ENGELBERG CENTER for Health Care Reform at BROOKINGS

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MEETING SUMMARY

Designing Pilot Programs to Distribute Patient Medication Information

Background

Ensuring that patients have access to consistently high-quality information on how to take their medications safely and effectively is an important component of delivering better care. Current medication information, and the way it is delivered, doesn't meet patient needs, and the U.S. Food and Drug Administration (FDA) has said it will take steps to reform current approaches to consumer medication information, Medication Guides, and patient package inserts with the goal of ensuring patient medication information (PMI) is concise, clear, consistent (with the approved professional labeling, among different manufacturers, and across distribution platforms), and patient-centric. There is consensus among health care professionals, pharmacies, academics, associations, publishers, and technology vendors that this goal is important and feasible. However, achieving it will require a broad-based collaboration among key stakeholders.

Meeting Objectives

In cooperation with FDA, the Engelberg Center for Health Care Reform at Brookings convened an expert workshop to discuss: (1) the ideal goals and objectives of demonstration pilots, designed to evaluate feasibility of various PMI distribution channels and assess patient and provider preference for new PMI, (2) how to develop PMI for use in the pilots, and (3) the framework, development, and evaluation strategy for proposed pilots.

Stakeholder Roles in PMI Demonstration Projects

PMI demonstration pilots should engage members of the health care community involved in the development, distribution, and use of PMI. Key constituencies include health care professionals, pharmacies, professional societies, publishers and technology vendors, manufacturers, consumers, and FDA. FDA has agreed to work with manufacturers as requested on the development of PMI prototypes intended to be used in the pilots.

Conducting Pilots with Real Products in Real Patients

To obtain the most useful information, these pilots should be conducted with real patients, and the PMI that is used should be for real pharmaceutical products. Manufacturer representatives from GlaxoSmithKline, Eli Lilly and Company, and Pfizer, Inc. highlighted the importance of testing PMI for a range of products, from relatively simple products (e.g., once-daily oral medications with few side effects), to more complex products that may have Medication Guides, black box warnings, and/or directions for use with accompanying devices (e.g., inhalers or injection devices).

Standards and Principles Guiding Distribution Pilots

Patients can receive medication information through multiple channels (e.g., pharmacies, health plans, health care professionals, manufacturers, or from various websites) and in multiple formats (e.g., paper, e-mail, web-based, video, etc). As technology advances additional innovative channels and formats may become available and patients' preferences will vary. Successful PMI distribution systems will be flexible

enough to account for technological improvements and patient preference. Thus, it is important that pilots test multiple distribution channels and formats.

Experts suggest that including a control arm that receives only existing documents, such as Medication Guides and Consumer Medication Information (CMI) could provide a valuable baseline for comparison with patients who receive the new PMI document. They encourage incorporating controls into pilots when possible, but acknowledged that some pilots may be less suited to including controls.
During the workshop, a few organizations suggested specific demonstration pilots. Catalina Health Resource outlined a possible paper-based retail pharmacy pilot that utilizes their technology platform to deliver test PMI in lieu of existing documents. Medco Health Solutions proposed testing concurrent paper and web-based distribution in both mail-order and retail pharmacies. The National Library of Medicine suggested an online channel for patients to directly access PMI that could mirror their DailyMed website. The PDR Network laid out principles for a pilot testing an e-prescribing distribution channel.

Defining Metrics for Evaluation
Data collection and evaluation is crucial, and should capture relevant information about the impact of PMI distribution on patients and health care professionals.

Potential patient-centric evaluation metrics could include, but are not limited to:

- Distribution – do patients get the PMI?
- Utilization – what do patients do with PMI? Do they read/ save/ refer back to it?
- Patient preference – do they find single page PMI useful? How does this compare to what they previously received, such as CMI?

Experts note, though, that clinical outcomes are more difficult to measure since PMI only indirectly affects outcomes, and will likely require less precise quantitative evaluation.

Potential metrics for evaluating the impact of new PMI on the developers and delivery system could include but are not limited to:

- Manufacturer development/delivery – what manufacturer resources are required to develop PMI? Are distribution options practical and capable of fulfilling manufacturer needs?
- Feasibility – is it feasible for health care providers to disseminate PMI consistently through the format and channels provided? Could non-professional personnel (e.g., manufacturers, PMI publishers, system and technology vendors, etc.) improve the distribution process for PMI?
- Incorporation into workflow – does distribution interrupt workflow? What is the cost to provider organizations of distributing PMI through these channels?
- Utilization – do health care professionals prefer the new PMI when counseling patients?

Next Steps
Brookings will continue discussions with FDA and key stakeholders to plan for deployment of initial PMI pilots.