Transcript Details

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The FDA's Adverse Event Reporting System (FAERS) Public Dashboard

Transcript: The FAERS Public Dashboard

[Welcome to The Director's Corner, an audio podcast series featuring the director of FDA Center for Drug Evaluation and Research.]

Colleen Labbe: Many listeners may be familiar with the FDA's Adverse Event Reporting System or FAERS. Data in FAERS supports the FDA's post-marketing safety surveillance program for drug products and therapeutic biologic products. Recently, CDER's Office of Surveillance and Epidemiology created and released a tool that makes FAERS data easier to query and retrieve. This new interactive dashboard is designed to expand access of FAERS data to the general public. Today, I'm talking with Janet Woodcock about the new FAERS Dashboard and how it can best be used. Dr. Woodcock, thanks for joining me again.

Dr. Janet Woodcock: Happy to be here.

Colleen Labbe: So first, let's clarify what FAERS is. What type of data can be found in this database?

Dr. Janet Woodcock: Well, FAERS is a database. It basically contains reports about adverse events and medication errors related to human drugs and biologics that are submitted to FDA and the information FAERS dates back to 1968 so it's a pretty substantial amount of information. Now, for healthcare professionals and consumers, patients submitting information to FAERS is voluntary. Most data is originally submitted by healthcare providers and some consumers, and much of it is submitted to industry who then work up and analyze the reports. Then the manufacturers are required, once they receive a full report, to work it up and then investigate it and then report it to the FDA. All the reports that we receive from these different channels on adverse events and medication errors are entered into FAERS.

Colleen Labbe: Okay, so it seems like FAERS could be a treasure trove of information but there are limitations to it. What are those limitations?

Dr. Janet Woodcock: Well, they're limitations or you might call them sort of, warnings that you can draw false conclusions, and many people do that when they first start to look at a database like this. You can't really read a dashboard like this and directly make determinations about drug safety. You have to realize that we get reports all the time about drugs, and there's a background rate, for example, that we get. And the FAERS data by themselves are not indicators of a safety profile for a drug. And when drugs first launch, there may be a large number of reports that are received and it doesn't necessarily mean a drug is super dangerous. So, if you have concerns about what you find in this dashboard, you should talk to your doctor about safety concerns. So, although the FAERS data has reports on specific drugs, you can't be using it to determine with certainty that the drug caused the adverse event or reaction. People are often sick and they have different illnesses that happen. They're often taking many drugs. They have many other things

going on so you can't draw a direct line often between the drug and the side effect, but it is a signal that should be looked at. So, you know, obviously, there are other factors though that could have caused that side effect. Another thing that often trips people up when they first start looking at these data are the duplicates, as people submit a report and then they'll submit follow up and maybe some other healthcare professionals will also report the same event. And one of the things our safety evaluators always do is try to put these all together so that we count it as one event. But we've seen many cases where people counted five or seven events because they're multiple reports. You don't want to do that. And you can't use FAERS to look at the rate of occurrence of any side effect because you don't know how many people took the drug. Obviously, if only a few people take a drug and you see some very serious side effect, then that's a very high rate, but if millions of people are taking the drug and you see a side effect, well, it might be a one in a million effect. We use other information that we can get to look at how much of the drug has been dispensed in a given year, how many people have taken it and so forth, and try to get a better handle on what the frequency of the event might be, and information in the report is not necessarily verified or medically confirmed. That is one of the things we ask the sponsors, the manufacturers, to do, is go investigate when they get a report so that we get better information on what happened. I also would like to note to people who are very interested in using this that the FAERS Dashboard is going to be updated on a quarterly basis. It's possible there's gonna be a lag time between, depending on when you look at it, between what we've received into the system and what we've put up. So people should just be aware that when they're trying to use the system, depending on when you access it, there may be some more data that hasn't yet come into the system, but will in the next quarter.

Colleen Labbe: Okay, so what was the driver for developing the new FAERS Dashboard tool? How does it help users?

Dr. Janet Woodcock: Well, prior to this, we made data available on a quarterly basis that was in a format that couldn't be easily searched or sorted. It really had to be, a researcher had to download that and put it into a form and, and really be a researcher to be able to use these data. And you needed to have specific analytic tools and understand how to transform the raw data into analyzable form. So, the dashboard is the same data but presented in more user-friendly format that allows people who are on the system to search and organize based on a wide range of criteria, such as what reports did we get in a given year, what reports we get around a specific drug, who was, what type of person was the reporter? Was it a healthcare professional? Consumer? And what were the outcomes that were seen? We had a lot of demands for improving data access and transparency, and this dashboard is a response to that.

Colleen Labbe: So, we know that FAERS data is just one tool that FDA uses to track the safety of drugs in the post-market phase. What else does the agency use to track and evaluate safety data?

Dr. Janet Woodcock: Well, it is true that FAERS reports are a really important source actually of new findings about drugs that are marketed. And so many of the new safety findings that we announce originally come from the FAERS signal. But we consider that a signal and something that needs to be investigated to see that it's true, and so we have many other activities, such as literature reviews, consultation with other clinical experts in the field, going back and looking at the clinical trials. We have our Sentinel Network that we use to a great extent, to look into the signals that we see out of FAERS and to see whether they actually can be found in health claims data, which is what Sentinel has. And we can use other large healthcare databases, as well. So we do those kinds of investigations. And based on all the studies and then the findings, we may take action. We might update the label, for example, but in extreme cases, we might restrict the use of the drug or even remove the drug from the market.

Colleen Labbe: Well Dr. Woodcock, thanks so much for sitting down with me today to discuss this new feature.

Dr. Janet Woodcock: Most welcome.

Colleen Labbe: If our listeners would like to view the new dashboard tool, go to fda.gov and search for FAERS Public Dashboard.

[Thanks for listening. For more information about what you heard today, please visit our web site at fda.gov/drugs.]