HealthBlawg :: David Harlow's Health Care Law Blog

Interview of
Dave Fischer, Executive Director of MITA
(Medical Imaging and Radiation Therapy Manufacturers Alliance)

February 25, 2010

David Harlow: This is David Harlow at HealthBlawg, and I have with me today Dave Fischer who is the Executive Director of the Medical Imaging and Radiation Therapy Manufacturers Alliance, or MITA. It's an organization that represents most of the manufacturers of equipment in this area and works to establish some common principles and protocols for this industry. Dave, I appreciate you taking the time to speak with HealthBlawg.

Dave Fischer: Of course.

David Harlow: Dave, I am interested - as we all are - in exploring questions about patient safety in dealing with imaging technologies, particularly in light of the news about CT scanner dose issues, initially sat Cedars-Sinai last fall and then, as came out, elsewhere in the country. And now we're looking at an information gathering process and probably a regulation development process with FDA as a result of the public hearing that's being held next month. And I'm interested in hearing from you about where you see the industry right now, how you see the industry as a whole responding to this issue and how you see the interplay between the equipment-related issues and the professional practice related issues whether it's physician issues or technologist issues.

Dave Fischer: Sure, I think might be instructive to start with describing just for a minute the distinct difference between imaging manufacturers and imaging technologies and radiation therapy technologies. The diagnostic technologies, for example CT, on the ionizing radiation side of the equation are specifically designed for detecting abnormalities in a patient. And over the course of nearly a decade MITA and its member companies have been working to reduce dose for the use of those technologies. And the thing I think whether it's through new innovative technologies or new practices, new information provided to operators, we've been working diligently to reduce dose and to provide the same quality of image for the patients and their providers. On the radiation therapy side of the equation, actually the intent of the therapy is to use radiation to kill cancer cells. And so the focus there is to focus the radiation to a specific spot without damaging surrounding tissues. And so when folks talk about or people talk about dose reduction, they are generally talking about the diagnostic side of the equation. Now, with regard how we have been responding to radiation dose issues and you've mentioned a number of things that have been in the press recently, like I said a moment ago, on the diagnostic imaging side our companies have spent years developing technologies to reduce the amount of radiation that a quality scan requires as well as providing operators with additional information about the amount of radiation a particular scan will utilize to make that image. And many of these features are designed specifically to reduce

radiation and to make the operator aware of the amount of radiation so that changes can be made prior to the scan to reduce the amount of radiation a patient will actually receive. Now, how do manufacturers interact or what's the partnership between all of the different folks who work on this? Now, I think like I just mentioned, it clearly is a partnership. The equipment that we manufacture is a tool that physicians, medical physicists, technologists all use to screen patients or treat patients or determine if they have disease. And in all of these cases, we have to work in partnership with all of these providers to ensure the safe and effective use of our equipment.

David Harlow: Now, one of the issues raised in anticipation of the FDA hearings is a question about establishing radiation dose reference levels, which relates to one of the things you were just saying. And I'm wondering what you see as the way forward for incorporating this information and failsafe controls into the everyday workflow of the professionals using this requirement.

Dave Fischer: I'm glad you asked about that. One of the things that we've announced this week with regard to reducing radiation dose and making operators more aware of dose is the CT manufacturers have all agreed to three things. One, to what we call a dose check or the MITA dose check initiative. Those items are first, a dose alert - already the equipment provides the operator with a dose level for a particular scan. However, we believe it's important to put that level into context, and so we're creating a tool that will allow providers or hospital imaging centers to enter in reference levels just as you mentioned just a moment ago to provide the operator with a data point to help them understand where the dose in the scan they are about to do - the dose level for that scan ranks in the overall distribution of dose for that particular type of scan. And so it's like a yellow light. It's an alert to allow that make sure the operators know this is above our reference level, we need to have a very good reason for that. Second thing, --

David Harlow: So if I can interrupt you just to make sure we understand that. What you're saying is that you're going to create the technology to establish a set of guardrails if you will and each institution would calibrate those guardrails.

Dave Fischer: I think it is a decent analogy. I mean, we're creating the tool to inform the operator but it will require the imaging facility or the hospital to provide the data, the information, the value that would cause that pop up screen to come up. In addition, I've mentioned the yellow light, we've also created a red light, which is a dose warning if a particular scan has the potential to be dangerous to a patient. A perfect example of this is a scan that has enough radiation to cause deterministic effects, like hair loss or burns. Now, there is almost no reason why a CT machine would ever cause that unless it had been set inappropriately. And so we want to make sure that if that is set that way that we have a red light that pops up - a warning - to the operator to let them know there is something wrong here that you need to check out. The last thing, and this is something I think that will fit very nicely into the President's recent proposal for a national dose registry. We believe that this dose information needs to be recorded in a standard manner. It currently is recorded in the DICOM system, which is the language of interchange, the exchange language that allows imaging products to all communicate

with each other. But recording this dose image in a standard manner will also facilitate the use of a national dose registry as well as facilitate the analysis of dose to make sure to better understand how it use, how it changes, how it varies.

David Harlow: And what do you see as the likely timeline for implementation of this system? You say that CT manufacturers have agreed to move forward with this; will this involves significant retrofitting of existing systems?

Dave Fischer: CT manufacturers will begin to apply this technology to their new releases beginning this year.

David Harlow: So new releases meaning software upgrades to machines that are –

Dave Fischer: That are being sold, correct. And then additionally we will also begin pushing out this technology to the installed base as well.

David Harlow: You mentioned earlier the notion that doses on average per study have been reduced overtime. And my question there is - another analogy if you will, the introduction of the catalytic converter reduced automobile emissions tremendously but then again the volume of vehicle miles has increased tremendously since that time. So what are we looking at in terms of controls on the uses of the technology, the numbers of scans per thousand population, is that on your radar screen as well?

Dave Fischer: Absolutely. One of the things that we're strong supporters of is something called appropriateness criteria, there was actually legislative language with that theme that was included in a physician payment update bill about a year and a half ago. What the appropriateness criteria means is we want to make sure that the patients gets the right scan at the right time. What that means is we want to incorporate into the physicians' thinking that CT or other diagnostic imaging is appropriate for certain conditions in certain periods and it should be used in those times in those periods. We do not support the idea of the principle of maximizing CT scans or any diagnostic tool. We believe we should be using the right scan at the right time.

David Harlow: And so are you working through that initiative with clinical groups, professional organizations to develop the evidence based guidelines that may affect utilization?

Dave Fischer: Manufacturers can't practice medicine and so we really have to leave it to the professionals in that area. But I can tell you that the Center for Medicare and Medicaid Services is beginning to implement the demonstration program that was included in the MIPPA bill.

David Harlow: Do you participate with the professional associations, societies in terms of education programs in order to get the word out about issues like this?

Dave Fischer: Oh, absolutely. Another example is the Image Gently Campaign, which is run by the American College of Radiology. We're a participant in the Image Gently Campaign which is specifically designed to reduce radiation in pediatric medicine so that is one example of our efforts to work closely with the radiologists, the physicians, medical physicists in that effort. We will be cosponsoring both a CT dose summit and a radiation therapy dose summit in the coming month. We believe very strongly in the partnership that I mentioned earlier between all the providers and the manufacturers.

David Harlow: Is it too early to see a result from that partnership, from those educational efforts? I ask because in recent weeks there has been news about evidence based medicine studies that show relative benefits of different approaches to managing care – I'm thinking specifically of stents versus medications in the cardiac arena - and despite the evidence, clinical practice does not seem to be shifting.

Dave Fischer: There is a larger issue within our healthcare system about variations in care across the country. What we feel like as manufacturers what we feel we can do is do our best to make sure we're educating our customers as well as the national societies and also in our local level to try to make sure they understand our views on the applicable reasons for these tests.

David Harlow: What else can you tell us about communications with either the FDA or with other regulators at the federal and state level, or professional associations at the federal and state level, dialog around this issue and where you see this going in the context of the upcoming of public hearing at the end of March?

Dave Fischer: Last fall, MITA convened a stakeholders meeting with radiologists, physicists, technologists as well as the FDA, to discuss the issues of radiation dose and we have been working since then on this topic with them and communicating with them. Those meetings were the beginning of our own efforts to create the MITA dose check initiative. And we welcomed the FDA's announcement a couple of weeks ago. Much of what they have proposed are things that we agree with and we intend to work closely with the FDA and participate fully in the FDA's process moving forward.

David Harlow: One of the other points that you've endorsed is the expansion of mandatory accreditation for advanced imaging facilities and my sense is that many if not most payers already require some sort of accreditation in order to bring facilities into their networks. Do you see an additional significant opportunity for further accreditation?

Dave Fischer: I believe the accreditation program that was included in the MIPPA bill that that I mentioned earlier is for the non-hospital setting. We support examination of whether or not that policy needs to be expanded to include hospitals. Generally speaking, I think there is a lot of value to accreditation in the sense that it ensures that an imaging facility is up to speed on all of the different techniques, that their machines work appropriately. And I think its also important to remember this is a new program that has

just gotten of the ground. And so I believe there is a lot of room for moving providers into that category.

David Harlow: Another issue raised in these endorsements is the notion of some standards for personnel involved in the imaging exams and radiation therapy treatments. And I'm wondering whether you see our 50-state system as an impediment to achieving this sort of standardization?

Dave Fischer: Our organization hasn't taken a position on whether or not the minimum standards that we support should be a national-based system or a state-based system. I think the key is that we establish the standards for training and education for the personnel performing medical imaging exams in the radiation therapy arena, I'm sorry in the radiation arena.

David Harlow: We spoke a little bit about a national dosage registry and I'm wondering whether there is any comparable registry in place today where the infrastructure could be built on that is in current use among the professionals who'd be called upon to using this registry?

Dave Fischer: I do not know the answer to that question.

David Harlow: Is that something that you have been involved in looking at talking about what the infrastructure would be for that registry?

Dave Fischer: The challenge with a registry system like this is that we have, as everyone knows, a fragmented healthcare system, that is the nature of our system. And as we add health information technology we gain additional ability to gather this information and to understand it. While it's true that the imaging sector is fairly advanced in regard to exchanging information - like I mentioned the DICOM standard earlier - and in recording dose information, having that information at a single hospital doesn't provide you the same robust information that it would if it's captured by a city or a state or a hospital system or a national version of that. And so what I think is critical first about our dose check initiative is (1) standardizing the recording of that information so it's more easily accessible and then (2) just the ongoing development and advancement of health information technology which will facilitate the sharing of that information over time.

David Harlow: So you're saying that just as an example, the DICOM standard could be used in order to support a registry that would be interoperable or could receive information and share information with existing provider systems in place?

Dave Fischer: Absolutely, it's already functioning, it includes radiation dose information and in fact the FDA mentions the DICOM standard in their white paper.

David Harlow: What would you expect that future to bring this says public hearing is called for the end of next month, what do you as happening over the next 6 to 18 months as a result of that hearing?

Dave Fischer: I expect we're going to see additional efforts. I could speak from my own organization's perspective. I mentioned today our dose check initative for CT: we're already exploring ways to expand that effort to include radiation therapy, nuclear medicine as well as x-ray. So we believe that including additional information for the providers and the operators of this equipment is essential to reducing medical errors and we will continue that effort. I expect that FDA will continue to examine this. I do not know whether or not they will issue regulations or how will impact the clearance process. But we intend to work with FDA closely to ensure that the newest innovations are able to get to market and to make sure that medical radiation is reduced and medical errors as well.

David Harlow: Well, thank you very much. I've been speaking with Dave Fischer, Executive Director of the Medical Imaging and Radiation Therapy Manufacturers Alliance. Thanks again, Dave.

Dave Fischer: Thank you.