3.1 To Understand the application of Incident Reports

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1. Japan Council for Quality Health Care (JQ)
2. International Society for Quality Health Care (ISQua)
3. Kyushu University Hospital
4. Ministry of Health, Labour and Welfare, Japan
Aims
To learn about;
• importance of data analysis
• how to use data (short-, mid-, long-term implications)
• what types of product are produced through RLS (quarterly report, annual report, monthly alert, database, etc at institutional and national levels)
• How products of RLS is useful in healthcare delivery.
Overview of the nationwide adverse event reporting/learning system (2004 - )

**Adverse event**
- Hospitals (Mandatory)
  - University Hospitals
  - National Hospitals etc.
- Hospitals (Voluntary)

**Near-miss**
- Hospitals (Voluntary)

Web-based reporting
- Coding
- Text
- Aim
- Outline
- Background
- Preventive measure

On-site visit
- (Voluntary survey)

**Aim**
- Patient safety and prevention of accident (No blame)

**Steering Committee**
- (Experts, Patient representative)

**Expert Panel**

**Secretariat**

**Annual/Quarterly report**

**Monthly alert**

**Database**

**Training program (RCA)**

**General public**
- Health care professionals/facilities
- Government
Development of reporting and learning systems in Japan

2001

R/L system of Near-Miss/Adverse Event

i) R/L system of Near-Miss

ii) R/L system of Adverse Event

2004

Revision of the government ordinance for R/L system of Near-Miss/Adverse Event

Subsidiary budget for R/L system of Near-Miss/Adverse Event

2006

Revision of “Health Care Act” to mandate internal R/L system to all medical institutions (Hospitals, Clinics)

Subsidiary budget for R/L system of Pharmaceutical Near-Miss

2008

R/L system of Pharmaceutical Near-Miss

JQ

MoHLW

MoHLW; Ministry of Health, Labour and Welfare

• R/L system of Near-Miss
• Operator: Pharmaceuticals and Medical Devices Agency (PMDA)
Web-based reporting/learning system (2004 - )

Specifics
i. Reporting management
   • Reporting by institutions
   • Tabulation to produce tables

ii. Registration management
   • Registration of institutions (ID, PW)
   • Communication with institutions on incidents

iii. Homepage management
   • Posting of products
   • News

Costs
i. Development of entire system
   • ~1 million USD at the launch (2004)

ii. Periodical renewal of the system
   • ~500,000 USD / ~5 years

iii. Homepage management
   • ~10,000-20,000 USD / year
### "Prescription"

<table>
<thead>
<tr>
<th>Code of incident types</th>
</tr>
</thead>
<tbody>
<tr>
<td>備方</td>
</tr>
<tr>
<td>備方延延</td>
</tr>
<tr>
<td>備方制間違</td>
</tr>
<tr>
<td>重複備方</td>
</tr>
<tr>
<td>重複備方延延</td>
</tr>
</tbody>
</table>

### "Other incident types"

- 補充
- 設計
- 調製
- 製剤
- 製剤管理
- 与薬準備
- 与薬

- 過剰投与
- 傷害投与
- 投与方向延延
- 投与方向制間違
- 重複投与
- 患者投与
- 投与制間違
- 投与時間・日付間違
- 重複投与
- 患者投与
- 投与方向延延
- 投与方向制間違
- 重複投与
- 重複投与
**Aim of the procedure(s)**

**what happened?**
Text: Probable cause(s)

Text: Preventive measure(s)
Text: Additional information

Attatchment: Drag & Drop
Importance of data analysis: How to improve quality and safety?

i. What is the probable cause of incident?
   - RCA: Root Cause Analysis
   - System approach: human factor’s viewpoint

ii. How do those who reported feel rewarded?
   - Feedback
   - Tangible improvement

iii. Create virtuous circle
   - Report, Feedback, Improvement
I do not report ...
I do report ...

I value the importance of patient safety incident reporting
I work in an organisation that has a blame-free culture
I learn from reporting
The process of reporting an incident is simple
The system is anonymous and confidential
I feel it is my duty to do so
I know what and how to report incidents
I do not fear being punished
I am rewarded for reporting
I value the feedback received
There are clear guidelines and policies for reporting
The patients have been seriously harmed
There is a clear policy in place to reporting incidents
The system is accessible
Overview of the nationwide adverse event reporting/learning system (2004 - )

**Adverse event**
- Hospitals (Mandatory)
  - University Hospitals
  - National Hospitals etc.
- Hospitals (Voluntary)

**Near-miss**
- Hospitals (Voluntary)

**Japan Council for Quality Health Care**

**Aim**
- Patient safety and prevention of accident (No blame)

**Steering Committee**
- (Experts, Patient representative)

**Expert Panel**

**Secretariat**

**Web-based reporting**
- Cording
- Text

**Hospitals**
- Mandatory
  - University Hospitals
  - National Hospitals etc.
- Voluntary

**On-site visit**
- (Voluntary survey)

**Annual/Quarterly report**

**Monthly alert**

**Database**

**Training program (RCA)**

**General public**

**Health care professionals/facilities**

**Government**
Contents of Annual/Quarterly report *

- Outline of the system
- Numerical analysis
- Thematic analysis
  - “New themes; 240 themes
  - “Recurrent” themes; 127 themes

* 67 Quarterly reports & 16 Annual reports
Types of Adverse Event

- **Medication**: 8%
- **Blood transfusion**: 0%
- **Procedures**: 28%
- **Medical devices**: 2%
- **Tubes**: 8%
- **Examinations & Lab tests**: 6%
- **Nursing care**: 35%
- **Others**: 13%

2019 Annual Report of JQ’s AE/Near-miss reporting system
### Frequent AEs (10 cases or more / yr)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overdose administration</td>
<td>54</td>
</tr>
<tr>
<td>Wrong drug</td>
<td>22</td>
</tr>
<tr>
<td>Overdose prescription</td>
<td>20</td>
</tr>
<tr>
<td>Wrong patient</td>
<td>19</td>
</tr>
<tr>
<td>Wrong drug dispensing</td>
<td>17</td>
</tr>
<tr>
<td>Faster setting of injection rate</td>
<td>17</td>
</tr>
<tr>
<td>Wrong method of administration (Wrong injection route, etc.)</td>
<td>12</td>
</tr>
<tr>
<td>Failure to prescribe</td>
<td>11</td>
</tr>
<tr>
<td>Administration of Contraindicated drug</td>
<td>11</td>
</tr>
<tr>
<td>Underdose administration</td>
<td>11</td>
</tr>
<tr>
<td>Failure to administer</td>
<td>11</td>
</tr>
</tbody>
</table>

(Annual report 2019)
Disclosure on the web of Numerical Tables & Individual Cases

Ex) “131” Tables disclosed on No.61 Quarterly report
# Themes of analysis in past quarterly reports

<table>
<thead>
<tr>
<th>Report</th>
<th>Theme</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>67th report</strong>&lt;br&gt;(2021-4)</td>
<td>Medication error related to chemotherapy for outpatient (series 2)</td>
</tr>
<tr>
<td></td>
<td>Error in care related to &quot;Medical Device-related Pressure Ulcer (MDRPU)&quot;</td>
</tr>
<tr>
<td><strong>66th report</strong>&lt;br&gt;(2021-3)</td>
<td>Discontinued injection of catecholamine due to delayed exchange of prefilled syringe</td>
</tr>
<tr>
<td></td>
<td>Error that residents are involved</td>
</tr>
<tr>
<td><strong>65th report</strong>&lt;br&gt;(2021-2)</td>
<td>Adverse event involving resident (series 2)</td>
</tr>
<tr>
<td></td>
<td>Wrong injection through mix-up of &quot;SILECE®&quot; and &quot;SERENACE®&quot;</td>
</tr>
<tr>
<td></td>
<td>Wrong injection through mix-up of &quot;MEYLON®7%&quot; and &quot;MEYLON®8.4%&quot;</td>
</tr>
<tr>
<td></td>
<td>Wrong procedure to use tracheal tube with speaking valve</td>
</tr>
<tr>
<td><strong>64th report</strong>&lt;br&gt;(2021-1)</td>
<td>Adverse event involving resident (series 1)</td>
</tr>
<tr>
<td></td>
<td>Adverse event involving Covid-19</td>
</tr>
</tbody>
</table>
### Thematic analysis “Wrong dosage of administration of heparin solution”

#### Thematic analysis; 10-20 pages
Thematic analysis “Wrong dosage of administration of heparin solution”

Tables

- Report counts by year
- Site of occurrence in facility
- Clinical department of occurrence
- Specific working-process of occurrence
- Years of career of staffers involved
- Wrong dosage by injection route, brand name of heparin product, planned dose/wrong dose, duration of administration
- Treatment necessary for patient with wrong heparin administration
- Case presentations
- Probable causes
- Preventive/Improvement measures
Thematic analysis “Wrong dosage of administration of heparin solution”
Thematic analysis “Wrong dosage of administration of heparin solution”

Tables
- Report counts by year
- Site of occurrence in facility
- Unit of clinical specialty of occurrence

- You will learn what sort of AEs are taking place, how they are happening and what type of preventive/improvement measures are taken in other facilities through collective analysis of Annual/Quarterly report.

- Treatment necessary for patient with wrong heparin administration
- Case presentations
- Probable causes
- Preventive/Improvement measures
Access to individual thematic analysis on the web

- PDFs referring to individual themes are posted on the web.
- Themes are classified and displayed by unique colors.

Themes:
- Medication
- Nursing care
- Procedures
- Medical device
- Tubes
- Others
- Exam/Lab test

220 themes are posted.
Production flow on thematic analysis (initial & recurrent event) and Monthly Alert in JQ

- Reporting of AE/Near-miss to JQ
- Thematic analysis
- Other themes
- Patient safety information (12 issues / year)
- Thematic analysis of recurrent event

Report (4 issues / year)
Staff lineup of the Division of Adverse Event Prevention, JQ

**RLS-Hospital/Clinic**
- Physician (1), full-time, dual assignment to RLS-Pharmacy
- Nurse (2), full-time
- Clerical staffers (2), full-time

**RLS-Pharmacy**
- Physician (1), full-time, dual assignment to RLS-Hospital/Clinic
- Pharmacist (2), full-time
- Clerical staffer (1), full-time
### Thematic analysis of “recurrent event”

<table>
<thead>
<tr>
<th>No.</th>
<th>Date</th>
<th>Event Description</th>
<th>Recurrence of</th>
</tr>
</thead>
<tbody>
<tr>
<td>67</td>
<td>2021-4</td>
<td>Serving of diet allergic to patient; Recurrence of &quot;Monthly alert No.69&quot;</td>
<td></td>
</tr>
<tr>
<td>66</td>
<td>2021-3</td>
<td>Wrong prescription of powdered medication: mix-up of active ingredients and entire powdered product; Recurrence of &quot;Monthly alert No.9&quot;</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Arrival of a patient at MRI suite with magnetic body; Recurrence of &quot;Monthly alert No.10 and No.94&quot;</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wrong site insertion of chest tube; Recurrence of &quot;Monthly alert No.9&quot;</td>
<td></td>
</tr>
<tr>
<td>65</td>
<td>2021-2</td>
<td>Mix-up of syringes with drugn solution; Recurrence of &quot;Monthly alert No.15&quot;</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wrong diagnosis in pathological test: Contamination of a specimen derived from different patient; Recurrence of a theme in the quarterly report No.24</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wrong ingestion of PTP package while taking drug tablets; Recurrence of &quot;Monthly alert No.57 and No.82&quot;</td>
<td></td>
</tr>
<tr>
<td>64</td>
<td>2021-1</td>
<td>Disconnection of tubes of a mechanical ventilato; Recurrence of a theme in the quarterly report No.24</td>
<td></td>
</tr>
</tbody>
</table>
Thematic analysis

Monthly Alert (2012, 2018)

Inadequate Checks Concerning Diagnostic Imaging Reports

Three cases have been reported involving a situation in which, although the diagnostic imaging report had been delivered after having conducted imaging examinations, the content was not checked and the physician failed to notice a diagnosis that she had not anticipated, thereby giving rise to the possibility that treatment was delayed (information collection period from January 1, 2008 to December 31, 2011). The information is partly included in "Individual Theme Review" pp. 231 in the 5th (Quarterly) Report.

Cases in which, after having conducted imaging examinations, the physician failed to check the content of the diagnostic imaging report and did not notice a diagnosis that she had not anticipated, thereby giving rise to the possibility that treatment was delayed, have been reported.

Objective of the Imaging Examination | Content Not Checked
--- | ---
Thorough examination for the purpose of a catheter ablation | Suspected pulmonary adenocarcinoma
Follow-up after a synthetic blood vessel graft replacement | Suspected primary lung tumor
Follow-up for an internal iliac artery aneurysm | Suspected lung cancer

All three reported cases involved a failure to check the diagnostic imaging report following a CT examination.
Thematic analysis; “Failure to Confirm CT, MRI etc. Imaging Report”

- Patient diagnosed with “Abdominal Aortic Aneurysm” underwent CT scanning for following up the possible growth of it.
- Vascular physician recorded the finding of the CT image on medical chart.
- One year later, nephrologist, another physician in charge of the patient, learned from another hospital that the patient developed lung cancer.
- Reviewing the CT imaging report issued by radiologist one year ago, it described as “There is a lesion highly suspicious of lung cancer”.
- CT imaging reports mentioned to “Cancer”.
- The physician in charge ignored cancer in organs that he/she did not specialize in.
- Nine similar cases including two fatal cases were verified through internal investigation.
- Preventive measures should be in place in expedited manner.
Preventative action by University Hospital Group

Japan National University Hospital Alliance (JANUHA, Chair; Tokyo Medical and Dental University Hospital, Members; 45 National University Hospitals) carried out fact-finding survey; i) and ii) and conducted iii) in relation to physician’s failure of confirming radiological imaging report;

i. Questionnaire survey in 2017

ii. On-site interim survey program in 2017

iii. On-site survey program in 2021
Q: “Is physician reminded of the new issuance of imaging report when it is produced by radiologist?”

- Only 58% (25/43) institutions are installed with notification system on issuance of the imaging report.

- Physicians need to keep the CT taken in mind not to fail to refer to the report. This could cause an error.

Notification system rapidly spread in the alliance during 2018-2020.

Our painful court ruling: Failure to confirm CT imaging report with finding of brain tumor, Fukuoka district court, Jun 21, 2019

- The event took place in 2006.
- Physician in Kyushu University Hospital overlooked a finding: “Suspicious of brain tumor” in imaging report.
- The District Court sentenced Kyushu University Hospital to be charged of 150 Million JPY (1.4 million USD).
<table>
<thead>
<tr>
<th>検査目標</th>
<th>検査目的</th>
<th>検査所見</th>
<th>診断結果</th>
</tr>
</thead>
<tbody>
<tr>
<td>[検査目的]</td>
<td>[検査目的]</td>
<td>[検査所見]</td>
<td>[診断結果]</td>
</tr>
</tbody>
</table>

検査報告書（CT）

患者ID: [名前]

生年月日: 1983/01/01

年齢: 40歳

性別: 男性

依頼診療科: 外科

入院/外来: 外来

依頼者名: [名前]

検査日付: 2021/01/01

検査番号: [番号]

検査部位: 胸部大動脈（CT）

造影剤: 生理食塩水100ml

臨床診断: [診断]

【検査目的】

【特別指示】

検査所見:

診断結果:

PD

S/P

Known

BD
Prevention by newly equipped vigilance module in EHR

- **Clinical division**
- **Types of report (Radiology/Endoscopy/Pathology)**

- **CT/MRI/X-ray**
- **ID**
- **Name**
- **Not-confirmed**
- **Issued date of report**
- **Confirmed**
- **Date of order**

From “Day/Month” to “Day/Month”
Air Embolism Due to a Central Venous Line Left Open

Seven cases have been reported in which air entered a blood vessel because a connection to a central venous line was removed in a way that left the line open to the air. (Information collection period: from January 1, 2013 to July 31, 2017.) The information is compiled based on “Individual Theme Reviews” p.130 in the 43rd Quarterly Report.

Cases have been reported in which air entered a blood vessel and had an impact on the patient, because a connection to a central venous line was removed in a way that left the line open to the air.

In six of the seven reported cases, the central venous line connection was removed while the patient was in a sitting position.

**Image of case 1**

- **Closed-system connector**
- **Patient’s arm**
- **Air error**
- **Patient’s x-ray**

**Purpose of Removing Connection**

<table>
<thead>
<tr>
<th>Purpose of Removing Connection</th>
<th>Number of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Changing clothes</td>
<td>2</td>
</tr>
<tr>
<td>Heparin lock</td>
<td>2</td>
</tr>
<tr>
<td>Removal of infusion line</td>
<td>2</td>
</tr>
<tr>
<td>Blood collection</td>
<td>1</td>
</tr>
</tbody>
</table>

**Case 1**

The nurse helped the patient change his clothes while the patient was in a sitting position. When doing so, the connection between the closed-system connector and the infusion line could not be removed, so the closed-system connector was removed without first closing the central venous catheter clamp. The central venous catheter was left open to the air, allowing air to flow in and causing a vascular obstruction due to air embolism.

**Case 2**

When carrying out a heparin lock of a central venous catheter, the nurse assumed that the central venous catheter had a closed-system connector and removed the infusion line. However, it did not have a closed-system connector, so the central venous catheter was left exposed to the air. The patient’s face turned pale and the patient collapsed on the bed. A head CT was taken, with a finding of a suspected air embolism.

**Preventive measures taken at the medical institutions in which the events occurred**

- All staff will be made aware that, where a closed-system connector is not being used, removing the connection to a central venous catheter without first closing the clamp exposes it to the air, leading to the risk of air entering a blood vessel.
- When removing the connection to a central venous line, staff will check that the line on the patient’s side is closed by ensuring either that the line is fitted with a closed-system connector or that the clamp is closed.

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*The Japan Council for Quality Health Care (JCQC) is not responsible for any legal matters related to this report.*

*This information is compiled on the basis of the reports submitted to the JCQC by accredited organizations in order to improve patient safety.*

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**Japan Council for Quality Health Care**

公益財団法人 日本医療機能評価機構

"Patient Safety Information" (Monthly alert)
Title: Air Embolism Due to a Central Venous Line Left Open

Key statement: Cases have been reported in which air entered a blood vessel and had an impact on the patient, because a connection to a central venous line was removed in a way that left the line open to the air.

Illustration to facilitate better and instant understanding of the key statement.

Case presentations:

Case 1:
The nurse moved the patient to change their clothes while the patient was in a sitting position. When doing so, the connection between the closed-system connector and the infusion bag could not be removed, and the unclosed-system connector was removed without first closing the central venous catheter clamp. The central venous catheter was left open to the air, allowing air to flow in and causing a compressible obstruction due to an air embolism.

Case 2:
When changing the patient’s position, the clinician assumed that the central venous catheter had a closed-system connector and removed the infusion bag. However, they did not have a closed-system connector, so the central venous catheter was left exposed to the air. The patient’s face turned pale and the patient collapsed on the floor. A head CT was taken, with a finding of a suspected air embolism.

Preventive/improvement measures:

- All staff will be made aware that, where a closed-system connector is not being used, removing the connection to a central venous catheter without first closing the clamp exposes it to the air, leading to the risk of air entering a blood vessel.

- When removing the connection to a central venous line, staff will check that the line on the patient’s side is closed, ensuring that the line is filled with a closed-system connector such that the clamp is closed.
Collection of AE illustrations

**Image of case 1**

1. The surgical site is on the right, right...
2. I will operate on the right-hand side.

**Image of case 2**

1. I heard the sounds. Please start the enteral nutrients.

**Table**

<table>
<thead>
<tr>
<th>Site of Sample Collection</th>
<th>Examination Result</th>
<th>Treatment Ordered or Carried Out</th>
<th>Background</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left arm</td>
<td>Blood glucose level 650mg/dL</td>
<td>Administration of Humulin R 10 units</td>
<td>- The patient had undergone breast cancer surgery and a sign stating “Do not use the right arm to take blood samples or measure blood pressure” was at the head of the patient’s bed.</td>
</tr>
<tr>
<td>Not specified</td>
<td>Rise in blood glucose level</td>
<td>Excessive Insulin therapy</td>
<td>- The staff member was concentrating on taking the blood sample and did not notice that the patient was receiving an infusion.</td>
</tr>
<tr>
<td>Right arm</td>
<td>Sodium 110mEq/L Potassium 7.8mEq/L</td>
<td>Administration of Cacideol / GI therapy</td>
<td>- The patient had a PIC catheter indwelling in the left arm. The staff members did not know that taking a blood sample from a limb during an infusion could affect the examination results.</td>
</tr>
</tbody>
</table>
人工呼吸器装着患者の移乗・体位変換は3人で行ってください！

例：人工呼吸器装着中の患者がリハビリで車椅子に乗るため、看護師とリハビリスタッフで移動した際にトラキオが誤拔去された。誤拔去時はプロトコールに沿って対応し呼吸状態の変化は見られなかった。体位変換は2人で行い、3人対応を終えた。

当院ルールは3人介入です

対策：
- 体位変換・移乗の前に気管チューブ・トラキオチューブの固定を確認する。
- 体位変換・移乗は3名で行い、役割を決め、声かけをしながら行う。
- 1名は人工呼吸器回路を保持し過度のテンションがかからないよう留意する。

1名は人工呼吸器の回路を保持し、挿入部の観察を行い、過度のテンションがかからないように留意すること。
Unsung Cinderella “MIDORI”, a patient ward pharmacist
Distribution of monthly alert

Medical institutions & professionals including 5,956* institutions receiving it through FAX, i.e. approximately 70% of Japanese hospitals

* Registration figure as of Sep, 2020
Collaboration with “Global Patient Safety Alerts”, initiative by “Healthcare Excellence Canada”
Choose “Adverse event” and/or “Near-miss”
Choose “Type of events”
Type key word for search: “Dialysis”

1,452 AEs are matched.

“Browse” button
“Download” button by digital file format
Database of AE / Near-miss on homepage

Each line indicates individual case including “coding” and “text” data.
Sharing data with independent vigilance system

- **Report on pharmaceutical side effect**
- **Adverse event of medical device**

**Manufacturer**

- **Medical institution**
  - AEs, Near-miss
  - Collecting incident reports and disclosure
  - Periodical reports of RLS targeting medical institutions and pharmacy
  - Incident database
  - Alerts

**Pharmacy**

- **Near-miss**

**Incidents on Database**

- **Disclosure**
- **Notice on HP**
- **Examine if advisory to manufacturer is necessary**

**Resources**

- Periodical reports of RLS targeting medical institution and pharmacy
- Database on the web
- Vigilance system on pharmaceutical products and medical devices **on mandatory basis**
- Report from medical institutions **on mandatory basis**

**Pharmaceutical products/Medical device Safety Panel**

- **Mission**: Deliberation on taking measure for product safety
- **Periodical reports of RLS targeting medical institution and pharmacy**
- **Database on the web**
- **Vigilance system on pharmaceutical products and medical devices** on mandatory basis
- **Report from medical institutions on mandatory basis**

**Pharmaceutical products/Medical device Safety Advisory Committee**

- **Mission**: Deliberation on how to enhance product safety
- **Convened as needed, open session**

**MoH facilitates distribution of the products.**

**Human error prevention**

**Preventive measures and idea of effective implementation**

**Exacerbation of product safety**

**Report**
From Reports to Knowledge for Patient Safety Improvement through Advancements in Artificial Intelligence

Japan Society for the Promotion of Science (JSPS) Grant-Aid for Scientific Research B (2018-2021)

Project Investigator ; Dr Zoie SY WONG
Associate Professor, Graduate School of Public Health
St. Luke’s International University
Case; Overdose prescription

• Physician intended to prescribe 2mL of incremin syrup. But prescribed **20mL of incremin syrup instead of 2mL** for 2-month-old baby in fact.

• Physician didn’t check the order after prescribing. Pharmacist didn’t notice that the dose was wrong on prescription checking and dispensed 20mL of incremin syrup. Patient received 20 mL of incremin syrup which was ten-fold of planned amount.
People involved: Physician

Intended to prescribe:

Strengthen-related 2ml

Right drug:

Strengthen-related

20ml of incremin syrup instead of

of

Strengthen-related

2ml

People involved: Physician
didn't check the order after prescribing

Dispensing
Click to obtain relevant learning resource’s hyperlink along with the annotation.
<table>
<thead>
<tr>
<th>Language</th>
<th>Entity</th>
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</thead>
<tbody>
<tr>
<td>プレドニオン</td>
<td><strong>Entity Type:</strong> Drug</td>
</tr>
<tr>
<td>Is this annotation correct?</td>
<td>YES  NO</td>
</tr>
<tr>
<td>New Entity: C</td>
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<tr>
<td>Entity Type: Strength_amount</td>
<td></td>
</tr>
<tr>
<td>Entity Type: Route</td>
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</tr>
<tr>
<td>Entity Type: Frequency</td>
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<td>Entity Type: Drug</td>
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<tr>
<td>Entity Type: Strength_amount</td>
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<td>Entity Type: Duration</td>
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<td>Entity Type: Strength_amount</td>
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<tr>
<td>15ml</td>
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<tr>
<td>Is this annotation correct?</td>
<td>YES  NO</td>
</tr>
</tbody>
</table>
Research through collective analysis of AEs related to laparoscopic surgery

ORIGINAL ARTICLE

Characteristics of Medical Adverse Events/Near Misses Associated With Laparoscopic/Thoracoscopic Surgery: A Retrospective Study Based on the Japanese National Database of Medical Adverse Events

Takashige Abe, MD, PhD,* Sachio Murai,* Yasuyuki Nasuhara, MD, PhD,† and Nobuo Shinohara, MD, PhD*

Objectives: The aim of this study was to clarify the characteristics of adverse events/near misses during laparoscopic/thoracoscopic surgery. Methods: Using relevant key words for minimally invasive surgeries, 540 records were identified in the database of the Japan Council for Quality Health Care. After data review and the classification of adverse events, 746 events associated with laparoscopic (laparo group) and/or thoracoscopic (thoraco group) surgery were identified. We calculated the frequency of each event, compared the frequency regarding recurrent

Since the report “To Err is Human, Building a Safer Health System,”1 health care workers have re-realized that medical accidents are inevitable events during daily clinical practice, and, among medical practices, surgical procedures particularly pose a potential risk to patients, which could result in significant complications.

Recent progress in minimally invasive surgery, such as thoracoscopic/laparoscopic/robotic surgeries, has provided several advantages including reduced pain, less scarring, lower-
Notice from pharmaceutical companies alerting “Sound-alike drugs” through citation of JQ’s database

“SILECE” & “SERENACE”

“RUPAFIN” & “LUSEFI”

“GRACEPTOR” & “PROGLAF”
Notice from pharmaceutical companies alerting “Sound-alike drugs” through citation of JQ’s database

Alert on prescription error of “Almarl” and “Amaryl”

4 AEs were quoted from the database of JQ’s Reporting & Learning system.

Case 1
Case 2
Case 3
Case 4
Sound-alike drugs

“Almarl” vs “Amaryl”

“Almarl”

The brand name was relinquished from the market and replaced with generic name in 2012 for patient safety reason.
Distribution of data/knowledge through SNS (Facebook) (2014~)

- Quarterly/Annual report,
- Thematic analysis
- Thematic analysis of recurrent event
- Monthly alert, etc.
No-fault compensation/investigation/prevention system for cerebral palsy, 2009～

No-fault compensation (Insurance)

- Petition (Report of CP)
- Review
- Payment

Investigation/Prevention with Patient Representatives

- Medical chart, Birth care record, laboratory data, etc.
- Family’s Voices

- Proceeding irrespective of negligence

Prevention, early settlement of conflicts and Improvement of quality
Disclosure of individual investigative report on the web
Table of contents of annual “Prevention report”

1. Qualitative and thematic analysis

2. Epidemiological and quantitative analysis
## Thematic analysis

### 2. Obstetric complications

<table>
<thead>
<tr>
<th>Management of umbilical prolapse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management of intrauterine infection</td>
</tr>
<tr>
<td>Management of uterine rupture</td>
</tr>
<tr>
<td>Management of placental abruption</td>
</tr>
<tr>
<td>Maternal education on placental abruption</td>
</tr>
<tr>
<td>Management of premature birth</td>
</tr>
<tr>
<td>Management of multiple pregnancy</td>
</tr>
<tr>
<td>Management of pregnancy-induced hypertension</td>
</tr>
<tr>
<td>Management of feto-maternal transfusion</td>
</tr>
</tbody>
</table>

### 3. Neonatal management
Recommendations published by Prevention Committee (for Obstetrician/Midwife)

- Educative recommendations on neonatal resuscitation standard.
- Training course of evidence-based neonatal resuscitation procedure developed by “the Japanese Society of Neonatology” has been constantly held on regional basis for obstetricians and midwives.
✓ **Educative statement on how to observe newborn after birth.**

✓ **Careful observations by mother when she holds her baby closely with her body immediately after birth are carefully described so that she would notice such incidents as sudden pulmonary and cardiac arrest, loss of control over body temperature etc.**
Disclosure and publicity

- **Quarterly** report: No. 1-68
- **Annual** report: 2005-2020
- Reports are released through press conferences.
Takeaways

- Successful reporting and learning system never fails to deliver feedback to medical institutions, medical professionals and the society.
- The feedbacks are exemplified in this lecture by periodical report, monthly alert, database of individual event, materials for education et cetera.
- Those products should be easily accessed by users and stakeholders i.e. accessed through the web page.
- Arrival of new product and relevant information of the reporting system may be noticed to users through SNS for effective spreading.
- The feedback could be referred in forefront of medicine and manufacturers for incident analysis, manual publication, risk management, patient safety research, product improvement et cetera.