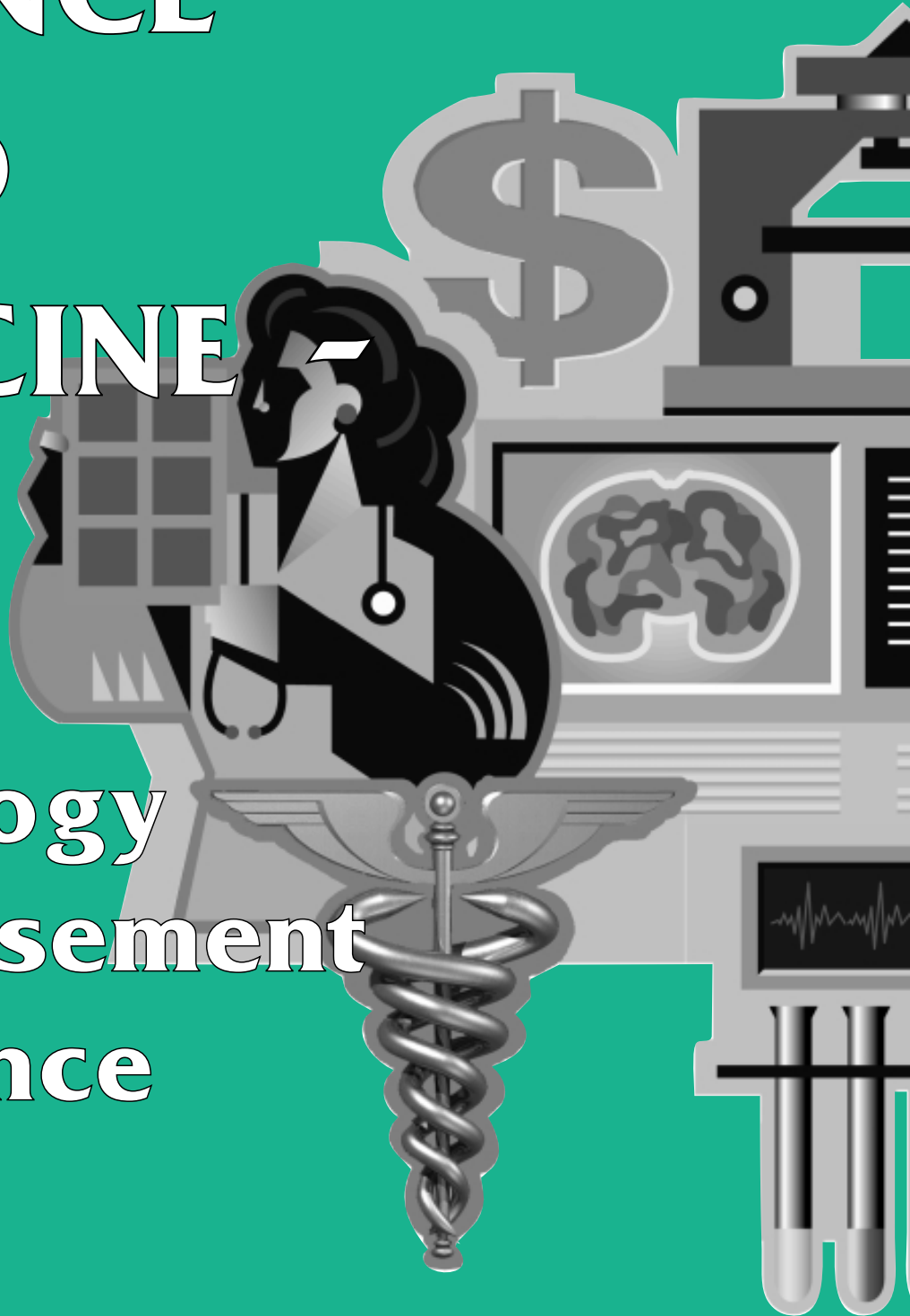


Proceedings From The

EVIDENCE BASED MEDICINE

The Key to New Technology Reimbursement Conference

June 8, 2001
Crystal City, Virginia



Proceedings from the Evidence Based Medicine conference, sponsored by AACC and supported with a generous educational grant from Bayer Corporation.

Bayer 
Diagnostics Division

From the President

Dear Colleague:

On June 8, 2001, The American Association for Clinical Chemistry conducted a highly rated and successful conference, which brought together the key government and private sector leaders to discuss reimbursement problems affecting new technologies and the increasing use of Evidence Based Medicine in making payment decisions. I am pleased to provide you with a summary of the proceedings from that meeting.

I would like to take this opportunity to personally thank the members of the Evidence Based Medicine Planning Group, which put together this productive and exciting program: Robert Christenson, PhD, Chair; James Boyd, MD; Michael Laposata, MD, PhD; and Christopher Price, PhD. Thank you for once again putting on a great program. Also, I would like to extend a special thanks to Bayer Corporation for their generous support of this educational endeavor.

Sincerely,

Larry Kricka, DPhil

President

AACC



PROGRAM FACULTY

Grant Bagley, MD

Partner, Arnold & Porter,
Washington, DC

Robert Christenson, PhD

Director, Clinical Chemistry,
Toxicology, & Rapid Response
Laboratories, University of Maryland
School of Medicine, Baltimore, MD

Peter Kazon, JD

Partner, Mintz Levin, Washington, DC

David Perez, MD

Contractor, Medicare Part B Medical
Director, Trailblazer, Richmond, VA

Carole Redding Flamm, MD, MPH

Senior Scientist, Blue Cross Blue
Shield Association Technical
Evaluation Center, AHRQ Evidence
Based Practice Center, Chicago, IL

Gregory Raab, PhD

Raab and Associates,
Bethesda, MD

Bernard Statland, MD, PhD

Director, Office of Device Evaluation,
Food and Drug Administration,
Rockville, MD

Bruce Steinwald, MBA

Independent Consultant,
Washington, DC

Mitchell Sugarman, MBA

Director, Medical Technology
Assessment, The Permanente
Federation, Oakland, CA

John Whyte, MD, MPH

Acting Director, Coverage and
Analysis Group, Items and Devices
Division, Centers for Medicare and
Medicaid Services, Baltimore, MD

Deborah Zarin, MD

Director, Technology Assessment
Program, Center for Practice and
Technology Assessment, Agency for
Healthcare Research and Quality,
Rockville, MD

Technological Innovations

EVIDENCE BASED MEDICINE - THE KEY TO NEW TECHNOLOGY REIMBURSEMENT

Clinical laboratories and in vitro diagnostic (IVD) manufacturers find themselves on the threshold of a great era of technological innovation. Emerging assays and medical devices are poised to change the face of U.S. medicine, but an antiquated, inefficient, and unpredictable laboratory reimbursement system may be a difficult obstacle for fledgling laboratory assays and devices to overcome. What can be done to ensure adequate, fair and timely reimbursement for tomorrow's technology? Since the evaluation of "evidence" is the cornerstone of Medicare's current coverage process, Evidence Based Medicine (EBM) may hold the key to new technology reimbursement in the future. On June 8, 2001, the American Association for Clinical Chemistry (AACC) brought together federal and local Medicare policymakers, researchers, laboratorians, IVD manufacturers and others to discuss how EBM could be used to help streamline the laboratory services reimbursement process.

"I have never experienced an innovation rate of the magnitude that we as an IVD industry are facing right now," declared Rolf Classon, MBA, President of Bayer Diagnostics (Tarrytown, NY). "This year, between 500 and 1,000 proposals of different kinds of technology and discovery are coming in to us as a diagnostics company. This didn't happen

ten years ago. I believe that we are at the threshold of an era that will be unparalleled from an innovation point of view."

In this new era of innovation, it will be increasingly important to demonstrate the value of laboratory tests. Even though new assays and technologies coming from genomics and proteomics research may be limitless, the health care dollars used to purchase new assays and technologies will continue to be limited.

"Being prepared to rapidly adopt and pay for these new tests and technologies will be one of the great challenges for all of us for the future," noted Classon. "But how do we effectively establish the value of a test? How do we demonstrate that value to all of the stakeholders in the health care delivery system? And how do we gain appropriate consideration of the value of a new test from reimbursement authorities? These are issues that are critical to resolve so that we can go forward and maintain our leadership position in medical discovery and health care delivery throughout the world."

WHAT EBM IS AND WHY IT MAY HOLD THE KEY TO NEW TECHNOLOGY REIMBURSEMENT

Today in health care, everyone is demanding more accountability, said Deborah Zarin, MD, Director of the Technology Assessment Program at the Agency for Healthcare Research and Quality (AHRQ) (Rockville, MD). It's essential to make certain that new tests, devices, procedures, and therapies are evaluated using data-driven processes in order to ensure they are used appropriately in clinical practice and result in the best possible patient outcomes. AHRQ's approach to fostering this kind of "data-driven" health care is to fund EBM

research, and develop new methods and mechanisms for performing technology assessments. Currently, AHRQ funds technology assessments that are done at 12 AHRQ-affiliated technology evaluation centers (TECs) throughout the U.S.

"The role of AHRQ is to conduct specific assessments, and we do that both intramurally with staff and extramurally through our evidence-based practice centers," explained Zarin. "We function as a science partner for the Center for Medicare and

"The IOM committee quickly concluded that in many respects, new laboratory tests and technology are the leading edge of treatment. Much of tomorrow's medical decisions will flow from the results that come from clinical laboratory services, and if new tests don't make it into the system in a timely way, the rest of the health care system is thrown off course."

—Bruce Steinwald, MBA, member of the Institute of Medicine Committee on Medicare Laboratory Payment Policy

OBSTACLES TO NEW TECHNOLOGY COVERAGE AND PAYMENT

Even if IVD manufacturers follow the advice of Zarin and Flamm in designing appropriate studies, there's no guarantee that using EBM will help them get through the process of gaining reimbursement more quickly. Reform of the U.S. reimbursement system is sorely needed if EBM is going to be used in a timely manner to evaluate the flood of new technologies that are coming in the near future.

"For manufacturers, there's a known world of FDA regulation. There is a well-worn path to market, and it may be long, troublesome, and difficult, but it's predictable and understandable. Conversely, the road to coverage and payment is not at all clear," commented Gregory Raab, PhD, of Raab & Associates, Inc. in Bethesda, MD.

Raab is not the only one who believes the U.S. laboratory reimbursement system needs reform. An Institute of Medicine (IOM) committee formed to study Medicare laboratory payment policy came to the same conclusion. "We certainly knew very quickly in our process, which began in early 2000, that the current Medicare payment policy for laboratory medicine is woefully outdated," said Bruce Steinwald, MBA, a member of the IOM panel on Medicare Laboratory Payment Policy (Washington, DC). "As far as administrative simplicity and efficiency is concerned, the system really is kind of a mess, and clearly can be improved upon."

Among the IOM's recommendations for reform were the institution of a single national rational fee schedule, the development of a data-driven system for refining and updating such a fee schedule, and the abolition of the medical necessity documentation requirements that currently plague clinical laboratories. "There's plenty of evidence that suggests requiring labs to submit ICD-9 codes as proof of medical necessity doesn't work and no evidence that it does, and by work what I mean is, does it really result in the right test being performed at the right time for the right patient? Clearly it doesn't," said Steinwald. "It creates administrative complexity, it doesn't as far as we can tell reduce whatever fraud and abuse there is and in my view, it's one of these shin-kickers that drives a wedge between the government and the people that it depends on to provide services to its beneficiaries."

Other problems exist as well. "Last year, AdvaMed [formerly the Health Industry Manufacturers Association] hired the Lewin Group to look at the reimbursement process, and they came up with some remarkable findings. They found that with respect to timeframes, it takes between 15 months and five years to get to a point where a medical technology is reimbursable within the system," said Raab. "If the CPT code the American Medical Association (AMA) has assigned isn't right, but you have everything else, it could take you 15 to 27 months to get that

straightened out. If you have a coding and payment issue, but you have coverage, it could take you 15 months to four years to get a resolution."

Grant Bagley, MD, an attorney in the law firm of Arnold & Porter (Washington, DC) and former Director of HCFA's Coverage and Analysis Group, is candid about the problems that await companies these days in the coding, payment, and coverage process. "If anyone has been through the process of getting a code, I think you'll find that it's not very timely, codes are only given out once a year, it is absolutely not open, because you don't have any insight into the process at all, and it is completely unpredictable," he said.

With breakthrough technology, there is additional frustration, because CMS will use two seemingly arbitrary methods to set payment rates. "What Medicare did, absent of any direction from the Congress, is develop two administrative techniques to set payment—cross-walking and gap-filling," Raab explained.

Cross-walking refers to the practice of pricing a new test at the rate of an older test that is deemed to be similar in nature. "In the last few years, there have been some changes, and now when CMS makes that cross-walking determination, it might set the price at a multiple of the old code—say, double the price of the old code—or sometimes at a fraction of the price, for example, at seventy percent of the existing price of the similar test," said Peter Kazon, JD, of Mintz, Levin, Cohn Ferris, Glovsky and Popeo, P.C. (Washington, DC).

Cross-walking is much easier for CMS to do than gap-filling, and the agency tends to cross-walk new codes rather than gap-fill them, Kazon added. This is problematic because in many instances the cross-walk may not be appropriate, and the new payment rate may be set in an arbitrary manner.

Of 57 new laboratory CPT codes published last year by the American Medical Association (AMA) 56 were cross-walked to existing CPT codes. "Of these 56 new cross-walked tests, there's a number of possibilities for questionable decisions, and no explanation of how the agency arrived at their decisions to pay more for some tests and less for others. On cross-walked decisions, there are no published criteria guiding the process, no description of the process, and no participation by stakeholders in the process," stressed Raab.

Gap-filling, a process CMS uses to set prices for new tests that cannot be cross-walked, is controversial as well. With gap-filling, CMS looks at the amounts its local Medicare carriers are paying for the new test, and then uses the median price among carriers to set a new national limitation amount for the test. The national limitation amounts (NLAs) basically "cap" the price Medicare contractors can pay for tests covered under Medicare.

Medicaid Services [CMS—formerly HCFA] on issues related to technology assessment and coverage, as well as collaborate with the Veteran's Administration, the Department of Defense, and international agencies that do the same kinds of assessments.”

Zarin added that with the information overload that exists today, there's a need for synthesis, and this is where technology assessment and EBM come into play. Zarin and others believe that EBM, defined as “decision-making based upon data regarding the likely impact of different treatments on specific outcomes for specific populations,” by David Sackett and colleagues in the *British Medical Journal* (1996;312:710-2), could be effectively used to prove the value of a laboratory assays or devices in the process of making Medicare or other insurance coverage decisions.

“EBM starts with research. Somebody has to extract the data and synthesize it, then make recommendations or decisions. Ideally, there would then be a method for measuring and monitoring quality and outcomes, and then that would feed back into research, and it becomes a cycle. We need every step in the cycle for people to be able to make good decisions.”

Companies seeking a positive coverage decision for their test or technology may see the technology assessment stage of the process as being yet another barrier to market, noted Zarin. “However, I think the information that needs to be gleaned from the technology assessment is key information not only for coverage purposes, but for the clinical decision-maker as well. The purpose of performing a technology assessment is really to aid in clinical decision-making as well as to aid in policy decision-making.”

So far, AHRQ's technology evaluation centers have conducted more than 300 technology assessments, performing about 25 per year. “We don't look at costs, and we are not determining coverage recommendations. Our criteria are based on clinical effectiveness, and our conclusions are that a technology meets or does not meet our list of five key criteria,” explained Carole Redding Flamm, MD, Senior Scientist at the Blue Cross Blue Shield Technology Evaluation Center (Chicago, IL). “That information, however, is used by our subscribers and our health plans as one piece of the information used to make a coverage decision.”

FDA—ONLY THE FIRST STOP ON THE ROAD TO REIMBURSEMENT

Unfortunately, evidence-based studies or technology assessments often can't be performed until there is enough data to systematically evaluate an assay or device. This means that, usually, technology assessment can't adequately be performed until after a product is cleared or approved by the Food and Drug Administration (FDA) and has been adequately studied by scientific researchers. Waiting for such studies before making coverage decisions may delay widespread adoption of new IVD products. One solution mentioned at the conference was to have a process in which companies could consult with CMS from the beginning so that the studies needed to demonstrate the clinical utility of the test can be performed in tandem with studies required for FDA approval or clearance. Currently, AHRQ and the technology evaluation centers only look at FDA-approved devices in their assessments.

In an ideal world, FDA approval would automatically allow an assay to be covered by Medicare and other insurers, but this is not possible because FDA and CMS use different criteria to evaluate new technologies. “We want to find ways in which we can work together with CMS. I think the important difference, however, is that the criteria the FDA uses—safe and effective—is different than what CMS uses, which is the reasonable and necessary criteria,” explained Bernard Statland, MD, PhD, Director of the FDA's Office of Device Evaluation (Gaithersburg, MD).

“The 510(k) route through the FDA enables certain kinds of devices to get through without ever really testing them in a patient population. But a lot of people don't understand that the most basic questions about whether a test or technology is helpful to patients isn't always answered when a device receives FDA clearance or approval,” said Zarin.

In addition, under law, CMS can make no payments for expenses incurred for items or services which are not reasonable for the diagnosis or treatment of illness or injury, said John Whyte, MD, MPH, Acting Director of the Coverage and Analysis Group at CMS (Baltimore, MD). “The premise that a device, procedure or service might be of some benefit to some patient under some circumstances is not a criterion that the Medicare program can base coverage on. We need to know that something works and is reasonable and necessary before we can actually cover it. The FDA may put the product on the shelf, but CMS is the one that decides whether or not to buy it,” Whyte said.

Zarin and Flamm advise IVD companies to design studies up front that will satisfy FDA criteria for clearance and approval, and CMS criteria for coverage. They and other speakers at the conference provided tips for performing these studies. “It's really important to think about the questions that are going to be asked at the end when you are designing the clinical trials at the beginning,” noted Zarin.

OBSTACLES TO NEW TECHNOLOGY COVERAGE AND PAYMENT

Even if IVD manufacturers follow the advice of Zarin and Flamm in designing appropriate studies, there's no guarantee that using EBM will help them get through the process of gaining reimbursement more quickly. Reform of the U.S. reimbursement system is sorely needed if EBM is going to be used in a timely manner to evaluate the flood of new technologies that are coming in the near future.

"For manufacturers, there's a known world of FDA regulation. There is a well-worn path to market, and it may be long, troublesome, and difficult, but it's predictable and understandable. Conversely, the road to coverage and payment is not at all clear," commented Gregory Raab, PhD, of Raab & Associates, Inc. in Bethesda, MD.

Raab is not the only one who believes the U.S. laboratory reimbursement system needs reform. An Institute of Medicine (IOM) committee formed to study Medicare laboratory payment policy came to the same conclusion. "We certainly knew very quickly in our process, which began in early 2000, that the current Medicare payment policy for laboratory medicine is woefully outdated," said Bruce Steinwald, MBA, a member of the IOM panel on Medicare Laboratory Payment Policy (Washington, DC). "As far as administrative simplicity and efficiency is concerned, the system really is kind of a mess, and clearly can be improved upon."

Among the IOM's recommendations for reform were the institution of a single national rational fee schedule, the development of a data-driven system for refining and updating such a fee schedule, and the abolition of the medical necessity documentation requirements that currently plague clinical laboratories. "There's plenty of evidence that suggests requiring labs to submit ICD-9 codes as proof of medical necessity doesn't work and no evidence that it does, and by work what I mean is, does it really result in the right test being performed at the right time for the right patient? Clearly it doesn't," said Steinwald. "It creates administrative complexity, it doesn't as far as we can tell reduce whatever fraud and abuse there is and in my view, it's one of these shin-kickers that drives a wedge between the government and the people that it depends on to provide services to its beneficiaries."

Other problems exist as well. "Last year, AdvaMed [formerly the Health Industry Manufacturers Association] hired the Lewin Group to look at the reimbursement process, and they came up with some remarkable findings. They found that with respect to timeframes, it takes between 15 months and five years to get to a point where a medical technology is reimbursable within the system," said Raab. "If the CPT code the American Medical Association (AMA) has assigned isn't right, but you have everything else, it could take you 15 to 27 months to get that

straightened out. If you have a coding and payment issue, but you have coverage, it could take you 15 months to four years to get a resolution."

Grant Bagley, MD, an attorney in the law firm of Arnold & Porter (Washington, DC) and former Director of HCFA's Coverage and Analysis Group, is candid about the problems that await companies these days in the coding, payment, and coverage process. "If anyone has been through the process of getting a code, I think you'll find that it's not very timely, codes are only given out once a year, it is absolutely not open, because you don't have any insight into the process at all, and it is completely unpredictable," he said.

With breakthrough technology, there is additional frustration, because CMS will use two seemingly arbitrary methods to set payment rates. "What Medicare did, absent of any direction from the Congress, is develop two administrative techniques to set payment—cross-walking and gap-filling," Raab explained.

Cross-walking refers to the practice of pricing a new test at the rate of an older test that is deemed to be similar in nature. "In the last few years, there have been some changes, and now when CMS makes that cross-walking determination, it might set the price at a multiple of the old code—say, double the price of the old code—or sometimes at a fraction of the price, for example, at seventy percent of the existing price of the similar test," said Peter Kazon, JD, of Mintz, Levin, Cohn Ferris, Glovsky and Popeo, P.C. (Washington, DC).

Cross-walking is much easier for CMS to do than gap-filling, and the agency tends to cross-walk new codes rather than gap-fill them, Kazon added. This is problematic because in many instances the cross-walk may not be appropriate, and the new payment rate may be set in an arbitrary manner.

Of 57 new laboratory CPT codes published last year by the American Medical Association (AMA) 56 were cross-walked to existing CPT codes. "Of these 56 new cross-walked tests, there's a number of possibilities for questionable decisions, and no explanation of how the agency arrived at their decisions to pay more for some tests and less for others. On cross-walked decisions, there are no published criteria guiding the process, no description of the process, and no participation by stakeholders in the process," stressed Raab.

Gap-filling, a process CMS uses to set prices for new tests that cannot be cross-walked, is controversial as well. With gap-filling, CMS looks at the amounts its local Medicare carriers are paying for the new test, and then uses the median price among carriers to set a new national limitation amount for the test. The national limitation amounts (NLAs) basically "cap" the price Medicare contractors can pay for tests covered under Medicare.

Gap-Fill Pricing

The original NLAs were set in 1984, and instead of adjusting each test cap every year, over the years, Congress has reduced all the test caps in one fell swoop by cutting the entire NLA schedule by percentage points. In 1984, for example, Medicare paid labs 100% of the NLA. Now, Medicare pays labs only 74% (last year Congress enacted legislation increasing the NLA for new technologies to 100 percent of the median, however).

Even Medicare contractors admit that there is no clear policy for gap-filling new laboratory tests. “There’s not a lot written in the manuals on gap-fill pricing. To understand the process, you really have to look outside any portions of the Medicare manual or the Medicare intermediaries manual from the

laboratory codes and look at Durable Medical Equipment (DME), rare and unusual services, physician services and ambulance services,” said David Perez, MD, Medical Director at Trailblazer (Richmond, VA), a Medicare carrier that serves the Washington, DC, Maryland, and Virginia region of the country and has affiliates in other regions. “Consequently, the methodology used to perform gap filling varies from Medicare contractor to Medicare contractor.”

The bottom line, said Raab, Kazon, and Bagley is that there is a lot of uncertainty in the processes of price setting, coding, and coverage. “In addition, there’s very little opportunity to challenge these decisions once they are made,” said Kazon.

SOLUTIONS FOR THE FUTURE

If many of these problems aren’t addressed, said Raab, the system may not be able to handle the new technologies that are on the horizon. “I see access issues coming up, and I see pressure on the hospital labs and independent labs having no choice but to manage their business through all sorts of cross-subsidies rather than just taking what Medicare pays,” he commented.

Some favor a system that is more national in nature, with fewer local carriers and one path to Medicare coverage. The medical device industry generally wants to maintain a local system, however, since reimbursement for new technologies is usually first worked out at the local level. “More than 90% of products and services are covered through local medical review policies (LMRPs), and only about 10% are covered through national coverage decisions,” noted Whyte, adding that, at present, there are about 6,000 LMRPs and only 250-300 national coverage decisions.

“If you look at the coverage criteria that have been proposed by the Medicare Carriers Advisory Committee, they are incredibly rigid standards of evidence that are applying evidence-based medicine standards, and appropriately so” added Bagley. “However, there is a fear among those in industry that if you don’t have enough evidence to get a national coverage decision, you’ll get a national non-coverage decision, and a national non-coverage decision becomes purgatory forever. So, you’re much better off never going to the national arena. You may have interesting pricing when you go to the local carriers, but at least you can get some payment.”

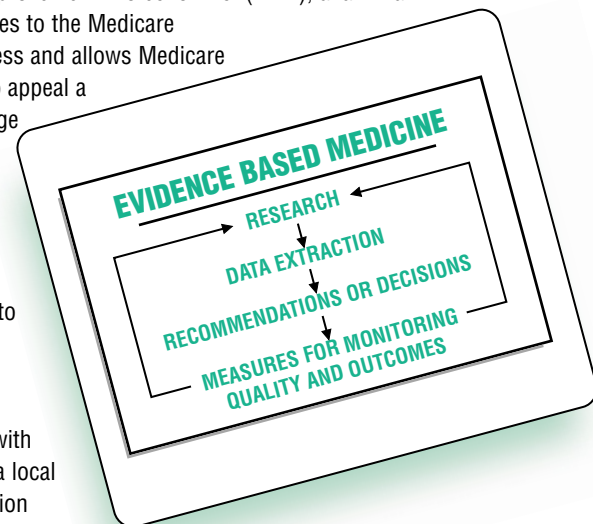
There could be some potential for combining the regulatory and reimbursement steps, creating a system in which an IVD company has its initial pre-market meetings with both CMS and the FDA. “I think industry has to weigh in on this. Some companies want to have it done almost as one unit. Other companies are interested in having it be discrete,” said Statland. “We’re [the FDA] certainly open to the possibility. We have to make it easier,

and we have to streamline it, and I think that’s one of the challenges.”

“I think we may see the day when in vitro diagnostics—and they will most likely be the first ones because they are most appropriate—will go through parallel track approval in which CMS and FDA sit down at the table and articulate what their needs are,” said Bagley.

Before that day comes, CMS will have to undertake a number of administrative changes to make its processes more user-friendly. The Benefit Improvement Protection Act (BIPA), a law that requires changes to the Medicare coverage process and allows Medicare beneficiaries to appeal a general coverage decision, could help in this arena. Under the law, LMRPs will be transformed into local coverage determinations (LCDs). “CMS will come out with a definition of a local coverage decision which will be something different than a local medical review policy,” said Bagley, but the plan is to have one web site that will house all of the local coverage decisions, called www.medicarelcd.net.

New BIPA regulations are expected to be released by October, and Whyte confirmed that the agency anticipates releasing a Federal Register notice on new BIPA requirements within the next few months.



Coverage Criteria

Some members of Congress have also exerted pressure on CMS, sending the agency a letter with a wish list for administrative reform. “Many have written to the agency saying that we need to do better in terms of getting payment coding and coverage more streamlined. That is a top priority of the new administrator as well as the deputy administrator,” said Whyte.

“Administrative changes are a good idea because they allow for public input, and they are done through a notice and comment process,” noted Bagley. “An agency does have a certain amount of discretion, but CMS has been slow to use it in the past.”

Whyte and colleagues from CMS emphasized that the agency is working on becoming more open, and they urged IVD manufacturers to contact them with questions and problems. “The bottom line is that folks should contact CMS as early as possible,” said Mitchell Burken, Acting Division Director in CMS’ Coverage

Division (Baltimore, MD). “As you are working with FDA, please feel free to work with CMS as well early in the game.”

As CMS undergoes reform, there may be an expanded role for EBM in new technology reimbursement. In the future, CMS will ultimately have to decide which new technologies have value in the diagnosis and treatment of Medicare beneficiaries and which do not, and EBM could potentially serve as a model for a consistent coverage determination process. “It’s very easy to calculate cost, and price is relatively straightforward, but I think our challenge is to understand what value truly is,” concluded Statland.

FIVE CRITERIA USED BY AHRQ’S TECHNOLOGY EVALUATION CENTERS TO EXAMINE NEW TECHNOLOGY

Does the technology being assessed have final FDA approval?

Does the available evidence permit conclusions on the effect of health outcomes, i.e., is there an adequate quantity and quality of evidence to draw conclusions?

If there is sufficient evidence to permit conclusions, is there also a net benefit in terms of health outcomes? Do the benefits outweigh the harms on health outcomes?

Is there a way to compare efficacy or to compare the new technology to alternative technologies?

Clinical effectiveness—Will you see the same outcomes and the same improvements in general practice that were demonstrated in clinical trials?

WHAT TO KEEP IN MIND WHEN DESIGNING A CLINICAL TRIAL

“There’s no way to research whether a test should be covered, but we can research, for example, what the test is designed to do and what evidence is there to show that it actually does it,” explained Deborah Zarin, MD, Director of the Technology Assessment Program at the Agency for Healthcare Research and Quality (AHRQ). Here are some tips that she and others have for IVD manufacturers and laboratorians involved in clinical trials who want to simultaneously prepare for a future technology assessment.

In addition to examining test performance, i.e., sensitivity and specificity, examine the test’s impact on clinical management. For example, will it change any treatment or intervention decisions for a patient, and will that have an impact on health outcomes?

Be clear about the proposed clinical use and test the appropriate hypotheses, and determine where your test fits in a clinical strategy.

Review Medicare Coverage Advisory Committee criteria. Most recently, MCAC has said that it generally wants to be able to answer two questions when looking at diagnostic tests. First, is the evidence adequate to determine whether the test provides more accurate diagnostic information compared to an alternative? Second, if the test changes accuracy, is the evidence adequate to determine how the changed accuracy affects health outcomes?

Choose the appropriate diseased and non-diseased groups.

Identify a reference standard, if possible, and use the experimental and reference test in all subjects.

Conduct blind readings of the experimental and reference tests.

Don’t use super-sick and super-normal people.

Have a good statistician or biostatistician involved early on. For companies who can’t afford to do large clinical trials, modeling done by a good statistician may be an acceptable alternative.

For additional information on EBM and Medicare reimbursement issues, consult the following websites:

AACC

<http://www.aacc.org>

AdvaMed

<http://www.advamed.org/>

Agency for Healthcare Research and Quality

<http://www.ahrq.gov/>

Bandolier

<http://www.jr2.ox.ac.uk/Bandolier/index.html>

Center for Medicare and Medicaid Services

<http://www.hcfa.gov/>

Centre for Evidence Based Medicine

<http://www.library.utoronto.ca/medicine/ebm/>

Local Medicare Coverage Decisions

<http://www.lmrp.net>

Medicare Coverage Advisory Committee

<http://www.hcfa.gov/coverage/8b1.htm>

National Institutes of Health Office of Medical Applications of Research

<http://www.odp.od.nih.gov/omar/>

For more information about AACC membership, services activities and educational programs, please visit our website at www.aacc.org or call 800-892-1400.



Advancing
Clinical Laboratory
Science Worldwide

2101 L Street, NW, Suite 202
Washington, DC 20037-1526
Phone 202.857.0717
Fax 202.887.5093

Thanks
Special thanks to
Sue Auxter for
editing the EBM
proceedings