される．ただし，EDISやCDSSシステムを導入するに当たっては良いことばかりでは無く，使いにくいインターフェースは作業効率を落とし死亡率を上昇させる [73] といった負の面もあるため綿密な計画と慎重な導入が必要である．

VI. 結論

米国におけるHIT，EDIS，CDSSを総覧して主にCDSSについて概説した．本項で述べたCDSSは，継続的に科学的根拠を蓄積・改良するEBMの進展，さらに個々の医療機関の実態に合わせた救急医療の質の向上や効率化を図る上で有益な手段となると考えられる．今後日本において，こうしたシステムの実地医療機関への導入が図られることで，日本人の救急疾患の特徴といった知見の蓄積や疫学研究の進展が望まれる．

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