

The Sentinel System Story: Toolkit

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The Sentinel System Story: For Health Advocacy Groups

FDA's Mission—Protecting Patients

Patients, caregivers, health advocacy groups, and disease organizations require information and transparency regarding the potential benefits and risks and safety of the medical products they use. One of the U.S. Food and Drug Administration's (FDA) principal missions is continual monitoring of drugs, medical devices, and vaccines, once these products reach the market. In addition to having its own team of healthcare professionals to oversee and analyze the ongoing safety of drugs, vaccines, and medical devices from clinical trial and post-market safety data, FDA is using emerging technologies that capture additional sources of information to enhance patient safety, while still protecting personal privacy and confidentiality.

FDA Creates the Sentinel System

In 2007, Congress passed the FDA Amendments Act (FDAAA), requiring that FDA establish an *active monitoring system* for drugs by using electronic healthcare data.

FDA responded to this Congressional mandate by creating the Sentinel System. This system is a highly responsive, flexible, and rapid electronic surveillance system that increases FDA's capacity to protect and inform consumers and, particularly patients and their caregivers, who are treated with medications and vaccines for their conditions and diseases.

The Sentinel System relies on: 1. **Electronic Health Information.** The Sentinel System receives aggregated, de-identified health information from an array of sources, namely: health insurance companies (information from claims data) and hospitals (information from electronic health records). 2. **The Sentinel System's Team of Experts.** The Sentinel System's team is comprised of experts from the FDA, medical schools, insurance companies, and hospitals.

The Patient Perspective

The Sentinel System engages patients as advisors to help develop policies and better communicate information about this safety surveillance tool to both the public and patients. It is also important to emphasize that the information flowing to the Sentinel System protects patients' anonymity and confidentiality. The Sentinel System and the FDA almost always receive only aggregated information derived from the records of many people. When data about individuals are required, individual identifiers are removed.

How the Sentinel System Works

The core function of the Sentinel System is to evaluate treatments and outcomes of large groups of patients treated with a particular drug, medical device, or specific vaccine. The main concern of the Sentinel System is evaluating whether patients are having an unexpected adverse event from a medical product.

For example, some of the basic questions are: *How many patients on "Drug A" are having negative side-effects? How many of them are males or females? How many are young, old, pregnant, or taking other medical products? Are the side-effects the result of taking "Drug A" or for another reason?*

What does the FDA do with all of this information?

The Sentinel System asks questions of many participating organizations, aggregates their responses, and presents the findings to the FDA for its subsequent evaluation and ultimate decision(s) regarding a particular medical product's safety or continued use. The FDA can pursue the following channels after receiving this information: 1. **Non-medical product related.** Scientists may determine there is no link between the health events observed and the medical product. FDA will issue a statement informing patients and physicians that it evaluated the product and did not find any correlation between observed events and use of the medical product. 2. **Labeling.** FDA may decide that the medical product requires additional labeling to alert physicians and patients on the risks and possible adverse events regarding a particular medical product. 3. **Restricted Use.** In other instances, the conclusion might trigger an FDA warning to physicians to only prescribe a particular drug or vaccine to certain types of patients. 4. **Media Alerts/MedWatch.** The FDA could trigger a MedWatch alert. MedWatch is FDA's Safety Information and Adverse Event Reporting Program which provides timely new safety information on medical products. 5. **Removal of the Drug or Vaccine.** The FDA can remove a drug or vaccine from the market when its risks outweigh its benefits.

Examples of the Sentinel System

Example 1

In 2012, FDA received reports of health events possibly related to a new anticoagulant. The initial reports involved patients with severe bleeding, potentially caused by the new drug. The Sentinel System gathered information from tens of thousands of patients being treated with the new drug. At the same time, the Sentinel System also analyzed information from an equally large group of patients who were taking the older, more commonly-used, drug. All of this information showed no evidence that the patients on the new anticoagulant medication were at higher risk of suffering severe bleeds than the patients taking the older drug. The conclusion was that patients could continue taking the new drug while the FDA continued to evaluate its safety.

Example 2

In 2013, FDA used the Sentinel System to evaluate a vaccine to prevent diarrhea in infants. In response to reports FDA received that some infants experienced side effects from the vaccine, the Sentinel System gathered information from approximately 500,000 infants who had been vaccinated. From the Sentinel System's analysis, FDA concluded that the side effect did occur, but was extremely rare and occurred in less than 2 out of every 100,000 babies. FDA concluded that the benefit of the vaccine outweighed this risk, but the agency alerted clinicians and parents about the possibility of this adverse effect.

[Respecting and Protecting Patient Privacy](#)

The Sentinel System studies summary information from large groups of patients treated with the same drug, medical device, or vaccine, whenever possible. When individual level data are needed, all individual patient identifiers are removed.

The Sentinel System Story: For the Public

Get to know the FDA

The U. S. Food and Drug Administration, known as the FDA, is one of the oldest patient protection agencies in the country. One of the FDA's most important jobs is to make sure medicines, vaccines, and medical devices are safe. The FDA's scientists and other healthcare professionals learn a lot about medical products. The FDA lets doctors and patients know about the best way to use medicines and vaccines. The FDA also lets them know about side effects when they use medicines, vaccines, and devices.

The FDA has systems that allow people to report concerns with medical products. In the past, it could take a long time to get enough information to learn about these concerns. FDA created the Sentinel System to make the process easier and faster.

What makes up the Sentinel System?

The Sentinel System has 3 major parts: 1. **Electronic Health Information**. The biggest part of this electronic information comes from health insurance bills. A smaller amount comes from medical records. 2. **Team of Experts**. The Sentinel team is made up of scientists, healthcare professionals, and computer programmers. 3. **Special Computer Programs**. Computer programs help answer questions about how drugs and vaccines are working. These programs look for certain groups of patients who might have bad side-effects after taking a drug or getting a vaccine. Remember, these programs do not look at your personal identity and confidential information.

How does the Sentinel System work?

The Sentinel System answers questions like these: *How many people are taking the same drug or getting the same vaccine? How many are having bad side effects? How many are men and women? How many are young, old, pregnant, or take other drugs?*

What does the FDA do with all the information?

The FDA gets important answers from the Sentinel System about bad side effects in certain drugs or vaccines. The FDA studies this new information along with other information it gets from doctors and drug companies. The FDA decides the best way to make doctors and patients aware of side effects. The FDA can send out a communication to doctors and patients to warn about potential safety issues.

What's so special about the Sentinel System?

The Sentinel System is special in 4 ways: 1. The Sentinel System can get information about a large number of people who take the same medicine or get the same vaccine. 2. The Sentinel System counts how many patients are having the same bad side effects. 3. The Sentinel System finds out about side effects patients are getting by looking at information from medical insurance bills and electronic health records. 4. The Sentinel System protects patient privacy. It doesn't know your identity.

Sentinel in action

Example 1

In 2012, the FDA got reports from doctors about patients taking a new medicine to help prevent blood clots. The reports were about patients bleeding too much when they took the new medicine. The Sentinel System looked at a big group of patients on the new medicine. Then, it looked at a big group of patients on an older medicine. This information did not suggest the new medicine was less safe than the older medicine. Patients could continue taking the new medicine while additional studies were performed.

Example 2

In 2013, the FDA used the Sentinel System to look at the safety of a vaccine that was given to about 500,000 babies. The FDA found out that some of the babies who got the vaccine had side effects, but these side effects were very rare. The vaccine caused the side effect in less than 2 out of every 100,000 babies! With this new information, FDA let doctors and parents know that it was better to get the vaccine. But doctors should be aware of this very rare side effect, so that they can treat it, if it happens.

Protecting your privacy

No one at the FDA looks at your personal information. They do not look at your name, address, phone number, etc. The Sentinel System learns about big groups of patients taking the same medicine or getting the same vaccine.

Reporting your safety concerns

If you get a bad side effect from taking a drug or getting a vaccine, contact your doctor. You can also file a report with the FDA to let them know how you are feeling. Here are two FDA links: [FDA Adverse Event Reporting System \(FAERS\)](#) and the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

FAQs for Health Advocacy Groups

What is the Sentinel System's Engagement Partners Workgroup?

It is a workgroup launched in January 2016 by the FDA to raise awareness about the Sentinel System as a valuable health and safety tool involving the following stakeholders: 1) The Public, 2) Health Plan Members, 3) Health Advocacy Groups, and 4) Providers.

What did this Sentinel System Workgroup actually do?

The Workgroup developed customized narratives for each stakeholder. Each narrative describes, the "How?", "What?", and "Why?" of the Sentinel System. For more information, please refer to "The Sentinel System Story: For Health Advocacy Groups", or check out this link: www.sentinelinitiative.org.

What about Privacy and Confidentiality?

Each Sentinel System narrative emphasizes that the Sentinel System studies aggregate data and that all identifiers are removed, such as name, address, telephone number, Social Security Number, etc.

What can I do to share this message with our members?

You can feature the Sentinel System Story and your critical role in its success, through a variety of media channels to your members.

What media channels are you referring to?

For example, you can describe the Sentinel System in your member newsletter, organization's website, brochures, pamphlets, Facebook, Twitter, etc.

Am I required to use all of these channels to tell the Sentinel System story to our members?

No. We would encourage you to reach out to as many members as possible, using the most effective media channels in which you typically communicate to your members.

Is there a budget for these strategies?

Unfortunately, no. We appreciate everything you have done and continue to do to increase the value of this critically important safety tool.

Is there someone I can talk to or will give me feedback? Who can I call, if I need assistance?

For help, please contact the Stakeholder Engagement Workgroup Lead, Steve Mikita, at smikita@agutah.gov and Susan Forrow, Senior Project Manager, Sentinel Operations Center, susan_forrow@harvardpilgrim.org.

What is the Sentinel System?

One of the FDA's biggest jobs is to make sure drugs, vaccines, and medical devices are safe. FDA wants to know if patients get bad side effects from these products. To make it faster and easier to learn about problems, FDA created a special program called the Sentinel System.

How the Sentinel System Works



Sentinel System's 3 important parts

- **Information:** The system looks at billing claims and patient records.
- **Expert Team:** Sentinel works with scientists, doctors and computer experts.
- **Computer Programs:** They study large groups of patients who take the same medicine, or use the same device.



Personal privacy

- No one at FDA or the Sentinel Operations Center has access to your name, address, or any other information that identifies you.
- For more information, visit sentinelinitiative.org.



Sentinel asks questions like:

- How many patients take the same drug?
- How many patients are getting bad side effects (swelling, bleeding, etc.)?
- Are side effects more common after taking one drug than after another drug that treats the same problem?



How does FDA use the information?

- FDA can choose to collect more information.
- FDA can provide updated safety information for patients and providers.
- If you have concerns about your own medical products, please contact your doctor.