The Value of the Clinical Laboratory

SUSAN LECLAIR

There is some history to suggest that when the motion to compose the Declaration of Independence came to the floor of the Second Continental Congress, several members of the Congress asked why it was necessary to publish anything since they already knew the reasons. John Adams is supposed to have said," Well, of course, we know the reasons but what about the rest of the world. "

In the aftermath of the ACA validation by the Supreme Court and the continued scrutiny of patients, regulators, insurances, etc. at the continued increasing cost of health care, it is incumbent on every aspect of health care to ask themselves the question: What is our value, not only in terms of cost but also in terms of the care we give. And make no mistake, we, no less than physicians or nurses, give care. It is care in terms of numbers and identifications but it is still care. It matters if we know what our value is but no one else does. Someone must decide what is our value and what are the criteria by which we will measure that value. Who exactly should do that?

Within the law there is an entity called an Accountable Care Organization (ACO). The individual ACO's will determine the goals and criteria by which it will prove that corporate entity as a whole is in compliance with the ACA law and regulations concerning the provision of care. Obviously, this includes the clinical laboratory. Every healthcare institution likely will become its own ACO or will become part of a system-wide ACO. Reimbursement moneys will flow through the ACO to specific entities and the money will flow to those centers who prove their worth – not to themselves but to others. So if the laboratory in EACH instance does not actively participate, the money will flow to someone who does. Many of your institutions have already set up the committees to do this. Are you on one of these committees? Is anyone from your laboratory? Do you really want the Director of the Laboratory making these decisions or the “Director of Diagnostic Services”? Do you want the doctoral level scientists making these decisions? Who do you think would have the most valuable information concerning repeat ordering of the tests or what to do at 3:00AM or how to handle follow up testing? Who is best suited to demonstrate quality, efficiency, and transparency in the clinical laboratory? If not you, who? One recent concept calls for the laboratory to be merge within radiologic imaging in order to get more efficiency of data collection and utilization.

The range of care provided and the criteria by which that care is measured must (you might want to argue) be done at a local level. Some facilities will have a need to perform some tests while others do not. For example, a hospital in Colorado might have a greater need to perform testing for *Yersinia pestis* while a facility in Connecticut might be more interested in Lyme Testing. One early set of guidelines was an attempt by the federal regulators to control testing using a rubric they first titled "Unbelievable Medical Edits" in which they tried to limit testing frequency. This one was easy to debunk since it called for only one immunoglobin assay per day. IgG on Monday, IgM on Tuesday, etc. It also limited CBCs and individual hemoglobin values to one a day, a difficulty if one were interested in pre and post surgical values. What is important here is that this concept made it all the way to publication for comment prior to implementation. Could similar ideas come from your hospital's ACO? If so, how would you know?

Professional organizations across the US have developed or are developing task forces and committees to develop a framework for their members to use in their own institutions but the actual work of protecting patients from poorly thought out laboratory standards is to make them ourselves at our own institutions. Like many others, we have had a speckled history of action and inaction. How many times have each of us not done something because we expected “someone else” to do it. There is no someone else this time. The action has to come from every single laboratory. You can not hope that someone at the hospital down the street is going to

do your job. You can not hope that someone on the day shift or from some other specialty will step up to volunteer on the committee. You have to do it but you do not have to do it alone.

It is our hope that ASCLS will construct a committee or task force to provide the background and information needed to members to help them become members of the ACO's committees and to advocate for the clinical laboratory. Increasingly we live in an age of accountability, but how would you prove the "value" and "quality" of what your lab does for patients? We know why we are important. It is probably time to let everyone else know.