

Challenge for preventing medication errors-learn from errors-: What is the most effective label display to prevent medication error for injectable drug?

メタデータ	言語: eng 出版者: 公開日: 2017-10-05 キーワード (Ja): キーワード (En): 作成者: メールアドレス: 所属:
URL	http://hdl.handle.net/2297/9509

Challenge for Preventing Medication Errors

-Learn from Errors- :

What Is the Most Effective Label Display to Prevent Medication Error for Injectable Drug ?

Hiroyuki Furukawa

Center for Clinical Trial Management, Kanazawa University Hospital,
13-1, Takara-machi, Kanazawa-city, Ishikawa,
920-8641, Japan
sambista-knz@umin.ac.jp

Abstract. In the medical institutions, more than 50% of the error report is related to the administration of pharmaceuticals. And the half of the report is related to the administration of injectable drug.

By analyzing the error report, the inducing factor of medication error are not only the name similarity (sound alike) and the appearance similarity (look alike) of the preparations but also the display of the ingredient amount of the injectable drug which has 3 types ("X% YmL", "Xmg/mL YmL", and "Xmg/YmL").

The difficulty of the calculation seems to differ in these three types of display. Comparison of the right answer in these three types of display is tried for 6 subject groups which are three health care providers (physician, nurse and pharmacist) and their students. As a result, the calculation right answer percentage was high in "Xmg/YmL", "Xmg/mL YmL" and "X% YmL" in turn.

Keywords: medication error, error inducing factor, display of the ingredient amount.

1 Introduction

In the medical institutions, more than 50% of the error report is related to the administration of pharmaceutical preparations. And the half of the report is related to the administration of injectable drug (Fig.1). By analyzing the error report, the major inducing factors of medication error are the name similarity (sound alike) and the appearance similarity (look alike) of the pharmaceutical preparations.

It is not easy to calculate the right dose of the injectable drug prescribed in clinical situation, and the calculation result can not be sufficiently confirmed in emergency condition. As a result, the wrong dose can be administered to patients without recognizing calculation error.

By reviewing the measure to prevent calculation error in clinical setting, Ministry of Health, Labor and Welfare (MHLW) sent the notice to pharmaceutical companies on June 2nd of 2004 in Japan (Fig.2).

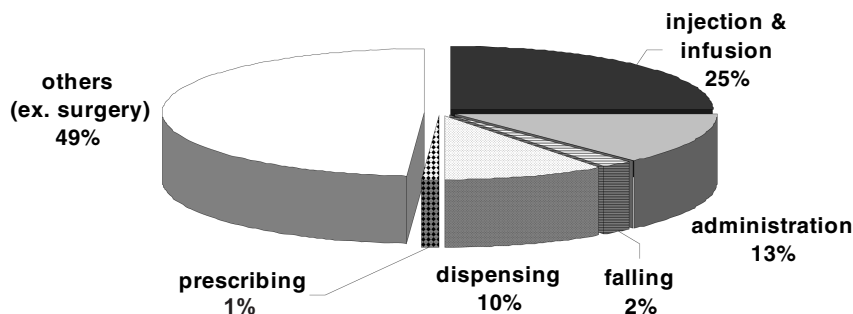


Fig. 1. Classification of Error Report in Japanese Medical Institution

June 2, 2004
薬食第 0602009 号
平成 16 年 6 月 2 日

Japan Pharmaceutical Manufacturers Association
日本製薬団体連合会会長
米国研究製薬工業協会在日技術委員会代表
欧州製薬団体連合会技術小委員会委員長

Ministry of Health, Labor and Welfare
厚生労働省医薬食品局長

Notice : Reinforcement to prevent medication error
医薬品関連医療事故防止対策の強化・徹底について

標記については、平成 12 年 4 月 28 日付け医薬第 462 号 厚生省医薬安全局長通知「医薬品・医療用具等関連医療事故防止対策の推進について」、平成 12 年 9 月 19 日付け医薬第 935 号 厚生省医薬安全局長通知「医療事故を防止するための医薬品の表示事項及び販売名の取り扱いについて」（以下「935 号通知」という。）、及び平成 15 年 11 月 27 日付け薬食第 1127003 号 厚生労働省医薬食品局長通知「医薬品の販売名・外観の類似性による医療事故防止対策の徹底について」により、関係企業における積極的な取組を要請しているところである。

また、医療事故防止対策については、平成 13 年 5 月より「医療安全対策検討会議」を設置し検討を進めており、医薬品の類似性に関連した事故の防止対策については、「医薬品・医療用具等対策部会」の下に「医薬品類似性ワーキンググループ」を設置し、具体的な対策の検討を行っているところである。

今後、これまでの「医薬品類似性ワーキンググループ」の検討結果（厚生労働省ホームページ <http://www.mhlw.go.jp/himg/2004/05/0392-8.html>）に掲載）を踏まえ、医療事故を防止するための医薬品の取扱いとして下記の対策を行うことが重要であることから、貴会員企業に対する周知徹底方を要請する。

なお、医薬品類似性ワーキンググループの検討結果を踏まえ、別紙のとおり、各自治体の長に対して通知したので、併せて御了解願いたい。

記

一、取組の経緯に基づいた適切な対策の検討について

(別添 1)

Prevention of error to recognize the strength's label
規格に係る誤りを防止するための表示の取扱いについて

1. 目的
規格単位の思い込みや換算間違いが原因の一つと考えられる医薬品の取り違えが生じていることから、このような間違いを防止するための対策として、規格に関する情報を含んだ販売名の表示に加え、容器、包装に記載すべき事項等を規定する。
2. 適用範囲
軟膏剤、液剤、顆粒剤、散剤、シロップ剤、点眼剤等、一回の投与時に各製剤の一部を使用する製剤及び注射剤について適用する。
3. 直接の容器への記載事項等
(1) 散剤、液剤等一回の投与時に各製剤の一部を使用する製剤については、直接の容器、包装に調剤時の採取単位となる基準単位（g、mL）当たりの有効成分量を表示する。
なお、販売名に基準単位当たりの有効成分量に関する情報を付した場合には、直接の容器、包装に濃度を表示する。
(例) 散剤の場合：100mg/g
(例) 液剤の場合：100mg/mL
(2) 注射液であって、販売名に有効成分の濃度に関する情報を付したもののについては、直接の容器、包装に容器当たりの有効成分量及び容量を表示すること。
(例) 販売名「○注 2% 5mL アンブルの場合：100mg/5mL
(3) 表示場所については、販売名の付置する等々視認性を高める工夫を要すること。

Display the amount and the volume of the active ingredient at the container label of injectable drugs.
ex. Drug A 2%5mL ⇒ Drug A 100mg / 5mL

Fig. 2. Notice from MHLW : Reinforcement to Prevent Medication Error (June 2, 2004)

2 Objective

The label type of injectable drugs' strengths for preventing calculation errors is evaluated by comparing the correct answer rates to three label types, which are "X% YmL", "Xmg/mL YmL", and "Xmg/YmL.

Table 1. Number of Trial Subject

Subjects	Number
physician	44
Nurse	506
pharmacist	206
Medical Student	85
Nursing Student	162
Pharmacy Student	211

Q1 Physician ordered “Administer Xylocaine® 30mg, intravenously” .

What “mL” should you administer to the patient ?



2%5mL

printed on the label

Fig. 3. Calculation Example A

Q2 Physician ordered “Administer Xylocaine® 30mg, intravenously”.

What “mL” should you administer to the patient ?




20mg/mL 5mL

printed on the label

Fig. 4. Calculation Example B

Q3 Physician ordered “Administer Xylocaine® 30_{mg}, intravenously”.

What “mL” should you administer to the patient ?



100mg/5mL

printed on the label

Fig. 5. Calculation Example C

3 Method

In this research, two objects are investigated.

3.1 Calculation of Dosage in Example Case

Three label types are showed to three health care providers (physician, nurse, pharmacist) and their students by presentation of images on screen for 30 seconds (Table 1, Fig.3-5).

Calculation of the dosage is tried by each health care providers and their students within the presentation time (30 seconds).

3.2 Label Type of New Preparations

Label type of new preparations marketed after the notice of MHLW was examined (June in 2004 – December in 2006).

4 Results

4.1 Calculation of Dosage

The correction rates to “X% YmL” are 25.0% (physicians), 2.6% (nurses), 35.4%(pharmacists) , “Xmg/mL YmL” are 79.5% (physicians), 36.6% (nurses), 72.6% (pharmacists), “Xmg/YmL” are 88.6% (physicians), 51.2% (nurses), 85.2% (pharmacists) (Fig.6).

In all surveyed health care providers, correction rates increased “X% YmL”, “Xmg/mL YmL” and “Xmg/YmL” in turn, significantly($p < 0.01$, chi-square test). And same results were observed in the health care students (Fig.7).

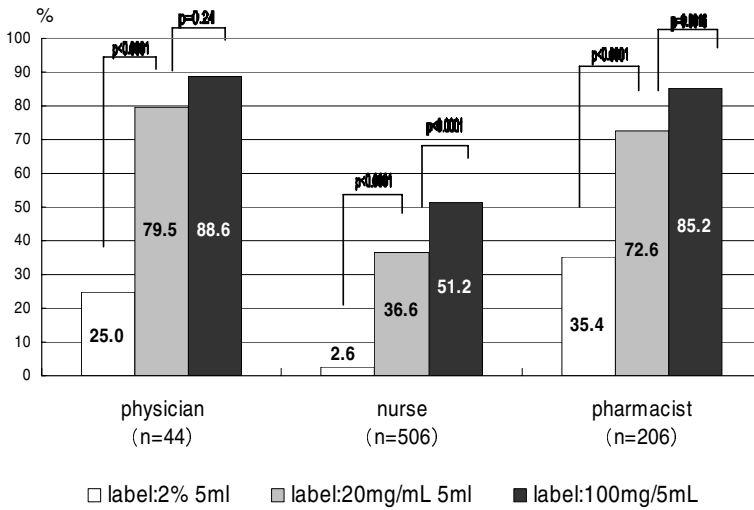


Fig. 6. Comparison of Right Calculation Percent in Each Health Care Providers (p:chi-square value)

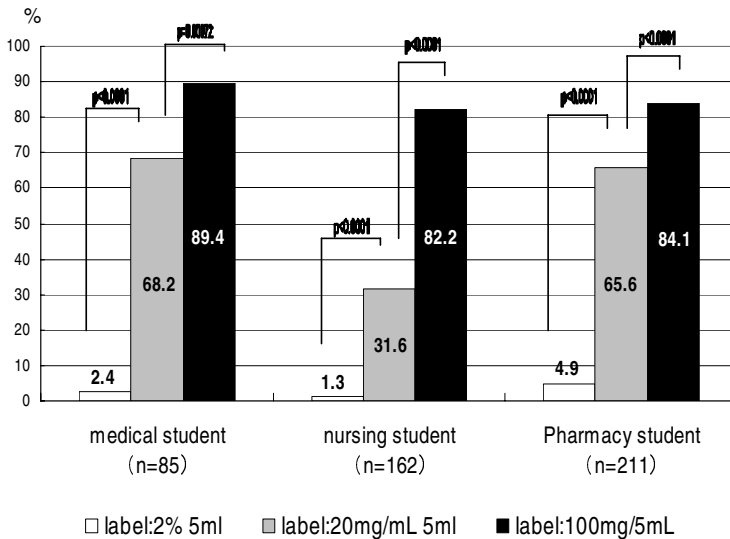


Fig. 7. Comparison of Right Calculation Percent in Each Health Care Students (p:chi-square value)

These results indicate the most effective label type to prevent calculation errors is “Xmg/YmL” for injectable drugs’ strengths.

4.2 Label Type of New Preparations

The injectable drug which was marketed after the notice was 83 preparations (brand based), and 7 combination preparations, 5 transfusion preparations and 28 solid preparations to dissolve before use which can not display "Xmg/YmL" are 43 in 83 preparations (Fig.8).

Only 4 of 43 preparations which can display "Xmg/YmL" were displayed in "%", and all of these 4 preparations are found "Xmg/YmL" on preparation label together.

As the result, "Xmg/YmL" were displayed in all of 43 preparation labels.

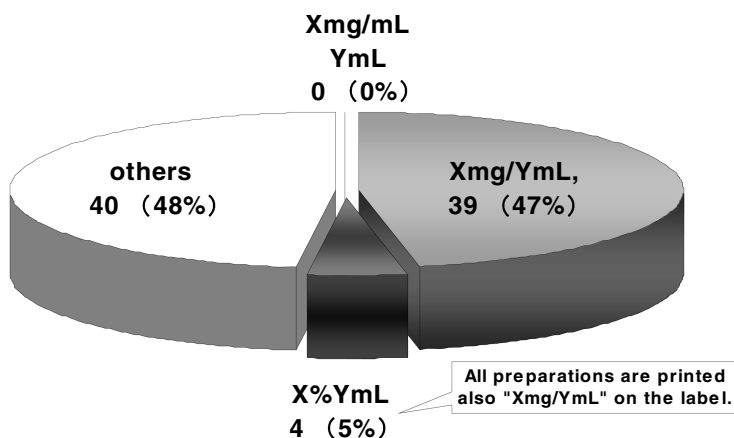


Fig. 8. Label type of new preparations marketed after the notice of MHLW

5 Conclusion

The most effective label type of injectable drugs' strengths for preventing calculation error is "Xmg/YmL" in this research, and the most effective "Xmg/YmL" is same as the indication in the notice from MHLW on June 4, 2004.

"Xmg/YmL" label is well accepted to the pharmaceutical companies after the notice of MHLW.

Acknowledgments. I appreciate all the health care providers and their students who cooperated with this investigation.