ENGELBERG CENTER for Health Care Reform at BROOKINGS

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DISCUSSION GUIDE

EXPERT WORKSHOP

Designing Pilot Programs to Distribute 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 engage the broader health care community (from manufacturers to pharmacists) in 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. Workshop attendees noted creating high-quality, useful PMI requires the creation of evaluation metrics, which should focus on immediate effectiveness (e.g., readability and comprehensibility) rather than long-term effectiveness metrics (e.g., patient outcomes). Only after PMI has demonstrated immediate effectiveness does it make sense to study the impact of PMI on patient outcomes.

The second public workshop engaged a broader community of stakeholders to explore strategies for ensuring that PMI is easily accessible and effectively distributed to patients. The workshop discussed patient preferences for access to and distribution of PMI and underscored the importance of clearly delineating the roles that each stakeholder will play in the development and distribution of PMI. Considering logistical challenges, the workshop participants discussed models for effective distribution of PMI within the current delivery systems while remaining flexible enough to accommodate future changes, such as innovative electronic distribution channels and options to customize PMI to better meet patient needs.

Discussion during the second workshop motivated several independent groups to engage with Brookings on the design and implementation of pilots to evaluate channels for distributing PMI for real drugs adapted to model FDA's Rheutopia prototypes. This meeting will discuss the goals, design, and evaluation of these pilots and consider how they can best inform FDA's future plans for reforming PMI.

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[1] Kimberlin CL, 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.

A Future Vision for PMI

Unlike other sources of medication information aimed at a health professional audience, PMI is intended to be a patient-centric document that includes both risk and benefit information. It is designed to be used by patients as a tool and a resource after a medication has been prescribed.

No evidence exists regarding optimal page length; however, FDA may choose to require adherence to the strict limit of a one-page single-sided document to ensure that PMI is succinct. Ideally, PMI will link to longer and more detailed resources (e.g., through web-based portals). This will ensure that all patients obtain the most essential information to take their medication properly, but also give patients that want more information the ability to obtain it.

Several participants during the public workshop indicated a preference for information customized to their specific needs (e.g., specific warnings for pregnant women or special considerations for diabetic patients). It is important to support the development of accurate personalized information that will help drive better decisions. As a foundation for future personalization, it is critical to develop standardized PMI for the entire indicated patient population. Therefore, the community should focus on creating good "source documents" and reliable distribution pathways while also exploring strategies to amend source documents to better meet patient needs.

Expert Workshop: Designing Pilot Programs to Distribute Patient Medication Information

Workshop Objectives

The primary objective of this small expert workshop is to discuss the design of PMI distribution pilots to inform the rollout of FDA's proposed "one document solution." Several independent groups have tentatively committed to conducting pilots and will present outlines for their pilots during the workshop. Participants will discuss: (1) the ideal goals and objectives of distribution pilots, (2) how to develop PMI for use in the pilots, and (3) the framework, development, and evaluation strategy for proposed pilots.

Workshop objectives will be met through presentations and a robust moderated discussion between panelists and the expert attendees.

FDA Perspective: Past and Future for PMI

FDA leadership will open the meeting by providing the background for their efforts that have led to the "one document solution," including steps that the Agency has taken to address the inadequacies of the current system. Furthermore, FDA will outline what they hope to accomplish through the distribution pilots.

Session I: Goals and Objectives of PMI Distribution Pilots

Establishing clear goals and objectives for PMI distribution pilots will ensure that information gleaned from these pilots is useful and informative for rollout of FDA's proposed standardized PMI. In session I, panelists will explore gaps in the understanding of the current PMI distribution paradigm. Taking into account pragmatic constraints, the panel will assess the current ability of pharmacies to access medication information from a central online repository such as DailyMed. Considering existing capabilities as well as gaps in knowledge, panelists will also explore approaches to designing "ideal" multi-site evaluation programs for PMI distribution, keeping in mind pilot objectives, potential limitations, and any other special considerations.

Session II: Developing PMI for Use in Pilots

FDA has stated that to obtain the most useful information, these pilots should be conducted with real patients and PMI for real pharmaceutical products. Several manufacturers have tentatively committed to participating in the pilots. In this session, representatives from the pharmaceutical industry will elaborate upon the selection of suitable products, the process by which they envision developing the PMI for the distribution pilots, and the role that they would like FDA to play in the process.

Session III: Potential Distribution Pilots

Multiple organizations have expressed interest in conducting distribution pilots to begin evaluating PMI including:

- In-pharmacy distribution
- Print distribution for mail-order prescriptions and electronic distribution for prescriptions filled at retail pharmacies
- Publicly-available online source for PMI

In the first part of session III, representatives from these organizations will present outlines of their proposed pilots, focusing on how these pilots will be identified, designed, structured, implemented, and evaluated. Panelists will discuss the role that different stakeholder groups might play in designing and implementing the pilots, as well as reasonable goals for the pilots (e.g., outcomes, timelines, and patient-reach based upon the organization's member demographic and size of the membership).

Moderated discussion will follow these presentations, and meeting participants will have the opportunity to comment on the pilots and discuss their ability to address the issues identified during session I. Participants will also be encouraged to propose alternative or future avenues to address these questions.