REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 1-I-17

Subject: Universal Color Scheme for Respiratory Inhalers (Resolution 906-I-16)

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Referred to: Reference Committee K (L. Samuel Wann, MD, Chair)

INTRODUCTION

Resolution 906-I-16, "Universal Color Scheme for Respiratory Inhalers," introduced by the Resident and Fellow Section and referred by the House of Delegates asked:

> That our American Medical Association work with leading respiratory inhaler manufacturing companies and health agencies such as the Federal Drug Administration and the American Pharmacists Association to develop consensus of a universal color scheme for short-acting beta-2 agonist respiratory inhalers that are used as "rescue inhalers" in the United States;
>
> That our AMA work with leading respiratory inhaler manufacturing companies to ensure the universal color scheme for respiratory inhalers would allow for the least disruption possible to current inhaler colors, taking into account distribution of each brand and impact on current users if color were to change;
>
> That our AMA work with leading respiratory inhaler manufacturing companies to ensure that universal color scheme for respiratory inhalers be designed for adherence and sustainability, including governance for future companies entering the respiratory inhaler market, and reserving colors for possible new drug classes in the future.

Traditionally, in the United Kingdom, Canada, and parts of Europe short-acting β_2-adrenergic agonist (SABA) respiratory inhalers are colored blue and referred to as "relievers" or "rescuers," while inhaled corticosteroids (ICS) are colored brown, orange, or red and are referred to as "preventers" or "controllers." No convention exists in the United States for the coloration of respiratory inhalers.

CURRENT AMA POLICY

Policy H-115.980, "Distinctive Labeling of Vials and Ampules, Prefilled Syringes, Ophthalmic Solutions and Related Liquid Medications," is somewhat related to this resolution, calling for the development of appropriate guidelines aimed at developing easily identifiable labeling to optimize the safe use of liquid medication. No current AMA policy related to color coding of respiratory inhalers exists.

Action of the AMA House of Delegates 2017 Interim Meeting: Council on Science and Public Health Report 1 Recommendation Adopted as Amended, and Remainder of Report Filed.

METHODS

English-language articles were selected from a search of the PubMed database through July, 2017 using the search term "inhaler" coupled with "color" and "colour." Additional articles were identified from a review of the references cited in retrieved publications. Searches of selected medical specialty society and international, national, and local government agency websites were conducted to identify relevant clinical guidelines, position statements, and reports.

COLOR CODING

Color coding is the systematic, standard application of a color system to aid in the classification and identification of drug products. Conceptually, a color coding system allows users to associate a color with a function. Color coding as an aid to patient safety requires the use of consistent coloring schemes by all manufacturers.

Color Coding and Medication Errors

In a 2004 report, titled "The Role of Color Coding in Medication Error Reduction," the Council on Scientific Affairs (CSA) (predecessor to the Council on Science and Public Health) noted controversy among experts and a variety of potential problems with color coding of pharmaceutical products, which suggest that a universal color scheme should not be universally adopted.[1] Several organizations involved in medication error prevention, including the American Society of Health-System Pharmacists (ASHP), Institute for Safe Medication Practices (ISMP), U.S. Food and Drug Administration (FDA), and the pharmaceutical industry either oppose color coding or recommend caution in its application.[2-5] The report also noted a lack of evidence proving that color coding reduces medication errors; this lack of evidence still exists.[1,6]

The result of the CSA report was a directive that was sunsetted in 2014 after AMA provided testimony to the FDA regarding the report's findings, which identified potential problems associated with the color coding of pharmaceutical products.[7] The FDA released a draft guidance in 2013, entitled "Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors."[5] The draft guidance recommends avoiding color coding in most instances and goes on to note that "[c]olor coding schemes developed to decrease error may actually increase error when the color is relied upon as a shortcut to proper identification (i.e., not reading the label)."[5] FDA intends to finalize this guidance.

FDA notes limited applications of color coding that are appropriate and were established before the 2013 guidance document, such as the caps of ophthalmic solutions that indicate the therapeutic class of a drug. These classifications, however, are generally not useful to end users outside of ophthalmology and these color classifications have caused problems with users having difficulty differentiating between drugs within the same therapeutic class.[5] Additionally, the color-coding of surgical anesthesia syringes has been adopted with the intention of reducing the risk of accidental syringe swapping by surgical users, but limited evidence has not shown that drug errors have been eliminated.[8] In both examples, the end user populations are limited groups, not a large outpatient patient population.

Additional Disadvantages of Color Coding of Pharmaceutical Products

In addition to the lack of scientific evidence that proves color coding reduces medication errors, experts in the field of medication errors also cite other reasons why the widespread adoption of color coding systems for pharmaceutical products should be done with great caution.[1,3,5,6,9-12] Potential problems include:

- There is a limit to the number of discernable colors available for commercial use.
- Subtle distinctions in color are poorly discernable unless products are adjacent to one another.
- Color coding of drug classes can increase the chance of "intraclass" medication errors.
- Colors may fade when exposed to light.
- It is not always possible to exactly reproduce Pantone colors from batch to batch.
- Approximately 8% of men and fewer than 1% of women have some difficulty with color vision (colorblindness).
- Color coding can be error-prone if it is not applied consistently across the industry, or within a single manufacturer's product line.
- Physicians and other health professionals may be unable to remember large or multiple-color coding systems.
- Color coding may offer a false sense of security and, in some instances, result in failure of the physician or other health professional to "read the label."

COLOR CODING OF RESPIRATORY INHALERS

The coloring of outpatient SABA inhalers as blue and ICS as brown/red/orange in the United Kingdom and Canada is an informal convention that has been an accepted practice for several decades. No regulations have been issued by the United Kingdom Medicines and Healthcare Products Regulatory Agency, the European Medicines Agency, or Health Canada, and no formal agreement exists for manufacturers, regarding a color convention for respiratory inhalers. As a general principle, the three health agencies recommend against color coding.[9,13,14] The European Medicines Agency has stated that "there can be no substitute for carefully reading the label before any medicine is taken."[15] Color of inhalers is not addressed in guidelines for the management of asthma.[16,17]

With the increasing diversity of inhaler devices, including combination products, entering the market in the United Kingdom and Canada, color coding is becoming more complex and inconsistent. The recent Health Canada approval of a long-acting β_2-adrenergic agonist (LABA) and ICS combination inhaler in the color blue[18] has raised concerns.[19] The existence of a generic salbutamol (a SABA) inhaler in brown in the United Kingdom adds confusion to the color coding convention.[15] Manufacturers have been called on to consider universal concepts such as color coded dots or bands that correspond to different types of medications.[20] However, the aforementioned disadvantages of color coding pharmaceutical products such as colorblindness and limited color availability persist and no formal action has been taken to ensure universal concepts.[21]

Color Coding Respiratory Inhalers and Patient Adherence

A small survey of health care professionals in the United Kingdom found that the existing color convention for inhalers appears to be helpful in aiding communication between health care professionals and patients and can be helpful for reinforcing the different roles of inhalers and aiding in medication adherence.[13] However, it should be noted that this communication between patients and physicians regarding inhaler color in the United Kingdom is likely aided by the color convention that has existed and been known for decades. A parallel situation of familiarity with a color convention does not exist for patients in the United States. The authors of the survey also

noted a lack of studies regarding color-standardization in general and specific issues surrounding color coding such as color blindness.

Poor adherence to maintenance therapy is common among asthma patients and a complex challenge to overcome.[22] Individualized action plans developed in a collaborative fashion between asthma patients and their physicians that focus on self-management are typically employed to promote adherence and appropriate clinical use of different inhalers. Inhaler color was of little importance in action plan discussions; emphasis was placed on when to use medications, skills training for use of inhalers, and education for asthma symptom management.[22,23]

CONCLUSION

Although looked to for simplicity, limited evidence exists that color coding systems reduce medication errors in outpatients. Disadvantages of using color coding systems have been cited and experts either oppose color coding or recommend caution in its application. The FDA, Health Canada, and health agencies in the United Kingdom emphasize the best course of action before administration of any medication is to read the label. Even though the health agencies of United Kingdom and Canada recommend against color coding, an informal respiratory inhaler color coding convention exists in these countries. However, because of continued development of new products, including combinations, this color coding convention is becoming inconsistent and more complex. Experts evaluating the adherence of patients using inhalers have suggested that individualized counseling with personalized action plans and inhaler skills training are the best approach for improving adherence. With the lack of evidence to support a color coding scheme for outpatient respiratory inhalers, there is no justification for urging manufacturers to change inhaler colors, the potential cost associated with such a change which may be passed along to patients, and disruption to the current market of familiar inhaler products.

RECOMMENDATION

The Council on Science and Public Health recommends that the following statement be adopted in lieu of Resolution 906-I-16, "Universal Color Scheme for Respiratory Inhalers," and the remainder of the report be filed:

> Our American Medical Association supports research into mechanisms to improve patient understanding of their respiratory inhaler medications with the aim of improving safety and reducing unintentional medication errors, such as inhaler skills training, individualized action plans, and distinctive packaging features for rescue inhalers. (New HOD Policy)

Fiscal Note: Less than $500

REFERENCES

1. Council on Scientific Affairs. *The Role of Color Coding in Medication Error Reduction.* American Medical Association;2004. 5-A-04.

2. American Society of Health-System Pharmacists. Use of Color to Identify Drug Products (9608). Updated 2013; https://www.ashp.org/-/media/assets/policy-guidelines/docs/browse-by-document-type-drug-products-labeling-packaging.ashx?la=en. Accessed July 7, 2017.

3. Institute for Safe Medication Practices. A spectrum of problems with using color 2003; 8(23):https://www.ismp.org/newsletters/acutecare/articles/20031113.asp. Accessed July 7, 2017.

4. Epson. Enhancing Pharmacy Labeling with Color to Improve Patient Safety. 2011.

5. U.S. Food and Drug Administration. Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors. 2013; https://www.fda.gov/downloads/drugs/guidances/ucm349009.pdf. Accessed June 26, 2017.

6. Filiatrault P, Hyland S. Does colour-coded labelling reduce the risk of medication errors? *Can J Hosp Pharm.* 2009;62(2):154-156.

7. Council on Science and Public Health. *CSAPH Sunset Review of 2004 House Policies.* American Medical Association;2014. 1-A-14.

8. Fasting S, Gisvold SE. Adverse drug errors in anesthesia, and the impact of coloured syringe labels. *Canadian Journal of Anaesthesia.* 2000;47(11):1060.

9. Health Canada. Good Label and Package Practices Guide for Prescription Drugs. 2016; https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/good-label-package-practices-guide-prescription-drugs.html. Accessed July, 11, 2017.

10. Cohen M. *Medication Errors.* 2nd ed. Washington, DC: American Pharmaceutical Association; 2007.

11. Wildsmith JAW. Doctors must read drug labels, not whinge about them. *BMJ : British Medical Journal.* 2002;324(7330):170-170.

12. Maxwell D. Distinguishing inhalers to aid blind people. *Bmj.* 1992;305(6863):1226.

13. Fletcher M, Scullion J, White J, Thompson B, Capstick T. Is the 'blue' colour convention for inhaled reliever medications important? A UK-based survey of healthcare professionals and patients with airways disease. *NPJ Prim Care Respir Med.* 2016;26:16081.

14. National Health Service National Patient Safety Agency and the Helen Hamlyn Research Centre. Design for patient safety: A guide to the graphic design of medication packaging.

2007; 2nd edition:http://www.nrls.npsa.nhs.uk/resources/collections/design-for-patient-safety/?entryid45=63053. Accessed July 11, 2017.

15. Partridge M. Coloured inhalers. *Bmj*. 1992;305(6858):890.

16. National Heart Lung and Blood Institute National Asthma Education and Prevention Program. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. 2007; https://www.nhlbi.nih.gov/health-pro/guidelines/current/asthma-guidelines/full-report. Accessed July 18, 2017.

17. Jones KP. Guidelines on the management of asthma. *Thorax.* 1993;48(10):1050.

18. Merck Canada Inc. Zenhale Product Monograph. 2016 Revised; http://www.merck.ca/assets/en/pdf/products/ZENHALE-PM_E.pdf. Accessed July 12, 2017.

19. McIvor AR. Inhaler blues? *CMAJ : Canadian Medical Association Journal.* 2011;183(4):464-464.

20. Jayakrishnan B, Al-Rawas OA. Asthma inhalers and colour coding: universal dots. *The British Journal of General Practice.* 2010;60(578):690-691.

21. Lawson E. Colour vision problems. *Br J Gen Pract.* 2010;60(580):854.

22. Pinnock H. Supported self-management for asthma. *Breathe (Sheff).* 2015;11(2):98-109.

23. Yin HS, Gupta RS, Tomopoulos S, et al. A Low-Literacy Asthma Action Plan to Improve Provider Asthma Counseling: A Randomized Study. *Pediatrics.* 2016;137(1).