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MYRINGOTOMY SURGERY: A QUANTITATIVE RETROSPECTIVE STUDY

Dr. C. F. Rocker, M. Eastman MN, RN
University of Victoria

Abstract

Introduction: Myringotomy surgery continues to be a standard method of treating children with otitis media. Otolaryngology surgeons in Vancouver Island, Canada frequently perform this surgery in the operating room (OR) using a general anesthesia because of lack of sedation options. Safety and risk factors for children receiving general anesthesia include both aspirations and adverse drug reactions. Additional considerations include; child and caregiver anxiety, child care responsibilities superseding lost family income or absenteeism from work, and travel time spanning six to seven hours one-way.

Purpose: The purpose of this study was to investigate differences between airway management and the use of anesthesia agents, in particular, intranasal fentanyl, when performing myringotomy surgeries.

Method: A retrospective study of one hundred sixty charts of children between 5 months and 12 years from 2013 to 2015 was conducted. The results were reviewed for pre and postoperative medications, fasting, intravenous access, anesthesia agents, airway management, adverse effects, and OR, recovery room, and admission to discharge times.

Results: Analysis revealed a trend toward improvement in standardizing less invasive procedures outside the OR. There was no significant difference between children receiving general anesthesia agent and intranasal fentanyl. Airway management was significantly increased with propofol use for general anesthesia maintenance.

Conclusion: This study identified the magnitude of variations in the approaches for children receiving an induction. The work presented here has profound implication for future studies of alternative methods of preparing children for myringotomy surgery, and one day may reduce the problem of OR shortages in Canada.

Key Words: myringotomy, ventilating tubes, fentanyl, preoperative, and postoperative
1. Myringotomy Surgery: A Quantitative Retrospective Study

One of the most frequent performed surgeries in Canadian pediatric day cares is bilateral myringotomy with ventilating tubes. At the Victoria General Hospital (VGH), Vancouver Island, British Columbia this practice happens in the operating room (OR) and engages a lengthy pre and post-operative progression of care. To reduce costs and length of stay while continuing to provide the safe care we are proposing that this procedure may well take place outside the OR; in a unit specific procedural sedation room using medications such as intranasal Fentanyl. A retrospective charts review is proposed to examine past practices about changing future ones that will provide similar/safe care, eliminate the need for OR and post anesthetic recovery room (PARR) time/space, eliminate/reduce post-operative agitation among children, improved parent satisfaction, and reduce wait times.

2. Background

Providing an optimal environment for carrying out myringotomies and ventilating tube placement remains an ambiguous plan for both our pediatric daycare and otolaryngology surgeons. According to, the Canadian Society of Otolaryngology, the procedure takes five to 10 minutes. By tradition, at VGH our children receive face-mask and intravenous anesthesia. Next, the child’s history is recorded separately by four members of the healthcare team; otolaryngology, surgeon, family physician, nurse, and anesthesiologist. Care is provided through a philosophy of family-centered care in which the care providers, patients, and families institute a mutually beneficial partnership. The health team consists of doctors, registered nurses, child life specialist, unit clerk, and porter that manage the child’s pre and post-operative care. Brown et al. argued that when teams work together, patients and families benefit from their support and improvements in efficiency.

Parents are requested to fast their children according to the hospital’s fasting guideline. Fasting consists of no solids foods after midnight along with no clear fluids three hours, bottle feed (formula) or tube feeds six hours, and breast milk/breastfeeding four hours before surgery. Solids consist of liquids with a solid component; orange juice, soup broth, Jell-O, gum, and candy; whereas, clear fluids are water or apple/grape juice. In contrast, a study from Switzerland comparing one and two-hour fasting times found that after fasting for one hour there was no difference in gastric pH or residual volume at one or two hours fast.

On admission to daycare the nurse records the child’s weight, vital signs, fasting times, allergies, consent, medication/medical history, anxiety level, Morse Fall Scale, Risk Violence Assessment, pre-op teaching (video), and does a chest assessment. A Child Life Specialist assesses the child’s fears and anxieties offering support where required. The child may be given Tylenol pre-op and regularly receives Maxilene tropically to the hand if the anesthesiologist starts an intravenous. The children entered the OR with one parent in attendance; quietly leaving after the child was sedated.

3. Literature Review

A two-year Canadian study (2010-2011) reported by the Canadian Institute for Health Information (CIHI) found that 19% of surgeries completed in Canadian day surgery operations under general anesthesia were myringotomies with tubes. Study results did not include data from the province of Quebec. The population of children receiving general anesthesia for myringotomy was aged one to five years.

According to the CIHI the average daily costs of hospital surgeries are $1,271 to $1,963 in New Brunswick and Alberta, respectively. The average anesthesia costs per surgery in Manitoba and Saskatchewan is $240 and $360, respectively. Bacchus and Fathers found the median patient wait for surgery after appointment varied across provinces; British Columbia at nine weeks and Quebec/Prince Edward Island four weeks. To add to the burden of care is indirect costs; loss of school, caregiver absence from work, and one in five families travel two or more hours to receive care.

Studies by Galinkin et al. and Finkel et al. found that the children might be disoriented, restless, and inconsolable after a myringotomy and tube placement because the rapid emergence from sevoflurane and halothane anesthesia or post-operative pain. Conversely, the use of intranasal fentanyl was associated with diminished post-operative symptoms of agitation along with no increases in discharge time, post-op vomiting, and hypoxemia. Intranasal fentanyl, a synthetic opioid...
analgesic provides rapid analgesia without intravenous access and has a short duration of action.\textsuperscript{11, 15} Rampersad, Jimenex, Bradford, Seidel, and Lynn\textsuperscript{13} suggested that post-operative agitation among the children is distressing for parents, and the child's agitation has the potential to interfere with nursing staff adequately monitoring the child post-operatively. Rampersad et al found that giving intranasal fentanyl with halothane or anesthetics lessen the child’s postoperative agitation. Hansen, Mathiesen, Trautner, and Dahl\textsuperscript{10} found no significant analgesic differences between using intranasal and intravenous fentanyl for post-operative pain. Hippard et al.\textsuperscript{9} found no difference in need for airway interventions with the use of intranasal fentanyl or IM/IV Morphine.

Post-operative pain associated with myringotomy surgery is minimal; however, giving lidocaine or Tylenol pre-operatively may aid in reducing post-operative discomfort.\textsuperscript{2, 17} Post-operative pains are often associated with surgical risks or damage occurring to the ear canal during the procedure. In opposition, pain relief is almost instantaneous after the procedure because of opening to the eardrum.

4. Method

In this study, we looked at possible associations and investigated potential relationships between children receiving intranasal fentanyl for myringotomy surgery and the institution’s current standard of practice (general anesthesia) significant to airway management. Hence, a retrospective study was undertaken at Vancouver Island’s tertiary care center; VGH. The advantage of a respective study is its rich readily accessibility to data that may generate hypotheses for future prospective research.\textsuperscript{6} A disadvantage is its reliance on accurate medical records and bias from investigator’s self-selection.

To complete the study Institutional Review Board approval (#9H2015-054) was obtained from the Research and Capacity Department, Island Health. Charts were reviewed for medications, fasting, preoperative, operative, and postoperative times. Inclusion criteria included ASA 1Classification; that is, healthy patient with no systemic disease and no regular medications. Exclusion criteria included children and infants receiving tonsillectomies and other related otolaryngology surgeries.

Inter-rater reliability involved the same abstractors collecting data from the same charts on two separate occasions. No missing data was identified. Medications were assigned numbers (1 to 7) indicating anesthesitst preference for starting with a lighter sedation; (1) Fentanyl, (2) Midazolam, (3) Dexmedetomidine, (4) propofol, (5) remifentanil, (6) morphine, and (7) Hydromorphone.

Data was collected from 160 children, 37.5\% female (n = 60) and 62.5\% male (n = 100). The children ranged in age from five months to 12 years with an average age of 4 years three months. The Statistical Consulting Centre, University of Victoria, using statistical software R completed the data analysis.

5. Results

Our results found inconsistencies in fasting times. Figure 1 revealed that fasting times ranged from 1.57 ± 18.37 hours for clear fluids and 2 ± 20.25 for solids with an average range of 9.9 and 11.1 hours, respectfully. These inconsistencies may have resulted from scheduling delays/changes, overnight fast after the evening meal, or parents/child arriving late for an appointment. Six of the children (n = 6) fasting < 3 hours and receiving only breast milk were assessed by the anesthesiologists and found satisfactory to proceed with the surgery; no complications resulted. (Figure 1)

OR times ranged from 10 ± 17 minutes. Total OR time included anesthesia ready, positioning, prep drape, incision start, incision stop, and patient exists OR. Adjusting for age found no significant difference in time spent in the OR. Figure 2 shows a box plot of the data for the times that the children entered and exited the OR (M = 13.24, SD = 5.42). (Figure 2)

Preoperatively 39.37\% children (n = 63) were given either one or two medications. Figure 3 shows children (n = 60) received Tylenol 15 mg/Kg of body weight, Ibuprofen (n = 26), Midazolam (n = 4), and Clonidine (n = 3); whereas, 60.63\% of children (n = 97) received no premedication. Tylenol and Ibuprofen were given as a prophylactic to provide postoperative analgesia. The rationale for administering Midazolam and Clonidine was anxious, frightened,
uncooperative, and to calm the child. No significance differences were found in patient outcomes.

(Figure 3)

Maxilene was administered to 91.25% children (n = 146) and 8.75% children (n = 14) received no topical anesthetic. Anesthesiologists started 62 IVs; successfully (n = 60) and unsuccessfully (n = 2). Intravenous access provided no further benefit to this healthy population of children.

Inhaled anesthetic agents administered to children (n = 132) included sevoflurane, N₂O₂/O₂ with or without intranasal Fentanyl. Figure 4 shows 32% children (n = 42) received only intranasal Fentanyl, 9 (7%) intranasal Fentanyl and N₂O₂/O₂, 28 (21%) intranasal Fentanyl and Sevoflurane, 4 (3%) intranasal Fentanyl, Sevoflurane, and N₂O₂/O₂. Twenty-five (19%) of children received no medication and sevoflurane, 5 (4%) no medication and N₂O₂/O₂, and 19 (14%) no medications, Sevoflurane, and N₂O₂/O₂. No delirium, agitation, or respiratory depression was reported. N₂O₂/O₂ was not given as a standalone agent; instead, it was given with Fentanyl, Sevoflurane or both. No nausea, agitation, laryngospasm, or respiratory depression was reported in children receiving inhaled agents or Fentanyl.

(Figure 4)

Figure 5 includes frequency of medications other than fentanyl administered by anesthetists during surgery, droperidol (n = 1), Hydromorphone (n = 1), midazolam (n = 3), dexmedetomidine (n = 3), Tylenol suppositories (n = 6), lidocaine (n = 6), dexamethasone (n = 7), remifentanil (n = 10), morphine (n = 11), ondansetron (n = 21), ketorolac (n = 30), propofol (n = 32) without incident.

(Figure 5)

Table 1 shows the relationship between medications and airway management. In Table 1 propofol is significantly associated with higher airway management levels than no medication even after adjusted for gas use (F₁,₁₅₀ = 2.592, p < .01, R = .13, R² Adjusted = .08).

(Figure 6)

Figure 6 shows a boxplot of airway management that includes (1) pre-O₂ (n = 21), (2) O₂ mask/nasal prongs (n = 7), (3) O₂ by mask (n = 20), (4) bag and mask (n = 58), (5) mask induction (n = 2), (6) LMA (n = 42), and (7) intubation (n = 1). Medications supported with airway management included fentanyl (n = 53), midazolam (n = 2), dexmedetomidine (n = 2), Propofol (n = 18, remifentanil (n = 8) morphine (n = 11), hydromorphone (n = 1), and no medications (n = 65). The medium airway supports for no medications, fentanyl, midazolam, dexmedetomidine, and hydromorphone was bag and mask. The medications propofol, remifentanil and morphine are significantly associated with higher levels of airway management than no medication. During an intubation one child (n = 1) receiving Morphine experienced apnea; the child remained in PARR for one hour 40 minutes and in hospital overnight for pulse oximetry monitoring without event.

(Figure 7)

In figure 7 post-op medications administered by PARR nurses included fentanyl (n = 2), Ventolin (n = 1), and Combivent nebulizer (n = 1). One child (n = 1) who had received Clonidine preoperatively and awoke in the PARR screaming and crying received medication and was discharged without incident. A second child (n = 1) given a LMA experienced a barky cough, strider, and some laryngeal edema received Combivent nebulizer in the PARR resulting in improved respirations and the child was, transfer to the ambulatory care unit without incident. A third child with a history of asthma requiring jaw support from the anesthetist was given a Ventolin neb for a wheeze was discharged from the PARR without incident.

The ambulatory care nurses administered; Tylenol (n = 18), ibuprofen (n = 3), morphine (n = 3), Gravol (n = 2), ondansetron (n = 1). The children receiving Gravol and ondansetron experienced only nausea and no emesis. No medications were administered to 81% of the children (n = 131) postoperatively and each child was discharged from ambulatory care as per physician protocol; one hour after entering PARR. Follow-up appointments were scheduled with the office nurse for two weeks post discharge.

(Figure 7)
Figure 1. Fasting times subsequent to receiving fluids and solids.

Figure 2. Box plot for times of children entering and existing the OR showing medium (solid horizontal lines), 50% sample (box), range (whiskers) and outliers (circles) for OR time.

Figure 3. Oral Medications Administered to the Children Preoperatively.
Figure 4. Intra nasal Fentanyl and Inhaled Anesthetic Agents

Figure 5. Medications administered during surgery.

Figure 6. Box plot for Airway Management showing Medium (solid horizontal lines), 50% sample (box), range (whiskers) and outliers (circles) for airway supports.
Table 1: Model for Relationship between Medication(s) and Airway Management

| Medication | Estimate | Std. Error | t value | Pr(>|t|) |
|------------|----------|------------|---------|---------|
| (Intercept)| 3.01538  | 0.24690    | 12.213  | < 2e-16 *** |
| Fentanyl   | -0.03425 | 0.36841    | -0.093  | 0.92605 |
| Midazolam  | -0.01538 | 1.42905    | -0.011  | 0.99142 |
| Dexmedetomidine | -0.01538 | 1.42905    | -0.011  | 0.99142 |
| Propofol   | 2.37350  | 0.53018    | 4.477   | 1.48e-05 *** |
| Remifentanil | 2.23462 | 0.74583    | 2.996   | 0.00319 ** |
| Morphine   | 1.34825  | 0.64898    | 2.077   | 0.03944 * |
| Hydromorphone | -0.01538 | 2.00584    | -0.008  | 0.99389 |

Figure 7. Post operative medications administered in the PARR and ambulatory care unit.
6. Conclusion

Our study is the first Canadian study to review inconsistency of pre-op and post-op care, fasting times, airway management, and anesthetic agents used for children undergoing myringotomy surgery. Children receiving only Intranasal Fentanyl with, or without airway support had the same outcomes as children receiving general anesthesia; sevoflurane, N₂O/O₂, and other inter-operative medications. The study supports the need for standardization of pre and post-op care and sedation used for children receiving myringotomy surgery. Healthy children (ASA 1) receiving myringotomy surgery could easily be accommodated in a pediatric ambulatory setting and freeing up OR time/space, reducing wait lists, and diminishing the exposure of children to general anesthesia; at the same time, promoting best patient management.

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Reference


Contact to the Author:
Dr. C. F. Rocker
Email: carolrocker@shaw.ca
Postal Address: University of Victoria
3800 Finnerty Rd, Victoria, BC V8P5C2
Address: 4 6300 Genoa Bay Rd, Duncan, BC V9L5Y4
Safe surgical care
RISK OF CORPORATE LOBBYING IN HEALTHCARE: THE USE OF SOCIAL NETWORK ANALYSIS TO INVESTIGATE THE EXTENT AND NATURE OF TRANSACTIONS BETWEEN THE PHARMACEUTICAL INDUSTRY AND U.S. PHYSICIANS

Bartoccioni F, M.D. 1,3,4*, Dubinski M2, Temirkhanova M, M.D. 2-4, Akhmetov Y5 M.D., Calabrese B D2, Pelagagge K2

1: Azienda Sanitaria Locale Viterbo, Viterbo
2: HTAcamp no profit association, Via Bogliasco 38, Rome, Italy
3: Catholic University of Sacred Heart, Hygiene and Public Health Department, Rome, Italy
4: Kazak National Medical University named after S.D. Asfendiyarov A, Almaty, Kazakhstan
5: Astana Medical University, Astana, Kazakhstan

Abstract

Objectives: OECD in its website highlights that lobbyists can influence government decisions and are part of the policy-making process in modern democracies. Lobbying can provide governments with valuable insights and data but it can also lead to unfair advantages for vested interests if the process is not transparent and carried out with integrity. Citizens interests are put at risk when negotiations are carried out behind closed doors. The Patient Protection and Affordable Care Act, signed by President Barack Obama in March 2010, obligates manufacturers of drugs, devices, biological therapeutics and medical supplies to disclose all payments and transfers of value given to U.S. physicians. Data is made available by the Centers for Medicare and Medicaid services through Open Payments, a federal program designed to inform the general public about the financial relationships of physicians, hospitals, manufacturers and group purchasing organizations. The aim of this study was to investigate whether social network analysis can be used to provide insight into the financial relationships between pharmaceutical companies and physicians highlighting possible lobbying risks that will eventually at the end reflects on the patient safety.

Methods: Data used in this study was publically available through the Open Payments program. The used dataset included information on ownership and investment payments in the last five months of 2013. In addition, information on personal and professional details of the recipients was included.

Results: Social network analysis yielded 123 clusters, differing in structure and size. Further analysis of the two largest clusters revealed that not only the structures of these clusters were different, but also the terms of interest, the quantity of money and the companies’ strategic plans. Using various
centrality methods, we were able to identify the most influential cluster in the network. Finally, NodeXL software has allowed us to determine which companies were involved in this particular cluster.

Conclusions: Together, our results show that social network analysis is a useful tool to unravel possible lobbying risks investigating interactions between the pharmaceutical industry and physicians.

Key Words: Patient Protection and Affordable Care Act, Open Payments, Social network analysis, pharmaceutical industry, lobbying, corporate lobbying

7. Introduction
Physicians and hospitals may have financial relationships with health care manufacturing companies. These companies often provide physicians with funding for research and travel expenses, presentation fees, meals and gifts. In March 2010, President Barack Obama signed the Patient Protection and Affordable Care Act1, ushering in an era of healthcare reform. Section 6002 of this bill, the Physician Payment Sunshine Act2, requires manufacturers of drugs, devices, biological therapeutics, and medical supplies to disclose all payments and transfers of value given to physicians and teaching hospitals. In addition, this Act requires manufacturers and group purchasing organizations (GPOs) to report physicians, and their immediate family members, who have an ownership interest in their company. This information must be reported every year. The Social Security Act requires Centers for Medicare and Medicaid Services (CMS) to collect this information from applicable manufacturers and GPOs and to make this information available to the general public through a federal program3 called Open Payments4. The Physician Payment Sunshine Act5 is designed to bring transparency to financial relationships between physicians, teaching hospitals and the pharmaceutical industry6. Although relationships between the pharmaceutical industry and physicians may lead to the development of beneficial new technologies, they also lead to wasteful healthcare spending and inappropriate influence of the pharmaceutical industry on research, education and clinical decision making. The Open Payment program provides information on the nature and extent of these relationships, including fees for speaking engagements, funding for travel expenses, meals, entertainment, gifts, educational materials, journal reprints and the payment for participation in advisory boards. Insight into these financial relationships is essential to prevent inappropriate influence of the pharmaceutical industry on physicians7-8.

The aim of this study was to investigate whether social network analysis can be used to provide insight into the nature and extent of the financial relationships between pharmaceutical companies and physicians. Social network analysis software was used to map network metrics of the healthcare system. This study revealed a complex and widespread system of interactions between the pharmaceutical industry and physicians. In addition, our results suggest a strong correlation between the structures of the clusters, the strategic plans of the companies and the involvement of physicians. Together, our results show that social network analysis is not only a useful tool to unravel the interactions between the pharmaceutical industry and physicians, but can also be used to identify the most influential companies and physicians.

8. Materials and methods
2.1 Data collection
Data used in the analyses was publically available through the Open Payments program. The database “Ownership Payment Data with Identifying Recipient information – Detailed Dataset 2013 Reporting Year” was downloaded from https://openpaymentsdata.cms.gov/. This dataset included information on ownership and investment payments in the last five months of 2013. In addition, information on personal and professional details of the recipients was included. Fields were selected to give attribution to arcs and vertices (Table S1). The Applicable_Maker_Payment_ID (AMAGPO-ID) and the
Physician_Profile_ID (PhP-ID) fields were used as vertices. The following fields were selected as arcs or edges: Physician_Ownership_Transaction_ID, Dollar_Amount_Invested, Value_of_interest, and Terms_of_Interest. Relational data was stored as an edge list.

2.1 Social network analysis
Social network analysis was performed using NodeXL (version 1.0.1.333), an open-source template for Microsoft® Excel. This template was available from CodePlex, Microsoft’s free open source project hosting site and was sponsored by the Social Media Research Foundation9. Since the transaction of money is one-directional (i.e. from companies to physicians), our network was set as a directed network10. The network can be classified as bimodal since both people and companies were visualized in nodes. The network basic parameters were calculated, including Vertices, Unique Arcs, Arcs With Duplicates, Total Arcs, Self-Loops, Reciprocated Vertex Pair Ratio, Reciprocated Arc Ratio, Connected Components, Single-Vertex Connected Components, Maximum Vertices in a Connected Component, Maximum Arcs in a Connected Component, Maximum Geodesic Distance (Diameter), Average Geodesic Distance, Graph Density, and Graph Modularity. We also recorded the value of the transactions. The vertices were clustered using the Clauset-Newman-Moore algorithm11. The group metrics, including internal and external groups arcs, and the number of vertices per group, were subsequently calculated. The Fruchterman-Reingold force directed graph12-14 drawing algorithm was used to create a relative network (Figure 1A). Using this algorithm, a network was created in which nodes are positioned in a two-dimensional manner. Finally, different centrality methods were used to characterize a node’s role, position, communication and influence, including in-degree frequency, out-degree frequency, Betweenness Centrality, Closeness Centrality, Eigenvector Centrality and PageRank.

3. Results
3.1 Size and structure of clusters
To visualize the interactions between pharmaceutical companies and physicians, a Fruchterman-Reingold force-directed graph was generated (Figure 1A). Additional graphs were created to visualize the positions of companies (Figure 1B) and physicians (Figure 1C) within the network. To cluster the vertices and to subsequently determine the number of clusters within the network, the Clauset-Newman-Moore algorithm was used. This analysis revealed the existence of 123 distinct clusters within the network (data not shown). To provide insight into the number of companies and physicians involved in each cluster, the number of vertices per cluster was determined. The size of the clusters within the network ranged from 2 to 248 vertices or nodes. Groups were ranked based on the number of nodes per cluster. (Figure 1D). A network graph was subsequently created from the 50 largest groups (Figure 1E). Analysis of this graph revealed that the majority of the groups were ‘star’ structured, indicating that most groups consisted of one company to which multiple physicians were connected.

3.2 Direction of interaction
To determine the number of interactions within and between groups, the numbers of internal and external arcs or edges were calculated. The total number of internal arcs per group ranged from 1 to 1344. The highest number of interactions were observed within groups 1, 2, 3 and 7 (Figure 2A). External arcs, or interactions between groups, could be observed for a few groups, albeit at a very low frequency (Figure 2B). The number of external arcs appears to be much lower in comparison to the number of internal arcs, indicating that interactions are usually restricted to members within the same group. Analysis of the number of connected components in the network, revealed the existence of 110 components in which individual groups were connected to each other, but not to other groups (Table 1). Although
interactions between groups do occur, as was visualized by the number of connected components, interactions between different groups appear to be less common than interactions within groups.

To confirm that the transfer of money and value was one directional, namely from companies to physicians, reciprocated vertex pair ratios and reciprocated arc ratios were calculated. These results confirm that the transfer of money and value was indeed one directional (data not shown).

To determine the number of connections for each individual node, the degree centrality was calculated. Since our network is directed, both in-degree and out-degree connections could be analyzed. In addition to out-degree connections (range 0-251) (Figure 2C/D), in-degree connections could also be observed (range 0-13), albeit at a much lower frequency (Figure 2E/F). Most of the vertices with the highest number of in-degree and out-degree connections appear to be located within group 1.

We subsequently calculated the amount of money and value transferred within the network. These calculations reveal that, in the last five months of 2013, companies paid physicians up to $44,154 in money or $41,580 in value (Table 1). To determine in which clusters the transfer of money or value was the highest, small investments were excluded from the analysis (Figure 2G/H). This filtering method revealed that the individual investments of group 1, albeit frequent, did not exceed $10,000 in money or value.

3.3 Information and influence

The page rank algorithm was used to estimate the access of individual nodes to information. Vertices with a page rank of at least 30 were shown in Figure 3A. These results indicate that information spreads more easily within small clusters.

The closeness centrality algorithm was used to provide insight into the companies’ abilities to obtain information from and spread information to companies in other groups. The proximity to others is a reflection of a person’s or company’s role in the network. The highest closeness centrality appears to be located in small peripheral groups (range 0-1) (Figure 3B/C). These results indicate that there is only limited interaction between large groups and other groups in the network.

The capacity of an individual to act as a bridge between two or more communities that otherwise would not be able to communicate with each other, allows such an individual to become more influential. To visualize which companies and physicians preside over such a communication bottleneck, the betweenness centrality algorithm was used (range 0-231,368). A betweenness centrality of at least 20,000 could be observed for several nodes in the network, including a few nodes located in group 1 (Figure 3D). These results indicate that, in addition to a number of companies and physicians in group 1, only a few other companies and physicians preside over a communication bottleneck.
To determine the influence of nodes in the network, the eigenvector centrality algorithm was used. The eigenvector centrality ranged from 0 to 0.0051 (data not shown). Only a few nodes exhibited an eigenvector centrality of at least 0.0001 (Figure 3E). These nodes all belonged to group 1. The eigenvector centrality of group 1 appeared to be at least 0.0049 (Figure 3F), suggesting that this group is, by far, the most influential one.

3.4 Terms of interest of the two largest groups

The two largest groups were selected for further analysis. Group 1 and 2 were similar in size, namely 248 and 246 members, respectively (Figure 1D). Network analysis revealed that the largest cluster, group 1, consisted of 8 different companies and 240 physicians. Within this group, 1344 connecting arcs could be observed (Table 1). The number of connecting arcs within this group was 38% of the total number of arcs in the entire network. The second largest cluster, group 2, consisted of one individual company and 245 physicians. Within this group, 259 connecting arcs could be detected (Table 1), which is approximately 7% of the total number of arcs in the network.

To provide insight into the number of transactions per member, the arc : vertex ratios were calculated. The arc-vertex ratio of group 1 was 5.41. This ratio suggests a large exchange of transactions within this cluster. In contrast, the arc/vertex ratio of group 2 was 1.05, indicating that physicians in this cluster only communicated with the one company in this cluster, but not with each other. A network graph was created from these two groups (Figure 4A). Analysis of this graph revealed that both groups differ in structure. Group 1 appears to be ‘nebula’ structured, while group 2 appears to be ‘star’ structured (Figure 4A). These results indicate that group 2, like the majority of the groups in the network (Figure 1E), is a highly-centralized ego-network in which a single company involves a large number of physicians.

To investigate whether members in these two groups communicate in an efficient manner, the geodesic distance was determined. For these two groups, both the average and maximum geodesic distance were lower in comparison to the entire network (Table 1). This indicates that the communication within groups 1 and 2 is more efficient in comparison to communication within other groups in the network (Table 1). In addition, the modularity of both groups 1 and 2 appears to be significantly lower compared to the modularity of the entire network, indicating that while, in general, the connections between nodes in different groups are limited, nodes in group 1 and group 2 do communicate with nodes in different groups (Table 1).

NodeXL software has allowed us to identify the different nodes in the network. Identification of the 8 different companies in group 1 revealed that most of these companies are either involved in laser surgery (3) or cryosurgery (4). The eighth company is a medical service company. Group 2 consisted of only 1 central company. This company is involved in oncology. Further analysis of these two groups revealed that the terms of interest differ between both groups. Physicians associated with companies in group 1 are primarily involved via membership in units limited liability company-ownership interest (Figure 4B; Table S2). Holders of membership interests have a voting and profit interest in a company. In addition, a small percentage of physicians are involved in companies via limited partner interest (Figure 4B; Table S2). In contrast, the central company in group 2 primarily involves physicians with preferred stock, a different class of ownership (Figure 4C; Table S2). Owners of preferred stock have a high claim on the assets and earnings, but no voting rights. Together, these results demonstrate that not only the number of companies associated with the two largest groups is different, but also the types of transactions and the terms of interest.
Table 1: This is the annotation of the table below.

<table>
<thead>
<tr>
<th>General Metrics</th>
<th>Group 1 Metrics</th>
<th>Group 2 Metrics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vertices</td>
<td>2330</td>
<td>248</td>
</tr>
<tr>
<td>Unique Arcs</td>
<td>3269</td>
<td>1314</td>
</tr>
<tr>
<td>Arcs with duplicates</td>
<td>263</td>
<td>30</td>
</tr>
<tr>
<td>Total Arcs</td>
<td>3532</td>
<td>1344</td>
</tr>
<tr>
<td>Minimum vs. Maximum dollar amount</td>
<td>0 vs. 44,154,926</td>
<td>0 vs. 49,275</td>
</tr>
<tr>
<td>Minimum vs. Maximum value of interest</td>
<td>0 vs. 41,580,000</td>
<td>0 vs. 67,500</td>
</tr>
<tr>
<td>Self-loops</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Connected Components</td>
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<td>1</td>
</tr>
<tr>
<td>Maximum Vertices in a Connected Component</td>
<td>649</td>
<td>248</td>
</tr>
<tr>
<td>Maximum Arcs in a Connected Component</td>
<td>1638</td>
<td>1344</td>
</tr>
<tr>
<td>Maximum Geodesic Distance (Diameter)</td>
<td>18</td>
<td>4</td>
</tr>
<tr>
<td>Average Geodesic Distance</td>
<td>6.066769</td>
<td>2,200377</td>
</tr>
<tr>
<td>Graph Density</td>
<td>0.00062452</td>
<td>0.021695834</td>
</tr>
<tr>
<td>Modularity</td>
<td>0.798357</td>
<td>0.011036</td>
</tr>
</tbody>
</table>

Table S1. Field selection and attribution to arcs and vertexes.

<table>
<thead>
<tr>
<th>Selected Fields</th>
<th>Used as</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Physician_Ownership_Transaction_ID</td>
<td>Arc attribute</td>
</tr>
<tr>
<td>2. Applicable_Manufacturer_or_Applicable_GPO_Making_Payment_Name</td>
<td>Vertex attribute</td>
</tr>
<tr>
<td>3. Applicable_Manufacturer_or_Applicable_GPO_Making_Payment_ID</td>
<td>Vertex (from)</td>
</tr>
<tr>
<td>4. Physician_Profile_ID</td>
<td>Vertex (to)</td>
</tr>
<tr>
<td>5. Dollar_Amount_Invested</td>
<td>Arc attribute</td>
</tr>
<tr>
<td>6. Value_of_Interest</td>
<td>Arc attribute</td>
</tr>
<tr>
<td>7. Terms_of_Interest</td>
<td>Arc attribute</td>
</tr>
</tbody>
</table>
### Table S2. Type of transactions within groups 1 and 2.

<table>
<thead>
<tr>
<th>Group</th>
<th>Terms of interest</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Membership Units in Limited Liability Company-Ownership Interest</td>
<td>1330</td>
</tr>
<tr>
<td></td>
<td>Limited Partner Interest</td>
<td>14</td>
</tr>
<tr>
<td>2</td>
<td>Preferred stock</td>
<td>264</td>
</tr>
<tr>
<td></td>
<td>Stock investment</td>
<td>1</td>
</tr>
</tbody>
</table>

### 10. Discussion

In this study, we have performed social network analysis to visualize the relationships and financial interactions between physicians and pharmaceutical companies. Our results revealed the existence of a large number of clusters. These clusters not only differ in size and structure, but also the terms of interest, the quantity of money and the companies' strategic plans.

Clustering analysis yielded 123 different groups. The majority of the groups appear to be 'star' structured, indicating that most groups consisted of one company to which multiple physicians were connected. These physicians were, in general, not connected to each other or to other companies. The largest group, in contrast, appeared to be 'nebula' structured due to extensive interactions between companies and physicians. 'Nebula' structured clusters are usually more influential than 'star' structured clusters. The eigenvector centrality algorithm was used to determine which groups were the most influential ones. This algorithm revealed that the largest group was also the most influential group in the network. Although the number of transactions appears to be highest in 'nebula' type clusters, such as group 1, the value of the transactions appears to be higher in 'star' structured clusters. On average, the transactions within group 1 were low in value, which renders them almost invisible for external audits by the government. Since physicians associated with companies in group 1 are primarily involved via membership in units limited liability company-ownership interest, these transactions are probably profit based. Our results show that clusters in which transactions are frequent but low in value can be more influential than clusters in which transactions are infrequent but high in value. The structure and influence of group 1 would enable companies in this group to exert lobby activities in order to influence the market and regulatory authorities. To reduce unwanted influence of these companies on research, education and healthcare, research should focus on investigating whether companies in group 1 do exert their power to influence physicians.

Data from the Open Payments program has also been used to investigate the interactions between the pharmaceutical industry and otolaryngologists. Rathi et al. revealed that otolaryngologists, in comparison to other surgical specialties, appear to have more limited financial ties with the pharmaceutical industry. In 2013, otolaryngologists primarily received payment for consulting, speaking at non-accredited educational and other promotional events, meals and beverages.

The sunshine act has allowed us to investigate the financial interactions between the pharmaceutical industry and physicians in the U.S. on a large scale. However, the initial Open Payments roll-out from 2013 appeared to be problematic for both manufacturers and physicians and ultimately resulted in thousands of payment records being "de-identified" or removed from the database. In addition, the database used in this study only contained information on those transactions that were made in the last five months of 2013. To obtain a complete overview on the different types of transactions and the involvement of physicians, it would be essential to evaluate an entire year's payments. Another limitation of the current study is that, using the 'open payments' database, we were not able to identify the relationships between physicians. This lack of information creates a virtual 'structural hole' or a 'brokerage structure'. Although these type of relationships can be identified using a multimodal network analysis, as used in this study, a more open database with different types of information, including the physicians' affiliations, background and personal communication, would be required. Despite the limitations of the
database used in this study, our results indicate that social network analysis can be used to detect irregularities in the system of transactions between companies and physicians and to identify influential clusters and companies. Another disadvantage of the approach used in this study is the low density of the network. Although the current analysis was sufficient to identify influential clusters, to provide further insight into the interactions within and between clusters, and the influence of specific companies within the different groups, network analysis should be performed on individual clusters.

5.1 Future perspectives
To fully understand the influence of the pharmaceutical industry on research, education and healthcare, future research should focus on identifying the most influential companies within clusters. In addition, research should focus on investigating through which type of physicians companies exert their influence and whether clusters can become more influential by involving physicians in more than one company. Understanding the extent and nature of the interactions between the pharmaceutical industry and physicians and identifying the most influential companies, will help to fight backstage lobbies and reduce wasteful healthcare spending and inappropriate influence.

6. Author contributions
FB designed the study, collected and analyzed all data, and wrote the paper. MD, MT, YA, BC, KP have discussed the data and wrote the paper. All authors approved the submitted manuscript.

Reference
31.

Contact to the Author:
Bartoccioni F, M.D.
Email: filippobartoccioni@gmail.com
Postal Address: Via Bogliasco 38, 00165 Rome, Italy
NURSES PERCEIVED BARRIERS OF USING CODE NARRATOR TO DOCUMENT Cardiac Arrest in the Electronic Medical Record

Fatima Arastu, Cherie Fontes, Seema Sulemani
Holy Names University, School of Nursing

Abstract
Cardiac arrest is a life threatening emergency situation for all the patients admitted to the hospital. Accurate documentation of all the interventions during cardiac arrest also referred, as code blue is required to identify quality outcomes and performance of resuscitation interventions. The literature demonstrates that the transition from paper documentation to electronic documentation improves the accuracy and ultimately the quality of care during a code blue. In Northern California, at a 613 bed, Level I trauma center, the hospital utilizes Code Narrator, an added feature of the Electronic Medical Record (EMR) flow sheet that captures code blue data in real time. The study was conducted by a triad of graduate nursing students from Holy Names University to understand the nurse's perceived barriers to documenting codes in real time in the EMR. This quality improvement project consisted of a sample size of 111 nurses that completed surveys in April 2016 over a period of two weeks. The survey included demographic data and nine multiple-choice questions that inquired the nurses barriers to utilizing Code Narrator, a program offered through EPIC software; such as lack of standard roles, training and education, and ease of use. The key elements from the survey were analyzed using descriptive statistics to determine the correlation between the perceived barriers and real-time documentation in EMR. Based on these results, investigators formulated a recommendation plan to optimize the use of Code Narrator. Of the participants surveyed, 70% said that real time documentation during code blues improved patient outcomes. Therefore, accurate and complete documentation of all interventions during cardiopulmonary resuscitation (CPR) is necessary to improve quality outcomes.

Key Words: Code Narrator, real-time documentation, nurses perceived barriers

1. Introduction
Patient safety has become a national focus. Cardiac arrest also referred to as a code, results in numerous deaths and morbidity in the hospital setting every year. In 2004, the Institute for Healthcare Improvement's (IHI) "save a 1000 lives campaign" rallied institutions to deploy a Rapid Response Team (RRT) as an initiative to improve patient outcomes. The Joint Commission accreditation process shifted from survey...
preparation to a focus of always being prepared and routine standards of resuscitation practices. The key to successful code implementation is staff education and training. In the current healthcare system, due to shrinking budgets and lack of immediate resources, new policies and programs can be challenging. Hence, leaders need to be more creative in providing staff education and reinforcing documentation during situations when a patient is deteriorating.

Code Narrator is an added feature in EPIC, an Electronic Medical Record (EMR) flowsheet, used to capture documentation of cardiac arrest in real time. In Northern California, at a 613 bed, Level I trauma center, Code Narrator profile is available to all Emergency and Intensive Care Unit (ICU) nursing staff to document in real time. However, it is not being optimized to its full capacity in the ICU department. With the goal to transition the paper documentation of code blue consistently to Code Narrator in ICU, it is essential to understand the nurses perceived barriers that exist and inhibit the use of Code Narrator to its full potential. This study assisted in developing a robust plan to improve optimization of Code Narrator and accuracy in documentation. Accuracy in capturing data during codes will have a more meaningful impact on patient outcomes, research, and billing purposes. Documentation that does not meet the “gold standards” set by Joint Commission or American Heart Association (AHA) may have legal implications.

2. Literature Review

An in depth search of the current literature was done using CINAHL, Proquest, and OVID databases using keywords: CPR, cardiac arrest documentation, emergency documentation during cardiac arrest, electronic medical records, technology during cardiac arrest, role delegation and code team structure and barriers. In order to establish standards and guidelines to facilitate the research related to cardiac arrest worldwide, a symposium was held in 1992, at Utstein Abbey, Norway that was attended by executives’ world wide. During the conference, effectiveness of different systems and interventions were reviewed, resulting in the formulation of Utstein’s gold standard guidelines. These guidelines are to start CPR within one minute, to deliver the first defibrillation within three minutes when ventricular fibrillation or pulseless ventricular tachycardia is the initial rhythm, successful intubation within five minutes, and administer the first dose of intravenous or intraosseous epinephrine within five minutes. Utstein’s guidelines provide uniformity in reporting CPR interventions in a timely manner that has been proven necessary to improve patient outcomes. Documentation of these guidelines is essential in evaluating the effectiveness of the interventions. Inadequate documentation of these interventions delays care and ultimately is responsible for increased morbidity. The timely capture of interventions during CPR is crucial for planning and delivery of care in the post CPR phase. The EMR has replaced paper documentation, yet in most emergency departments trauma resuscitations are still primarily documented on paper. Resuscitations are done at a rapid pace and organizations have identified concerns about the timeliness and thoroughness when documenting in the EMR.

2.1 Role Standardization

Evidence based research confirms that code team restructuring provides a defined number of code team participants, with clear identification and primary responsibilities, which will improve patient outcomes. One of the studies reviewed 118,387 adult in-hospital cardiac arrest records from January 2002 to August 2008 from 549 hospitals in the US, which demonstrated effective leadership and teamwork, rather than individual skill and knowledge, is crucial for the success of resuscitation efforts. The recommendation is to use closed loop communication, ensuring the leader is clear and concise in relaying information to all team members. Hence, leadership and team training became the main focus of the AHA recommendations in 2010.

2.2 Documentation

For centuries healthcare organizations documented the care provided to patients in a paper format. The EMR provides a structured format in the form of flow sheets to document information related to vital signs as well as describe a patient’s condition. Although the EMR was introduced in the early 1980s, the accuracy of documentation during emergent conditions is still unproven using EMR. According to American
Recovery and Reinvestment Act (ARRA) of 2009, hospitals across the US are expected to become meaningful users of electronic health records by 2014. With nurses representing the largest portion of healthcare providers, use of electronic nursing documentation ensures important patient information is readily available. Use of EMR for documentation improves the overall quality of care to hospitalized patients and meets the meaningful use criteria per ARRA\textsuperscript{13, 14}.

In the US, the Institute of Medicine (IOM) reported in 2006 that medical errors are the eighth leading cause of death and cost approximately $36.7 billion, of which $17 billion is associated with preventable errors\textsuperscript{15}. Utilizing real time documentation, charting while care is being provided rather than at completion of care, will help to decrease those documentation errors. The benefits of utilizing an EMR include a decrease in missing records, less medication errors, and minimum transcription errors\textsuperscript{16}.

2.3 Code Technology
Nurses are the largest group of users that document most frequently in the EMR. A study conducted by Carrington and Effken showed there are often discrepancies between the care given and the care actually documented\textsuperscript{17}. It is important to understand the strengths and weaknesses of the EMR as well as alternative technology available. A few of the electronic systems to document codes are Code Narrator, Eventdoc, and Full Code Pro application. Randomized studies and trials done with these applications reiterate that conventional paper documentation is often inaccurate and unreliable\textsuperscript{18, 19, 20, 12, 7, 8}.

The most critical function of real time documentation is to not only track but to evaluate if interventions were appropriate and contributed to improving quality of life. Access to real time documentation not only allows physicians to make informed decisions but also will assist risk management in determining if the organization is following standards and determine liability. Accurate documentation also assists in identifying gaps in standards followed and introduce appropriate process improvement methods.

3. Framework
Clinical scholars and health service researchers at the University of Pennsylvania, in collaboration with the Penn’s School of Nursing Faculty, and a team of Advance Practice Nurses (APN) developed a Transitional Care Model (TCM) designed by Dr. Mary Naylor in 1981. This was initially tested to allow early transition of the care of low birth weight infants, from hospital to home, where the follow up care was provided by the APNs. Transitional care can be defined as several environments and services that enable the safe passage of patients across all the continuums of healthcare\textsuperscript{22}. As indicated by Dr. Naylor, streamlining the documentation in the EMR will provide easy access to the data in the EMR and reduce expenditures related to the quality of care. It will also standardize the practice of code interventions and assist in capturing data efficiently\textsuperscript{23}. If designed and used appropriately, documenting in the EMR will minimize the risk related to the disproportion of health care costs related to paper documentation cost, paper chart audits, and enable large data storage, which will be available for future quality improvements, by readily identifying the gaps in delivery of care during codes. The TCM was utilized as a framework to drive this quality improvement project.

3.1 Operational terms and concepts
Code blue or code. AHA reports sudden loss of heart function as cardiac arrest and recommends Advanced Cardiac Life Support (ACLS) guidelines to perform interventions for CPR, which in most of the hospitals across US, is described as either code blue or simply a code. Throughout this paper, the events related to CPR are referred to interchangeably as code blue or a code. The interventions during a code blue can be recorded on paper or electronically. As a result of the chaos and emergency during code blue, historically the documentation has been done on paper. However, with the introduction of the EMR, and as supported by the literature reviewed, electronic charting captures better and more accurate data. Hence, at this Level 1 trauma center, in Northern California, a quality improvement project was conducted to assess the perceived barriers of the nurses for optimum utilization of Code Narrator in the EMR.
Code narrator (Dependent variable). At this level I trauma center, EPIC is the EMR software utilized for patient records and “Code Narrator” is a part of the EPIC software. Code Narrator is a specific flow sheet that needs to be opened at the beginning of every code. Once started, the recorder assigns roles to code team members. All medications must be ordered under the physician team leader prior to administration. All interventions are documented through selected tabs as being performed24.  

Code narrator ease of use (Independent variable). There are several issues with Code Narrator that make it difficult to use. All vital signs need to be entered manually every time and filed by the recorder, which should be automatically transmitted, as is done directly from bedside monitor in other areas of the patient chart in the EMR. Once the Code Narrator is started, the recorder is unable to navigate to other parts of the EMR to obtain pertinent patient information, such as history, allergies, notes, or medications until the code is ended. When the recorder attempts to order medications, all dosages of medications appear in the search field, rather than the ACLS recommended medications and dosages24.  

Training and education (Independent variable). All training and education related to Code Narrator use in the EMR requires a carefully planned didactic class, hands on training, and practice, with the best and worst case scenarios. In addition due to the complexity of the operations related to Code Narrator, confusion during codes, and infrequent use, an annual review of system and software upgrades is recommended for all users. For the purpose of this quality improvement project ideally a 90 min training session, which includes 30 min of didactics and 60 min of practice sessions, for all users, and a 2 h training session for the super users will be considered adequate training. Super users will be the department charge nurses and float nurses, who are resourceful and are available at all times to address any concerns related to use of Code Narrator.  

Role standardization (Independent variable). AHA utilizes ACLS protocol to treat a patient in cardiac arrest. One of the latest recommendations, as per the revised 2010 guidelines, is role standardization of the healthcare team that responds to the code. Role standardization involves each team member having a clearly defined role and also an assigned role to carry out the complex and lifesaving interventions during the code. The important roles, as recommended by AHA, are team leader, recorder, compressors, respiratory, vascular access or medication nurse, and code cart nurse25.  

The clear understanding of the code team roles, in addition to adequate training and education related to Code Narrator use, are crucial for the documentation of codes in the EMR. Further, the functionality of the Code Narrator related to vital signs and all interventions during a code, easy access, and promptness are all key for utilization of Code Narrator by the nurses during a code25.  

Demographics (Independent variable). The demographics related to the use of Code Narrator could not be eliminated. The age of the nurses, years of experience, number of years in the current unit, number of codes participated in, and comfort level with documentation in EMR all need to be considered to determine the nurse’s ability to successfully use Code Narrator to document codes.  

The research related to perceived barriers of the nurses to utilize the EMR during emergency situations is limited. This provided an excellent opportunity for the researchers to develop strategies to enable nurses to capture code in real-time. Based on these findings, the proposed study was done to determine if a lack of standardized roles and education and training on the use of “Code Narrator” in EPIC were the perceived barriers to nurse’s ability to document codes in real time accurately in the ICU.

4. Methods  
4.1 Design  
The design for the study was a qualitative improvement project to understand the nurse’s perceived barriers that impact their ability to document in Code Narrator during codes. The dependent variable; the use of Code Narrator, and the independent variables; education, training, demographics and role delegation were compared. The study also compared the relationship between age of the nurse and their comfort level with using the EMR. In addition, the study compared the proportions to assist researchers to better understand how specific independent variables impact the use of Code Narrator. The permission to conduct the study at a Level I trauma center in Northern California was obtained. The proposal was submitted and approved by Holy Names University’s (HNU) Institutional Review Board (IRB) prior to proceeding.
4.2 Participants
Nurses working, day and night shift, on three units at a Level I trauma center were eligible to participate in the study. The three units included in the study were a coronary care unit, a postsurgical and trauma intensive care unit, and a cardiothoracic surgery intensive care unit. Of the 340 eligible participants, 157 nurses were requested by researchers to participate in the study. The nurse participant’s chosen were a sample of convenience based on their assignment, work schedule, shift time, census and acuity of their patients. Of the 157 nurses that were requested to participate, 111 (n=111) nurses completed the survey.

4.3 Ethical Considerations
HNU IRB approval and clinical agency consent permission was obtained. All three investigators who had access to the data and to the participants, completed human subject training in study delivery that allowed for protection of data and participants throughout the quality improvement project. In order to minimize and protect extraneous variables, the investigators used standardized scripts, attire and processes for data collection and storage. Upon collection of survey, investigator’s debriefed the participants and provided information for follow up regarding the study. Researchers ensured the participants understood that their privacy will be maintained and that any personal information obtained through survey will not be made available to the public. During the debriefing, surveyors minimized the threat to internal validity by advising the participants to not discuss the survey until the project is completed and results are analyzed.

4.4 Instruments
The paper survey included five multiple-choice demographic questions, nine multiple-choice questions regarding nurses perceived barriers to documenting in Code Narrator, and four open-ended questions to allow for participant feedback. Four of the demographic questions pertain to age, years of experience, and number of codes, all using ratio measurement. The last demographic question was to determine the comfort level of nurse’s documentation in EMR using an ordinal measurement. There are five ordinal yes/no answers to questions regarding education and training, roles of team members, and impact on quality outcomes. There are four questions that were focused on current practice and recommendations using nominal measurement. The four open-ended questions are reviewed by the investigators to determine themes and were grouped into key elements for statistical analysis. The goal of the survey was to determine the nurse’s perception of the education and training received in Code Narrator, understanding of role delegation and standardization, and obtain nurse’s recommendations to optimize the use of Code Narrator in the ICU.

4.5 Procedure
All efforts were taken by the investigators to standardize the procedure for data collection. All investigators agreed to dress in black slacks and a black blouse, wear a Holy Names University name tag, and a visitor access badge provided by the Level I trauma center. Participants consisted of 10-20 RNs working 12-h day and night shift on Monday, Thursday and Saturday on all three ICU units, depending on the daily patient census, for a total of 111 RN participants. The investigators randomly approached and invited the participants in-person to participate in the survey, which took less than one minute. Participants signed the consent form, which described the quality improvement project, risk to the participant, and confidentiality of the survey. The investigators provided a blank copy of the consent form to the participant after signing, which enabled the participant to contact the investigators for any further questions related to the study by email or phone. It took participants less than two minutes to read and sign the consent form. After the consent was signed, participants completed the survey, which took 3-10 min to complete. Upon completion, participants were thanked for their participation and debriefed immediately. Researchers sorted surveys by unit and assigned participant numbers. All surveys were divided by unit and coded with a specific numerical identifier and all personal details were excluded. Each researcher then entered the results for a designated unit in the data analysis tool based on the values assigned to the responses from the data codebook. Signed consent forms from the participants and completed surveys were scanned into one researcher’s computer, which is password protected, and paper documents were then shredded. All documents stored in researcher’s computer will be destroyed three years after completion of study. Demographic information and responses were not shared with department administrators or the organization.
Any information obtained through the surveys was not made available to the public.

4.6 Time Frame
Investigators were on-site for a duration of four days; Monday, Thursday, and Saturday, over a period of two weeks, during April 2016. The researchers were present on the unit for a minimum of three hours at the end of day shift and three hours at the beginning of night shift. The data collection and analysis began with distribution and collection of the first survey and ended two days after the collection of the last survey. Completed survey results were compiled after two weeks and grouped into key elements by the investigators.

5. Results
5.1 Data Analysis
Collected survey data was analyzed using descriptive statistics. Reports of the study were reported aggregated to the organization. The findings were used to determine the correlation between the nurse's perceived barriers and real-time documentation in the EMR, which facilitated investigators to formulate recommendations for an implementation strategy. In the current study, investigators were not manipulating the independent variables. The study design was a qualitative research study that used measurement methods; ratio, ordinal, and nominal. The independent variables were: demographics; education and training; and role standardization. The researcher's developed a codebook, which assigned numerical values to each categorical data and defined the variables. Content analysis of open-ended questions was assigned a theme based on key elements and assigned a numerical value. Each researcher entered the survey data from one unit on a standardized data analysis tool. Questions with additional opportunity for comments were assigned as a subcategory. For example, question 8 (Q8) allowed the participant to add additional comments, which was then categorized as question 8A (Q8A).

The data entry was completed over five days and analyzed by statistician and researchers. Researchers provided the statistician with the completed data collection tool and requested to determine the significant statistical relationship between independent and dependent variables.

5.2 Statistical Analysis
Demographics. Of the 157 RNs requested to complete the survey on all three units, researchers received 111 completed surveys (n=111), which was a 70.7% participation rate. The average age of participants that completed the survey were 26-30 years (21%) and 31-35 years (21%). The median age of nurses that participated in the survey were 31-35 years. The median years of employment at the organization was less than five years (57%). The median years of employment on their current unit were also less than five years (61%). On average, 64% of nurses stated they had participated in less than five codes in the previous 12 months and 63% of nurses stated that they were very comfortable in documenting in the EMR.

There was a statistically significant relationship between the age of the nurse and their comfort level in using EMR with a X-squared of 32.7862 and p-value of 0.000295. Figure 1 shows the relationship between age and comfort level in documenting in EMR. The higher the age, the less comfortable nurses were with documenting in EMR. It was found that there was not a statistically significant relationship between the number of codes participated and designated team member roles during a code with a X-squared of 3.0579 and p-value of 0.3828. There was also not a statistically significant relationship between standardized roles and designated team member roles with a X-squared of 0.8498 and p-value of 0.99.

![Figure 1. Age of RN and comfort level with documenting in EMR](image-url)

Education and training. The majority of participants (62%) stated that they currently documented codes on a code blue worksheet and 58% of participants responded that they were never trained on Code Narrator. Of the 42% that said they had received training, 63.8% of those felt the training was inadequate. Only 23% of participants felt that training was too short and there was not enough practice time, whereas, 44% of participants found that the Code Narrator...
was not user friendly and the program was difficult to navigate.

**Role standardization.** According to 43% of participants, the role of the primary nurse was to maintain IV access and administer medications (see Figure 2). Of the participants that completed the survey, 79% said that there were designated team member roles and 73% of those said that the roles were standardized and clear to all team members (see Figure 4). Only 12% of participants said that roles were assigned during the code and not necessarily predetermined.

![Figure 2. Role of the primary RN during a code](image)

**Recommendations.** On average, 34.5% of participants recommended that in order to transition from paper to Code Narrator during code blue, additional training and simulation labs to practice on Code Narrator is essential for its optimization. In addition, on average 18% suggested improvement in the functionality of Code Narrator in the following areas; streamline ACLS medications, cross-over vital signs from flow sheet, allow the minimization of the screens, and enable navigation between the flow sheets in the patient's chart. Of participants surveyed, 70% felt that real time documentation during code blue improves patient outcomes.

6. **Discussion**

The results from the study supported the researcher’s hypothesis that the majority of participants perceived that a lack of training and education in Code Narrator inhibited their use. However, role standardization proved otherwise and it's still unclear. Results of the study showed that participants felt there were designated roles that were clear and standardized, however, only 43% of participants had an agreement on the role of the primary nurse during a code. However, 28% selected multiple answers for the role of the primary RN, which shows role standardization is unclear. The researchers requested from the organization any educational and training information that was provided to the staff to determine the duration and type of training that was received. The investigators were unable to obtain this information. In conclusion, the results of the survey, in relation to education and training, were purely based on the responses from the participants.

Based on the barriers and recommendations identified from the participants, researchers were able to formulate the following key recommendations for optimal use of Code Narrator in the EMR:

- **Structured training for all staff in ICU on Code Narrator**
- **Yearly computer practice modules and competency**
- **Further clarification and standardization of roles during code and revision of standard work for each team member during code blue**
- **Quarterly simulation lab practice**
- **Improve functionality of Code Narrator software: include crisis nurses and end users to reformat**
- **Management support in implementation of Code Narrator and consistency through quality audits and encourage nurse participation in resuscitation committee to improve quality outcomes**
- **Increase computer availability during code blue. For example, iPad on crash cart as designated code computer or additional computers in room for charting**
- **Designated super user and trainer for each unit**

**Extraneous Variables**

Some of the extraneous variables that impacted the project were the nurse's receptiveness and willingness to participate depending on the acuity, census and staffing level, the culture of the unit,
the approach of researchers, impending labor negotiations, possible sharing of survey questions, and the time frame of survey completion. On days that the census and acuity was high, nurses were more reluctant to participate, as they were short staffed. The researchers approach to the participants varied depending on their personality and ethnicity. Although the researchers had agreed on a standardized approach to request participation in the study, this was not done by all researchers. To control internal validity, the plan was for each researcher to approach nurses individually, utilizing the prepared script, to request participation. This was done the majority of the time except by one researcher on one shift. In that situation, the researcher approached the charge nurse to announce the reason for the study and she then introduced the researcher at the shift huddle to all the nurses working that shift. This could have provided the opportunity for participants to discuss the topic and compare ideas, prior to completing the survey, and created a potential bias amongst participants. Also, the organization was going through union negotiations with a potential work stoppage. This had nurses working under distress and may have impacted their willingness to participate in an improvement project at this time. Those willing to participate were debriefed following collection of the survey and asked not to share questions or their responses with other nurses until the study is completed. However, the researchers were unable to ensure that nurses did not discuss the study after collecting the survey. The researchers time frame of survey completion may have impacted the results. Researchers were on the unit to collect surveys between 4 p.m. to 11 p.m., which only covered the end of day shift and beginning of night shift.

7. Conclusion
The objective of the quality improvement project was to support real time documentation during codes. The study showed that 70% of participants agreed that real time documentation during cardiopulmonary resuscitation improves patient outcomes. The study assisted researchers in formulating recommendations that can be utilized by the organization to transition from paper documentation to the EMR during codes.

7.1 Limitations
The survey responses from the participants could have been different had a research assistant been involved in data collection instead of the primary investigators themselves, or non-nursing personnel to minimize the effects of extraneous variables. Due to the contradictory responses between survey answers on role delegation and standardization of roles, the responses were skewed and impacted the overall results. Based on the answers received, it was determined there was a need for additional questions on the survey in those areas for further clarification. The results of the specific survey questions may have limited the results of the study.

7.2 Future Studies
A comparative study between the three units could be further conducted to determine the differences of nurses perceived barriers based on the patient population and acuity on the unit. Similar studies, in other Northern California hospitals, that utilize EPIC software for EMR, could be replicated to understand real time documentation during codes. The strength of this quality improvement project is that this study can be implied to all nurses working at this Level I trauma center. This study can also be used to identify the perception of the nurses who are currently using Code Narrator successfully in the Emergency Department (ED) of this trauma center. It would allow for further testing of whether the ED setting affects the use of EMR in documenting codes. The functionality of EPIC software during CPR needs to be studied further for simplification in meeting the AHA recommended guidelines.

Reference


Contact to the Author:
Fatima Arastu
Email: Fatima_Arastu@my.hnu.edu
Postal Address: 550 Canyon Oaks Drive, Unit F
Oakland, CA 94605
EVALUATION OF INPATIENT DEATH REPORT: 10-YR EXPERIENCE

Masahiro Ito¹, Yukio Yuzawa², Yuichi Hirose¹, Chizuru Fujita¹, Noriko Hamaguchi¹, Terumi Kinoshita¹, Junichi Yamagami¹, Yoshitaka Katou¹, Keiko Tomomatu¹, Atushi Sugiooka³, Kiyotaka Hoshinaga⁴

1: Department of Quality and Safety in Healthcare. Fujita-Health University
2: Director, Fujita Health University Hospital
3: Vice president, Fujita-Health University
4: President, Fujita-Health University

Abstract

Background: We used inpatient death reports developed in our hospital during February 2006. To determine the number of patient deaths resulting from medical accident, the death reports were prepared by the physician that diagnosed death, and a third person inspected the decision making process.

Methods: Our group investigated the inspection process performed after a death, including the third person’s uninvolved assessment. Inpatient death reports between February 2006 and March 2016 were statistically analyzed.

Results: There were a total of 9,700 inpatient death reports with an average of 96.5 deaths per month. The number of possible medical accidents or unknown death causes (including suspicious deaths) was 3.6 per year and the number of cases of distrust or dissatisfaction of the family was 5.8 per year. Unfortunately, the number of serious medical accidents was 0.9 per year.

Conclusion: The average number of serious medical accidents was considerable in according with Heinrich’s Law. As such it is more important to not miss serious cases, than to identify thousands of minor events. This incident reporting system is a new and important effort for preventing serious incidence as well as for identifying minor events.

1. BACKGROUND

Patient safety research is nascent because current evidence does not provide a reliable estimate on the frequency of incidents related to patient safety in medical care or on the associated disease burden. Well-designed epidemiological investigations are required for identifying contributory factors¹. Most medical and nursing schools in Japan, the US and Canada educate on the topic of patient safety, however the number of hours devoted is modest and teaching methods are suboptimal. Nevertheless, continued inclusion and improvement of patient safety education is a worthy achievable goal²,³,⁴. The process of continuous reflection, education, and action, in which safety events are reviewed as a part of an extended morbidity and mortality meeting, is associated with a reduction in patient safety incidents (PSI). We recommend that PSI reflection should be introduced in mortality and morbidity
meetings with mandatory attendance of the entire, multidisciplinary health care team. We are now focusing on a new patient safety system regarding inpatient deaths as these cases can sometimes include possible medical accidents or unknown death causes (i.e. suspicious deaths).

We utilized an inpatient death report developed in-house during February 2006 and continually used it for 10 years. The physician who diagnoses the death writes a report, and a third person inspects the decision-making process. The purpose of this report is to identify the possibility of medical accidents in the treatment.

2. METHODS

Our university was established in 1964. Fujita Health University is a private, higher education institution located in the large town of Toyoake (population 50,000–249,999), Aichi, Japan. It is one of the largest medical facilities in Japan with 1,435 beds and 11,000 surgical procedures performed every year. It provides a wide range of advanced medical care with an average number of inpatients at 1,241 per day and that of outpatients at 2,155 per day. Several facilities and procedures are offered, including but not limited to cancer treatment, an ER and advanced medical care. The cumulative incident and accident reports totaled 7889 cases in 2015 (Figure 1).

We started using the inpatient death report that we originally developed in February 2006 (Figure 2).

Figure 1: Incident and accident reports: green represents claims; red, incidents; and blue, accidents.

Figure 2: Inpatient death report (in Japanese): The doctor who confirmed the death completed the report. Details: Name, age, disease, diagnosis, explanation given by a doctor to the family, family’s response to explanation, explanation of the need for autopsy, possibility of unknown death or medical accident, and distrust or dissatisfaction expressed by the family.

3. RESULTS

A total of 8,542 inpatient death reports were recorded with an average of 89.3 cases per month between February 2006 and March 2016 (Figure 3). The ratio of deaths among in- and out-patients was 8.5:1.5 in 2015 (Figure 4). We investigated the process involved in inspection performed after a death by conducting statistical analysis of inpatient death reports.

The number of possible medical accidents or unknown death causes (including suspicious death) was 4.3 cases per year, and the number of cases of familial distrust or dissatisfaction with the hospital was 10 per year. Unfortunately, the number of serious medical accidents was 0.9 cases per year (Figure 5).

These cases were reported to a medical accident investigation committee comprised of members from outside the hospital and the survey results were reported to the Japanese government.
3.1 An example of a serious case:
A patient with von Recklinghausen’s disease (a 54-yr-old male) was admitted to the emergency room with a massive hemorrhage of the right kidney (Figure 6). Right nephrectomy and evacuation of the hematoma was performed. Suddenly, the inferior vena cava started bleeding, which could not be stopped, leading to death from blood loss (Figure 7).

The safety management team was contacted and it was judged that a sudden change during the operation resulted in an unexpected death in conjunction with the medical intervention.

The hospital director decided to investigate the process of death using an analytical model. It was found that determining the weakness of the blood vessel, regardless of whether it was an artery or a vein, was macroscopically difficult, and achieving hemostasis was impossible. The report stated that this was an example of a case where the warning signs should have been recognized due to the weakness of the blood vessel in the von Recklinghausen’s disease patient (Figure 8).

4. DISCUSSION
An incident reporting system is the most commonly used method to identify patient safety in a hospital. However, non-reporting of incidents for various reasons is a serious problem. One report states that the rate of non-reporting of inpatient falls in a Japanese acute care hospital is comparable to that shown in previous studies in other countries, and the same barriers exist among medical staff as those reported in previous studies6. Another report describes the largest retrospective study of hospital falls and encompasses data from almost 500 institutions of varying types. It describes wide variations in recording and reporting of falls. As falls are the most commonly occurring patient safety incidents, there is a pressing need for improvements in local reporting, recording, and focused analysis of incident data. These data should also be used at local and national levels to better inform staffs and target fall prevention strategies as well as to explore reasons for the large apparent differences in fall rates between institutions7.

In a university hospital providing advanced medical care, the unexpected death from a safety incident is a burden on the physician places the hospital at risk, and alters the life of patients’ and their families.
The number of serious medical accidents in our system was 0.9 cases per year. However, as Heinrich's Law implies, it should be more important to not miss a few serious cases than to report thousands of minor incidents.8,9,10 This incident reporting system was thought to be a new, important effort for preventing serious cases as well as minor incidents. The construction of an organized medical care safety management system will lead to improvement in future medical care such as medical quality improvement and medical transparency.

Figure 6: Computed tomography scan: the patient who arrived in the emergency room of von Recklinghausen’s disease with massive hemorrhage of the right kidney.

Figure 7: Sudden bleeding from the inferior vena cava that could not be stopped, resulting in death from blood loss. The blue arrow is the bleeding point.

Figure 8: Difficulty in judging the weakness of this blood vessel macroscopically, regardless of artery or veins, thus making hemostasis impossible.

Reference


Contact to the Author:
Masahiro Ito
Email: masito911@yahoo.co.jp
Postal Address: Department of Quality and Safety in Healthcare. Fujita Health University
MEDICAL SAFETY AWARENESS SURVEY OF HOSPITAL NURSES IN JAPAN

Takahiro Miyoshi¹, Yukiko Kai²
1: Department of Fundamental Nursing, Kurume University School of Nursing
2: School of Nursing, Faculty of Medicine, University of Miyazaki

Abstract

Purpose: The purpose of this study was to examine medical safety awareness among hospital staff in several hospitals in Miyazaki Prefecture.

Methods: We conducted a field survey on hospital staff’s medical safety awareness using a questionnaire and the Medical Safety Climate Scale created by Matsubara. Results were compared between nurses and other professionals (T test), and according to work experience (analysis of variance, multiple comparison). We also reviewed opinions about medical safety.

Results: We collected 540 surveys (response rate, 74.6%; valid response rate, 95.6%). Differences were recognized in medical safety awareness between nurses and other professionals as well as by work experience.

Conclusions: Compared to allied professionals, nurses found it more difficult to communicate due to an authority gradient. Furthermore, all participants felt that free and open communication was necessary regardless of occupation. It also became clear that a negative perception of errors exists. Health care organizations should aim to achieve high safety consciousness through continual encouragement and education of nurses.

Key Words: errors, medical professionals, medical safety awareness, medical safety climate scale, communication

1. Introduction

Globally, extensive research has examined organizational safety awareness. Miyachi1) stated, “It is important to work on improving the working environment by surveying workers and staff with questionnaires, and by using that data to objectively and quantitatively evaluate and analyze the good and the bad of the safety climate to foster a good safety climate.” However, no previous research has followed this advice in the Miyazaki Prefecture. Additionally, while working as a nurse in hospitals in Miyazaki Prefecture, one of the authors observed that medical incidents were sometimes not reported even when noticed, leading to a reduced number of filed incident reports. Accordingly, we considered that hospital staff may perceive medical safety requirements negatively. To test
this possibility, we surveyed medical safety awareness among medical practitioners, focusing on nurses in the field and using the Medical Safety Climate Scale developed by Matsubara.2) This survey was conducted to generate data to inform improvements in healthcare professionals’ education and working environment and promote organizational safety consciousness.

2. **Purpose**
This research aimed to examine medical safety awareness among hospital staff in several hospitals in Miyazaki Prefecture.

3. **Definitions**
Medical safety climate: a group’s medical safety awareness and consciousness.
Medical safety awareness: appropriately directing one’s attention to medical safety.

4. **Working Hypothesis**
We hypothesized that nurses negatively perceive medical safety reporting because they fear attracting individual blame through error. We further hypothesized that medical safety awareness varies depending on occupation type and years of experience the nurses have, and this may be a contributing factor that interferes with team-based medical care.

5. **Method**
5.1 **Research Design**
A quantitative approach involving anonymous self-administered survey questionnaire was used.

5.2 **Participants**
Participants were 748 full-time nursing staff and allied professionals (e.g., doctors, pharmacists, therapists, medical technicians) in hospitals A–D, which had 100–300 beds each, in Miyazaki Prefecture. All staff at each hospital were included, except for part-time staff.

5.3 **Questionnaire**
The questionnaire was structured in two parts; its wording and applicability were verified using a preliminary survey.

5.3.1 **Medical Safety Climate Scale**
There are two types of Matsubara’s Medical Safety Climate Scale (8 factors, 33 items), one for nursing staff, pharmacists and medical technicians, and another for doctors and medical interns. The scale examines the following factors:

Factor 1: Free communication flow
Factor 2: Continuous improvements
Factor 3: Reporting/rules compliance
Factor 4: Patient/family involvement
Factor 5: Supervisors’ safety leadership
Factor 6: Allied professionals’ safety leadership
Factor 7: Safety management committee’s leadership
Factor 8: Rules/equipment availability

Answers were obtained using a Likert-type scale ranging from 1 (I disagree) to 5 (I agree). Additionally, factor 3 is a reversed item. The question was reversed in a way that the higher the score, the more positively affirming is the statement. Matsubara’s research2) has verified the reliability and validity of the scale.

5.3.2 **Medical safety awareness**
The question items (1) to (3) were created based on prior research3) 4).
(1) Possible responses to the item “Did this survey increase your awareness regarding medical safety?” were yes or no; participants gave open-ended explanations of their response.
(2) “Elements that help create a safer organization” used 14 multiple-choice items.
(3) Responses to the item “Problems with medical safety and report systems” were open-ended.

5.4 **Data Collection**
Subjects received the questionnaire and an envelope from each department head. Following completion of the survey, participants individually sealed their response in the envelope and dropped it into a collection box. A time limit of two weeks from the survey’s distribution date was set; the researchers collected the responses after this time limit lapsed.

5.5 **Survey Period**
September 17–30, 2013

5.6 **Data Analysis**
SPSS version 20.0 was used for data analysis. Statistical significance was set at $p < 0.05$.

5.6.1 **Understanding working conditions using the Medical Safety Climate Scale**
(1) Comparing nurses with similar professionals
We performed t-tests to compare participants’ mean score for each factor.
(2) Comparison based on years of experience
Nurses were split into the following experience categories: 1–2 years, 3–5 years, 6–10 years, and ≥11 years. Analysis of variance (ANOVA) and multiple comparison analysis were used to compare mean scores between these categories. Scores for reverse-scored items were reversed.

5.6.2 Selection items and open-ended questions examining medical safety awareness
(1) Responses to the question “Did this survey increase your awareness regarding medical safety?” were tallied through simple aggregation; this result and participants’ responses to the open-ended question were used to evaluate increases in participants’ awareness. (2) Responses to the section “Elements that help create a safer organization” were calculated per item using the percentage of participants selecting that item. The $\chi^2$ test was used to compare nurses with other professionals. (3) Responses to “Elements that help create a safer organization” were divided into four groups based on nurses’ years of experience (as described above) and compared using the $\chi^2$-test. (4) “Problems with medical safety and report systems” and “Other thoughts and opinions” were addressed using open-ended questions. In this report, we aggregated only nurses’ responses and categorized these based on common themes.

5.7 Ethical Considerations
Approval for this research was obtained from the Medical Ethics Committee, University of Miyazaki, Faculty of Medicine (Approval Number 2013-023), and Hospital A Ethics Committee (Number 25-4). A request to participate in the study and an explanation of the research’s scope was provided to each Director of Nursing in Hospitals A–D and received approval. Participants received a written explanation describing how the results would be shared and stating that participation was voluntary, that they could withdraw at any time and for any reason without penalty, and that their privacy would be protected. Submission of a response was considered to indicate consent to participate. Use of the Medical Safety Climate Scale was granted by Matsubara over the phone and through a signed document.

6. Results
6.1. Participant characteristics
The response rate was 74.6% (558 of 748 potential participants). Out of the collected responses, 95.6% were deemed valid (540 of 558). Valid responses were distributed as follows: Hospital A: 87, Hospital B: 57, Hospital C: 267, and Hospital D: 129. Participants’ occupations were as follows: nurses: 419, doctors: 25, pharmacists: 17, therapists: 45, medical technicians: 34 (non-nurses: 121). On average, nurses were aged 34.8 ± 10.0 years and had 11.1 ± 9.0 years of experience. Allied professionals were aged 36.3 ± 10.1 years and had 12.6 ± 8.6 years of experience. Nurses’ experience was distributed as follows: 1–2 years: 65 participants; 3–5 years: 84; 6–10 years: 77; ≥11 years: 175, unspecified: 18.

6.2 Reliability of the Medical Safety Climate Scale
Cronbach’s $\alpha$ was used to examine the reliability of the Medical Safety Climate Scale. Factor 4 (Patient/family involvement) scored 0.76, all other factors scored ≥0.84, and the complete scale scored 0.85. These results supported the scale’s internal consistency reliability.

6.3 Examining working conditions using the Medical Safety Climate Scale
6.3.1 Nurses compared with other professionals
Nurses gave lower scores on “Free communication flow,” “Continuous improvements,” and “Allied professionals’ safety leadership” than allied professionals did ($p < 0.01$; Table 1). No other differences were significant.

6.3.2 Comparison based on nurses’ years of experience
The 1–2 year group had significantly higher scores on “Report ing/rules compliance” than the ≥11 year group ($p < 0.001$). The 3–5 year group had significantly higher scores on “Safety management committee’s leadership” than the ≥11 year group ($p < 0.05$). The 1–2 year group had significantly higher scores on “Rules/equipment availability” than the 6–10 year group and the ≥11 year group ($p < 0.05$). No other differences were significant.

6.4 Changes in medical safety awareness
6.4.1 Closed and open-ended responses were collected for the question “Did this survey increase your awareness regarding medical safety?” A total of 331 participants (61.3%) responded affirmatively; these participants tended to report that the survey caused them to “reflect on my own actions.” One hundred and seventy-nine participants (34.6%) responded negatively (indicating no change in awareness); these participants tended to report that they were “already conscious of medical safety in daily practice.” Thirty participants did not provide valid responses.

6.4.2 Regarding “Elements that help create a safer organization.”
(1) Comparing nurses with other professionals
Nurses gave lower scores than allied professionals for “Free communication flow,” “Reporting/rules compliance,” and “Safety management committee’s leadership” (p < 0.05; Table 2). Nonetheless, almost half of nurses (46.5%) responded affirmatively to “Free communication flow.” Nurses gave higher scores than other professionals for “Managing working hours” (p < 0.001). No other differences were significant.

(2) Comparison based on nurses’ years of experience
Participants’ years of experience significantly affected the proportion of participants selecting “Continuous improvement with rules and processes,” “Safety management committee’s leadership,” and “enhancing medical safety education” (p < 0.05). No other differences were significant.

6.4.3 Nurses’ responses to open-ended questions regarding “Problems with medical safety and report systems.”
Codes are presented in < >, subcategories are presented in << >>, and categories are presented in [ ].
Twenty-three subcategories and five categories were extracted from 212 codes (Table 3). In order of frequency, the most common categories were as follows: [Lack of understanding regarding medical safety], [Worries regarding the work environment], [An environment not conducive to stating one’s opinion], [Lack of information sharing], and [No reporting system has been set up]. The most common subcategories were as follows: <<Some doctors have an uncooperative attitude towards medical safety>>, <<Lack of medical safety education>>, <<Too few reports on close calls and medical incidents>>, <<Work is very complicated>>, <<Lack of staff>>, and <<Too much emphasis on individuals being pursued when a report is made>>. These extractions were common through hospitals A–D.

7. Discussion
7.1. The situation regarding medical safety awareness
Using the Medical Safety Climate Scale, we were able to verify that nurses had a significantly lower score than other professionals on “Free communication flow” and “Allied professionals’ safety leadership.” This suggests that nurses experience more difficulty in communicating due to an authority gradient, compared with allied professionals. As Yamauchi states, “It is necessary to minimize the authority gradient, and create an environment where people can point out matters they noticed and exchange opinions frankly”; it is necessary to create an environment that allows smooth communication between superiors and subordinates.
Nurses with more experience tended to give lower scores for medical safety awareness. This may be because although “veteran nurses are not only capable of providing high-quality care, but are also able to contribute to medical safety by showing their matured experiences through their work to younger workers,” and are perceived as practicing with full awareness, they themselves tend to believe that they could do better and therefore evaluate themselves lower.

7.2. Changes in medical safety awareness
Nurses and other professionals rated “Free communication flow,” “Continuous improvement of rules and processes,” “establish conferences to prevent recurrences” as important in “Elements that help create a safer organization.” Nurses less commonly selected “Reporting/rules compliance”; this may be because “nurses have always felt ensuring safety was an important task, and when accidents, close calls, and medical incidents occur, they were to report to administrators to analyze the situation together to avoid a repeat in the future. This is something they do as a matter of routine,” and thus for nurses, it is likely that reporting and following the rules are already part of their consciousness and mode of operation.
Nurses may have considered “Managing working hours” necessary because nursing tends to involve changing demands and irregular workflow.
depending on which other professionals are involved or on the patient’ condition.
Nurses with more experience were more likely to rate “Continuous improvement with rules and processes” and “Enhancing medical safety education” as necessary. This may be because nurses become increasingly accustomed to their working environment over time, leading experienced nurses to more calmly compare their ward’s condition with others. Therefore, assigning responsibilities to nurses according to their experience may lead to improvements in organizations’ medical safety awareness.

Responses to open-ended questions indicated that nurses held negative perceptions of reporting safety incidents because they anticipated that making a report would lead to the blaming individual nurses, and accordingly felt uncomfortable making reports. Morinaga et al. stated that in promoting measures to point out errors, health care administrators should shift “from the concept that 'errors and accidents should never happen,' which makes erring a taboo, to the concept that 'humans will always err' and therefore "in order to prevent accidents, we must share the errors." Accordingly, health care administrators should use continual education to dispel such taboos and encourage sharing of errors.

8. Conclusion
The present findings generally support this study’s hypothesis. Additionally, considering the general level of medical safety awareness among hospital staff, continuing to improve health care environments and educate health care professionals will lead to improvement in key outcomes.

The authors plan to conduct a longitudinal survey to accumulate additional data on organizational medical safety. Through objective evaluations and analysis, we believe this will lead to improvement in the environment within organizations as well as in education. The task at hand is then to create a ripple effect that leads to developing and fostering a safety climate and culture.

9. Acknowledgement
The authors express their gratitude to all who cooperated with and assisted in this study.

Citations and References
75. Yamauchi K, Tamari E, Matsuura T. Everybody’s medical safety, the basic of the basics (No.5): let’s collaborate with allied professionals to stay safe! Nursing Today 2012;27: 94-96 [In Japanese]
76. Sakaguchi M. Considering medical safety by your career. Kango 2008;60: 85-88 [In Japanese]
77. Shimamori Y. Rethinking the healthcare delivery system to ensure safety—what is required of nursing administrators to ensure medical safety. The Journal of the Japan Academy of Nursing Administration and Policies 2013;17: 6-14 [In Japanese]
78. Morinaga K, Yamauchi K, Matsuo T. Research on recovery from team errors in preventing medical accidents. Journal of the Faculty of Humanities, the University of Kitakyushu 2003;10: 55-62 [In Japanese]

Contact to the Author:
Takahiro Miyoshi
Email: takahiro_miyoshi@med.miyazaki-u.ac.jp
Postal Address: 777-1 Higashi-Kushihara-machi, Kurume-shi, Fukuoka, 830-0003, Japan
Table 1. Comparison of nurses and allied professions by factors of the Medical Safety Climate Scale (n = 540)

<table>
<thead>
<tr>
<th>Factor (item numbers)</th>
<th>Number of items</th>
<th>Score range</th>
<th>Nurses (n = 419) (mean ± SD)</th>
<th>Allied professionals (n = 121) (mean ± SD)</th>
<th>Total (n = 540) (mean ± SD)</th>
<th>t</th>
<th>p</th>
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</thead>
<tbody>
<tr>
<td>Free communication flow (1-5)</td>
<td>5</td>
<td>5-25</td>
<td>16.8±3.9</td>
<td>18.7±3.9</td>
<td>17.3±4.0</td>
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<td>Continuous improvements (6–10)</td>
<td>5</td>
<td>5-25</td>
<td>17.8±3.3</td>
<td>19.1±3.8</td>
<td>18.1±3.5</td>
<td>-3.614</td>
<td>0.000**</td>
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<td>Reporting/rules compliance (11–14)</td>
<td>4</td>
<td>4-20</td>
<td>16.1±3.1</td>
<td>15.9±3.0</td>
<td>16.0±3.1</td>
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<td>0.645</td>
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<tr>
<td>Patient/family involvement (15–17)</td>
<td>3</td>
<td>3-15</td>
<td>9.9±2.1</td>
<td>10.0±2.1</td>
<td>9.9±2.1</td>
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<td>0.684</td>
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<tr>
<td>Supervisors’ safety leadership (18–21)</td>
<td>4</td>
<td>4-20</td>
<td>15.2±3.0</td>
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<td>Allied professionals’ safety leadership (22–25)</td>
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<td>4-20</td>
<td>11.6±3.4</td>
<td>13.6±3.2</td>
<td>12.0±3.4</td>
<td>-5.881</td>
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<td>Safety management committee’s leadership (26–29)</td>
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<td>4-20</td>
<td>14.5±3.1</td>
<td>14.9±3.1</td>
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<td>Rules/equipment availability (30–33)</td>
<td>4</td>
<td>4-20</td>
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<td>-1.051</td>
<td>0.294</td>
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</table>

Note. T-tests were used to compare the two groups. *p < 0.05. **p < 0.01.

Table 2. “Elements that help create a safer organization” Difference in answers between nurses and allied professionals (n = 540)

<table>
<thead>
<tr>
<th>Selection items</th>
<th>Nurses (n = 419)</th>
<th>Allied professionals (n = 121)</th>
<th>Total (n = 540)</th>
<th>χ²</th>
<th>df</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Free communication flow</td>
<td>195 46.5</td>
<td>71 58.7</td>
<td>266 49.3</td>
<td>5.534</td>
<td>1</td>
<td>0.017**</td>
</tr>
<tr>
<td>Continuous improvement of rules and processes</td>
<td>185 44.2</td>
<td>56 46.3</td>
<td>241 44.6</td>
<td>0.172</td>
<td>1</td>
<td>0.68</td>
</tr>
<tr>
<td>Reporting/rules compliance</td>
<td>130 31.0</td>
<td>54 44.6</td>
<td>184 34.1</td>
<td>7.733</td>
<td>1</td>
<td>0.006**</td>
</tr>
<tr>
<td>Patient/family involvement</td>
<td>80 19.1</td>
<td>27 22.3</td>
<td>107 19.8</td>
<td>0.613</td>
<td>1</td>
<td>0.439</td>
</tr>
<tr>
<td>Supervisors’ safety leadership</td>
<td>101 24.1</td>
<td>29 24.0</td>
<td>130 24.1</td>
<td>0.001</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Allied professionals’ safety leadership</td>
<td>79 18.9</td>
<td>29 24.0</td>
<td>108 20.0</td>
<td>1.534</td>
<td>1</td>
<td>0.245</td>
</tr>
<tr>
<td>Safety management committee’s leadership</td>
<td>67 16.0</td>
<td>31 25.6</td>
<td>98 18.1</td>
<td>5.861</td>
<td>1</td>
<td>0.022**</td>
</tr>
<tr>
<td>Rules/equipment availability</td>
<td>90 21.5</td>
<td>18 14.9</td>
<td>108 20.0</td>
<td>2.559</td>
<td>1</td>
<td>0.122</td>
</tr>
<tr>
<td>Enhancing medical safety education</td>
<td>162 38.7</td>
<td>44 36.4</td>
<td>206 38.1</td>
<td>0.210</td>
<td>1</td>
<td>0.672</td>
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<tr>
<td>Improve accident report system</td>
<td>77 18.4</td>
<td>30 24.8</td>
<td>107 19.8</td>
<td>2.433</td>
<td>1</td>
<td>0.122</td>
</tr>
<tr>
<td>Establish conferences to prevent recurrences</td>
<td>170 40.6</td>
<td>55 45.5</td>
<td>225 41.7</td>
<td>0.921</td>
<td>1</td>
<td>0.348</td>
</tr>
<tr>
<td>Human resource placement</td>
<td>184 43.9</td>
<td>48 39.7</td>
<td>232 43.0</td>
<td>0.690</td>
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<td>0.466</td>
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<tr>
<td>Managing working hours</td>
<td>182 43.4</td>
<td>26 21.5</td>
<td>208 38.5</td>
<td>19.100</td>
<td>1</td>
<td>0.000**</td>
</tr>
</tbody>
</table>

Note. *p < 0.05. **p < 0.01. The χ² test was used to compare the two groups. Items in this factor were multiple-choice.
Table 3. “Problems with medical safety and report systems” (Responders = 125; Code number = 212)

<table>
<thead>
<tr>
<th>Category</th>
<th>Subcategory</th>
<th>Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of understanding regarding medical safety (84)</td>
<td>• There are individual differences in level of awareness in medical safety (30)</td>
<td>B,C,D</td>
</tr>
<tr>
<td></td>
<td>• Some doctors have an uncooperative attitude towards medical safety (14)</td>
<td>A,B,C,D</td>
</tr>
<tr>
<td></td>
<td>• Lack of medical safety education (12)</td>
<td>A,B,C,D</td>
</tr>
<tr>
<td></td>
<td>• Too few reports on close calls and medical incidents (10)</td>
<td>A,B,C,D</td>
</tr>
<tr>
<td></td>
<td>• Not enough analysis on cause of incidents that occur (8)</td>
<td>B,C,D</td>
</tr>
<tr>
<td></td>
<td>• Not enough evaluation or review on countermeasures (5)</td>
<td>A,C</td>
</tr>
<tr>
<td></td>
<td>• The improvement plans on past incidents fade away (3)</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>• Hard to communicate with the doctor (2)</td>
<td>A</td>
</tr>
<tr>
<td>Worries regarding the work environment (58)</td>
<td>• Work is very complicated (27)</td>
<td>A,B,C,D</td>
</tr>
<tr>
<td></td>
<td>• Lack of staff (16)</td>
<td>A,B,C,D</td>
</tr>
<tr>
<td></td>
<td>• Not enough equipment to protect the safety (10)</td>
<td>B,C</td>
</tr>
<tr>
<td></td>
<td>• Medical safety management system is insufficient(3)</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>• Need manual system development (2)</td>
<td>D</td>
</tr>
<tr>
<td>An environment not conducive to stating one’s opinion (37)</td>
<td>• Too much emphasis on individuals being pursued when a report is made (13)</td>
<td>A,B,C,D</td>
</tr>
<tr>
<td></td>
<td>• An atmosphere that makes it hard to report (8)</td>
<td>B,C,D</td>
</tr>
<tr>
<td></td>
<td>• A negative impression towards incident reports (7)</td>
<td>C,D</td>
</tr>
<tr>
<td></td>
<td>• Not enough cooperation within the department (4)</td>
<td>C,D</td>
</tr>
<tr>
<td></td>
<td>• Not enough cooperation among the departments (3)</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>• A trusting relationship with the superior has not been established (2)</td>
<td>B,D</td>
</tr>
<tr>
<td>Lack of information sharing (29)</td>
<td>• Information within the hospital as a whole is not shared (22)</td>
<td>A,C,D</td>
</tr>
<tr>
<td></td>
<td>• Information within the department is not shared (6)</td>
<td>A,B,C</td>
</tr>
<tr>
<td></td>
<td>• Not enough information is collected from the concerning party (1)</td>
<td>A</td>
</tr>
<tr>
<td>No reporting system has been set up (4)</td>
<td>• Not easy to input in the report system (4)</td>
<td>A,C</td>
</tr>
</tbody>
</table>

Note: Multiple-responses
UNKNOWN MICROORGANISM-LIKE PARTICLES IN NORMAL BLOOD

Dr. Louis Van Hecken M. D.

Abstract

We see in the light microscope unknown microorganism-like particles in the normal blood. Our hypothesis as to the origin of these microorganism-like particles: 1) They result from the breakdown of platelets. 2) They are excreted via the stomach and bladder. 3) Insufficient clearing of these microorganism-like particles can play a role, together with other risk factors, in atherosclerosis, infectious diseases. For example: increased risk of pneumonia after splenectomy, spontaneous bacterial peritonitis in ascites due to cirrhosis. 5) Disturbances of the internal environment through catheters, artificial valves, intravenous drug use, and chemotherapy, lead to increased breakdown of platelets, and thereby an increased risk of sepsis, such as catheter sepsis. We suggest that these microorganism-like particles are a certain stadium of the well-known microorganisms who are causing the most common infectious diseases as well as arteriosclerosis. E.g. Staphylococci, streptococci, hemophilus, E. coli.

To complete the picture: we see also microorganism-like particles in normal urine (supplement 1) and in gastric juice (supplement 3). Reason why, we believe they are excreted in the urinary system to become E. Coli in the urine, and in the gastro-intestinal system to become E. Coli in the stool.

Another reason why we believe that microorganism-like particles are formed from the breakdown of blood platelets, is, that we have discovered blood platelets in the normal urine (supplement 2).

1. OBSERVATION: UNKNOWN MICROORGANISM-LIKE PARTICLES IN NORMAL BLOOD

In contrast to what we have been taught, we have now arrived at the conclusion that microorganism-like particles exist in normal blood. We observe these when viewing a drop of blood from an
EDTA-tube, at maximum magnification, under a phase-contrast microscope. It is our opinion that these microorganism-like particles are formed from the breakdown of platelets and that they can develop to “adult” microorganisms.

2. **HYPOTHESIS:**

**MICROORGANISM-LIKE PARTICLES ARE FORMED FROM THE BREAKDOWN OF PLATELETS AND CAN DEVELOP TO WELLKNOWN MICROORGANISMS**

Little is currently known about the breakdown of platelets. It is not known where they are broken down, and what the resulting products of their breakdown are. (Bernards and Bouman. Human Physiology. Fifth revised printing. 1990). On the other hand, more and more studies show the importance of Platelet Derived Microparticles (PDM).

It is also known, that sepsis is characterized by thrombocytopenia. Our explanation: platelets have broken down to form microorganisms. The time that platelets can be kept in a bag was reduced from five, to three days, because fatalities occurred due to sepsis after transfusions with platelets. Our explanation: platelets have partially converted into microorganisms during this five-day period. They have “decayed”. Countless pieces of clinical evidence also point to the presence of microorganisms in the circulating blood. One example is the microorganisms which are found in atherosclerotic plaque.

Why is there an increased incidence of pneumococcal pneumonia in patients who had their spleen removed? Are these patients exposed to increased levels of pneumococci after removal of the spleen, or did the splenectomy remove a filter which clears pneumococci from the blood? We will consider the second possibility.

We can observe microorganism-like particles moving around in the blood. Since these have not previously been named, we named these ‘hemoconia’ (see explanation below), based on their appearance: thread-shaped hemoconia, kernel-shaped hemoconia, cluster-shaped hemoconia, chain-shaped hemoconia, and thread-shaped hemoconia.

All of these microorganism-like particles are regularly encountered in normal blood.

It is our opinion that if these are not removed from the blood, they are capable of causing disease.

As staphylococci grow in a cluster shape, (“staphyllos” means cluster) we suspect that the cluster we observe here, is a precursor to the staphylococcus aureus bacteria. The chain-shaped organism is reminiscent of streptococci which propagate in the form of a chain. (“Streptos” means chain)

Why are women who use tampons at risk of toxic shock syndrome?

Our explanation is as follows: the blood which is absorbed in the tampon undergoes a normal breakdown process. The breakdown of platelets, which are destroyed during clotting, releases microorganism-like particles which – as we suppose- develop to microorganisms which can lead to blood poisoning.

It is possible to culture staphylococci from menstrual blood, as well as from used tampons.

Why does bacteremia regularly occur in urinary tract infections? Urosepsis is known to occur in hospitals. It is our opinion that this happens because the bacteremia occurs before the passing of urine. A hematologist asked us: “then why are not all blood cultures positive?” Our opinion is that these microorganism-like particles cannot (yet) be cultured. For example, in 5-31% of endocarditis cases, blood cultures are also negative.

We found an explanation for microorganisms that cannot be cultured, in an experiment with hay. If hay is placed in water, after a period of time the hay bacillus appears. If this liquid is boiled, the bacillus is killed, and the liquid becomes sterile. If, however, the liquid is then left to sit for a few days, the bacillus occurs again. It appears to have survived the boiling process in a type of spore-form.

The microorganism-like particles that we see in the blood then, are most likely spore-forms, or a particular stage of the microorganisms in question. An analogy would be, that the platelets are being ‘boiled’, broken down, into non-reproducing spore-
forms. We have named those “hemoconia”, analogous with “lactoconia”. Lactoconia are microorganisms found in milk, for which no explanation has been given. (Pinkhof-Hilfman Medical Dictionary). Our explanation: Through the pasteurization process, the mature lactobacillus has been transformed into smaller spores, called lactoconia. If we leave the pasteurized milk to rest for a few days, the lactobacillus returns, and the milk turns sour.

In our opinion, the kernel-shaped, dumbbell-shaped, cluster-shaped, chain-shaped, and thread-shaped microorganism-like particles, are precursors to some of the most common microorganisms: staphylococci, streptococci, pneumococci, hemophilus, E. Coli.

These common microorganisms are, in turn found in common diseases in humans: laryngitis, ear infections, bronchitis, pneumonia, bladder infections, and endocarditis. The question of where these microorganisms come from has been of interest for years. How can microbes from outside the body penetrate deep inside the body, and all the way into the heart, even in arteriosclerotic plaques?

We have come to the surprising conclusion, that they are formed within the human body itself.

We conclude that these are formed from the breakdown of blood cells.

“Cluster-shaped microorganism-like particle” Magnification 1000X. Phase-contrast microscope.

“ Thread-shaped microorganism-like particle” Magnification 1000X. Phase-contrast microscope.

Microorganisms are found in atherosclerotic plaque.

Are blood platelets broken down into microorganisms?
A schematic drawing of microorganism-like particles observed in the blood, in gastric juice and in the urine.

Fatal septicemia involving beta-hemolytic streptococci, 16 years after splenectomy.

Hypothesis: the spleen clears the blood of infectious agents. When the spleen is removed, levels of these infectious agents rise, which can, sooner or later, lead to septicemia.

We strongly discourage the use of tampons during menstruation. This may lead to blood poisoning, or “Toxic-shock Syndrome”.

In his time, Louis Pasteur was strongly opposed to the theory of “spontaneous generation”, and he won his argument. But in the blood, it is not a “spontaneous generation”, but rather a spontaneous breakdown process, which leads to these microorganisms. This is very different. Platelets contain hereditary material. They also contain several types of “kernels” which are visible under an electron microscope, as well as a system of channels which could facilitate transport of materials. Because scientists regularly shield themselves behind Pasteur’s theory, we visited the places where he lived and worked: Dole, Arbois, and Paris, France. We saw the jars which remained sterile, because they were airtight. This was the supposed proof that microorganisms always come from outside the body. But blood is not a broth. It is a living tissue, with cells that are generated and broken down. Importantly, Pasteur only had a simple light microscope available to him, and not a phase-contrast microscope. It would have been impossible for him to see platelets, let alone even smaller elements.
3. CASE STUDY
A 60-year-old male is admitted to the UZ Louvain (Leuven), Belgium. He develops a major sepsis in the form of bacterial peritonitis. Later he develops catheter sepsis. In this expression: “Spontaneous Bacterial Peritonitis (SBP)”, we recognize a confirmation of our view, which is that bacteria are created spontaneously from the body’s own blood cells.

In this patient’s case, the internal environment was seriously disturbed due to liver cirrhosis. The patient’s blood culture was positive for staphylococci. The tip of the catheter also tested positive for staphylococci.

Our theory: Due to the disturbances in the patient’s internal environment, caused by liver cirrhosis and uremia (through the catheter), microorganisms were able to develop and cause sepsis.

We were able to support our theory (microorganism production through the breakdown of platelets) with the patient’s lab results.

During the first two days after admission to hospital, platelet count was reduced from 134,000 to 100,000, and 95,000, finally decreasing to 69,000. Two days after this extreme reduction, the patient developed a fever. The following day, sepsis was confirmed with a hemoculture which was positive for staphylococci. The patient died as a result of this sepsis.

Our explanation: The platelets have been converted to microorganisms.

OUR CONCLUSION: MICROORGANISMS ARE CREATED FROM THE BREAKDOWN OF PLATELETS

4. MICROORGANISMS AND BLOOD
In our theory we will devote some attention to white blood cells, as there is a connection between white blood cells and viruses. Through deleukocytation, it is possible to avoid viral infections in a blood transfusion. Viruses multiply inside the white blood cells, and are subsequently released from them. A well-known example is AIDS, where CD4 white blood cells are annihilated as a result.

In contrast, malaria invades the red blood cells as a medium for reproduction. The parasites are then released ‘en masse’, which leads to fever attacks. It is clear that many microorganisms have a strong affinity with blood.

Staphylococci produce an enzyme called coagulase, which dissolves the blood. Streptococci produce streptolysine, which is used to dissolve clots. Hemophilus means: blood loving. Streptococcus sanguis: idem.

Many microorganisms need blood in order to reproduce. Hence, many human microorganisms have a strong relationship with the blood. Therefore, we can also see the dangers of catheters. Platelets stick to the catheter, break down and can possibly lead to sepsis. In intravenous drug use, the sensitive platelets are damaged due to the toxic environment, and create a serious danger of infection.

Even the direct infusion of liquid into the blood, by means of an intravenous drip, could have an influence on the fragile platelets, and potentially cause infections, the so-called “hospital infections”. The internal environment of the human body is extremely delicate. If caution is indicated for an intravenous drip, then in light of our findings, extreme caution ought to be taken with blood transfusions, as it appears that blood is not sterile, but contains potentially dangerous microorganisms.
5. MICROPARTICLES: THE SMALL STRANGERS
Research is being conducted at the AMC in Amsterdam (The Netherlands) on microparticles. Their descriptions provide some similarities to our findings, as described in the article below:

6. SUMMARY

A. Observation: we see unknown microorganism-like particles in the normal blood.

B. Our hypothesis as to the origin of these microorganism-like particles:

1) They result from the breakdown of platelets.
2) They are excreted via the stomach and bladder.
3) Insufficient clearing of these microorganism-like particles can play a role, together with other risk factors, in atherosclerosis.
4) Insufficient clearing of these microorganism-like particles is partially responsible for infectious diseases. For example: increased risk of pneumonia after splenectomy, spontaneous bacterial peritonitis in ascites due to cirrhosis.
5) Disturbances of the internal environment through catheters, artificial valves, intravenous drug use, and chemotherapy, lead to increased breakdown of platelets, and thereby an increased risk of sepsis, such as catheter sepsis.
6) Disturbances of the internal environment through uremia, alcoholic liver cirrhosis with jaundice, and intravenous catheters, also lead to increased platelet breakdown, with resulting sepsis.

C. We suggest that these microorganism-like particles are a certain stadium of the well-known microorganisms who are causing the most common infectious diseases as well as arteriosclerosis. E.g. Staphylococci, streptococci, hemophilus, E. coli.

D. Platelet Derived Microparticles, already described in literature, form a possible link to this theory.

E. To complete the picture: we see also microorganism-like particles in normal urine (supplement 1) and in gastric juice (supplement 3). Reason why, we believe they are excreted in the urinary system to become E. Coli in the urine, and in the gastro-intestinal system to become E. Coli in the stool.

F. Another reason why we believe that microorganism-like particles are formed from the breakdown of blood platelets, is, that we have discovered blood platelets in the normal urine (supplement 2).

Supplement 1:
UNKNOWN MICROORGANISM-LIKE PARTICLES IN NORMAL URINE
Traces of microorganism-like particles are not only found in the blood, but also in the urine. When we look to a drop of fresh, unconcentrated urine under the microscope, we do not see microorganisms. Therefore, urine is said to be sterile. If, however, we stain this drop of urine with a drop of crystal violet stain at the edge of the cover slip, we see a multitude of previously unknown microorganism-like particles. These are not visible in a drop of saline, nor are they visible in a drop of crystal violet. We have named these microorganism-like particles "cystoconia". We believe the microorganism-like particles that are formed in the blood, the "hemoconia", are excreted in the urine, in the form of "cystoconia".

Countless kernel-shaped microorganism-like particles in normal urine, stained with crystal violet. Magnification 100X. Bright field.

Supplement 2:
PLATELETS IN NORMAL URINE
Using the same crystal violet for staining a drop of fresh urine, we have also found forms, which in our opinion are platelets.

Since red and white blood cells can be found in urine, it makes sense that platelets could occur here as well. These are best viewed with a dark field. Just like platelets in the blood, these have a central body with extensions. The extensions are hollow tubes and have a bent form, therefore eliminating possible confusion with crystals. We see these in large numbers in the urine of diabetic patients. This leads us to suspect that they play a role in diabetic nephropathy.

We believe that the previously unknown microorganism-like particles have developed into culturable microorganisms. Because urinary tract infections are common in diabetics, and because we find many platelets in the urine, this also supports our theory that microorganisms are formed from the breakdown of platelets.

Supplement 3: MICROORGANISM-LIKE PARTICLES S IN NORMAL GASTRIC JUICE

Lastly, we have also found microorganism-like particles in gastric juice. These we have called “gastroconia”. They are the equivalent of the “cystoconia” in urine.


Microscopic view of gastric juice (obtained during gastroscopy), showing countless kernel-shaped microorganisms. Crystal violet stain. Magnification 100X. Bright field.

Since Helicobacter pylori is found in the stomach wall in a large percentage of the population, it makes sense that these originate inside the body, and not from the outside as is generally accepted. Further evidence shows that Helicobacter is also found in atherosclerotic plaque.

Contact to the Author:
Dr. Louis Van Hecken M. D.,
General Practitioner
Email: louis.van.hecken@skynet.be
Postal Address: BE- 2450 Meerhout, Belgium.
19-09-2016
Accuracy of fall risk predicting in hospital.
-Evaluate of fall risk behavior assessment tool by case control study-

AKIKO HIYAMA
Sapporo City University, School of Nursing, Japan

Abstract
Falling is the most common hospital adverse event in Japan, up to 24% of overall accident, and 9% of fallers had a serious injury or death. This study was clarified predicting accuracy of fall risk behavior assessment tool (FRBA-Tool). I determined to describe accuracy of FRBA-Tool by case control design. The case sample consisted of 62 falls and 316 control charts that sample collected 20 generic wards, 4 hospitals in Japan. Logistic regression after adjusting for age, identified each 18 items of FRBA-Tool associated with fall. Stepwise regression analysis suggested four significant items that were "moving unstably by fever and anemia, and conditions inducing dizziness and seizure" (OR: 2.3), "moving lightheadedness due to hypnotic, sedative and psychotropic drugs" (OR: 2.3), "starting an action without having to check the safety of the surrounding because of hearing and vision impairment" (OR: 3.8), and "moving the center of gravity through movement such as by holding the position after a sudden change of direction and position" (OR: 3.5). I gave the weighting four item's score, and draw ROC curve. Using total score cut-off point of 3 (AUC .79, P<0.01). Accuracy of FRBA-Tool score, a sensitivity of 84% (95%CI: 0.75-0.93) and specificity of 63% (95%CI: 0.57-0.68), positive predictive value of 2.25 (95%CI: 1.88-2.67), negative predictive value of 0.26 (95%CI: 0.15-0.45) were calculated. The results suggest that FRBA-Tool is good at sensitivity and lacks specificity.

Key Words: fall prevention, risk assessment, risk behavior

1. Introduction
Falls represent the most frequent adverse event in Japanese hospitals, accounting for up to 24% of overall accidents, and with 9% of fallers experiencing a serious injury or death\(^1\). Falls can be prevented, if the nurse is able to anticipate or predict the risk. To prevent falls in the hospital, the nurse can assess the patient's risk of falling. There have been a number reports evaluating the ability of a fall risk assessment tool to predict the patient's risk of fall in different settings\(^2\). From a fall risk assessment viewpoint, various factors surrounding the patients have been examined. Specifically, functional or organic impairment and intrinsic or extrinsic fall factors that were integral to the person have been investigated. Intrinsic
factors include a history of falling, reduced vision, unsteady gait, poor balance, altered mental status, cognitive impairment, decreased functional ability, and chronic disease. Extrinsic factors include poor lighting, condition of the ground surface, type of foot covering, inadequate assistive devices, structural design of bathrooms and grab bars, design of furniture, and improper use of assistive devices. Falls occur when patients do not control their position with respect to risk factors. To prevent patient fall, risk assessment should involve multiple approaches. This study suggested that the assessment should change from a physiological or environmental assessment to a behavioral assessment. Thus, the purpose of this study was to evaluate the accuracy of a fall risk behavior assessment tool (FRBA-tool) in predicting fall risk in the hospital.

2. Methods
2.1 Research design
The accuracy of the fall risk behaviors assessment tool was determined using a retrospective design, based upon the data in using patient’s medical files from prior hospitalizations.

2.2 Setting
This study was conducted at four JCQHC (Japan Council for Quality Health Care) certified hospitals in Sapporo City, Hokkaido, Japan; i.e., subjective hospitals demonstrated satisfactory compliance with the applicable JCQHC accreditation standards. The Medical Care Act in Japan classifies General beds as not involving those for Psychiatric, Infectious disease, Tuberculosis, or Long-term care. The four hospitals were teaching hospitals with 80 to 312 beds, including general beds.

2.3 Sample and data collection
The study was approved by the human research committee of the researcher’s institute. A fall was defined in this study as an unexpected event in which the participant comes to rest on the ground, floor, or at a lower level. The case sample consisted of 62 patients with falls and 316 control charts collected from 20 generic wards at 4 hospitals in Japan. Patients admitted to hospital over the study period (from September 2013 to August 2014) were enrolled. Inpatient administrative records, fall risk assessment results, and fall incident reports were combined to collect data for the analysis.

2.4 Instruments
The instrument used for data collection was organized to collect 2 types of data: (1) general and medical information and (2) fall-related information. General information included gender and age. Medical information included the diagnosis and length of the hospital stay. The number of falls during admission, fall risk behavior assessment tool (FRBA-tool), and the fall risk assessment tool output were included as the fall-related information. The FRBA-tool was used to predict falls in hospitals that had developed quantitative analyses based upon the behaviors of inpatients that had fallen. The FRBA-tool consisted of 18 items (table 1) for which criterion-related validity and construct validity had been verified. Patients were assessed binary scores, 0 or 1, by research nurses. The fall risk assessment tool consisted of 41 items that were endorsed for use in hospitals by the Japanese Nursing Association. Fall risk assessment tool (JNA): (1) age, (2) history of disease, (3) perception (3 items), (4) motor function (4 items), (5) mobility (5 items), (6) cognition (4 items), (7) medication (5 items), (8) elimination (8 items), (9) treatment stage (5 items), (10) personality (5 items).

2.5 Ethical consideration
Ethical approval was granted by the Institutional Review Board of the researcher’s institute. The data collection forms were anonymized, with no referral to names or identification numbers.

2.6 Data analysis
SPSS 22.0 software (IBM Corp, U.S.) was used for the data analysis. The FRBA-tool score was examined using logistic regression. Logistic regression, after adjustment for age, identified 18 items that were associated with falls. The prediction accuracy of the FRBA-tool was assessed by sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and the area under the receiver operating characteristics curve (ROC). Sensitivity referred to the number of fallers that were correctly identified by the FRBA-tool, divided by the total number of fallers. Specificity referred to the number of non-fallers that were correctly identified by the tool, divided by the total number of non-fallers. PPV was the rate of actual fallers compared with the prediction of falls: sensitivity/(1- specificity), and
NPV was the rate of actual non-fallers compared with the prediction of non-falls: (1-sensitivity)/specificity. The ROC plots the 1-specificity vs. the sensitivity, and the area under the ROC represents the AUC. The validity of the FRBA-tool method was used to determine the correlation with the fall risk of the fall risk assessment tool (JNA).

3. Results

3.1 Demographic data
A total of 62 falls and 316 non-falls were recorded. Of the fallers, 30 (48.4%) were male and 32 (51.2%) were female, with no significant difference between genders. The mean age of the fallers was 76.2 years (SD = 27.2) compared with 62.9 years (SD = 27.2) for the non-fallers (Table 2).

3.2 Accuracy of the fall risk behavior assessment tool
Twelve items showed significantly larger proportions among the fallers compared with the non-fallers (Table 3). Stepwise regression analysis suggested four significant items, including “Moving unstably, due to fever and anemia, and conditions inducing dizziness and seizure” (OR: 2.3), “Moving while lightheaded, due to hypnotic, sedative and psychotropic drugs” (OR: 2.3), “Starting an action without checking the safety of the surroundings, due to hearing and/or vision impairment” (OR: 3.8), and “Changing the center of gravity through movement, such as a sudden change of direction and position” (OR: 3.5) (Table 4). Four items were provided a score weighting and an ROC curve was constructed. Using a total score cut-off point of 3 (AUC .79, P<.01) (Figure 1), the accuracy of the FRBA-Tool was determined, with a sensitivity of 84% (95%CI: 0.75-0.93) and a specificity of 63% (95%CI: 0.57-0.68) (Table 5). The mean score of the FRBA-tool was 2.9 (SD = 2.9, range = 0-16). The FRBA-tool and the JNA tool score showed a moderate correlation (r=.70, P <.01).

4. Discussion
Inattention has been identified as a strong predictor of falls\(^4\), which is disappointing when determining the risks during transferring or ambulating. As it is difficult for medical staff to assess attention or cognition, I considered such fall risks as behavior. Comparing the differences between the patients who were fallers and non-fallers, this assumption was supported because there was a significant difference in risk behavior between these groups. These results suggest that fall risk can be predict by behavioral assessment. Behavioral factors have become useful as quick assessment tools, and by focusing on behaviors output under various conditions, it would be also possible to eliminate effects due to organic or functional changes.

Furthermore, in comparison of the JNA tool actually used in the hospital and the FRBA-tool, there was a moderate correlation, which supported the validity of the measurement concept. The most common assessment tools are the Morse Fall Scale\(^5\), Hendrich II Fall Risk Model\(^6\), and the St. Thomas’s Risk Assessment Tool\(^7\), which have been evaluated in a number of different settings. In a meta-analysis of the fall risk assessment tool, STRATIFY has the highest reported sensitivity (.80), MFS has the highest reported specificity (.68). In comparison of these tools, the FRBA-Tool is considered good at sensitivity but lacks specificity. Consequently, the FRBA-tool could be used in general wards in Japanese hospitals. However, due to the low specificity of the tool, higher specificity would be required for daily use in hospitals.

5. Limitations
Firstly, items that were not considered different between the falling and non-falling patients were primarily affected by the fact that the evaluation condition was rare. However, the item; “Reaching over something or leaning forward in an unstable body posture”, could be caused by ambiguity in the evaluation criteria. Although most items were valid, the results of the current study suggested the need for modification of one item. Secondly, the retrospective nature of the data collection could not eliminate the potential influence of bias in the sample collection. Consequently, it was necessary to test by prospective design.

6. Conclusion
The accuracy of the fall risk behavior assessment tool for a general ward of hospitalized patients showed a sensitivity of 84% (95%CI: 0.75-0.93) and specificity of 63% (95%CI: 0.57-0.68), positive predictive value of 2.25 (95%CI: 1.88-2.67), negative predictive value of 0.26 (95%CI: 0.15-0.45). These results suggested that the
FRBA-Tool had good sensitivity for the prediction of fall, but lacked specificity.

Table 1: Fall risk behavior assessment tool (FRBA-tool)

| Check | 1 Moving with reduced lower limb strength, due to muscle weakness and motor dysfunction | 2 Moving unstably, due to fever and anemia, and conditions inducing dizziness and seizure | 3 Moving while lightheaded, due to hypnotic, sedative and psychotropic drugs | 4 Moving hastily, due to urinary urgency and performing of a task under pressure | 5 Moving while lightheaded, due to a semiconscious state, in the absence of sedative or psychotropic drugs | 6 Moving without selecting an appropriate moving assistance tool | 7 Moving unstably, due to interference by a tube for intravenous drip or an IV stand | 8 Moving with a lack of attention to safety, due to poor concentration | 9 Starting an action without checking the safety of the surroundings, due to hearing and/or vision impairment | 10 Moving unstably, due to impaired posture adjustment, asynergy | 11 Moving without paying attention to footwear, clothing, linens | 12 Changing the center of gravity through movement, such as a sudden change of direction and position | 13 Moving unstably, due to interference by a tube for intravenous drip or an IV stand | 14 Starting to move without reliable grip on the support apparatus | 15 Moving obstacles or steps with uncontrolled body balance | 16 Moving without paying attention to a slippery floor | 17 Moving with insufficient balance control, due to impairment of the upper limb | 18 Reaching over something or leaning forward in an unstable body posture |

Table 2: Characteristics of the study participants

<table>
<thead>
<tr>
<th>Faller (n=62)</th>
<th>Non-faller (n=316)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Mean, SD)</td>
<td>76.2 (27.2)</td>
<td>62.9 (27.2)</td>
</tr>
<tr>
<td>Hospital days</td>
<td>30.6 (28.8)</td>
<td>19.8 (33.1)</td>
</tr>
<tr>
<td>Gender (Frequency, %)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>30 (48.4%)</td>
<td>155 (49.8%)</td>
</tr>
<tr>
<td>Women</td>
<td>32 (51.6%)</td>
<td>156 (50.2%)</td>
</tr>
</tbody>
</table>

n=378

Table 3: Comparison of items of FRBA-tool between the faller and no-faller groups

<table>
<thead>
<tr>
<th>Faller (n=62)</th>
<th>Non-faller (n=316)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Moving with reduced lower limb strength, due to muscle weakness and motor dysfunction</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>2 Moving unstably, due to fever and anemia, and conditions inducing dizziness and seizure</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>3 Moving while lightheaded, due to hypnotic, sedative and psychotropic drugs</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>4 Moving hastily, due to urinary urgency and performing of a task under pressure</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>5 Moving while lightheaded, due to a semiconscious state, in the absence of sedative or psychotropic drugs</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>6 Moving without selecting an appropriate moving assistance tool</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>7 Moving unstably, due to interference by a tube for intravenous drip or an IV stand</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>8 Moving with a lack of attention to safety, due to poor concentration</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>9 Starting an action without checking the safety of the surroundings, due to hearing and/or vision impairment</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>10 Moving unstably, due to impaired posture adjustment, asynergy</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>11 Moving without paying attention to footwear, clothing, linens</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>12 Supporting the body with those that have not been fixed</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>13 Changing the center of gravity through movement, such as a sudden change of direction and position</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>14 Starting to move without reliable grip on the support apparatus</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>15 Moving obstacles or steps with uncontrolled body balance</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>16 Moving without paying attention to a slippery floor</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>17 Moving with insufficient balance control, due to impairment of the upper limb</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>18 Reaching over something or leaning forward in an unstable body posture</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Chi-squared test
Table 4: Results of logistic regression model predicting fall by FRBA-tool

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>OR</th>
<th>95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Moving unstably, due to fever and anemia, and conditions inducing dizziness and seizure</td>
<td>2.262</td>
<td>[1.210, 4.230]</td>
<td>0.011</td>
</tr>
<tr>
<td>3</td>
<td>Moving while lightheaded, due to hypnotic, sedative and psychotropic drugs</td>
<td>2.292</td>
<td>[1.116, 4.709]</td>
<td>0.024</td>
</tr>
<tr>
<td>9</td>
<td>Starting an action without checking the safety of the surroundings, due to hearing and/or vision impairment</td>
<td>3.784</td>
<td>[2.010, 7.122]</td>
<td>0.000</td>
</tr>
<tr>
<td>13</td>
<td>Changing the center of gravity through movement, such as a sudden change of direction and position</td>
<td>3.514</td>
<td>[0.973, 12.685]</td>
<td>0.055</td>
</tr>
</tbody>
</table>

Stepwise regression analysis using method of maximum likelihood, Adjusted for 18 FRABA-tool item and age, OR means odds ratio, CI means confidence interval, n=378

Table 5: Measures of precision for FRBA-Tool

<table>
<thead>
<tr>
<th></th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>0.839 [0.747, 0.930]</td>
</tr>
<tr>
<td>Specificity</td>
<td>0.627 [0.573, 0.680]</td>
</tr>
<tr>
<td>Accuracy</td>
<td>0.661 [0.614, 0.709]</td>
</tr>
<tr>
<td>Positive likelihood ratio</td>
<td>2.246 [1.878, 2.666]</td>
</tr>
<tr>
<td>Negative likelihood ratio</td>
<td>0.257 [0.147, 0.450]</td>
</tr>
</tbody>
</table>

Figure 1: ROC curve of FRBA-Tool
Reference


Contact to the Author:
AKIKO HIYAMA
Email: a.hiyama@scu.ac.jp
Postal Address: Kita 11 Nishi 13 Chuoku Sapporo City, Hokkaido, Japan
[Short communication]

MEASURES TO PREVENT MEDICATION ERRORS WITH LEADERSHIP BY THE HOSPITAL DIRECTOR

Taiko TERASHIMA¹, Noriko KATAOKA², Naoko SASAKI², Tomoko WAKAMATSU²
¹: Department of Nursing, Japanese Red Cross Hokkaido College of Nursing, Kitami, Japan
²: Department of Nursing, Ebetsu Tanifuji Hospital, Sapporo, Japan

Abstract

This report aimed to assess factors contribute to the prevention of medication errors in a process from decision-making by a hospital director to implementations of changes in medications in a mid-sized hospital. We retrospectively extracted incidents reports on mix-ups due to similar names and multiple standard units in medicines, and reviewed the reports. The following were implemented: removing the medication from list of available medications in Computerized Prescription Order Entry, changing to another medicines with the same chemical potency, removing multiple standard units from stored in wards. After implementation of these changes, similar errors have not reoccurred. We assessed the following factors: replacing by medicines that could avoid the risk, prompt decisions by the hospital director at conferences, deprioritized the convenience for each department, and smooth agreements from staff. It is difficult for the nursing department to propose changing or storing medicines to physicians who have the authority to order medications. Moreover, it is accompanied by an increase in cost and effort. The leadership of the hospital director is essential to promptly implement changes.

Key Words: medication errors, incident reports, medical safety measure, leadership, changing medications

1. Introduction

Almost all medical institutions in Japan have made efforts to prevent medication errors.¹-⁴ Japan Council for Quality Health Care has repeatedly provided information on medical safety related to mix-ups due to similar names and multiple standard units in medicines to medical institutions.⁵-⁶ In a mid-sized general hospital (122 beds) located in Hokkaido, Japan, such incidents have occurred last year.

A committee on medical safety measures required by Medical Care Act has been set up in the hospital.¹ The committee in the hospital consists of members from the departments of medical care, pharmacy, nursing and management. In order to respond in a timely manner, the hospital director and department chiefs in the members of committee have a meeting every week (Fig.1). In response to the above incidents, the hospital
director can make immediate decisions to adopt change in medications at the committee meetings. Prompt implementation of these decisions led to prevention of medication errors.

2. Objective
This report aims to assess factors that contribute to prevention of medication errors in the process from decision-making by the hospital director to implementation of changes in medications in the mid-sized general hospital in Hokkaido, Japan.

3. Methods
In-hospital incident and accident reporting documentations from January 2015 to March 2016 were used. Prior to using these paper-based documentations which have stored by the committee of medical safety management, the permission were obtained from the hospital director. We retrospectively extracted incident reports on mix-ups due to similar names and multiple standard units in medicines, and reviewed the circumstances of the incident and safety measures adopted as a result. Reviewers included a former nursing director, a nursing ward chief who is also manager of medical safety management committee, and a nursing researcher.

4. Results
Of the 274 reports, 62(22.6%) were medication-related incidents. Five incidents involved mix-ups due to similar names and multiple standard units. The following three changes in medications were implemented:

4.1 Removing the medication from list of available medications in Computerized Prescription Order Entry (CPOE)
A physician intended to prescribe HEPARIN SODIUM INJECTION, but he incorrectly selected HEPARIN CALCIUM INJECTION which was displayed at a top of the search string from the list in CPOE. In this case, the patient did not receive the wrong medication because of the patient received HEPARIN SODIUM INJECTION via a verbal physician order. HEPARIN CALCIUM INJECTION, which is used less often, was removed from the list of available medications in CPOE. New rules, such as contacting a pharmacist when physicians need to use HEPARIN CALCIUM INJECTION, have been made. Moreover, an alert function to the prescription screen for high-risk drugs have been added to the new rules.

4.2 Changing to another medicine with the same chemical potency
A nurse incorrectly administered ROZEREM (hypnotic) tablets to the patient when the physician ordered LORAZEPAM (antianxiety agent) tablets. Both medicines were stored in all wards at all times. Although nurses have been alerted and both medicines are placed away from each other in a strongbox, the same errors were found during routine confirmation of the amount of remaining medicines in other wards. RO and LO are the same Japanese Katakana character (Fig.2). WYPAX tablets were selected instead of ROZEREM.
4.3 Removing multiple standard units from storage in all wards
A VOLTAREN suppository was administered by a nurse who misidentified the order, leading to an overdose in a patient with fever. This error was detected when confirming the amount of remaining medicine in the ward. A change to only storing one standard unit was made in all wards, and physician orders for elderly patients with fever have been standardized with the use of an ALPINY suppository.

After implementation on these changes, similar errors have not reoccurred, so we considered the changes to be effective. We assessed the following factors.

1) Medications involved in errors were replaced by medicines that could avoid the risk, rather than continuing use of the same medication with caution.
2) The purpose of the changes is patient safety; therefore, the convenience for each department was deprioritized.
3) The hospital director, as Chief Executive Officer, made decisions promptly by at conferences. Dissatisfaction with implementation did not occur among personnel.
4) Because of the hospital size, changes to procedures were communicated quickly and agreements from staff were obtained smoothly.

5. Discussion and Conclusions
Measures for prevent medication errors that represent a fundamental solution for all of the departments where that medication is used are desirable. Since nurses are ultimately administer medications to patients, they are at risk of making medication errors.7-8 However, it is difficult for the nursing department to propose changing or storing medicines to physicians, who have the authority to order medications. Moreover, it is accompanied by an increase in cost and effort. In this report, we shown that changing medicines cloud be an effective measure against medication errors. The leadership of the hospital director is essential to promptly implement changes. Ginsburg et al.9 suggests that formal leadership support for safety is of particular importance in small organizations where the economic burden of safety programs is disproportionately large and formal leadership is closer to the front line. The hospital director has participated voluntarily without fail every year in medical safety workshop organized by the branch office of the Ministry of Health, Labour and Welfare. We think that the director’s policy of making patient safety the top priority is reflected in the personnel.

Reference

Contact to the Author:
Taiko TERASHIMA
Email: terashima@rchokkaido-cn.ac.jp
Postal Address: 664 Akebono-cho Kitami-shi
Hokkaido 090-0011 Japan
Japanese Red Cross Hokkaido College of Nursing
INVESTIGATION OF NEAR-MISS EXPERIENCES OF NURSING STUDENTS

Yukiko Kai 1, Miho Urakawa 2, Takahiro Miyoshi 3
1: School of Nursing, Faculty of Medicine, University of Miyazaki, Japan, 2: Department of Nursing, Kurume University Hospital, 3: Department of Fundamental Nursing, Kurume University School of Nursing

Abstract

Purpose: The purpose of this study was to investigate the actual situation of recognition of near-miss experiences among nursing students during clinical training. The results will be utilized in clinical training and medical safety lectures.

Methods: We conducted a questionnaire survey of 3rd year students in 2014 and another survey when they were 4th year students in 2015. We compared the results of the effectiveness of clinical training and medical safety education to understand the influences on students’ recognition of near-miss incidents. The data were tested with the χ² test and the results were analyzed. Changes in the recognition of near-miss incidents before and after lectures were categorized.

Results: Questionnaires were collected from 41 3rd year and 50 4th year students. There was no significant difference in the occurrence of near-miss incidents between the two groups. However, 4th year students commented that they try to avoid causing any incidents and they would feel regret if they did cause any incidents. As for 3rd year students, they were not aware of any near-miss incidents. After medical safety education, they were able to recognize potential incidents. In addition, 4th year students realized that near-miss incidents that lead to medical malpractice could occur.

Conclusions: 3rd year students learned the term “near-miss incident” but were not aware of procedures for reporting incidents. However, 4th year students were able to recognize incidents after receiving clinical training and medical safety education. To make patient safety the first priority, nursing students must learn from near-miss incident experiences and utilize knowledge from medical safety education.

Key Words: nursing students, near-miss experiences, recognition and investigation, clinical training, medical safety education, questionnaire
1. Introduction
With recent advances in medical care and shorter hospitalization periods, requirements for safer and higher level nursing practice are increasing. Since the patient mix up incident in Yokohama, Japan in 1999, greater emphasis has been placed on safety as part of nursing education. According to Shio et al.1), clinical nursing training currently “emphasizes the importance of taking sufficient measures to ensure patient safety when having students perform nursing actions” in alignment with the Ministry of Health, Labour, and Welfare’s basic nursing education skill levels (March 2003), which proposed that, at each school’s discretion, top priority be given to ensuring patient safety and safeguarding their rights. As a result, nursing students gain hands-on experience in fewer skills and are experiencing many near misses during clinical training; Kusaka et al.2) reported that “1 in 10 individuals repeatedly experience incidents or accidents.”

In the present study, we used a revised version of a questionnaire developed by Iwano3) to investigate changes in near-miss experiences among nursing students after 1 year.

2. Methods

2.1 Definitions
Based on the National University Council for Medical Safety’s “Definition of medical accidents,” near-miss experiences (hereinafter referred to as incidents) in the present study are defined as “incidents occurring during clinical training in which no harm was caused to patients but that were frightening and sobering experiences for nursing students”.

2.2 Working hypothesis
Participants comprised senior (4th) year nursing students who had completed all of their clinical training, taken medical safety lectures during the first semester of the 4th year prior to their clinical training, and amassed clinical training experience in the year since the 3rd year survey was conducted. Therefore, compared to the 3rd year, they were expected to have greater knowledge, have undergone changes in awareness regarding near misses, and be more self-motivated to handle incidents, such as by reporting incidents to clinical practice instructors and teachers. They were also expected to engage in more behaviors that considered patient safety.

2.3 Survey

2.3.1:Participants
Participants comprised a total of 64 4th-year nursing students who had taken medical safety lectures and completed all of their clinical training. Individuals with professional nursing experience were excluded.

2.3.2:Anonymous, questionnaire survey (drop-off survey)

a) In order to assess the realities of incidents, a yes-no question item (“Do you know about the existence of incident reports?”) was added to the 4th year version of the questionnaire used in the 3rd year.

b) Regarding post-incident awareness, participants were asked about 1) whether they wrote an incident report (yes-no answer); 2) post-incident handling of the situation (free comments); 3) awareness at the time of the incident (28-item multiple choice and free comments sections); and 4) future handling of incidents (free comments).

c) A new question about cognition after medical safety lectures in the first semester of the 4th year was included in the 4th year version of the questionnaire.

2.3.3:Survey period
3rd year: July–October 2014
4th year: July–August 2015

2.4 Analysis

1) The realities of incidents were compared between the 3rd and 4th year using a χ² test with significance set at p<0.05 or <0.01. SPSS (version 20.0 for Windows) was used for all statistical analysis. Simple tabulation was used for the question “Do you know about the existence of incident reports?”

2) Regarding post-incident awareness, simple tabulation was performed for the question “Did you write an incident report?” while responses to questions on “post-incident handling”, “awareness at the time of the incident” and “future handling” were categorized.

3) Responses to questions on “changes after medical safety lectures in the first semester of the 4th year” were categorized.

2.5 Ethical issues
Before revising the original questionnaire, verbal consent via telephone and signed consent were obtained from Iwano. The voluntary nature of participation as well as the study objectives, methods, protection of privacy, and that responses and comments would remain anonymous were explained to the participants. Participants were informed that questionnaires would be shredded after analysis. The present study was approved by the Ethics Review Board of the University of Miyazaki, Faculty of Medicine (Approval no. 2015-093).

3. Results
Questionnaires were collected from 41 and 50 students in the 3rd and 4th years, respectively (collection rates, 64.0% and 78.1%, respectively; valid response rates, 100% and 100%, respectively).

3.1 Realities of incidents during clinical training
1) Heard of the term incident
No significant difference was observed between the 3rd and 4th years, with all students responding that they “had heard of the term”.

2) Knowledge of incident reports written after the incident
A total of 45 students (90.0%) in the 4th year were aware of the existence of incident reports.

3) Experience of incidents
No significant difference was observed between the number of students who had experienced an incident in the 3rd (n=17 [41.5%]) and 4th years (n=23 [46.0%]).

4) Incident settings
Incidents most commonly occurred during “personal hygiene care” followed by “other” and then “transfer and transport” in the 4th year (23 responses; Fig. 1) compared to checking of vital signs followed by “transfer and transport” and then “infection prevention” in the 3rd year (17 responses). Most incidents occurring in “other” settings (4th year only) comprised “intended nursing action stopped by a nurse or instructor due to insufficient study or preparation” (7 responses). Significant differences were observed between the number of 3rd and 4th year responses for “personal hygiene care” (p=0.002) and “other” (p=0.004).

In the 4th year, 7 students responded that they had “written an incident report after an incident”. Other common responses were “reported to instructor”, “submitted to conference”, and “told a friend” in the 4th year (34 responses) and “did nothing”, “reported to instructor” and “reported to charge nurse” in the 3rd year (18 responses).
3.2 Post-incident awareness

1) Awareness at the time of the incident
A total of 221 responses were obtained from 40 students (multiple responses possible) in the 3rd and 4th years regarding “awareness at the time of the incident” (3rd year: n=17, 62 responses; 4th year: n=23, 159 responses).

Responses were classified into 13 subcategories within 5 categories. The category “worry about the patient” contained the subcategories ‘contrition’, ‘anxiety regarding patient status’, ‘feelings when was able to avoid’; “awareness regarding causes and countermeasures” contained the subcategories ‘lack of attention’, ‘insufficient confirmation’ and ‘report’; “reaction at the time of failure” contained the subcategories ‘unintentionality and carelessness’ and ‘antipathy’; “expression of emotion” contained the subcategories ‘regret’, ‘shock and confusion’ and ‘anxiety’; and “assuming things easily” contained the subcategories ‘no awareness of incident’ and ‘over-confidence’. The most responses were obtained in the category “worry about the patient” followed by “awareness regarding causes and countermeasures”, “reaction at the time of failure”, “expression of emotion”, and then “assuming things easily.”

The most common response for “awareness at the time of the incident” was “feeling of contrition toward the patient” followed by “anxiety regarding whether the patient was alright”, “shock at having caused a near miss”, and “did not think that own support or care would become a problem” in the 4th year (159 responses) and “did not foresee an incident” followed by “regret the near miss”, “feeling of having caused a near miss”, and “no real sense of having caused a near miss” in the 3rd year (62 responses).

2) Future handling of incidents (free comments)
A total of 115 responses were obtained from 61 students in the 3rd and 4th years (3rd year: n=14, 22 responses; 4th year: n=47, 93 responses).

Responses were classified into 14 subcategories within 3 categories. The category apply lessons learned in the future contained the subcategories ‘confirm’, ‘be conscious’, ‘review’, ‘do not cause again’, ‘reflect’, ‘prevent’ and ‘do not forget’; “handling of near misses” contained the subcategories ‘initiatives regarding near misses’, ‘do not forget human characteristics’, ‘report’, ‘make preparations’, ‘do not fall back on familiarity’, and ‘individual tendencies’; and “feelings toward the patient” contained the subcategory ‘consideration toward the patient’. The most responses were obtained in the category “apply in the future” followed by “handling of incidents” and then “feelings toward the patient”.

The most common response for “future handling” was “confirm” followed by “pay attention”, “be conscious”, and then “report” in the 4th year (93 responses) and “be conscious” followed by “take care” and then “can happen to anyone” in the 3rd year (22 responses).

3.3 Changes after medical safety lectures in first semester of the 4th year
A total of 73 responses were obtained from 42 students (4th year only; Table 1)

Responses were classified into 7 subcategories within 2 categories. The category “things learned from lectures” contained the subcategories ‘inattentiveness’, ‘human error’, and ‘fear’; and “apply in the future” contained the subcategories ‘initiatives regarding near misses’, ‘confirm’, ‘be conscious’, and ‘reflect’. The most responses were obtained in the category “things learned from lectures” followed by “apply in the future”.

The top 3 responses were “can happen to anyone” (8 responses; 11.0%), “may be linked to medical accidents” (7 responses, 9.6%), and “take care” (5 responses, 6.8%).

By category, the most responses for “things learned from lectures” (46 responses) were in the subcategory ‘inattentiveness’ (24 responses, 32.9%) followed by ‘human error’ (15 responses, 20.5%) and then ‘fear’ (7 responses, 9.6%). The most responses for the category “apply in the future” (27 responses) were in the subcategory ‘initiatives regarding near misses’ (12 responses, 16.4%) followed by ‘confirm’ (8 responses, 11.0%), ‘be conscious’ (5 responses, 6.8%), and then ‘reflect’ (2 responses, 2.7%).
Table 1. Changes after medical safety lectures in the first semester of the 4th year

(4th year only; free responses) \(n=73\)

<table>
<thead>
<tr>
<th>Category</th>
<th>Subcategory</th>
<th>4(^{th}) year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Things learned from lectures (46)</td>
<td>Inattentiveness (24)</td>
<td>Can happen to anyone (8)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>May be linked to medical accidents (7)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Something familiar (2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Carelessness (2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Near misses are not linked to accidents (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Don’t know when one will cause a near miss (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Are easy to cause due to assuming things (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>It is not unusual for a near miss to occur at any time (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Perceive a near miss as representing oneself (1)</td>
</tr>
<tr>
<td></td>
<td>Human error (15)</td>
<td>People, objects, time, and self-management can prevent medical accidents (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Near misses happen to both veterans and beginners (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Various systems are in place to prevent accidents (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remember the phrase “All people can cause errors” (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Medical accidents can be prevented by eliminating near misses (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Handling human errors is fundamental (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Some “incidents” are not noticed individually (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The Swiss Cheese Model was easy to understand (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Near misses identify weaknesses for us (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inappropriate optimistic views towards each other (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intentions and subsequent responses are important (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Recognize the importance of near misses (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Learned the important points of caution (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Humans cause mistakes (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Relates to quality of service (1)</td>
</tr>
<tr>
<td></td>
<td>Fear (7)</td>
<td>Fear (4)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Possible to become a central player (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Be held accountable (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Anxiety (1)</td>
</tr>
<tr>
<td>Apply in the future (27)</td>
<td>Initiatives regarding near misses (12)</td>
<td>Analysis and investigation of near misses (3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Systematically prevent near misses (2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intend not to cause near misses in the future (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Utilize accident-prevention systems (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Be self-aware regarding near misses (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Create a reporting-friendly environment (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Respond rapidly (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Share examples of cases (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Perform appropriately (1)</td>
</tr>
<tr>
<td>Confirm (8)</td>
<td></td>
<td>Take care (5)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Confirm (3)</td>
</tr>
<tr>
<td>Be conscious (5)</td>
<td></td>
<td>Pay attention (3)</td>
</tr>
</tbody>
</table>
4. Discussion
4.1 The realities of incidents during clinical training
In the 3rd year, students had already heard the term “near miss” in lectures and clinical training. However, 10% of students were unaware of the existence of incident reports, indicating that just hearing the term before clinical training did not equate to understanding. These findings agree with those of Hatakeyama[4] who found “half of students had experienced a near miss” and “factor analysis of accidents was insufficient and, as a result, the students were repeating near misses a couple of times even while feeling shocked”. The same students were also repeating incidents in the present study.

In the 4th year, students appeared to have 2 different tendencies: 1) to utilize the experiences for personal learning and growth; and 2) to forget about them. The top 3 of the 12 categories for settings of incidents were “personal hygiene care”, “other”, and “transfer and transport” in the 4th year and “checking of vital signs”, “transfer and transport”, and “infection prevention” in the 3rd year. Regarding the frequency of incidents, the findings of the present study match those of Sasaki et al.[5], who reported that “Many near-miss experiences occur during performance of basic living support skills, which students have frequent opportunities to perform”. Significant differences on the $\chi^2$ test were only observed for “personal hygiene care” and “other” (4th year only). Most incidents occurring in “other” settings (4th year only) comprised “nursing action stopped by a nurse or instructor due to insufficient study or preparation” (n=7). Expansion of the nursing process during clinical training in the 4th year deepened students’ understanding of patients while actively implementing nursing plans made them conscious of incidents.

The most common settings of incidents were “checking of vital signs” in the 3rd year and “personal hygiene care” in the 4th year. This difference may be because students in the 3rd year only interact with their own patients while in the 4th year they have more opportunities to be involved in nursing practice and personal hygiene care for patients other than their own. Koizumi[6] stated that “Many student near-miss experiences are caused by the student’s psychological state, such as nervousness or impatience, or insufficient understanding of patient characteristics”. During actual nursing practice, students caused near misses due to insufficient assessment or understanding of patient status and being forced to be impatient or nervous, thereby increasing the opportunities to receive instruction or guidance.

Furthermore, although no significant difference was observed between the 3rd and 4th year, “transfer and transport” is always performed with a nurse or instructor and therefore supervised. Thus, students receive direct guidance causing them to be aware of near misses. The high frequency of responses for incidents occurring during “infection prevention” was presumably because actions such as wearing gowns, washing hands, and using hand sterilizer are constantly being performed.

4.2 Awareness of incidents
In the 4th year, only 7 students responded that they had experience writing an incident report, clarifying that while students are aware of the existence of incident reports, they do not write them. Takahashi et al.[7] reported that, regarding incident reports, subjects “responded that the format is difficult to write (25.9%), by writing it down I feel will be blamed (24.9%), and it’s too much trouble (20.8%)”. Therefore, students do not write incident reports because they feel that by writing the report, they would be blamed and that the increased amount of recording is too much trouble. Conversely, while 30% of students in the 3rd year responded that they “did nothing”, showing they did not understand the importance of reporting incidents, after experiencing clinical
training and taking medical safety lectures in the 4th year, students understood the importance of reporting incidents and were able to shift toward reporting behavior.

At least twice as many responses were obtained regarding awareness at the time of the incident in the 4th year compared to the 3rd year, clarifying that there was wider range of awareness in the 4th year. The most common responses were in the category “worry about the patient” containing the subcategories ‘apology’, ‘anxiety regarding patient status’ and ‘feelings when an accident was avoided’. Thus, the number of responses in the 4th year was much higher than that in the 3rd year. Kidoguchi et al. stated that “Experiences of incidents and accidents are important learning opportunities for students while reviewing incidents is important from the perspective of deepening learning”. In the year between the 3rd and 4th year, clinical training experiences and lectures enabled students in the 4th year to experience aspects such as emotions and awareness of near misses and to think of and give consideration to patient safety as the top priority.

In terms of “initiatives regarding near misses” with regard to “future handling”, more students in the 4th year appeared to think about concrete measures for handling near misses based on clinical training experiences and things learned in lectures. According to Matsumoto et al., “By experiencing clinical training, students’ learning about medical safety becomes more concrete”. The present study also obtained free responses of “act carefully”, “respond calmly”, and “take countermeasures” for “initiatives regarding near misses”, suggesting that students in the 4th year were examining situations based on their clinical training experiences.

4.3 Changes after medical safety lectures in the first semester of the 4th year
The most common response for “things learned from lectures” was ‘inattentiveness’. According to Maeda et al., “Regardless of their experience of near misses, all students fear the possibility that they will cause a medical accident or mistake”. Responses within ‘inattentiveness’ included “can happen to anyone”, “are familiar occurrences”, and “do not know when one will cause a near miss”. Accordingly, students are aware that near misses can happen to them. Hatakeyama stated that “The objectives of medical safety education are to bring awareness of the relationship between dangers in the medical setting and nursing techniques and tasks and to bring understanding of the seriousness of the effects of mistakes or inappropriate actions on patients”. Thus, by taking lectures and learning about accidents, students feel more familiar with medical accidents and near misses and are able to put themselves into and therefore consider a situation. However, the 7 students who responded “fear” are unlikely to be able to put themselves into and understand a situation even if they can objectively perceive the seriousness of medical accidents.

Initiatives regarding near misses’ was the most common response in the category “apply in the future”, with free responses including “analyze and investigate near misses” and “systematically prevent near misses”. In terms of “future handling”, while many responses referred to individual-based activities and responses, other responses demonstrated visualization of near misses and responses from a team perspective such as “systematically prevent near misses” and “share examples of cases”. Maeda et al. stated that “In Japan to date, the standard approach has been to point the finger of blame, such as asking “who caused the accident”, and often punishing one individual to close the case. However, it is important to change from focusing on responsibility to cause”. Free responses referring to “analysis and investigation” also indicate that acquisition of a causal focus enabled students to perceive thorough investigation of the cause of the near misses as a factor in “apply in the future”.

5. Conclusion
The present study compared “the realities and awareness of near-miss experiences” between the 3rd and 4th years of nursing education. Numerical data were not obtained but free responses demonstrated that clinical training experiences and things learned in lectures enabled more students in the 4th year to shift to self-motivated handling behaviors while deepening their knowledge and understanding of near misses. Thus, compared to the 3rd year, more students in the 4th year thought about patient safety as a top priority and the present findings mainly supported the working hypothesis.

According to Okuda et al., “After experiencing an incident, when students became mentors to
junior students, they were able to relate to incidents and accidents caused by the junior students, and were able to look back on their own experience”. As instructors, our goal should be to guide students to perceive near-miss experiences as part of their overall experience and learning and to apply their experiences while being aware that near misses are familiar and can also happen to them and that they should work to prevent recurrence.

As the present study was a questionnaire survey that only covered near misses about which students were aware, there were limitations to the assessment of changes, awareness at the time of the incident, and potential near misses.

Reference
3. Iwano O, Kai Y: Recognition and Investigation of near-miss experiences of nursing students — Comparative study by the clinical practice experience —, The Journal of Japan Academy of Nursing Administration and Policies 2015, 46, 437
4. Hatayama K: An Investigation of Incidents and Accidents during nursing students’ practical training — Focuses on reviewing and emotion of students —, Health Sciences University of Hokkaido Nursing Welfare Department Society 2012, 8(1), 51-55
9. Matsumoto K, Ito C: A Research of Nursing Students’ Learning Experience for Patient Safety, Sonoda Women’s University Library 2010, 44, 133-146
11. Okuda K: Nurses’ Feelings after their Accidents or Incidents, The Japanese Red Cross College of Nursing 2006, 20, 43-53

Contact to the Author:
Yukiko Kai
Email: yukiko_kai@med.miyazaki-u.ac.jp
Postal Address: 5200 Kihara, Kiyotake, Miyazaki, Miyazaki 889-1692
[Short Communication]

RISK OF DIS-LIPIDS SYNDROMES IN MODERN SOCIETY

Aurelian Udristioiu
Department of Biochemistry, Clinical Laboratory, Emergency County Hospital Targu Jiu & Titu Maiorescu University, Bucharest, Romania

Abstract
Aim of this work was to emphasis the preclinical evaluation of dis-lipids syndromes types at the patients which were presented to a routine control for checking health status, in the hospital ambulatory.

Material and Method: Were analyzed 60 patients, registered in Clinical Laboratory, assessing by running on the Hitachi 912 Analyzer, the principal biochemical parameters of lipid metabolism: Cholesterol, Triglycerides and fractions of Cholesterol, HDL and LDL. From the total of 60 patients 35 were females and 25 males.

Results: The persons with an alarm signal of atherosclerotic process were in 28 % and persons with low HDL was in 17%. The cases with atherosclerotic index, report-LDL/HDL>3.5 for men and 2.5 for women were in 14 % , the cases with predictive value with coronary risk, report-CO/HDL>5 were presented in 5 % and the cases with dis-lipid syndrome type 2- 4, with high Cholesterol and Triglycerides, were presented in 30% percent.

Conclusions: Lipids controls, and its fractions, are necessary to be prevented atherosclerotic process in the incipient status of ill.

Key Words: low density lipoproteins, very low density lipoproteins, intermediate density lipoproteins, cholesterol, triglycerides, chylo-microns.

1. Introduction

In the all developed countries, the numbers of obese persons, diagnosed with insulin resistance (IR) have increased rapidly to >40% in recent years. IR is a patho-physiological state characterized by a subnormal physiological response to insulin concentrations. This state precedes the development of metabolic syndrome (MS). Insulin resistance is often considered a pre-diabetic condition [1].

MS consists of multiple, interrelated risk factors of metabolic origin that appear to promote the development of atherosclerotic cardiovascular disease (ASCVD) and which are strongly associated with type 2 diabetes mellitus or the risk for this condition [2].
The metabolic risk factors consist of atherogenetic dyslipidemia (elevated triglycerides and apolipoprotein B, small LDL particles, low HDL cholesterol [HDL-C] concentrations), elevated blood pressure, elevated plasma glucose, a prothrombotic state, and a proinflammatory state [3].

The World Health Organization (WHO) has slightly different criteria for metabolic syndrome, including high insulin levels, elevated fasting blood glucose, or elevated post-meal glucose alone with at least two of the following criteria: abdominal obesity (defined as a waist-to-hip ratio greater than 0.9), a body mass index of ≥30 kg/m2 or a waist measurement >37 inches, a lipid panel showing a triglyceride level ≥150 mg/dl or an HDL cholesterol >35 mg/dl and blood pressure ≥ 140/90 (or receiving treatment for high blood pressure) [4].

Dis-lipids syndromes mean the metabolic statuses with qualitative and quantitative modifies of lipoproteins. Hyper-lipids syndromes means increases concentration of triglycerides and or cholesterol past acceptable limits in function of age, sex and health status. Hyper-cholesterol isolate status means high concentration of fraction low density lipoproteins (LDL), hyper-triglyceride status means high concentration of very low lipoproteins, (VLDL) and seldom chylo-microns and hyper-lipids mixed syndromes mean together high LDL and VLDL increased, seldom intermediate density lipoproteins (IIDL). Lack of receptors for LDL to fibroblasts cells and adipose cells will develop familial high-cholesterol with increases in serum of LDL-oxizing, together with cholesterol and triglycerides which will determine premature atherosclerosis [6], [Figure 1].

The rapport: Total Cholesterol/ HDL (high density lipoproteins) have the predictive value for coronary risk if its value is higher or equal with 5. The report LDL/ HDL, with predictive value past >3.5 for men and past>2.5 to women, mean atherosclerotic incipient index [7].

The diet and exercise combination presented in this study proved to be an effective treatment for MS, and this or a similar regimen should be recommended by physicians to patients who show signs of MS. For patients who show limited results from exercising on a stationary bicycle (or other exercising methods), drug treatment, such as specific treatment for dyslipid disorder, administration of leptins, leptin genes, or promoter drugs may be necessary, in addition to physical exercise and maintenance of an appropriate diet [8].

Further studies, which should include an appropriate control group, are necessary to confirm these findings, which can be regarded at present as only a hypothesis derived from the signs and symptoms of MS.

![Figure 1. Metabolism of LDL-Co with cholesterol biosynthesis and modulating oxidative stress](image)

## 2. Scope

The aim of this work was to emphasis the preclinical evaluation of dis-lipids syndromes types at the un-treated patients for any disease, which were presented to a routine control for checking heath status in ambulatory.

### 2.1 Material and Method

In our study we have analyzed 60 patients, registered in Clinical Laboratory, assessing by running on the Hitachi 912 Analyzer, with the principal biochemical parameters of lipid metabolism: Cholesterol, Triglycerides and fractions of Cholesterol, HDL and LDL. Cholesterol was determined enzymatic using cholesterol esterase and cholesterol oxidase reagents. Cholesterol esters is cleaved by the action of cholesterol esterase to yield free cholesterol and fatty acid; Cholesterol esters + H2O > cholesterol > cholesterol + RCOOH; Cholesterol is converted by oxygen with the aid of cholesterol oxidase to cholest -4-en, one and...
hydrogen peroxide. The hydrogen peroxide created forms a red dyes-tuff by reacting with 4 amino-phenazine and phenol under the catalytic action of peroxidase. The color intensity is directly proportional to the concentration of cholesterol and can be determined photometrical.

Triglycerides are esters of the thryglicerid alcohol glycerol with 3 long-chain fatty acids. To glycerol follows by oxidation to dihydroxy-acetone-phosphate and hydrogen peroxide. The hydrogen peroxide produced then reacts with 4-amino phenazine and chlorophenol under the catalytic action of peroxidase to form a red dyestuff, (Trinder endpoint reaction).

The cholesterol concentration of HDL-cholesterol was determined enzimatical by cholesterol esterase and cholesterol oxidase coupled with polyethylene,(PEG) to the amino groups (approx 40 %). Cholesterol esters are broken down quantitatively into free cholesterol and fatty acids by cholesterol esterase. In the presence of oxygen, cholesterol is oxidized by cholesterol oxidase to ∆4-; cholestenone and hydrogen peroxide. The color intensity of this of dye is directly proportional with to the cholesterol concentration and is measured photometrical.

LDL Cholesterol was measured direct by Analyzer Hitachi 912 with the specific reagents. Cholesterol esters are broken down quantitatively into free cholesterol and fatty acids by cholesterol esterase. LDL-cholesterol esters >> Detergent >> Cholesterol + free fatty acids: LDL cholesterol + O2 Cholesterol oxidase à ∆4 – cholestenone + H2O2; 2H2O2 + 4 aminoantipyrine + Peroxidase purple blue pigment + 5H2O. In the presence of oxygen, cholesterol is oxidized by cholesterol oxidase to cholestenone and hydrogen peroxide.

From the total of 60 patients 35 were females and 25 males. (Mean age for females was 27-45 years females and 37-52 years for males). All patients have not been in evidence with known cardiovascular, chronic, metabolic or endocrine diseases. All our results obtained were in validation after that was accomplished calibrations, internal controls and reference interval established on 120 known apparent health patients, analyzed in clinical laboratory, on each parameter measured. Interval References: Cholesterol = 114-225 mg/dl, Triglyceride = 53-145 mg/dl, HDL=36-60 mg/dl) and LD=48-130 mg/dl.

2.2 Result

By processing of results from upper table we registered following synthesis:, the persons with metabolic lipid health, were registered in 23% percent, the patients which has presented isolate high LDL as an alarm signal of start, atherosclerotic process, were in 28 % percent in time that low HDL was in 17% percent.

The cases with atherosclerotic index, Report-LDL/HDL>3.5 for men and 2.5 for women were in 14 % percent, the cases with predictive value with coronary risk, Report-CO/HDL>5 were presented in 5 % percent, the cases with dis-lipid syndrome type 2- 4, with high Cholesterol and Triglycerides were presented in 30% percent. The results of investigative cases are synthesized in tables, [1, 2, 3, 4].

2.3 Discussion

Cholesterol is a steroid with a secondary hydroxyl group in the C3 position. It is synthesized in many types of tissue, but particularly in the liver and intestinal wall. Approximately three quarters of cholesterol is newly synthesized and a quarter originates from dietary intake. Cholesterol esters are elevated by the action of cholesterol esterase to yield free cholesterol and fatty acids [9].

The determination of triglycerides is utilized, nephrosis, liver obstruction, lipid metabolism disorders and numerous other endocrine diseases. Triglycerides: Reference of reagent = 50-150 mg/dl, expected range <= 2.26 mmol/L (<2 00mg/dL), properly interval of reference := 53-145 mg/dl [10], [Table 1]

HDL is responsible for the reverse transport of cholesterol from the peripheral cells to the liver. Here, cholesterol is transformed to bile acids which are excreted into the intestine via the biliary tract. Monitoring of HDL – cholesterol in serum is of clinical importance since an inverse correlation exists between serum HDL – cholesterol concentrations and the risk of atherosclerotic disease [12].

Elevated HDL-cholesterol concentrations are protective against coronary heart disease, while reduced HDL-cholesterol concentrations, in conjunction with elevated triglycerides, increase the cardiovascular risk. HDL cholesterol is affected by a number of factors e.g. smoking, exercises, hormones, sex and age Education Program (NCEP) National Cholesterol guideline; shows low HDL cholesterol (major risk factor for CHD), ≥60mg/dL (1.56 mmol /L): high HDL cholesterol (negative risk factor for CH, [Table 2].
LDL plays a key role in causing and influencing the progression of atherosclerosis and in particular, coronary sclerosis. The LDL is derived from VLDL rich in triglycerides by the action of various lipolytic enzymes and which are synthesized in the liver. The elimination of LDL from plasma takes place mainly by liver parenchymal cells via specific LDL receptors, [13]. Elevated LDL concentrations in blood and an increase in their residence time coupled with an increase in the biological modification rate results in the destruction of the endothelial function and a higher LDL-cholesterol uptake in the monocytes/macrophages system as well as by smooth muscle cells in vessel walls. The majority of cholesterol stored in atherosclerotic plaques originates from LDL [14].

The LDL – cholesterol value is the most powerful clinical predictor among all of the single parameters with respect to coronary atherosclerosis. Therefore, therapies focusing on lipid reduction primarily target the reduction of LDL-oxidated – cholesterol, which is then expressed in an improvement of the endothelial function, prevention of atherosclerosis and reducing its progression as well as preventing plaque rupture. Expected: Reference of Reagent= 39-120 mg/dl [Table 3].

Weight loss is generally good for you if you are seriously overweight, but bone loss can cause significant problems later in life. In the study, rats who received leptin had a weight reduction of about 20 percent, but they did not have any bone loss. The rats that lost weight were able to maintain that weight loss. They also had large reductions of abdominal fat, also known as "bad" fat, which is known to contribute to weight-related health problems [15].

Leptin is required for normal skeletal growth and maintenance. The hormone also plays a significant role in the body's ability to maintain weight, telling your brain how much fat you have and if fat stores are sufficient. But people appear to develop leptin resistance with weight gain, and the brain no longer receives accurate messages.

### Table 1: CHOLESTEROL and TRIGLYCERIDES

**CLINICAL INTERPRETATION OF RESULTS:**

According to the recommendations of the European Atherosclerosis Society:

<table>
<thead>
<tr>
<th>Lipids</th>
<th>mg/dL</th>
<th>Lipid metabolism disorder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholesterol</td>
<td>&lt;200</td>
<td>44 case = 26.4% No</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>&lt;200</td>
<td></td>
</tr>
<tr>
<td>Cholesterol</td>
<td>200 – 300</td>
<td>11 cases = 6.6% Yes if</td>
</tr>
<tr>
<td>HDL – cholesterol &lt;45 mg/dL for women and &lt; 35% for men</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cholesterol</td>
<td>&gt;300</td>
<td>5 cases=3% Yes</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>&gt;200</td>
<td></td>
</tr>
</tbody>
</table>

Table 1. Results of investigated cases for Cholesterol and Triglycerides

Desirable cholesterol level: < 5.2 mmol/L (<200 mg/dL), borderline high cholesterol: <5.2-6.2 mmol/L (200 – 239 mg/dL), high cholesterol: ≥6.2 mmol/L (≥240 mg/dL), cholesterol reference reagent = 180-240 mg/dl

### Table 2: HDL - CLINICAL INTERPRETATION OF RESULTS

<table>
<thead>
<tr>
<th>No risk</th>
<th>Moderate risk</th>
<th>High risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td>Men</td>
<td>Men</td>
</tr>
<tr>
<td>Mg/dL</td>
<td>&gt;55</td>
<td>35-55</td>
</tr>
<tr>
<td>Women</td>
<td>Women</td>
<td>Women</td>
</tr>
<tr>
<td>mg/dL</td>
<td>&gt;65</td>
<td>45-65</td>
</tr>
</tbody>
</table>

Table 2. Expected values: for HDL-Co National Cholesterol Education Program (NCEP) guidelines: < 40mg/dL (1.04mmol dl): low HDL cholesterol (major risk factor for CHD), ≥60mg/dL (1.56 mmol /L): high HDL cholesterol (negative risk factor for CHD)

### Table 3: LDL - INTERNAL QUALITY CONTROL ON HITACHI ANALYZER

<table>
<thead>
<tr>
<th>LDL-Cholesterol</th>
<th>Within-run LDL-CO</th>
<th>Between-run</th>
</tr>
</thead>
</table>
Table 3. Precision work for LDL-Co. Expected values: optimal =<100 mg/dl, 60-99 mg/dl, near optimal= 100-129mg/dl, borderline high=160-189, very high >190, with properly reference interval =48-130 mg/dl.

3. Conclusion

Lipids controls, on fractions of Cholesterol, LDL, HDL, Triglycerides are necessary to be prevented atherosclerotic process in incipient status of ill. Familial dis-lipids syndromes must be analyzed at young ages, to different, apparent health persons, with ages past 35 years. Further information must to be accomplished by electrophoresis lipid, ultracentrifugation in density gradient, and measurement of apo-lipoprotein-B, by ELISA equipment [Table 4].

Table 4: This is the annotation of the table below.

<table>
<thead>
<tr>
<th>Type</th>
<th>Electrophoresis Aspect</th>
<th>Lipo-protein Composition</th>
<th>Causes</th>
<th>Mechanism</th>
</tr>
</thead>
<tbody>
<tr>
<td>IV VLDL</td>
<td>Composition</td>
<td>Triglycerides 60%</td>
<td>Ester Cholesterol endogenous 12%</td>
<td>Phospho-lipids 15% and major Apo-protein B100.</td>
</tr>
<tr>
<td>II a LDL</td>
<td>Composition</td>
<td>Cholesterol Esters+40%, Cholesterol 10%, Trygliceride=10% and ApoB100=20%</td>
<td>Family High - Cholesterol</td>
<td>Deficit of receptor LDL</td>
</tr>
<tr>
<td>II b LDL and VLDL</td>
<td>Increasing level of Plasmatic fraction Pre-beta and beta</td>
<td>VLDL and LDL</td>
<td>High-lipids Family with combination</td>
<td>Amplification of synthesis Hepatic of apo B</td>
</tr>
<tr>
<td>III IDL</td>
<td>Band beta large</td>
<td>VLDL→ LPL→ =IDL with low Triglycerides.</td>
<td>High-lipids with Increasing IDL</td>
<td>Abnormally APO -E.</td>
</tr>
<tr>
<td>IV</td>
<td>Increasing of level Plasmatic al fraction Pre-beta</td>
<td>VLDL</td>
<td>Familial High-triglycerides</td>
<td>Increasing of synthesis Hepatic apo- B and triglycerides</td>
</tr>
<tr>
<td>V</td>
<td>Increasing of level Plasmatic fraction Pre-beta</td>
<td>VLDL and Chilo-microns</td>
<td>Familial High Triglycerides</td>
<td>Amplification of synthesis hepatic triglycerides.</td>
</tr>
</tbody>
</table>

Table 4. The combination of fractions cholesterol in dis-lipids familial syndromes

ABBREVIATIONS: LDL-low density lipoproteins, VLDL-very low density lipoprotein, IDL-intermediate density lipoproteins
Reference


Contact to the Author:
Aurelian Udristoiu
Email: aureliann2007@yahoo.com
Postal Address:
[Short Communication]

Using the Balanced Scorecard to Improve Management in Healthcare Facilities

Yasuhiko SUEMORI 1, Shunsuke ADACHI 2, Okihiro MARUTA 1
1: Kyushu University, Japan, 2: Shimonoseki City University, Japan

Abstract
Healthcare is a multidisciplinary profession in which professionals with different areas of expertise work together, communicate, and share resources. Effective healthcare teams therefore require the relevant team management tools. The Balanced Scorecard (BSC) is one of the quality management and performance improvement tools readily available for use in healthcare facilities. The BSC is facilitative in terms of developing a mission, forming strategic goals, and linking of the mission and strategic goals to specific operational initiatives. Clinical safety is one of the most important strategic goals from the quality perspective of the BSC. In Japan, the BSC is popularly regarded as the key management tool supporting healthcare strategies, including clinical safety. 49 hospitals have adopted the BSC for their management system. 71 percent of them are private hospitals while 29% are public facilities. The BSC in 41% of the facilities have division-specific scorecard systems. Their scorecards may be adapted according to attributes of institutions, that is, not-for-profit or for profit. Private facilities tend to adopt the original form that prioritizes “finance” at the top of the scorecard, public hospitals tend to prefer other types. The diversification of the “customer” perspective is one of further institution-specific characteristics. The BSC requires the careful adjustment of goals in order to meet the changing strategic plan. Our interview research also found that many health care providers find implementing management systems such as the BSC to be challenging. To engage physicians in the development and running of management systems is also challenging.

1. Introduction
Our primary discussion issue is that proper formulation of strategy, including clinical safety, is critical for the sustainable success of healthcare facilities. The Balanced Scorecard (BSC) is originally created by Kaplan and Norton, and it has been used as a key strategic management tool. The BSC is now recognized globally in healthcare sector (see Aidemark 2001, Inamdar and Kaplan2002, Zelman and Pink2003, Northcott and France 2005, Dyball et al.2011, Suemori et al.2015). We have conducted the research study by referring to the published documents in Japan and some interviews with the department managers to review the contributions, problems, and limitations associated with the BSC in health care organizations.

2. Classification of the strategy map
Strategy map is a diagram to visualize how the strategic goals are pursued in an organization. In the basic formulation of the strategy map, the
usual order is (from bottom to top) perspective of ‘learning and growth’, ‘business processes’, ‘customers’, and lastly, ‘financial performance’. This indicates that the cause-effect chains are predominantly in that direction. In early experiences using the BSC in health care organizations, this order was often accepted as appropriate. However, there has been increasing resistance in health care organizations, especially those in the public sector, to placing the financial perspective at the apex of the strategy map representing the ultimate goal.

As described in Figure 1, we can classify four types of the strategy map by focusing on the placement of perspective of ‘finance’. ‘First-layer’ model is the one which places ‘finance’ on the top of strategy map. This is original and normal type proposed by Kaplan and Norton (2000) for private sector organizations. ‘Second-layer’ model is the one which places ‘finance’ at second layer from the top under ‘customer’ perspective. ‘Parallel’ model is the one which places ‘finance’ in line with ‘customer’ on the top of strategy map. ‘Second-layer’ and ‘Parallel’ models are also proposed by Kaplan and Norton (2001) for public sector institutions, such as nonprofit, government, and health care organizations. Additionally, there can be ‘Bottom’ model which places ‘finance’ at the bottom of strategy map. While ‘First-layer’ model can be reclassified as ‘for-profit’ type, ‘Second-layer’, ‘Parallel’, and ‘Bottom’ model can be reclassified as ‘not-for-profit’ one.

Figure 1: Types of Strategy Map

3. Japan’s situation

We collected cases from academic journals or books, and got 49 samples of BSC practices in hospitals in Japan. It included 35 private hospitals and 14 public one. 24 of 35 private hospitals adopt ‘for-profit’ type strategy map, while 12 of 15 public institutions use ‘not-for-profit’ one. As described in Table 1, therefore, ‘for-profit’ or ‘not-for-profit’ attributes of hospitals tend to decide which type of strategy map they choose (chi-square value=6.813, df=1, p=.009).

(Table 1)

There is diversification in which hospitals use BSC at overall level or only specific division of their organization. 20 of 49 hospitals prepared strategy map for only specific department. In terms of perspective of ‘customer’, 19 hospitals identify customers other than ‘patient’. It includes doctor or staff in other department as ‘internal’ customers and student or resident physician as ‘potential’ staff in addition to patient as ‘external’ one. Interestingly, hospitals using BSC at only level of specific division tend to diversify customers in their strategy map (chi-square value=14.400, df=1, p=.000).

(Table 2)

Moreover, 25 of 49 hospitals stated that they utilize consulting or seminar of external professions certified by an academic organization, Japan Association for Healthcare Balanced Scorecard Studies (HBSC). HBSC officially proposes to adopt ‘for-profit’ type of strategy map. As a consequence, even ‘public’ hospitals tend to employ ‘for-profit’ type of strategy map locating ‘finance’ at the top if they are advised by outside consultant (chi-square value=5.880, df=1, p=.015).

(Table 3)

We also made interview at a public institution included in these case hospitals, Kyushu Medical Center (KMC). As described in Figure 2, KMC uses ‘Second-layer’ type of strategy map, and prepares strategy map for a specific division, Operating Room (OR). In KMC, the problem of doctor shortage affects the strategy map. In this strategy map, job seekers (residents) are included as ‘potential doctor’ in its strategic target. That is, KMC made a condition on the improvement of the workplace in consideration of resident satisfaction.
The increase in the number of residents can lead to increase operation, thus, to make profits. As a result, it can result in the improvement of patient satisfaction. However, a doctor as head of OR in KMC said, “To focus on financial aspect is still challenging. It’s being hard to set the right key performance indicators. It’s been significant to establish our own strategy map through the discussion among our entire staff members”.

Figure 2: Strategy map of OR in KMC

4. Conclusion
In Japan, the BSC has already been popularly regarded as the key management tool for hospitals supporting healthcare strategies including clinical safety. There are some structural variations and we can classify them into four types by the placement of perspective of ‘finance’ in the strategy map. There is another emerging diversification in which hospitals use BSC at overall level or only specific division of their organization. In addition, more than half of the hospitals utilize consulting or promotions of external academic professions. As a consequence, even ‘public’ hospitals tend to employ the ‘for-profit’ type strategy to meet the views of the outside consultants. Whereas, according to our interview research, doctors tend to show their hesitation to ‘for-profit’ strategy. This discrepancy between the general tendency of the general views supported by the consultants and the doctors’ ideas can disturb the introduction process of the BSC. Effective adoption requires the adaptation and the development of the general instrument to the specific realities of the healthcare organizations.

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<th>Attribute of institution</th>
<th>Type of strategy map</th>
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<tr>
<td></td>
<td>For-profit type</td>
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<tr>
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<tr>
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<td></td>
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<td>Total</td>
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</tr>
<tr>
<td></td>
<td>% 53.1%</td>
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Table 2: Relation between organizational level and diversification of customer

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<tr>
<td>specific division</td>
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Table 3: Relation between utilization of external consultation and type of strategy map

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<td>%</td>
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Reference
11. Dyball, M. C., L. Cummings and H. Yu., Adoption of the Concept of a Balanced Scorecard within NSW Health: An Exploration of Staff Attitudes, Financial Accountability & Management, 2011; 27(3); 335-361.

Contact to the Author:
Yasuhiko SUEMORI
Email: kayaker@suemori.name
Postal Address: 6-19-1 Hakozaki Higashi-ku 812-8581 Fukuoka,Japan
IARMM Purposes, Charters & Activities

Purpose
Because of rapid globalization of society and progress in technological innovations, problems related to global environment issues, life-style disease, community health, occupational health, medical accidents, food product health, international health, mental health and health problems for aging population are on the rise. Whilst we all recognize the importance of the practice of risk management sciences for prevention of those problems by risk assessment, it is essential to integrate interdisciplinary research in such fields as political economics, administration studies, sociology, environmental science, ecology, behavioral science, information science, education, ethics, epidemiology and statistics, not just to develop technologies to implement government policies and countermeasures. This Society, therefore, seeks to contribute to the promotion of scientifically sound countermeasures and solutions by encouraging the free exchange and interplay of international research activities. The most distinctive features of this Society will be:

1) Focusing on health risks associated with the occurrence of unpreferable health conditions, to carry out evidence-based health policy study by means of numerous analyses of countermeasures for preventive management of health risks.
2) To promote advancing the techniques and theory of “management” as required by the science of preventive medicine.

OVER ALL
A mailing list, and provide information by means of English journals and newsletter, etc., on internet. Planning to conduct education and research programs and symposia by lecturers. International electronic forum and electronic symposium are provided.

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IARMM World Congress will be held every several years.

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1. The member (Conference President) who wishes to conduct the Special Conference of IARMM should submit the outline of the Conference to IARMM Congress Chairperson or President to make the contract with IARMM Chair and President.
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IARMM doesn’t have any responsibility your financial issues to carry out your conference, because it is clear that every Conference president can collect those financial resources by himself/herself.
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2) Oversea membership registration of your conference, if this assistant is necessary for you.
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The journals will be officially available to other member societies under agreement of IARMM for payment and publication policy. All manuscripts should be submitted to JMS. Annual subscription fee of IARMM members is included in the annual membership fee. Annual subscription fees for non IARMM members are 200 USD.

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IARMM President, WHRMC Chair. Emeritus SU, former Profs. D.Med. EPFL, USM, TWU etc.

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<th>Name</th>
<th>Position and Specialization</th>
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<td>Canada</td>
<td>Bjoern Bruecher</td>
<td>Prof. MD New Westminster College, Vancouver, Canada. Bon Secours Cancer Institute, USA (surgery)</td>
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<td>Canada</td>
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<td>China</td>
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<td>Japan</td>
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<td>Macedonia</td>
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<td>Prof. Medical University, St. Cyril and Methodius (surgery)</td>
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<td>Taiwan</td>
<td>Mingi Chan-Liao</td>
<td>Honor Hospital Director, MD Jen Ai Hospital, Taichung (clinical safety)</td>
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<td>Spain</td>
<td>Maria Angeles Cuadrado Cenzual</td>
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<td>Prof. Dr. University of College London, School of Pharmacy (medication safety)</td>
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<td>Dean Ian Curen</td>
<td>Prof. MD Queen Mary University of London (medical education)</td>
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<td>USA</td>
<td>May C. M. Pian-Smith</td>
<td>Assoc. Prof. Harvard Medical School (anaesthesia)</td>
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<tr>
<td>USA</td>
<td>Milenko J. Tanasijevic</td>
<td>Assoc. Prof. Harvard Medical School (pathology &amp; clinical laboraory)</td>
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IARMM Offices

(Head Office)

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E-mail: head.office01@iarmm.org
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1) Manuscript should be written in English. Each manuscript should be sent by e-mail to the following Editorial Office. Also, one original and two copies should be submitted.
2) The English abstract (250 words) should be attached to manuscripts.
3) The title page of the manuscript should include name(s) of author(s), affiliated organization(s), address of representative author, type of contribution, running title (not more than 60 letters including spaces) and number of tables and figures.
4) Manuscript should be typed in double-spacing on A4 (ca. 22x28 cm) paper.
5) Original article should be limited to 8 printed pages including tables and figures. This would be equivalent to 20 pages of double-spaced text. Exceeded print page will be charged by 100 USD per page.
6) Short communications and case studies should be limited to 2 printed pages including tables and figures. This would be equivalent to 5 pages of double-spaced text.
7) Key words up to 10 words will be placed after the abstract for reviews, originals, and field studies, but only after the title of the title page for short communications and case studies.
8) Tables and figures should be of adequate quality to withstand reduction in size. Each table and figure should be submitted on a separate A4 sheet. Their location in the text should be indicated in the margin of the text.
9) The following units and symbols should be used for quantities and measurements: km, m, cm, mm, μm, nm, Å, kg, g, mg, μg, ℓ, ml, μl; yr (year), wk(week), d(day), h(hour), min(minute), s(sec), ms, μs.
10) References should be numbered according to the order in which they appear in the text and should be listed at the end of the text according to the following format. The number of the references should be indicated in the text as … [1] … [2] … [3] … [4] … [5] …

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Conf. name: Date: Safe Environment and Progressive Skills Toward Smart Healthcare --- Based on Quality and Quantity Aspects

Date: 6 (Wed) - 8 (Fri) September 2017

Venue: Ambasciatori Palace Hotel, Rome, Italy

URL: http://www.iarmm.org/6WCCS/