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In Conversation With… Rebecca Smith-Bindman, MD

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Editor's note: *Rebecca Smith-Bindman, MD, is professor in residence at the University of California, San Francisco. She is a national leader in the impact of radiologic testing on patient outcomes, and in the safety—particularly in terms of radiation dose—of radiographic imaging.*

Dr. Robert Wachter, Editor, AHRQ WebM&M: How did you get interested in the topic of safety in radiology?

Dr. Rebecca Smith-Bindman: My research has focused broadly on the impact of imaging on patient outcomes—both positive and negative. These days computerized tomography (CT) is the workhorse of radiology. One of the potential harms of using CT scanning when it's not necessary is having unnecessary exposure to ionizing radiation, a known carcinogen. We do a lot of CT scans. For every thousand US citizens, we do about 200 CT scans a year and the radiation doses associated with CT scans are a lot higher than they are for conventional x-rays. The CT scan of a chest might have 500 times the dose of a chest x-ray. So if you're looking at the overuse of CT, then radiation becomes a very concerning harm if that test is not necessary. That's the first way I got interested. I was looking at utilization of imaging and a very large database of national imaging rates, and I was surprised at how rapidly CT use was growing. Separate from that, it was not only that we were doing a large number of CTs, but also the way we were doing them was leading to higher doses than needed for diagnosis. We found that CTs were being done in a way that was particularly and unnecessarily unsafe because it was using many times the amount of radiation needed. When I first started looking at these data, it was quite shocking to be honest.

RW: Were you more shocked by the radiation dose per scan or the number of scans or kind of the combination of the two?

RSB: The frequency that these tests were used was surprising. The radiation doses that we found were shocking. And lowering the radiation doses used seemed like an easier problem to work on than the much broader and complex issue of overuse of these tests. However, related to the doses used, there is no value to anyone in using doses that are higher than needed for medical diagnosis.

RW: When you began to see these high doses of radiation, was it obvious that there were wide variations and that some places had lower doses than others? Or was it surprising that everybody had higher doses

than you thought might be necessary?

RSB: The former is probably a better characterization. In general the doses are higher than they need to be, and that feels like something we can address. The first study that we did looked at CTs done for a dozen different indications. We had about a thousand of each type of exam across four San Francisco Bay Area institutions. When we looked at patients grouped by clinical condition being assessed—such as PE or stroke—the doses were all over the map, even within institutions. If you went in the morning in a given institution your dose would be different than if you went in the afternoon or in the middle of the night. If you went to the institution across the street, the doses were profoundly different. The doses were higher than they should be, but they were also highly, highly variable, and that was the most striking finding.

After we looked into it more closely, it turns out that there were very few guidelines about what doses should be. The doses you typically get are based on phantom studies. Phantom studies are very sophisticated plastic dummies put in a CT scanner. You radiate the dummy and that tells you about the dose. It turns out those doses have very little resemblance to the doses used in clinical practice. When people scan a plastic dummy, you set a protocol that you follow very closely. But when you scan actual patients, you veer very far away from that single set of instructions.

RW: Is this collective inattention because people weren't paying much attention, and the doses therefore were set haphazardly without a lot of thought? Or is there some philosophy out there that somehow higher doses led to better pictures?

RSB: In general, the higher doses of radiation that you use the greater the information collected and as a result, the greater the clarity, precision, and accuracy of the images that you generate. So higher dose often translates into more detailed images. However, while this is generally true, it is also true that the benefits tend to plateau: after you reach a certain dose, going even higher does not result in better images, and in general we are very high in the dose threshold, where there is room to reduce doses without reducing diagnostic accuracy.

Next, the technology has rapidly evolved for CT scanning, tremendously since a few decades ago. It used to take a while to get images through the chest, whereas, now you could image the entire body in a fraction of a second. By being able to acquire the images so much faster, we are now able to get more of them, and that has led to the development of fancy protocols where you get many more images than we had in the past. Instead of just getting a picture of the chest during one phase of the cardiac cycle, we might go through several phases of the cardiac cycle with early, mid, and delayed contrast bolus injection images. Essentially we're imaging the chest three or four times, when we used to just image it once. The machines couldn't do that 2 decades ago; they would overheat.

Now we can scan so quickly that we've developed these elaborate protocols that require repetitive imaging and that results in a higher dose to the patient. In some cases, these repetitive protocols are necessary and have enabled CT to answer a more diverse range of clinical questions. However, part of the incentive for developing these protocols is that the manufacturers have competed on these increasingly wonderful images they were able to generate, which led to the use and development of more complicated protocols that led to higher and higher doses of radiation. The people tasked to buying the machines (radiologists,

physicists, administrators) have not been very sensitive to radiation issues. Further, the use of many of these higher dose protocols has not been driven by evidence-based studies of what's better for diagnosis. Physician preference and manufacturer promotion of these capabilities led to people buying this equipment and using these newer fancy protocols when in fact they may not even help with diagnosis in most cases. Thus often these higher dose studies may generate more beautiful images—which radiologists enjoy reviewing because of their clarity—but they may not improve the likelihood of the physician making the correct diagnosis or patient outcomes.

RW: Do you think the inattention to the issue of radiation risk was because people didn't think through the cumulative impact or because they didn't know how bad it was?

RSB: You would think that if you're going to develop and promote higher dose multiphase studies that you'd say, "Use them wisely and judiciously because they have a higher dose." No one did that. No framework was adopted for summarizing or reporting the radiation information either to the doctor or in the medical records. So there was inattention to the issue and then we were so enamored with these new technologies that we further ignored the issue. The doses crept up and no one really noticed it.

What really raised awareness of the issue was radiation overdoses at Cedars-Sinai in 2009—though it happened at many other hospitals after those were first identified—these were patients who received really high doses. These patients got doses comparable to treatment for brain cancer when they went in for a diagnostic CT, they lost their hair, and it raised awareness that if you use CT and you do it improperly, it can really be unsafe and cause harm. The 400 or so patients who underwent those CTs—some were older patients who had strokes or were suspected to have strokes—had a brain perfusion scan, which is a high dose setting. But many of the people who had those studies were infants and small children who weren't at risk of stroke and in fact didn't need to have a CT at all, let alone a high dose brain perfusion scan. The brain perfusion scan had just become a common study type, even for patients who should not have had this type of study. But the fundamental problem is no one was looking at the doses they got. They were using high dose protocols when low dose protocols could be used, and no one was watching this issue whatsoever. When I was a resident you wouldn't get a CT scan in a pregnant woman without really, really, really thinking hard about it. Whereas in the last 5 years we've become blasé about it and we get CTs in anyone—small children, pregnant women—without even thinking about it. So as the doses went up, we were thinking about this problem less, and when attention came to this issue it really raised the question: Are we using this technology in the safest way possible? I think the answer is no, we have much to do to improve that.

RW: For some safety hazards, when things go wrong you see the results right away. This is one where you may not see the results for 20 years.

RSB: There are two kinds of effects we talk about for radiation. One is the effect that you see right away, and it means the doses are just really high so you see the harm right away—the deterministic effect—that's what happened with the hair loss. While this harm received a lot of attention, it is rarely related to diagnostic CT (i.e., it should never occur that doses for diagnostic imaging get into this range). The other kind of effect is the one that I'm actually more concerned about—stochastic effects—effects that you might not see for 2 years, 5 years, 10 years, 20 years, and that's the increased risk of cancer. Those risks in my

mind are much more important because of the number of people affected. We do about 75 million CTs a year in the US. The number of patients who have severe side effects (where the radiation is so high) is a handful; it's perhaps a few thousand patients per year. The number of patients to get routine doses of CT that are higher than needed, which puts them at risk of developing future cancers, could be far higher, since so many individuals are exposed. That's the group that we need a whole lot of effort on collecting doses that we're using, tracking doses over time, and putting systems in place to improve the doses that we use.

RW: People are paying attention to this cumulative effect of the doses, and the numbers are pretty scary. What are you and others doing to try to change this?

RSB: California is the first state in the nation to pass a law that now requires reporting in the patient's medical record the radiation dose used for every CT scan and then reporting doses that are higher than various thresholds. We're not as a community doing a great job yet in complying with the law in a consistent fashion, but now people are looking at and knowing the doses being used. That's a huge first step. I submitted a quality measure to the National Quality Forum that provides a really simple framework for looking at the radiation doses that you use for CT. It's a way of looking at dose that every hospital, every facility, every single person, every 5000-member doctor group could do. We have created an audit function, where a facility that wants to know how they compare to other facilities can upload their CT data, and we will give them an automatic, instantaneous audit of how their doses compare to other facilities with the same equipment on patients, adults and children, using the National Quality Forum measure. We just received a Patient Centered Outcomes Research Institute grant focused on this topic, and our hope is to be able to make this widely available as a first step towards collecting CT radiation dose data to determine benchmarks of how we should be optimizing dose.

As a pilot, we did a randomized trial at a hospital where we gave technologists feedback on the doses they used, and we showed that we could lower the doses the technologists used 10% to 20% from a simple audit and 6-hour educational intervention. On a practical level, everyone who owns or uses a CT scan needs to look at the doses that they're using. There's no way to improve what you're doing unless you know what you're doing. Once you see what you're doing, you need to figure out how to improve what you're doing. In some cases that means very simple things: shorten the scan length, don't use as many repetitive scans, train your technologists better. Sometimes it's more complicated: buy new software, or replace 25-year-old hardware. Sometimes it's easy; sometimes it's not so easy. We're developing strategies that we hope can be scaled up rapidly to allow us all to get on the same page.

RW: Let's shift gears to unnecessary or inappropriate use. Obviously you can take the radiation dose from whatever it is to zero if someone doesn't do a scan that the patient didn't need. What kind of progress do you think we've made there?

RSB: Until the last couple of years all of the factors that drive utilization have led to more and more imaging. These include strong financial incentives, concerns about medical liability, and patient demand. The most important driver of inappropriate imaging, though, is a lack of the data about when we should do imaging. That uncertainty has led to overimaging. We have a 15-center AHRQ-funded randomized trial to figure out how do we image patients best who present to emergency departments with flank pain for

suspected kidney stones and the study has a broad range of endpoints—patients' pain, time in the emergency department, admission to the hospital, total amount of testing and costs, which I think will help inform how to image these patients using a diverse group of outcomes. The absence of good data for most clinical questions has led to overimaging for many years, and that's starting to change.

You asked about what clever solutions will lead to more appropriate use of imaging. First you have to impact those drivers of imaging, including financial incentives. Some of the changes in the reimbursement for imaging have been pretty substantial. They went into effect in 2011 and 2012 and are contributing to some small declines in imaging. Getting patients more engaged partly means understanding that everything we do in health care—be it imaging or drug treatment or surgery—has pluses and minuses. And for imaging we hadn't acknowledged that there are minuses. Patients are becoming more engaged in this topic and, as they understand both the risks and benefits of imaging, won't necessarily always want more imaging. Then we need to educate our physicians about the pluses and minuses as well.

Numerous surveys have asked physicians and patients what they know about potential harms of medical imaging, be it radiation risk or false-positives or overdiagnosis, and the results have been surprising. Doctors and patients alike know very little about those things. We need to improve that. There's some work going on to engage physicians and patients in shared decision-making about imaging. There's work in decision support tools to bring some of what we know about appropriate and inappropriate imaging into the decision-making process. Unfortunately, the evidence that can guide imaging is in short supply and, for most clinical questions, doesn't really exist. It's hard to change practice without having the evidence basis for doing that.

RW: In many ways your work has legitimized a new kind of a discussion with a patient. It's not that I'm not getting the CT scan because I'm worried about the cost. It's because I'm worried about radiation or its potential harm to you. In some ways it's made that conversation easier, although I guess sometimes I feel like it's not completely the whole truth. It's a piece of the truth, but there is a cost issue. How do you feel about that?

RSB: I was recently accused of trying to use the radiation issue to reduce inappropriate imaging. In my mind anything that reduces inappropriate imaging is beneficial to the patient. I believe in educating patients and explaining that there are risks and benefits in everything we do, including medical imaging. From my point of view, a lot of things are pretty easy to understand, but others are really complicated to understand in medicine. For example, overdiagnosis is an issue I take very seriously, and one where I think patients can really be harmed as a result of overimaging and overdiagnosis. And yet it's complicated. While physicians may understand that, for example, finding and treating a small prostate cancer in an elderly man may have no impact on his survival and may only lead to complications that affect his quality of life, the patient may not see or understand this perspective. The issue is subtle because most people who have a cancer found are thrilled that it's been found, and they feel that they're saved even when you as a physician are thinking maybe that didn't help the patient very much. The issue related to radiation exposure is actually much easier easy to understand. We're going to be doing this to you and this could be causing cancer as opposed to finding it. It's an issue that patients can understand. Some patients may become anxious knowing that the test exposes them to radiation, but the simple truth is that everything in medicine

has tradeoffs, and more is not necessarily better.

RW: You've been doing things that are really important for patient care and for the system. But I imagine you've gotten some pushback within your own community. Could you tell us if you have and does any part of that surprise you?

RSB: I would say that the response from my community has been mixed. The RSNA is a very large annual radiology meeting in Chicago. Around 70,000 people attend every year. This year there was a full day session, attended by more than a thousand people focused on a mock trial organized around the case of a woman who had repeated CT scanning in the emergency room—all of the imaging examinations were negative—and who developed breast cancer 6 years later and died. Her husband sued because he thought that the cancer came from the radiation from the CT and that she should have been told that there was some risk in the exposure to CT. In the mock trial story, everyone settled but the radiologist, so the focus was on both a discussion of the risk of CT and issues around communication. So that was the trial, there were real malpractice lawyers from Chicago, a real judge and a real jury were brought in which was really exciting, and then they had expert witnesses on both sides and we discussed the overuse of imaging, the causality of cancer, and the standard of care. The mock trial got a lot of attention and I have to give credit to the RSNA for allowing and promoting this in-depth discussion about these important issues. I heard there was some pushback from the manufacturers who were concerned about the focus on these issues, but in the end the organization endorsed this discussion. I think that shows a high level of understanding that issues of overuse, radiation exposure, and medical safety of imaging are important for our community of radiologists to address.

Sometimes in my day-to-day interactions with radiologists and physicists, there's concern that bringing a lot of scrutiny to this issue is not good for us. I think that's disappointing. Because from my point of view, radiologists know the most about this topic of how to use imaging in the safest way possible. We should be leading efforts to increase its safety as opposed to trying to suppress those efforts or suggest that we do not know if radiation is harmful. We know radiation used in medical imaging is potentially harmful, and therefore we need to make sure we use imaging judiciously.

RW: Who won the trial?

RSB: It was a 6-to-7 split. The people who voted for our side (that argued that her cancer more than likely came from the radiation exposure) awarded the patient's husband a million dollars. I was floored with this result, as the case was set 15 years ago, and thus the trial was about a standard of care for communication 15 years ago. But a private practice radiologist at the end—during a very exciting question and answer and comment period—got up and said, "Look, anyone in the audience who thinks you can get away with this now is crazy. You can't be doing repeated, unnecessary scans and not explaining to the referring clinician and the patient that there's a risk here. That's our responsibility." I can understand the split vote in the past. But going forward all of us need to start doing this. His comment was what we ended our session with. And I was really very pleased. I thought that this was a great educational opportunity but he also set the stage. This is what it means to be a radiologist now—it means we have to ensure the safety of what we do.