Risk Management, Traceability and Measuring Productivity with POAS - Point of Act System -

Masanori Akiyama MD, PhD
Tokyo Medical University, Dept of Medical Informatics
Massachusetts Institute of Technology Sloan School of Management
Board member, Japan Society for Medical Informatics

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Injection operations from the perspective of medical safety

An inter-divisional safety system is needed...

A system is needed that reflects changes and cancellations in the information given to medical staff within a timeframe of 2 seconds.

Digitalization of this section was achieved with the use of POAS.
A system with the same granularity of paper = paperless

1. Electronic medical charts for peace of mind and safety
   Compliance with the new Pharmaceutical Affairs Law, and traceability of drugs and medical supplies

2. Real-time updating within 2 seconds on any terminal in the hospital
   1. Prevention of medical accidents and utilization of IT.
   2. Realize zero-inventory (to reduce costs)
   3. True information sharing

3. Material flow, wards, Pharmaceutical Department and ME control room

A system with greater granularity was needed to achieve process controls for medical procedures.

How is this different from conventional systems?

Conventional systems
- Enter schedule
  - Before action
    - Digitalize slips
    - Record of action schedules
  - After action
    - Record only the fact that the action was considered to have been taken (that insurance claims have been filed).
    - Even “real-time” systems had time lags (from 10 minutes to several hours)
- Is different from actual state.

POAS
- Enter action
  - Before action
    - To-do list of planned actions
    - Confirm immediately before action (within 2 seconds)
  - When action is performed
    - Recorded at the time of confirmation
    - Manage the “alibis” of actions and objects
    - Convert to data used for insurance processes
  - Completely consistent with the actual state

Slip granularity
Granularity of single items
Challenges of hospital information systems

From a safety standpoint
- Support for sudden changes with injections
- Real-time
- Traceability

From a management standpoint
- Synch with material flows
- Management support (Accurate costs for precision management and other tasks)

A system is needed that supports drug products barcodes.

A system is needed that synchs with material flow from the moment it is introduced.

A system that enables safety measures and improves management efficiency

- Real-time management is crucial to ensure safety.
  - Medical accounting calculations (eliminate billing omissions)
  - Reduce patient waiting times

Management must be performed on a per-day basis to ensure safety. This would be impossible using electronic medical chart systems that are merely extensions of medical billing systems.

- Unable to obtain in paper form (no slips).
  - Information is also obtained automatically.

Costs that consequently cannot be covered by insurance. (Unnecessary costs) can be managed.
EAN/UCC: Product Identification through the Supply Chain

PHYSICAL ITEMS & DATA FLOW

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**Granularity of slips**

- GTIN
- GTIN
- SSCC
- GTIN
- GTIN

- RSS
- UCC/EAN-128
- UCC/EAN-128
- UCC/EAN-128
- RSS

**Item data, sales catalog, ship notice, invoice**

**request for quotation, planning schedule, PO**

**Electronic Commerce Information Flow**

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**The evolution of hospital information systems**

**First generation (medical affairs and specimen exams)**

**Second generation (ordering)**

**Third generation (paperless electronic medical charts)**

**Fourth generation ubiquitous medical information systems**

- Ward, emergency, operating room and ICU
- Space of implementation
- Medical affairs section / Exam section
- Divisions that pose the greatest risk of danger and cost the most
- Information space
- Outpatient and nurse station
- Various divisions
- Medical slips
- Slips and reports
- Medical affairs section / Exam section
- Slips, instruction books and medical charts
- Outpatient and nurse station
- Various divisions
- Medical slips
- Slips and reports
- Medical affairs section / Exam section
- Slips, instruction books and medical charts
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- Medical slips
- Slips and reports
- Medical affairs section / Exam section
- Slips, instruction books and medical charts
Problems with material flow systems

Order → Purchase → Inventory → Issue injection → Drug mixing → Auditing → Mixed injection → Implement

The management of unnecessary expenses or expenses that are not covered by insurance is crucial to efficient management.

Automatically acquire information that could not be obtained on paper (no slip).

Consumption point of conventional electronic medical charts

Results in hidden inventory from unreturned items.

Ward

Medical billing

Pharmaceutical Department

POAS

Medical affairs

Drug mixing

Audit

DO

Action ended

Action in progress

Audited

Instruction

Include in cost when canceled

Do not include in cost when canceled

Action ended

Instruction given before the change was made.

The most dangerous. Also results in unnecessary costs.

Results in hidden inventory from unreturned items.
Information

**granularity**

Order

Act1
Task: 5W1H

Act2
Task: 5W1H

Act3
Task: 5W1H

Data unit = Slip (payment) unit

**Management of the number of items**

Injection prescription

11/1
Rp1) 5% glucose 500 ml
Vitamedin 1A morning

Rp2) Raw food 500 ml
K2 1A evening

Rp3) Raw food 100 ml
Pansporin 1 g
Morning and evening

Information

Order

Act1
Task: 5W1H

Act2
Task: 5W1H

Act3
Task: 5W1H

Data unit = People’s actions (changes) single item based

**Individual (ID) management**

Data unit = People’s actions (changes) single item based

**Individual (ID) management and digital forensics**

Data unit (of P=G persons E) Action (change) single item based

The log is recorded in a distributed way in real-time.

**POAS Grid Engine (PGE)**

With POAS, changes are reflected quickly and recorded.

With POAS, changes are reflected quickly and recorded.

**Physician**

Enter prescription

**Change the prescription if you see these exam results!**

**Ward**

**Mixing**

**Administration of drugs**

**Removal**

**Pharmacy**

**Administration based**

**Administration based**

**Administration based**

**Administration based**
Simultaneous log in and bi-directional real-time
Physicians and nurses can share the same data simultaneously.

The concept of data sharing in an information system

Realize bi-directional, real-time (within 2 seconds) sharing of information using IT.
The same data are shared between physicians and between the physician and the nurse at the same time.
Capable of analyzing accidents from various perspectives

Provides an accurate picture of not only the person who caused the accident, but of the actions of other medical staff as well as the situation in the ward and outpatient clinic.

The problem can be resolved not as an issue of individual responsibility, but as one that relates to the organization.

Planar analysis? Organizational (systemic) issues

Objective and methods

- Objective: An analysis was performed on treatment information compiled by performing data mining on electronic medical charts. All the admission data at the National International Medical Center for a period of one year from November 2003 was used to extract elements that can be connected to medical safety measures.

- Method: All the treatment information used in this study was based on anonymous personal information obtained from admission data and appropriate security measures were taken to maintain information security. Additionally, a treatment information data warehouse optimized for this study was created. XML-based full automatic registration was used to ensure real-time and accurate entry of data.
Period in question: November 2003 through October 2004

Method of observation: Summarized for the entire hospital and for each ward by month, by day of week and by time.

System: The PDA sounds an alarm when there is an attempt to perform an IV drip using a non-mixed injection *3.

Report: Summary of the number of reports. Comparison of the information contained in reports and information recorded on the system.

Interview: With wards that exhibited large fluctuations between different days of the week and those with characteristic alarm rates.

Flow from injection order to action:

- Order (physician)
- Receive instruction (nurse)
- Audit (pharmacist)
- Mixed injection
- Action
- End of implementation

*Cannot perform mixed injection unless an instruction is received and an audit has been performed. Action cannot be taken unless mixed injection is performed.*
The effects of making injection action entries (calculated from performance data)

- Issue injection prescription
- Perform mixed injection
- Action entry

Ward / Outpatient (HIS) 750 orders/day 2,329 drugs/day
IV drip bottle 570 orders/day (1006 Rp/day) 1,770 drugs/day
Nurse station (HIS) 570 orders/day (1006 Rp/day) 1,770 drugs/day
Bedside (Mobile terminal) 1006 Rp/day

Canceled or changed orders
180 orders/day (318 Rp/day)

Canceled or changed orders
180 orders/day (318 Rp/day)

Changes made to route speed
116 orders/day (204 Rp/day)

Changes made to route speed
116 orders/day (204 Rp/day)

About 37 thousand/month

There is a possibility of misadministration of about 40% if the change of order is not communicated in real-time.

Chronological record of medical actions taken (for one month)

Covers not only records of injections and IV drips, but also records of nursing actions and care actions taken, and observations made.

400 thousand/month -> About 80 million logs and 18 million records accumulated over two years.

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Basic analysis: From the frequency distribution of variables  (1/3)

Items newly added in and after December are shown in the pink fields.

Datamart items

Target variable
Comparison of the number of times mixed injections were checked and error rate (%) (by different time segments)

The number of check actions and the error rate have a slightly negative correlation.

The smaller the number of injections a nurse performs that day, the higher the alarm rate.

Alarm status by different time segments

Time segments with higher alarm rates become even clearer when seen in 30-minute increments.
2. Study of alarm status of “First injection/IV drip” (1)

Study regarding the phenomenon where the alarm is more likely to be triggered on the first injection or IV drip on a nurse’s shift.

There was a significant increase in the alarm rates for first injections. 
\[ P=0.000000000000000000000082397(10^{-23}) \]

The alarm rate for a nurse’s first injection of the day was unusually high.
4. Unusually high alarm rates among certain nurses or physicians

Distribution of alarm rates for number of actions taken by nurses:
There were certain nurses with relatively higher alarm rates.

Alarm rates by nurse:
- Nurses with relatively high alarm rates
- Physician in charge with relatively high alarm rates

Distribution of alarm rates for number of actions taken by physicians:
Similarly, there were physicians with relatively high alarm rates.
Results and discussion

The alarm rate was the highest in April with high rates prevailing through June and declining from July onward.

According to decision tree analysis:
1. Alarm rates rose during the late night (24-04), morning (09-09) and afternoon (13-18) time segments.
2. Alarm rates for the first injection of the day were high regardless of the time segment.
3. Alarm rates rose when the time on duty that day exceeded 6.5 hours. Alarm rates were higher the smaller the number of injections or IV drips performed that day by the nurse. Alarm rates were also higher around shift change times. And the rise in the alarm rate for the first injection was significant ($P=8.2\times10^{-23}$).

High alarm rates before 10 AM.
High alarm rates during time segments where physicians frequently changed their instructions. Nurses would forget to mix drugs that were placed in cold storage.

From the distribution of alarm rates for the number of actions taken by a nurse, we have discovered that 1-2% of the nurses had consistently high alarm rates or were “repeaters.”

While risk management traditionally tended to focus on mental aspects, scientific analysis allows us to identify background elements.

Effects

- Data mining or the analysis of electronic medical charts contributes not only to statistical analyses performed from a purely medical standpoint, but also to risk management in medical practices.
- It was deduced that a system that accommodated barcodes applied to every single item would be effective.
- Systems using POAS are useful for medical safety and for improving management efficiency.
POAS’s characteristics

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<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
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<td></td>
<td></td>
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</tr>
<tr>
<td>925</td>
<td>300</td>
<td>6,800</td>
<td>32</td>
<td>12</td>
</tr>
<tr>
<td>1,205</td>
<td>1,900</td>
<td>20,000</td>
<td>300</td>
<td>10</td>
</tr>
<tr>
<td>1,203</td>
<td>500</td>
<td>8,000</td>
<td>200</td>
<td>7</td>
</tr>
<tr>
<td>1,178</td>
<td>1,000</td>
<td>3,500</td>
<td>65</td>
<td>6</td>
</tr>
<tr>
<td>1,154</td>
<td>1,320</td>
<td>7,700</td>
<td>155</td>
<td>2</td>
</tr>
<tr>
<td>1,150</td>
<td>700</td>
<td>7,000</td>
<td>108</td>
<td>4</td>
</tr>
<tr>
<td>800</td>
<td>600</td>
<td>10,000</td>
<td>300</td>
<td>7</td>
</tr>
<tr>
<td>54</td>
<td>550</td>
<td>2,000</td>
<td>30</td>
<td>7</td>
</tr>
</tbody>
</table>

Inventory was cut to a tenth.
A cost reduction of 225.5 million yen was achieved for pharmaceuticals and 241.62 million yen for medical supplies.

POAS-based hospital management

- Prevent medical accidents.
- Thorough inventory management
- Keywords are “real-time entry” and “single item management.”
- The accurate acquisition of information on bedside actions is crucial.
- Acquire cancellation and change data.
  - Only about 60% can be acquired in conventional systems.
  - POAS gives an overall picture.
- This improves medical safety and management efficiency.
Cost calculation process (difference between the allocation method and POAS)

Material costs (pharmaceuticals, medical supplies, etc.)

<table>
<thead>
<tr>
<th>Department</th>
<th>Material costs</th>
<th>Revenues</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1 million yen</td>
<td>2 million yen</td>
</tr>
<tr>
<td>B</td>
<td>100 thousand yen</td>
<td>4 million yen</td>
</tr>
<tr>
<td>C</td>
<td>500 thousand yen</td>
<td>4 million yen</td>
</tr>
</tbody>
</table>

8 million yen

Directly charge actual amount used

Allocation method

Department A: 400 thousand yen
Department B: 800 thousand yen
Department C: 800 thousand yen

Revenue comparison (public and private hospital system, Leaf system)

Profit

-30,000
-40,000
0
10,000
20,000

Revenue and expenditure
Public and private hospitals
Leaf

Actually in the black

Current allocation methods are not capable of making accurate calculations of costs that would result in a deficit.
The analysis identifies profit and deficit elements by categorizing all data records into groups.

**RBF analysis test (1)**

The analysis identifies profit and deficit elements by categorizing all data records into groups. The analysis method includes the following 3 approaches:

1. Analysis based on all records. Analysis method: Decision Thursday
2. Analysis by department. Analysis method: Decision Thursday
3. Analysis based on all records. Analysis method: RBF

Number of data records: 1,585

* RBF analysis = Radial Basis Function
RBF analysis test (2)

First, the primary cause for Group (8)'s low rate of return on cost—100% or less (deficit)—was analyzed. The majority of causes in the case of groups determined to be in the red were related to emergencies.

RBF analysis test (3)

The characteristics of pediatric patients are prominent in Group (7), which is almost in the red.
Cost comparison
(Pediatric Department)

- Overall characteristics
  - The cost difference for prescriptions, injections and specimen exams is prominent.
  - Under the allocation method, costs tend to be distributed proportionately less than what they actually are (direct-charging method).

- Prescription
  - The difference between fixed costs is prominent.

- Injections
  - The difference in pharmaceutical costs under the allocation method were the most prominent (-753,508 yen / -46%)

Comparison of costs by account item under the direct-charging and allocation methods. (Pediatric Department) (unit: yen)

* Pathological and endoscopic exams were excluded because their revenue and expenditure add up to zero.
Ward costs, operations, anesthetics, treatments and nurse costs were excluded because these were excluded from the allocation.
Groups that were almost in the red—excluding Group (8), which was actually in the red—were designated to be “potentially profitable groups” and were compared against groups with the highest rate of return on cost (profitable groups).

The profitable and potentially profitable groups were compared based on their rate of return on cost. Experienced physicians are more profitable because they are more skilled!
Concept of the new hospital management support system

This system focuses on the medical action taken, enabling operators to calculate costs by patient and disease, and is not limited merely to cost calculations by division that were available on conventional systems.

Concept of the new hospital management support system

The balanced scorecard evaluates not only the resulting performance but also the process leading up to the results.

Develop a strategy -> KPI (Key Performance Indicator) -> Management and evaluation of actual actions
The BSC (Balance Score Card)

This was developed as a system for evaluating corporate (business) performance and has been attracting attention as a method for achieving corporate visions. This method focuses on various events, not only from a cost management perspective, but through a balance of four contrasting perspectives to verify the level of achievement from each of these perspectives.

- **Customer’s perspective**
  - Improve patient services

- **Financial perspective**
  - Improve corporate foundation

- **Perspective of operational processes**
  - Improve the quality of medical practices

- **Learning and growth perspective**
  - Develop human resources

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Example of class identification: Results from a model for identifying patients with a one-year life expectancy

Rate of correct identification: 83% = (3291+852) / 4962

n = 4962 patients (total: 659 patients)

<table>
<thead>
<tr>
<th>Y1</th>
<th>Y1</th>
<th>Number above Leaf node</th>
<th>Number below Leaf node</th>
<th>Upper column: Number of &gt;Y1 incidents / number of &lt;Y1 incidents</th>
<th>Lower column: Purity (percentage of the group with the greater number of incidents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>2341</td>
<td>130</td>
<td>17.0%</td>
<td>91.1%</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>3078</td>
<td>908</td>
<td>13.2%</td>
<td>88.9%</td>
</tr>
</tbody>
</table>

The method focuses on the square terminal node for an incident count of 100 or greater for either “<Y1” or “>Y1” and extracts locations where the purity is 85% or greater.

(10) In contrast to the fact that 93.9% of the patients died within one year when one criterion, [(PIVKA > 8255 mAU/ml)], was met; (9) And the fact that 91.7% of the patients died within one year when two criteria, [1034 < PIVKA < 8255] and [AFP > 1215 ng/ml], were met; (4) We have developed a model whereby 85.5% of the patients survived for one year or longer when three criteria, [PIVKA < 1034], [T-Cho > 102 mg/dl] and [AFP < 531], were met.
**Data integration in conventional systems**

1. Gather data on patients who have been released, receive care and are at home.
2. Share information through data transmission
3. Differences in granularity between systems are corrected manually.

**Utilization of a ubiquitous network**

1. Mobile networks are used.
2. Community coordination: acute stage hospitals, recuperative hospitals and clinics
3. Coordinated residential nursing, caring and welfare
   **These are coordinated in real-time**
EAN/UCC: Product Identification through the Supply Chain

Electronic Commerce Information Flow

Changes to the system: Barcodes on pharmaceuticals

The Ministry of Health, Labour and Welfare will be issuing instruction
To be institutionalized by the Ministry of Health, Labour and Welfare

- Introduce barcodes to drugs and medical supplies to protect patients from medical accidents.
- Begin supplying products with identification labels for unit dosages (administration unit: by single tablet, single ampule or single vial of the drug) on all drugs.
- The Pharmaceutical Department will be primarily responsible for introducing barcodes for each administration unit.
- The FDA (Food and Drug Administration) has announced the Bar Code Label Requirement for Human Drug Products and Blood in March 2003 to ensure patient safety and drug traceability. This requirement was enacted as a regulation in February 2004.
- This is likely to have a major impact on the Japanese market so we must act quickly.

Study group for the standardization of code labeling. Safety Measures Section, Bureau of Drugs and Food Ministry of Health, Labour and Welfare
Ubiquitous service platform

For example, in the case of the clinical path screen, display data related to the path integrated from different systems.
IC tag-based models in the overall pharmaceutical industry

Benefits for the wholesaler
- Quality assurance
- Automate and increase the efficiency of inspection tasks
- Automate and increase the efficiency of inventory management
- Acquire tracking data
- Improve traceability
- Quick response to complaints and inquiries
- Increase the efficiency of return management tasks
- Increase the efficiency and accuracy of sales information management
- Prevent theft and illicit distribution
- Increase the efficiency of recovery tasks
- Automate expiry date management

Benefits for the manufacturer
- Quality assurance
- Increase the efficiency of the manufacturing processes
- Automate and increase the efficiency of inspection tasks
- Automate and increase the efficiency of inventory management
- Acquire tracking data
- Improve traceability
- Increase the efficiency of return management tasks
- Quick response to complaints and inquiries
- Increase the efficiency of recovery tasks
- Prevent counterfeit drugs from abroad
- Increase the efficiency and accuracy of sales information management

Benefits for recycling and disposal companies
- Transparency distribution records
- Prevent illegal disposals.

Benefits for the medical institution
- Automate and increase the efficiency of inspection tasks
- Automate and increase the efficiency of inventory management
- Automate expiry date management
- Quick response to complaints and inquiries
- Ensure that correct dosage guidance is given.
- Automate and increase the efficiency of the management of administration records
- Improve safety and peace of mind.
- Prevent drug misidentification
- Prevent dosage errors
- Prevent patient misidentification
- Increase the efficiency of recovery tasks
- Acquire tracking data

Benefits for the pharmacy and drug stores
- Automate and increase the efficiency of inspection tasks
- Automate and increase the efficiency of inventory management
- Acquire tracking data
- Quick response to complaints and inquiries
- Increase the efficiency and accuracy of sales information reporting
- Automate expiry date management
- Ensure that correct dosage guidance is given.
- Increase the efficiency of recovery tasks

Patient's benefits
- Improved service
- Quality assurance
- Side-effect management
- Drug combination management
- Drug dosage time management
- Increase the efficiency of recovery tasks
- Acquire tracking data
Verification of the use of electronic tags in medical applications

Research leader  Masanori Akiyama

Overview of the research
- Develop technologies that enable electronic tag-based traceability schemes for drugs and blood to improve medical safety.
- Measure the affects of electronic tags and readers on pharmaceuticals as well as the affects of radiation and sudden temperature changes on electronic tags, and gather information. Conduct verifications on the traceability of drugs and blood products using electronic tags.
- Verification of security, privacy management and the management of patient condition, status and drug administration records, and traceability.

Research organizations
- **Tokyo Medical University**
  Overall design of the research and directions. Responsible for blood traceability experiments.
- **Tokyo Medical and Dental University**
  Responsible for drug traceability experiments.
- **Kanto Medical Center NTT EC**
  Provides the field for drug traceability experiments.
- **Hitachi Ltd.**
  Assists drug traceability experiments. Provides MUChip technology.
- **CSK**
  Assists blood traceability experiments.
- **Other executive committee members**
  Provide experiment fields. Give advice from the standpoint of their respective specialties. Participate in discussions on research strategies.
The evolution of hospital information systems

First generation (medical affairs and specimen exams)

Second generation (ordering)

Third generation (paperless electronic medical charts)

Fourth generation ubiquitous medical information systems

Ward, emergency, operating room and ICU  Medical affairs section / Exam section

Material flow  Space of implementation

Information space  Slips, instruction books and medical charts

Slips and reports  Medical slips

A material flow-based system is crucial

Ensure safety in divisions that pose the greatest risk of danger.

Emergency support (vocal implementation)  Various divisions

Outpatient and nurse station  Various divisions

Think!
What kind of system do you want, if your son or daughter were patients?

Thank you for your attention.
Any Questions?

E-mail: poas@mit.edu

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