

June
2007

Volume 25
Number 2

FORUM

© 2007 CRICO/RMF



Improving Patient Safety in Office-based Practice

Issue Editor: Deborah LaValley, BSN, RN, CPHQ

- i [Commentary](#)
by Luke Sato, MD
- 1 [Office-based Malpractice Cases: An Incentive for Action](#)
by Deborah LaValley, BSN, RN, CPHQ
- 3 [Key Characteristics of a Highly Reliable Office Practice](#)
by Ann Louise Puopolo, BSN, RN, and Jennie Wright, BA, RN
- 5 [Case Study: No Screening Test Offered](#)
by Jennie Wright BA, RN, and Patricia Dalton
- 6 [Case Study: Failure to Act on Incidental Finding](#)
by Jennie Wright BA, RN, and Peter McCormack, JD
- 8 [Are PCPs Nearing Extinction? An Interview with Dr. Richard Parker](#)
by Debbie LaValley, BSN, RN, and Jock Hoffman
- 10 [Where Errors Occur: Inadequate Family and Medication Histories](#)
by Jeffrey L. Schnipper, MD, MPH
- 13 [Management of Critical Test Results: The NSMC Experience](#)
by Anthony J. Guidi, MD
- 14 [Closing The Loop For Specialty Referrals at MGH Senior Health](#)
by Katherine Hesse, MD, MSW
- 15 [Establishing a Common Mission to Address Office-based Risks](#)
by Sharon Lucie and Jennie Wright, BA, RN
- 16 [The Ambulatory Practice of the Future](#)
by Nicola Majchrzak, MPH, MSW, and David Judge, MD
- 18 [Cancer Screening: The United States Preventive Services
Task Force Recommendations](#)
by Diana Petitti, MD, MPH
- 20 [Complexities of Cancer Screening: Considerations for Clinical Practice](#)
by Marc B. Garnick, MD
- 22 [Additional Resources](#)
by Judith Jaffe, MSLIS

Commentary: Outpatients Deserve Patient Safety Improvement, Too

by Luke Sato, MD

Dr. Sato is Chief Medical Officer for CRICO/RMF

The current patient safety movement first gained momentum in hospitals (foremost in anesthesiology) but, more recently, the focus has been widening to include outpatient care. As parent health care organizations began to address inpatient safety, they recognized that their outpatient partners needed to be included in the improvement process, and the malpractice claims data bear that out. As health care delivery has shifted more toward outpatient practices, so too have the settings for alleged medical errors (see [LaValley, page 1](#)). And we know, based on multiple studies of medical error, claims and suits represent just a small proportion of all the preventable adverse events that actually occur.

We know too, the devastating impact an adverse event has on the patients, their families, and also the physicians, nurses, and staff involved. An adverse medical event is often life altering, and when that event is later understood to have involved preventable errors, practice-altering solutions need to be developed, implemented, and spread. The Harvard-affiliated organizations, their associated office practices, and CRICO/RMF are committed to that goal. It is an ambitious endeavor.

A Non-organized Network

CRICO-insured office practices are affiliated (often loosely) with a “parent” institution in the Harvard medical system. Those “networks” of practices, however, are not always well organized for making universal improvements at the practice level. The practices within a given affiliation often operate independently in terms of protocols, systems, training, and quality improvement efforts. To achieve a goal of significant patient safety improvement—especially in primary care practices—by relying solely on the already overburdened PCP to address those needs independently is simply too much to ask (see [Richard Parker interview, page 8](#)).

Not that the spirit isn't willing. The hard part of patient safety improvement in the office practice is not motivating dedicated caregivers to do the right thing. The hard part is developing and sustaining an organizational approach that is more efficient and sustainable than each individual practice-based approach. That requires both parties, physician groups and parent organizations, working toward a common goal. The good news is that the CRICO-insured organizations, and their practice affiliates, have begun that work.

At the practice level, a great deal is being achieved with grass roots efforts (see [Guidi, page 13](#); and [Hesse, page 14](#)). Through both its research/demonstration project grants, and its Office Practice Evaluation (OPE) program, CRICO/RMF has been witness to numerous innovations making a difference in office-based

patient safety (see [Lucie, page 15](#)). But, while that approach serves as a good way to pilot new interventions, it is inefficient for systemwide improvements.

We at CRICO/RMF have seen the most success, in terms of patient safety improvement, when the relationship between the parent organization and affiliates is built beyond a financial structure. The

more both parties can collaborate on mission, systems, and support services, the easier it is to introduce innovations and respond to emerging risks. The parent organizations that strive to accomplish that have developed a more comprehensive network model and are fully committed to providing the outpatient practices with the leadership and resources necessary to sustain and systematize innovations (see [Majchrzak, page 16](#)).

We hope that the inpatient patient safety improvement experience has shortened the learning curve for outpatient providers. Certainly, clinicians can see that the patient safety movement is not some short-lived concept. They also understand that many techniques and tools developed for hospital patient safety can now be applied to office-practice settings (see [Schnipper, page 10](#)). Of course, office practices cannot individually match the framework and support services of a large hospital on their own. Both sides know that continuous patient safety improvement in the office setting demands greater collaboration. For the individual practice groups, that may mean adopting solutions that were not home grown. For the parent organization, implementation of patient safety improvements in multiple unique settings requires, perhaps, greater patience and more diverse management than for inpatient interventions. An ambitious endeavor indeed.

Recognizing that attention to the office practice is crucial to our mission of decreasing missed and delayed diagnoses (the top area of high-severity malpractice claims); Forum is highlighting the office setting in this issue. We invite you to join the ongoing efforts of CRICO/RMF and our guest authors to identify risk, develop and promote risk reduction efforts, and continue to extend patient safety principles into to the office environment. ■



Office-based Malpractice Cases 1997–2006: An Incentive for Action

by Deborah LaValley, BSN, RN, CPHQ

Ms. LaValley is a Senior Loss Prevention Specialist for CRICO/RMF and Issue Editor of Forum.

The majority of health care is carried out in outpatient settings (primarily physicians' offices and emergency departments).¹ Malpractice cases reflect this: from 1997–2006, more than 800 CRICO-insured clinicians were named in 623 office-based cases.² Those cases accounted for more than one-quarter of CRICO's total cases, defendants, and incurred dollars (see Table 1).

Mirroring the national trend,³ more than half (52 percent) of CRICO's office-based claims alleged either a delayed or missed diagnosis (Table 2). The most common diagnoses identified within these cases were cancers (Table 3). Also frequently alleged were: failure to diagnose infection, myocardial infarction, benign tumors, and strokes. The key issues in office-based failure to diagnose cases were: poor clinical judgment (i.e., patient assessment), poor clinical systems (patient follow-up, reporting findings, identifying provider coordinating care) and inadequate communication and documentation. Table 4 illustrates where along the diagnostic path errors are most frequently alleged. Conducting an adequate history/physical, ordering of diagnostic tests, and test interpretation are key areas of concern.

Cases alleging mismanaged medical treatment or medication errors (both 13 percent) were the next most common allegations made in CRICO's office-based claims. The treatment cases frequently alleged improper performance of a treatment or procedure, inadequate patient assessment, and communication breakdowns. The majority of medication cases were related to improper medical management or education/communication errors.

The Challenge

While some types of medical error occur in all settings, ambulatory care presents unique challenges for patient safety improvement. Primary care providers' job functions are increasingly complex; more of those providers are non-physician personnel, and patients are frequently handed off between clinicians.⁴

Despite the prevalence of outpatient care—and the accompanying malpractice allegations—office practice patient safety efforts have received little of the attention (and funding) devoted to hospital-based initiatives. But the problem is not hidden from those in a position to fix it. In response to an electronic survey in 2003, American medical leaders identified the top five actions they felt could improve the quality of office-based health care:

1. institute affordable, standards-based, common language EMR/EHR including lab, radiology, and hospital connectivity;
2. create functioning caregiving teams of physicians, nurses, pharmacists, and others;

From 1997–2006, office or clinic-based events accounted for:		
■	27% of all CRICO cases	
■	25% of all CRICO defendants	
■	29% of all total incurred losses	
	All CRICO Cases	Office-based Cases
Claims and suits	2,340	623
Defendants	4,803	1,220
Closed cases	2,299	617
Closed with payment	725 (32%)	200 (32%)
Total incurred losses	\$812,000,000	\$233,000,000
Average indemnity payment	\$487,000	\$469,000
Defendants	All CRICO Cases	Office-based Cases
Staff physicians	1,963	637
Residents	419	35
Fellows	101	17
Non-MD clinicians	659	132 ^b
Institutions	1,661	399
Total	4,803	1,220

a Aggregate of expenses, reserves, and payments on open and closed cases

b Includes 27 registered nurses and 20 nurse practitioners

3. institute e-prescribing;
4. better educate patients; and
5. implement office-based decision support systems.⁵

Over the past 10 years, most of the CRICO-insured institutions have employed many, if not all, of those ideas in the inpatient settings through a comprehensive commitment of resources and culture change. Spreading and adapting those initiatives to individual office practices requires a different model (probably many different models) and an unprecedented collaboration between the hospitals and their satellite providers.

Despite numerous systems and strategies that can be used to improve practice performance, the outcomes are still heavily reliant on the practice culture,⁶ and, the incentive of not being sued. Miller and Bovbjerg found that safety improvements were less influenced by litigation-related financial costs than by ancillary costs, including:

- physician morale and psychological costs, which can exact a substantial toll on individual physicians and demoralize other medical group members;
- intellectual capital costs, especially costs of diverting scarce manager and support staff resources into time-consuming, organizationally disruptive litigation-related activities; and
- reputation costs, such as the effect on the group's reputational assets, and thus, future revenues.³

Office-based Malpractice Cases 1997–2006 (continued)

Table 2

CRICO Office-based Cases

Asserted 1997–2006
(N=623 cases, \$233M incurred losses^a)

Just over half (52 percent) of the office-based cases involved an allegation of diagnostic error.

- 50% of office-based diagnosis-related cases involved cancer
- 38% of office-based diagnosis-related cases alleged an indicated diagnostic test was not ordered
- 55% of office-based diagnosis-related cases alleged poor follow-up of a referral or test result

Top Allegations	Cases	Incurred Losses
Diagnosis-related	324	\$170,507,000
Medication-related	84	\$20,409,000
Medical treatment-related	24	\$21,493,000
Communication-related	24	\$2,971,000
Surgery-related	20	\$6,144,000

Top Risk Management Issues ^b	Cases	Percent of Cases
Failure/delay in ordering test	142	23%
Inadequate communication of patient information among providers	80	13%
Narrow diagnostic focus	66	11%
Insufficient education re: medication	64	10%
Failure to obtain a consult/referral	62	10%
Failure to establish differential diagnosis	60	10%
Failure to rule out abnormal finding	56	9%
Poor selection/management of medication	45	7%
Failure to identify provider coordinating care	43	7%
Inadequate history/physical	39	6%

a Aggregate of expenses, reserves, and payments on open and closed cases
b A single case may involve multiple risk management issues

Table 3

Top Diagnosis-related Cases

Office-based cases asserted 1997–2006
(N=324 cases, \$154M incurred losses)

Diagnosis	Cases	Incurred Losses ^a
Colorectal cancer	39	\$29,744,000
Prostate cancer	23	\$13,294,000
Infection	20	\$9,156,000
Lung cancer	19	\$9,760,000
Myocardial infarction	18	\$9,207,000
Breast cancer	17	\$10,252,000
Benign tumor	11	\$3,685,000
Head/neck cancer	9	\$7,219,000
Pulmonary embolism	8	\$5,288,000
Cardiovascular disease	8	\$3,819,000

a Aggregate of expenses, reserves, and payments on open and closed cases

Table 4

Malpractice Allegations Along the Diagnostic Path

Office-based cases asserted 1997–2006
(N=324 cases, \$154M incurred losses)

Diagnostic Path	Cases ^a	Incurred Losses ^b
Patient notes problem and seeks care	4%	3%
Physician performs history/physical	27%	38%
Order of diagnostic lab tests	62%	68%
Performance of tests	8%	8%
Interpretation of tests	25%	29%
Receipt/transmittal of test results	14%	11%
Follow-up plan and referral (if indicated)	56%	65%
Patient adherence with plan	10%	5%

a A single case may cite errors in more than one step in the diagnostic process
b Aggregate of expenses, reserves, and payments on open and closed cases

Continued from *previous page*

Miller and Bovbjerg also found providers who felt that liability impeded patient safety improvement by increasing the fear of pretrial discoverability of information. That fear, in turn, restricts the free flow of information 1) within the group, 2) between the group and the hospitals where it admits patients, and 3) between the group and specialist subcontractors. Fear that disclosure could increase the number of claims and make those cases actively pursued harder to defend essentially drives information underground... a form of negative defensive medicine.³

Although malpractice data are only the tip of the iceberg when looking at medical errors, they provide a means for focusing on those processes that contributed to patient harm. The major drawback is that the events often took place three or more years prior. For more timely assessment, the use of office practice patient safety evaluations can help organizations identify potential risks currently resident within that setting. CRICO/RMF, through its Office Practice Evaluation (OPE) incentive program, is now rewarding practices that meet specific safety standards as measured through the survey process.⁷ That process serves to pinpoint opportunities for improvement, to highlight best practices that address key claims-related risks, and to encourage the application of those best practices before an untoward event occurs.

Change happens slowly in complex systems and organizations, but patients should not have to wait for preventable errors to be identified and addressed. To that end, CRICO/RMF is working to accelerate the development of improvements that can be shared across the CRICO-insured community, through its patient safety research grants⁸ and its ongoing support of education and training for both inpatient and outpatient health care providers. ■

Notes and References

- Berwick D, Kilo C. Idealized design of clinical office practice: an interview with Donald Berwick and Charles Kilo of the Institute for Healthcare Improvement. *Manag Care Q.* 1999 Autumn;7(4):62–9.
- Professional liability claims and suits filed against a CRICO-insured physician, institution, or employee by patients seen in a physician's office or clinic. Cases stemming from ambulatory care in an emergency department or day-surgery center were excluded.
- Miller RH, Bovbjerg RR. Efforts to improve patient safety in large, capitated medical groups: description and conceptual model. *J Health Polit Policy Law.* 2002;27(3):401–40.
- Pope C. Quality quagmire: why systems and processes are important to your practice but often ignored. *MGMA Connex.* 2005;5(2):40–5.
- Lundberg GD. Improving the quality of care in physician office practice. *MedGenMed.* 2003;5(4):38.
- Kaissi A, Kralowski J, Dowd B, Heaton A. The effect of the fit between organizational culture and structure on medication errors in medical group practices. *Health Care Manage Rev.* 2007;32(1):12–21.
- Since 1998, the CRICO/RMF Office Practice Evaluation program has surveyed nearly 600 practices within the Harvard-affiliated health care networks.
- CRICO/RMF and its subsidiary, Healthcare Safety Research Institute (HSRI), award grants for research and demonstration projects aimed at achieving greater understanding of patient safety issues, their etiology, and potential interventions. For details see www.rmfi.harvard.edu/research-resources/grants.

Key Characteristics of a Highly Reliable Office Practice

by Ann Louise Puopolo, BSN, RN, and Jennie Wright, BA, RN

Ms. Puopolo is Director of Loss Prevention/Patient Safety for CRICO/RMF. Ms. Wright is Risk Assessment Program Manager for CRICO/RMF.

Regardless of size, specialty, or setting, physician office practices share a common goal of providing high-quality and safe patient care. While myriad systems and practice techniques are needed to meet that goal, CRICO/RMF has found—through years of malpractice claims analysis and proactive office practice evaluations—six characteristics that are the foundation for highly reliable office practices.

1) Assessment and Diagnosis

An appropriate history and physical examination must be completed with evidence that a diagnosis has been reached, or considered, and that a subsequent treatment plan has been put into place. To accommodate the hectic pace in most offices, a highly reliable practice employs processes that assist providers by prompting them to obtain vital information. This is accomplished either by using paper or electronic templates for documenting assessments, or by providing patients with self-administered questionnaires to be reviewed by the provider during the encounter. After a thorough assessment is completed, diagnosis and development of a treatment plan are key components of the process. Documentation of the plan and clinical rationale is vital, both to enhance continuity of care and reduce liability.

Elements of a complete assessment

- updated allergy status;
- updated list of medications;
- updated problem list;
- updated personal and family history;
- components of the physical examination, including a review of systems; and
- clinical rationale and documentation of diagnosis and treatment plan.

2) Disease Management

Practices that uniformly comply with nationally recognized standards, such as HEDIS or ADA guidelines, have processes in place to prompt and track disease-specific tests and/or examination of relevant organ systems. For instance, all diabetic patients have the following laboratory tests done periodically:

- blood sugar level: every 3–6 months,
- HbA_{1c}: every 6–12 months,
- lipid profile and micro albumin: annually,
- foot and retinal exams: annually.

Asthmatic patients have spirometry testing done, receive annual influenza vaccinations, and are educated regarding self management.

3) Health Screening

Many elements of test result management are necessary to ensure appropriate follow up of health screening results. A highly reliable practice has systems in place that confirm the following:

- Factors such as age, gender, and relevant personal and family history are considered when determining appropriate health screens. Decision support tools are used to assist providers in determining the appropriate health screens to offer.
- Processes are in place to monitor that ordered health screens are completed and, if not, that the provider is notified.
- Outstanding health screens are reconciled with incoming results, guaranteeing that results are received.
- Patients can expect to be notified of *all* health screen results; this promotes partnership in care and provides a final check that the health screen has been completed. Notification of results are evident in the medical record.
- A follow-up plan is developed for abnormal screening results with evidence of communication of the plan to the patient.
- Follow-up of abnormal health screens is monitored to ensure that the patient receives appropriate testing.
- Based on findings, a diagnosis is established and is evident in the medical record.

4) Test Results Management

In a highly reliable office practice, processes are well established for *all* ordered tests. This includes the following:

- Ordered tests are reconciled with incoming results. Outstanding requisitions can then be investigated and followed up as appropriate.
- Patients can expect to be notified of *all* test results. This promotes partnership in care and provides a final check on completion of the test. Notification of results is evident in the medical record.
- Abnormal test results are noted and a follow-up plan is developed with evidence of communication to the patient.
- *Critical/concerning* test results are monitored to ensure that the patient receives appropriate testing and follow-up.

Continued on next page

ABOUT FORUM

FORUM provides in-depth analyses of specific medical malpractice cases and issues along with practical loss prevention advice and case abstracts.

The Massachusetts Board of Registration in Medicine has approved **FORUM** as qualifying for the equivalent of AMA Category 1 continuing medical education credit suitable for the Massachusetts requirement in risk management education.

COPYRIGHT AND PERMISSIONS

All rights reserved; use by permission only.

Images on page i ©2007 Getty Images.

Letters to the Editor and requests for **Permission to Reprint** should be addressed to the Editor, at:

CRICO/RMF

101 Main Street
Cambridge, MA 02142

E-mail: Forum@RMF.Harvard.edu

Fax: 617.495.9711

DISTRIBUTION

FORUM is published quarterly by CRICO/RMF, and is available at www.rmfm.harvard.edu/forum.

CRICO/RMF is the patient safety and medical malpractice insurance company owned by and serving the Harvard medical community since 1976.

FORUM is distributed at no charge to institutions, staff, and physicians insured by the Controlled Risk Insurance Company (CRICO). Subscribe on line at www.rmfm.harvard.edu/forum.

STAFF

Editor

Jock Hoffman

Issue Editor

Deborah LaValley, BSN, RN, CPHQ

Editorial Staff

Tom A. Augello

Jessica Bradley, MPH

Kathleen Dwyer, MS, NP

Robert Hanscom, JD

Judith Jaffe, MSLIS

Missy Padoll

Ann Louise Puopolo, BSN, RN

Luke Sato, MD

Maryann Small

Jennie Wright, BA, RN

Winnie Yu

Production Designer

Alison Anderson

While myriad systems and practice techniques are needed to meet that goal, CRICO/RMF has found—through years of malpractice claims analysis and proactive office practice evaluations—six characteristics that are the foundation for highly reliable office practices.

Continued from [previous page](#)

5) Referral Management

Communication is optimized by defining the role of each provider (specialist and PCP) for coordinating care, monitoring treatment, and ensuring follow-up. Systems are in place to promote clear, concise communication.

Referral management processes

- Ordering providers communicate the reason for the referral and any relevant test results to the specialist.
- A mechanism is in place to assure that *critical* referrals are completed appropriately and, if not, the specialist notifies the ordering provider.
- A referral reconciliation process guarantees that *critical* referrals are received and available to the ordering provider.
- *All* referrals are reviewed by the ordering provider with evidence of review in the medical record.
- Patients are aware of specialists' findings and follow-up recommendations (and evidence of the notification can be found in the medical record).
- Evidence of a diagnosis and treatment plan incorporates the specialist's findings.

6) Internal Office Function

A highly reliable practice has an infrastructure that promotes the identification, analysis, and response to performance and systems issues, including procedures for reporting adverse events to the sponsoring institutions and regulatory agencies.

Effective practices need not be complex, electronic, and expensive; paper-based solutions are frequently easier to initiate and within the reach of many practices. Through its Office Practice Evaluation program, CRICO/RMF has compiled a comprehensive catalogue of best practices found in office settings. *What Works: Effective Practices for Office-based Care* is available through the CRICO/RMF web site at www.rmfm.harvard.edu/patient-safety-strategies/office-practices. ■

No Screening Test Offered

A 62-year-old woman with a family history of colon cancer and personal history of abdominal pain, anemia, and weight loss was not offered colon cancer screening before she was diagnosed with metastatic colon cancer.

by Jennie Wright BA, RN, and Patricia Dalton

Ms. Wright is Risk Assessment Program Manager for CRICO/RMF. Ms. Dalton is a CRICO/RMF Claims Manager.

CASE STUDY

Key Lessons

- Primary care physicians should universally offer appropriate health screening per age, gender, and risk factors, and document any patient refusal.
- Do not assume that a patient will refuse recommended screening.
- Extend and document outreach for patients who fail to keep scheduled examinations.

Clinical Sequence

A 62-year-old female patient presented in April 1997 to her long-time PCP with complaints of blood in her stool. A guaiac test in the office was negative. Her medical history included hypertension, arthritis, peptic ulcer disease, obesity, and coronary artery disease. She had never received colorectal cancer screening. Based on a 20-year relationship that included frequently missed appointments, the physician believed she would refuse screening tests for colorectal cancer.

The patient returned in July with abdominal pain. The physician prescribed an H₂ blocker and noted a plan to obtain an upper right quadrant ultrasound if she had no improvement in her symptoms. No evidence of a stool guaiac or patient-reported bloody stool was documented.

Failing to keep the next two appointments, the patient presented in August of the same year with improvement of her abdominal pain and a stable weight. She was not anemic, and a CEA was within normal limits.

During the next two years, the patient was seen for chest, abdominal, and back pain, as well as hypertension. She was prescribed Biaxin and Prilosec for presumptive H. Pylori. No evidence of a comprehensive examination during this period, or the years prior, was documented.

In June 2000, a comprehensive examination noted a nine-pound weight loss, and a review of systems was characterized as negative “in general.” Documentation does not include family history. (Subsequent legal investigation revealed that the patient’s sister had died of colon and lung cancer in 1997.) The patient had a pelvic exam during this visit, and subsequently a screening mammogram. Lab results included low MCV/MCH; hemoglobin was 12.1, and hematocrit was 37 percent, both on the low end of the normal range and decreased somewhat from previous measures. Recommendations on the lab sheet suggest follow up to include additional hemoglobin and stool tests.

The patient next presented to the practice in October, with a tooth infection. Follow-up included an appointment with her physician, which she did not keep.

In December, the patient went to the ED complaining of chest and abdominal pain. Chest X-ray was positive for pulmonary nodules and suggestive of metastatic disease. She died from metastatic colorectal cancer a month later.

Allegation

The patient’s children sued both the PCP and the medical group, alleging failure to provide proper screening and testing, resulting in a delay in diagnosing colon cancer.

Disposition

The case was settled in the high range (>\$500,000).

Inadequate documentation was key to the settlement of this case. The record includes no initial evaluation or work-up, no family or social history, no medication list or charting of health maintenance. Despite the fact of a sister who died of colon cancer, the patient was not offered appropriate screening.

The PCP’s reasoning that the patient’s history of non-compliance influenced his non-recommendation of a colonoscopy was not supported by expert reviewers; it should have been offered and documented. Experts felt that the standard of care was not met since the patient was not offered appropriate screening due to presumed refusal.

Analysis

1. The patient did not receive colorectal cancer screening appropriate to her risk, based on age, presentation, or family history.

Current guidelines from CRICO/RMF and national organizations recommend that everyone over the age of 50 receive some type of screening for colorectal cancer. Patients with symptoms, such as anemia, weight loss, or rectal bleeding should be referred to a specialist for a complete diagnostic workup. A single fecal occult blood test (FOBT) in the office alone does not qualify as a diagnostic workup nor adequate screening.

2. The physician did not know the patient’s sister died of colon cancer, and a family history was not documented.

Family history should be updated annually, as it is subject to change and may affect cancer and disease screening. The use of a questionnaire or prompt on an exam template can facilitate this process. Patients who refuse or are unable to complete the questionnaire should have an oral review of risk factors, including family history, and notes about the conversation should be put in the medical record.

3. The patient was not approached about a colon cancer screening test. The physician’s long term relationship with the patient, and her history of missed appointments, resulted in his making assumptions of her probable refusal for an FOBT series or a colonoscopy, even though she had been willing to undergo cervical and breast cancer screening.

Continued on [page 7](#)

Failure to Act on Incidental Finding

A 62-year-old man died from lung cancer nearly two years after X-rays in the ED, following a fall, revealed an incidental finding of a lung nodule.

by Jennie Wright BA, RN, and Peter McCormack, JD

Ms. Wright is Risk Assessment Program Manager for CRICO/RMF. Mr. McCormack is a CRICO/RMF Claims Manager.

Key Lessons

- Miscommunication of abnormal test results and failure to designate a service for follow-up can lead to serious consequences.
- A clear process for notifying the responsible service must exist to ensure adequate communication of important incidental findings.
- PCPs need processes to ensure that they receive and view all abnormal test results relating to their patients.
- Thorough review of tests and adequate documentation in the medical record help establish physician credibility when defending against subsequent allegations of negligence.

Clinical Sequence

On November 26, 1999, a 62-year-old man was evaluated in the ED for shoulder injuries following a fall. He was a one-pack-a-day smoker for many years, and had a history of depression and low back pain. Workup included a left shoulder and chest X-ray, which the ED physician read as showing no fracture or other significant findings. The patient was discharged home with a diagnosis of shoulder contusion and pain.

Four days later, a radiologist performing the final X-ray interpretation noted a nodule in the left lung and recommended follow-up. Per departmental procedure, the radiology report was faxed to the ED and a copy was sent to the PCP. The radiologist did not call either the PCP or the ED.

On December 21 and 31, 2000, the patient saw his PCP for symptoms of back and shoulder pain related to his accident. He was referred to physical therapy and orthopedics. Documentation does not indicate that the prior ED X-rays were present and/or reviewed by the PCP.

In August 2001, the patient presented to the ED with chest and shoulder pain. A chest X-ray was read as normal by the ED attending. Post-discharge, the final reading of this X-ray was abnormal, with a large mass in the left lung. The PCP was not on call when this event occurred; the patient was not made aware of this finding.

In September 2001, the patient saw his PCP for muscular pain. A shoulder X-ray was normal. Treatment included continuation of pain killers and physical therapy.

On October 17, 2001, the patient presented to the ED with intermittent back and chest pain. A chest X-ray showed 75 percent white-out. The patient was admitted to the hospital where a CT scan revealed a left hilar mass with metastases. Subsequent CT scans revealed widespread metastatic disease.

His died within a week.

Allegation

The patient's children sued the ED physician, radiologist, and PCP alleging failure to identify and follow up on a lung nodule, resulting in the patient's death from lung cancer.

Disposition

The case was settled in the high range (>\$500,000).

The providers who treated this patient relied on informal norms that had evolved in each of their clinical settings (in Radiology, the norm was not to call the ED with abnormal findings; in the ED, the norm was not to have a specific person take ownership of communicating abnormal test results; in the physician's office, the norm was not to "flag" the abnormal radiological reports before they ended up in the chart). With these norms as the backdrop, it was impossible to obtain trial experts who could effectively defend the care that the entire system provided to the patient. While there was a causation defense related to the ultimate prognosis for this type of lung cancer, it was not definitive and was solely of value as a negotiating tool.

Analysis

1. Although each service operated strictly within the expectations of its domain, the PCP was unaware of an important incidental finding. Neither Radiology nor the ED had reliable processes to ensure communication and receipt of this finding to either the PCP or the patient.

Establishing protocols regarding who is responsible for ensuring the communication of an incidental X-ray finding to the appropriate physician for follow up can avoid the problem of "no one" being responsible. Independent services need to collaborate to clarify responsibility, set clear expectations, and develop reliable and verifiable processes to assure that worrisome test results are brought to the attention of the PCP. Validation that they have been received by the PCP (or covering physician) is a critical step to ensure that results have been received and seen by the appropriate parties. Designated staff may be assigned to manage the process, thereby reducing physician workload while ensuring completion of the process and minimizing risk.

2. This patient presented to multiple providers, including his PCP, with back and shoulder pain. From his perspective, he was acting appropriately, both in seeking emergency care and following up with his PCP at the right intervals. He expected that all information obtained in the ED would be reviewed by the PCP as part of his examination. His family contended that his PCP's failure to obtain and review the findings resulted in a delay in his diagnosis and treatment and potentially limited his life expectancy.

Most patients are unaware of the complexities of ensuring that diagnostic tests reach the appropriate provider, and—not unreasonably—expect that the clinician will review the relevant information prior to determining a treatment plan. All relevant information should be readily available to the treating provider and it is his or her responsibility to have that information at the time of the visit. Both hospital and office-based processes are necessary to ensure that this expectation can be met.

3. Lack of a process to ensure provider review of all incoming test results, and review of this patient's chart in the office, created several missed opportunities for earlier diagnosis of this cancer.

PCPs are responsible for overseeing their office-based processes. They need to be involved in the development and oversight of test result management systems in order to ensure that they view all relevant test results without fail. Physicians cannot act on abnormal results that they don't see. The presence of a radiology report in the patient's chart that was filed without the PCP's review indicates a failure in the test result management process.

4. Expert reviewers for the defense could not support the physician's documentation practices nor his admittedly inconsistent practice of reviewing the record prior to the visit.

Review of previous notes and test results prior to a patient's visit is essential to making a full patient assessment and timely diagnosis. Documentation should always include clinical rationale for decision-making and a prescribed treatment plan. Scant documentation of a patient's history or the components of the evaluation not only undermines subsequent care, it may contribute to a perception of inattention to detail and a lack of credibility in any subsequent litigation.

No Screening Test Offered

A long term relationship between patient and physician is usually a positive attribute and patients often take very seriously the recommendations of a trusted doctor. Knowing a patient very well can lull a clinician into a lack of objectivity. Willingness to undergo other screening tests can suggest willingness to undergo colorectal cancer screening. Regardless of the relationship, all diagnostic and screening tests should be reviewed with the patient. Counseling, education, and physician recommendations along with patient response, including deferral or refusal, should be documented.

4. This was a non-compliant patient, who missed many appointments and requests to follow up over 20 years.

Patients who routinely fail to keep appointments are at risk for "loss to follow-up." The physician should be made aware of patients who fail to keep an appointment or repeatedly cancel appointments so that he/she can review the record and initiate appropriate outreach. All outreach efforts should be documented in the medical record.

5. The patient was not notified of the need for follow-up testing for June 2000 blood work when she returned to the practice for episodic care in September. Lack of office practice processes to ensure continuity resulted in failure to follow up on an abnormal test result, even when the patient was in the office with another complaint.

Recommendations for follow-up should be prominently displayed in the medical record either on the problem list, or in the MD notes. Providers should routinely review documentation of previous visits before evaluating a patient with an episodic concern, and ongoing problems should be addressed with the patient at that time.

6. Scant documentation with illegible components made it difficult to determine whether there was appropriate patient assessment and appropriate clinical rationales.

Difficulty in deciphering notes and minimal documentation impedes the ability to defend a claim. Lack of documentation of a family history and evidence of discussion of screening pose obstacles for the defense. Standard templates, including patient questionnaires and physical examination forms with prompts for age and gender-appropriate health screening and counseling, can encourage appropriate documentation.

Are PCPs Nearing Extinction? An Interview with Dr. Richard Parker

by Debbie LaValley, BSN, RN, and Jock Hoffman

Ms. LaValley is a Senior Loss Prevention Specialist for CRICO/RMF and Issue Editor of Forum. Jock Hoffman is Editor of Forum.

The erosion of the enjoyable aspects of practicing general medicine in an office practice is well chronicled. Vacancies are becoming harder to fill and keeping established providers from seeking alternatives is difficult. Selling primary care as a career choice is a tough challenge in light of the stresses and strains imposed on those who choose that path.

But, then again, complaining about your job is as American as apple pie. What *Forum* wanted to examine was how this evolution in health care delivery is affecting patient safety. To explore that, we spoke with Dr. Richard Parker, an internist at Healthcare Associates, Beth Israel Deaconess Medical Center (Boston) and Medical Director for the Beth Israel Deaconess Physician Organization. Dr. Parker occasionally serves as an expert witness in medical malpractice trials.

Forum: Dr. Parker, how do the challenges that internists face these days impact patient safety?

Richard Parker: Doctors are asked to see patients even faster than we used to just a few years ago: it is now 30-40 minutes rather than an hour for a new visit, and just 20 minutes instead of 30 minutes for a follow-up visit. That substantially increases the risk of the doctor missing something important that could lead to an adverse outcome. A doctor needs to be thinking clearly, needs to be at least a little bit relaxed, needs to be paying attention to the patient. He or she has to be in a reasonable frame of mind to do the work.

How can a physician prepare to be in that frame of mind when he or she comes into the office in the morning?

We need to pay more attention to the whole issue of morale. I believe that doctors who feel good about their work, who are generally well rested, who feel supported by their practice on a daily basis, who feel supported by their leadership, and who have a reasonable schedule, are more likely to connect better with their patients and have fewer adverse events. The converse of that is doctors who feel stressed, harried, pushed around, and uncared for. Quite likely, the work product that comes out of those people is not going to be as good.

Let me give you an example: imagine a complicated patient calls on a Friday afternoon. The satisfied physician is more likely to say, "Yes, I will add Mrs. Jones onto my schedule. She has a fever and a rash and I know her well and I need to see her."

The doctor who is unhappy, or perhaps even depressed, may be more likely to say, "You know what? That's not my job. She can go to the ER, or someone else will have to take care of it." Those little decisions, on the margins, can really have an enormous effect on the outcome for a patient.

Is primary care really losing its appeal among physicians, or is that just an urban legend?

The marketplace is speaking. We have seen a growing difficulty in hiring and retaining high quality internists because many of them perceive the job as overworked, underpaid, and not worth the stress. I dearly hope that the market and the system will adjust so that this very important job, which includes coordination of care for ill individuals—as well as being on the frontline of diagnosing diseases and caring for chronic diseases—is appropriately valued once again.

How do we do that?

Like anything else, before you can have a treatment you need the diagnosis, and the diagnosis to this problem resides partly in the Medicare fee schedule which codifies how internists and procedural specialists are paid. Specialists have been very successful in lobbying in Washington for rates of reimbursement higher than those for nonprocedural doctors. That has to be corrected in order to right the balance between procedural and nonprocedural physicians.

What can patients do to get better care?

Act like a lobbyist. Patients who advocate for themselves in an organized fashion probably get better care. An organized patient prepares ahead of time. Even though doctors may cringe when they see "the list," at least they can ask the patient which are the most important items for today's visit and then, if there is not enough time, invite the patient to return another day to cover the remaining concerns.

Why would a physician cringe?

Because a physician seeing a patient who comes in with a list of 12 problems will often not be able to satisfy that patient during that visit; there is not enough time. Doctors can, however, communicate very effectively in short periods of time, so the brief visit can be used efficiently. But that often means talking less, listening more actively, and paying close attention to expectations.

What gets in the way of the doctor doing a full assessment?

One issue is the patient who comes in with an agenda ("the list")—perhaps with multiple physical and emotional problems on her mind—and we never get around to the cancer screening issues. That is where a systems approach can help remind the doctor that this patient still has not had a mammogram, Pap smear, or colon cancer screening. Regardless of the patient's episodic agenda, the physician is obligated to have a system to keep track of health maintenance needs.

A different sort of challenge is presented by the patient who comes in with a constellation of symptoms that seems confusing and cannot be solved in one visit. In this situation, the physician needs to ensure follow-up to go over the problem again and review all data already gathered. If the patient is referred to a specialist, two-way communication assures that the specialist knows the question being asked and that the internist hears the specialist's opinion. If the problem remains unresolved, the internist is responsible to oversee the ongoing care and keep the door open to further investigation.

Can technology help?

Yes, but not all EMRs (electronic medical records) are created equal. Some systems can be very helpful and some can be downright irritating. And, some can be both! When a system ends up nattering in the faces of doctors so frequently with reminders about this, that, and everything, then the doctor begins to tune out most, if not all, of it. When the system that is supposed to be the solution does not take human factors into account, it becomes neutralized.

On the other hand, a good information system, set up correctly, can really help doctors not miss things. But of course, good information systems are very expensive to set up and incur significant time costs (missed work) for doctors in the transition from paper to EMR. It is a complex and expensive undertaking, which explains why it is not as prevalent as it should be.

Is there a way to make that EMR "noise" useful for reminding the practicing internist to do the colonoscopies, mammograms, et cetera?

Systems or no systems, noise or no noise, physicians are responsible for the care of their patients. I am responsible to make sure that my patients over the age of 50 get screened for colon cancer. Certainly, I welcome any help the EMR or the staff can give me. The tough question is, what works best?

The leadership within an organization must set the priorities. Real leadership means including the physicians on the front line in the discussion. For example, we might ask of our primary care providers "Focus on screening for colon, breast, and cervical cancer, and we will put the systems and staff in place to help you accomplish those goals." The leadership within an organization decides what the priorities are and then engages the doctors and staff in accomplishing the goals.

Is the doctor responsible for contacting no-show patients and helping to reschedule the test?

The doctor's responsibility is proportional to the gravity of the diagnosis for which the test was ordered. If I think a patient has active tuberculosis, and I send him for a chest X-ray, and he doesn't go for it, then I had better take every step imaginable to get that patient back in here to get that chest X-ray.

On the other hand, if I send a teenager with a possible toe fracture upstairs for an X-ray, and she decides not to get it, I don't think anyone thinks I need to chase her down.

Who's responsible for closing the loop on abnormal results and referrals?

It depends.

Say, for example, a physician detects a worrisome breast lump and advises the woman to obtain a mammogram and see a surgeon. The high intensity of that situation obliges the physician to make sure she goes for that test, even to the extent of (if necessary) repeated letters and phone calls (which should be documented). On the other hand, say the physician advises a patient to get labs done for cholesterol and the patient declines. The physician has much more discretion about whether to chase down that patient.

In my practice, I send letters to every patient who has a test and I find that it provides a safety net. If I miss a test result and the patient doesn't get a letter, they call me up and ask why. I realize that many of my colleagues may feel they don't have the time to do that but, whatever system they do use, they are responsible for tests that they order.

What is the internist's role when test results come back with an unanticipated abnormal finding, such as a pulmonary nodule on a chest X-ray?

The doctor who orders the test is responsible for reading the entire report and acting on any significant abnormalities. This represents a major burden for internists as he or she reads so many reports each day. Part of the problem here is information overload. We are ordering more tests than ever before.

Is that unreasonable?

Yes. Patients request too many tests and doctors order too many tests. Often, doctors feel pressured to order the tests because they are afraid of missing something (and then being sued). But, excessive testing leads to false positives that then lead to yet more expensive testing, often with procedures that have morbidity associated with them. In the end, it is not of benefit for the patient and it drives up health care costs.

When patients see more than one physician, whose job is it to coordinate their care?

When doctors are working within the same system—more specifically, when they are using a shared electronic medical record—the coordination of care is fairly easy. Doctors and nurse practitioners can forward their notes to each other and share them along with labs, X-rays, reports, et cetera in a medical record that everyone has access to.

Where Errors Occur: Inadequate Family and Medication Histories

by Jeffrey L. Schnipper, MD, MPH

Dr. Schnipper is the Director of Clinical Research for the BWF Hospitalist Service and Associate Physician in the Division of General Medicine at Brigham and Women's Hospital (Boston), and Instructor in Medicine at Harvard Medical School.

One of the first tasks taught during medical training is taking a complete and accurate medical history. Billings and Stoekle, in *The Clinical Encounter: A Guide to the Medical Interview and Case Presentation*, explain that one of the purposes of the medical interview is to elicit the “standard database” on each patient, including the past medical history, medications, allergies, family history, and social history.¹ However, while these tasks are quickly learned during medical training, it is clear that obtaining and maintaining a complete and up-to-date database—and providing that information when needed to all medical personnel—is hindered by the complexity of our health care system, advances in medical science, and the aging of our population. Two particular pieces of this database, family history and medication history, are recognized as places where errors occur, errors that can lead to patient harm if not corrected.

Family History

Family history often provides the first clues that a patient may be at high risk for developing certain conditions. While the primary care provider (PCP) is on the front line for making this identification, this process is less than ideal in most office settings.² Malpractice data show that many high-risk patients are not in fact identified, even those with strong family histories (see [LaValley, page 1](#)). (Equally troubling are those cases in which the risk was identified, but proper action, such as increased surveillance, risk factor modification, and/or genetic testing, was not always taken.) As the genetic basis of more conditions is identified and the potential to take action increases, failure to take and update a patient's family history will expose providers to greater liability.

One recent study at Partners Healthcare³ illustrates this problem: 53 percent of patients surveyed had no easily retrievable family history information in the electronic health record (at Partners, the Longitudinal Medical Record, or LMR).⁴ When asked about six medical conditions (coronary artery disease, colon cancer, breast cancer, diabetes, osteoporosis, and glaucoma), from 12–41 percent of the 163 patients reported positive family histories. For 82–97 percent of those cases, *the survey was the only source of this information*, i.e., it was not documented in the medical record. Depending on the condition, this information increased the patient's risk level for developing the disease in 33–95 percent of cases. The study also found that communicating this new family history information to physicians through an electronic clinical message and note in the LMR *was not sufficient* to achieve recommended follow-up care in the majority of cases.

The causes for this problem include:

- patients are not always aware of their family histories;
- physicians are not trained in taking a complete family history;
- physicians do not have time to take a complete history during a typical office visit;
- family histories are collected infrequently, sometimes only at the first encounter;
- family history, when collected, is often incomplete, i.e., without enough information to calculate risk (e.g., degree of relatedness, age of onset); and
- even if the provider has all the information, he or she does not have enough guidance on appropriate actions to take.

The solutions are difficult, especially with ever-shorter medical visits. Provider training, process redesign, and information technology are needed to ensure that family histories are taken properly, and updated regularly. Provider training should focus on taking a complete history, including the relationship of each family member to the patient and age of onset of the condition (see *accompanying Tips*). Process redesign could include having patients or caregivers complete structured family history forms, e.g., in the waiting room, perhaps with the help of medical assistants. PCPs could then verify this information during the visit and add the annotated form to the medical record. These forms could include guidelines to risk-stratify patients and recommend specific follow-up actions.⁵

Lastly, information technology could facilitate this process. For example, Partners Healthcare has developed a module within its shared electronic patient portal (Patient Gateway) that asks patients to update their family history online in the weeks prior to an upcoming visit.⁶ The system uses branching logic to simplify data entry and focus on conditions where evidence-based actions are most likely to be needed. During the visit, the PCP can verify the information and add it to the medical record. Regardless of how the information is entered, the Partners LMR allows for family history data to be stored in a structured format, automatically calculates the risk level for the patient, and provides decision support on actions to take.

Medication History

Perhaps an even bigger threat to patient safety are problems that arise from an incomplete or out-of-date medication history. Outpatient medication lists, even within electronic medical records, are notoriously inaccurate. In another recent study at Partners of 936 patients taking 5,799 medications, a survey found that:

- two percent of the medications listed in the LMR were never taken,
- 10 percent were being taken differently than indicated in the record,
- 22 percent were no longer being taken, and
- patients in the study were taking an additional 308 medications that were not in the LMR medication list.

The causes for such inaccuracies are many. Patients may have multiple outpatient providers, each of whom prescribes a subset of a patient's medications, and none of whom may have the knowledge of all the patient's medications nor responsibility for ensuring the accuracy of the regimen as a whole. Incomplete data sources and communication among providers and patients may exacerbate this problem. Patients may not fully understand their medication regimens.⁷ Finally, acute care hospitalizations and subsequent discharges home often lead to drastic changes in medication regimens along with inadequate patient education, discontinuity of care, and miscommunication among providers.⁸⁻¹¹

Medication discrepancies, i.e., unexplained differences between regimens patients think they should be taking and those ordered by their physicians—or between documented regimens across different sites of care—are common, especially after hospital discharge.¹² In a study at Boston's Brigham and Women's Hospital (and consistent with other studies), approximately half of all patients have at least one unexplained medication discrepancy at the time of hospital discharge compared with their preadmission regimens.¹³ Moreover, just three days after discharge, 29 percent of patients had an unexplained discrepancy between the discharge medications and what they were actually taking. One month after discharge, 90 percent of LMR medication lists had at least one error.

Solutions to this problem will, again, need to be multifaceted. Physicians need guidance on taking an accurate medication history (*see Tips*). When possible, patients should be encouraged to keep their own medication histories (forms can be found on the AARP web site,¹⁴⁻¹⁵ among other places) and to update them whenever they see a medical provider, go to a pharmacy, change a medication, or at least twice a year. If patients or non-clinical caregivers are incapable of maintaining the list, then the PCP may want to take responsibility for maintaining this list and communicating with a patient's other providers.

The Joint Commission now requires hospitals to reconcile inpatient and discharge medications with a patient's preadmission medications, and to then communicate that information to the next provider of care.¹⁶ This process must be followed up

Tips for Taking an Accurate Family History

1. Focus on those conditions (below) for which a) the disease burden is high, b) family history can be accurately reported and is an established risk factor, c) evidence-based interventions for prevention exist, and d) family history alters management decisions:
 - colon cancer
 - breast cancer
 - coronary artery disease
 - diabetes mellitus
 - osteoporosis
 - glaucoma
 - asthma
 - stroke
2. A full family history for breast and colon cancer should include other associated cancers, e.g., endometrial, ovarian, stomach, kidney, bladder, pancreatic, and brain cancer.
3. Ask about all first-degree and second-degree relatives: parents, siblings, children; aunts, uncles, grandparents, nieces, nephews, grandchildren, and half-siblings.
4. Ask about the age of onset for each relative.
5. Make sure patients understand not to include relatives by marriage, but to include relatives who are no longer alive, and to include paternal relatives for female conditions such as breast cancer.

Tips for Taking an Accurate Medication History

1. Ask about:
 - medication allergies and reactions;
 - a typical day and what medications the patient takes at different times of the day;
 - if the patient receives medication prescriptions from more than one provider (obtain contact information for each provider);
 - the patient's local pharmacy(ies) and phone number or town;
 - how sure the patient is of his or her medications and who best knows the medications;
 - various types of medications: tablets, oral liquids, eye drops, ear drops, nasal sprays, inhalers, patches, creams, lotions, injections, suppositories;
 - over-the-counter products, herbals, vitamins, and supplements;
 - the indication for each medication;
 - the strength, dose, and frequency of all medications (e.g., one 20mg tablet twice a day; 440 mcg inhaler, two puffs twice a day);
 - as-needed medications and how often the patient uses them;
 - how long the patient has been taking each medication;
 - the last time the patient took each medication;
 - how many doses (if any) the patient has missed in the last week (explore reasons for non-adherence: cost, access to a pharmacy, lack of appreciation of need for medication, side effect, etc.); and
 - potential side-effects: type, duration, severity, previous actions taken by patient and prescriber.
2. Compare patient/caregiver information to objective sources of information: e.g., prescription pill bottles, outpatient medication lists, recent discharge or transfer orders, pharmacy refill information.
3. Explore discrepancies among the various sources of information.
4. Obtain additional objective information if the patient is unsure of medications or any discrepancies among sources.

Continued on next page

Continued from [previous page](#)

with post-discharge medication reconciliation, ideally during the patient's first post-discharge visit with his or her PCP. This requires a review of what medications the patient was taking prior to admission, the discharge medication regimen, and the patient's clinical status, and then creating a new post-discharge medication list to be communicated with the patient and all providers. Partners is working on a post-discharge reconciliation screen within its LMR, but paper processes are also feasible.¹⁷ Going forward, medication information, including lists from outpatient electronic health records and hospitals, as well as pharmacy and claims information, will need to be available in a standard electronic format that can be communicated across all sites of care so that an accurate medication list can be obtained wherever care is delivered. ■

References

1. Billings JA, Stoecle JD. *The clinical encounter: a guide to the medical interview and case presentation*. Chicago: Year Book Medical Publishers, Inc.; 1989.
2. Murff HJ, Byrne D, Syngal S. Cancer risk assessment: quality and impact of the family history interview. *Am J Prev Med* 2004;27:239-45.
3. www.partners.org
4. Volk LA, Staroselsky M, Newmark LP, et al. Do physicians take action on high risk family history information provided by patients outside of a clinic visit? Paper presented at: MedInfo, 2007; Brisbane, Australia.
5. For example, the CRICO/RMF Breast Care Management Algorithm and the CRICO/RMF Colorectal Cancer Screening Algorithm both feature a risk assessment checklist that includes family history in guiding providers to the appropriate level of testing.
6. Wald JS, Middleton B, Bloom A, et al. A patient-controlled journal for an electronic medical record: issues and challenges. *Medinfo* 2004;11:1166-70.
7. Kripalani S, Henderson LE, Chiu EY, Robertson R, Kolm P, Jacobson TA. Predictors of medication self-management skill in a low-literacy population. *J Gen Intern Med* 2006;21:852-56.
8. Alibhai SM, Han RK, Naglie G. Medication education of acutely hospitalized older patients. *J Gen Intern Med* 1999;14:610-16.
9. Beers MH, Dang J, Hasegawa J, Tamai IY. Influence of hospitalization on drug therapy in the elderly. *J Am Geriatr Soc* 1989;37:679-83.
10. Kripalani S, Phillips CO, Basaviah P, Williams MV, Saint SK, Baker DW. Deficits in information transfer from inpatient to outpatient physician at hospital discharge: a systematic review. *J Gen Intern Med* 2004;19 (S1):135.
11. Calkins DR, Davis RB, Reiley P, et al. Patient-physician communication at hospital discharge and patients' understanding of the postdischarge treatment plan. *Arch Intern Med* 1997;157:1026-30.
12. Coleman EA, Smith JD, Raha D, Min SJ. Posthospital medication discrepancies: prevalence and contributing factors. *Arch Intern Med* 2005;165:1842-47.
13. Schnipper JL, Kirwin JL, Cotugno MC, et al. Role of pharmacist counseling in preventing adverse drug events after hospitalization. *Arch Intern Med* 2006;166:565-71.
14. American Association of Retired Persons. Mi registro de medicacion. http://assets.aarp.org/www.aarp.org/_articles/health/docs/PersonalMedRecordSP.pdf. Accessed October 20, 2006.
15. American Association of Retired Persons. My Personal Medication Record. http://assets.aarp.org/www.aarp.org/_articles/learntech/wellbeing/medication-record.pdf. Accessed October 20, 2006.
16. See 2007 National Patient Safety Goals 8, 8A, and 8B: www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/07_hap_cah_npsgs
17. Several examples are available in *What Works: Effective Practices in Office-based Care* at www.rmfi.harvard.edu/patient-safety-strategies/office-practices.

Continued from [page 9](#)

Where I see problems occurring most is when patients obtain care at different systems. They come to see one doctor at Hospital A and go two blocks down the street to Hospital B and see another doctor who does not have access to Hospital A's information system. Communication cannot be as good under these circumstances. I have seen a number of lawsuits filed because patients went to multiple medical centers and no one person knew all of what was going on... and things were missed.

Whose responsibility should it be for coordinating such situations?

It is always easy to say that it should be the internist, but I think that if the internist has encouraged the patient to stay within the institution—so that continuity of care can be achieved—and the patient still chooses to go out of the system, then it is harder for the internist to be held completely responsible. Doctors do need to communicate across institutions, but we need to better educate patients who choose to go across institutions that there may be problems with the coordination and the continuity of their care. Of course, the ultimate solution is having all doctors and hospitals on one information system like Great Britain, Denmark, and the Veterans' Administration have achieved.

Are office staffs being asked to do too much, or not enough?

Better allocating of staff roles can improve care and decrease adverse events. For example, our practice cares for approximately 40,000 patients. Rather than relying on the memories and abilities of individual physicians, it may make more sense to have nurses look at patient registries and medical records to find out who might be missing a screening test.

Are hospitalists helping primary care providers?

It depends. Hospitalists are well trained, have the advantage of being on site most of the day, and provide a high level of care—those are all pluses. On the negative side, hospitalists, by definition, are unfamiliar with most of the patients who get admitted. They may not know some of the subtle historical issues that could be important about any given patient. I do know that our hospitalists work hard to communicate with the referring doctors during the hospitalization and at the time of discharge. That's another place where electronic medical records and systems can really facilitate the communication of accurate medication lists that are vital.

Why do people choose general internal medicine as a career?

People who are dedicated to caring for patients over a long period of time and enjoy building relationships with patients—and even their families—are best suited for internal medicine. I saw a patient in the hospital today with pneumonia complicated by myocardial infarction, someone whom I have cared for for 20 years. When he saw me, he broke in to a big smile. ■

Management of Critical Test Results: The North Shore Medical Center Experience

by Anthony J. Guidi, MD

Dr. Guidi is the Chair, Department of Pathology, North Shore Medical Center (Salem, MA) and leader of the NSMC Communicating Critical Clinical Information Committee.

The management of critical test results (CTR) represents a significant challenge for diagnostic centers and ordering physicians. Mismanagement of CTRs, many of which reflect potentially life-threatening conditions, has led to adverse patient outcomes and consequent malpractice claims against physicians who order tests, physicians who interpret tests, and health care organizations that manage the communication process. For these reasons, compelling “drivers” for communication improvements include the Joint Commission, the Massachusetts Coalition for the Prevention of Medical Errors, and various risk management organizations.

Several years ago, North Shore Medical Center (NSMC) assembled a multidisciplinary committee to develop and implement systems to comply with the standards related to CTRs promulgated by the Joint Commission and the Mass Coalition. Included were physician and non-physician stakeholders representing both diagnostic centers and caregivers on the receiving end.

The first task required stratifying laboratory, radiology, and cardiology results into levels of urgency. Using the priority template suggested by the Mass Coalition, we defined:

- **red** as true critical, or “panic” results requiring acknowledged communication within minutes (e.g., potassium ≥ 6 mmol/l);
- **orange** as time sensitive results (but less urgent than red) requiring acknowledged communication within hours (e.g., EKG with new atrial fibrillation); and
- **yellow** as results requiring acknowledged communication within days (e.g., new lung nodule on chest X-ray).

Challenges to the development of the CTR lists included the fact that a) not all physicians agree on thresholds; b) the same test result may have different implications in different clinical settings; and c) due to the varied and subjective nature of many radiology results, it was difficult to formulate detailed lists. Nevertheless, we achieved consensus lists that require periodic review and modification.

Determining modalities that allowed effective, efficient, and documented communication of CTRs required the greatest time investment for the committee. Implementation of these modalities, and development of reliable metrics to gauge the success of the process, proved to be challenging.

Early on, we realized that we could not have a “one size fits all” solution appropriate for all diagnostic centers due to: a) the difference in the volume of lab CTRs (35,000 per year) compared with radiology CTRs (5500 per year); and b) the difference in the nature of most lab CTRs (numeric, instrument-derived, predominantly red and orange) compared with radiology CTRs (textual, radiologist-derived, predominantly orange and yellow).

Moreover, the varied nature of the medical staff receiving the information proved challenging. Because NSMC has a mix of employed and private practice physicians, as well as network and non-network physicians, there was much diversity with respect to the use and/or adoption of network pagers, answering services, e-mail, and other communication methods. The committee realized that, because adoption of a standard communication modality among diverse physicians was unlikely, the processes and technologies had to offer flexibility while still ensuring reliable and timely communications.

The NSMC Radiology Solution

For its relatively low-volume radiology CTRs, NSMC chose to implement the Voicelink system (*see www.Vocada.com*) that allows a radiologist to dictate a critical or priority test result as a voicemail message. That message can then be automatically delivered to the ordering physician using a variety of devices (pager, cell phone, answering service, e-mail) in a manner customized to the preference of the receiving physician, and appropriate to the level of urgency of the result. If the first communication is unsuccessful, Voicelink is programmed to pursue a number of escalation strategies to make sure the result is received. If the escalation efforts fail, Radiology is notified of the failure and can then activate secondary fail safe procedures. All communications are automatically documented by the system.

The NSMC Laboratory Solution

For the high volume laboratory CTRs, NSMC has employed a module (Callback) offered by its laboratory information system. This module allows all pre-defined CTRs to flow to client service representatives as soon as the test is completed. Callback displays the contact information of the ordering physician, and allows the client service representative to document details of the interaction, including the name of the recipient and verification of the Joint Commission read back process.

Results

Implementation of Voicelink and Callback each required a vigorous education campaign for test centers and ordering physicians. Both systems have allowed NSMC to develop metrics that have proven useful for identifying failed communications, thereby allowing root cause analyses and further process refinements. Currently, NSMC communicates CTRs successfully (within goal timeframes) 98.5 percent of the time. Although both systems have inherent limitations, both have given NSMC much more reliable communication strategies for CTRs than existed one year ago. That *should* translate to better patient care. ■

Closing The Loop For Specialty Referrals at MGH Senior Health

by Katherine Hesse, MD, MSW

Dr. Hesse practices geriatric medicine at Massachusetts General Hospital.

Geriatric patients often have multiple medical problems requiring coordination of care with many different specialists. The complexity of these patients' medical needs requires the primary care physician (PCP) to be even more vigilant of new diagnoses, new study results, and, especially, new treatment plans. Medication interactions, medication side effects or contraindications, patient understanding of the disease process, and patient compliance are challenges faced when a physician diagnoses a new condition or prescribes new treatments for older patients. As part of the diagnostic process, patients may be referred to specialists for consultations; a process fraught with many potential communication and handoff issues.

Timely communication between PCPs and specialists is critical, but often is inefficient. Because of variations in practice patterns, specialty consultation notes containing vital information may be delayed and errors in treatment may occur because the PCP is not "up-to-date" with the plan. Prompt knowledge of the specialist's advice by the PCP is required for safe patient care.

Geriatric patients also may have additional problems that can interfere with successful specialty referrals. Communication difficulties (hearing and/or vision), cognition problems (dementia) and social limitations (problems with transportation, family assistance, finances) may result in missed appointments and misunderstanding of the advice given. In addition, the patient may not be able to provide the specialist with needed information for the consultation—especially troublesome if the specialist cannot readily access critical referral information sent from the PCP.

MGH Senior Health, a primary care geriatric practice affiliated with Partners Healthcare (Boston), identified several difficulties the practice and its patients were experiencing making successful referrals. The solution was a proactive system based on the Partners Longitudinal Medical Record (LMR) and its integrated Clinical Message system, an internal e-mail.

Patient Appointments

Recognizing that patients often have difficulty making appointments with specialists (e.g., the specialists are not taking new patients, have too narrow a specialty, require long waits for appointments, or employ complex office phone trees/voice mail systems), Senior Health integrated specialty referrals into its routine practice. Now, when a PCP wishes to refer a patient to a specialist, the clinical liaison (a support staff position) is notified by Clinical Message and the request is saved in the

LMR. The request includes the specialty, preferred consultant, diagnosis, the referral question, timeframe, and relevant notes. With this information, the clinical liaison is able to schedule a specialty appointment and provide necessary information. In addition, for those specialists who use the LMR, the referral information is readily available for review at the time of the appointment. For those who do not use the LMR, the clinical liaison will fax the information to the specialist.

The patient is given a letter with the appointment information including the physician, date, time, place, phone number, and directions (all recorded in the LMR). The clinical liaison then sets up a reminder to call the patient one day prior to the scheduled appointment. The key event, however, is a post-dated message to the primary care physician, which "pop ups" one day *after* the scheduled appointment as a reminder of the consultation. The LMR message remains on the Clinical Message list until the physician deletes it.

Consultation Note

The PCP, now reminded of the consultation by the Clinical Message, will stay alerted to look for the consultation note. If the consultant records his or her notes in the LMR, the PCP simply checks for the report. Specialists who do not post their reports to the LMR may e-mail the note or send a copy via paper mail. If the consultant's report is not received within an appropriate timeframe, the PCP will return the Clinical Message to the clinical liaison, requesting that he or she call the specialist and obtain the consultation note. If the patient did not attend the appointment, the clinical liaison reports this to the PCP and contacts the patient to ascertain why the appointment was cancelled, documenting this in the LMR. If the patient is reluctant to reschedule the appointment, the PCP can then discuss the importance of the evaluation and arrange appropriate follow-up. After the PCP receives and reviews the consultation, the task is deleted from the Clinical Message list as the loop is closed on that referral.

This process has been so successful that it is now also used at Senior Health for specialty testing such as radiology, cardiovascular testing, rehabilitation requests, and other referrals that require timely information flow to the PCP. The physicians are particularly pleased with this process because it allows them to track the process from the initial referral to the final report without difficulty. The support staff are, likewise, pleased because their work is well documented and is now integrated into the care the team provides for the practice patients. ■

Establishing a Common Mission to Address Office-based Risks

by Sharon Lucie and Jennie Wright, BA, RN

Ms. Lucie is Director for Operations, Charter Professional Services Corporation, Salem, Massachusetts. Ms. Wright is Risk Assessment Program Manager for CRICO/RMF.

In 2006, the CRICO/RMF Office Practice Evaluation (OPE) program resurveyed 12 internal medicine practices affiliated with North Shore Medical Center (NSMC) that had initially been surveyed in 2003. Reassessment demonstrated significant improvements in practice performance, including development of processes responsible for test result and referral management, as well as medical record documentation.

An affiliate of NSMC and Partners Healthcare, Charter Professional Services Corporation (CPS) is a large, multispecialty physician group composed of 90 physicians and nurse practitioners located in 16 offices across the north shore of Massachusetts. The 2003 survey indicated numerous opportunities for improvement. CPS leadership, although eager to undertake the effort, understood that changing the culture and day-to-day practices across a diverse network was a daunting challenge.

In 2003, as CPS committed to comprehensive cultural and organizational change, a key goal was to shift the self image of physicians who viewed themselves as independent practitioners toward a feeling of membership in a physician group. This would be crucial in developing a unified approach to the delivery of care. To create the appropriate venue, a physician/management team comprising senior management and physician leaders was created to function as a governing body and to provide a forum in which to discuss operational issues. Physician leaders provide a bridge between the physicians in the field and the management team responsible for implementation of operational elements of the organization. This leadership—with its vision of a “group without walls”—provides physician models, embraces the quality improvement process, and represents the operational concerns of the physicians at large.

Developed in tandem, and of equal importance, are monthly management meetings which include the practice managers overseeing the day-to-day operations of the CPS office practices. These meetings are viewed as opportunities for frontline staff to identify and provide potential solutions to practice-based concerns. Sharing of common experiences and participating in collaborative resolution are important components of critical functions: team building, information sharing, and problem solving. Also initiated were a series of operational changes which would unify disparate practices.

Standardization of office-based systems and processes began in June 2003 with the introduction of an electronic practice management system for all CPS office practices. The management system encompasses appointment scheduling, referral management, and coding and billing functions. The staff training required to institute the new system provided CPS with an opportunity to standardize processes and sustain the momentum of cultural change. Staff from the office practices were required

to attend training sessions for software orientation. These sessions also provided a forum for staff to share common concerns and develop an ongoing, informal support network.

The use of a common, electronic medical record is key in helping individual practices see themselves as part of a larger working group. In 2006, CPS rolled out the Partners-based LMR, a standard electronic medical record product recently certified by the Certification Commission for Healthcare Information Technology. In preparation, frontline focus groups were assembled to design effective integration of the LMR into the daily workflow.

Concurrent to the rollout of some of the more advanced features of LMR, CPS made a commitment to participate in the CRICO/RMF Office Practice Incentive Pilot program through which each participating practice is assessed on six characteristics (see [Puopolo, page 3](#)), determined to be instrumental in reducing risk and delivering reliable, quality patient care. Prior to the rollout of modules like Results Manager, the LMR's functionality was evaluated in relation to these six characteristics. Staff tasks were redesigned to incorporate several of the six characteristics, including reconciliation of test results and monitoring completion of critical referral requests. Practices then piloted the LMR and trialed new workflows, providing an opportunity to identify and troubleshoot issues in advance. Mandatory training sessions were implemented both in formal sessions and at office locations. The fact that practices had the opportunity to pilot and adapt to the LMR minimized resistance during general rollout and training. It was important to staff that functional limitations and time consuming aspects of workflow were recognized in advance of training.

Using upcoming participation in the OPE reassessment as an endpoint, CPS staff reviewed their day-to-day office processes in relation to the six characteristics. A “hit list” identifying which office-based processes were lacking was then developed. For each hit list item, a work plan was created by frontline members of select practices. Work plans were then trialed and rolled out to all 16 practices.

Two key factors were instrumental in developing a unified group practice committed to providing safe patient care. Most important was appealing to the common desire of all members of the health care team to “do the right thing.” To rekindle or reinforce that desire, the CPS management and training team held meetings to encourage the practice staff to share personal experiences of near misses and/or poor outcomes that they were involved in or that affected a loved one. National benchmark data were then presented to reinforce the stories and provide

Continued on page 17

The Ambulatory Practice of the Future

by Nicola Majchrzak, MPH, MSW, and David Judge, MD

Ms. Majchrzak is Project Manager for the Ambulatory Practice of the Future (APF) at Massachusetts General Hospital. Dr. Judge is the APF Medical Director.

"We will design the ambulatory care practice that delivers ideal care in the ideal environment to optimize outcomes for all."

—APF Steering Committee

At Massachusetts General Hospital (MGH), four entities¹ have joined efforts to redesign ambulatory care delivery to meet the needs and expectations of those receiving and providing care. A group of innovators comprising patients, physicians, nurses, medical administrators, engineers, architects, and information systems and technology experts are challenging many traditional assumptions that are part of the current ambulatory care experience.

Primary care physicians (PCPs) increasingly feel frustrated that the care they are providing patients is slipping farther away from the care that they would like to provide (see [Parker, page 8](#)). They find less time to maintain relationships with patients, use their skills to diagnose complex medical illness, and oversee coordination of care across the spectrum of each patient's medical needs. Such a scenario can lead to fragmented and poorly coordinated care and increase the potential for preventable adverse events (see [LaValley, page 1](#)).

The frustration of working in this system is compounded by an outdated reimbursement model that encourages unnecessary appointments and does not reward time spent on communication, education, and shared decision-making that can improve prevention and maintenance of chronic illness. Few potential solutions for these problems have been synthesized and fully integrated into real world practices; most of those that have been implemented have been fragmented and difficult to measure in a systematic way.

A new care model under development at MGH, the Ambulatory Practice of the Future (APF),² will demonstrate solutions to the challenges facing primary care and remove the barriers described above. This model relies on building a collaborative relationship between patients and a care team, enabling patients and their families to take on more of the responsibility of managing health and chronic illness. A culture, and an effective system, that support the patient as a central member of the care team will make great strides toward improving the health of those patients.

The APF, tentatively scheduled to open in late 2008, will be a functioning practice serving as a living laboratory: implementing and measuring the impact of the new model on quality, safety, and experience of care. The goal is to translate the successful features of this model into conventional primary care settings.

The APF patient/care team relationship will be a true partnership. Through a robust electronic portal, patients and their designees will have full access to their medical records and test results as well as access to important customized information and education about their health and medical problems. This tool will help patients better manage their health between visits to the doctor. They will be able to amend their electronic health record (e.g., updating family medical history or medications—see [Schnipper, page 10](#)) to ensure constant accuracy which will help inform medical decisions. Comprehensive, accurate electronic medical records will assist providers in proactive patient population management and aggressive prevention efforts, enhancing care quality and safety.

Each APF patient will be assigned to a personalized care team (doctor, nurse, and others). Each care team will include a care coordinator to assist with all needs and a wellness advisor to work on health goals. Others (family, friends, nutritionist, therapists) will join the patient's team as needed. Together with the care team, each patient will develop a shared care plan that will promote goal setting for health management. The care team members will truly know their patients, facilitating a highly effective relationship.

The APF will continuously seek to bring innovative technology to patients that will enable virtual care through web-based communication and mobile technology. Patients will be able to schedule their own office visits via the electronic scheduling system and will have vastly improved access to their care team through face-to-face visits, e-mail visits, and other types of remote or virtual visits. Home visits will be conducted when appropriate.

When patients do come to the APF office for a visit, they will experience a comfortable and inviting environment. APF patients will be able to obtain on-line health education information from the APF library or from an expert health educator. The exam room will be warm and inviting. The patient's electronic medical records and test results will be prominently displayed on a wide screen monitor to promote open communication and collaboration. Point of care diagnostic technology, including lab tests and X-rays will reduce the need to go to other locations for these procedures. The APF will also be built with flexibility and change in mind so that it may continuously evolve.

A care model that promotes the highest degree of communication and collaboration between patients and the care team—both during and between episodes of care—will be a safer care model. In addition, effective patient education to promote increased self-management of chronic illness and shared decision making will lead to better care outcomes. With these important principles in mind, the APF design team is already conducting several pilots that will inform the overall design.

Toolkits that provide patients with the tools and knowledge necessary for the management of disease in partnership with their care-team have the promise of improving quality of care while reducing the time and cost associated with conventional chronic disease management models. Initial efforts are focusing on the development of a toolkit for a diabetic population with depression.

Pre-visit packets, which include medication lists, are part of the effort to adequately prepare the patient for the office visit. Information is sent to the patient in advance of his or her appointment together with a medication list generated from the electronic medical record for the patient to review and edit to ensure accuracy.

Shared decision making is being piloted in all MGH primary care offices. Videos are prescribed to patients outlining options of approaching a health care issue. Once the patient has seen the video, the patient and the rest of the care team discuss which option is most appropriate. This collaborative nature of decision making is a stark contrast from the conventional, physician-centric care model.

Web-based remote office visits in which patients can communicate in real-time via video-conferencing technology are underway in one of our primary care practices. The current pilot involves urgent care visits using this modality which are then repeated face-to-face in the practice in an effort to sort out which types of visits may be appropriate for this technology.

Remote monitoring of disease-specific parameters (e.g., blood glucose in diabetics) is being designed for rollout in late 2007. Patient blood sugars will be uploaded from the glucometer to a central database that synthesizes the data and feeds them back to both the patient and the care team in a useful manner. Future iterations of this system will include decision support messaging to enhance diabetes management.

Each of these pilots will help inform the APF design. Our model will enhance the care experience for patients and the care team while providing the highest level of quality and safety. MGH feels that great value lies in fostering the development of the patient/care-team relationship and that emphasis on this partnership is crucial to maximizing care outcomes and reducing safety concerns of the current system. ■

References

1. Massachusetts General Physicians Organization, Stoeckle Center for Primary Care Innovation, Center for the Integration of Medicine and Innovative Technology, and Center for Connected Health.
2. www.massgeneral.org/stoecklecenter/apf.htm

Continued from page 15

further evidence for the need to improve care. In addition, all staff participated in a two-hour internal risk management seminar to reintroduce patient safety and risk management principles. Through these activities, the common mission of providing safe patient care was established.

Subsequently, CPSC engaged in self-audits based on the six characteristics. The self-administered audits identified individual offices not yet using the approved processes and workflows. These issues were addressed internally. With resolution of practice-specific issues underway, and as a final test of the sustainability of cultural and system improvements, CPSC invited CRICO/RMF to re-evaluate its performance.

Results

CPSC operations and practice management staff met with OPE surveyors in advance of the 2006 evaluations. CPSC staff were familiarized with the evaluation process and OPE staff were provided a review of the functionality of the LMR. Because office staff were familiar with the interview and medical record requirements, the actual evaluations were efficient and non-disruptive.

Due to the pre-work done in advance of the re-evaluation, we had few surprises. In February 2007, the CRICO/RMF OPE team presented data comparing the 2003 and 2006 evaluation results, which demonstrated significant improvement, especially in documentation practices. This was attributable, in large part, to the standardized and consistent use of the LMR. In addition, training of frontline clinical staff was seen as having been critical in this process. Ongoing training, especially in the office environment, is vitally important in maintaining and expanding LMR functionality and continuing to maintain existing workflow processes.

While technological advances, such as the LMR and practice management systems, are powerful tools used to improve the quality of care and reduce risk in the office setting, the major substrate, that element which promotes the adoption of change, continues to be appealing to the heart of caregivers and releasing a passionate desire to do the right thing. This, combined with initiating quality as an agenda item at management meetings, linking technological upgrades with improved patient care, providing staff with initial technology training and ongoing education in the office setting, and evaluating performance using both internal and external audits, are the key elements which—from our perspective—have resulted in positive change in the patient care arena at CPSC. ■

Cancer Screening: The United States Preventive Services Task Force Recommendations

by Diana Petitti, MD, MPH

Dr. Petitti is Vice Chair, United States Preventive Services Task Force, and in practice at the Department of Preventive Medicine, University of Southern California.

The major goal of the United States Preventive Services Task Force (USPSTF) is to provide clinicians and policy-makers with a reliable and accurate source of evidence-based recommendations on a range of preventive services. To accomplish this goal, the USPSTF systematically reviews the evidence concerning both the benefits and harms of widespread implementation of preventive services. It then assesses the certainty of the evidence and the magnitude of the benefits and harms. Based on this assessment, the USPSTF assigns a letter grade to each preventive service signifying its recommendation about provision of the service. A positive recommendation to provide a service routinely is dependent on a conclusion that certainty is at least moderate that the net benefits (i.e., benefits minus harms) are moderate.¹

The USPSTF is recognized as setting a standard for rigorous review of evidence and for developing processes to link evidence with clinical recommendations based on explicit, reproducible, and coherent standards. A number of organizations, including the Academy of Family Practice and the American College of Physicians, recognize the USPSTF recommendations as authoritative for preventive screening in adults.

Following the recommendations of the USPSTF does not protect a physician from a lawsuit when a patient has cancer diagnosed at a late stage. Physicians are not protected even from entirely frivolous lawsuits. Following the USPSTF recommendations is, however, a defense against a claim that a person should have been screened when the USPSTF has not recommended screening. Former members of the USPSTF have been called on as experts in malpractice cases against physicians who did not perform screening tests for prostate cancer, for example; the defendants have generally prevailed when they adhered with the USPSTF recommendations.

Screening Recommendations for Cancer

The USPSTF addresses the evidence about screening for the following cancers: bladder, breast, cervical, colorectal, lung, ovarian, pancreas, prostate, skin, and testes.²

The USPSTF recommends routine screening for adults at average risk as follows:

- cervical cancer, using the Pap smear for sexually active women until age 65;
- colorectal cancer, starting at age 50; and
- breast cancer, using mammography, for women ages 40–74.

For both colorectal and breast cancer, the recommendation to screen is based on evidence from randomized clinical trials of screening that showed that screening led not only to diagnosis at an earlier stage but also to a net reduction in mortality from

the cancer.^{3–4} For cervical cancer, there are no randomized trials, but a large body of evidence links more widespread screening with lower cervical cancer mortality.⁵

The USPSTF makes a specific recommendation *against* screening for bladder, ovarian, pancreatic, testicular cancer and against lung cancer screening using chest radiography or sputum cytology. The USPSTF judges the evidence to be insufficient to make a recommendation for or against routine screening for oral cancer, prostate cancer, skin cancer, and for lung cancer screening using CT.

Overdiagnosis, Indolent Cancers, Cancers with Unmodifiable Prognosis

Only recently has overdiagnosis of cancer by screening been acknowledged (see [Garnick, page 20](#)). The harm is that the person who is “diagnosed” with cancer suffers the harms of treatment but gains none of its benefits. The magnitude of the problem is uncertain, but for some screening test—in particular CT screening for lung cancer—the problem of overdiagnosis may be quite large. The USPSTF attempts to take into account overdiagnosis by weighing the harms against the screening benefits overall. For now, overdiagnosis is one of the several harms against which screening benefits are weighed.

Screening detects some early stage tumors that have a low potential to become clinically manifest or affect lifespan. As yet, medicine has no way to distinguish reliably early-stage tumors detected by screening that have propensity to metastasize from early-stage tumors that are biologically programmed to have a slow clinical course, or even to regress. Much research is being done to identify biologic markers that will predict prognosis so that management can be tailored according to prognosis.

Screening also detects some cancers that are already widespread and whose clinical course is not modified by treatment. This results in a life lived longer with cancer, but not a life lived longer.

The fact that screening detects neoplasms that would not progress, are indolent, or whose course is not modified by treatment is one of the reasons why the USPSTF holds screening tests for cancer to a high evidence standard. For example, diagnosis of prostate cancer with little or no potential for progression or metastasis is a particular concern for prostate cancer screening. Diagnosis of lung cancer with no potential for modification by treatment is a particular concern for lung cancer screening.

Reliance on randomized trials with delay in cancer-related mortality that assign people to be screened or not screened overcomes the problems due to detection by screening of a mix of indolent and aggression lesions. Again, the rigorous evidence standards for USPSTF recommendations guards against harms.

Identification of High Risk

The growth of knowledge about the heterogeneity of the underlying risk of cancer and the role of genetics in determining the biology of cancer has been spectacular. Of particular significance, information about a person's family history of cancer can identify when the "average person" cancer screening strategy needs modification (*see also Schnipper, page 10*). The details of the USPSTF recommendations about cancer screening that appear in the section of their summary called "Clinical Considerations" are often overlooked. This section of the recommendations offers advice for a nuanced approach to cancer screening that includes consideration of family history. Thus, the "Clinical Considerations" sections of the USPSTF summary on screening for colorectal, breast, and ovarian cancer remind physicians that a family history of these cancers means a higher risk of cancer. The higher risk justifies starting colorectal cancer screening at an earlier age and using colonoscopy for people with a family history of colorectal cancer and starting mammography at age 35–40 for women with a family history of breast or ovarian cancer.

In formal evaluations, a self-reported family history both of colorectal cancer and of breast cancer has been shown to be very accurate.⁶ Two questions would identify the overwhelming majority of people who are candidates for a modified screening schedule for the cancer screening tests that the USPSTF recommends:

1. Has colorectal cancer occurred in a first-degree relative (mother, father, sibling) at less than age 60?
2. Has breast or ovarian cancer occurred in a mother or sister?

In addition to mammography screening, the USPSTF recommends that women whose family history is associated with an increased risk for deleterious mutations in *BRCA1* or *BRCA2* genes be referred for genetic counseling and evaluation for *BRCA* testing.⁷ A question about whether breast or ovarian cancer has occurred in a mother or sister would trigger a decision for this referral.

...[T]he "Clinical Considerations" sections of the USPSTF summary on screening for colorectal, breast, and ovarian cancer remind physicians that a family history of these cancers means a higher risk of cancer.

Summary

The USPSTF has provided guidance for cancer screening that is firmly grounded in evidence. Screening test recommendations for average risk populations take into account overdiagnosis and the detection of indolent lesions. The work of the USPSTF is widely available on the web⁸, in the form of a pocket guide in PDF form⁹ and a downloadable PDA.¹⁰ The use of guidelines from an authoritative body can help a physician practice evidence-based medicine and avoid lawsuits.

The notion of "personalized medicine" is gaining recognition among consumers of medical care. New approaches to patient management are sure to emerge soon from the technical advances that grow from our rapidly advancing understanding of the human genome. Taking a family history as one component of a comprehensive medical history is rapidly becoming critical to provision of evidence-based cancer screening. ■

References

1. Harris RP, Helfand M, Woolf SH, et al for Methods Work Group, Third US Preventive Services Task Force. Current methods of the US Preventive Services Task Force: a review of the process. *Am J Prev Med* 2001;20(3 Suppl):21-35.
2. www.ahrq.gov/clinic/cps3dix.htm#cancer
3. www.ahrq.gov/clinic/USPSTF/uspsbrca.htm
4. www.ahrq.gov/clinic/USPSTF/uspsc Colo.htm
5. www.ahrq.gov/clinic/USPSTF/uspscerv.htm
6. Murff HJ, Spigel DR, Syngal S. Does this patient have a family history of cancer? An evidence-based analysis of the accuracy of family cancer history. *JAMA* 2004;292:1480-89.
7. www.ahrq.gov/clinic/USPSTF/uspsbrgen.htm
8. www.ahrq.gov/clinic/cps3dix.htm
9. www.ahrq.gov/clinic/pocketgd.pdf
10. <http://epss.ahrq.gov/PDA/index.jsp>

Complexities of Cancer Screening: Considerations for Clinical Practice

by Marc B. Garnick, MD

Dr. Garnick is a Clinical Professor of Medicine at Beth Israel Deaconess Medical Center (Boston)

Improvements in cancer diagnosis, staging using sophisticated analytic techniques, predicting behavior with molecular probes, targeting therapies that are specific to an individual's cancer, and even understanding the genetic makeup of many common cancers provide a level of excitement for all. But the good news has its limits and caveats, which usually receive less attention.

Many people (patients and providers) may mistakenly believe that early detection is synonymous to cure. Media coverage of a national celebrity's screening colonoscopy,¹ male politicians urging blood testing for prostate cancer,² and front page coverage for new diagnostic techniques in breast cancer screening³ all raise optimism among the lay public. And, while some cancer screening is beneficial (*see Pettiti, page 18*), screening may be indiscriminately applied to cancers where an earlier detection does not result in better outcomes.⁴

Our increasing understanding of (some) cancers expands far into the biology of the cancer cell—its development, growth, behavior, and even genetic alterations that enable growth and metastases to occur. This research indicates that by the time a common cancer is diagnosed—by the most modern means—that cancer has been present in the patient's body for anywhere between five and eight years, in the commonly referred to “pre-clinical” phase.⁵ So, while screening studies can detect cancers in their “earliest” clinical phases, in fact, nearly 70–80 percent of that cancer's natural history has already elapsed. During that long natural history—well before it is diagnosable—most of the cancer's spread has likely occurred, though still beneath the limits of current detection capabilities.

For example, consider two newsworthy cases: Elizabeth Edwards (breast cancer metastasized to bone⁶) and Tony Snow (colon cancer metastasized to liver⁷). Both cases involve patients who suffered relapses not long after the primary diagnosis. What received less media attention was the fact that these metastatic foci occurred well before the primary cancer was diagnosed, i.e., they did *not* occur in a relatively short window of time following their original diagnoses. This metastatic potential represents the genetic make up of the individual's cancer cells; it was *not* acquired during some arbitrary period of time that elapsed following their diagnosis. The more we learn, the more we understand that this scenario is, overwhelmingly, the norm. Obviously, that directly challenges the argument that an earlier diagnosis would have given the patient a better chance.

The legal implications of the “early is better” argument often promoted by medical professionals are significant. For example, studies that report more successful cancer survival rates as a result of screening are cited in malpractice allegations that a

physician did not order a screening test. A patient whose cancer could have, hypothetically, been detected earlier places the physician in a precarious position when the patient presents “evidence” that cancers detected under these circumstances are reported to result in more favorable outcomes. Such evidence, however, may not be valid.

Rather than over emphasizing the relationship between early detection and life-extending treatments or cures, patients—and physicians—are better served by a two-way discussion about the more sobering realities of cancer screening and diagnosis, i.e.:

- a screening study may lead to a false positive test and its associated emotional distress,
- the need for diagnostic procedures performed on a cancer that may never have needed to be diagnosed, and
- harms resulting from treatments that result in unfavorable quality of life outcomes without providing any impact on overall survival.

A patient who has realistic expectations is a true partner in making decisions about screening (and the results) and perhaps less likely to pursue a “loss of chance” malpractice allegation. Of course, physicians still must take an accurate history (including a family history), elicit important factors that place an individual patient at higher risk of harboring a disease, and be knowledgeable about outcomes and biases of screening studies to enable patient counseling where shared decisions can be formulated. And, all of this—whether the decision is for or against screening—must be properly documented in the medical record.

Screening Biases

Understanding the biases of screening studies is as important to patients as it is to physicians. There are four important considerations in the interpretation of screening studies.

Selection bias

Of the potential screenees who could participate in a study, only a subset actually do present for screening.⁸ Why did these patients come in for screening? What are their demographics? Were they more compulsive, or did they have concerns about their health? Patients who present for screening studies may have characteristics not representative of larger populations.

Lead time bias

A lead time bias challenges the assumption that diagnosing and treating a cancer early in its existence will result in a longer survival. In rare cases this may be true; more often it is not.⁹ Assume, for example, that a cancer will kill a particular person eight years after it starts. If the cancer is diagnosed in the fifth year of its natural history, the patient will live three more years.

If the cancer is diagnosed in the third year (by screening), the patient will live five more years. One could assume that the earlier diagnosis provided the patient with a longer life span, but that is not true. Detection via screening just gave us more time to know the patient had the disease. The duration of survival after diagnosis is not sufficient to state that earlier diagnosis would have been associated with a longer survival.

Length bias

Multiple screening tests favor the diagnosis of slow growing tumors. Fast growing tumors may be missed during the first screening test, but show up during the subsequent one. Study results that state that earlier diagnosis finds more favorably staged cancers are only taking a snapshot of that cancer in a point of time and do not provide for when, in the course of that cancer, the process of metastases took place.

Over diagnosis

Imagine two similar patients: one has screening and is diagnosed with cancer; the other does not undergo screening. Both patients die of non-cancer causes. At autopsy, we learn that the non-screened patient had a similar cancer to the one detected in the screened patient. It is fair to say that that particular cancer never required a diagnosis, since it was biologically inactive during the patient's lifetime. Yet the patient whose cancer was detected via screening suffered potential morbidities as a result of treatment.

As screening tests detect ever smaller cancers, the problem of over diagnosis is likely to increase, as illustrated in the recent computed tomography screening and lung cancer outcomes study that demonstrated greater detection, but no meaningful reduction in the risk of advanced cancer or lung cancer mortality.¹⁰ The American College of Physicians, too, just recently challenged the dogma that all women ages 40–49 undergo screening mammograms, given a better assessment of risk associated with the procedure. Similar recommendations have also been advocated by the Canadian Task Force of Preventive Health Care.¹¹

A Question of Liability

The complexities surrounding cancer screening have profound implications related to medical malpractice claims alleging a failure or delay in diagnosis. If a physician chooses not to order a screening test, or fails to follow up on an abnormal test, only later to find a diagnosis of cancer, is there medical liability?

The question of liability is answered by the legal process triggered by a malpractice lawsuit. The likelihood of litigation increases when the patient's expectations do not align with the physician's—if the patient assumes that a different chronology would have led to a different outcome.¹² Certainly patients and physicians expect abnormal findings to be followed up, but it is also imperative that the physician provide the reasons and limitations for ordering the test in the first place. A discussion

can then occur between the patient and physician regarding expectations and limitations of an abnormal test, if found, in a system referred to as “shared decision making.”

In the case example on [Page 5](#), the 62-year-old woman with a family history of colon cancer *should* have had a screening colonoscopy or other gastrointestinal evaluation. However, this may not have prevented the cancer that was eventually diagnosed or even altered this patient's subsequent fate. Moreover, a patient with a family history really does not fall within the true definition of routine screening,¹³ but rather one with increased risk.

In the case example on [Page 6](#), the 62-year-old man with the missed lung nodule should have had an earlier follow-up of the abnormality. But even the earliest detection of such nodules is unlikely to be associated with alterations in outcomes, regardless of when they are detected. Both the colon and lung cancer patients discussed have likely suffered adverse consequences as a result of their intrinsic biology of their respective cancers, rather than the specific timing of the cancer diagnosis.

Despite that harsh reality, we must strive to minimize the risk of these occurrences by putting into place foolproof processes to 1) ascertain that an appropriate medical history is taken and placed in the medical record to determine whether a reasonable excess risk of cancer exists, such as in the setting of a strong family history or occupational exposure; 2) perform (and document) an appropriate physical examination that assesses normal, equivocal, or abnormal findings, and 3) review abnormal laboratory or radiographic values. Of equal importance is the education of our patients about the limitations and consequences of this type of testing to minimize false expectations. ■

Notes and References

1. O'Neil J. Vital signs: testing: lining up for healthy colons. *New York Times* July 15, 2003 (health news).
2. Anonymous. Upfront: unacceptable delay: six thousand men will die while NCI Stalls, NPCC says. Upfront, April 1999. Accessed via www.psa-rising.com 23 April 2007.
3. Kriege M, et al. Efficacy of MRI and mammography for breast-cancer screening in women with a familial or genetic predisposition. *N Engl J Med* 351: 427–37, 2007.
4. <http://familydoctor.org/725.xml>
5. Tannock IF. Principles of cell proliferation: Cell Kinetics. In DeVita VT, Hellman S, and Rosenberg SA. *Cancer: Principles and practice of oncology*. 3rd edition JB Lippincott. Philadelphia: 3–13, 1989.
6. Kolata G. The basics: a leading cause of death, but less so. *New York Times* April 15, 2007.
7. Rutenberg J. Bush spokesman schedules surgery to remove growth. *New York Times* March 24, 2007.
8. Kramer BS. The science of early detection. *Urol Oncol* 22: 344–47, 2004.
9. Connor RJ, Prorok PC and Weed DL. The case-control design and the assessment of the efficacy of cancer screening. *J Clin Epidemiol* 44:1215–21, 1991.
10. Bach PB, Jett JR, Pastorino U et al. Computed tomography screening and lung cancer outcomes. *JAMA* 297:953–61, 2007.
11. Ringash J. Preventive health care, 2001 update: screening mammography among women aged 40–49 years at average risk of breast cancer. *CMAJ* 164:469–76, 2001.
12. Shroder FH and Erasmus MC. Early detection of prostate cancer. What do we tell our patients? *Can J Urol Suppl* 2: 37–42, 2006.
13. National Cancer Institute. Cancer Screening Overview. Accessed via <http://www.cancer.gov/cancertopics/pdq/screening/overview/healthprofessional> 23 April 2007.

Additional Resources

by Judith Jaffe, MSLIS, Knowledge Manager, CRICO/RMF.

The following additional resources related to patient safety in the office setting were selected from the PubMed (Medline) database of indexed biomedical literature published since 1999. Links are provided to abstracts and full text, where available.

Electronic Health Records

Cooper JD. Organization, management, implementation and value of EHR implementation in a solo pediatric practice. *J Healthc Inf Manag.* 2004 Summer;18(3):51-5.

Garrido T, Jamieson L, Zhou Y, Wiesenthal A, Liang L. Effect of electronic health records in ambulatory care: retrospective, serial, cross sectional study. *BMJ.* 2005;330:581. [free full text](#)

Models

Scherger JE. Primary care needs a new model of office practice. *BMJ.* 2005 Jun 11;330(7504):E358-9. [free full text](#)

Talbot JF. Managing for change. Models and questions for group practice leaders. *Med Group Manage J.* 1999 Sep-Oct;46(5):50-4, 56, 58.

Organizational Culture

Jessee WF. Trust. A new imperative for medical groups. *MGMA Connex.* 2003 Aug;3(7):5-6.

Kaissi A, Kralewski J, Dowd B, Heaton A. The effect of the fit between organizational culture and structure on medication errors in medical group practices. *Health Care Manage Rev.* 2007 Jan-Mar;32(1):12-21.

Quality

Lundberg GD. Improving the quality of care in physician office practice (IQCPOP). *MedGenMed.* 2003 Dec 24;5(4):38.

Pope C. Quality quagmire. Why systems and processes are important to your practice but often ignored. *MGMA Connex.* 2005 Feb;5(2):40-5, 1.

Solberg LI, O'Connor PJ, Christianson JB, Whitebird RR, Rush WA, Amundson GM. The quest for quality: what are medical groups doing about it? *Jt Comm J Qual Patient Saf.* 2005 Apr;31(4):211-9. [PubMed abstract](#)

Risk Management

Baum, N. Informed consent—more than a form. *J Med Pract Manage.* 2006;22(3):145-48. [PubMed abstract](#)

Elder NC, Graham D, Brandt E, Hickner J. Barriers and motivators for making error reports from family medicine offices: a report from the American Academy of Family Physicians National Research Network (AAFP NRN). *J Am Board Fam Med.* 2007;20:115-123. [free full text](#)

Gandhi TK, Kachalia A, Thomas EJ, et al. Missed and delayed diagnoses in the ambulatory setting: a study of closed malpractice claims. *Ann Intern Med.* 2006; 488-496. [free full text](#)

Safety

Elder NC. Patient safety in the physician office setting. *AHRQ WebM&M* [serial online]. May, 2006. Accessed May 4, 2007. [free full text](#)

Kaushal R, Upadhyayula S, Gaba DM, Leape LL. The wild west: patient safety in office-based anesthesia. *AHRQ WebM&M* [serial online]. May, 2006. Accessed May 4, 2007. [free full text](#)

Raebel MA, Chester EA, Newsom EE, et al. Randomized trial to improve laboratory safety monitoring of ongoing drug therapy in ambulatory patients. *Pharmacotherapy.* 2006 May;26(5):619-26. [PubMed abstract](#)

Wachter RM. Is ambulatory patient safety just like hospital safety, only without the "Stat"? *Ann Intern Med.* 2006; 547-549. [free full text](#)