Engaging Patients: Building Trust and Support for Safety Surveillance
Tuesday, June 23, 2015

Meeting Summary

Introduction

The Sentinel System is an active surveillance system relying on a distributed data network[1] to rapidly conduct analysis of electronic health care data available from over 178 million patients nationwide.[2] Sentinel is an important FDA safety surveillance tool and its underlying distributed data infrastructure is increasingly being recognized to have the potential to support the needs of diverse stakeholders including other public health agencies, health systems, regulated industry, and the clinical research enterprise. Despite Sentinel's importance in safety surveillance, patients are largely unaware of Sentinel's public health mission and commitment to protecting patient privacy. Therefore, it is both timely and critical to identify opportunities to raise awareness and build trust for Sentinel safety surveillance among patients, consumers, and the general public.

In support of FDA's commitments to transparency and active engagement with stakeholders in Sentinel, Brookings convened an expert workshop in 2012 focusing on patient and consumer engagement. Discussions from this workshop resulted in recommendations on how to better engage patients and consumers, including the opportunity for Sentinel Data Partners to use their existing relationships with patients and communication channels to improve general awareness of Sentinel. On June 23rd, 2015 the Center for Health Policy at Brookings convened an expert workshop to further explore strategies for improving awareness and disseminating information about the Sentinel System to patients.

In attendance were 42 participants, comprising representatives from Sentinel Data Partners, patient focused organizations (e.g., consumer advocacy groups), experts in patient privacy, ethics, and health literacy, and representatives from the FDA. Specific objectives included:

- Present Sentinel Data Partner experiences in member outreach with the aim of identifying best practices and key barriers to communication.
- Develop guiding principles for communicating about Sentinel to patients and how to strategically frame messaging to prevent misperceptions related to privacy and use of health information within the Sentinel System.
- Explore practices of patient advocacy organizations and how these practices could support or complement Sentinel Data Partner communications

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[1] A distributed data network (DRN) refers to data that reside and are maintained within a data holder's organizational firewall, but can be accessible for analysis via programming code that is securely "distributed" to a network of participating organizations through a centralized query process. Once the query is received, analytical commands are executed on data that conform to a common data format used by network partners. After completing the analysis, summary level data is returned to the initiator of the query. The advantages of a DRN analysis include: no patient identifiable information is shared outside of the organization's firewall (which facilitates compliance with all applicable privacy and security laws), analytic results are voluntarily shared by each organization, and use of the common data model supports consistent interpretation and understanding of the data.

[2] http://www.mini-sentinel.org/

Workshop Summary

Potential Roles of Sentinel System Stakeholders: The Need for Coordination and Partnership.
There was general consensus amongst participants that patients typically know very little about post-market safety surveillance or think about how medical products get to the shelves of their local pharmacy or grocery store. It is considerably less likely that patients are aware of how FDA monitors medical products through surveillance activities like the Sentinel System. As such, it is critical to increase awareness of: (1) the public health value of Sentinel and (2) Sentinel's emphasis on patient privacy (i.e., patient data is important and privacy is protected).

To begin improving awareness, participants discussed possible opportunities where each stakeholder might be uniquely positioned to engage with patients. A description of potential opportunities for each stakeholder, along with consideration of key challenges, is described below.

Food and Drug Administration and Sentinel System Coordinating Center
Participants agreed that FDA is a trusted source of information by the public and should have a role in facilitating Sentinel System communications. Existing communication channels discussed by participants included the Sentinel Initiative public website maintained by FDA, the Mini-Sentinel public website maintained by the Sentinel Coordinating Center through contract with FDA, and drug and safety information websites and alerts managed by FDA (e.g. MedWatch). These channels could help coordinate the communication about Sentinel activities. Some participants commented that the Mini-Sentinel website, in particular, may be useful for subject matter experts, but does not provide relevant and succinct information on Sentinel for the average patient or individual to comprehend. Additionally, some participants thought the FDA could play an active role in coordinating the communication of Sentinel, but acknowledged their available infrastructure may not be sufficient to increase awareness of Sentinel. Lastly, while FDA has public communication channels to disseminate information learned by FDA to better understand the safety profile of specific drugs, these channels may not be well suited for general dissemination about Sentinel goals and policies (e.g., privacy protections). In addition, they are not necessarily frequently accessed, especially by the average patient, and thus are likely inadequate to achieve broad messaging aims about Sentinel and safety surveillance.

Sentinel Data Partners who Represent Insurers
Of the possible stakeholders that could facilitate Sentinel communications, participants dedicated the most time to discussing the role of Sentinel Data Partners and the possibility of leveraging the existing relationships with patients and communication channels they have to engage their members. There is a direct opportunity to engage with the populations of patients and members whose data are contributing towards Sentinel safety surveillance. Sentinel Data Partners also have a growing array of communication tools most often aimed at communicating health insurance benefits (e.g. receiving explanations of benefits, understanding how to access benefits, and paying medical bills) at their disposal including commercial websites, EHRs and patient portals, and social media, in addition to more traditional means of communication.

These tools could be used to disseminate information, but there are barriers. For example, these communications are often technical and confusing. Consequently, when patients receive notices from a health insurer they are often ignored because they are not viewed as discernible. Also, while insurers are increasingly moving towards more patient-centered communications, workshop participants noted difficulties organizations have with tailoring messages to specific patients – some based on personal

experience – such as providing a patient with the wrong message (e.g., messages sent to all patients taking a medication with multiple indications when the intended audience is only a patient with a particular disease). Any communication outside of this paradigm may be viewed as inappropriate, irrelevant or untrusted (Sentinel data partners that are not strictly health insurers, such as Kaiser or Hospital Corporations of America, likely face a different set of considerations with patient communications).

<u>Health System Providers</u>
Participants discussed the potential role of providers in communicating specific safety issues, once they are identified, that are germane to an individual patient. Providers are the best sources of information about the specific benefits and risks of a particular medication given the unique context and preferences of their patients. While there are challenges for providers to know which of their patients' data are represented in the Sentinel System, general awareness of the system among providers and how it operates could help reinforce messaging when there are safety communications from the FDA regarding specific drugs.

<u>Patient Advocacy and Consumer Organizations</u>
Participants also noted organizations that specialize in patient advocacy could serve as key partners in developing and disseminating Sentinel communications. These organizations have in depth experience working directly with patients to communicate aims of and build support for clinical research, health advocacy, and improved health care delivery. Key insights gained could inform how best to communicate about Sentinel and provide direct channels for this communication.

While numerous opportunities were identified by participants for how stakeholders could improve communication about Sentinel, there was also general consensus that stakeholders should collaborate closely on communication to overcome the inherent limitations faced by each stakeholder. Therefore, a centralized approach was suggested to leverage the comparative advantages of each stakeholder to effectively communicate about Sentinel to patients. This formal structure could also be used to facilitate ongoing engagement and continuously refine messaging and mechanisms of delivery.

Participants discussed approaches for developing a foundational message to improve Sentinel System engagement and key messaging points to raise awareness of Sentinel's public health value and commitment to patient privacy. The remaining sections of this summary identify three priority areas as essential to advancing progress:
1. Establishing principles and messaging objectives.
2. Developing engagement strategies.
3. Identifying effective mechanisms and technologies to deliver messages.

Establishing Principles and Messaging Objectives
Participants agreed that the development of a foundational message will require clearly defined communication objectives. Participants broadly agreed the objective, initially, might be providing patients with broad information about Sentinel. To give more specificity to the objective, one participant posed the following question, "what do we want patients to know, feel, and do?" as a framework to consider messaging objectives. Based on this suggested framework, discussion about the objectives of Sentinel communications is summarized below.

What should patients know?

Participants thought a starting objective might be ensuring patients are aware of Sentinel activities and the important contributions Sentinel makes to understanding medical product safety. At the message's core, participants thought it important for patients to know the value of safety surveillance activities and how different surveillance programs and tools are used by FDA to protect public health, including but not limited to the Sentinel System. That is to say, FDA monitors drug safety and makes safety decisions by combining evidence from different sources to further assess a suspected or known risk. In addition, patients should know where to access more information about Sentinel if desired.

What should patients feel?

In developing the specific text of the foundational message, participants noted difficulties with current terminology used to describe these activities. Terms such as "surveillance" and "big data" are confusing and can be perceived differently by patients, depending on their previous experiences with the health system and levels of health literacy. Although Sentinel is implemented in accordance with all applicable laws meaning de-identified and aggregated summary data are only involved and all privacy and confidentiality protections are met and exceeded – the foundational message must acknowledge these more personal aspects and sensitivities regarding use of personal health information to lesson potential misperceptions.

One participant emphasized a successful message should be evaluated in terms of relationship management. Patients must care enough about the relationship to receive, consider, and act on any communication. To facilitate this relationship, participants developed set of guiding principles, each representing an engagement objective that must be achieved in the message: Trust, Relevance; and Meaningfulness.

Trust is at the foundation of communication. To establish trust, the message must clearly address the sensitivities regarding data use and participation. Some participants thought a Sentinel "promise" for data use could provide a starting point to build trust. As part of this promise, the message would need to also address key points like the difference between safety surveillance and research, and why patients are not asked to give explicit permission for participation and why they cannot opt out. To communicate this, health literacy is an important consideration and potential key barrier to adequate comprehension. Transparency is an important component in facilitating trust. Truthful and transparent messaging could still be unsuccessful if misperceptions of terms commonly used to either describe the Sentinel System, such as "surveillance" and "big data", are not interpreted as intended.

After trust, the next objective the message should achieve is conveying the problem's *relevance*. One participant noted from their organization's experience three key components are needed to ensure relevance: clearly framing the problem, its salience, and how their data will play an important part in unlocking the solution to the problem. Drug safety surveillance is unequivocally a relevant problem for the entire population and does require a large number of individuals contributing data to effectively monitor safety. Participants noted emerging evidence suggesting that if patients are told how their data will be used, even without specifics, to achieve health system goals there is more willingness to participate and support initiatives. Although soliciting data from patients is not the aim of the foundational message, providing information about potential data use could help foster support for Sentinel and safety surveillance.

The last objective for what patients should feel about the Sentinel System is its ***meaningfulness*** as a partner to reach their personal health goals. Ultimately, patients will ask themselves "is my relationship with Sentinel meaningful enough to learn how it could support my own health goals? Therefore, it will be important for the communication to clearly articulate this in terms of both personal benefit and Sentinel's potential role in supporting health goals.

What are patients expected to do?
There might be different levels of actions depending on the intended outcome of the message. Some participants thought providing information about Sentinel activities, a key challenge in gaining broad support, is a good place to start for a patient engagement goal. This means improving broad awareness of Sentinel so when a safety signal is detected patients are aware that health data collected by their insurer may be used in a Sentinel analysis of drug safety. One measure of success for reaching this goal could be patients knowing or at least becoming familiar with the Sentinel System brand, and knowing where to access additional information about Sentinel if desired.

To summarize, patients should know what Sentinel is and what it is not in broad terms. Further, patients should know the Sentinel System is only one component of FDA's safety surveillance portfolio of activities and is most commonly used in combination with other surveillance techniques to better understand known risk. This information should make patients feel they can trust the message and their participation in Sentinel will solve meaningful public health problems while also facilitating achievement of personal health goals. After receiving the message patients should know where to access additional sources of information about Sentinel, which could lead patients to being more capable of knowing what to do and who to contact in the event of experiencing a safety issue themselves.

Engagement Strategies
To achieve these messaging objectives, participants discussed numerous engagement strategies and communication mechanisms that could be adopted or adapted by Sentinel Data Partners. Strategies discussed fell under two categories: (1) strategies to build trust and (2) strategies to build comprehension.

Strategies to Build Trust through Effective, Ongoing Engagement with the Audience
Trust is a fundamental building block to effectively communicate Sentinel. There are numerous opportunities to establish patient trust, and the following strategies are aimed at learning about patient needs and concerns to craft a high impact message. Many participants recognized that the use of data in today's world almost automatically makes people apprehensive. They were strongly assertive in noting that a top priority for patient engagement is establishing trust through being able to successfully assure them that their personally identifiable information is well protected.

Trust Surveys (i.e. brand trust)
One participant noted there are approximately 45 instruments used to measure trust in health services research, with the underlying point being trust is a complicated concept to measure. Another participant suggested a brand recognition survey of the FDA would be a good place to start understanding how patients perceive the FDA. Participants raised the possibility of including the Sentinel and FDA logos as part of this survey research too for improving brand recognition.

Leveraging Resources and Tools of Patient Focused Organizations

Patient advocacy groups and other patient networks have been instrumental in bringing the patient voice into health care delivery, research, and policymaking. These trusted institutions are able to mobilize and tap into the concerns, ideas, beliefs, etc. of large patient populations, and have invaluable experience identifying the most effective approaches to engage patients with the aim of improving the quality of evidence available. Workshop participants agreed there would be value in leveraging these experiences and the patient channels that exist within these organizations. One best practice shared was prioritizing how patients mutually benefit from sharing their information. This could be part of the "Sentinel promise" as detailed under the trust principle. It may be uncomfortable for some people to realize that clinical decisions are often not evidence-based, and when the evidence does exist it is limited to highly-controlled clinical trials potentially not representative of their personal profile. For this reason, the Sentinel foundational message must be sensitive to how patients might interpret the need for medical product safety surveillance and the risks involved with drugs approved by the FDA. Patient advocacy organizations could help strengthen this message and use their expertise in working with not only condition or disease-based patient groups, but also socioeconomic, geographic, and ethnically diverse groups of patients. For example, participants noted certain ethnic groups might be best reached through trusted community institutions or members and not through traditional health system channels.

Focused Efforts to Identify Patient Needs Using the Community Engagement Studio
Understanding your target audience is fundamental to any marketing or communications campaign and key building block for developing a trusted relationship. One promising approach shared at the workshop was the Community Engagement Studio (CE Studio). The CE Studio is a methodology for convening patient "experts" using dynamic, roundtable discussions intended to solicit patient, community or other stakeholder input. While traditionally used to connect the clinical research enterprise with patients, participants agreed the CE Studio could help Sentinel Data Partners identify key messaging points with different patient groups and serve as a tool to test messaging strategies. Leading a successful CE Studio depends on effective problem framing, strategic recruitment of patient experts with an appropriate background/orientation for the challenge, and identifying a trusted discussion facilitator, ideally from the community. By adapting this methodology to patient engagement in the Sentinel System, messaging could be improved by using CE Studios for the following:
- Building trust with communities;
- Refining the message over time by understanding what is working and what can be improved;
- Identifying key concerns patients have with Sentinel to improve communication messaging; and
- Maximizing resources for optimal message crafting and delivery.

Strategies to Improve Intended Audience Comprehension of the Message
Comprehension is closely tied to personal characteristics often used in consumer market research to segment audiences, for example socioeconomic variables like age, gender, education, and income. Segmenting the audience opens up opportunities for targeted messaging (i.e. health messages that are crafted to a group of patients that share similar characteristics) or tailored messaging (i.e. health messages that fit a specific individual's need for information). Segmentation also informs how and when to engage in broad, population level messaging. The combination of targeted, tailored, and broad-based messaging are all likely needed to effectively communicate Sentinel, and participants highlighted the below strategies to support these different messaging approaches.

Multi-channel Communication with Varied Messaging Depth

The principle of multichannel marketing is simple; firms must have a ubiquitous presence to stay in contact with their customers, which could also be applied to the Sentinel messaging strategy. One participant noted a personal example of receiving the same message across different channels (e.g. twitter, radio, and newspaper), which motivated them to take the intended action of the communication. The objective of multi-channel communication is to create a single, integrated messaging strategy, relying on different channels with varying message depths. This includes long and short versions (e.g. Twitter version) of the message, and mixing narrative with audio and visual messaging (e.g. YouTube videos). One participant thought a "meet Sentinel" video or even more broadly, safety surveillance at FDA could help make messaging more personalized by introducing FDA staff in the video. Overall, the main key to multichannel communication is ensuring that depth of messaging across channels remains consistent and meets the overall communication objective.

Simplify Messaging through Meaningful Examples and Story-telling
Participants, due to the complicated and abstract subject matter that comprises the Sentinel System, thought tangible examples of how Sentinel has improved population health in a clear and understandable way would be an important component of the message. Several mentioned the term, "value proposition" when discussing the importance of letting people know why Sentinel is important to them. In addition to narrative, encouraging graphical depictions of this impact could be useful. Participants referenced PowerPoint slides the Sentinel Coordinating Center uses to demonstrate time and cost advantages of using Sentinel to detect safety signals versus traditional, passive surveillance techniques. Participants emphasized the need to make these examples understandable and logical to the average patient, raising concerns with the current Sentinel examples posted on the Mini-Sentinel website, which may not be user-friendly for the broad population in their current format.

A variety of participants noted that "success stories" should play an integral part in communicating Sentinel's value. Use of story-telling, metaphors and analogies, were also mentioned as an effective strategy shown to vastly improve comprehension. Participants discussed a couple examples. Realizing a key principle for soliciting stakeholder buy-in is identifying value from participation, one participant used airport operations as a useful metaphor. Individuals are more acceptable of personal information to airline operators, for example such as their weight if asked, where weight of the combined travelers is an important safety consideration if travelling on a small plane. While many individuals might be sensitive and hesitant to give this information in other contexts they could be more open to sharing their personal information because: 1) the individual knows how it is being used; and 2) they share a common goal with airline operators to ensure flight safety. Using clear and common sense analogies could help patients understand the value Sentinel provides to them as an individual.

Delivery Mechanisms
Message structure, medium, and frequency of delivery are essential to successfully convey a refined message to patients. As noted in the multichannel communication strategy, the message should reach patients multiple times and through multiple mediums to improve comprehension. The following are examples of communication tools that stakeholders currently use and could be further leveraged to communicate information to patients about Sentinel.

EHRs, Patient Portals, and Stakeholder Websites
Sentinel is possible because of a growing national infrastructure based on digital information systems such as electronic health records. Participating Sentinel Data Partners have an EHR, which must include

a patient portal as required by the Office of the National Coordinator for Health Information Technology to be certified. These technologies bring new opportunities for the health system to engage with patients in their care, and provide a medium for delivering Sentinel messaging. However, one participant cautioned more research is needed to know at what point during the care process would be most appropriate to message Sentinel. For instance messaging as part of a clinical encounter or follow up might not be an appropriate time. Additionally, Sentinel Data Partners and other Sentinel stakeholders that have their own commercial websites could use these channels to also deliver the Sentinel foundational message.

Communication Media
Participants thought social media would be an important channel for message delivery due to pervasive population use. The varied types of social media could be used strategically to facilitate different depths of messaging, and play an important role in multi-channel communications. However, several participants mentioned social media should still be complemented with more traditional communication media such as radio and newspaper articles so that patients, particularly the elderly, can receive messaging through more familiar media.

Patient-Powered Informatics Platforms
Informatics platforms, especially those designed by patient advocacy organizations, can quickly and efficiently connect patients and caregivers, and facilitate the sharing of clinical experience. This data facilitates learning of how diseases act in the real world, and accelerates the discovery of new therapies. The platform also serves as a source of information on patient treatments, symptoms, and research. Not only does this support information sharing and dialogue, but it can be leveraged to better tailor and deliver messages to patients by understanding their interests and needs.

Community Engagement Mechanisms
Some participants emphasized the need for non-technology based delivery mechanisms, such as face-to-face meetings, community town hall meetings, or public gatherings at religious affiliated institutions, which would be more effective for certain groups of patients. Another participant recommended that community services geared towards public health and prevention that target the chronically ill would be well suited channels to deliver messaging.

Conclusion and Next Steps
Participants agreed increasing public awareness and understanding of Sentinel is critically important for Sentinel and its continued success, but will require more research and strategy development to effectively craft and deliver the Sentinel foundational message. To guide the development of this messaging, a set of trust building principles was developed, which could inform strategies for how Sentinel Data Partners and other stakeholders might engage patients more effectively and with different communication channels. In addition, a number of key takeaways were emphasized during the day's discussion:

1. The foundational message, initially, should not solely focus on Sentinel, but rather serve as a component of the broader FDA strategy to implement safety surveillance and protect public health. The objective of the message, at first, might entail broad yet frequent patient messaging to improve awareness of Sentinel and provide details on how to access additional information about Sentinel if needed. At its foundation, this message might not solely focus on the Sentinel System, but also

improve awareness of safety surveillance activities and the role of Sentinel within these activities more broadly. To monitor the success of this communication campaign for raising awareness, trust and brand surveys could be developed for baseline benchmarking and assessment over time. As patients increasingly become aware of Sentinel, other opportunities could arise to build patient support for the Sentinel System.

2. <u>Each stakeholder has unique channels, technologies, and relationships with the target audience which includes patients and consumers.</u> Sentinel Data Partners could identify strategic communication points in the continuum of care, which might include broad messaging on Data Partner websites, targeted messaging during pharmacy fills, or using patient portal platforms and social media – all of these are potential options to consider. Participants agreed a combination of strategies and communication channels are needed to meet diverse population needs for information. For example, patient advocacy groups could leverage their information sharing platforms to both deliver the message and help further clarify questions that patients might have using trusted "communities" or advocates. Also, stakeholders might consider using resources such as the Community Engagement Studio to obtain specific and strategic feedback for crafting and delivering an effective message. The Community Engagement Studio could help solicit answers on key questions such as:
   - What are the biggest concerns patients have when learning about Sentinel safety surveillance?
   - What are the best strategies or approaches for addressing these concerns in the message?
   - What are the most effective settings for communicating the message and how it is delivered to different demographics? When should broad and targeted messaging be used?

   The FDA could complement these efforts with an agency communication campaign to better inform the public about safety surveillance. This communication campaign could leverage different channels of communication including audio visual technology, such as developing a "Meet Sentinel" video.

3. <u>A centralized, but inclusive process, is needed for stakeholders to coordinate message development and pool existing resources.</u> To promote authentic messaging, a centralized process is needed to bring stakeholders together to pool expertise and resources, and coordinate message delivery and refinement over time. This process could be inclusive and designed for direct engagement with patient stakeholders. Through this mechanism stakeholders can become more in tuned with patient priorities and concerns, and collaborate more effectively together to identify the most appropriate strategies for messaging. The FDA would likely play a central role in convening stakeholders for such aims.

These discussion points are an important step forward to improve awareness of Sentinel and more broadly safety surveillance activities led by the FDA through effecting messaging to patients. Robust communication is critical for the continued success of these initiatives and many opportunities exist to facilitate this messaging, including mechanisms already employed by the Sentinel System Coordinating Center intended to obtain patient feedback. This workshop has laid a foundation for messaging that stakeholders can both use and further refine as they incorporate principles, tools and other actionable strategies to improve communication with patients.