

## **Researchers Find Deadly Prescription Drug Effects Six Years Before FDA**

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Northwestern University's Charles Bennett, M.D., is a super sleuth of potentially deadly prescription drug reactions. He leads a national SWAT team of doctors called RADAR (Research on Adverse Drug Events and Reports) based out of Northwestern's Feinberg School of Medicine. They swoop in to investigate early signs of trouble years before the Food and Drug Administration (FDA) takes notice.

A new study by Bennett, the A.C. Buehler Professor in Economics and Aging at Northwestern's Feinberg School of Medicine, and a hematologist and oncologist at Northwestern Memorial Hospital, found RADAR identified serious drug reactions six years earlier than the FDA and drug companies.

RADAR's proactive safety efforts and reports also were much more comprehensive than those from the FDA or drug companies, according to the study. RADAR's reports provided doctors with important medical insights as well as guidance for prevention, diagnosis and treatment.

The study was published May 28 in Archives of Internal Medicine.

Since Bennett launched RADAR in 1998, his research has resulted in black box warnings on billion dollar drugs that may have saved thousands of lives. He has also provided guidance to help physicians more safely administer drugs. More than 100,000 people die each year from reactions to medications. The FDA is under attack for its passive and inefficient methods of learning about these problems.



Why is RADAR so nimble? Bennett's network includes hematologists and oncologists around the country and the world. His phone rings weekly with calls from concerned doctors alerting him to possible new trouble. After such a call, Bennett probes for clues that led to a lifethreatening reaction to a drug. 'What's the age and weight of the patient, x-rays, details of the physical exam and blood tests?' he'll ask. He'll canvas doctors to see if they've seen similar cases. If a vital piece of evidence is missing, Bennett even will track down a doctor at home on a Sunday and ask her to drive back to her office to check a chart. Then Bennett and his team fit all the puzzle pieces together to figure out what happened and how to prevent it in the future.

The new study also shows, however, that the FDA and drug companies were faster than RADAR to spread the word about serious adverse drug reactions. RADAR relies on publishing its studies in peer-reviewed medical journals, a process that takes longer than the FDA's warning letters to doctors and the drug companies' package inserts.

Thus, it's time for a formal collaboration between RADAR and the FDA to wed their strengths, said Bennett, who also is co-director for cancer control of the Robert H. Lurie Comprehensive Cancer Center.

"We need to work together as partners," Bennett said of the FDA. "Pharmaceutical side effects are one of the top five causes of death in this country. We want to move it out of the top five. This is the way to start that process and save thousands of lives."

Bennett envisions a formal partnership with the FDA in which he would share RADAR's investigations on safety issues, arrive at a joint insight on drug problems and have the FDA distribute the information to doctors.

"The old way of doing business was a large number of incomplete



reports that took an average of seven years to find adverse reactions to drugs," Bennett said. "We propose with our system we can cut that to between one to two years. That's a six-year savings. For a billion dollar drug, can you imagine how many people that's affecting?"

In the study, Bennett compared RADAR's reports on serious events associated with 14 drugs and drug-coated cardiac stents to FDA and drug company reports. The FDA had more reports than RADAR, but RADAR's reports were more complete. Pharmaceutical companies sent out safety notifications two years earlier than RADAR reported its results in journals. However, drug companies' doctor notifications were less likely than RADAR's to include information on the incidence of the drug reaction, outcomes and treatment or prevention.

"Our hypothesis is that the quality, not the quantity counts," Bennett said. "A small number of very good case reports is better than a large number of very bad case reports."

Bennett leaped into pharmacovigilance -- as the field is called -- when a bad drug reaction got personal. Nearly ten years ago, he was sitting in a case conference when he heard about a woman whose kidneys, brain and blood vessels had mysteriously shut down. No one could figure out why. Bennett visited the woman, who was being kept alive on a ventilator. He immediately recognized his father's best friend. Bennett dug in and eventually identified a side effect of a drug that hadn't been well recognized. He saved her life. The drug was pulled from the market.

RADAR, whose research has been primarily funded by The National Institutes of Health, focuses on hematology and oncology because that is Bennett's expertise. Bennett hopes his RADAR model will be adopted by researchers in cardiology, ophthalmology and other fields.

Source: Northwestern University



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