ENGELBERG CENTER for Health Care Reform at BROOKINGS

July 2010

MEETING SUMMARY

Expert Workshop: The Science of Communicating Medication Information to Consumers

Background

In order to use prescription medications safely, consumers need to receive clear, actionable information. This medication information must be accurate, balanced, and delivered in a consistent and easily understood format. In 2008, an evaluation of Consumer Medication Information (CMI) showed that while 94 percent of consumers received CMI with new prescriptions, only 75 percent of information met the minimum criteria for usefulness, demonstrating that this need is not being met.[1] At present, the sources of written prescription information patients receive are numerous, uncoordinated, and sometimes inaccurate or conflicting. At the point of dispensing, a patient may receive any or all of the following: patient package inserts (PPI), CMI, or Medication Guides.

Through a cooperative agreement, the Engelberg Center for Health Care Reform at Brookings is collaborating with the Food and Drug Administration (FDA) to convene three workshops to discuss optimizing, implementing, and evaluating adoption of a single standard medication information document to replace PPI, CMI and Medication Guides. The objectives of the first workshop, convened on July 21, 2010, were to discuss: (1) the overarching principles for communicating prescription information effectively; (2) metrics for evaluating CMI; (3) the most useful content and format of a single medication information paper document, as represented in FDA's three prototypes; (4) FDA's proposed strategy for evaluating the prototypes; and (5) how patients will receive medication information in the future and whether this has implications for near-term initiatives centered around a single document solution. Participants included experts representing academia, medical professional groups, and various stakeholders from the private sector, including manufacturers, consumer organizations, and publishers of CMI. This document highlights the major points of discussion that took place during the workshop.

Scope and Intended Use of Patient Medication Information (PMI)

At the outset of the meeting, FDA stated that the purpose of written medication information is to help patients take their medication properly once they are home. It should be given after the provider and patient have decided upon an appropriate treatment course and should complement verbal instructions from providers. FDA does not intend for written information to replace provider counseling. FDA intends for it to serve as a use-aid for patients and not as a decision-aid. Therefore, experts suggested calling this information more aptly "patient medication information" (PMI) rather than consumer medication information (CMI).

FDA envisions that PMI will provide basic directions for use of easily administered products, such as oral medications. PMI is not intended to include directions for complex administrations that require accompanying devices, such as injectables. For products that require complex administrations, FDA expects that providers would demonstrate and teach patients proper administration. In these cases, more complicated written administration instructions would be included as a separate document. This type of information was outside of the scope of this workshop.

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[1] Kimberlin DL, Winterstein AG. Expert and Consumer Evaluation of Consumer Medication Information-2008. US Food and Drug Administration. November 4, 2008. Available at: http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/UCM117149.pdf. Accessed June 10, 2010.

Developing Appropriate Content for PMI

Experts identified the lack of patient-friendly information as a flaw of currently available prescription information. Much of the existing PMI uses terminology that targets prescribers as the audience, and experts expressed a need for the content of new PMI to be patient-centric – developed specifically to address the needs of patients. To address this, some experts suggested simplifying PMI language and tailoring it to patient-level understanding, particularly for indication and side effects. For example, some PMI has indication sections that are very specific and mirror what is included in professional labeling, which may include information such as what products patients must previously have tried and failed before receiving a particularly treatment (e.g., "for patients refractory to…" or "second-line treatment after failure on…"). For patients, this information may be not only extraneous, but also confusing.

When discussing FDA's three prototypes, experts had differing opinions on what content should be included, including whether PMI should contain benefits in addition to risk information. The goal of PMI ultimately dictates appropriate content, and experts presented a number of highly valid but different goals for PMI: as an alert to patients of medication risks, as a reference sheet to supplement the information patients receive from providers, and as a set of instructions for appropriate use. Each of these goals requires different content.

Experts thought that providing additional contextual information (such as the style used in prototype 2) enhances patient understanding.[2] Therefore, they saw value in including additional context and simple rationale explaining when and why patients should contact their physician about their medication.

Developing the Right Format for PMI

In addition to FDA's three prototypes, experts provided a few alternate prototypes, but each had strengths and weaknesses, illustrating that there are multiple effective PMI formats. No definitive evidence currently exists on what format works best. To address the lack of evidence, experts agreed that prototypes must be tested with patients, the final arbiters of optimal format.

Although there is no evidence on optimal page length, FDA firmly stated that PMI must stay within the single-sided one-page limit. This decision was based on concern of non-adherence to page limits from past experience, such as with Medication Guides, where manufacturers exceeded specified page limits. There are, however, several variable elements that might influence success of PMI, such as the order in which the information is presented, font choice, and font size, all of which must be tested with patients to determine the best mix of elements.

Several experts, though, agreed that an actionable document, with actionable headers, such as prototype 3, is more useful to patients than the question and answer format used in prototypes 1 and 2.

Strategies for Evaluating PMI Effectiveness

FDA stated that developing evaluation metrics and standards is critical for implementing a new PMI document. They estimate that there are as many as 22,000 products that need PMI, but the agency is not resourced to individually review each of these documents. Even if FDA reduced this number, as experts suggested, by mandating the creation of the same PMI document for both generics and branded versions of a product, the number still remains too high for FDA's individual review. Instead, by setting clear, standardized metrics for evaluation, FDA can provide guidance to manufacturers for creating PMI.

[2] FDA's draft prototypes 1, 2, and 3 are attached to the pre meeting discussion guide as appendix B. These documents can be found at: http://www.brookings.edu/events/2010/0721_CMI.aspx.

Experts discussed a range of metrics for PMI evaluation:

Metrics to evaluate immediate effectiveness:

- Readability
- Comprehensibility
- Patient ability to apply the information

Metrics to evaluate the long-term effectiveness:

- Improvement in long-term treatment adherence
- Reduction in cost
- Improved patient outcomes (e.g., reduction in hospital readmissions)

Metrics that evaluate immediate effectiveness will quantify the influence of PMI on patients as they review and digest the information. Evaluations of long-term effectiveness are more difficult to conduct. Assessing long-term effectiveness requires coping with a number of confounding factors, such as provider counseling, and requires measuring distribution and use of PMI, which is outside of FDA's regulatory authority. These factors are further compounded by technological limitations within our existing health care system. Thus it is currently more practical to evaluate immediate effectiveness rather than long-term effectiveness. Although potential metrics to evaluate both have been identified, thresholds for meeting them have not been established.

FDA's Proposed Consumer Testing Study to Evaluate the Prototypes

FDA presented and sought feedback on their proposed strategy for testing the prototypes among patients. The design includes three parts:

1. Live pretest: small sample of in-person testing (n = 180)
2. Internet with hard copy prototype: patients receive one of the prototypes in the mail and answer questions via the Internet (n = 900)
3. Internet with electronic prototype: patients have an electronic copy of the prototype and answer questions via the Internet (n = 200)

Some experts expressed hesitation with the use of the Internet and the ability to obtain a representative sample, including a low-literacy population. They encouraged FDA to find ways to integrate more in-person interviews, particularly in low-technology, low-literacy populations, and to tap into networks to access a broad patient sample. However, as one expert highlighted, the use of the Internet presents advantages from a practical standpoint for conducting a large-scale quantitative study to identify the best of FDA's three prototypes for further refinement.

Future Considerations for PMI

Experts stated that paper-based PMI remains necessary and is not likely to disappear in the foreseeable future. However, several offered long-term visions for integrating technology with PMI distribution (e.g., patient portals and smart phones).

E-mailing PMI to patients seems to be the most realistic next step in the integration of PMI and technology. Experts anticipated this distribution method having minimal effect on the format and content of paper-based PMI. It was noted however, that e-mail distribution presents additional considerations, such as an opt-in requirement, concerns about security of the information, and patient privacy.

One expert pointed out that with increased use of technology in the future, information should ideally be organized into discrete chunks, allowing patients to easily select the exact piece of information they want. Organizing information into chunks, such as grouping all safety-related information together, potentially lends

itself to web-based distribution, but other future technology interfaces can also draw upon this platform. Furthermore, future mechanisms for PMI distribution, such as the Internet and smart phones, have the potential to allow PMI customization to meet patient needs, including patient-specific dosing and tailored information based upon age, gender, etc. These mechanisms also pose challenges and will require further discussion.

Summary and Next Steps

In closing, this meeting highlighted several areas that require further exploration and evidence development including optimal formatting and evaluation metrics. On October 12th, the Engelberg Center for Health Care Reform at Brookings will convene the second in this series of meetings on effective PMI. This will be a large public meeting to discuss strategies to ensure that patients have access to effective PMI. A series of panel discussions will explore patient expectations for PMI and how they access it, along with feasible solutions for delivering high-quality PMI to patients.