ENGELBERG CENTER for
Health Care Reform
at BROOKINGS

Exploring the Promise of Patient Medication Information

The Brookings Institution • Washington, DC
Tuesday, July 1, 2014

9:00 a.m. **Welcome and Overview**
Mark McClellan, Engelberg Center for Health Care Reform at Brookings
Bryon Pearsall, U.S. Food and Drug Administration

9:15 a.m. **Session I: Lessons Learned from Patient Medication Information Projects**
Julie Aker, Concentrics Research
Michael Wolf, Northwestern University
Oluwamurewa Oguntimein, U.S. Food and Drug Administration
Ruth Day, Duke University
Paul Wilson, Adheris Health
Gregory Daniel, Engelberg Center for Health Care Reform at Brookings

10:15 a.m. **Moderated Discussion with Session I Panelists followed by Public Q & A**
Gregory Daniel – *Moderator*

Lead Respondent:
Sally Okun, PatientsLikeMe

11:00 a.m. **Break**

11:15 a.m. **Session II: Moving Patient Medication Information Forward**
Mark McClellan – *Moderator*

Marc Boutin, National Health Council
Angela Patterson, CVS Caremark MinuteClinic
Ronna Hauser, National Community Pharmacists Association
Kevin Nicholson, National Association of Chain Drug Stores
Amy Ebel, GlaxoSmithKline

12:15 p.m. **Closing Remarks**
Mark McClellan and Bryon Pearsall

12:30 p.m. **Adjournment**

Convened by the Engelberg Center for Health Care Reform at Brookings and supported by a cooperative agreement with the U.S. Food and Drug Administration.

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Discussion Guide

Introduction

As the integration of health information technology and modern care delivery continues to improve, opportunities for patients and consumers to proactively interface with their health information and care decisions are rapidly increasing. Through tools such as electronic personal health records or mobile medical and fitness applications, the ability of a patient to monitor and manage many aspects of their health has never been more promising. A fundamental part of that level of patient-driven health management is having trusted, accurate, clear, and understandable information on medications, either through physical documents provided by a prescriber or pharmacist, or electronic documents accessible online. Such information could support safe and effective medication use and have significant downstream impacts on medication adherence and mitigation of potentially avoidable adverse events. In short, providing patients with access to reliable and digestible information on their medications is a cornerstone of any continuing effort to engage patients in their health care.

Background

In order to use prescription medications safely, consumers must receive clear, actionable medication information. This information should be delivered in a consistent format that is comprehensible across a spectrum of health literacy levels. However, current sources of written prescription information are numerous, uncoordinated, and sometimes conflicting.

Currently, consumers receive the following documents at the point of dispensing:

- Patient Package Inserts (PPI): Prescription information developed by manufacturers, reviewed and approved by the Food and Drug Administration (FDA), and required to be dispensed with specific products or classes of products (oral contraceptives and estrogen-containing products). Other PPIs are developed and submitted by the drug manufacturer on a voluntary basis and are reviewed and approved by FDA.
- Consumer Medication Information (CMI): Prescription information written by pharmacies or a third party that is not FDA-reviewed or approved, and is voluntarily distributed from pharmacies to consumers.
- Medication Guides: Prescription information developed by manufacturers for medications "that pose a serious and significant public health concern." Medication guides are reviewed and approved by FDA and must be given to consumers each time the medication is dispensed.[i]

Efforts to understand how well patients interface with these different formats have demonstrated that the current medication information paradigm is not meeting the needs of the patient. According to a report by the Institute of Medicine, as many as half of all American adults find it difficult to comprehend and act upon health information.[ii] Essentially, a lack of consumer-friendly information and simple,

patient-centric language has erected a barrier to understanding medication information and optimally using it to treat and prevent adverse events. The existence of multiple medication information formats and inconsistent information for the same drug at different pharmacies has further hindered the ability of consumers to take their medications appropriately. A new method for presenting and distributing medication information is of pressing public importance.

In 2008, a diverse group of stakeholders submitted a Citizen's Petition to FDA requesting that the Agency address this issue through an overhaul of written prescription information. The petition called for the adoption of a single, standardized medication information format, and over the next few years, FDA and various partners worked to debate and design a new document.[iii] Public hearings, expert workshops, and sponsored research led to the creation of several potential formats for Patient Medication Information (PMI). Based in part on the efforts taken to develop PMI and the plan to move the initiative forward, the citizen petition was withdrawn in 2010.[iv]

Ongoing Efforts to Advance the PMI Initiative

Over the past few years, stakeholders from industry, the federal government, patient groups, and academia have conducted various studies to test and evaluate PMI.

Brookings PMI Expert Workshops

Through a cooperative agreement with FDA, the Engelberg Center for Health Care Reform at the Brookings Institution convened a series of workshops focused on optimizing, implementing, and evaluating the adoption of PMI.

The first expert workshop in July 2010 focused on the overarching principles for effectively communicating prescription information and metrics for evaluating the immediate effectiveness of PMI (e.g., readability and comprehensibility). Stakeholders also discussed the most useful content and format of a single medication information paper document in addition to FDA's strategy for evaluating prototype documents.

The second public workshop in October 2010 engaged a broader community of stakeholders to explore strategies for ensuring that PMI is easily accessible and effectively distributed to patients. Workshop participants discussed patient preferences for accessing PMI and underscored the importance of clearly delineating stakeholder roles in the development and distribution of PMI. There was also discussion of models for effective distribution of PMI within current and future health care delivery systems and potential strategies for monitoring and ensuring PMI's effectiveness.

The third expert workshop in February 2011 explored the ideal goals and objectives of demonstration pilots designed to evaluate the feasibility of various PMI distribution channels and assess patient and provider preferences for new PMI. Several independent groups presented outlines for potential distribution pilots and experts commented on pilot design, implementation of pilots, and proposed strategies to evaluate distribution through pilots. A Brookings working group was established to help guide these potential pilot studies.

Comprehension Studies

Many stakeholders have conducted research to explore the health literacy and patient comprehension issues that could be addressed through a new PMI format. Merck, for example, engaged with academic researchers to conduct a study focused on optimizing both the content and testing process of their medication information. FDA contracted with RTI International to conduct a study focused on improving

the readability, accessibility, and navigability of several PMI prototypes. Still other researchers focused on medical cognition and further revisions to the content and format of medication information that could potentially make medication information more useful to patients.

These studies reveal the importance of early content testing across a wide array of patients to ensure the development of an effective prescription medication document. Maximizing the utility of the information contained within PMI will require learning from these studies to ensure that format and content are working together to serve the patient.

Distribution Studies

Improved medication information is only as useful as the methods for placing it in the hands of patients. To that end, stakeholders have engaged in pilot distribution studies to test modes of PMI access. A partnership between Adheris Health (formerly Catalina Health Resources) and a large national pharmacy chain tested in-store distribution of three prototype PMI documents drafted by industry members of the Brookings-led PMI working group. Expert members of that working group helped Adheris outline the study and draft questionnaires for follow-up. The new PMI documents were distributed to over 32,000 patients at participating pharmacies, and results revealed that over 90% of patients received the new PMI document and deemed it useful.[v]

Ongoing exploration of other avenues for accessing PMI is in progress. Brookings is working with The National Library of Medicine (NLM) to engage with pharmacy and electronic health record systems to discuss how they might incorporate PMI documents from an online central repository developed by NLM into their software and business processes.

Meeting Objectives

This public meeting will provide an opportunity for researchers engaged in PMI efforts to communicate to the health care community and public the progress that has been made in this space over the past several years. Stakeholders at the frontline of the PMI initiative will be asked to explore strategies for ensuring that PMI has a positive impact on the consumers who will be served by these documents.

Session I: Lessons Learned from Patient Medication Information Projects

In session I, panelists will present findings and key takeaways from their research on various aspects of PMI, including studies on comprehension and cognition, PMI usability and navigability, approaches to PMI distribution and patient preferences, and the importance of optimizing PMI testing methods and procedures. Respondent panelists will share insights from the patient perspective and engage in an interactive discussion with presenters following the presentations. Ultimately, the lessons learned from recent PMI research will serve to enhance the PMI initiative moving forward.

Session II: Moving Patient Medication Information Forward

It is essential for PMI to be consumer-friendly, easily accessible and navigable, and to be distributed through various channels. In session II, representatives from some of these diverse stakeholder groups will share their perspectives on the future of PMI and assess their roles in moving PMI forward. Stakeholders at the frontline of efforts to improve PMI, including patients, providers, pharmacies, industry, and other groups, will continue to play an important role in shaping PMI and leveraging promising strategies to make high quality PMI a reality.

Next Steps

Implementing PMI and integrating it into the health care ecosystem will be an important goal for all stakeholders in the near future. Brookings and FDA look forward to hearing from these vested stakeholders and working with them to move this important initiative forward.

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[i] Consumer Medication Information (CMI): Expert and Consumer Evaluation of Consumer Medication Information-2008: Questions and Answers." *U.S. Food and Drug Administration*. U.S. Food and Drug Administration, 24 May 2010. Web. 8 June 2014. <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ReportsBudgets/ucm163786.htm>.

[ii] *Health Literacy: A Prescription to End Confusion*. Rep. Washington: National Academics, 2004. Institute of Medicine, Apr. 2004. Web. 17 June 2014. <http://www.iom.edu/Reports/2004/health-literacy-a-prescription-to-end-confusion.aspx>.

[iii] *Citizen Petition Requesting FDA Action on a "One Document Solution" for All Pharmacy-Based Communications*. Rep. N.p., 30 June 2008. Web. 5 June 2014. <http://www.pharmamedtechbi.com/~/media/Images/Publications/Archive/The%20Pink%20Sheet/71/010/00710100020/single_pharmacy_leaflet_petition.pdf>.

[iv] *Withdrawal of Citizen Petition Requesting FDA Action On A "One Document Solution" For All Pharmacy-Based Communications*. Rep. N.p., 23 Nov. 2010. Web. 12 June 2014. <http://www.regulations.gov/#!documentDetail;D=FDA-2008-P-0380-0008>.

[v] Wilson, Paul. "Making Prescription Medication Information User- Friendly: The Time Has Come." *PM360*. N.p., 19 Nov. 2013. Web. 19 June 2014.