fully, while the other exaggerates so that its votes are always "strong." One might expect that this would bias negotiation outcomes to favor the exaggerator.

As we can see, even though exaggerating votes has substantial negative impact on social welfare, agents are individually incentivized to exaggerate, thus re-creating the prisoner's dilemma game. The underlying problem is simple: exaggerating agents are able to induce the mediator to accept all the proposals that are advantageous to them, while preventing the other agents from doing the same. What we need, therefore, is an enhancement of the negotiation protocol that incentivizes truthful voting, preserving equity and maximizing social welfare.

Simply placing a limit on the number of strong votes each agent can use does not work. If the limit is too low, we effectively lose the benefit of vote weight information and get the lower social welfare values that result. If the strong vote limit is high enough to avoid this, then all an exaggerator has to do is save all of its strong votes until the end of the negotiation, at which point it can drag the mediator towards making a series of proposals that are inequitably favorable to it. The idea of the truthful voting is beyond a topic of this paper. Addressing the proof of truthful voting or concrete example of is one of the important future work in our study.

4. EXPERIMENTAL RESULTS

4.1. Setting

We conducted several experiments to evaluate our approach. We employed the common testbed data structure based on XML proposed in Fujita et al. (2009). A common testbed creating tool based on XML mainly covers the utility functions based on constraints. This paper proposed a testbed generating tool that inputs configuration data and outputs XML formatted files that represent agent utility spaces. Also, this paper defined the agent's utility space information based on XML tags. By defining the testbed data as XMLs, users can easily read the files and change the data structure.

In each experiment, we ran 100 negotiations. The following parameters were used. The domain for the issue values was $[0, 9]$. The number of constraints was 10 unary constraints, 5 binary constraints, 5 trinary constraints, and so on. (a unary constraint relates to one issue, a binary constraint relates to two issues, etc). The maximum value for a constraint was *100 $\times$ (Number of Issues)*. Constraints that satisfy many issues have, on average, larger utility, which seems reasonable for many domains. In the meeting-scheduling domain, for example, higher order constraints concern more people than lower order constraints, so they are more important. The maximum width for a constraint was 7. The following constraints would all be valid: Issue 1 = $[2, 6]$, Issue 3 = $[2, 9]$. The number of agents is 10 in these experiments. The issues related to the constraint are decided based on the structure of interdependency graph in Section 2.2

The number of small issue-groups is ten in these experiments. Interdependency graphs are generated by the following two types based on the testbed: "1) Sparse Connection" and "2) Dense Connection." Actually, the difference between the two types is only the possibility of connecting to other issue-groups: the possibility of "1) Sparse Connection" is 0.4, and the possibility of "2) Dense Connection" is 0.8 written in Section 2.2. Figure 5 shows the examples of interdependency graphs and the distribution between the number of issues and the sum of the weight of connections the node has to other issues in two cases. As plotted graphs in Figure 5 show, the property of "1) Sparse Connection" is closer to the scale-free distribution, in which the number of links originating from a given node exhibits a power law distribution, than that of "2) Dense connection." In other words, the property of "2) Dense connection" is closer to the distribution of random graphs. The highest point in "2) Dense connection" is higher and more tightly-packed than that in "1) Sparse Connection."

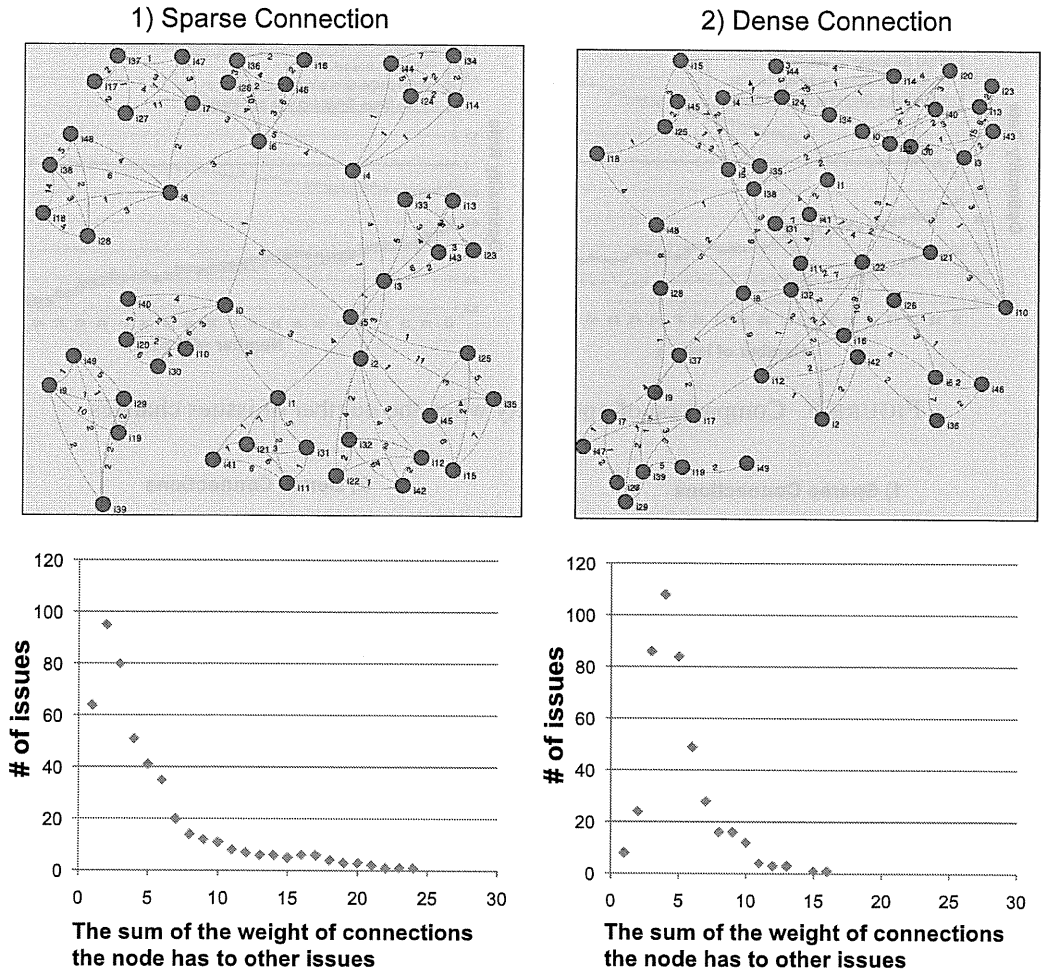

FIGURE 5. The Sparse and Dense Connection

We compare the following methods. "(A) SA based on Vote" is a method proposed in Klein et al. (2003), using a simulated annealing based on the agents' votes without generating issue-groups. "(B) Issue-Grouping based on vote" is the issue-group protocol proposed in this paper, using a simulated annealing based on the agents' votes we described above. "(C) Issue-Grouping with Maximizing" runs SA with several random starting points and pick the best solution for finding the social welfare utility functions with issue-grouping. The aim of employing this method is to evaluate the self-performance of issue-grouping.

The parameters for simulated annealing in (A) are as follows. The SA initial temperature is 50.0 and decreases linearly to 0 over the course of 500 iterations. The initial contract for each SA run is randomly selected. The parameters for simulated annealing in each group in (B) are as follows. The SA initial temperature is 50.0 and decreases linearly to 0 over the course of 50 iterations in each group. The initial contract for each SA run is randomly selected. The parameters for simulated annealing in each group in (C) are as follows. The SA initial temperature is 50.0 and decreases linearly to 0 over the course of 100 iterations in each group. The initial contract for each SA run is randomly selected. The number of edges to be progressively removed from the graph (clustering parameter) for all agents is 6.

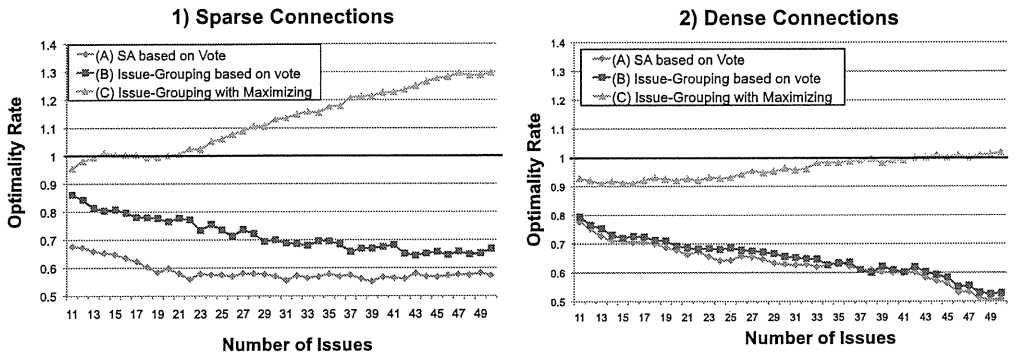

FIGURE 6. Comparison of optimality when the number of issues changes

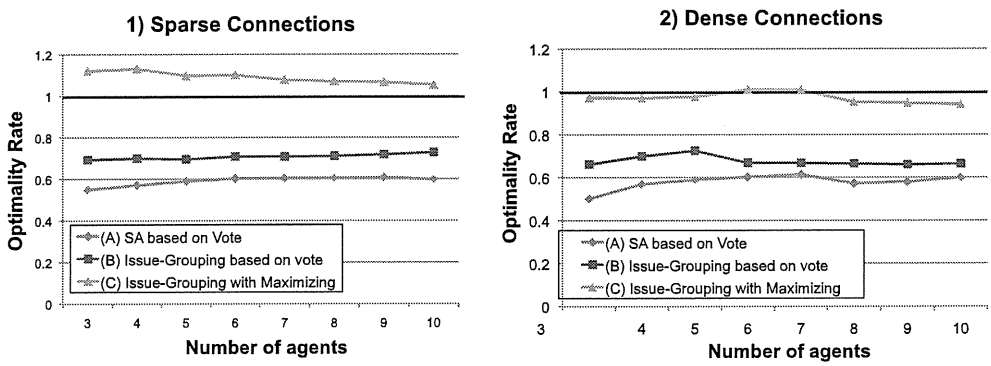

FIGURE 7. Comparison of optimality when the number of agents changes

We used simulated annealing (SA) (Russell and Norvig (2002)) gathering all the individual agents' utility functions into one central place in order to approximate the optimum social welfare for each negotiation test run. Exhaustive search was not a viable option because it becomes computationally intractable as the number of issues grows. The SA initial temperature is 50.0 and decreases linearly to 0 over the course of 2,500 iterations. The initial contract for each SA run is randomly selected. The optimality value for a negotiation run, in our experiments, is defined as *(social welfare achieved by each protocol) / (social welfare calculated by SA)*.

Our code is implemented in Java 2 (1.6) and run on a core 2-duo CPU with 2.0 GB memory on Mac OS X (10.6).

4.2. Experimental Results

Figure 6 and 7 compare the optimality rate in the sparse connection and dense connection cases. "(B) Issue-Grouping based on vote" proposed in this paper achieves higher optimality than "(A) SA based on vote," which means that the issue-grouping method achieves efficient and scalable negotiation. "(B) Issue-Grouping based on vote" decreases the optimality rate as the number of issues increases. The main reason is that the complexity of negotiation is higher as the number of issues becomes larger. The optimality rates of "(C) Issue-Grouping with Maximizing" is more than one when the number of issues is more than 20. This means that the method with issue-grouping can find high quality solutions than the one without

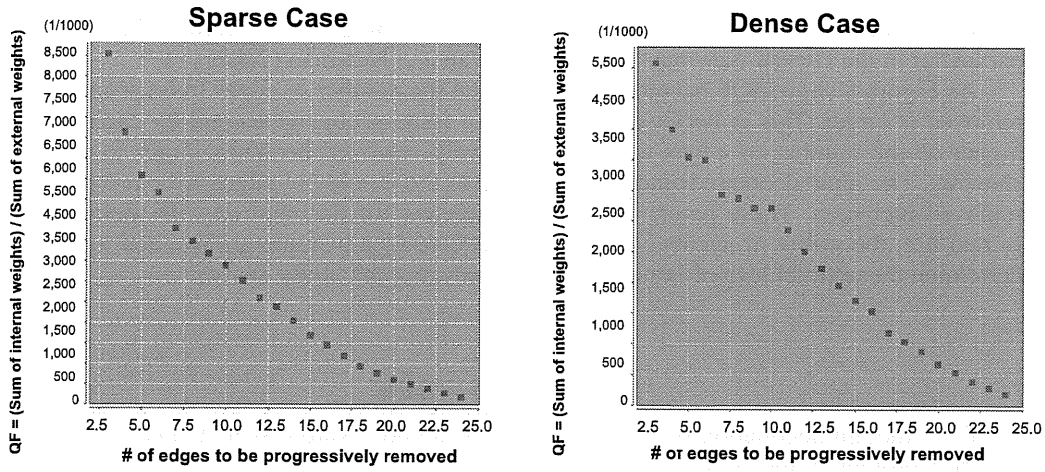

FIGURE 8. Number of edges to be progressively removed (Clustering parameter) v.s. QF

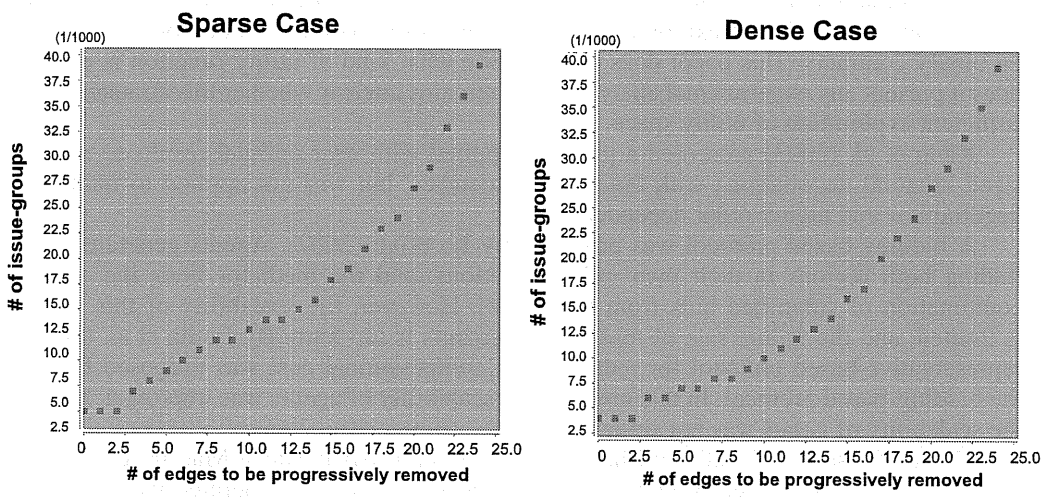

FIGURE 9. Number of edges to be progressively removed (Clustering parameter) v.s. The number of issue-groups

issue-grouping. The optimality rate is almost same when the number of agents changes as Figure 7 showing.

The optimality rates of "(B) Issue-Grouping based on vote" in "1) Sparse Connections" are lower compared with those in the "2) Dense Connections." This is because the issue-grouping method proposed in this paper can achieve high optimality if the number of ignored interdependencies is low; In fact, there can be more independent issues or small interdependent issues in "1) Sparse Connections." In real-world negotiation, a situation like sparse connection is more common.

Figure 8 shows a scatter diagram (vertical: QF, axis: number of edges to be progressively removed) when the number of agents is 3 and 20. *QF = (Sum of internal weights of edges in each issue-group) / (Sum of external weights of edges in each issue-group).* The ignored weights of edges in generating issue-groups are fewer as QF increases. The axis line means the parameter of generating issue-groups in all agents. The number of issues is 500 in the

"1) sparse connection" case. The number of edges to be progressively removed is clustering parameter in the Girvan-Newman algorithm(Girvan and Newman (2002)).

As Figure 8 shows, QF becomes smaller when the number of edges to be progressively removed is larger. This is because the number of issue-groups generated by each agent is higher as the number of edges to be progressively removed becomes larger as Figure 9 showing. The rapid decrease sometimes happens as the number of edges to be progressively removed increases. These points are good parameters for decomposing the issue-groups. In real life, the utility of agents contains an adequate idea of issue-groups, and agents can determine the optimal idea of issue-groups by analyzing the utility spaces.

5. RELATED WORK

Even though negotiation seems to involve a straightforward distributed constraint optimization problem (Greenstadt et al. (2006); Maheswaran et al. (2005)), we have been unable to exploit existing work on high-efficiency constraint optimizers. Such solvers attempt to find the solutions that maximize the weights of the satisfied constraints, but do not account for the fact that the final solution must satisfy at least one constraint *from every agent.*

Lin and Chou (2003) explored a range of protocols based on mutation and selection on binary contracts. This paper does not describe what kind of utility function is used, nor does it present any experimental analyses, so it remains unclear whether this strategy enables sufficient exploration of utility space.

Klein et al. (2003) presented a protocol applied with near optimal results to medium-sized bilateral negotiations with binary dependencies, but was not applied to multilateral negotiations and higher order dependencies.

A bidding-based protocol was proposed by Ito et al. (2007). Agents generate bids by finding high regions in their own utility functions, and the mediator finds the optimum combination of submitted bids from the agents. However, the scalability of this protocol is limited, and the failure rate of making agreements is too high. By Fujita et al. (2008), a representative-based protocol for reducing the computational cost was proposed based on the bidding-based protocol. In this method, the scalability of agents was improved; however, the scalability of issues was not sufficient.

Marsa-Maestre et al. (2009); Marsá-Maestre et al. (2010); Marsa-Maestre et al. (2009) proposed an auction-based protocol for nonlinear utility spaces generated using weighted constraints, and proposed a set of decision mechanisms for the bidding and deal identification steps of the protocol. They proposed the use of a quality factor to balance utility and deal probability in the negotiation process. This quality factor is used to bias bid generation and deal identification, taking into account the agents' attitudes toward risk. The scalability of the number of issues is still a problem in these works.

Hindriks et al. (2006) proposed an approach based on a weighted approximation technique to simplify the utility space. The resulting approximated utility function without dependencies can be handled by negotiation algorithms that can efficiently deal with independent multiple issues, and has a polynomial time complexity. Our protocol can find an optimal agreement point if agents don't have in common the expected negotiation outcome.

Fatima et al. (2007a,b) proposed bilateral multi-issue negotiations with time constraints. This method can find approximate equilibrium in polynomial time where the utility function is nonlinear. However, this paper focused on bilateral multi-issue negotiations. Our protocol focuses on multilateral negotiations.

Zhang (2009) presents an axiomatic analysis of negotiation problems within task-oriented domains (TOD). In this paper, three classical bargaining solutions (Nash solution, Egalitarian solution, Kalai-Smorodinsky solution) coincide when they are applied to a TOD with mixed

deals but diverge if their outcomes are restricted to pure deals. However, this paper focuses on the bilateral negotiations.

Jonker et al. (2007) proposed a negotiation model called ABMP that can be characterized as cooperative one-to-one multi-criteria negotiation in which the privacy of both parties is protected as much as desired. This paper models a mechanism in which agents are able to use any amount of incomplete preference information revealed by the negotiation partner in order to improve the efficiency of the reached agreements. Moreover, this paper shows that the outcome of such a negotiation can be further improved by incorporating a "guessing" heuristic, by which an agent uses the history of the opponent's bids to predict his preferences. This paper mainly focuses on the privacy issues of the negotiation mechanisms.

Robu et al. (2005); Robu and Poutre (2006) presented the utility graph for issue interdependencies of binary-valued issues. Utility graphs are inspired by graph theory and probabilistic influence networks to derive efficient heuristics for non-mediated bilateral negotiations about multiple issues. The idea is to decompose highly non-linear utility functions in sub-utilities of clusters of inter-related items. They show how utility graphs can be used to model an opponent's preferences. In this approach agents need prior information about the maximal structure of the utility space to be explored. However, our approach has the advantage that outcomes can be reached without any prior information and that it is not restricted to binary-valued issues.

Shew and Larson (2008) proposed multi-issue negotiation that employs a third-party as a mediator to guide agents toward equitable solutions. This framework also employs an agenda that serves as a schedule for the ordering of issue negotiation. Agendas are very interesting because agents only need to focus on a few issues. This paper also focuses on bilateral negotiations, however, this framework can apply to the negotiations among more than two agents.

Hemaissia et al. (2007); Hemaissia-Jeannin et al. (2008) proposed a negotiation protocol for the multi- lateral multi-issue negotiation in a cooperative context. This paper uses sharp recommendations to help in accelerating the search of a consensus between the cooperative agents and in finding an optimal solution. Also, this paper shows that the protocol has the sub-game perfect equilibria and these equilibria converge to the usual maximum solution. However, this paper mainly focuses on a crisis management problem.

6. CONCLUSION

In this paper, we proposed a new negotiation protocol, based on grouping issues, which can find high-quality agreements in interdependent issue negotiation. In this protocol, agents generate their private issue interdependency graphs, the mediator identifies the issue-groups based on ideas of issue-groups from agents, and multiple independent negotiations proceed for each issue sub-group. We demonstrated that our proposed protocol has a higher optimality rate than the method without issue-grouping.

In future work, we will conduct additional negotiation, after the concurrent sub-contract negotiations, to try to increase the satisfaction of constraints that crossed sub-contract boundaries. In addition, the asymmetry property of issues exists in real life; for example, some agents know parts of all issues. Therefore, analysis of the asymmetry property of issues based on game theory or simulation will be important. Addressing the proof of truthful voting or concrete example of is also one of the important future work in our study written in Section 3.2. The constraints in our utility space have a utility associated to them, and it is better to generate efficient issue-groups that the interdependency rate is employed to the utility of the constraints. The detailed study of the interdependency rate is also an important future works in our protocol. Finally, we can adapt Newman's fast partition algorithm to make it

determine the clustering coefficient dynamically, without having to pre-specify a number of clusters (something like this has already been proposed for collaborative tagging research).

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Analysis of Questionnaire Data Concerning Bar Codes Printed on Ampoule Labels

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Although previously only the benefits of medicines were of interest, recently the safety of their use has attracted attention to prevent medical accidents. Our investigation shows that many medicinal near-miss incidents occur because of similarity in names or appearance among different products. To avoid such confusion, the Ministry of Health, Labour and Welfare in Japan issued a declaration obligating pharmaceutical companies to display bar codes on the label of ethical medicines to avoid medical accidents. To identify what health care professionals perceive as the ideal layout of a label including the bar code, and to assess their awareness of the declaration and response, we conducted a questionnaire survey targeted at pharmacists and nurses.

In this article, we apply a data/text-mining technique to find relationships between respondent attribute data and response data concerning the ideal bar code display for ampoules and awareness of the issued declaration.

Key Words
Accident prevention; Data mining

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INTRODUCTION

The safety of medication use should be a priority, to prevent medical accidents by ensuring the appropriate use of correct medications. In our previous study, we analyzed medical near-miss case data collected by the Japan Council for Quality Health Care and found that similarities in name or appearance tend to induce confusion (1). The Japanese Ministry of Health, Labour and Welfare (MHLW) has made it compulsory for pharmaceutical companies to display a bar code on the label of ethical medicines in an effort to eliminate medication errors. Declaration no. 0915001 of the Pharmaceutical and Food Safety Division required the printing of a bar code on packages for injection medicines and biological medicines as of September 2008,[1] and aimed at having bar codes printed on dose packages for oral medicines and external medicines in the next several years. Recently, MHLW announced the results of an investigation of the progress in adoption of the bar code display (2). However, few studies have investigated how health care professionals perceive the bar code system, since its utilization is currently not obligatory.

The aim of this study is to show the mentality of health care professionals regarding the bar code required by the declaration. We focus on two perspectives: how health care professionals deal with the bar code on packages, and if they recognize its importance and expect to use it. First, we investigated how health care professionals deal with medicine packages on which bar codes are printed. Though the bar codes are expected to help ensure identification and confirmation of the medicine, they occupy a portion of the label and may conflict with the visibility of items traditionally printed on the label. For this reason, we need to identify the optimal layout that includes the bar code. Second, we investigated if health care professionals were aware of the importance of the declaration at an early stage (from the perspective of utilization of the bar code system) and how they expect to utilize the bar code (from the viewpoint of scanning locations and the timing of implementation).

In this article, we show the results of analyses applied to data obtained via a questionnaire. We identified a relationship between respondent attributes, responses related to the desirable layout of the label, and the awareness of the declaration.

TARGET DATA AND TOOLS

In our analysis, we used response data from a questionnaire titled, The Questionnaire Survey About the Bar Code Display on the Labels of Injection Drugs conducted from January to March 2007. The questionnaire was printed on paper

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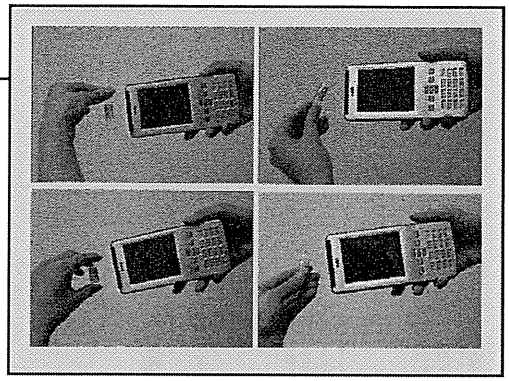


FIGURE 1

Options offered to respondents as the way to hold an ampoule for scanning. An ampoule can be held at the top, right side up (upper left); at the top, upside down (upper right); pinched between top and bottom (lower left); or held at the bottom (lower right).

and consisted of 11 questions concerning the ideal layout of a label on ampoules and perception of the bar code declaration. We received responses from 566 health care professionals, including 258 pharmacists (248 hospital pharmacists) and 259 nurses (239 hospital nurses) from eight locations in Japan, including Hiroshima, Gifu, Kanazawa, Kobe, and Nagoya. To investigate perceptions of health care professionals about utilizing the bar code printed on labels, we focused on pharmacists and nurses who directly deal with medicine packages. We excluded physicians because their primary mission is to prescribe appropriate medicines, not to deal with medicines directly.

To identify the ideal layout of the ampoule label on which the bar codes are printed, we focused on the following factors:

1. The way an ampoule is held to scan it with a handheld-type bar code reader (Figure 1). We assumed that the bar code is scanned in pharmaceutical departments and general wards.
2. The ideal position of the bar code (Figure 2) and the direction of the product name (Figure 3) on the label.
3. Awareness of the declaration to display bar codes on labels of ethical medicines, and categories of ethical medicines that need to display the bar code with the expiration date and manufacturing number, which are currently optional.
4. The place to scan the bar code and timing of implementing bar code use in the hospital.

METHODS

DECISION TREE ALGORITHM

To determine the relationship between respondent attributes and the preferred way to utilize the bar code, we utilized a commonly used decision tree algorithm. The algorithm recursively finds the condition of explanatory variables that effectively classifies the data so that they form the groups in which the objective variable has a similar value. The result shows the principal condition that determines the value of the objective variable. Let us illustrate this algorithm briefly based on the sample data shown in Figure 4. We can see that the value in the Bought column is equal to Y if the age is less than 29.5 and that it is not related to gender. If we set the value in the Bought column as an objective variable, and the age and gender as ex-

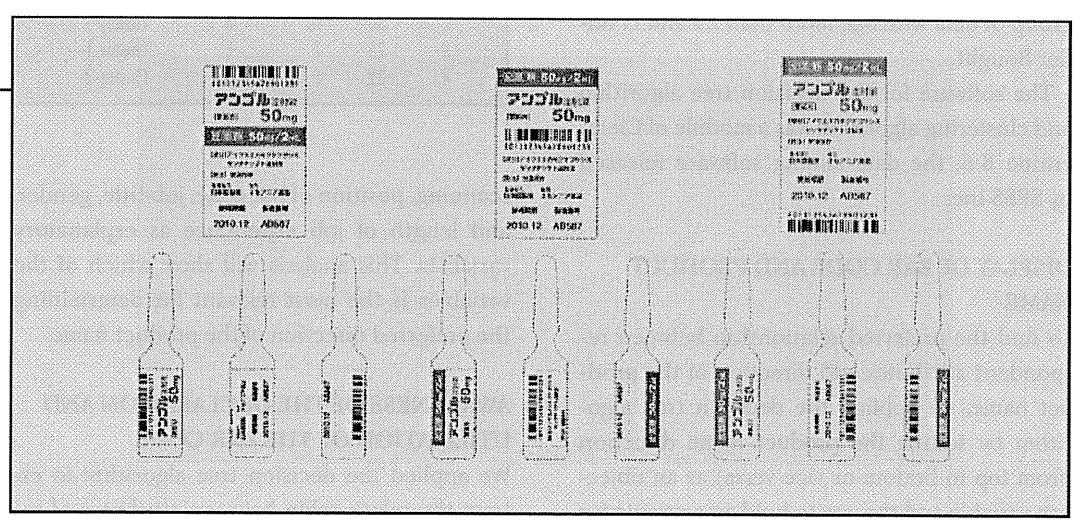


FIGURE 2

Options for position of the bar code: the top of the label (left), the center of the label (center), and the bottom of the label (right). The medicine name printed on the label is "アンプル注射液50mg (AMPOULE injection 50mg)," which is fictional and presented as an example.

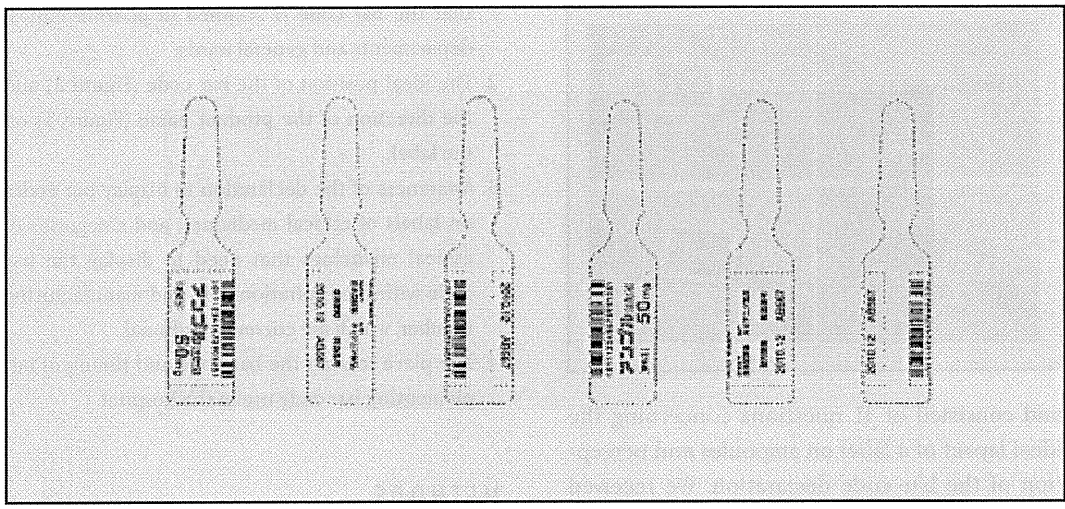


FIGURE 3

Options for direction of the product name, which can be printed from top to bottom (left) or from bottom to top (right).

planatory variables, we obtain the decision tree showing that the condition of age is principal.

CLUSTERING ALGORITHM

To find groups of data with similar values, we utilized a two-step clustering algorithm. This algorithm first finds definite groups of small size (subclusters) and then merges them into resultant groups (clusters). The number of clusters is determined based on the Bayesian information criterion, which is usually used for model selection. Applying this to the columns Age and Bought in the sample data from Figure 4, we find two clusters (Figure 5). Cluster 1 refers to the group of data with age no more than 29 and Y under Bought, and Cluster 2 refers to the group of data with age more than 29 and N under Bought.

The software for the decision tree algorithm and clustering algorithm was a module of Clementine 8.6, the data-mining software released by SPSS Inc.

DISPLAY OF BAR CODE AND PRODUCT NAME

To find the preferred relationship between respondent attributes and direction of the product name, we applied the decision tree algorithm by setting the product name direction (from top to bottom or vice versa) as an objective variable and the way to hold an ampoule for

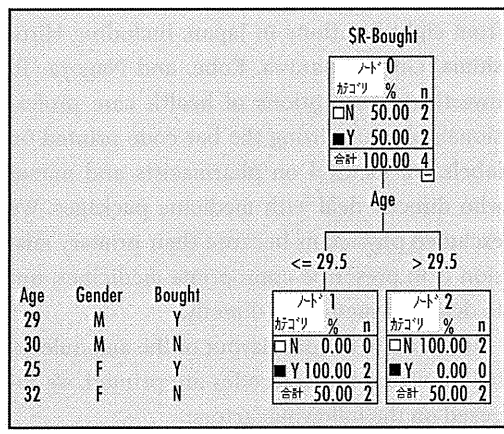


FIGURE 4

Sample data (left) and sample decision tree (right).

	Age	Gender	Bought	ST-TwoStep
1	29	M	Y	Cluster-1
2	30	M	N	Cluster-2
3	25	F	Y	Cluster-1
4	32	F	N	Cluster-2

FIGURE 5

Sample output of a two-step clustering algorithm.

scanning, position of bar code, job title, gender, and length of job experience as explanatory variables. This analysis will show which of the variables is the most relevant for determining the preferred direction of the product name.

AWARENESS OF THE DECLARATION AND UTILIZATION OF THE BAR CODE

We applied the decision tree algorithm to extract the relationship between attributes of re-

spondents and awareness of the declaration to display bar codes on ethical medicine labels. The objective variable was awareness of the declaration, while the explanatory variables were job title, gender, period of job experience, and number of beds in the hospital at which the respondent works. This clarifies the type of health care professionals who are not aware of the declaration, who are the objective to be enlightened on its significance.

To gauge the trends in opinions of health care professionals concerning where the bar code display should be utilized in a hospital, we examined the relationship between respondent attributes and the location where they presumed to scan the bar code. We applied the decision tree algorithm by setting the scanning location as an objective variable and job title, gender, length of job experience, and number of beds as explanatory variables. Since there are many options for scanning locations, they are not suitable as objective variables in a straightforward way (decision tree algorithms can only have one objective variable). To resolve this difficulty, we extracted the selection pattern of the scanning location via a two-step algorithm and set the resultant clusters as an objective variable.

IMPLEMENTING USE OF THE BAR CODE

Since it is optional to display the bar code with the expiration date and manufacturing number, we first extracted the selection patterns of medicine categories that display those bar codes using a two-step algorithm. To view the trend holistically, we classified the size of the hospital where respondents work into three categories (<300 beds, 300–500 beds, and >500 beds), and the length of work experience into two categories (>5 years or ≤5 years). Subsequently, we applied the decision tree algorithm to view the relationships of the above clusters to respondent attributes. Since the volume of data included in each cluster was not sufficiently uniform after application of the above procedure, we balanced the size of clusters without changing the distribution of the value of each variable.

The respondents had four options for the time of implementation: (a) in 2007, the year when ethical medicines with bar code displays came onto the market; (b) after September 2008, when the bar code was displayed on all injection drug labels; (c) from 2009 to 2011, the target period in which to display the bar code on internal or external medicines; and (d) at the time when their hospital employed a system for implementing the bar code. After balancing the data volume, we applied the decision tree algorithm to extract the relationships between timing of implementation to respondent attributes.

RESULTS

DISPLAY OF BAR CODE AND PRODUCT NAME

Applying the decision tree method, we found the following trends. Respondents who hold the bottom of the ampoule or pinch it between top and bottom during the scan tended to prefer the product name to be displayed from bottom to top, which is presently the method adopted for more than 90% of injection drugs. Nurses who hold the top of the ampoule tended to prefer the name to be displayed from top to bottom. Conversely, pharmacists who hold the top with the ampoule right side up tended to prefer the name to be displayed from bottom to top, while those who hold the top with the bottom up tended to prefer the name displayed top to bottom (Figure 6).

This can be summarized as the pharmacists tending to prefer the name printed from the side closest to them to the side away from them. Taking into account that the bar code reader is the handheld type, we can interpret this result as a preference to read the product name from the side of the bar code reader when they hold the scanner with their right hand. On the other hand, nurses who hold the top of an ampoule seem to prefer the name to be printed so that it can be easily seen when they draw the injection into the syringe. If this is true, this indicates the possibility that nurses should confirm the medicine after they cut the top of the ampoule and does not assume that they should check it using the bar code in advance.

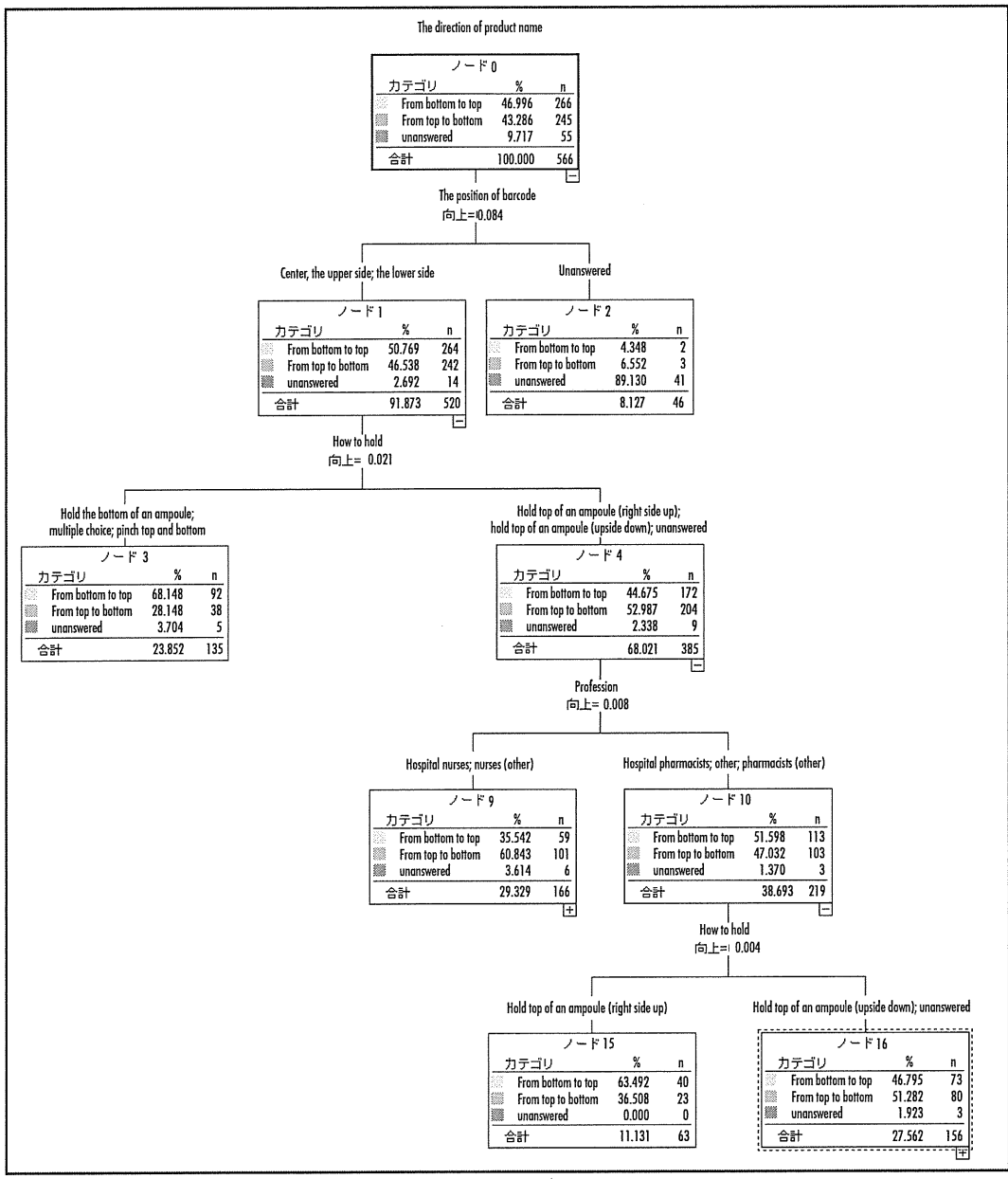


FIGURE 6

Relationship between direction of product name and other factors.

AWARENESS OF THE DECLARATION AND UTILIZATION OF THE BAR CODE

The resultant decision tree showed that only pharmacists with more than 5 years' work experience tended to be aware of the bar code declaration. Based on this result, we applied Pearson's chi-square test to the number of respondents categorized by the following conditions: whether the respondent was a veteran pharmacist with over 5 years of job experience, and whether the respondent was aware of the declaration (Figure 7). Since the chi-square value was 73.29 and the *P* value was less than 0.01, there is a significant difference in awareness of the declaration depending on career. This suggests that only directors of pharmacies, who are usually veteran pharmacists, were aware of the declaration.

Figure 8 shows that the patterns of scanning locations are divided into six clusters: "only in

FIGURE 7

Relationship between awareness of the declaration and career attributes of respondents.

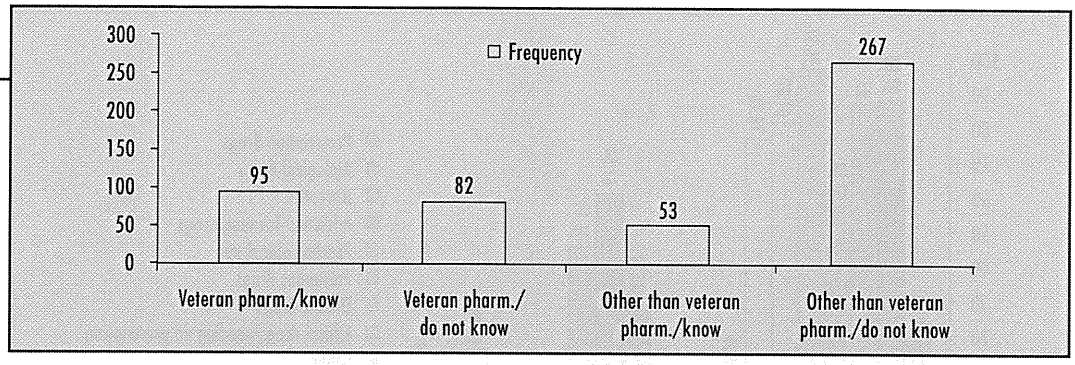


FIGURE 8

Clusters of bar code scanning locations. The vertical axis shows the percentage of respondents who selected each location.

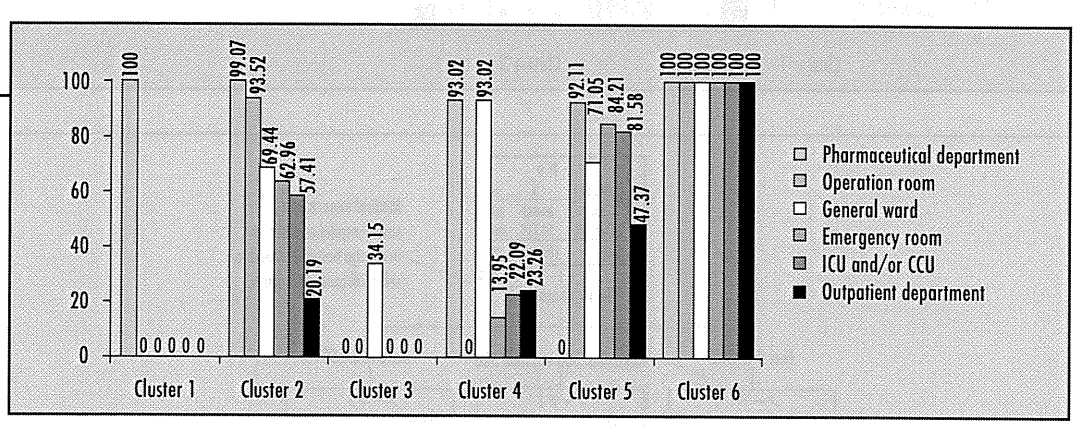
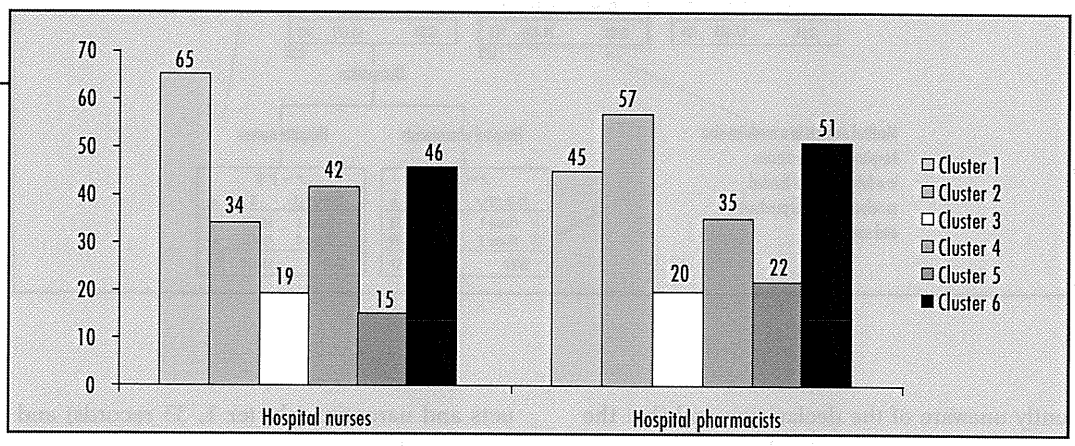


FIGURE 9

Relationship between scanning location clusters and respondent profession. The vertical axis shows the number of respondents belonging to each cluster.



the pharmaceutical department" (cluster 1, 127 records), "in all but the outpatient departments" (cluster 2, 108 records), "in the general wards" (cluster 3, 41 records), "in the pharmaceutical department and general wards" (cluster 4, 86 records), "in all but the pharmaceutical department" (cluster 5, 38 records) and "in all departments" (cluster 6, 112 records). Letting the clusters be the objective variable and applying the decision tree algorithm, we found that nurses tended to select cluster 1, while pharmacists tended to select cluster 2. Figure 9 shows the number of respondents belonging to each cluster for pharmacists and nurses. Focusing on cluster 1 and cluster 2, we again applied the chi-square test to the data of hospital nurses and hospital pharmacists, and found a significant difference ($P = 0.0034$).

This result suggests that health care professionals other than veteran pharmacists are cur-

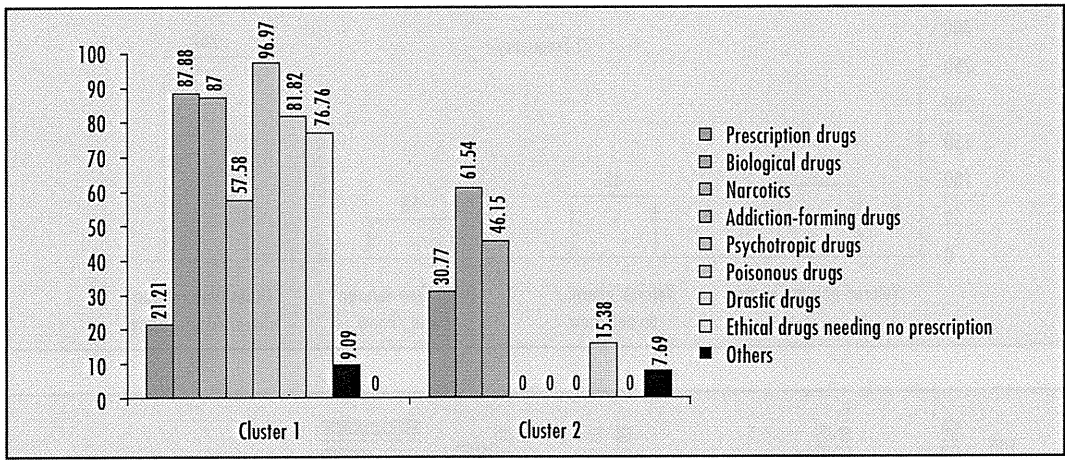


FIGURE 10

Clusters of medicines requiring display of bar code with expiration date and manufacturing number. The vertical axis shows the percentage of respondents who selected each group of drugs.

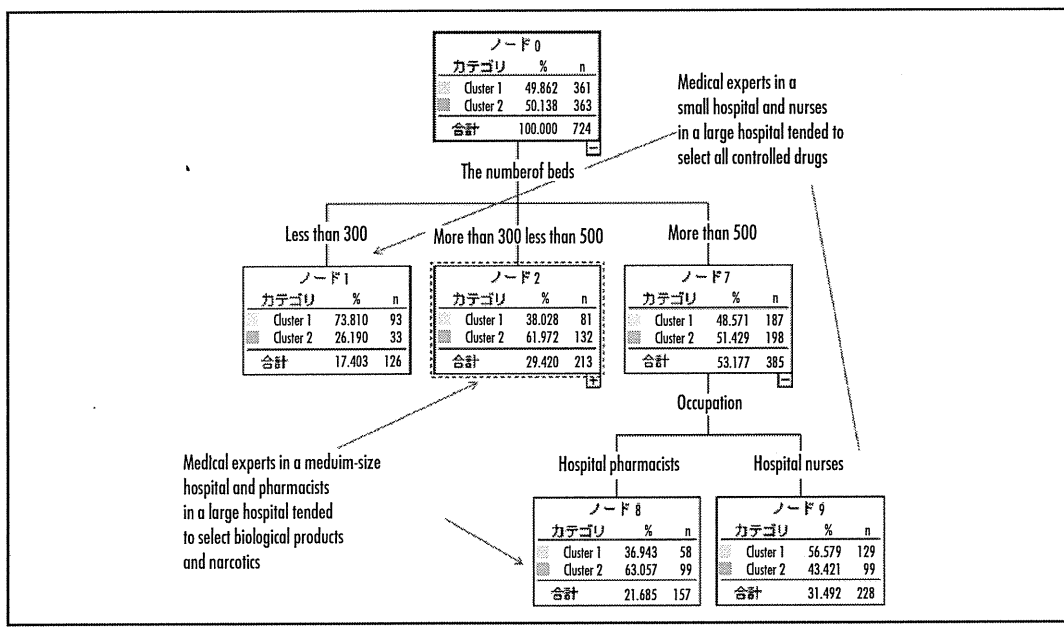


FIGURE 11

Relationships between respondent attributes and clusters of medicines requiring bar codes with expiration and manufacturing dates.

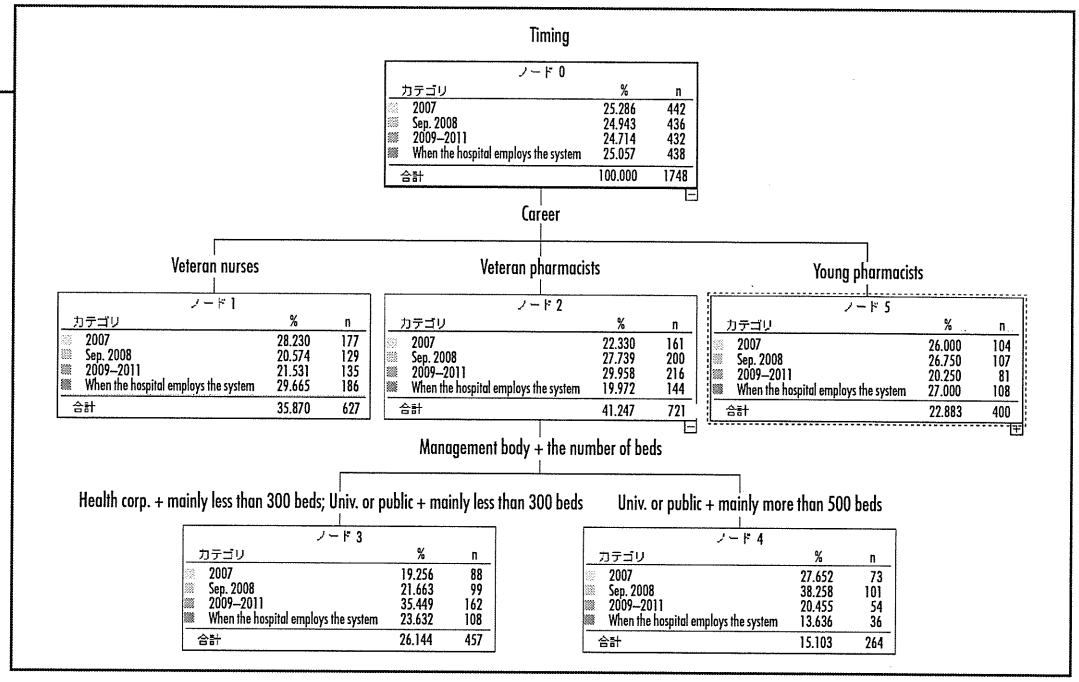
rently unaware of the declaration and that the pharmaceutical division is where the bar code will be utilized most immediately. However, to prevent any confusion of ampoules, it is desirable to understand the significance of the bar code and utilize it not only at the time of dispensing a prescription, but also at all subsequent phases.

IMPLEMENTING USE OF THE BAR CODE

We obtained two clusters of medicines requiring display of bar codes with an expiration date and manufacturing number: biological products and narcotics (cluster 1, 33 records) and all controlled medicines except prescription drugs and ethical drugs, which need no prescription (cluster 2, 13 records; Figure 10). The resultant decision tree shows that cluster 1 tended to be selected when the number of beds is fewer than 300 or when respondents were nurses working at a hospital with more than 500 beds, while cluster 2 tended to be selected in other cases (Figure 11). We can therefore see a tendency for relatively large hospitals to limit the use of bar codes to medicines for which lot information is important, since it is difficult to

FIGURE 12

Relationship between respondent attributes and timing of implementation.



deal with a large number of medicines with various kinds of bar codes.

Regarding the time of implementation, Figure 12 shows that veteran nurses and young pharmacists tended to respond "at the time when the hospital employs a system for implementing the bar code," though veteran pharmacists responded, "from 2009 to 2011." In addition, veteran pharmacists tended to hope for earlier implementation if they worked for a relatively large hospital that was university affiliated, national, or local public. This shows that veteran pharmacists tend to consider it realistic to utilize the bar code within a reasonable time after it has become somewhat popular. The result might also suggest that nurses and young pharmacists perceive the timing of implementation passively.

SUMMARY AND DISCUSSION

We applied data mining techniques with a focus on the decision tree to relate respondent attribute data to response data concerning the bar code display to ensure safety in the use of ampoules for injectable preparations. We also discussed preferences in the display of labels with the bar code, and data on health care professionals' awareness of the declaration. The results show the following tendencies:

- Pharmacists prefer a product name that can be easily read when they scan the bar code, though nurses prefer the name to be printed from top to bottom. This suggests a difference in the conditions for using the ampoules between pharmacists and nurses. The difference may be that pharmacists focus on the identification of medicine during a scan at the timing of compounding, while nurses focus on identification at the time of injection preparation and presume not to use the bar code.
- Only veteran pharmacists were aware of the declaration obligating the bar code to be on the label of ethical medicines. Nurses expect that the bar code will be scanned only in the pharmaceutical department.
- Pharmacists in large hospitals expect medicines requiring bar codes with expiration date and manufacturing number to be limited to biological products and narcotics, though nurses expect the bar codes to apply to most controlled medicines.
- Young pharmacists and nurses expect to utilize the

bar code at the time when the hospital implements the system, though veteran pharmacists expect to utilize it at a reasonable time after the bar code has become somewhat popular.

Overall, we can see a difference in response patterns between pharmacists and nurses, presumably caused by the conditions under which they deal with ampoules. There might also be a gap in perception of the purpose of the bar code system between them. The bar code is expected not only to confirm medicines but also to guarantee traceability during distribution. Though pharmacists might understand the importance of the bar code system as an extension of the distribution system, it is possible that nurses merely regard it as an additional check system.

It is also notable that the information necessary for understanding the significance and effectiveness of the bar code is not shared with nurses and young pharmacists. This may be why they have not considered the utilization of the bar code concretely. To deliver medicines to patients safely, it is preferable to scan the bar code at multiple points to increase traceability in a hospital. From this point of view, it is possible that young pharmacists and nurses do not have the perspective of incorporating multiple-point scanning into the safety system of a hospital and regard it as an optional system to identify a medicine. If so, the bar code system will be less effective in ensuring safety.

Taking the responses of veteran pharmacists into consideration, we can see that relatively large hospitals that were university affiliated, national, or local public have already developed the bar code system independent of the declaration submitted by MHLW. As for other hospitals, we can expect that the bar code system will be introduced in a few years.

It is obviously necessary for authorities and pharmaceutical companies to widely enlighten all health care professionals, not only pharmacists, concerning the objectives and importance of the bar code system, and also offer them an image of its practical use. Understanding the objectives and building the scanning into an appropriate workflow will allow the proper administration of a highly reliable medication delivery system.

NOTE

1. The Pharmaceutical Affairs Act defines biological medicines as products made from organisms other than plants that require particular attention from a health care perspective. The declaration gives weight to tracking these medicines because of their risks, such as infection. Additionally, there are some kinds of controlled medicines, such as narcotics, addiction-forming medicines, psychotropic medicines, drastic and poisonous medicines, and so on. In general, a prescription is necessary to use ethical medicines, though there are some ethical medicines that do not need prescription.

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The authors report no relevant relationships to disclose.

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Furukawa Hiroyuki

患者安全管理の基本知識：エラー報告と分析 －安心で安全な薬物治療を提供するために－

はじめに

何もしなければ，エラー（まちがい）は起きない．逆に，何かすれば，エラーが起きる．この“何”を“仕事”に置き換えてみる．つまり，仕事をすると，仕事に関係するエラーが起きる．変な言い方だが，エラーするということは，仕事をしている証拠である．

「仕事にエラーは付きもの」と言っても，医療行為におけるエラーは患者の不利益に直結するので，エラー減少に向けた取り組みが必要である．ここでは，①ヒューマンエラーの誘因，②エラー報告時の注意点，③エラー分析方法，④対策の検証実例についてまとめる．

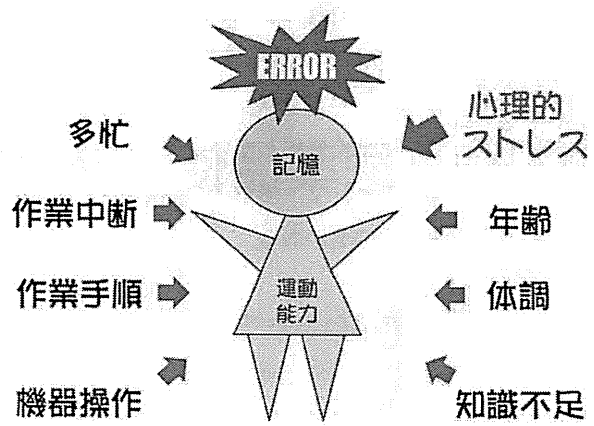

図1　ヒューマンエラーの発生原因

人は誰でもエラーする

誰もが，エラーは避けたいと思っている．しかし，「人は誰でもエラーする」という認識を持つことが出発点である[1]．

ヒューマンエラーを引き起こす原因は様々である．個人の加齢や体調変動に伴う機能低下だけでなく，取り巻く環境，作業手順の複雑さ，複雑な機械操作，そして，職場や私生活で抱える問題や人間関係に起因する心理的ストレスもまた，集中力を低下させ，自分の意図に反して，エラーが発生する（図1）．特に，“心理的ストレス”への対応が，重要性を増すと思われる．

＊金沢大学附属病院医療安全管理部准教授

エラー事例を共有する／エラーから学ぶ

患者本人やスタッフからエラーの指摘を受けたり，作業後に自分自身でエラーに気付いたりすると，非常に動揺する．自分のエラーは，できれば人に知られたくないというのが正直な気持ちである．そして，できるなら，他人に知れ渡る前にエラーの事実を消滅させたいというのが本音である．

しかし，どんな場合であっても「エラーの事実を隠す」ことは厳禁である．「人間は誰でもエラーする」のであるから，何も対策を取らなければ同じエラーが繰り返されることになる．もし，発生したエラー事例からエラーを引き起こした根本原因を抽出し，それを除去することができれば，同じようなエラーの再発を減少させることが可能である．

えた」という書き方ではなく，「薬剤Aを投与すべきところ薬剤Bを投与した」というような表現が必要である．

エラー報告の必要性は理解していても，実際に報告しようとすると心理的な抵抗がある．その理由として，次の7点があげられる[2]．

①嫌なことを思い出したくない．
②報告する必要性が理解できない．
③これ以上，余計な仕事をしたくない．
④報告すれば，エラーの多い職員として悪く評価される心配がある．
⑤報告すると，わずらわしいことに巻き込まれる．
⑥関係者に，告げ口したと思われたくない．
⑦報告したことが，どのように使われるのか心配である．

これらの心理的な抵抗を少しでも取り除くためには，エラー報告が勤務評価には全く関係しないこと，むしろ，報告すること（隠さないこと）で，当事者を病院が守ってくれるという事実を示す必要がある．

医療安全管理で用いられる分析法

優先すべき分析対象は，①患者への悪影響が大きいもの，②発生頻度の高いものである．エラー報告書に記載される「注意不足」や「確認不足」や「伝達ミス」は，ヒューマンエラーの直接原因であって，根本原因（root cause）ではない．つまり，直接原因だけで終了しないで，「なぜ注意できなかったのか？」「なぜ確認できなかったのか？」「なぜ伝達できなかったのか？」と，一歩進めて考えてみる必要がある．これが，エラー分析である．

医療安全管理においては，産業界で使われている分析手法を用いて，エラー発生に結びつく根本原因の分析を行うことが試みられている．ここで紹介する，『m-SHELL法』と『4M-4E分析法』という分析法は，「個人的要素」だけに限定しないで，個人に影響を与える様々な作業環境などを含めて，広くエラーを引き起こす原因を抽出するものである．これらの方法では，エラー発生に結び付いたと思われる要因や原因を可能な限り幅広く抽出することが重要である．

また，『根本原因分析法（Root Cause Analysis：RCA）』は，分析の過程で，『m-SHELL法』と『4M-4E分析法』を組み合わせると効果的である．

S：**S**oftware ソフトウェア
マニュアルなど
H：**H**ardware ハードウェア
道具、機器
E：**E**nvironment 環境
L：**L**iveware 個人的要素
性格なども含む
m：management 管理要因

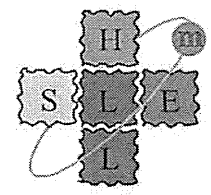

図3　m-SHELL法

m-SHELL法

最も知られているのがこの『m-SHELL法』である（図3）．これは，エラー発生原因を，Software，Hardware，Environment，Livewareという4要素に加えてmanagementの要素を加えて，それぞれの要素とその関連について分析する方法である．また，さらにPatient（機能低下，容態の急変，予測できない行動など）という要素を加えた『Pm-SHELL法』もある．

4M-4E分析法

この方法は，4M（Man，Machine，Media，Management）の視点から事故調査の要因や原因を抽出・分析を行うだけでなく，4E（Education，Engineering，Enforcement，Example）の視点から解決に向けた対策についての立案を行うことを特徴としている（表3）．

RCA[3]

この分析法は，表面的な問題点に即座に対処するというのではなく，問題や事象の根本的な原因を明らかにし，それらを除去することを目的としている．具体的には，①「できごと流れ図」（図4）の作成，②「なぜ？」という問いかけによる問題点の抽出，③背後要因の関連づけ，④根本原因の発見，⑤解決策の立案，⑥解決策の実行，⑦解決策の評価の順に分析が行われる．しかし，実行した解決策によって完全な再発防止が必ずしも実現できるとは限らないので，根本原因分析は繰り返して行い，継続して改善していくツールとして用いる必要がある．

他にも，設計の不完全や潜在的な欠点を見出すために構成要素の故障モードとその上位アイテムへの影響を解析する『設計故障モード影響解析法（Failure Mode

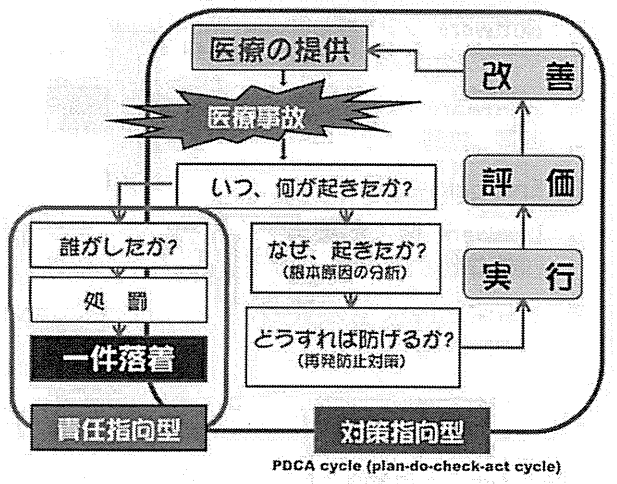

図2　エラー発生時の対応の変化

図1に示すように，エラー発生の原因は必ずしも個人の中にだけ存在するものではない．電話などで作業が中断された，複数機種の輸液ポンプを併用している，名称・外観が似た医薬品が使用されているなど，エラーを誘う原因は少なくない．

かつては，エラーによって患者に健康被害が発生すると，「誰がエラーしたのか？」という点にのみ関心が集中し，探し出した当事者を処分することで一件落着という「責任指向型」の対応が行われていた．しかし，2000年以降，全国の医療機関で自主的なエラー報告システムの導入が進み，報告されたエラー事例の分析を行うことで根本原因を抽出し，有効な再発防止策を検討し，それに基づいて業務手順を改善していくという「対策指向型」に移行している（図2）．

エラー発生の根本原因を分析するには，発生したエラーの事実関係を正確に知ることが基本である．事実関係に関する情報は，当事者とその関係者からの報告から知ることができる．

エラー報告時の情報項目

エラー報告時の必要な情報項目は，いつ（WHEN），どのような（WHAT）エラーが発生した（事実）かを時系列にわかりやすく記述し，関連するキーワードを具体的に示すことがポイントである．記述内容は多ければよいというものではない．記述が長いというだけで内容がほとんど理解できないものや，「言い訳」と「反省」が多くて事実関係や患者への影響など知りたい情報が十分に記述されていないものも少なくない．効果的な事例分析のために，必要情報項目の設定と，報告内容の記載方法についての教育が重要である．

例えば，分析に必要な情報項目として，①いつ起きたのか？（WHEN），②どこで起きたのか？（WHERE），③何が起きたか？（WHAT），④患者への影響，⑤直接原因（注意不足，多忙など），⑥根本原因（直接原因に結びついたと思われる根本にある原因），⑦エラー発見者，⑧報告者などについての項目をあらかじめ設定しておくことで，必要な情報の記載漏れを防止できる（表1，2）．また，記載時は，間違えたことによる患者への影響の大きさを予測できるよう「薬剤Aと薬剤Bを間違

表1　エラー報告例（1）

1	いつ	2010年3月2日　14時50分頃
2	どこで	薬剤部
3	何が起きたか? ①分類* ②エラーの概要	①薬剤の間違い ②処方はガスター錠（10mg）であったが，ガスター錠（20mg）を調剤した． 鑑査もすり抜け，患者からの電話連絡で発覚した． 患者は服用していない．
4	患者への影響	服用していないので，健康被害なし
5	直接原因	確認不足，注意不足
6	根本原因	• 規格が2種類あった． • 10mg錠に比べて，20mg錠のほうが数倍多く処方されている．
7	エラー発見者	患者本人
8	報告者	薬剤師（連絡先：電話番号）

※分類は，「患者間違い」，「薬剤の間違い」，「投与量（投与速度）の間違い」，「投与経路の間違い」，「投与すべき時間の間違い」，「その他（具体的に）」のどれかを記載

表2　エラー報告例（2）

1	いつ	2010年3月31日　18時50分頃
2	どこで	内科病棟
3	何が起きたか? ①分類* ②エラーの概要	①投与量の間違い ②「血液検査の結果，タキソール注の投与量を100mgから80mgに減量する」と主治医から口頭指示を受けたが，抗がん剤を調製する薬剤師に伝達を忘れた． 100mgのまま患者に投与された．
4	患者への影響	4月1日13時の時点で，特別な異常は認められていない．経過観察を継続
5	直接原因	伝達ミス
6	根本原因	口頭指示による投与量変更に関して，薬剤師に確実に伝達する院内手順がなかった．
7	エラー発見者	医師
8	報告者	看護師（連絡先：電話番号）

※分類は，「患者間違い」，「薬剤の間違い」，「投与量（投与速度）の間違い」，「投与経路の間違い」，「投与すべき時間の間違い」，「その他（具体的に）」のどれかを記載