FIGHTING BACK PART 1

TAKE CHARGE

Protect autonomy, put patients first

MIPS explained
Master the four categories
JAMA study a slap in the face to physicians

AMA recently published an article with findings from a study alleging an association between free meals for physicians and an increased rate of prescribing the branded drugs discussed during a lunch or dinner meeting. Of course, it wasn’t until you got to the very end of the piece that the authors came clean and admitted that there is no actual cause-and-effect relationship present.

The news media latched onto these findings and had a field day with the study, bashing doctors as immoral creatures who will prescribe anything in exchange for a free meal.

To paint the entire industry of physicians with such a broad brush is absurd. I believe that the vast majority of doctors, myself included, take many steps to try and avoid even a perceived conflict of interest by patients and others.

I prescribe what is best for my patients and is most effective, not what a free lunch or dinner suggests I prescribe. Despite what JAMA and the American Medical Association may think, my morals, values and ethical responsibility to my patients will not and cannot be compromised by a sandwich or even a prime rib dinner. To suggest so is simply ludicrous.

I have never been bought by the pharmaceutical industry, nor will I ever be. I practice and prescribe based on clinical guidelines and outcomes data in order to provide quality care in an affordable environment, so that my patients are not bludgeoned by high costs and copays. There are many variables to be considered in prescribing the right drug for a patient. A free meal is not one of them.

I believe patients are my priority because I took an oath to do what is best for them, not an oath to pharmaceutical reps to make them the beneficiary of my daily struggle to keep people healthy.

The JAMA article judges physicians based on thousands of lines of unexplained data made public by the Centers for Medicare & Medicaid Services’ Open Payments program, part of the Affordable Care Act. The researchers used this data as the basis for their so-called findings, despite the fact that the AMA has questioned the efficacy of this public data in the first place.

In my opinion, garbage data produces garbage results out, yet they published an article damning us all in a very public forum based on this flawed data.

Ironically, this is the association that is supposed to represent and advocate for physicians.

The AMA and JAMA should retract the article and apologize to the medical community since they admit that the data is inconclusive. As doctors, we deal in complexities and challenges every single day. We should be able to count on our representatives to protect our backs, not stab us in them.

George G. Ellis, Jr., MD, is an internal medicine physician practicing in Youngstown, Ohio, and chief medical advisor for Medical Economics. Do you think the study painted physicians in an unfair light? Tell us at medec@advanstar.com.
“Small practices ... ability to be successful in a value-based world will hinge on their ability to collect and measure data.”

DAPHNE SANEHOLTZ, JD, HEALTHCARE ATTORNEY

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50% of a physicians total MIPs score by 2019 will be based on the quality of the care they provide

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“Physician discussions about prevention [of Zika] are crucially important.”

NITIN DAMLE, MD, INTERNIST

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The board members and consultants contribute expertise and analysis that help shape the content of Medical Economics.

Mary Ann Bauman, MD
Internal Medicine
Oklahoma City, OK

John L. Bender, MD, MBA
Family Medicine
Ft. Collins, CO

Maria Y. Chandler, MD, MBA
Business of Medicine, Pediatrics
Irvine, CA

George G. Ellis Jr., MD
Internal Medicine
Youngstown, OH

David C. Judge, MD
Internal Medicine
Cambridge, MA

Jeffrey M. Kagan, MD
Internal Medicine
Newington, CT

Kenneth R. Kubitschek, MD
Internal Medicine
Asheville, NC

Melissa Lucarelli, MD
Family Medicine
Randolph, WI

Elizabeth A. Pector, MD
Family Medicine
Naperville, IL

John M. Fitzpatrick, JD
Wheeler Trigg Kenedy, LLP
Denver, CO

Alice G. Gosfield, JD
Alice G. Gosfield and Associates
Philadelphia, PA

James Lewis Griffith Sr., JD
Fox Rothschild Philadelphia, PA

Lee J. Johnson, JD
Mount Kisco, NY

Lawrence W. Vernaglia, JD, MPH
Foley & Lardner, LLP
Boston, MA
Fighting Back, Part 1
Protect your autonomy, preserve patient care

THE LAST WORD
The bedside talk every physician must have

All physicians must become aware of the costs of drugs and incorporate that into their decisions, writes Payal Kohli, MD

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Cover illustration by Raul Allen

Richard Baron defends MOC
Demonstrate scrutiny, ABIM head says MOC remains a benefit for internists

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Getting a handle on managing both revenue and cost begins with a simple test: following $1 of revenue through a practice, from booking to billing. Here’s how the NSCHBC tracks the revenue and expense trail for physician-owned, primary care groups:

<table>
<thead>
<tr>
<th>$1 – Total Practice Income</th>
<th>OVERHEAD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician income: 32.2¢</td>
<td></td>
</tr>
<tr>
<td>Personnel: 30.5¢</td>
<td></td>
</tr>
<tr>
<td>Administrative: 14.3¢</td>
<td></td>
</tr>
<tr>
<td>Facility: 8.3¢</td>
<td></td>
</tr>
<tr>
<td>Equipment: 2.1¢</td>
<td></td>
</tr>
<tr>
<td>Benefits: 5.1¢</td>
<td></td>
</tr>
<tr>
<td>Supplies: 7.5¢</td>
<td></td>
</tr>
</tbody>
</table>

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A PCSK9 INHIBITOR FOR INTENSIVE, PREDICTABLE LDL-C REDUCTION in adults with clinical ASCVD or HeFH on maximally tolerated statin therapy as an adjunct to diet

**Indication**

- Repatha® is a PCSK9 (proprotein convertase subtilisin/kexin type 9) inhibitor antibody indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL cholesterol (LDL-C).

- Limitations of Use: The effect of Repatha® on cardiovascular morbidity and mortality has not been determined.

**Important Safety Information**

- Contraindication: Repatha® is contraindicated in patients with a history of a serious hypersensitivity reaction to Repatha®.

- Allergic reactions: Hypersensitivity reactions (e.g. rash, urticaria) have been reported in patients treated with Repatha®, including some that led to discontinuation of therapy. If signs or symptoms of serious allergic reactions occur, discontinue treatment with Repatha®, treat according to the standard of care, and monitor until signs and symptoms resolve.

- Adverse reactions: The most common adverse reactions (> 5% of Repatha®-treated patients and more common than placebo) were: nasopharyngitis, upper respiratory tract infection, influenza, back pain, and injection site reactions.

- In a 52-week trial, adverse reactions led to discontinuation of treatment in 2.2% of Repatha®-treated patients and 1% of placebo-treated patients. The most common adverse reaction that led to Repatha® treatment discontinuation and occurred at a rate greater than placebo was myalgia (0.3% versus 0% for Repatha® and placebo, respectively).

- Adverse reactions from a pool of the 52-week trial and seven 12-week trials:

  Local injection site reactions occurred in 3.2% and 3.0% of Repatha®-treated and placebo-treated patients, respectively. The most common injection site reactions were erythema, pain, and bruising. The proportions of patients who discontinued treatment due to local injection site reactions in Repatha®-treated patients and placebo-treated patients were 0.1% and 0%, respectively. Allergic reactions occurred in 5.1% and 4.7% of Repatha®-treated and placebo-treated patients, respectively. The most common allergic reactions were rash (1.0% versus 0.5% for Repatha® and placebo, respectively), eczema (0.4% versus 0.2%), erythema (0.4% versus 0.2%), and urticaria (0.4% versus 0.1%).

Neurocognitive events were reported in less than or equal to 0.2% in Repatha®-treated and placebo-treated patients. In a pool of placebo- and active-controlled trials, as well as open-label extension studies that followed them, a total of 1,988 patients treated with Repatha® had at least one LDL-C value < 25 mg/dL. Changes to background lipid-altering therapy were not made in response to low LDL-C values, and Repatha® dosing was not modified or interrupted on this basis. Although adverse consequences of very low LDL-C were not identified in these trials, the long-term effects of very low levels of LDL-C induced by Repatha® are unknown.

Musculoskeletal adverse reactions were reported in 14.3% of Repatha®-treated patients and 12.8% of placebo-treated patients. The most common adverse reactions that occurred at a rate greater than placebo were back pain (3.2% versus 2.9% for Repatha® and placebo, respectively), arthralgia (2.3% versus 2.2%), and myalgia (2.0% versus 1.8%).

- Immunogenicity: Repatha® is a human monoclonal antibody. As with all therapeutic proteins, there is a potential for immunogenicity with Repatha®.

**Please see Brief Summary of full Prescribing Information on adjacent page.**

REPATHA® (evolocumab)

BRIEF SUMMARY OF PRESCRIBING INFORMATION

Please see package insert for full Prescribing Information

1. INDICATIONS AND USAGE

1.1 Primary Hyperlipidemia

REPATHA is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (CVD), who require additional lowering of low density lipoprotein cholesterol (LDL-C).

1.2 Homozygous Familial Hypercholesterolemia

REPATHA is indicated as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) for the treatment of patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.

1.3 Limitations of Use

The effect of REPATHA on cardiovascular morbidity and mortality has not been determined.

4. CONTRAINDICATIONS

REPATHA is contraindicated in patients with a history of a serious hypersensitivity reaction to REPATHA [see Warnings and Precautions (5.1)].

5. WARNINGS AND PRECAUTIONS

5.1 Allergic Reactions

Hypersensitivity reactions (e.g., rash, urticaria) have been reported in patients treated with REPATHA, including some that led to discontinuation of therapy. If signs or symptoms of serious allergic reactions occur, discontinue treatment with REPATHA, treat according to the standard of care, and monitor until signs and symptoms resolve.

6. ADVERSE REACTIONS

The following adverse reactions are also discussed in other sections of the label:

- Allergic Reactions [see Warnings and Precautions (5.1)]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Adverse Reactions in Patients with Primary Hyperlipidemia and in Patients with Homozygous Familial Hypercholesterolemia

REPATHA is not indicated for use in patients without familial hypercholesterolemia or atherosclerotic CVD [see Indications and Usage (1.1)].

The data described below reflect exposure to REPATHA in 8 placebo-controlled trials that included 2651 patients treated with REPATHA, including 557 exposed for 6 months and 515 exposed for 1 year (median treatment duration of 12 weeks). The mean age of the population was 57 years, 49% of the population were women, 85% White, 6% Black, 8% Asians, and 2% other races.

Adverse Reactions in a 52-Week Controlled Trial

In a 52-week, double-blind, randomized, placebo-controlled trial (Study 2), 599 patients received 420 mg of REPATHA subcutaneously once monthly [see Clinical Studies (14.1)]. The mean age was 56 years (range: 22 to 75 years), 23% were older than 65 years, 52% women, 80% White, 8% Black, 6% Asian, and 6% Hispanic. Adverse reactions reported in at least 3% of REPATHA-treated patients, and more frequently than in placebo-treated patients in Study 2, are shown in Table 1. Adverse reactions led to discontinuation of treatment in 2.2% of REPATHA-treated patients and 1% of placebo-treated patients. The most common adverse reaction that led to REPATHA treatment discontinuation and occurred at a rate greater than placebo was myalgia (0.3% versus 0% for REPATHA and placebo, respectively).

Table 1. Adverse Reactions Occurring in Greater than or Equal to 3% of REPATHA-treated Patients and More Frequently than with Placebo in Study 2

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Placebo (N=302)</th>
<th>REPATHA (N=599)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasopharyngitis</td>
<td>9.6%</td>
<td>10.5%</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>6.3%</td>
<td>9.3%</td>
</tr>
<tr>
<td>Influenza</td>
<td>6.3%</td>
<td>7.5%</td>
</tr>
<tr>
<td>Back pain</td>
<td>5.6%</td>
<td>6.2%</td>
</tr>
<tr>
<td>Injection site reactions†</td>
<td>5.0%</td>
<td>5.7%</td>
</tr>
<tr>
<td>Cough</td>
<td>3.6%</td>
<td>4.5%</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>3.6%</td>
<td>4.5%</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>3.0%</td>
<td>4.2%</td>
</tr>
<tr>
<td>Headache</td>
<td>3.6%</td>
<td>4.0%</td>
</tr>
<tr>
<td>Myalgia</td>
<td>3.0%</td>
<td>4.0%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>2.6%</td>
<td>3.7%</td>
</tr>
<tr>
<td>Musculoskeletal pain</td>
<td>3.0%</td>
<td>3.3%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>2.3%</td>
<td>3.2%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>2.6%</td>
<td>3.0%</td>
</tr>
<tr>
<td>Gastroenteritis</td>
<td>2.0%</td>
<td>3.0%</td>
</tr>
</tbody>
</table>

†includes erythema, pain, bruising

Adverse Reactions in Seven Pooled 12-Week Controlled Trials

In seven pooled 12-week, double-blind, randomized, placebo-controlled trials, 993 patients received 140 mg of REPATHA subcutaneously every 2 weeks and 1059 patients received 420 mg of REPATHA subcutaneously monthly. The mean age was 57 years (range: 18 to 80 years), 29% were older than 65 years, 49% women, 85% White, 5% Black, 9% Asian, and 5% Hispanic. Adverse reactions reported in at least 1% of REPATHA-treated patients, and more frequently than in placebo-treated patients, are shown in Table 2.

Table 2. Adverse Reactions Occurring in Greater than 1% of REPATHA-treated Patients and More Frequently than with Placebo in Pooled 12-Week Studies

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Placebo (N=1224)</th>
<th>REPATHA† (N=2052)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasopharyngitis</td>
<td>3.9%</td>
<td>4.0%</td>
</tr>
<tr>
<td>Back pain</td>
<td>2.2%</td>
<td>2.3%</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>2.0%</td>
<td>2.1%</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>1.6%</td>
<td>1.8%</td>
</tr>
<tr>
<td>Nausea</td>
<td>1.2%</td>
<td>1.8%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>1.0%</td>
<td>1.6%</td>
</tr>
<tr>
<td>Muscle spasms</td>
<td>1.2%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>1.2%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Cough</td>
<td>0.7%</td>
<td>1.2%</td>
</tr>
<tr>
<td>Influenza</td>
<td>1.1%</td>
<td>1.2%</td>
</tr>
<tr>
<td>Contusion</td>
<td>0.5%</td>
<td>1.0%</td>
</tr>
</tbody>
</table>

†140 mg every 2 weeks and 420 mg once monthly combined

Adverse Reactions in Eight Pooled Controlled Trials (Seven 12-Week Trials and One 52-Week Trial)

The adverse reactions described below are from a pool of the 52-week trial (Study 2) and seven 12-week trials. The mean and median exposure durations of REPATHA in this pool of eight trials were 20 weeks and 12 weeks, respectively.

Local Injection Site Reactions

Injection site reactions occurred in 3.2% and 3.0% of REPATHA-treated and placebo-treated patients, respectively. The most common injection site reactions were erythema, pain, and bruising. The proportions of patients who discontinued treatment due to local injection site reactions in REPATHA-treated patients and placebo-treated patients were 0.1% and 0%, respectively.

Allergic Reactions

Allergic reactions occurred in 5.1% and 4.7% of REPATHA-treated and placebo-treated patients, respectively. The most common allergic reactions were rash (1.0% versus 0.5% for REPATHA and placebo, respectively), eczema (0.4% versus 0.2%), erythema (0.4% versus 0.2%), and urticaria (0.4% versus 0.1%).

Neurocognitive Events

In placebo-controlled trials, neurocognitive events were reported in less than or equal to 0.2% in REPATHA-treated and placebo-treated patients.
Low LDL-C Levels
In a pool of placebo- and active-controlled trials, as well as open-label extension studies that followed them, a total of 1998 patients treated with REPATHA had at least two LDL-C values < 25 mg/dL. Changes to background lipid-altering therapy were not made in response to low LDL-C values, and REPATHA dosing was not modified or interrupted on this basis. Although adverse consequences of very low LDL-C were not identified in these trials, the long-term effects of very low levels of LDL-C induced by REPATHA are unknown.

Musculoskeletal Events
Musculoskeletal adverse reactions were reported in 14.3% of REPATHA-treated patients and 12.8% of placebo-treated patients. The most common adverse reactions that occurred at a rate greater than placebo were back pain (3.2% versus 2.9% for REPATHA and placebo, respectively), arthralgia (2.3% versus 2.2%), and myalgia (2.0% versus 1.8%).

Adverse Reactions in Patients with Homozygous Familial Hypercholesterolemia
In a 12-week, double-blind, randomized, placebo-controlled trial of 49 patients with HoFH (Study 4), 33 patients received 420 mg of REPATHA subcutaneously once monthly [see Clinical Studies (14.3)]. The mean age was 31 years (range: 13 to 57 years), 49% were women, 90% White, 4% Asian, and 6% other. The adverse reactions that occurred in at least two (6.1%) REPATHA-treated patients, and more frequently than in placebo-treated patients, included:
- Upper respiratory tract infection (9.1% versus 6.3%)
- Influenza (9.1% versus 0%)
- Gastroenteritis (6.1% versus 0%)
- Nasopharyngitis (6.1% versus 0%)

6.2 Immunogenicity
As with all therapeutic proteins, there is potential for immunogenicity. The immunogenicity of REPATHA has been evaluated using an electrochemiluminescent bridging screening immunoassay for the detection of binding anti-drug antibodies. For patients whose sera tested positive in the screening immunoassay, an in vitro biological assay was performed to detect neutralizing antibodies.

In a pool of placebo- and active-controlled clinical trials, 0.1% of patients treated with at least one dose of REPATHA tested positive for binding antibody development. Patients whose sera tested positive for binding antibodies were further evaluated for neutralizing antibodies; none of the patients tested positive for neutralizing antibodies.

There was no evidence that the presence of anti-drug binding antibodies impacted the pharmacokinetic profile, clinical response, or safety of REPATHA, but the long-term consequences of continuing REPATHA treatment in the presence of anti-drug binding antibodies are unknown.

The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to REPATHA with the incidence of antibodies to other products may be misleading.

8. USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Risk Summary
There are no data available on use of REPATHA in pregnant women to inform a drug-associated risk. In animal reproduction studies, there were no effects on pregnancy or neonatal/infant development when monkeys were subcutaneously administered evolocumab from organogenesis through parturition at dose exposures up to 12 times the exposure at the maximum recommended human dose of 420 mg every month. In a similar study with another drug in the PCSK9 inhibitor antibody class, humoral immune suppression was observed in infant monkeys exposed to that drug in utero at all doses. The exposures where immune suppression occurred in infant monkeys were greater than those expected clinically. No assessment for immune suppression was conducted with evolocumab in infant monkeys. Measurable evolocumab concentrations in combination at comparable levels to maternal serum, indicating that evolocumab, like other IgG antibodies, crosses the placental barrier. FDA's experience with monoclonal antibodies in humans indicates that they are unlikely to cross the placenta in the first trimester; however, they are likely to cross the placenta in increasing amounts in the second and third trimester. Consider the benefits and risks of REPATHA and possible risks to the fetus before prescribing REPATHA to pregnant women.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data
Animal Data
In cynomolgus monkeys, no effects on embryo-fetal or postnatal development (up to 6 months of age) were observed when evolocumab was dosed during organogenesis to parturition at 50 mg/kg once every 2 weeks by the subcutaneous route at exposures 30- and 12-fold the recommended human doses of 140 mg every 2 weeks and 420 mg every month, respectively, based on plasma AUC. No test of humoral immunity in infant lactation was conducted with evolocumab.

8.2 Lactation
Risk Summary
There is no information regarding the presence of evolocumab in human milk, the effects on the breastfed infant, or the effects on milk production. The development and manufacture of REPATHA have not been considered along with the mother's clinical need for REPATHA and any potential adverse effects on the breastfed infant from REPATHA or from the underlying maternal condition. Human IgG is present in human milk, but published data suggest that breast milk antibodies do not enter the neonatal and infant circulation in substantial amounts.

8.4 Pediatric Use
The safety and effectiveness of REPATHA in combination with diet and other LDL-C-lowering therapies in children with HoFH require additional data on dose exposureresponse relationships of LDL-C lowering with REPATHA. Data from the controlled trials, uncontrolled studies, and an open-label extension in children are not sufficient to allow for dosing recommendations in children. For these reasons, comparison of the incidence of antibodies to REPATHA is not possible.

8.5 Geriatric Use
In controlled studies, 1420 patients treated with REPATHA were ≥ 65 years old and 171 were ≥ 75 years old. No overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

8.6 Renal Impairment
No dose adjustment is needed in patients with mild to moderate renal impairment. No data are available in patients with severe renal impairment [see Clinical Pharmacology (12.3)].

8.7 Hepatic Impairment
No dose adjustment is needed in patients with mild to moderate hepatic impairment (Child-Pugh A or B). No data are available in patients with severe hepatic impairment [see Clinical Pharmacology (12.3)].

13. NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
The carcinogenic potential of evolocumab was evaluated in a lifetime study conducted in the hamster at dose levels of 10, 30, and 100 mg/kg administered every 2 weeks. There were no evolocumab-related tumors at the highest dose at systemic exposures up to 38- and 15-fold the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC. The mutagenic potential of evolocumab has not been evaluated; however, monoclonal antibodies are not expected to alter DNA or chromosomes.

There were no adverse effects on fertility (including estrous cycling, sperm analysis, mating performance, and embryonic development) at the highest dose in a fertility and early embryonic developmental toxicity study in hamsters when evolocumab was subcutaneously administered at 30, 100, and 1000 mg/kg every 2 weeks. The highest dose tested corresponds to systemic exposures up to 30- and 12-fold the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC. In addition, there were no adverse evolocumab-related effects on surrogate markers of fertility (reproductive organ histopathology, mating performance, sperm parameters) in a 6-month chronic toxicology study in sexually mature monkeys subcutaneously administered evolocumab at 3, 30, and 300 mg/kg once weekly. The highest dose tested corresponded to 744- and 300-fold the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC.

13.2 Animal Toxicology and/or Pharmacology
During a 3-month toxicology study of 10 and 100 mg/kg once every 2 weeks and 5 mg/kg once daily rosuvastatin in adult monkeys, there were no effects of evolocumab on the humoral immune response to keyhole limpet hemocyanin (KLH) after 1 to 2 months exposure. The highest dose tested corresponded to exposures 54- and 21-fold higher than the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC. Similarly, there were no effects of evolocumab on the humoral immune response to KLH (after 3 to 4 months exposure) in a 6-month study in cynomolgus monkeys at dose levels up to 300 mg/kg once weekly evolocumab corresponding to exposures 744- and 300-fold greater than the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC.

This Brief Summary is based on the REPATHA® Prescribing Information v2, 09/15

REPATHA® (evolocumab)
Manufactured by: Amgen Inc.
One Amgen Center Drive
Thousand Oaks, California 91320-1799
U.S. License Number 1080
Patent: http://pat.amgen.com/repidha/
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Billing confusion abounds with hybrid payment model

I recently read with interest the article by Dr. Joseph Scherger (“Direct primary care may become the norm,” June 25, 2016), in which he explores a hybrid payment model for primary care.

Although I find this very interesting, the fact of the matter is the insurances that I contract with indicated that this is in direct violation to our contractual agreement. They said that I may not charge the patient for any services whatsoever, that I must submit all bills to the insurance company for their review.

Services that are not covered by the insurance are not billable. For example, I offer a travel medicine clinic. I will have patients from other practices arrive indicating that since I participate in their insurance company that I may not charge them for the immunizations and must bill the insurance company.

I am required to give immunizations and then, after doing so and submitting the bills, the insurance company indicates that it is not a covered service and I may not bill the patient for such.

This is all, unbelievably, apparently legal according to the contracts that I have with the insurance company. Therefore, I find it highly unlikely that attempting to bill a patient $50 a month for the secretarial services, etc., will be allowed by any of the insurances.

M. Niziol, MD
DRYDEN, NEW YORK

The invasion of third parties into DPC is highly worrisome

(We need) more accountability between doctors and patients, not an encroachment of insurance and government...

This letter is in response to Dr. Scherger’s article, “Direct primary care may become the norm (June 25, 2016).” While I am heartened by the growth of direct primary care (to the point of leaving a full-time academic position to start my own DPC practice), there is one aspect of the article that I found chilling:

“Commercial insurance companies, Medicare and even Medicaid are starting to provide contracts to direct primary care physicians for populations of patients.”

One of the great joys of DPC is regaining one’s sense of professional agency and collaborating with patients in a way not possible in the insurance-based system. I am not surprised that commercial and governmental third-party payers want to co-opt the success of the DPC movement and get ahold of the "special sauce" that makes it so successful.

I am fearful that the efforts of DPC practitioners to accommodate “contracts” with these third parties will lead us down the same path that gave rise to the DPC movement in the first place.

What is needed is more accountability between doctors and patients, not an encroachment of insurance and government into our practices.

James O. Breen, MD
GREENSBORO, NORTH CAROLINA
Physicians should be in charge of how their services are sold, priced

I think it is sad the way the business of medical practice in individual offices is constantly squeezed the way it is.

From the extraordinary costs of malpractice insurance, license fees, maintenance of certification (MOC), hospital fees for privilege renewal, electronic health records (EHR), supplies, staff salaries as well as the usual expenses of rent, utilities and so on, that I’m constantly attacked for being expensive.

There’s the silliness of value-based pay, Merit-based Incentive Pay System, Alternative Payment Models and all the rest of the complicated systems just to get paid for an office visit. We have lost sight of the fact that office-based medical practice is a private business.

You need to remember the amount of money I make is directly related to the number of patients I see and the work I do. How is that any different than the company down the street that changes the oil in your car? The amount of income they have is based on if they change the oil in one car a day or 50 cars a day.

I don’t read anything about the huge profits that insurance companies make off patients. Rarely, do you hear about how services are denied by these companies although we experience this on a daily basis.

If I order a test/medication for a patient, it is because, after taking a history and doing the appropriate physical exam to determine what is needed by the patient, an educated medical decision is made. The test/medication is denied and I have to explain my reasoning to someone over the phone who doesn’t know the patient, doesn’t know their complaint and hasn’t done a history and physical.

I believe that the country needs to realize that the cost of healthcare is not due to what I get paid for an office visit. It is driven by the insurance with outrageous premiums.

I have read this before and it is true: “Physicians, like other companies in a competitive market, should be free to price and sell their services as they choose according to the market and the physician’s own policies.”

The government and insurance companies have no place dictating how medicine is practiced or paid for.

Stop with all the nonsense by the payers. Just pay me for what I do and stop practicing medicine unless you have a medical license in my state.

Lawrence Voesack, MD
ODESSA, TEXAS

There is a reasonable solution to minimizing defensive medicine

In “Defensive medicine versus value-based care (March 25, 2016),” Richard Roberts, MD, JD, suggested that a no-blame compensation system would be a good alternative to the current way of dealing with malpractice litigation.

Based on the workers’ compensation model, such a system would, as he said, treat patients fairly and get compensation to them much quicker than the time it takes with current methods.

At the same time, administrative costs would be minimized.

Physicians would be spared the threat of frivolous suits and the constant stress surrounding the adversarial litigation process that can go on for years.

This is a reasonable way to treat patients and doctors fairly and minimize defensive medicine.

One can only wonder why, during the past two decades or more, that physicians have voiced strong opposition to the current malpractice system and our lawmakers for the most part have been ineffective and made little headway in improving the system.

No-blame compensation systems (like health courts, another alternative model) have great potential and lawmakers are wrong not to take them seriously.

Edward Volpintesta MD
BETHEL, CONNECTICUT
Obama pushes “public option” to further Affordable Care Act impact

The number of Americans without health insurance has dropped dramatically, and has resulted in lower hospital readmission rates, according to research published by President Barack Obama.

The article—which was recently published in the Journal of the American Medical Association—also recommended the introduction of a “public option” plan in parts of the U.S. and for the federal government to push down drug prices.

Obama is the only author given credit for the article, however the President does credit seven staff members for assistance with writing, research and editing.

The article comes as the Affordable Care Act appears to remain a hot topic of debate in the impending presidential election.

Republican candidate Donald Trump has vowed to repeal the act if elected, while Democratic candidate Hillary Clinton has taken positions that mirror Obama’s latest position on drug prices, and on creating a public option for insurance.

Percentage of Individuals in the United States Without Health Insurance, 1963-2015

Year before main ACA coverage provisions took effect

Source: JAMA
HEALTHCARE'S TRANSITION to value-based payments is ratcheting up the pressure on independent medical practices battling for survival, and data is the ammunition they need to have any chance of winning.

The Medicare Access and CHIP Reauthorization Act (MACRA) Congress passed last year may be independent practices' biggest challenge yet. By the government's own estimates, it will result in Medicare reimbursement cuts to nearly 90% of solo practices, and 70% of practices with two to nine physicians.

Such practices are crucial to tamping down healthcare costs. To fight back, and preserve their independence, physicians need to demonstrate they are providing high-quality care to patients. That's because beginning in 2019, Medicare will reimburse most such practices according to their scores on the Merit-based Incentive Payment System (MIPS), which is part of MACRA. High-scoring practices will receive bonuses, while laggards will be penalized. These "payment adjustments" will begin at 4%, and top out at 9% in 2022.

"Whenever I talk to small practices, I start by letting them know their ability to be successful in a value-based world will hinge on their ability to collect and measure data," says Daphne Saneholtz, JD, head of the healthcare practice for the Columbus, Ohio-based law firm Brennan, Manna & Diamond.

The benefits of robust independent practices extend beyond the doctors who own them and the patients they treat. Such practices also are crucial to tamping down healthcare costs, according to an October, 2014 study published in *JAMA*.

Despite the challenges they pose, however, MACRA and MIPS need not spell the end of independent medicine. Practices that want to preserve their autonomy are already gearing up for the struggle. But it will require planning, creativity and hard work.

Dominic Gaziano, MD, a solo internist practicing in Chicago, is determined to maintain his independence. "I see other doctors selling their practices at an alarming rate, and I tell them, 'stick it out, you can do it yourself,' he says. "I truly believe independent doctors can do more, by letting the
patients be our masters and putting their interests first, and not a corporation or a hospital.”

THE CHALLENGES OF DATA COLLECTION

Given the already precarious finances of many small practices, even minor reductions in Medicare payments could lead to the dilemma of joining a health system or closing their doors.

Avoiding that fate requires data to show that they are controlling patients’ hypertension, getting them vaccinated, keeping them out of the emergency department, and the myriad other actions that define quality in today’s healthcare environment.

Many of those practices are finding the data collection requirements difficult to meet, Saneholtz says, both because they lack the necessary technology and their priorities lie elsewhere.

“Most small practices are singularly focused on providing medical services, because that’s what they went into medicine to do. Asking them now to layer on top of that a function of collecting and measuring data is really difficult,” she says.

CMS predicts that overall, slightly less than half of all practices will see their Medicare payments cut.

Physician societies and other groups affected by MACRA generally support its goal of further tying Medicare reimbursements to the quality of care and patient outcomes. But they have concerns about specific parts of the proposed rule for implementing the law.

Common concerns expressed to the Centers for Medicare & Medicaid Services in response to its request for comments on the proposed rule include:

- the January 1, 2017 start date for practices to start reporting their quality data for the Merit-based Incentive Payment Program (MIPS), the complexity of MIPS reporting requirements and the proposed rule’s impact on small and solo medical practices.

Here are summaries of comments and suggestions on the proposed rule submitted to CMS:

**American College of Physicians**

The College proposes an alternative scoring methodology for MIPS that “combines, simplifies, aligns and reduces the complexity of the four reporting categories that will qualify physicians for payment adjustments in 2019.” It also proposes alternatives to MIPS’s Advancing Care Information category that would “make it easier for physicians to report on and be successful in this category,” and recommends that practices with nine or fewer clinicians be “held harmless” from financial penalties until CMS finalizes its “virtual reporting” option for such practices.

**American Medical Association**

Recommendations include:

- Establishing a transitional period to give physicians sufficient time to have a successful launch of MACRA,
- Providing more flexibility for solo and small-group practices,
- Aligning the different components of MIPS so that it operates as a single program rather than four separate parts, and
- Simplifying reporting burdens and improving chances of success by creating more opportunities for partial credit and fewer required measures in MIPS.

**Patient-centered Primary Care Collaborative**

Recommendations include:

- Acknowledging the challenges faced by solo and small-group practices by “revisiting the proposed creation of virtual groups” and exempting these practices from financial penalties until the virtual group option is available,
- Delaying the start of the MIPS reporting period until at least July 1, 2017 and preferably January 1, 2018, thus “providing additional, much needed time for practices to prepare, and
- Streamlining quality measurement by adopting recommendations from the Core Quality Measures Collaborative. “Creating core sets of measures for primary care and subspecialists is essential for comparing physicians across payment models,” the collaborative says.
Fighting back

“Money

I truly believe independent doctors can do more, by letting the patients be our masters and putting their interests first, and not a corporation or a hospital.”

—Dominic Gaziano, MD, Internist, Chicago, Illinois

The place to start, experts say, is by learning at least the basics of MACRA and the MIPS scorecard—information that is available through the websites of the Centers for Medicare & Medicaid Services or Medical Economics (www.modernmedicine.com) or from local or national medical societies.

Given the law’s impact on the future of reimbursement, surprisingly few providers know much about it, says Chris Zaenger, CHBC, president of Z Consulting Group and a Medical Economics editorial consultant.

“I’ve had multiple discussions about MACRA with clients in the past few months, and most of them just look at me glassy-eyed,” Zaenger says. “The eye-opener is when I tell them the way they get paid is going to change dramatically over the next few years so they need to pay attention.”

Amy Davis, DO, is one who

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Amy Davis, DO, is one who
MEDICAL ECONOMICS ASKED THOUSANDS OF HEALTH PROFESSIONALS TO RATE THEIR EHR SYSTEMS IN 10 AREAS:

- Overall Opinion of EHR
- Total EHR Score
- Meaningful Use
- Billing and Coding
- Vendor Support
- Chronic Care Management
- Population Health
- Quality Metrics
- Quality of Care
- Patient Portal

Medent finished #1 in six of the categories and #2 in the other four, coming away as the #1 Overall EHR System in the nation.

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Money

Fighting back

20

has been paying attention. A solo practitioner specializing in palliative care in suburban Philadelphia, Davis has been reporting data to CMS as part of PQRS since 2012, thus giving her a head start in understanding MIPS and what’s required for data reporting. “But now that they’re developing the regulations I’m trying to learn as much as I can as fast as I can,” she says.

Acquiring that knowledge is especially important given that doctors may have only a few months at most between issuance of the final rule and the start of 2017, when they’ll probably have to begin reporting data for MIPS.

In addition to learning the basics of the law itself, experts say, doctors should review their Medicare Quality and Resource Use Reports (QRUR). These are reports that Medicare makes available to all practices, showing how the practice compares to its peers on a wide variety of cost and quality metrics.

“Those reports are really key, and practices should look at them to find out how they’re performing now,” Pfeifer advises. “Glean the information you can and make any changes necessary to improve your scores so that you’re in a good position for MIPS.” (For more information on QRUR reports and how to obtain them go to bit.ly/QRUR-reports).

CHOOSE THE BEST REPORTING CATEGORIES

Armed with information from the QRUR and some knowledge of how MIPS works, the next step is deciding which measures to report on. Those should include the activities the practice already does well, so as to obtain the highest scores possible. “Identifying the measures that are relevant to your practice, are helpful to patients and are easy to track, all of those are really important,” notes Pfeifer.

For Davis, the process of identifying categories is fairly easy: She plans to continue reporting in the same categories she’s used for PQRS. Her goal in the first year or two of MIPS, she adds, is simply to maintain her current level of Medicare reimbursement and not worry about trying to earn a bonus.

“I think the initial goal for small practices needs to be, ‘how do we stay afloat?’” she says. “The way I’m looking to do that is to get credit for doing what I’m already doing. The overhead involved for the points that get you a bonus is not cost-effective for a small practice like mine.”

For larger independent practices, though, qualifying for higher reimbursements under MIPS may well be cost-effective, and thus a goal they should aim for, says Lucien Roberts III, MHA, administrator of Gastrointestinal Specialists Inc., a 22-provider practice in central Virginia.

“The goal is not to think in terms of meeting the measures, but of beating them across the board so that you can qualify for increases,” he says. “But to do that you need to identify your measures and then consistently hit them.”

In addition to reporting PQRS and Meaningful Use data, Roberts says, Gastrointestinal Specialists has been developing its own set of internal quality measures specific to its specialty, such as endoscope withdrawal times. In addition to improving care, the process has helped prepare Gastrointestinal Specialists for MIPS.

“We’re not just thinking in terms of avoiding getting penalized or getting maybe a 1% bump,” he says. “We’re saying, ‘if we want to move the reimbursement needle we need to do better than average consistently.’”

FIND STRENGTH IN NUMBERS

For some solo and small practices, joining forces with others through an entity such as an accountable care organization (ACO) or clinically-integrated network (CIN) can help offset some of the costs data reporting, without foregoing independence. The internal medicine practice Pfeifer worked for was part of Advocate Physician Partners, which was both a CIN and ACO. Not only did being part of an ACO meet some of the practice’s reporting requirements for PQRS, she explains, it provided performance bonuses to member practices, helping to shore up her practice’s finances.

An additional benefit came in the form of easier information sharing with other providers and institutions. “That allowed us to track our ED visits, our hospitalizations and discharges, our specialist referrals, and helped us to manage those numbers,” she says.

Of course, knowledge of MIPS scoring and payment adjustments means little without the ability to actually collect and report the necessary data. And doing so is virtually
impossible without an EHR, say those with experience in reporting.

“If you weren’t using an EHR you need to get one and start using it,” says the AAFP’s Martin. “That’s a cost, but it’s also a necessity for any program you want to participate in, public or private. This isn’t just Medicare now, all the commercial payers are going to start mandating these capabilities as well.”

EHRs present their own challenges when it comes to data collection and reporting, however. Chief among these is cost. Martin notes that many vendors levy a charge for data extraction, saying it’s not a core function of the technology. Large healthcare systems may be able to absorb that charge, he says, “but if you’re a two-physician rural practice that’s a pretty big cost to you.”

Accuracy can be another pitfall of EHRs. When Gaziano wanted to begin attesting to meaningful use a few years ago, he discovered that his EHR was calculating some of the data he needed incorrectly. Now he does spot checks against the paper charts, which he keeps for times when his system goes down.

MAKE TECHNOLOGY WORK FOR YOU
But sometimes doctors themselves must shoulder part of the blame for problems they ascribe to EHRs, says Linda Delo, DO, a solo practitioner in Port St. Lucie, Florida who’s been reporting PQRS data since the program began in 2011. That’s because many don’t take the time to explore the technology’s full capabilities and configure it to their needs.

“These computers will do incredible things for you, but you have to take the time to program them,” she says. “Too many want to just go in and do the bare minimum to get by. They don’t take the next step to figure out how to make it really work for them.”

The critical step, say Delo and others, is to customize the EHR’s software to make data collection as easy as possible and integrated into the practice’s workflow. For example, Delo has created templates that enable her staff to enter quality-related information she needs to report on for her patients with diabetes, such as the date of the patient’s last foot or eye examination.

“When you take the time to program the technology to do what you want it to do it makes for a much easier workflow,” she notes.

Roberts’ staff at Gastrointestinal Specialists creates “short lists” of quality metrics for physicians’ use in the practice’s EHR. “That way it’s not something they have to remember, it’s part of the standard documentation,” he explains.

Expecting a time-pressed doctor to go to a different page every time he or she needs to document a quality metric means “you’re going to have a tough time hitting that target. So try to make it a habit rather than an extra burden,” he says.

Gaziano is using the approach of MIPS reporting requirements to re-visit how he uses his EHR throughout his practice. To that end, he has been having a recent medical school graduate with strong computer skills shadow him and suggest ways to gather quality data more efficiently.

“I understand enough about the changes going on in medicine to know that if I want to be active in 20 years,” he says, “I have to be as efficient as I can.”

MORE NEXT ISSUE
For more on the benefits of ACO participation, see the interview with Farzad Mostashari, MD, in our August 25 issue. Mostashari is president of Aledade, a start-up company that helps independent primary care practices with the process of joining ACOs.
Coding Insights

Understanding EHR note cloning

Q: Where can I find specific guidance on cloning and electronic health record (EHR) issues?

A: Regardless of the capabilities of their EHR, it is imperative that physicians understand the coding process, and only assign codes that reflect the actual level of medical decision-making and hence medical necessity.

The Centers for Medicare & Medicaid Services website has an “Electronic Records Toolkit” that addresses specific concerns and violations regarding note cloning, as well as the federal definitions of these. Some of the more relevant portions are described below.

COPY AND PASTE:
Selecting data from one location and reproducing it in another; also called “cloning,” “cookie cutter,” “copy forward” and “cut and paste.” Clinical plagiarism occurs when a physician copies and pastes information from another provider and calls it his or her own.

Healthcare professionals have stated that copying and pasting notes can be appropriate and eliminate the need to recreate every part of a note and re-interview patients about their medical histories. However, defaulting or copying and pasting clinical information using existing documentation from other patient encounters in a different health record facilitates billing at a higher level of service than was actually provided.

TEMPLATES: Using predefined text and text options to document the patient visit within a note.

Some EHR systems use templates that complete forms by checking a box, macros that fill in information by typing a key word, or auto-population of text when it is not entered.

Problems can occur if the structure of the note is not a good clinical fit and does not accurately reflect the patient’s condition and the services to him or her. These features may encourage overdocumented to meet reimbursement requirements even when services are not medically necessary or are never delivered.

MACROS: Expanding text associated with abbreviations or specific keystrokes.

Some EHR systems prompt physicians on what additional documentation is necessary to justify using a higher billing code, even when existing documentation is sufficient to justify the code that has been entered. In 2012, a joint letter from the Departments of Justice and Health and Human Services to several national hospital associations expressed concern that some providers might be using their EHR systems to upcode the documented intensity of care provided as a method of improperly increasing reimbursements. Both departments indicated their willingness to use the tools available to them to detect upcoding and prosecute offenders.

FABRICATION: Copying information or creating text to show that treatment was delivered or occurred at a level higher than what was actually provided.

Notice that the theme of many of these is the intent to upcode or increase reimbursement. Many providers simply use the tool that is at their disposal, or that they are given.

UPCODING: Using documentation to upgrade the level of care provided.

Some EHR systems prompt physicians on what additional documentation is necessary to justify using a higher billing code, even when existing documentation is sufficient to justify the code that has been entered. In 2012, a joint letter from the Departments of Justice and Health and Human Services to several national hospital associations expressed concern that some providers might be using their EHR systems to upcode the documented intensity of care provided as a method of improperly increasing reimbursements. Both departments indicated their willingness to use the tools available to them to detect upcoding and prosecute offenders.

Q: The majority of my primary care practice are middle-aged to older patient following up chronic...
problems, health maintenance or both. Our internal auditor keeps telling me that I need an history of present illness (HPI) on these when I have a complete exam and I typically list three or more problems in the assessment and plan. Since these follow up visits are a “2 of 3” code category, per Current Procedural Technology (CPT), Why do I need an HPI? This seems like just extra typing.

A: You are correct that the established patient code subcategory does not require an HPI, or even a history section. Be careful though: What the CPT says, and what a payer may look for in terms of either quality or completeness, may be quite different.

Not being familiar with the auditor’s specific concern I can’t say exactly why they want this—but I do have some thoughts on the subject. Some words you used in your question point this way.

Even if your Assessment and Plan (A/P) lists several diagnoses, are the status of each problem (i.e. stable, improving or worsening etc.) made clear? Is the treatment or management specified? A list of problems isn’t enough. Look to the General Principles of Medical Record Documentation found in the federal documentation guidelines. Some relevant excerpts:

The documentation of each patient encounter should include:

- The reason for the encounter and relevant history,
- physical examination findings and prior diagnostic test results,
- The patient’s progress, response to and changes in treatment and
- revision of diagnosis.

Note that these requirements are more specific than what it says in CPT; it requires a relevant history, and spells out some elements in the A/P that need to be documented for all encounters regardless of code type.

The 1997 guideline variance in the history area specifically outlined the “status of three or more chronic problems” as a way to deal with chronic disease management in the HPI.

There is another reason to provide a decent HPI. If the note consists solely of the exam and A/P, how do we know whether the A/P covers the needed ground—is complete or perhaps has superfluous issues included.

The HPI sets the agenda for the visit. Even if the A/P areas do a good job on spelling out the problems—we need an HPI to provide the context for the A/P. You’ll see this in charts where there are two problems mentioned in the HPI, but a third and sometimes a fourth appear in the A/P. This raises the question of “mentioned” versus “managed.”

Were all these problems actually managed today or just mentioned? If the scope of the visit is defined in the HPI, this wouldn’t happen. You should strive for a balance of HPI and A/P on the chronic disease follow up visits for a clear and easily understood encounter.

Q: Is there an actual Medicare guideline that says all the information needs to be in the body of the note? I have searched and searched and although a lot of websites say that, I am unable to locate the actual guideline from Medicare. Any help?

A: There is nothing that says that exactly that I know of. But go to the 1997 federal documentation guidelines. Within the guidelines go to the History section—the first italicized section—this refers to referencing other information.

Q: We have been successfully doing chronic care management using 99490 code. However, a few secondary insurance companies won’t pay the copayment. The explanations of denials include: “this service is not covered” and “this amount …not allowed due to clinical review of the appropriateness or necessity of this service” and “this service is not a benefit of federal employee program.”

I don’t understand—Medicare approves and pays their 80% of the 99490 service. How can a co-insurance deny the co-payment once Medicare has approved it?

A: This is becoming a rather familiar story. First of all, each of those secondary payers still has their own set of coverage and billing policies. Just because Medicare covers something doesn’t guarantee that a secondary payer will.

So each of those denial descriptions you’ve mentioned may mean exactly what they say.

A second potential issue here is that Medicare just started covering these services. At the time of your question we are still early in the year. It is entirely possible that some of these payers haven’t updated their edits or policies to reflect the recent change in federal coverage.

Some calls to the payer to check on coverage are in order. Remember that a first-round denial is not the final answer, it is the opening of the dialogue.
MIPS EXPLAINED

4 categories physicians must master

New Medicare payment system still coming into focus, but practices should act now

by ed finkel contributing author

REIMBURSEMENT UNDER Medicare is about to evolve yet again. While the rules are still being finalized, providers should be getting ready for their unveiling this fall.

The Centers for Medicare & Medicaid Services (CMS) recently announced its proposed rule for the Merit-based Incentive Payment System (MIPS), which will measure physician performance in four categories—resource use/cost, quality, advancing care information and clinical practice improvement activities—with bonuses or penalties that could eventually reach up to 9% of physicians’ Medicare reimbursements.

While the bonuses or penalties don’t start until 2019, physicians and practices must begin reporting their results in January, notes Robert Doherty, senior vice president, governmental affairs and public policy at the American College of Physicians (ACP).

“Ther’s talk that it’s two years down the road,” he says, referring to the 2019 date. But it’s not if CMS start collecting data in 2017.

The first three categories essentially replace and consolidate parts of existing performance measurement systems, combining parts of the Value-based Payment Modifier, the Physician Quality Reporting System (PQRS) and the electronic health record (EHR) incentive program (Meaningful Use).

The fourth category—which will measure a practice’s performance in areas like care coordination, beneficiary engagement and patient safety—marks a new front in Medicare’s attempts to rate doctors and practices.

Here’s how physicians can start preparing now to get their best scores in the four categories:

1/ QUALITY

The quality measure, which will hold the most weight at the outset (50%), provides physicians with a menu of 200 sub-measures from which they must choose six that best accommodate their practice or specialty. One of those measures needs to be an outcome measure, and one needs to be “cross-
cutting,” meaning that it’s applicable to all specialties.

This is somewhat streamlined from the nine measures required under PQRS and represents an improvement from the perspective of practices, says Owen Dahl, MBA, FACHE, a practice consultant. But what hasn’t changed for the better, Dahl says, is that CMS is still asking physicians for information and providing only modest feedback regarding long-term success and outcomes, “Physicians are supplying data, but it stops there, other than some abstract reporting from CMS about how effective the treatment plans—data sent—have really been in improving patient care. This is a universal frustration for all offices I talk with,” he says. Still, Dahl sees the new format as more customizable, flexible and closely aligned with how practices actually measure themselves.

General quality measures include activities such as effective clinical care, patient safety, community/population health and communication and care coordination. Specific measures range from the percentage of MIPS explained

THE ROAD TO MIPS

Under the proposed rule, starting in 2019, physicians and practices will choose either MIPS or, if they prefer and qualify, one of an array of alternative payment models (APMs.) These APMs will include accountable care organizations, patient-centered medical homes and bundled payment models as well as other “demonstration” projects. Practices in their first year of billing Medicare and those who fall below a still-to-be-defined minimum payment threshold will be exempt from MIPS.

Under MIPS, payments would be adjusted up or down by as much as 4% starting in 2019, rising to 9% for 2022 and beyond, depending on the composite score under the four quality measures. However, practices must begin reporting their quality data in 2017.

MIPS payments are required to be budget-neutral, meaning that doctors will be able to receive bonus payments only to the extent that others pay penalties. For that reason, the scoring will follow a bell-shaped sliding scale, in which those at the median will receive no adjustment to their payments.

Practices choosing the APM option will receive a 5% lump sum bonus without the risk of penalties, but the practice must qualify in the first place. In that light, since the requirements are still coming into focus, physicians should first prepare for MIPS while exploring possibilities for APM status by 2019, when the 5% bonuses take effect, advises the American Academy of Family Physicians. CMS has said it would like to move half of payments to APMs by the end of 2018.

MIPS became law through the 2015 Medicare Access & CHIP Reauthorization Act (MACRA). The 426-page proposed rule for implementing the legislation, released on May 9, is scheduled to take effect no later than November 1. It can be found in full at: bit.ly/MACRA-rule.
the patient population between ages 50 and 75 who had colorectal cancer screenings, to percentage of patients 65 or older with a history of falls who had a risk assessment performed in the previous 12 months. The specialty-specific measures are subdivided into allergy/immunology/rheumatology, anesthesiology, cardiology and the like.

Eric Schneider, MD, senior vice president for research and evaluation at The Commonwealth Fund, says that the new rule addresses the problem under PQRS that primary care physicians were being judged on measures better suited to specialists, and vice versa.

Because physicians and practices are allowed to pick which measures to use, they should examine the menu and figure out where they might do well, suggests Cristina Boccuti, MA, MPP, associate director of the program on Medicare policy at the Kaiser Family Foundation. Ideally, those choices would be based on more than just strong hunches but instead be derived from data that physicians’ offices compile either from their EHR or through a simple spreadsheet program or other type of practice registry. But failing that, they will just have to go with their “best guess,” she says.

Schneider suggests clinicians ask themselves, “What’s my current level of performance in each of the measures on the menu and how can I improve over time?” The selection of measures where you’re already high-performing could be important, but also the selection of measures where there’s room for improvement over time.

Doctors and practices also should select measures that reflect the types of clinical care they most commonly provide so they have sample sizes large enough to be statistically significant, Schneider says.

Harold Miller, president and chief executive officer of the Center for Healthcare Quality and Payment Reform, thinks the range of quality measures should be broader. The proposed list “doesn’t even come close to being able to address the various types of patient conditions and the different needs of patients,” he says. “You wind up with a lot of those measures being designed for patients with only one health problem and don’t work well for those with multiple health problems.”

Miller is also concerned that lower scores on quality measures sometimes occur because providers have taken on many patients with low incomes and/or who lack community or home supports. “There’s no change in the fundamental payment to address that. That could discourage physicians from taking on those patients,” he says. “If they have a patient population that may be sicker, or faces social challenges, physicians may be penalized for things that are out of their control.”

While in some senses CMS has streamlined the process for doctors, intensive compliance and reporting will not go away, Dahl says.

“The good news is, we don’t have three programs to monitor,” he says. “The bad news is, we still have programs to monitor and comply with.”
Introducing FLUAD™, a next-generation flu shot for the 65+ generation. Because people 65 and older can have weakened immune systems, they could benefit from a flu vaccine created especially for their generation.1,2 FLUAD was shown in clinical trials to provide a strong immune response and have an acceptable safety profile.2 Today, the 65+ generation is less concerned about being hip and more concerned about being healthy. FLUAD was designed specifically to help them stay that way.2 Right on!

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IMPORTANT SAFETY INFORMATION2

INDICATIONS
FLUAD is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUAD is approved for use in persons 65 years of age and older.

CONTRAINDICATIONS
Severe allergic reaction to any component of the vaccine, including egg protein, or after a previous dose of any influenza vaccine.

WARNINGS AND PRECAUTIONS
• If Guillain–Barré Syndrome (GBS) has occurred within six weeks of previous influenza vaccination, the decision to give FLUAD should be based on careful consideration of the potential benefits and risks.

• The tip caps of the prefilled syringes contain natural rubber latex which may cause allergic reactions in latex sensitive individuals.

ADVERSE REACTIONS
• The most common (>10%) local (injection site) adverse reactions observed in clinical studies were injection site pain (25%) and tenderness (21%).
• The most common (>10%) systemic adverse reactions observed in clinical studies were myalgia (15%), headache (13%) and fatigue (13%).

Please see Brief Summary of Prescribing Information for FLUAD adjacent to this ad.

1 INDICATIONS AND USAGE
FLUAD is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUAD is approved for use in persons 65 years of age and older. Approval is based on the immune response elicited by FLUAD. Data demonstrating a decrease in influenza disease after vaccination with FLUAD are not available. [see Clinical Studies (14)]

4 CONTRAINDICATIONS
Do not administer FLUAD to anyone with a history of severe allergic reaction (e.g. anaphylaxis) to any component of the vaccine, including egg protein [see Description (11)], or to a previous influenza vaccine.

5 WARNINGS AND PRECAUTIONS
5.1 Guillain-Barré Syndrome
If Guillain-Barré syndrome (GBS) has occurred within 6 weeks of receipt of prior influenza vaccine, the decision to give FLUAD should be based on careful consideration of the potential benefits and risks. The 1976 swine influenza vaccine was associated with an elevated risk of GBS. Evidence for a causal relationship of GBS with other influenza vaccines is inconclusive; if an excess risk exists, it is probably slightly more than 1 additional case per 1 million persons vaccinated. [see References (1)]

5.2 Preventing and Managing Allergic Reactions
Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

5.3 Latex
The tip caps of the prefilled syringes contain natural rubber latex which may cause allergic reactions in latex sensitive individuals. [see Description (11)]

5.4 Altered Immunocompetence
The immune response to FLUAD in immunocompromised persons, including individuals receiving immunosuppressive therapy, may be lower than in immunocompetent individuals. [see Concurrent Use With Immunosuppressive Therapies (7.2)]

5.5 Syncope
Syncope (fainting) may occur in association with administration of injectable vaccines including FLUAD. Ensure procedures are in place to avoid injury from falling associated with syncope.

5.6 Limitations of Vaccine Effectiveness
Vaccination with FLUAD may not protect all vaccine recipients against influenza disease.

6 ADVERSE REACTIONS
6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, the adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect rates observed in clinical practice.

Solicited adverse reactions were assessed in a multicenter, observer-blind, randomized controlled study [Study 1] conducted in the United States, Colombia, Panama and the Philippines. The safety analysis set included 3545 FLUAD recipients and 3537 AGRIFLU (Influenza Vaccine) recipients. The enrolled subject population in Study 1 was 65 to 97 years of age [mean 72 years] and 64% were female. Within each treatment group, 53% were Asian, 28% were Caucasian, 18% were Hispanic, 1% were Black, and fewer than 1% each were Native American/Alaskan, Pacific Islander/Hawaiian, or Other. Solicited local (injection site) and systemic adverse reactions were collected from subjects in Study 1 who completed a symptom diary card for seven days following vaccination. The reported frequencies of solicited local and systemic adverse events from Study 1 are presented in Table 1.

Table 1. Percentages of Subjects ≥ 65 Years of Age With Solicited Local and Systemic Adverse Reactions in Days 1-7 After Administration of FLUAD or AGRIFLU (a U.S. Licensed Comparator) NCT01162122

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>FLUAD (N=3418-3496)</th>
<th>AGRIFLU (N=3420-3488)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Local</strong></td>
<td>Percentage</td>
<td>Percentage</td>
</tr>
<tr>
<td>Injection site</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>Any</td>
<td>25.0</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>3.9</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>0.3</td>
</tr>
<tr>
<td>Tenderness</td>
<td>Any</td>
<td>21.1</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>3.0</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
<td>0.1</td>
</tr>
<tr>
<td>Erythema</td>
<td>Any</td>
<td>1.2</td>
</tr>
<tr>
<td></td>
<td>25 to &lt; 50 mm</td>
<td>1.1</td>
</tr>
<tr>
<td></td>
<td>51 to &lt; 100 mm</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>&gt; 100 mm</td>
<td>0.0</td>
</tr>
<tr>
<td>Induration</td>
<td>Any</td>
<td>1.3</td>
</tr>
<tr>
<td></td>
<td>25 to &lt; 50 mm</td>
<td>1.0</td>
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<td>51 to &lt; 100 mm</td>
<td>0.3</td>
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<td></td>
<td>&gt; 100 mm</td>
<td>0.0</td>
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<tr>
<td>Swelling</td>
<td>Any</td>
<td>1.2</td>
</tr>
<tr>
<td></td>
<td>25 to &lt; 50 mm</td>
<td>1.0</td>
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<td></td>
<td>51 to &lt; 100 mm</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>&gt; 100 mm</td>
<td>&lt;0.1</td>
</tr>
</tbody>
</table>
of age and older, comprising 5,754 who received FLUAD and 5,198 who received other US licensed influenza vaccines. The percentage of subjects with an unsolicited AE within 30 days following vaccination was similar between vaccine groups (16.9% FLUAD vs. 18.0% active comparator).

**Serious Adverse Events (SAEs) and Deaths:** In Study 1, in which subjects were followed for SAEs and deaths for one year following vaccination (N=3,545 FLUAD, N=3,537 AGRIFLU), the percentages of subjects with an SAE were similar between vaccine groups (7% FLUAD vs. 7% AGRIFLU). Four SAEs (1 FLUAD and 3 AGRIFLU) were assessed as related to study vaccination over one year of observation and 2 of these occurred (1 FLUAD and 1 AGRIFLU) within 21 days following study vaccination. There were 98 deaths (n=52 FLUAD, n=46 AGRIFLU) over one year of which none occurred within the first 21 days following vaccination.

In 14 additional randomized, controlled studies, SAEs were collected over a 3 to 4-week period in 4 studies, over a 8-week period in 1 study, and over a 6-month period in 9 studies (N=2,209 FLUAD, N=1,661 US licensed influenza vaccines). The percentages of subjects with an SAE within 30 days (1.1% FLUAD vs. 1.8% AGRIFLU) or within 6 months (4.3% FLUAD vs. 5.9% AGRIFLU) were similar between vaccine groups. The percentages of deaths within 30 days (0.3% FLUAD vs. 0.6% active comparator) or within 6 months (1.0% FLUAD vs. 1.5% active comparator) were also similar.

**Adverse Events of Special Interest [AESIs]:** Rates of new onset neuroinflammatory and immune mediated diseases were assessed in a *post hoc* analysis of the 15 randomized controlled studies over the time periods specified above for SAEs. The percentage of subjects with an AESI at any time after vaccination was similar between vaccine groups (0.9% FLUAD vs. 0.9% active comparator). There were no notable imbalances for specific AESIs.

**Safety of Annual Revaccination:** In 5 of the randomized, controlled trials, subjects were followed for SAEs and deaths for 6 months following revaccination (N=492 FLUAD, N=330 US licensed and non-US licensed influenza vaccines). After the second annual vaccination, the percentages of subjects with an SAE were similar between vaccine groups (6.1% FLUAD vs. 5.5% comparator influenza vaccines); 23 deaths (n=17 FLUAD, n=6 comparator influenza vaccines) were reported. Causes of death included cardiovascular events, malignancy, trauma, gastrointestinal disorders, and respiratory failure. Clinical characteristics of the deaths, including the variable causes, timing since vaccination, and underlying medical conditions, do not provide evidence for a causal relationship with FLUAD.

### 6.2 Postmarketing Experience

The following adverse events have been spontaneously reported during post-approval use of FLUAD in Europe and other regions since 1997.
Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine.

**Blood and lymphatic system disorders:**
- Thrombocytopenia (some cases were severe with platelet counts less than 5,000 per mm$^3$), lymphadenopathy

**General disorders and administration site conditions:**
- Extensive swelling of injected limb lasting more than one week, injection site cellulitis-like reactions (some cases of swelling, pain, and redness extending more than 10 cm and lasting more than 1 week)

**Immune system disorders:**
- Allergic reactions including anaphylactic shock, anaphylaxis and angioedema

**Musculoskeletal and connective tissue disorders:**
- Muscular weakness

**Nervous system disorders:**
- Encephalomyelitis, Guillain-Barré Syndrome, convulsions, neuritis, neuralgia, paraesthesia, syncope, presyncope

**Skin and subcutaneous tissue disorders:**
- Generalized skin reactions including erythema multiforme, urticaria pruritus or non-specific rash

**Vascular disorders:**
- Vasculitis with transient renal involvement

### 7 DRUG INTERACTIONS

**7.1 Concomitant Use With Other Vaccines**
There are no data to assess the concomitant administration of FLUAD with other vaccines. If FLUAD is to be given at the same time as other injectable vaccine(s), the vaccine(s) should be administered at different injection sites.

Do not mix FLUAD with any other vaccine in the same syringe.

**7.2 Concurrent Use With Immunosuppressive Therapies**
Immunosuppressive or corticosteroid therapies may reduce the immune response to FLUAD.

### 8 USE IN SPECIFIC POPULATIONS

**8.1 Pregnancy**
Pregnancy Category B: A reproductive and developmental toxicity study has been performed in rabbits with a dose level that was approximately 15 times the human dose based on body weight. The study revealed no evidence of impaired female fertility or harm to the fetus due to FLUAD. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this vaccine should be used during pregnancy only if clearly needed.

In a reproductive and developmental toxicity study, the effect of FLUAD on embryo-fetal and post-natal development was evaluated in pregnant rabbits.

Animals were administered FLUAD by intramuscular injection twice prior to gestation, during the period of organogenesis (gestation day 7) and later in pregnancy (gestation day 20), 0.5 mL (45 mcg)/rabbit/occasion (approximately 15-fold excess relative to the adult human dose based on body weight). No adverse effects on mating, female fertility, pregnancy, embryo-fetal development, or post-natal development were observed. There were no vaccine-related fetal malformations or other evidence of teratogenesis.

**8.4 Pediatric Use**
The safety and effectiveness of FLUAD in the pediatric population has not been established.

**8.5 Geriatric Use**
Safety and immunogenicity of FLUAD have been evaluated in adults 65 years of age and older. [See Adverse Reactions (6.1) and Clinical Studies (14)]

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This includes tasks such as the ability to prescribe electronically, send messages securely and show that a practice has systematically analyzed security risks. No longer required will be measures of clinical decision support and computerized provider order entry, she says. To score well on this measure, Boccuti suggests ensuring that your EHR system communicates well with others and has appropriate security measures in place.

Schneider says the ACI score broadens and specifies what will be measured, while simplifying the process somewhat. “The use of electronic information under Meaningful Use is sort of a check-box, did you or didn’t you meet the standard?” he says. The ACI barometer “allows for progress on six dimensions: protecting health information, patient access to electronic records, patient engagement, coordination of care, electronic prescribing and health information exchange.”

The updated system focuses more heavily on information exchange and patient engagement, based on the hope that providers and patients are sharing more electronic information, Schneider says. “The notion they’re building on there is to promote care coordination by enabling information to flow,” he says. “It isn’t that you have a patient portal and ‘X’ percentage of patients use it. Instead, you’re graded on how much information is being shared.”

Eliminating the clinical decision support and computerized provider order entry measures reflects the fact that those have become standard in EHR products. Consequently, it’s probably more appropriate to grade vendors rather than the providers on the presence or absence of those features, Schneider adds.

Dahl has found that practices generally are either very proficient with EHRs or have avoided them entirely, with very few in between. At the outset of MIPS implementation, he suggests continuing to use the patient portal and other systems put in place under Meaningful Use. Those who have gone beyond that, as one might expect, will be able to respond better to the reformulated measures under ACI and perhaps be ahead of the curve, he says. CMS has proposed point systems to track compliance with the new measures that Dahl summarizes as, “If you comply with a, b and c, you’ll get more points than if you don’t comply.”

“I have suggested to practices … to not jump on the bandwagon and try to solve everything right now,” Dahl says. “My message is, ‘Be aware of it.’ We don’t know how it’s going to evolve.”

**CLINICAL IMPROVEMENT ACTIVITIES**

Physicians and practices will choose from among 90 activities designed to measure capabilities in areas such as care coordination, beneficiary engagement and patient safety.

As listed in the proposed rule, these activities include measures such as improving hemoglobin A1c control for patients with diabetes, prevalence of strep testing for children with pharyngitis, and percentage of women ages 40 to 69 who have had mammograms.

Examples of activities under patient safety could include assessing medication adherence or ensuring proper reconciliation of medications from more than one pharmacy, Boccuti says.

These measures are based largely on the requirements for board certification of the various American Board of Medical Specialties (ABMS) subgroups, Schneider says. Practices can select activities similar to those that ABMS boards have begun adding in recent years in addition to their traditional focus on evaluation.

Physicians must choose at least one such activity, such as demonstrably improving care of patients with diabetes, and they can get credit for more than one. Schneider adds that primary care physicians are enthusiastic about the individualization of measure selections and points earned as a result.

Schneider says at this point there are no specialty-specific activities practices should hone in on because that focus will depend on several issues local to the practice, its capabilities and past performance. In short: Keep doing what you do best.

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MIPS explained

**RESOURCE USE & COST**

This component does not require reporting by physicians or practices. Instead, data are gleaned from claims sent to Medicare throughout the year, Boccuti says.

CMS has added more than 40 episode-specific measures to MIPS to address concerns from specialists that the legislation doesn’t include measures that accurately reflect the types of care they provide, Boccuti says.

In addition to using their resources more efficiently, practices should look at their most recently-used codes and ask patients to bring in their explanations of benefits, Dahl says. That way they can determine whether the hospital to which they might refer a patient provides the best value for the procedure the patient needs, he says. And if it doesn’t, they can look for alternatives.

**OTHER STEPS TO TAKE TODAY**

Across all of these measures, Dahl suggests understanding the broad concepts laid out in the activities without getting too immersed in details that could still be changed before the rule becomes final this fall.

“Think about how you might deal with it and gather data,” he says. “What are you doing for patient engagement and patient satisfaction scores, and how is that looking? What are you doing for safety, and are you doing any kind of measurements and monitoring of safe and unsafe practices, even to the point of making sure water on the floor is cleaned up?”

The American Academy of Family Physicians declined comment about the changes under MACRA. The American College of Physicians (ACP) is urging its members to familiarize themselves with MACRA’s requirements, offering assistance through briefing sessions.

Although finding the legislation potentially problematic because it’s required to be budget-neutral—meaning there will be losers as well as winners—on balance the ACP supports MACRA because it streamlines and combines existing programs in a way that will simplify requirements at least somewhat, says the ACP’s Doherty.

“We’re advocating for core sets of meaningful measures for each specialty,” he says. “Just because it can be measured doesn’t mean it should be. And other qualities, like compassion and time spent, are harder to measure. Like any proposed rule it won’t be everything we wanted, but they are taking meaningful steps.”

Shari Erickson, MPH, ACP vice president of governmental affairs and medical practice, notes that setting those thresholds will be tricky during the first year, given that there won’t be previous data across the categories.

In thinking through how to implement the necessary changes, physicians and practices should take bite-sized steps and not try to do everything at once, tailoring their approach to the size and nature of their practices, she says.

Among Erickson’s recommendations:

- make sure you understand the law;
- test your Meaningful Use procedures in 2016 because many of its components will continue forward;
- continue to participate in PQRS because it’s not going away all at once;
- survey the 90 options to date for clinical practice improvement activities to see which ones would best fit your practice; and
- use the to existing feedback reports to measure your performance.

Robert McLean, MD, chair of the ACP’s medical practice and quality committee, says that simplifying Meaningful Use will help practices such as his, Northeast Medical Group in New Haven, Connecticut. He has testified before Congress, expressing concerns about the paperwork he deals with while attempting to care for patients.

“I just don’t want to take time away from patients to deal with administrative issues on a daily basis,” McLean says. “It is pretty remarkable when you get notes from specialists with pages and pages of things completely unrelated [to medical care] because they have to check boxes related to Meaningful Use. It is getting increasingly difficult to garner meaningful information.”

The American Academy of Family Physicians also has advised physicians to be prepared for changes in the Composite Score.

- **Resource Use & Cost:** 10% of composite score in 2019 (15% in 2020; 30% in 2021)
The wearable future comes to medical practices

by MARY K. PRATT Contributing author

Smart glasses and other wearable technologies could become as ubiquitous in the exam room as a stethoscope or blood pressure cuff, giving doctors not only another tool to deliver quality care but helping to bolster their personal connections with patients.

“THERE IS A real phenomenon that doctors feel they’re staring at screens and not making eye contact with patients. But [wearable devices] could free you up so you can be more efficient and be more present with the patient while you do your work,” says Joseph C. Kvedar, MD, vice president of Boston-based Partners HealthCare Connected Health, a health IT consulting firm. “And we know that better relationships with patients almost always correlate to better outcomes for the patients.”

Indeed, wearable technologies are already making inroads in medicine, says Steve Collens, chief executive officer of MATTER, a Chicago-based incubator for innovators and entrepreneurs in healthcare. “It wouldn’t surprise me at all if in five years the majority of doctors are using wearables in their day-to-day practices. I don’t know what that will be yet, but I have no doubt it will be coming soon,” he says.

Leading the pack of contender wearable devices are smart glasses and head-mounted devices. Some of these tools give clinicians access to medical records, patient vital signs or medical instructions right in their fields of view, so they don’t have to look away from their patients to search for information using a keyboard.

Other smart glasses offer two-way audio and visual capabilities, allowing a healthcare provider in one location to consult with a clinician elsewhere who can see and hear everything the treating physician can.

These wearables are already available, and others are coming soon, says Angela McIntyre, a research director at research firm Gartner Inc. who covers wearable electronics. As an example, she points to Vocera Communication Badge, a hands-free device that enables secure communications either one-to-one or one-to-many in healthcare settings such as medical offices and hospitals.

She also cites identification badges equipped with radio-frequency identification technologies that allow scanners in clinical settings to record automatically clinicians performing certain routine tasks such as patient checks.

Analysts, doctors and industry leaders stress that the integration of wearables into clinical practices is only in its infancy. “You don’t hear about wide deployment. You hear about a couple of doctors putting something together, but I think those pilots are getting bigger,” McIntyre says.

One such pilot comes from Third Eye Health, a Chicago-based company founded in 2014. Among its products are smart glasses and smart watches that can transmit video and text in real time in a secure, HIPAA-compliant fashion.

Company CEO Dan Herbstman says Chicago-area Northwestern Medicine has some of its paramedics in the field using smart glasses containing Third Eye Health software to consult with hospital-based specialists about best possible treatments for stroke patients.

“You can really provide a remote person with a first-person view of what you’re doing, and it keeps your hands free to keep continuing care,” Herbstman says.

Harish Shownkeen, MD, medical director of the neurovascular and stroke program at Northwestern Medicine, was part of a team of doctors and emergency workers piloting Third Eye Health software this year. According to Shownkeen, the team wants to better evaluate stroke
Doctors feel they’re staring at screens and not making eye contact with patients. But [wearable devices] could free you up so you can be more efficient and be more present with the patient.”

He explains that EMS workers use an emergency scale to evaluate stroke patients in the field, but neurologists have a much more detailed evaluation process that can better determine the severity of a stroke in progress, and thus the level of emergency treatment needed. “We could be virtually present when the paramedics pick up stroke patients,” Shownkeen says.

That makes a significant difference in delivering care for a situation where minutes really matter to the potential outcome. Shownkeen points to a recent case where the neurologist evaluated the patient while EMS workers were treating him in the field, determined that the stroke was severe and prescribed an intravenous clot-busting drug.

That drug was prepped in the hospital while EMS was transporting the patient; as a result, the patient received the drug 23 minutes after arriving, well within the recommended standard of 60 minutes.

Shownkeen expects that the pilot program will be expanded so that EMS employees can use the technology to treat patients with other conditions. He says the healthcare team favors using the tablet, which hangs around the EMS worker’s neck and rests on his or her chest, because it provides a better, continuous view of patients.

In contrast, smart glasses would pan away from patients when the EMS workers turned to look at monitors or other people.

Experts say that expanding wearables beyond the testing phase won’t be easy, because there are numerous challenges to incorporating them into the clinical arena. The first challenge is developing more technologies that have proven reliable in real-world applications, Collens says. Determining who will pay for these technologies is the second big hurdle, he adds.

Technology and infrastructure challenges also abound, McIntyre says. Clinicians will have to integrate these technologies with other systems while also ensuring that they’re secure and compliant with HIPAA and other regulatory requirements. Users also have to ensure that they have the infrastructure required to support wearables, notably secure Wi-Fi capabilities and sufficient network bandwidth.

Meanwhile, vendors will need to demonstrate that their wearables are rugged enough to withstand the medical environment and can be sterilized without damage. And providers will have to adjust their workflow process to accommodate wearables and whatever increased data they pull into the doctors’ records.

Gerry Tolbert, MD, a family physician practicing in Kentucky who writes about technology in medicine, tested Google Glass equipped with medical software in his practice and predicts wearables will become a regular part of medical practices in the next five to 10 years.

He says he enjoyed using the smart glasses because it allowed him to see patient information and still interact directly with patients even though the technology is still immature, meaning that the technology must still evolve to the point where it’s easier to use to seamlessly incorporate into workflow.

Still, he says clinicians should be interested in trying out wearables when feasible, to help ensure vendors develop these products in ways that provide benefits to doctors and their staffs.

Tolbert says that once that happens, and vendors get the software and hardware to a point where the devices offer improved efficiencies, accuracies, diagnoses and other specific gains, clinicians will purchase them.

“The adoption rate is high when the benefits are high,” he says.
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Concierge medicine becomes an option in reform era

Once considered medicine for the rich, concierge practice may be worth exploring for doctors facing today’s challenges

by JANET COLWELL Contributing author

INTERNIST JEFFREY PUGLISI, MD, first considered changing to a concierge practice six years ago, when he took a second job as a home hospice director. At the hospice, he loved having the time to talk with patients and families who were going through difficult times—something that was becoming increasingly difficult in his private practice.

“That job changed everything for me overnight,” says Puglisi, one of three partners in Glenville Medical Concierge Care in Greenwich, Connecticut. “It made me take stock of what I really wanted to do in the future and where I saw myself in 10 to 15 years. My strength is in building relationships, and you can’t really do that when you’re seeing patients every six to eight minutes.”

According to a recent national survey of physicians, an increasing percentage of doctors feel overextended and are spending a significant portion of their working day on non-clinical paperwork (see sidebar, “Forces driving growth of concierge medicine.”) With the potential for steady revenue from membership fees, concierge practice has the potential to relieve some of the financial pressures and administrative burdens inherent in the fee-for-service environment, says Puglisi.

Concierge medicine—where practices charge an annual or monthly fee for enhanced services and greater access to providers—isn’t new, but its image among physicians and the public may be changing. Once synonymous with VIP medicine serving an elite clientele, some physicians are finding they can succeed without charging exorbitant fees by signing on more than a handful of wealthy patients.

While annual fees can be as high as $5,000 or more, the national average is around $1,800, according to the industry trade publication Concierge Medicine Today. The typical concierge patient tends to be financially upper middle-class, with an annual household income of between $125,000 and $250,000, says editor-in-chief Michael Tetreault.

While still a small slice of the physician workforce, concierge medicine is growing at a rate of about 5% to 6% annually across the United States, says Tetreault, with about 12,000 physicians now practicing some form of subscription- or retainer-based medicine.

“This is really a return to a more personal relationship and traditional approach to medicine,” says family physician Patrick To- karz, MD, chief medical advisor to Special-Docs Consultants, based in Highland Park, Illinois, which advises physicians on setting operations.
up concierge practices. “Concierge physicians are not driven by the need to maximize reimbursements, which allows us to be patient-centered rather than insurance-centered.”

GETTING STARTED
The first step toward making the transition is conducting market research, says Puglisi, who officially switched to a concierge model in May 2015. When he first became intrigued by concierge medicine, he attended conferences held by national trade groups such as the American Association for Private Physicians, talked to practice management consultants and visited established concierge practices.

Deciding whether or not to work with insurers was one of the first major decision points. Puglisi and his partners opted out of all insurance contracts, requiring instead that insured patients pay out-of-pocket at the time of service and seek reimbursement on their own for routine care.

While the majority of concierge practices continue to bill insurers, it often represents a service to patients rather than a significant income stream for the practice. For example, family physician Thomas LAGrelius, MD, owner of SkyPark Preferred Family Care in Torrance, California, says the bulk of his revenue comes from membership fees while 25% continues to come from Medicare, his only third-party contract. “Although Medicare payments have decreased, I am still able to charge adequate membership fees for services not covered by Medicare to make up the difference,” he says. “That allows me to maintain a small, high-quality practice.”

Labeling your practice “concierge” is a decision in itself, since retainer- or subscription-based medicine also encompasses direct primary care (DPC), notes Tetreault. Generally, concierge practices bill insurers for routine care while also charging a retainer, while DPC practices operate on a direct-pay basis with no middleman.

However, like Glenville Medical, not all concierge practices bill insurance so the distinction can be a bit murky for consumers. In general, DPC practices are a less-expensive option, with monthly fees averaging less than $100 compared with $175 and up at concierge practices. They also tend to have larger patient panels—600 to 800 per physi-

Tips for a Successful Transition
Switching from a traditional fee-for-service practice to concierge care can feel risky, and many doctors worry that they won’t be able to retain enough patients to make it financially viable. However, those who’ve been successful say it’s due to preparation and planning. Here are their tips for getting started:

Do your research
Before taking the plunge, attend professional meetings and visit established concierge practices, says Jeffrey Puglisi, MD, an internist and partner in Glenville Medical Concierge Care in Greenwich, Connecticut. It’s also important to study the demographics of your area to ensure it can support this type of practice. The average household income of patients at concierge practices is between $125,000 and $250,000, according to Concierge Medicine Today.

Don’t start from scratch
Concierge care works best when the physicians are established in the community with longtime relationships with patients, says family physician Patrick Tokarz, MD, who recently retired from a concierge practice in Alexandria, Virginia. Patients are more likely to see value in a concierge practice run by experienced physicians.

Look for cost savings
Because concierge practices typically have smaller patient panels—fewer than 600 patients per physician in most cases—they can afford to reduce costs related to coding and billing, says Puglisi. Glenville reduced its staffing by 30% after the switch.

Develop a timeline
Physicians should allow about six months to gradually implement changes and inform patients about the new practice before officially opening as a concierge office, says Puglisi. “Make sure your timeline is clearly written out,” he advises. “In a successful transition, the patients are well educated about why this is happening and you have a full practice when you’re ready to open.”

Set goals
Your fee structure, menu of services and targets for growth are highly dependent on your individual goals for the practice, say Tokarz and Puglisi. How many patients can you reasonably serve while offering the level of service you want to provide? What are your compensation goals?
Although Medicare payments have decreased, I am still able to charge adequate membership fees for services not covered by Medicare to make up the difference. That allows me to maintain a small, high-quality practice.”

—THOMAS LAGRELIUS, MD, OWNER, OF SKYPARK PREFERRED FAMILY CARE, TORRANCE, CALIFORNIA
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Any physician planning to make this change needs a clearly delineated timeline as to how they will implement it. If patients are clearly educated about why you’re transitioning, you’re more likely to have a full practice at the end of the day.”

— JEFFREY PUGLISI, MD, PARTNER, IN GLENVILLE MEDICAL CONCIERGE CARE, GREENWICH, CONNECTICUT

In some ways, transitioning to concierge medicine is like jumping off a cliff. But with enough experience and preparation, practices often find they are financially better off than they were in the past.”

— PATRICK TOKARZ, MD, CHIEF MEDICAL ADVISOR, SPECIALDOCS CONSULTANTS, HIGHLAND PARK, ILLINOIS

“In some ways, transitioning to concierge medicine is like jumping off a cliff,” says Tokarz. “But with enough experience and preparation, practices often find they are financially better off than they were in the past.”

Part of that preparation is implementing cost-saving strategies, he says. Because there are far fewer patient accounts to handle compared with a traditional fee-for-service practice, they often need less space and fewer employees. For example, Glenville Medical reduced its staff by 30% prior to the transition, says Puglisi. Besides eliminating insurance billing services, it also stopped providing lab services, determining that it would not be a viable service with a smaller patient panel.

“Making layoffs was difficult but we now have a staff that is appropriate for the size of our current practice,” he says.

Setting fees is another pivotal financial decision, he says. They have to be high enough to produce an adequate revenue stream but low enough to attract new patients.

Puglisi and his partners surveyed the market and settled on a mid-range price point for their geographic area. Determining the fees depends on the services you plan to offer and how many patients you can reasonably take on at that service level, he says.

“I’m doing home visits, coordinating care in the hospital, and providing 24/7 access,” says Puglisi. “If you offer that level of service for too many patients, you will dilute what you provide to them.”

Puglisi declines to disclose his patient panel size and fees. However, the average for concierge physicians in the Greenwich area is 300 to 500 patients per physician, with annual fees ranging from $2,500 to $5,000, according to SpecialDocs Consultants.

WORKFLOW
Although you may be able to cut back on staffing in a concierge office, the people who stay become even more important to the success of the practice, says Puglisi. It’s
vital that everyone in the office has a service mentality.  
“Your staff has to buy into the idea of concierge care and be very aware of their role in helping patients have a positive experience,” he says. “Your whole staff will be interfacing with patients over email and in person and should be very knowledgeable about how things work.”

For Tokarz, switching to concierge led to greater job satisfaction and improved teamwork among his staff. “In a high-volume traditional practice, there is often a feeling of antagonism and isolation between patients and staff because the staff feel like they have to be a barrier between providers and patients,” he says. “But with a lighter patient load, they can focus on actually helping patients and doing their jobs properly.”

The typical workday changes significantly after the transition to concierge, says Puglisi. With insurance reimbursement no longer dictating the pace, physicians can book longer appointments and set aside time for activities that may have gotten lost in the shuffle in the past, like emails and phone calls.

At Glenville Medical, each physician typically books two 90-minute appointments in the morning for complete physicals. Puglisi also spends time summarizing findings from those visits and drafting a letter to the patient, which he mails along with any test results. “I often speak to them on the phone as well after their appointment,” he says. “At the end of all that, I feel like we’re on the same page in terms of continuing to keep them healthy.”

The remainder of the day is filled with 30-minute slots for acute care visits and follow-up care as needed, he says. There is always room in the schedule to accommodate emergency visits and handle administrative tasks.

Along with home visits and coordinating care for hospitalized patients, physicians are kept busy, says Puglisi. But the atmosphere is much different from the frantic environment of his previous fee-for-service practice.

“I want patients to feel comfortable talking about their fears and anxieties and that was becoming more difficult in my old practice,” he says. “I also feel less stressed personally because I’m working fewer hours and providing the type of care I want to give.”

An estimated 12,000 U.S. physicians now operate subscription-based practices, which encompasses both concierge and direct primary care (DPC) models, according to data gathered by Concierge Medicine Today, an industry trade publication. While still a tiny percentage of the overall physician workforce, the movement is growing, experts say, as physicians become frustrated with a reimbursement system that forces them to squeeze more and more patients into an already busy schedule.

Results from the 2014 Survey of America’s Physicians, conducted by Merritt Hawkins for the Physicians Foundation, shed some light on the growth of concierge medicine and forces that may be driving the trend:

- 81% of physicians described themselves as either overextended or at full capacity, up from 75% in 2012 and 76% in 2008. Only 19% said they had time to see more patients.
- Physicians spend 20% of their time on non-clinical paperwork.
- 7% of physicians practice some form of direct pay/concierge medicine, while 13% indicate they are planning to transition in whole or in part.
- 17% of physicians aged 45 or younger indicate they will transition to direct pay/concierge practice at some point in their careers.
- About 6% of physicians said they will switch to a direct pay/concierge practice in the next one to three years.

Puglisi also likes having time for professional education, including travel to conferences and interacting with colleagues. Instead of feeling stressed at the end of the workday, he now feels productive and fulfilled, he says.

“A major cause of physician burnout is not enjoying your work and always feeling like you’re cutting corners,” he says. “When you’re in a practice where you’re working more and more hours and not giving type of care you want to give, something will give and often it’s burnout and depression.”
Legally Speaking

What new overtime rules mean for physician practices

by AMANDA L. WAESCH, JD and CHRIS ZAENGER, CHBC Contributing authors

In May 2016, the U.S. Department of Labor (DOL) released the long-awaited Final Rule revising the minimum salary requirement for an employee to qualify for the overtime exemption under the Fair Labor Standards Act (FLSA). How does this rule impact physician practices?

In the reverse, let’s say you have a full-time front desk supervisor who you are paying hourly at $23 per hour ($47,840 per year). She habitually works overtime and last year you paid her $55,600. Assuming she meets the federal and state definitions to qualify as an exempt employee, do you want to re-classify her as exempt and pay the $47,840? How will this impact her behavior? Will she need a part-time person or more hours from other staff members to get the work done?

The choice should be carefully considered, because any change in employee classification or reorganization of employee structure may impact employee morale. For employees whose salaries are on the border of the salary threshold, it is now more important than ever to ensure their correct exemption classification. If you discover improper classifications, use this time as an opportunity to reclassify the exemption status for these employees.

The DOL expects these changes in the overtime rule to increase payroll costs dramatically, especially for small businesses. In addition, because there will be significant payroll tax revenue as a by-product of the rule, you can expect that states will step up their audits of small business payrolls.

AS AN EXAMPLE, take a medical assistant that functions as a lead certified medical assistant. Currently she is paid $40,000 per year as a flat salary and does not receive overtime pay even though many weeks she works more than 40 hours. Let us further hypothesize that you had her clock in just like all other employees, and that she meets the definition of a supervisor and exercises independent judgement—two criteria often required under state laws. Reviewing her compensation last year you find that she worked 220 hours of overtime. Under the old law with a threshold of $23,660, you were fine. But on December 1 you will need to make a decision: (a) do you raise her pay to $47,476 (an 18.7% increase), (b) pay her hourly and pay her for overtime (an additional $6,346 if she works the same number of hours as last year), or (c) pay her hourly at $19.23 per hour ($40,000 per year at a standard 40-hour work week) and forbid overtime? Keep in mind that forbidding overtime does not exempt the employee from paying the overtime if the employee works it. But if an employee ignores the rule (documented, of course), this can be considered when evaluating her performance.

What you should do FIRST

- identify a work group to assist with complying with the new law. Members might include your office manager, a managing partner, a human resource specialist, your accountant, consultant or payroll service;
- review employee classifications and the practice’s compliance with wage and hour laws;
- review employee handbooks and policies and procedures;
- perform an immediate assessment and subsequent annual assessments of overtime paid per-employee, total overtime, and employee classifications;
- make any necessary changes; and
- budget for the changes.

What you should do NEXT

- send your legal questions to: medec@advanstar.com.

Amanda L. Waesch, JD, is a healthcare attorney at Brennan, Manna & Diamond, LLC with offices in Ohio and Florida. Chris Zaenger, CHBC, is a a consultant and owner of Z Management Group, Ltd. Send your legal questions to: medec@advanstar.com.
Practical Matters

5 ways to prevent a ransomware attack at your practice

by STEPHEN MCCALLISTER, CPEHR, CPHIT Contributing author

Warnings from government agencies and dramatic reports of hospitals grinding to a halt due to ransomware attacks have splashed across the news recently. Medical practices are an attractive target for ransomware, so physicians must prepare.

NO SINGLE solution will provide a silver bullet against ransomware, but you can mount an effective defense even if you don’t have a hospital-sized IT staff and budget. The most important thing to understand is that you need to act before ransomware locks up your data. As always, prevention is the best medicine.

Here are five ways physicians and their staff can protect against ransomware:

1. Provide your staff training to help them recognize suspicious emails, and to let them know that they should not open attachments or click on links to websites contained in emails. Help them to understand the techniques used to trick them into running ransomware or malware on the practice’s computer network. For example, often ransomware will be inside an email identifying the attachment as something innocuous such as an overdue invoice.

2. Train staff on what they should do if they see an email that looks suspicious — whether that’s deleting it or reporting it to IT or administration. Even if it’s not malware or ransomware, thank them for checking it out first.

3. Ensure that IT takes the same helpful and non-judgmental attitude with staff that your medical team takes with patients reporting problems. If it turns out not to be a problem, IT’s response should be, “Thanks for letting us know about this — truthfully, I prefer the two-minute problems to the ones that take hours or days to fix.”

4. Ensure that IT communicates with staff quickly and positively when a problem is identified. If one person received a ransomware email, chances are others might have as well. “We want to thank Jane Scott for alerting IT staff to a ransomware email—please delete it without opening if you receive it too.”

Remember, if staff members are afraid to report a problem, then IT probably will spend a lot of unnecessary time trying to find the source of the ransomware infection — if they don’t, the files restored from backup copies will be encrypted too.

5. Physicians shouldn’t make this “IT’s problem.” Your IT people need to plan and have systems in place, but ultimately they aren’t responsible for your practice’s business. Make ransomware a part of your risk management and business continuity plan and create clear expectations for how administration will be notified and involved in decisions—such as how much system downtime is acceptable and how decisions to pay a ransom to retrieve practice data will be made.

Stephen McCallister, CPEHR, CPHIT, is a health information technology consultant with over 20 years’ experience managing technology for healthcare organizations. This article was first published in our partner website, Physicians Practice. Send your questions to: medec@advanstar.com.
THE ZIKA SCARE

What doctors should tell their patients

The beginning of the Olympic Games and hot summer months means patients will be asking about the Zika virus

by JOHN HENRY DREYFUSS Contributing author

HIGHLIGHTS

As of early summer, the CDC had not reported any cases of direct transmission of the virus by mosquitoes to humans in the United States. However, experts agree that it is simply a matter of time before this happens, for several reasons.

WITH EVERY PASSING summer day, the Zika virus alarm becomes more urgent in the United States, making it more important that physicians both address it with their patients and dispel rumors.

Hundreds of pregnant women are infected with the virus and are being monitored by the Centers for Disease Control and Prevention (CDC) in New York, Texas and other states. Thousands of other people are infected nationwide.

"You will start to see Zika cases transmitted by mosquitoes in the southern United States," says Nitin S. Damle, MD, MS, FACP, a founding and managing partner at South County Internal Medicine Inc. in Wakefield, Rhode Island. "It could travel as far north as Maine. It is not exclusive to the south. Physician's discussions about prevention are crucially important."

Physicians can educate patients about Zika to prevent microcephaly and other birth defects caused by the virus, as well as Guillain-Barré syndrome and newly detected Zika-related eye injury in any infected adult.

However, not all healthcare providers are convinced that Zika poses an imminent threat to Americans. The disease may not spread as easily in the United States because living conditions—the use of air conditioning, closed windows in the summer, and window screens, among others—are very different compared with countries where Zika is epidemic. Also, the mosquito population—the ratio of mosquitoes to people—in the United States is lower than in countries such as Brazil, Mexico, Ecuador, Bolivia, and others, where Zika currently is more prevalent.

Nonetheless, the CDC recently held a briefing with governors from the states most likely to be affected by localized Zika outbreaks—Alabama, Arizona, California, Florida, Georgia, Hawaii, Louisiana, Mississippi, New York, and Texas. The states reviewed preparedness plans that include CDC emergency response teams ready to deploy should an outbreak occur. CDC-advocated mosquito control programs are now widespread in the United States.

By discussing the risks of Zika with patients, especially following travel to Zika-
concentrated areas such as Brazil and Puerto Rico, and advocating the use of condoms for any type of sexual intercourse—even among monogamous couples—physicians can help patients avoid transmitting the disease sexually. By recommending the use of EPA-approved insecticides and other methods, physicians can help patients avoid vector-borne infection.

As of early summer, the CDC had not reported any cases of direct transmission of the virus by mosquitoes to humans in the United States. However, experts agree that it is simply a matter of time before this happens, for several reasons.

First, Americans routinely travel to Zika-infested countries, are infected, and bring the virus home with them. Second, Americans spend more time outdoors in the summer. Both of the mosquitoes that carry Zika—the Aedes aegypti and Aedes albopictus—hunt during the day, as well as at dawn and dusk. According to the CDC, both types currently inhabit more than half of the continental United States.

**PHYSICIAN EDUCATION DISPELS MEDIA HYPER**

“One question we get from patients is whether Zika is real or if the media is hyping it,” says Wanda Filer, MD, FAAFP, president of the American Academy of Family Physicians and a family physician in York, Pennsylvania. “I tell them it’s serious.”

Damle, who is also president of the American College of Physicians and a member of the clinical faculty in the Alpert Medical School of Brown University, says the first thing physicians should do is take a good patient history and find out whether the patient has recently traveled to Zika-prevalent areas.

In addition, “The physician should ask whether a female patient is pregnant or planning to become pregnant,” says Damle. “Ask whether she has been exposed to Zika by a partner who has traveled to a Zika-infested area or has a partner who has been diagnosed with a Zika infection.”

“It is critically important that women who are pregnant or plan to become pregnant avoid Zika-infected areas,” adds Margaret “Peggy” Honein, PhD, MPH, an epidemiologist and chief of the birth defects branch of the CDC. “Parents must understand the

“Physician’s discussions about prevention are crucially important.”

—NITIN S. DAMLE, MD, MS, FACP, MANAGING PARTNER, SOUTH COUNTY INTERNAL MEDICINE INC., WAKEFIELD, RHODE ISLAND

**Common Symptoms**

Most people infected with the Zika virus will not know that they have the disease either because they have no symptoms or they mistake the symptoms for those of another disease or a simple allergy, according to the Centers for Disease Control and Prevention (CDC)

“For most people, Zika is a relatively mild, self-limiting disease,” explains Margaret “Peggy” Honein, PhD, MPH, chief of the birth defects branch at the CDC. “However, there are some serious neurologic sequelae such as Guillain-Barré syndrome.”

The most common symptoms of Zika are fever, rash, joint pain, conjunctivitis, myalgia and headache. These can last from three to seven days. Generally, the period between infection and symptomatic disease also is approximately three to seven days. The disease remains sexually transmissible in women for at least eight weeks and in men for at least six months. Initial infection is likely protective against a repeat infection. In rare cases Zika can progress to Guillain-Barré syndrome or newly detected Zika-related eye injury in an infected adult.

**Zika is a Sexually Transmitted Disease**

It is crucial for physicians to inform patients that Zika is a sexually transmitted disease. If a man is infected, the virus will remain in his semen for six months. Experts advise that men use a condom if they either have been infected with Zika or have simply traveled to areas where Zika is prevalent. The virus can be transmitted during oral, anal or vaginal intercourse.

A woman infected with Zika or who has traveled to an area where Zika is prevalent should wait at least eight weeks before attempting to become pregnant. If she wants to become pregnant but her partner has been infected or has traveled to Zika-prevalent areas, the couple should use condoms during sex and wait at least six months before attempting to conceive.
Talking Zika

**ZIKA VACCINE ON THE HORIZON**

The U.S. Department of Health and Human Services’ Office of the Assistant Secretary for Preparedness and Response (ASPR) plans to help bring a vaccine for the Zika virus to market immediately via Emergent BioSolutions Inc., the company that also developed the anthrax vaccine.

Emergent BioSolutions said that it obtained a contract with ASPR’s Biomedical Advanced Research and Development Authority (BARDA) to develop and manufacture three cGMP lots of a Zika vaccine for use in a phase 1 clinical trial.

“The threat posed by Zika presents an urgent need for vaccines and diagnostics,” says Richard Hatchett, MD, acting BARDA director. “To meet that need as quickly as possible, we need to leverage the infrastructure, experience and expertise available within BARDA, other federal agencies, industry and academia.”

In addition, the first U.S. test for the Zika virus became available in early May after Quest Diagnostics received an emergency use authorization for its Zika Virus RNA Qualitative Real-Time RT-PCR test (Zika RT-PCR test).

Until then, the only Zika tests authorized by the FDA were available from the Centers for Disease Control and Prevention (CDC), and were only used in qualified laboratories designated by the CDC.

Emergent Biosolutions will conduct a variety of studies via BARDA’s Center for Innovation in Advanced Development and Manufacturing in Baltimore, to move quickly through early stages of vaccine development and submit an investigational new drug request to FDA to begin clinical studies. To further speed development time, Emergent will use vaccine technology similar to that used in vaccines being developed to protect against similar viruses, such as Dengue.

Over the next 30 months, BARDA will provide more than $17.9 million to Emergent with the potential for additional work, totaling approximately $21.9 million.

However, at any stage in development, BARDA could transfer the technology to other vaccine manufacturers to utilize the technology to produce and market the Zika vaccine, HHS said.

In addition to this vaccine development, BARDA is sponsoring development of pathogen reduction technologies to reduce the risk from Zika in the blood supply. BARDA also is using its clinical studies network to collect blood samples needed to speed development of diagnostic tests.

BARDA is seeking additional proposals for products that could be used to prevent or detect Zika or other illnesses and injuries associated with public health emergencies.

Editor’s note: This article was first published online by our partner website, Formulary Watch.
Efforts to ease requirements for maintaining board certification have not quelled internists’ complaints about the time and costs the maintenance process demands. Still, the president of the American Board of Internal Medicine—the body that oversees certification for internists and many other subspecialties—remains convinced that maintaining certification is important for physicians, and that the board’s path for doing so is the best one.

“Putting out a credential that speaks to whether doctors are staying current in knowledge and practice, I think overwhelming numbers of doctors want to have a way to reassure themselves that they’re doing that,” says ABIM president Richard Baron, MD, MACP. “And they want a way to communicate to their patients and colleagues and institutions that they’re doing it.”

Even so, the ABIM has been trimming many of the changes it made to the maintenance of certification (MOC) process in 2014 and that led to the outcry among physicians. Last year, for example, the board invited practicing internists to review the outline—or “blueprint”—of the assessment exam and rate the topics it covers for their relative frequency and importance to everyday practice.

Then earlier this year the board announced plans to introduce a shorter assessment test in 2018, one that doctors can take on their own computers rather than in a central testing location. Doctors who do well on these assessments can “test out” of the current assessment, which is required every 10 years.

Baron’s comments were part of a wide-ranging interview with Medical Economics regarding MOC and issues facing the ABIM that took place during the American College of Physicians scientific meeting in May. The full transcript follows:

Q: **MEDICAL ECONOMICS:** One of the complaints we hear about MOC is that the process has very little relation to the kinds of problems most practices face on a day-to-day basis. Do you anticipate that the changes...
Richard Baron interview

you outline in the announcement are going to address that complaint?

Richard Baron, MD: I would say that a number of changes we’ve already made have taken important steps to address that. We’ve been engaged in what we call a blueprint review process where we invited practicing doctors, all board-certified doctors in a discipline, to give us feedback on what’s called the blueprint, which is the design specification for putting together the exam. We did it in IM in the MOC exam in the fall of 2015 and had very positive reviews from doctors that it was more relevant and moving in the right direction.

So crowd-sourcing in how to put the exam together has helped a fair amount in the relevance area and we’re rolling that out across all our disciplines. So I think we’ve taken a number of important steps there and will continue to.

The changes we made with ACCME [the Accrediting Council for Continuing Medical Education], creating a way for more CME programs that met ABIM standards to seamlessly generate MOC recognition is something we also think was in the direction of saying this is a program that gives people credit for the work they are doing that is substantive, valuable educational work.

Q: Can you point to any specific changes in the blueprint that you feel are making it more relevant to everyday practice?

RB: I’d have to say it’s too numerous to count. In other words, the blueprint review is pretty technical. It not only gets into different diseases but it gets into is it important to be able to diagnose this, to treat this? Is it important to understand the disease mechanisms? Those are all things that exam questions might test. So some of the things we’re asking doctors is, how important is this?

So for example a disease that you don’t see very often, that is very rare, but if you missed it the consequences for the patients are dire. That is something we want to keep on our exam, because missing that is really a problem even if it’s not something you see every day. So getting a crowd-sourced opinion on that of people helping us think through well how important is this really? And OK, I mean I carry around in my brain what antibiotics to treat meningitis, but I better understand meningitis when it happens, and I better understand the test I need to do when a patient shows up with a fever and a headache.

So that kind of thing, it was just a bunch of calibration across a very large exam.

Q: Another complaint we often hear from readers is the requirement to have to board in each subspecialty in which the physician practices as well as IM, and that the ABIM doesn’t advocate strongly enough on behalf of its members with hospitals that require this for admitting privileges. They want to feel that the ABIM is going to bat for them. Any response to that?

RB: Well, I think how people use ABIM credentials is very geographic and market-specific. When I finished my training in New York the first practice I did was in the NHS Corps in rural Tennessee. It was a community hospital with an ICU and CCU and no medical subspecialists. There were nine internists in the community. So when I had a patient with a heart attack I admitted them and took care of them in the CCU.

Three years later, when I moved to Philadelphia, I got admitting privileges in an academic health center. I admitted my first heart attack on a Thursday night, I was in the CCU writing orders and the nurse asked what cardiologist are you going to consult? I said will they come in tonight? The nurse said no, why would they need to? And I said well why would I need to consult a cardiologist? And the answer was you don’t have admitting privileges in our CCU because you’re not a board-certified cardiologist.

So it’s very market-dependent. Institutions are looking to maximize the quality opportunities they can get, and they want the best-trained doctors in their communities providing care in their institutions. We don’t tell anybody how to use the credential. We explain what the credential is. That’s our...
responsibility is for the credential to mean something and say what it means. But how it gets used is not something we decide.

Q: ME: But why not try to advocate more strongly and say, ‘this is a real burden for our members to get certification in an area they clearly already have competence in.’ Wouldn’t that help them?

RB: When you say they clearly already have competence in, that’s where things get sticky. Over time knowledge decays, over time people don’t know what they don’t know, treatment expectations change, treatment options change. I’d love to say that every licensed doctor in America always keeps up with that stuff, but that’s not how the world works. And putting out a credential that speaks to whether people are staying current in knowledge and practice, I think overwhelming numbers of doctors want to know that they’re doing that, want to have a way to reassure themselves that they’re doing that, and want a way to communicate to their patients and colleagues and institutions that they’re doing that. That’s what we do.

Q: ME: Despite the cost and time commitment required for that?

RB: The bulk of the time commitment is staying current in a rapidly-changing field. If we went out of business tomorrow, doctors would still need to spend a ton of uncompensated time reading journals, coming to meetings like this, studying. We don’t make people do that. We recognize that they have, and give them a way to acknowledge that they’ve done what they needed to do.

Q: ME: That’s a good segue to my next question, which is that doctors say that between requirements for CME and the easy access to information on the internet, that more than keeps them abreast of developments in their field, so why certify at all?

RB: First of all, the wide availability of the internet, the patients have that too. Yet there’s a significant difference in what we expect from patients with regard to knowledge and ability and what we expect from physicians with regard to knowledge and ability. So doctors know stuff that patients don’t know. And when they’re seeing patients—and I was in practice for many years—if you had to look up everything on every patient you see you’d never get through the day.

So everyone’s doing the time-lookup balance, so the more you know the sager you’re going to be in managing that tension. So the first thing I’d say is the availability of the internet doesn’t mean that knowledge doesn’t matter.

The second thing is everyone agrees CME varies enormously in quality and effectiveness. Everyone knows about courses you can go to on the cruise or at the ski resort and may or may not be getting any knowledge. And it’s important not just that your seat was in the seat, but that you actually know what you need to know to do what we do. And what we do is pretty important and it changes pretty rapidly and people are not good at assessing what they don’t know. People assume that what they know is the right thing, but as one of my colleagues said some years ago, 30 years of practice doing it the wrong way doesn’t make it right. And how you keep up and learn with changes is an important thing all of us care about.

And one more comment with respect to the internet. There are now credentials available on the internet too. My son’s getting married this month by somebody who went on the internet and clicked “become an ordained minister for free.” And he got that credential, and he’ll marry my son with legal authority in the state of New York. It’s OK with me that he’s marrying my son, and I think most of us really are proud of having a credential that distinguishes us in a world where what’s behind that credential really makes it valuable.

Q: ME: But of course, that’s not the same thing as getting licensed to
practice medicine. There is a lot more that’s required of you to do that.

RB: That’s true, but once you are licensed, first of all, only 81% of doctors are board-certified, 19% are not. So one in five doctors in this country is a licensed doctor who’s not board-certified, and I assume most of them are working.

Board certification has always been a standard that is higher than licensure, and people who hold it are proud to hold it because it’s higher than licensure. They could have gone out after one year of training in most states to independent practice, and most of them didn’t, because they wanted to learn more and be able to say they had acquired a set of skills.

It used to be that lifetime certification was a great way to do that. But with knowledge changing as fast as it does, it becomes pretty important to know who’s staying current.

Q: ME: What about the cutoff date? That’s not going to change at all under this announcement you made today?

RB: When a certificate is issued, we make commitments that we keep. So when we issued certificates before 1989 we said those would be lifetime certificates, and they are.

When we issued certificates after 1990 we said they would not be lifetime certificates, and they’re not. Part of what we started to do in 2014—and this was also something we heard a lot from younger doctors—was, ‘Wait a minute, how can anyone tell the difference between me, with this time-limited certificate, and this person who got a certificate in 1980, and for all you now hasn’t done anything?’

So we still report those people as certified, but we report separately whether they are participating in the maintenance of certification program, and we do that for precisely that reason. A number of so-called grandfathered doctors have signed up for the maintenance of certification program, because they want to have a way of saying to their patients, ‘I’m staying current. I’m at the top of my game. I’m practicing today’s medicine.’ We don’t make them do that to

On why CME alone is not good enough

“Everyone agrees CME varies enormously in quality and effectiveness. Everyone knows about courses you can go to on the cruise or at the ski resort and may or may not be getting any knowledge.”

still report them as certified, so that’s not changing.

Q: ME: Is there any evidence that certification, or lack of certification matters to patients?

RB: Absolutely. I think patients are desperate for high-quality information about doctors and who they’re seeing. Lots of doctors say to me, ‘no patient has ever asked me whether I’m board-certified.’ Well first of all, lots of patients I talk to say ‘I go on the internet or I look at the directory, and if that doctor’s not board-certified I don’t go.’ Lots of people tell me that. They’re not asking the doctor because they already know before they came.

So yeah, I think patients do care about it. I think patients don’t look too deeply the way doctors do at what’s behind the credential. But I think they respect it a lot more deeply than they do Yelp reviews.

Q: ME: It kind of makes you wonder how the 20% of doctors who aren’t certified are staying in business?

RB: Well as I say, I think it’s very market-dependent. And there are places where people are practicing and situations where people are practicing where they are filling a need. And someone says ‘I may not be as pushy here as I otherwise might have been.’

Q: ME: How would you characterize the ABIM’s relationship with the National Board of Physicians and Surgeons [an organization founded last year to offer doctors an alternative route to maintaining certification]? I assume you saw their announcement in the last couple of days about their agreement with the osteopathic association?

RB: To be honest, I didn’t actually see that announcement, and Dr. Teirstein [Paul Teirstein, MD, NBPAS founder and president] and I have spoken on a number of occasions.
I think it’s pretty clear what the difference is. Again, for NBPAS as I understand their requirements, it’s ‘send us copies of your CME certificates and a check and we’ll send you a certificate as long as you were originally ABMS board-certified in any ABMS discipline.’

There’ve always been boards like that. Rand Paul created his own ophthalmology board 25 years ago or so. And it hung around for a few years in Kentucky and then he stopped doing it. But there have always been boards out there. The difference between us and them is the standards. We have a set of standards, and when you asked earlier why we aren’t moving faster, why don’t we just have an answer to this, it’s because having meaningful standards that are real is very difficult to do and it takes a lot of work. We make that investment. And NBPAS, as far as I can tell, has not made that investment.

Now, they’ve been around a year and a half. The last I saw on their website they say they have 3,100 doctors who’ve signed up. There’s 900,000 doctors in the country. We have 200,000 doctors. I think that people are staying with us because we issue something that means something, as opposed to, if all you’re doing is the same thing you had to do for licensure anyway, what’s the value added? And I think people have been angry at us and they wanted to say, ‘we want an alternative.’ But I haven’t seen a lot of large reputable organizations get on that train, because they care about standards too.

Q: ME: So you’re not concerned that what NBPAS does may make what ABIM does irrelevant?

RB: I’m not concerned at all, I think if anything they make it more relevant, because they highlight the fact that we actually have a performance standard in the middle of our program.

Q: ME: Another big concern we hear is how ABIM spends its money. And today’s announcement didn’t really touch on finances at all. Are you concerned about the anger that’s out there about ABIM’s finances?

RB: A lot of people have raised issues about that. We are fully transparent about that. Go to our website, abim.org/finances and you’ll see a graphic that shows you where we spend our money and how we spend our money. You’ll see an audited financial statement posted on our website, which very few nonprofits do.

People have raised questions about compensation practices. We have a compensation committee that follows best practice standards, gets comparable figures on what people in senior executive positions get paid, which is how nonprofits set salaries.

To put it more bluntly, if I were trying to hire a cardiologist, and I said I’m going to pay you a general internist’s salary, I couldn’t hire a cardiologist on a general internist’s salary. And you can’t hire a chief operating officer of a $56 million-a-year company on the salary that you hire somebody to manage a one-doctor medical practice.

So we’re in a competitive market for talent. Our salaries are competitive, they are reviewed by an executive compensation committee, there’s an independent consultant that provides competitive data in the marketplace. So we have nothing to apologize for in our finances, That’s why we put it all out there.

We understand that every dollar we get we need to spend carefully. And we understand that doctors are concerned about the fees. And as we think about re-creating the program we will be looking at ways to re-structure fees. But what I pay in fees to ABIM is less than what I pay the Commonwealth of Pennsylvania for being licensed, less than what I’m paying the federal government for having privileges to prescribe narcotics.

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The bedside talk about cost every physician must have

With the ever-growing armamentarium of new therapies available today, a conversation about prescription drug costs with patients is rapidly becoming a reality for every physician.

I usually wait until the end of the office visit to bring up cost since patients tend to tune out everything else once they start thinking about money. Then, I pull out the most benign analogy I can think of—cars—to break the ice in the most gentle fashion.

Let me illustrate. A patient comes in with atrial fibrillation and has a high enough annual risk for stroke to warrant anticoagulation therapy based on his/her CHA2DS2-Vasc score. I start the conversation with the patient with a choice of rate vs. rhythm strategy.

Once he makes this decision, I turn to the decision of risks and benefits of anticoagulation for stroke prevention. By now, the patient's head is spinning with all these facts and decision fatigue has already permeated the visit.

Now, I am faced with offering the patient one of five choices for oral anticoagulant therapy: Warfarin, Pradaxa, Xarelto, Eliquis or Savaysa. To avoid information overload, I skip the discussion about each of the individual trials, their patient populations and their inclusion/exclusion criteria.

Instead, I start by asking the patient about cars. "If given a choice, would you rather choose a Toyota, a Tesla, a BMW or a Porsche?" Immediately, their response provides me with great insight into their approach to cost vs. benefit ratio. The Toyota driver may feel that a car’s purpose is to transport from one location to another in the most cost-efficient way and may be willing to tolerate a lower-cost vehicle that requires more frequent repairs (i.e. frequent INR checks with Warfarin, a generic low-cost drug.)

The BMW driver, on the other hand, favors luxury over cost and may be willing to pay the upfront cost of a more expensive vehicle in exchange for the convenience of fewer maintenance visits and better performance (i.e. Eliquis, which is more expensive but does not require INR check and has a slightly better safety to efficacy profile.)

A discussion about prescription drug costs can never be easy, but it is something we must all learn how to do with our patients because it is one of the biggest drivers of healthcare costs and dictates the degree to which patients are going to adhere to recommended therapies. In order to do this, however, we must all become aware of the costs of new drugs and incorporate that into our decisions of which drug to choose for which patient.

Even so, there remain drugs with prohibitively high costs that may never be within the average patient's reach. For example, the wholesale cost of Repatha, the new injectable PCSK9 inhibitor, is a mere $14,100 for a year’s supply. At that price, the drug becomes the equivalent of a Lamborghini, reserved only for an elite few.

That’s where the physician’s knowledge of cost combined with the knowledge of the efficacy and safety of the drug can allow for a truly informed discussion about drug selection, best tailored to each patient.

So I implore you to learn about costs for your most-frequently prescribed drugs, not just for the patient’s benefit and to achieve the best patient outcomes, but because knowledge of a drug’s cost is quickly becoming just as important as the drug’s efficacy or safety. And since physicians’ own preferences can sometimes influence the recommendations we make, perhaps we should all also ask ourselves, "What kind of car would I prefer to drive?"

Payal Kohil, MD, is an attending cardiologist for Kaiser Permanente in Denver, Colorado. Do you agree or disagree with the author? Send us your thoughts at medec@advanstar.com.

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