Practical Experiences for Medical safety measure in PMDA

Medical Device Safety Division & Medical Safety Information Group
Office of Safety
Pharmaceuticals and Medical Devices Agency
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1 Serious Medical Accident is caused by 29 Slightly Serious Accidents, 300 Incidents leading to Medical Errors.

- 1 Serious Medical Accident
- 29 Slightly Serious Accidents
- 300 Incidents leading to Medical Errors

Arising from user error related to similarity of drug naming or packaging, lack of understanding indication for use.
A lot of errors are prevented by several protective action, but a serious adverse event is caused by the chain reaction such as a red arrow passes through all holes of pieces of Swiss Cheese.
Human Error

- Human Error includes:
  - improper usage
  - unexpected usage by manufacturer

If an error was occurred by the following factors, it cannot be included in Human Error.

- Providing inadequate information to users
- Involving factors inducing mistakes in products
- Similar configuration between different products
- Similar naming between different products

Manufacturers need to review safety measures regarding their products.
Reduction of Medical Accidents in Medicine

Manufacturers need to take proactive safety measures from user’s standpoint.

Manufacturers need to gather information of incidents or accidents, and should take proper safety measures.

- It is important for us not to judge medical accidents occurring due to only human error without careful consideration.

Knowledge or recognition gap to products between user and manufacturer.

Proper usage defined and listed by manufacturer.

- No problems regarding naming or packaging?

Proper usage imaged by user.

- Human error?
Accessible Design


Guidelines for standards developers to address the needs of older persons and persons with disabilities

- Different caps in each contents
- Different sign in each bottles

Comparison of visibility in traffic signs
Example of Product Improvement

These product improvement achieved as the result of analysis and assessment from gathering incidents or accidents.

Case 1: Rotary knob of electrical cooker
Case 2: Dry-cell battery
Medical Safety Information Group’s Work, PMDA

Our mission is to evaluate necessities of medical safety measures from the viewpoint of products related to drugs and medical devices.

- Analysis of Project to Collect Medical Near-Miss/Adverse Event Information Report *
  * published by Japan Council for Quality Health Care

- Analysis of adverse event reports in drugs and medical devices.

- Consultation regarding medical safety measure.

- Publishing the PMDA Medical Safety Information.
Measures of Medical Accidents in Drugs

- Prevention of similar drug name and false-recognizable drug name
  - A drug name must not be the same in first three Japanese letter of the others.
  - A drug name is required to specify in the order of following rule:
    Brand Name, Dosage Form, Amount of Ingredient / Constituent Concentration
    (in the case of New Drug)
    Ingredient name, Dosage Form, Amount of Ingredient / Constituent Concentration, manufacturer name
    (in the case of Generic Drug)

- Measures for improvement of recognition
  - improvement of visibility about label and outer case design
  - display of water solution (used to dissolve medicine for injection)
  - display of application site
A nurse needed to administer a patient by injection, but she administered only water solution without dissolving a freeze-dried medicine.
Improvement of Labeling

[From viewpoint of ergonomic design]
It is necessary to use more classifiable and visible design.

In the label of water solution, the indication of "injection solvent" needs to become bigger than "water solution".
Improvement of Packaging

To solve the problem concerned with classifiable and visible design, for example it needs to improve package design of the tray and vial.

Other improvements, for example…

- Caution indicated to the outer case
- Classifiable design of the tray
- Modification of the package design
The drug holidays are needed to administer Oral-Methotrexate, but it had been administered to a patient everyday.
Improvement of Wrapping Design

Oral Methotrexate has a serious adverse event if it had been administered everyday.

So, it needs to …
- Make space writing daily dose timing
- Indicate reminder message for appropriate dose regimen
- Package weekly dosage in 1 sheet
Analysis of Accident Report (1)

- In a lot of cases, the accidents had been caused to patients staying in the hospital in order to treat other diseases except for underlying disease.
- The detachable wrapping design might have made lose remainder message indicating for proper dose regimen.
Analysis of Accident Report (2)

- Only 1 variety of wrapping design might have been selected from some varieties in 1 hospital.

- The reminder message indicating for proper dose regimen might have been separated.

- The daily dose timing might have not been written in the designated column of the wrapping sheet.

The wrapping design might have been considered without actuality of clinical usage in a hospital.
A drug for external use was administered as an injection.

A nurse had mistaken the usage of a drug which needs to mix two agents separated different compartments in one bag.

What is the best way relating labeling and packaging in order to solve the problems?

“Safety standard rule of labeling, packaging and brand name for prevention of medical accidents” Issued as No.935 notice by MHLW dated on Sep 19, 2000
Improvement of Packaging

“Notification of preventive measures not to infuse to a patient without blending 2 drugs relating to 2 partition separated drug” issued as No.0808001 notice by MHLW dated on Aug. 8, 2005

Manufacturer had conformed to the notification and considered effect of preventative measures on 2 partition separated drug, but as the result, a lot of cautions indicating on the bag caused confusion to users.

Why had manufacturer designed the package of the perfusion solution confused to users due to similarity of the package of the infusion drug.
Analysis of Accident Report (4)

**case**

The drug was needed to be dissolved by enclosed water solution and 0.5mL of them must be administered to a patient, but all of them were used.

**point**

- Proper dosage is indicated “100µg/0.5mL” on the package but enclosed water solution is total amount of 0.7mL.
- In spite of the caution message regarding proper dosage, it was read without carefully.

**Other improvements, for example...**

- Standardization of the indication regarding proper dosage
- Easily understandable and viewable caution message
Comparison of 2 Caution Letters for Users

医療機器適正使用情報

タニーミライフケーテルに関する重要なお知らせ

タニーミライフケーテルに関する重要なお知らせ

不具合事例

今般、ケーブルの断線により電源が投入できない事例が10件報告されております。

原因分析の結果、写真1,2でお示しした---

適正な使用方法について

添付文書の【禁忌・禁止】及び取扱説明書にも記載してある通り、カテーテルの先端には--------

--------のため、重篤な健康被害を生じる可能性がありますので、他のガイドワイヤーとの併用を行わないようお願いします。

重要なお知らせ

2019年〇月〇日

問合せ先：(株)○○機器工業 TEL 〇〇 06-××3
Checkpoints for Visibility and Classification, PMDA

- **Manufacturer’s factors**
  - Font color and size in cautions and indications for use, etc.
  - Layout design of messages
  - Contents for indications
  - Structures of packages

- **Hospital stuff’s factors**
  - Individual skill, Stuffing problems in the hospital
  - Individual experience
  - Accumulated knowledge of dealing with similar cases

- **Drug’s factor**
  - Potential risks of drugs
Issue of Package Design

- Depending on manufacture’s activity of gathering and reporting incidents or accidents
  - To make a database of package design
  - Unreported incidents and accidents
  - Manufacture’s activity of gathering accidents caused by package design problems

- Issue of risk analysis method
  - Including standardization for safe product design in standard such as the JIS or ISO
  - Establishment of criteria for safety assessment
  - Objective evaluation by third party organization
  - Mixture old products and new products after renewed product design
Incidents in Medical Devices

- Adverse event in relation to pre-filled syringe
- Compatibility between pre-filled syringe and syringe-pump
- Problem of abnormal flow rate influenced by viscosity of solution

The droplet size of the injection solution influenced by its viscosity or its surfactant would cause abnormal flow rate value of injection solution calculated in the droplet counter based on optical detecting technique.

The syringe pump needs to be set to its configuration suited to each syringe in different manufacturers.
Viewpoint of Ergonomic Engineering (1)

The medical device is needed to develop in consideration of user's characteristic features because it is one of the man-machine systems.

There is a risk that the dial switch might be turned from correct setting to incorrect setting, in the case of taking the handle for the purpose of moving the device.

There is a risk that the push switch might be changed from ON to OFF, in the case of taking the handle for the purpose of moving the device.
In the case of disconnecting AC-supply, several types of device’s indicators in each manufacturers announce DC-battery mode. Which type of the indicators can you allow?

The device’s indicator shows only a message regarding DC-battery mode. If users don’t find out the message and hear an alarm in relation to abnormal condition of DC-battery, can users understand whether the DC-battery would be over its life or not?

The device indicates DC-battery mode by only a small light. If users don’t find out the light and hear an alarm in relation to abnormal condition of DC-battery, can users understand whether the DC-battery would be over its life or not?
Risk Assessment in Manufacturer

Consideration for product name, containers, package

Clarification of proper usage • improper usage

Identification of hazard

Estimation of risks

Risk assessment

Decision to product name, containers, package

Where the hazard is hidden?

How rates and levels of occurrence of health hazard would be caused by user’s appropriate usage?

Consultation with PMDA
Consultation of Medical Safety

Manufacturers might need to consider risk assessment and improve the devices and drugs, when they would found that some cases included in incidents and accidents that users might have caused had been caused by the devices and drugs.

Approximately 90 consultation in the first half year, 2008 are consulted with PMDA.

The major contents are shown below.

**Major contents**

- Product name of drug
- Labeling and packaging of product
- Indication for use / Direction for use of product
- Compatibility of product
- Product improvement
Concept of PMDA Medical Safety Information

Among the medical incident reports and adverse drug reaction/malfunction reports that have been collected to date, information on similar events that have been repeatedly reported and cases leading to notifications for revisions to package inserts are described on the "PMDA Medical Safety Information" site in an easily understandable manner and widely disseminated.

■ No.1

Point to note in case of obstruction of feeding tube

■ No.2

Recall of Resuscitators

■ No.3

Precautions against improper connection of speech valves etc. to tracheostomy tubes

http://www.pmda.go.jp/english/
Point to note in case of obstruction of feeding tube

1. Precautions for clearing obstruction of feeding tube — 1

- A larger size syringe should be used (refer to the syringe sizes recommended in the package inserts of the manufacturer of each brand). Using a small syringe will increase the injection pressure and the risk of breaks and cracks forming in the feeding tube.

- If strong pressure resistance is experienced, subsequent flushing should be avoided, and the tube should be removed.

Example of proper flushing

Flushing should be performed slowly using a larger syringe filled with a suitable amount of saline water without applying force. If strong pressure resistance is experienced, subsequent flushing should be avoided.

Example of improper flushing

Using a small syringe is associated with the increased flushing pressure and the risk of breaks and cracks.

2. Precautions for clearing obstruction of feeding tube — 2

- A stylet or guide wire should not be used to clear the obstruction.

A stylet or guide wire should not be used to clear obstructions!

The use of a stylet or guide wire may cause the perforation of the tube and subsequent injury to the esophagus or stomach.

Refer to PSBA/SD Notification No.0615001 "Instructions to revise the package inserts of enteral feeding tubes etc." issued by the Pharmaceutical and Food Safety Bureau of the Ministry of Health, Labour and Welfare on June 18, 2007.

This notification is available on the Pharmaceuticals and Medical Devices Information website (http://www.info.pmda.go.jp/mdevices/md007/0615001.html) (in Japanese).

About this information

- PMDA Medical Safety Information is issued by the Pharmaceuticals and Medical Devices Agency for the purpose of providing healthcare professionals with clearer information from the perspective of promoting the safe use of pharmaceuticals and medical devices. The information presented here has been compiled, with the assistance of experts, from case reports collected as Medical Event Information Reports by the Japan Council for Safety Healthcare, and collected as Adverse Drug Reaction and Malfunction Reports in accordance with the Pharmaceutical Main Law.

- We have endeavored to ensure the accuracy of this information at the time of its compilation but do not guarantee its accuracy into the future.

- This information is not intended to impose constraints on the discretion of healthcare professionals or to impose obligations and responsibilities on them, but is provided as a support to promote the safe use of pharmaceuticals and medical devices by healthcare professionals.
Recall of Resuscitators

1. Request for cooperation in the voluntary recall of resuscitators

- Among manual resuscitators (commonly known as “Ambu bags”), there are some products in which the expiratory valve becomes occluded when ventilation is operated under high oxygen flow. Therefore, the voluntary recall of resuscitators is currently being conducted and your cooperation is requested.

- The Ministry of Health, Labour and Welfare (MHLW) has already issued a notification on this matter. If you possess a resuscitator which is not listed in the notification, please contact the Pharmaceutical and Food Safety Bureau of the MHLW.

HPS/AGC Notification no. O91-1001 issued by the General Affairs Division of the Health Policy Bureau, MHLW, and PHS/ARC notification No. O91-2001 issued by the Pharmaceutical and Food Safety Bureau, MHLW on September 14, 2007 “Voluntary Recall of Manual Resuscitators (Resuscitators)”

The notification on this matter has been uploaded onto the Pharmaceuticals and Medical Devices Information website (http://www.info.pmda.go.jp/mddevsafe/MLH/1402.html) (in Japanese).

2. Products targeted for recall

- Products targeted for recall are listed and shown in the following table and pictures. Please contact the relevant manufacturer/distributor if you possess any of these products.

For more information on the voluntary recall, please see the Pharmaceuticals and Medical Devices Information website:
http://www.info.pmda.go.jp/mddevsafe/MLH/1403.html

Note: This is a translation of the original Japanese text. Information is provided only in the event of inconsistencies, the Japanese text shall prevail.
Precautions against improper connection of speech valves etc.
to tracheostomy tubes

1. Precautions for speech valve connection — 1
   - Speech valves have a one-way valve structure (see the structure of a speech valve in the figure on the right). Connection of a speech valve to a non-fenestrated inner cannula or tracheostomy tube will prevent exhalation. It should be ensured to check breath sounds after connecting a speech valve.

2. Precautions for speech valve connection — 2
   - HMEs and speech valves are similarly shaped but differ in intended purpose and structure. Caution should be exercised not to confuse one with the other.
   - Generally, speech valves are 15 mm in diameter, which is the same as the diameter of HMEs. It should be ensured that the correct device is connected to the tracheostomy tube.

Caution should be exercised not to confuse them!
Thank you for your attention