

Useful Medication Information for Consumers



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ASHP

- **35,000 member professional and scientific society**
- **Pharmacists helping people make the best use of medicines**
- **Core focus on promoting safe medication use through:**
 - ❖ **federally recognized evidence-based drug information publishing**
 - ❖ **mission and vision**
 - ❖ **policy positions**
 - ❖ **guidance documents for best practices**
 - ❖ **high-level participation in key national safety and quality initiatives**



ASHP's Long History as a CMI Publisher

- **Almost 30 years of publishing consumer medication information (CMI)**
- **ASHP CMI is widely accessed via**
 - ❖ **National Library of Medicine's MedlinePlus consumer website**
 - ❖ **ConsumerReportsHealth.com website**
 - ❖ **ASHP's safemedication.com website**
- **MedGuide and Black Box Warning safety information integrated into ASHP CMI**
- **Hyper-links to full MedGuides embedded in ASHP's electronic CMI; URL's and patient access instructions included in printed versions**



ASHP's Long History advising FDA on Consumer Risk Communication

- **Member of Steering Committee that issued Action Plan for Provision of Useful Prescription Medicine Information (Keystone Guidelines) (1996)**
- **Public comment at FDA Drug Safety and Risk Management Advisory Committee on 2001 evaluation of CMI (2002)**
- **Provided FDA with detailed analysis of 2001 CMI evaluation showing only 50-65% of criteria directly attributable to professional labeling (PI) and required Keystone criteria**
- **Various NCPIE stakeholder initiatives to advise FDA (2003-present), including development of 2004 Assessment Tool for Determining Usefulness of CMI and advice on MedGuide dissemination**
- **Various advisory meetings with FDA staff on risk communication to consumers (2003-present)**
- **Testimony at FDA public hearing on MedGuides (2007)**



Current CMI Issues

2008 FDA Evaluation

- **Content publishers have made significant improvements towards compliance with the Keystone Guidelines and 2006 FDA Guidance document**
- **Areas not meeting adherence threshold fall into two main categories:**
 - ❖ **Content assessment criteria beyond scope of previously defined standards (Keystone & FDA Guidance)**
 - ❖ **Formatting/printing/legibility issues at the point of service**



Current CMI Issues

2008 FDA Evaluation (con't)

❖ **Content criteria concerns:**

- ❖ **Evaluation of content by expert panel extended beyond FDA-approved labeling (PI) for standards/criteria 1-6 to include tertiary and primary literature; Keystone & FDA Guidance describe these only in terms of PI information**
- ❖ **FDA Guidance specifies extension beyond PI for standard/criterion 7, but only if information was customized for specific patient**
- ❖ **Examples of “new” subcriteria used in evaluation:**
 - Requirement for a physical description of the drug or imprint code
 - Personal dosing instructions to be integrated into CMI document
- ❖ **Criteria more specific than outlined in Keystone or FDA Guidance**
 - Specificity & frequency of lab tests (versus advising of need for periodic tests, following MD's instructions)
 - Monitoring schedule (versus need for periodic monitoring)
- ❖ **Comprehensive vs Comprehensible**



Current CMI Issues

2008 FDA Evaluation (con't)

- **Printing and formatting issues**

- ❖ **High percentage of criteria not meeting goals**
- ❖ **Print size, line spacing, and ease of reading continued to have lowest scores (2008 vs 2001)**
- ❖ **Likely beyond control of content publisher**
- ❖ **Varied even with same content publisher (downstream effects)**
- ❖ **Content & formatting by publishers may not appear in printed document because of downstream changes**
 - Content sections
 - Font characteristics (e.g., style, emphasis)
 - Bullets
 - Headings
 - Separate lines
 - Spacing



What is Created by Publishers versus What is Dispensed to Patients

- **Failure of FDA to test content from source publisher versus point of dispensing**
- **Strong indicators that problem resides principally at point of service**
 - ❖ **Elimination of substantial content at point of service**
 - Same First DataBank leaflet with 760 vs 2457 words and 30% vs 88% adherence
 - Same Wolters Kluwer leaflet with 136 vs 2156 words and 11% vs 81% adherence
 - ❖ **Failure to adopt best practices for formatting and legibility at point of dispensing**



Current Issues

Multiple Sources of Consumer Risk Information

- **Consumer confusion, CMI vs. MedGuide vs. PPI vs. FDA Alerts (and often prescribers as well)**
- **Duplication of information in MedGuides; MedGuide content is not standardized by FDA**
- **Information overload to consumers**
- **True “usefulness” of the information (e.g., per Keystone guidelines & FDA Guidance) and effect on patient behavior/outcomes have not been adequately tested**



MedGuide Problems

Content

- **Variable content**
 - ❖ Will contain information that is “necessary for safe and effective use”
 - Too narrowly focused to cover what is “necessary”
- **Imbalanced description of benefits and risks**
 - ❖ Focus on risks of drug, often a single risk
 - ❖ Little if any balance regarding benefits of treatment
 - Antidepressants and risk vs benefit on suicidality
 - Cardiovascular risk of NSAIDs vs benefit of aspirin
 - Amiodarone warning against use outside labeling vs standard of care recs in ACLS (AHA CPR guidelines)
 - ❖ What are effects on patient behaviors & outcomes?
 - Unintended consequences



MedGuide Problems

Consumers

❖ Issues for the consumer

- ❖ Many MedGuides are too long
 - FDA 1998: “Lengthy information could result in unnecessary or even dangerous barriers to the effective communication of important concepts.”
 - FDA ignored its own advice of 2-page goal: 2007 Average \approx 8 pages long (range: 2–31 pages); some recent ones shorter
- ❖ Emphasis is on risk; little if any balance for benefit
- ❖ Consumer confusion with multiple medication information documents
- ❖ Do MedGuides actually enhance what is already integrated into CMI?



Recommendations

- **Conduct well-designed research to determine optimal content and format of CMI**
 - ❖ **Research must be patient/consumer-centered**
- **Goal should be single comprehensive yet comprehensible document**
 - ❖ **Test existing CMI with MedGuide integration from publishers vs stand-alone documents**
 - ❖ **Test additional prototypes as necessary**
 - ❖ **“Highlights” section of professional labeling not designed to serve as basis of integrated document**
- **Make use of current, well-established infrastructure for content development and deployment**
- **Ensure that guidance documents are as specifically detailed as any assessment criteria, including source information for content**
 - ❖ **PI should be minimum standard and content from other sources considered enhancements that exceed standard**
- **Fully engage stakeholders**



Recommendations

- **Clearly establish what is most important to communicate to consumers and how**
 - ❖ Risk/benefit
 - ❖ Safety information
 - ❖ How to use medications
- **Identify the best times to communicate each issue (e.g., risk/benefit discussion, safety & how to use) to consumers**
 - ❖ At the time of prescribing (could Drugs Facts Box prototype be used?)
 - ❖ First prescription
 - ❖ Each prescription refill
- **Ensure downstream adoption of optimal content and format**
 - ❖ Improve stakeholder engagement
 - ❖ Improve boards of pharmacy engagement
- **Fully consider economic impact on content publishers, system vendors, and pharmacies and develop realistic time-frame for adoption of any change**
 - ❖ Publishers already have invested heavily in adopting current guidelines
- **Do not implement change without sound evidence to support it**

