ENGELBERG CENTER for Health Care Reform at BROOKINGS

October 2010

MEETING SUMMARY

Ensuring Access to Effective Patient Medication Information

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 U.S. Food and Drug Administration (FDA) to convene a series of workshops to discuss optimizing, implementing, and evaluating adoption of a single standard medication information document to replace PPI, CMI, and Medication Guides. The first expert workshop discussed the overarching principles for communicating prescription information effectively, metrics for evaluating PMI, and the most useful content and format of a single medication information paper document, as represented in FDA's three prototypes and the proposed strategy for evaluating them.

The objective of this second workshop, convened on October 12, 2010, was to discuss strategies to ensure that PMI is easily accessible and effectively distributed to patients. The workshop explored the following: (1) patient preferences for access to and distribution of PMI, (2) potential roles that manufacturers, publishers, distribution partners, pharmacists, and physicians can play in the development and distribution of PMI, (3) models for effective distribution of PMI within current and future health care delivery systems, and (4) potential strategies for monitoring and ensuring the effectiveness of PMI. This document highlights major topics discussed during the meeting.

FDA Oversight of PMI

While stakeholders indicated that they would like FDA approval of all PMI, FDA maintained that they do not have sufficient resources to do so. Instead, they encouraged discussion about alternate solutions to ensure high-quality PMI. One example includes creation of a lexicon of commonly used terms and standardized language (e.g., patient-friendly terms to describe adverse reactions) with definitions agreed upon by the broader stakeholder community and tested by patients prior to adoption. This tool could be developed through a collaborative effort among stakeholders and FDA could be solicited for input at various points. Creating such a tool would improve standardization and comprehensibility of PMI without adding to FDA's regulatory burden.

FDA reiterated that they plan to adhere to the single-page limit for all source documents to ensure PMI brevity. The Agency has not yet decided whether PMI for brand name, innovator products, and generic

[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.

products would be the same. It was suggested that PMI could be developed by drug class as this would further decrease the number of PMI documents needed.

Developing Standardized PMI

PMI is a patient-centric document; hence, content should include the most salient information for patients to take their medication properly. Discussion about PMI content has largely focused on the appropriate balance between risk and benefit information, considering only severe side effects as risks. Yet for patients, the concept of risk expands beyond this to encompass milder side effects that may still affect patient adherence.

Participants discussed the need for a national educational campaign to accompany the new standardized PMI document. The audience and panelists both cited prevailing attitudes towards currently unwieldy CMI as potential barriers to broad patient receptivity of standardized PMI. Educational campaigns targeting both patients and health care professionals can encourage use of new PMI.

Collaboration and Delineation of Roles and Responsibilities

Participants acknowledged that successful distribution of PMI depends upon the collective efforts of multiple stakeholders including patients, health care professionals, sponsors, payers, PMI publishers, and distribution partners. However, effective collaboration requires clear delineation of the roles and responsibilities of each stakeholder group in the PMI distribution process, and commitment from each group to uphold defined responsibilities. Designating responsibility will help to ensure proper execution at each critical step of the distribution process and avoid pitfalls due to misunderstanding of roles.

Aligning Incentives to Support PMI Distribution

Well-conceived incentive programs may reduce or alleviate burdens of participating in the PMI distribution process. Pharmacists in particular play a critical role in efficient PMI distribution. However, pharmacies differ in their technological capabilities and their ability to adopt the proper technology to support standardized PMI, presenting challenges to a homogenous distribution strategy. Incentive programs for pharmacies may facilitate uptake of technology to support distribution of standardized PMI. Participants noted that the structure of such an incentive program warrants further discussion.

As a caveat to the discussion, it is important to note that the panels did not have payer representation. Payers may have a strong interest in supporting patient compliance, since failure to do so may lead to costly complications. Payers may therefore decide that it is mutually beneficial to incentivize pharmacies to distribute standardized PMI. Payer input will be important in future discussions about PMI implementation and distribution.

Developing Source PMI that will Allow for Future Customization

FDA envisions the creation of a central repository for all PMI documents to ensure consistency and integrity for each product at different points of distribution, but it remains unclear where the repository will be housed. Initially, PMI housed in the central repository will conform to the single page standardized format that complies with FDA's guidelines/rules for format and content. For the purposes of this summary, standardized PMI that replaces previous forms of information will be referred to as "source" PMI. Future technological advances present opportunities to customize source PMI to accommodate the more specific needs of individual patients and distribute PMI through multiple channels based upon patient preference (e.g., e-mail, patient-oriented websites). One panelist shared a current pilot project from his organization that tailors warning and contra-indication information for patients, while others proposed strategies for content and distribution customization.

However, participants cautioned against customizing source PMI too soon. The ability to customize relies first on having a solid foundation from which specific patient needs can be appended. Therefore, it is important to focus initially on widespread adoption and compliance with distribution of source PMI.

Distributing PMI

Participants noted that distribution efforts should first focus on a concrete and effective implementation plan for the paper document. Others thought that strategies to support distribution through electronic digital formats (e.g., cell and smart phones, other mobile devices, internet and websites, email, social media outlets) should also be considered. And some participants suggested a multi-modal system with the paper option as the default (i.e., patients would automatically receive paper PMI, but could opt for other forms of distribution, such as e-mail, if they preferred). FDA indicated that they would be interested in pursuing concurrent distribution pathways.

Multiple participants emphasized that when designing a centralized repository for source PMI, FDA should be cognizant of ensuring that the system has adequate flexibility to support future customization of and improvements to PMI. It was also noted that the system should be able to link to payers and other health care professionals using electronic prescribing systems and electronic health record systems.

Collaborative Efforts to Improve PMI

As FDA moves forward with rulemaking, it could take several years for new rules to be vetted and formalized. Stakeholders could work collaboratively to incrementally improve PMI in advance of rulemaking. The possibility of condensing and formatting current PPIs and Medication Guides into a single, standardized document could be explored. Another area in particular that could benefit from collaboration includes establishing acceptable thresholds for metrics to evaluate immediate effectiveness of PMI content (e.g., readability, comprehensibility). At present there is no consensus regarding acceptable thresholds and evidence to establish these thresholds is minimal.

Multi-stakeholder groups could also work together to establish metrics and define acceptable thresholds to evaluate PMI distribution strategies. Participants did not provide suggestions for how to measure distribution of paper-based PMI; however, they did discuss possible metrics for evaluating electronic distribution including frequency of use (e.g., if there is a website, how often to patients utilize that website), patient willingness to access the information, and level of patient satisfaction with each distribution strategy (i.e., do patients like receiving it in this form). It was noted, however, that appropriate metrics will depend upon the particular distribution channel used and thus it will be necessary to consider these factors when developing evaluation strategies.

Considerations for Pilot Studies

FDA encouraged stakeholders to initiate pilot studies to evaluate distribution strategies for both paper and electronic dissemination of PMI in advance of FDA rulemaking. A few participating organizations indicated that they were interested in conducting pilots to evaluate PMI content and distribution strategies. FDA noted that initial pilots should target the general population rather than try to evaluate effectiveness in specific subpopulations. Pilot studies that explore various methods for involving and engaging pharmacists, particularly in ways that they can help with PMI distribution and evaluation, would also be helpful.

Summary and Next Steps

In closing, this meeting highlighted a number of important considerations for effective distribution of PMI, including stakeholder cooperation and alignment. On February 23, the Engelberg Center for

Health Care Reform at Brookings will convene the third in this series of meetings on effective PMI. This will be an expert workshop that further explores potential pilot studies to evaluate standardized PMI. Panel discussions will explore design and production of a pilot evaluation for PMI distribution, incentives and policies to bolster compliance, and pilot evaluation metrics.