Exploring the Promise of Patient Medication Information

July 1, 2014

Meeting Summary

In order to deliver patient-centered care, the health care system must provide patients and their caregivers access to medication information that is accurate, clear, and comprehensible across the spectrum of health literacy levels. This is necessary both to optimize treatment regimens – for example, through improved adherence – and to prevent avoidable adverse events. Accomplishing these goals has the potential to improve health care outcomes and reduce health care spending. However, patients today are often presented with an overwhelming amount of information that is distributed in an uncoordinated and inconsistent manner. With this in mind, diverse stakeholder groups have proposed the development of a single, standardized Patient Medication Information (PMI) document to better serve patients and their caregivers.

Over the past few years, the Engelberg Center for Health Care Reform at Brookings has collaborated with the U.S. Food and Drug Administration (FDA) to engage stakeholders from across the health care community in a series of workshops focused on optimizing, implementing, and evaluating the adoption of PMI. In these meetings, experts in the health literacy field and key players in the health care sector have underscored the importance of finding multiple channels of distribution to increase access to PMI, as well as several elements of effective PMI, including consumer-friendly content, and formats that are easily navigable.

Recently, stakeholders have leveraged key findings from previous workshops and other stakeholders' efforts to develop methods and conduct research geared toward assessing the effectiveness of PMI and strategies to distribute PMI. On July 1, 2014, under a cooperative agreement with FDA, the Engelberg Center for Health Care Reform at Brookings convened a public workshop to explore: (1) lessons learned from health literacy researchers engaged in these PMI projects and (2) the role of stakeholders who regularly interface with PMI in moving the PMI initiative forward.

Medication Information: Changing the Status Quo

Meeting participants agreed that existing medication information documents are not sufficient to meet patients' needs. In Session I, researchers presented studies on different medication information formats, including: a prototype, single-page design introduced by FDA that visually segments six key categories of information into discrete sections or "bubbles;" proprietary versions of PMI that include additional augmentations for research purposes; and the current standard Consumer Medication Information (CMI) documents. Presenters compared both the FDA PMI prototype document and other versions with current CMI documents and found that the former were preferred because they were easier to understand and navigate. A common theme among the studies was that consumers preferred medication information documents that were developed according to PMI principles (e.g., one-page, simple, consumer-friendly documents) identified in the previous workshops. Ultimately, consumers found the PMI documents to be more usable, which motivated them to spend more time reading medication information. Studies presented at the meeting consistently showed that a single-page standardized PMI document can significantly increase patients' understanding of their medications.

Presenters in Session I demonstrated that it is possible to change the status quo and better serve patients. There were some differences in the methods they used to enhance PMI documents; however,

with that said, quality improvement is a continuous process and features to bolster the effectiveness of PMI will continue to be examined and improved upon. Therefore, some meeting participants urged stakeholders to move implementation of PMI forward with the understanding that future studies and developments may help to further refine PMI principles. These participants emphasized that enough information exists to create an effective PMI document that will provide more value than current medication information documents.

Supporting Access to High-Quality PMI

Meeting participants discussed the need for PMI to be created in a format and style that different demographics (e.g., age and education level) can comprehend and use to optimize their treatment regimens and prevent avoidable adverse events. However, the value of effective PMI will not be realized unless patients and their caregivers have convenient access to the documents. To identify how to achieve this objective, some participants conducted studies that explored how to best distribute PMI documents according to consumers' preferences.

Currently, paper is the main source of CMI distribution and is preferred in certain demographics. However, given that technology is playing an increasingly important role in how consumers receive information on a variety of topics – including prescription medication information – it is important to explore other methods of PMI distribution that go beyond the traditional provision of paper documents at pharmacies. This may include electronic versions of PMI that are accessible on websites, via email, or through applications on smartphones. One strategy identified by participants as a mechanism to support access to PMI is the development of an electronic central repository for all PMI documents. Such a repository could be accessed directly by patients and their caregivers. Additionally, electronic health record (EHR) vendors, pharmacies, providers, and others involved in health care delivery could access the repository to further increase access to PMI. Improving provider access would also support clinicians in their efforts to educate patients using a more consumer-friendly resource.

FDA is currently working with stakeholder groups, including the National Library of Medicine (NLM), to explore the possibility of housing all approved PMI documents in a central repository that would allow for both electronic and paper distribution of PMI. Participants agreed that this is a promising strategy because it would allow for multiple channels of distribution that would align with varying consumer preferences. They also acknowledged the importance of patient engagement throughout the process of implementing PMI.

Engaging Stakeholders at the Frontline of the PMI Initiative

Representatives from diverse stakeholder groups emphasized the importance of PMI in supporting shared decision-making among patients and providers. They indicated that the implementation of PMI would empower patients to become more knowledgeable about their medications and treatment regimens while enhancing providers' ability to educate them. With regard to moving the PMI initiative forward, stakeholders discussed the need to create a shared vision of objectives and goals, in addition to finding consistent methodology to make information more useful for patients and providers.

Participants also highlighted the importance of ensuring the feasibility of different approaches to distributing PMI. For example, stakeholders who distribute paper versions of PMI have varying capabilities to print different PMI formats and features, which may pose difficulties for both physical distribution and assuring manufacturers that clear, unadulterated content is making its way into the hands of patients. Other stakeholders, especially pharmacies, may have difficulty accessing PMI documents housed in an online repository due to internet connectivity challenges or organizational

policies that preclude live access to the web from work terminals. Methods for distributing PMI, and any repository used to house the documents, should also identify mechanisms for communicating that the documents are up-to-date. Testing modes of distributing PMI to address these challenges and detect any unforeseen difficulties in delivering PMI to patients and consumers will be an important part of the PMI initiative over the coming months.

Next Steps

Research to strengthen the design and implementation of PMI will be ongoing as a part of a continuous quality improvement process. However, several participants indicated that a sufficient amount of valuable research has been conducted to substantially improve on the status quo and that the focus should shift toward implementation of PMI. Next steps for the PMI initiative include integrating PMI into the health care ecosystem, finding further distribution channels for PMI (e.g., mobile applications, using the central repository, etc.), and further engaging stakeholders at the frontline of the initiative to ensure the smooth implementation of these critical documents.