

Commentary: The Role of Clinical Practice Guidelines in Malpractice Litigation¹

By Michelle M. Mellow, J.D., Ph.D.

Michelle Mellow is Assistant Professor of Health Policy and Law in the Department of Health Policy and Management at the Harvard School of Public Health

Clinical practice guidelines have garnered significant attention in the last 10 years as a possible mechanism for reducing the costs of medical malpractice litigation and defensive medicine. Would-be tort reformers have suggested using guidelines as evidence of the standard of care. Under some proposals, noncompliance with certain practice guidelines would constitute conclusive evidence of negligence. Under other proposals, plaintiffs would not be allowed to use noncompliance with guidelines to prove negligence, but clinicians would be permitted to invoke their compliance with guidelines as a defensive measure.

Proponents of these reforms argue that declaring in advance that practice guidelines will constitute the legal standard of care would reduce uncertainty amongst clinicians about what the law requires. Additionally, practice guidelines—which represent the consensus of a panel of leading experts—would be more authoritative than opinions offered in court by “hired gun” expert witnesses.

Opponents point out that so many different guidelines have been promulgated that physicians would be at a loss to know which was the “right” set to follow, and that physician compliance with some guidelines is still so low that the guidelines cannot yet be said to represent medical custom, which has traditionally constituted the legal standard of care.

Admissibility

Given the amount of discussion that has been circulating about these proposals, many physicians are left wondering, just what is the current legal status of practice guidelines? Are practice guidelines admissible under state rules of evidence? If so, how much weight do they carry on the negligence issue? Because medical malpractice is a matter of state law, the answers vary by state. Massachusetts has had very few cases in which practice guidelines have been invoked, thus their legal status is therefore somewhat uncertain. But a few conclusions can be drawn.

With respect to the admissibility issue, all courts agree that when offered for the purpose of establishing the standard of care, guidelines are hearsay evidence. Consequently, they are inadmissible unless the offering party can show that they fall under an *exception* to the hearsay rule. It appears that some guidelines will be admissible in Massachusetts courts under the hearsay exception for so-called “learned treatises.” Massachusetts provides, by statute, that statements of facts or opinion in a medical publication, if authored by a recognized expert in the field, are admissible in medical malpractice actions.²

Additionally, the Massachusetts Supreme Court has adopted a rule of evidence providing more broadly that statements contained in a learned treatise may be called to the attention of an expert witness upon cross-examination...if the treatise is a “reliable authority.”³ Guidelines contained in standard textbooks⁴ or authored by professional societies and government agencies would seem to fall within these provisions, but it is less clear whether guidelines developed by individual hospitals, HMOs, or malpractice insurers fit the bill. Admissibility decisions likely will turn on whether the litigant can show that the authors of the guidelines are experts in the field and the guidelines themselves are recognized by physicians as authoritative.

Evidentiary Weight

Assuming that the court is willing to admit practice guidelines as evidence of the standard of care, what weight will this evidence be given? A few states, most notably Maine, have adopted laws providing that a physician’s compliance with certain guidelines will be an absolute affirmative defense to a negligence claim; plaintiffs are not permitted to use a physician’s noncompliance with guidelines to prove negligence.⁵ Massachusetts follows a more traditional approach: guidelines are considered relevant—but not conclusive—evidence on the question of whether the physician departed from the standard of care. A judge or jury will consider the guidelines along with other evidence, such as an expert’s testimony about his or her experience and observations of prevailing medical practice.

The bottom line is that compliance with practice guidelines will not conclusively defeat a negligence claim, but it may work to the clinician’s advantage—if the guidelines are widely recognized as authoritative. Conversely, a defendant who departed from authoritative guidelines may have to explain why in court. Since compliance with many guidelines in existence today is very low,⁶ the defendant may be able to show that the particular set of guidelines invoked by the plaintiff does not represent prevailing medical custom, and therefore is not probative of the legal standard of care. As guidelines become a more prevalent and accepted part of everyday practice, however, we are likely to see them play a greater role in court, too. ■

References

- 1 Adapted from *Of Swords and Shields: The role of clinical practice guidelines in medical malpractice litigation*. *University of Pennsylvania Law Review*. (Forthcoming January 2001):149.
- 2 Mass. Gen. Laws ch. 233, § 79C.
- 3 *Commonwealth v. Sneed*, 597 N.E.2d 1346 (1992).
- 4 *Brusard v. O’Toole*, 710 N.E.2d 588 (Mass. 1999).
- 5 Me. Rev. Stat. Ann. tit. 24, §§ 2971-2979.
- 6 Grilli R, Lomas J. Evaluating the message: the relationship between compliance rate and the subject of a practice guideline. *Medical Care*. 1994; 32:202.

For clinicians who provide breast care

Sample CRICO Case

A 34-year-old female patient presented to her internist with a right breast lump that decreased in size following her period. Her family history included a grandmother with breast cancer. The location of the breast lump was not documented. After the patient's next period, the physician documented the decreasing lump. A month later, the physician ordered a mammogram, but the test was not performed. The record contained no note about his rationale for ordering the mammogram, instructions to the patient, or further mention of the lump during several visits over 16 months. Eighteen months later, the patient returned with a large, red, ulcerating right breast mass, and biopsy revealed a poorly differentiated tumor with lymphatic involvement.

Background

Failure to diagnose breast cancer is among the leading allegations against physicians both within CRICO and nationally. Many of these allegations have similar themes amongst the reasons for missed diagnoses.

RMF coordinated development of the *Breast Care Management Algorithm* to give physicians and others who are responsible for primary breast care suggested steps for follow-up on breast complaints (abnormal mammogram, breast lump, discharge, or pain).

Harvard's initial guidelines were promulgated in 1995, updated in 1998, and revised completely in 2000. The 1995 algorithm used the medicine of that time to describe suggested steps in breast care. The decision that the algorithm needed thorough revision was based on:

- ◆ an increase in the number of breast cancer claims,
- ◆ changes in the technology for diagnosing breast cancer, and
- ◆ a CRICO-sponsored study of primary care sites which indicated that the existing algorithm was not being followed by primary care providers in treating a breast complaint.

The algorithm is designed to improve patient care by addressing the risks related to preventable diagnostic error, and to reduce malpractice claims and loss. The Fall 2000 rollout of the revised guidelines will include efforts to measure the impact of the algorithm on patient care.

Using the Algorithm

The *RMF Breast Care Management Algorithm* is intended for clinicians who provide breast care to patients. This includes primary care physicians, nurse practitioners, gynecologists, ob/gyns, and general surgeons. The expectation is that a diagnosis of breast cancer is assumed until it is either ruled in or ruled out.

The algorithm provides suggestions along the path of care for patients who present with an abnormal mammogram, breast lump, or other breast complaint. The design assumes that much of the diagnostic journey can be carried out by the primary care physician, and indicates at what point he or she may need to refer the patient to a breast specialist.

Structure

The three-page algorithm tracks four main paths a PCP is likely to encounter in providing follow-up care for a breast complaint. Each branch leads the PCP through multiple decision points toward an ultimate recommendation for either a surgical referral or follow-up by the PCP.

The four main branches of the algorithm begin from:

- ◆ a screening mammogram
- ◆ abnormal nipple discharge
- ◆ a palpable mass, and
- ◆ **breast pain.** *SEE SAMPLE*

Next Steps

Prior to distribution, the algorithm was reviewed by breast specialists, oncologists, mammographers, and primary care physicians from CRICO institutions and elsewhere. With confidence that this algorithm represents current clinical and risk management practice, RMF wants to measure whether this algorithm actually changes physician behavior. Educational follow-up will be ongoing, and replication of methods that seem particularly effective will be encouraged at all sites providing primary breast care.

Patient education tools are also being created. The goal is to help patients understand the science of the diagnosis of breast cancer and counter some public myths, including the efficacy of the mammogram in diagnosing breast

Developed by the Harvard/RMF Breast Care Guidelines Update Project Committee (1999-2000)

Phillip Arena, M.D.

Troyen Brennan, M.D.
(Chairman)

Sherry Haydock, M.D.

Carolyn Kaelin, M.D.

Jack Meyer, M.D.

Russell Phillips, M.D.

Ann Louise Puopolo, B.S.N., R.N.

Norman Sadowsky, M.D.

Barbara Smith, M.D.

Susan Troyan, M.D.

The *RMF Breast Care Management Algorithm* is not to be construed or to serve as a standard of care. This model should be considered only as a management guideline. Adherence to it will not ensure a successful outcome in every case.

For all clinicians who conduct psychiatric evaluations

Sample CRICO Case

A 27-year-old patient was admitted to a psychiatric facility with a diagnosis of severe depression with suicidal ideation. Several weeks later, the patient was given his first overnight pass to go home with his mother. The patient's anti-depressant medication was not mentioned in the pass order written by the physician, and he went home without it. His mother called the next morning to say that the patient was anxious and did not sleep. She was instructed to bring him back to the hospital. While stopped en route at a bridge toll booth, the patient left his mother's car and jumped off the bridge to his death.

Background

Lawsuits arising from patient suicide account for the largest single category of suits and the largest dollar amounts in settlements against psychiatrists insured by CRICO. But the potential for suicide is certainly not confined to patients being treated by psychiatrists or in psychiatric departments. Non-psychiatric physicians, in their own practices, are treating an increasing number of depressed patients often with anti-depressant drugs. This implies an increasing need for sophistication in identifying patients at risk of killing themselves. Two separate studies have demonstrated that only one of six physicians had prior knowledge of the suicidal preoccupations of patients who took their lives.

The shortening duration of inpatient psychiatric admissions, and the fact that the risk of suicide is higher in the months immediately following hospital discharge, raises the need for careful suicide risk assessment. Regular, documented attention to this problem is a priority.

The aim of the advisory group convened by RMF in 1995 was twofold: 1) review the patient suicide experience in the Harvard medical institutions and 2) develop loss prevention and defense strategies that would positively affect the quality of patient care and reduce the likelihood and impact of litigation.

The *RMF Guidelines for Identification, Assessment, and Treatment Planning for Suicidality* were developed with the hope that the affiliated psychiatric services and psychiatric hospitals would make them a systematic part of daily patient care. In specific, the guidelines were designed to provide:

- ◆ A model for the assessment of suicidality in all clinical settings, and
- ◆ Information to be incorporated into institution-specific protocols.

Using the Guidelines

The guidelines serve as a model for the assessment of suicidality in all clinical settings. They are designed to improve patient care by addressing the risks related to preventable assessment error, and to reduce malpractice claims and loss. The guidelines are intended for use by clinicians conducting psychiatric evaluation:

- ◆ during an initial interview or on admission to a facility or program, and prior to discharge;
- ◆ with the occurrence of any suicidal/self-destructive behavior or ideation; or
- ◆ on the occasion of any noteworthy clinical change (e.g., significant new symptoms, mental status changes, stressors).

Structure

The 13-page guideline provides comprehensive lists of factors and questions, as outlined below, for clinicians to consider in the suicidality assessment process.

Next Steps

Ongoing evaluation by mental health professionals on the effectiveness of these guidelines serves to confirm or update the outline. For example, in response to the need expressed by CRICO-insured providers, RMF subsequently coordinated development of the *Decision Support Outline for Emergency/Crisis Coverage of a Suicidal Patient* (see Page 6) as a supplement to the parent assessment guidelines.

Developed by the RMF Suicide Risk Advisory Committee (1995)

Douglas Jacobs, M.D., (chairman)

Thomas G. Gutheil, M.D.

James Harburger, M.D.

Martin J. Kelly, M.D.

John T. Maltzberger, M.D.

Michael C. Miller, M.D.

Ronald Schouten, M.D., J.D.

Lloyd I. Sederer, M.D.

Consultants

Margaret Brewer, R.N., M.B.A.

James M. Ellison, M.D., M.P.H.

Reviewers

William Adams, M.D.

Andrew Brotman, M.D.

Randolph Catlin, M.D.

The *RMF Guidelines for Identification, Assessment, and Treatment Planning for Suicidality* are not to be construed or to serve as a standard of care. This model should be considered only as a guideline. Adherence to it will not ensure a successful outcome in every case.

Sample section

How You Can Help

As with any risk management recommendation, the practical application and benefit analysis is best determined by the clinicians asked to employ it over time. RMF is keenly interested in your feedback related to understanding and referencing these guidelines. **For more information or to offer feedback**, contact RMF Director for Risk Assessment Services, Mary Schaefer, at (617) 495-5100, ext. 288, or by e-mail to mschaefer@rmf.harvard.edu ■

CONTENTS

Identification and Assessment

- Data for Assessing Suicidality/ General Psychiatric Evaluation
- Psychiatric Diagnosis
- Other Conditions Which Can Increase Suicide Risk
- The Detection of Suicidality
- **Suicide-specific Questions** *SEE SAMPLE*
- Treatment Planning
- Collect Data Before Treatment Planning
- Identify a Range of Treatment Alternatives
- Involve the Patient and Family in the Treatment Planning Process
- Incorporate Existing Treatment Modalities Into the Plan
- Be Aware that Contracts Will Not Guarantee the Patient's Safety
- Choose Appropriate Levels of Observation, Supervision, & Privileges
- Document the Treatment Planning Process and the Plan

Appendix I: Disorders Correlated with Suicidal Behavior

- Mood Disorders (15 percent lifetime risk of suicide)
- Panic Disorder (7-15 percent risk)
- Schizophrenia (10 percent risk)
- Alcoholism (3 percent risk)
- Borderline Personality Disorder (7 percent risk)

Appendix 2: Detection of Suicidality

- Suicidal Intent and Lethality
- Presence of a Suicidal Plan
- History of Overt Suicidal/Self-destructive Behavior
- The Patient's Physiological, Cognitive, and Affective States
- The Patient's Coping Potential

Appendix 3: Risk Factors: Explicit Criteria

- Under 30 (Adolescents and Young Adults)
- Over 30

Suicide-specific Questions

- 1) Is the patient able/competent to participate in treatment?
- 2) Is the patient able to develop a therapeutic alliance?
- 3) Are suicidal thoughts/feelings present?
- 4) What form does the patient's wish for suicide take?
- 5) What does suicide mean to the patient?
- 6) Has the patient lost or anticipates losing an essential sustaining relationship?
- 7) Has the patient lost or anticipates losing his/her main reason for living?
- 8) How far has the suicide planning process proceeded?
- 9) Have suicidal behaviors occurred in the past?
- 10) Has the patient engaged in self-mutilating behaviors?
- 11) Does the patient's mental state increase the potential for suicide?
- 12) Are depression and/or despair present?
- 13) Does the patient's physiologic state increase the potential for suicide? (e.g., physical illness, intoxication, pain, delirium, organic impairment)
- 14) Is the patient vulnerable to painful affects such as aloneness, self-contempt, murderous rage, shame, or panic?
- 15) Are there recent stresses in the patient's life?
- 16) What are the patient's capacities for self-regulation?
- 17) Loss of coping mechanism?
- 18) Are epidemiologic risk factors present?

Web Site Address

www.rmfm.harvard.edu/rmLibrary/clinical-guidelines/suicide

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Contact RMF (617-495-5100, ext. 255)

RMF Decision Support Outline for Emergency/Crisis Coverage of a Suicidal Patient

For psychiatrists, mental health clinicians, and social workers in the outpatient environment

Sample CRICO Case

A 31-year-old male with a history of a previous suicide attempt cancelled his outpatient psychiatry appointment. The patient's mother stated that she called the psychiatrist's office to report that her son was decompensating; there was no recorded entry of such a phone call in the patient's medical record. The next day, the patient called and told the on-call crisis physician that he was experiencing tension, paranoid thoughts, and suicide ideation (but with no plan to act on it). The patient also related that he had left his job a few days ago, and that he had stopped taking his medications. Although the on-call physician did not know the patient, a contract for safety was made with the patient. The next day, the patient committed suicide. The patient's family filed a malpractice suit alleging that he should have been hospitalized.

Background

The project to create a suicide decision support tool, emanated from a request by Harvard Vanguard Medical Associates. That group was seeking risk management assistance on how to document the care and management of chronically suicidal patients. They were especially concerned about the safety of chronically suicidal individuals being seen as outpatients. The project was later expanded to include risk issues related to acutely suicidal patients.

A second rationale for this project arose from an increase in CRICO outpatient suicide-related cases during the 1990s. Outpatient suicides accounted for 65 percent of CRICO suicide cases in that decade.

RMF coordinated development of *The Decision Support Outline for Emergency/Crisis Coverage of a Suicidal Patient* primarily for mental health providers who may practice in an outpatient setting, including emergency or coverage situations.

Specifically, the goal was to:

- ◆ Support the efforts of mental health clinicians evaluating a patient's suicide risk in an outpatient/crisis setting, or when covering for another clinician. The patient contact could be face-to-face, or by telephone.
- ◆ Provide assistance in evaluating the level of care each patient requires.
- ◆ Provide guidance on medical record documentation when evaluating a patient at risk for suicide.

These guidelines, published in 2000, are an extension of RMF's *Guidelines for the Identification, Assessment and Treatment Planning for Suicidality* published in 1996 (Page 4).

Using the Outline

The *Decision Support Outline* reflects current clinical and risk management practices. It was developed specifically for psychiatrists and mental health clinicians, including master's degree-prepared nurse clinicians and social workers who work in the outpatient environment. The outline is designed to improve patient care by addressing the risks related to preventable assessment error, and to reduce malpractice claims and loss.

Structure

The outline serves as a memory aid for clinicians making initial risk assessments either face-to-face or by telephone with unfamiliar patients (e.g., while covering for another clinician or in an emergency department role). The four-page guideline provides lists of factors and questions for clinicians to consider while conducting an evaluation.

Next Steps

Evaluation by mental health professionals on the effectiveness of the tool would serve to confirm or update the outline.

How You Can Help

As with any risk management guideline, the practical application and benefit analysis of the *Decision Support Outline for Emergency/Crisis Coverage of a Suicidal Patient* is best determined by the clinicians asked to employ it over time. RMF is keenly interested in your feedback related to understanding and referencing this guideline. **For more information or to offer feedback**, contact RMF Director for Risk Assessment Services, Mary Schaefer, at (617) 495-5100, ext. 288, or by e-mail to mschaefer@rmf.harvard.edu ■

Developed by the RMF Suicide Risk Advisory Committee (1999-2000)

Michael C. Miller, M.D. (chairman)
Thomas G. Guthell, M.D.
James Harburger, M.D.
Ronald Schouten, M.D., J.D.
Kim Nelson, R.N., J.D.

Reviewers

Lloyd I. Sederer, M.D.
Robert Ronis, M.D.
Emile Risby, M.D.
Lesley Nan Fishelman, M.D.

The *RMF Decision Support Outline for Emergency/Crisis Coverage of a Suicidal Patient* is not to be construed or to serve as a standard of care. This model should be considered only as a guideline. Adherence to it will not ensure a successful outcome in every case.

Sample section

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- Determine the Chief Complaint
- Establish Rapport
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- Determine Current Suicide Risk
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- Probe for Current Suicidal Thoughts
SEE SAMPLE
- Assess Ability to Establish Treatment Plan
- Evaluate the Level of Care Required
- Communication
- Provide Documentation
- Options If Initial Screening Leaves Questions
- Definition of "Patients with Chronic Suicide Ideation"
- Implications for Treatment

Determine Current Suicide Risk

- 1) Does the patient have an acute change in health status or a new medical/neurological diagnosis that requires evaluation?
- 2) Were there prior suicide ideas, plans, or attempts?
- 3) Are there depressive symptoms/vegetative symptoms (especially hopelessness)?
- 4) Are there psychotic symptoms/thought disorder?
- 5) Are there anxiety or panic symptoms?
- 6) Is there a history of alcohol or substance use/current intoxication?
- 7) Is there a family history of suicides or suicide attempts?
- 8) Does the patient have access to weapons, particularly firearms?
- 9) Does the patient have access to dangerous or lethal medications or chemicals?
- 10) What are the patient's current supports?
 - a) Family/community
 - b) Treatment team
 - c) What are the patient's perceptions of those supports?
- 11) What is the patient's employment status?
- 12) What is the patient's marital/relationship status (married, partnered, single, alone, living with someone, recent breakup vs. ongoing relationship)?
- 13) Does the patient have children?
 - a) Are appropriate child care arrangements in place during the crisis?
 - b) How does the patient perceive the impact on the children of the psychological distress (including possible suicide)?
 - c) Might the patient be thinking about "taking the kids with" him or her?

Probe for Current Suicidal Thoughts

- 1) What is the patient's intent?
- 2) What is the patient's motive (relief, mobilize supports, revenge, reunion)?
- 3) How often and for how long does the patient think about suicide?
- 4) Does the patient have a suicide plan?
 - a) Method contemplated (lethality)
 - b) Extent of planning
 - c) Likelihood of being discovered
 - d) Presence or absence of hope, and of various deterrents to suicide, including religion

Web Site Address

www.rmhf.harvard.edu/private/suicide-support

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RMF Guidelines for Prescribing Psychiatrists in Consultative, Collaborative, or Supervisory Relationships

For psychiatrists providing patient care in collaboration with other therapists and clinicians

Sample CRICO Case

Sixteen months after starting Clozapine under weekly monitoring by his psychiatrist, a 48-year-old patient presented to a hospital emergency department complaining of bowel discomfort. He was treated for fecal impaction. Five days later, still not feeling well, he cancelled his regular (Clozapine) blood work appointment. He was told to have his internist order the blood test during an appointment scheduled for the next day. Noting that the patient was still suffering from fecal impaction, the internist instructed him to restart the magnesium citrate, call in three days, and schedule an appointment for the next week. The next day, the psychiatrist received the blood test results showing an elevated white count. He repeatedly instructed the patient to see his internist immediately, explaining that the infection could be fatal. When the patient did call, his physician was not in the office. The next day, a mental health aide visiting the patient at his home encouraged him to go to the hospital. The patient did not go that day; two days later, while en route to the hospital, the patient died of sepsis secondary to peritonitis.

Background

In 1995, RMF convened a committee to address the risks of psychiatrists providing patient care in collaboration with other therapists and clinicians. RMF had seen an increase in psychiatric care claims stemming from outpatient treatment, reflecting potential problems with communication and coordination among providers. Over the next year, RMF coordinated development of the *Guidelines for Prescribing Psychiatrists in Consultative, Collaborative, or Supervisory Relationships*.

Developed by the RMF Psychiatry Guidelines Task Force (1995-1996)

Lloyd I. Sederer, M.D. (co-chairman)

James M. Ellison, M.D. (co-chairman)

MaryAnne Badaracco, M.D.

George Dominiak, M.D.

William Falk, M.D.

Gordon Harper, M.D.

Burt Johnson, M.D.

Nancy Nitenson, M.D.

David Osser, M.D.

Randall Paulsen, M.D.

Peter Reich, M.D.

Andrew Stoll, M.D.

Gail Tsimprea, Ph.D.

The *Guidelines for Prescribing Psychiatrists in Consultative, Collaborative, or Supervisory*

Relationships are not to be construed or to serve as a standard of care. This model should be considered only as a guideline. Adherence to it will not ensure a successful outcome in every case.

Comments were elicited from psychiatrists, psychologists, social workers, nurses, interns, residents, and primary care providers before finalizing the recommendations.

The goals were to:

1. Clarify the role of a prescribing psychiatrist when the patient is being concurrently treated by another clinician or facility, or the psychiatrist is providing psychotherapy and the patient's primary care physician is prescribing medications;
2. Improve the quality of care delivered to psychiatric patients; and
3. Reduce the possibility for errors and claims resulting from a lack of coordination of care in the delivery of treatment to psychiatric patients.

Using the Guidelines

In 1998, Lloyd Sederer, M.D. and James Ellison, M.D. presented the guidelines to the psychiatric departments of all participating CRICO-insured institutions. The participating psychiatrists used them to promote discussion of customs, norms, and systems issues at their respective institutions. RMF provided a model presentation with short cases to enhance discussions. The guidelines would be a good teaching tool for psychiatric interns and residents, but it is unclear if this is happening.

Also in 1998, the guidelines presented to the American Psychiatric Association (APA) and the Massachusetts Psychiatric Society (MPS). All audiences were enthusiastic. While some mild disagreement was expressed about what the responsibility of a supervisor should be (from both supervisors and supervisees) and some confusion about the definitions of collaboration and consultation, the APA and MPS members were pleased to see some guidance in an area that can be confusing.

Structure

The *RMF Guidelines for Prescribing Psychiatrists* are designed to improve patient care and reduce malpractice claims and loss by addressing the preventable risks related to communication and coordination amongst multiple practitioners providing psychiatric and medical care. The definitions and matrices in the guidelines serve to clarify the varying roles and responsibilities in consultative, collaborative, and supervisory relationships.

The eight-page guideline provides definition and matrices—as outlined below—for psychiatrists and other treating clinicians to consider while coordinating patient care.

Next Steps

The committee has considered a study based on record review to see if the rate of documentation for discussions about consultation, collaboration, or supervision increased after the rollout of the guidelines. As yet, such a study has not been pursued. A handy reference tool (algorithm, "cheat-sheet", etc.) might increase the practical application of the guidelines.

RMF Guidelines for Prescribing Psychiatrists in Consultative, Collaborative, or Supervisory Relationships

Sample section

I. ASSESS THE CONTEXT AND CIRCUMSTANCES	Consultation	Collaboration	Supervision
<p>Communicate with the Other Clinician(s)</p> <p>1) Determine who else is clinically involved in the patient's care.</p> <p>2) Determine why have you been asked to assist.</p> <p>3) Discuss your treatment styles and goals. If a provider's treatment of a patient appears to be problematic, discuss your concerns with that clinician, particularly addressing any issues involving the safety of the patient or others.</p>	<p>Informal consultation may not include all elements listed in this column.</p> <p>Treatment styles: When consulting to a PCP, e.g., assess the PCP's experience and comfort with psychiatric illness and prescribing psychiatric medications.</p>		<p>These responsibilities may be assigned to the supervisee, as appropriate.</p>
<p>4) Define your respective roles.</p>	<p>Roles: Generally, in a consultation you are asked to give an opinion which the consultee is free to follow or not, based on his/ her knowledge of the patient.</p>	<p>Roles: In a collaboration you deliver direct care to the patient concurrent with other licensed or credentialed mental health or health care professionals.</p>	<p>Roles: Supervision is a formal arrangement in which you train and evaluate another mental health professional. Some kinds of voluntary, educational arrangements are referred to as "supervision;" if this type of arrangement begins to become more consultative, consider following the consultation guidelines.</p>
<p>When working with a resident as a consultant, collaborator, or supervisor, consider inviting the resident to attend or participate in your evaluation of the patient if this would be an appropriate teaching exercise and if the patient consents.</p>			
<p>5) Clarify communication expectations among providers. Address content, frequency, and preferred methods of communication.</p>	<p>Communication: If you are asked to consult or collaborate with a clinician who is being supervised:</p> <ul style="list-style-type: none"> • Ask that clinician to inform his/ her supervisor about your participation in the assessment or care of the patient. An RNPC should inform his/her supervising physician, a resident should inform his/ her direct supervisor, and • Determine whether you will communicate with the clinician, the supervisor, or both. 		
<p>6) Establish a communication plan for emergencies.</p>			

How You Can Help

As with any risk management recommendation, the practical application and benefit analysis of the *RMF Guidelines for Prescribing Psychiatrists in Consultative, Collaborative, or Supervisory Relationships* is best determined by the clinicians asked to employ it over time. RMF is keenly interested in your feedback related to understanding and referencing these guidelines. **For more information or to offer feedback**, contact RMF Communications Director, Jock Hoffman, at (617) 495-5100, ext. 240, or by e-mail to jhoffman@rmf.harvard.edu ■

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- Formal Consultation
- Collaboration with Licensed Clinicians
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- Planning Next Steps

Clinical Standards for the Obstetrical Services of the Harvard Medical Institutions

For obstetricians, nurse midwives, obstetrical nurses, and administrators

Sample CRICO Case

A pregnant patient with a history of increasing blood pressure was admitted for induction during her 41st week because of oligohydramnios. Eighteen hours later, the baby was delivered through thick meconium. Fetal tracings indicated a deterioration during the final hour prior to delivery. The child experienced growth retardation, left hemiplegia, mild spastic quadriplegia, and—later on—speech problems. Suit was brought against two obstetricians alleging delay in the treatment of fetal distress. Legal discovery for the case revealed a disagreement among the clinicians as to who was notified of the fetal tracings.

Background

From 1990-99, obstetrical cases accounted for four percent of CRICO's claims; 48 percent of those cases closed with payment. Obstetrics has always been an area of high risk—from an underwriting perspective—for CRICO (and other malpractice insurers). Back in 1987, following their review of CRICO claims, the Harvard-affiliated obstetrical chiefs initiated development of clinical standards to:

- ◆ provide a practical guide for the provision and documentation of generally accepted levels of care during prenatal visits, labor, and delivery;
- ◆ influence physician, midwife, and RN behavior so that birth outcomes improved;
- ◆ ensure that parents' expectations are reasonable and that they are well-informed throughout the pregnancy;
- ◆ improve documentation of obstetrical care during all phases of pregnancy; and
- ◆ improve the quality, coordination, and timeliness of care by providing adequate provider participation in obstetrical care.

The initial guidelines were completed in 1988 and were revised in 1990, 1995, and 1998.

Using the Standards

The objective in developing and implementing the *Clinical Standards for the Obstetrical Services of the Harvard Medical Institutions* was to influence clinician behavior so that outcomes are improved, patient expectations are reasonable and informed, and preventable malpractice claims and losses are averted.

Having been revised in 1998, the obstetrical standards represent current clinical and risk management practices. They are used variably by the CRICO-insured institutions. For example, Harvard Vanguard Medical Associates and North Shore Medical Center use the guidelines for purposes of teaching and discussion.

Structure

The 18 Clinical Standards offer a framework for providing obstetrical care, rather than an inflexible set of mandates. In some instances, these guidelines were codification of existing hospital procedures or of recommendations found in *Guidelines for Obstetric-Gynecologic Services of the American College of Obstetricians and Gynecologists (ACOG)* or *Guidelines for Perinatal Care of the American Academy of Pediatrics and ACOG* at the time the Harvard guidelines were written or revised.

Next Steps

Harvard's obstetrical standards group, comprising physician, midwife, and nursing chiefs from the CRICO-insured institutions was reconvened by RMF in September with a draft revision of the guidelines anticipated by April 2001. Inclusion of additional guidelines (perhaps one related to shoulder dystocia) will be considered at that time.

How You Can Help

As with any risk management recommendation, the practical application and benefit analysis is best determined by the clinicians asked to employ it over time. RMF is keenly interested in your feedback related to understanding and referencing these guidelines. **For more information or to offer feedback**, contact RMF Loss Prevention Consultant, Heidi Groff, at (617) 495-5100, ext. 278, or by e-mail to hgroff@rmf.harvard.edu. ■

Web Site Address

www.rmf.harvard.edu/rmLibrary/clinical-guidelines/ob-guideline/

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Developed by a multidisciplinary group of obstetricians, nurse midwives, and obstetrical nurses from the CRICO-insured institutions (1988-1998).

The *Clinical Standards for the Obstetrical Services of the Harvard Medical Institutions* are not to be construed or to serve as a standard of care. This model should be considered only as a guideline. Adherence to it will not ensure a successful outcome in every case.

Sample section

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- 9 Assessment of fetal maturity in normal gravidas prior to repeat cesarean delivery or elective induction of labor
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- 13 Operative vaginal delivery *SEE SAMPLE*
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- 18 Screening for and reporting of adverse patient outcomes and untoward events

Guideline 13: Operative Vaginal Delivery

The vacuum extractor or forceps shall only be used if all of the following are met:

- 1) The clinician has clinical privileges to use vacuum extractor or forceps;
- 2) The fetal head exclusive of any caput has reached at least station +2 cm (on a scale from -5 to +5) and clinical pelvimetry indicates that delivery without fetal or maternal trauma can reasonably be expected.
- 3) The cervix must be completely dilated and the membranes ruptured.
- 4) The clinician must know precisely the station, position and attitude of the fetal head to permit an accurate cephalic application of the forceps blades, or vacuum cup.
- 5) Adequate anesthesia has been administered.
- 6) For vacuum extraction, careful pelvic examination to rule out any maternal tissue (cervix or vagina) trapped between the cup and the fetal head must be done after the cup is applied at low negative pressure and before inducing the high negative pressure needed for traction.^a
- 7) Capability to perform an emergency cesarean section, if unexpected difficulties are encountered, is available.

Under very unusual circumstances, such as sudden, severe fetal or maternal compromise, application of the forceps above station +2 (on a scale from -5 to +5) may be attempted while simultaneously initiating preparations for a cesarean delivery.

In the event of failure of vacuum extraction, all the clinical issues should be carefully reevaluated before further attempts at operative vaginal delivery.

The clinician shall prepare for the patient's medical record a detailed dictated operative note which includes the station and position of the fetal head, the fetal status at the time of application of the vacuum extractor or forceps, indications, and clinical rationale, including substantive risks discussed with patient. In addition to a dictated note, a short written summary should be placed in the medical record immediately following delivery.

^a American College of Obstetricians and Gynecologist, ACOG Technical Bulletin Number 152: Operative Vaginal Delivery, (Washington, D.C.: The American College of Obstetricians and Gynecologists, February 1991), p. 2-4.

For general surgeons and general surgery residents

Sample CRICO Case

A 38-year-old female undergoing an elective cholecystectomy tolerated the procedure well, and was extubated in the OR and sent to recovery in good condition. Several days post-op, she developed severe right upper and lower quadrant pain associated with hyperbilirubinemia. The right hepatic duct presented with a small bile leak which was repaired. A suit was filed naming the hospital, surgical resident, and attending physician alleging careless and unskillful care. During discovery, it became unclear whether or not the patient had known that a resident was going to perform her surgery. The staff surgeon to whom patient was assigned was not present in the OR when the duct injury occurred.

Background

A 1993 review of CRICO surgery-related medical malpractice claims identified resident supervision as a particularly problematic area—involving a quarter of the general surgery claims examined. Decisions by attending physicians to handoff important aspects of care and over-delegation of responsibility to residents were allegations particularly difficult to defend.

The key areas identified as needing improvement were:

- ◆ resident supervision,
- ◆ patient communication,
- ◆ informed consent,
- ◆ patient follow-up,
- ◆ documentation, and
- ◆ flow of information.

A framework for quality improvement was developed on the premise that the performance surgical residents can be influenced by aiming intervention at the residents, the attendings, the workplace, and the organization as a whole. Subsequently, RMF coordinated development of guidelines designed to:

- ◆ improve the quality of care received by surgical patients,
- ◆ address resident supervision issues revealed in medical malpractice claims,
- ◆ foster an environment in which health care providers can learn from their successes and failures, and
- ◆ provide a useful teaching tool to reaffirm practice.

Developed by the RMF Resident Supervision Guidelines Task Force (1993)

Albert Bothe Jr., M.D.
Roger Christian, M.D.
Fred Ackroyd, M.D.
Mark Weinstein, M.D.

The *RMF General Surgery Resident Supervision Guidelines* are not to be construed or to serve as a standard of care. Adherence to it will not ensure a successful outcome in every case.

Using the Guidelines

RMF's *General Surgery Resident Supervision Guidelines* were aimed at enhancing surgical patient care by reducing preventable supervision errors. They were constructed as general statements so that each institution could tailor policies and practices to its own organization. Keeping this list of recommendations in mind can help attendings and residents recognize when assistance is needed and promote reassurance in seeking such help.

The guidelines were designed to address:

- ◆ assessment of resident abilities,
- ◆ appropriateness of independent patient care assignments,
- ◆ development of performance evaluation standards,
- ◆ supervisory physician support and teaching, and
- ◆ moonlighting issues.

Since 1993, acceptance and implementation of RMF's *General Surgery Resident Supervision Guidelines* has intersected with other quality improvement efforts, including changes in supervision *requirements* dictated by Medicare. Nevertheless, the recommendations outlined in the RMF guidelines remain sound.

Next Steps

Liability in surgical specialties is an area of increased focus for RMF. Viewed in the context of supervision, claims factors include errors in interpretation, communication breakdowns leading to delayed diagnoses, and sometimes underestimating the gravity of the situation until it is too late.

Not seeking help when necessary, failure to supervise adequately, key information not reaching the right people, and a perceived lack of caring are critical quality of care issues. Because the authority gradient seems to often be a barrier to communication, the guidelines play a part in the kinds of renewed efforts needed to transform systems, behaviors, and practices necessary to build a culture of safety and reduce medical error.

How You Can Help

As with any risk management recommendation, the practical application and benefit analysis is best determined by the clinicians asked to employ it over time. RMF is keenly interested in your feedback related to understanding and referencing these guidelines. **For more information or to offer feedback**, contact RMF Loss Prevention Consultant, Kathy Dwyer, at (617) 495-5100, ext. 503, or by e-mail to kdwyer@rmf.harvard.edu ■

Full text

Achieving the balance between resident supervision and autonomous experience is a constant challenge in physician training. Supervision adequate to enhance the quality of patient care requires that the degree of autonomous resident functioning is appropriately assessed, supervisory physicians are readily available to evaluate and support resident care decisions, and residents can recognize when assistance is needed and feel comfortable seeking this help.

Assessment of Residents' Ability to Function Independently

- 1) The assessment of a resident's abilities shall serve as the basis for determining the minimum level of supervision required for different activities. This shall include the evaluation of technical, patient management, and communication skills.
- 2) Objective criteria to evaluate a resident's progressive level of ability to function independently in these skill areas shall be developed and consistently applied. Such measures may include:
 - assessments of supervisory physicians
 - residency program director assessment
 - in-service exams
 - volume and distribution of clinical experience (both operative and non-operative)
 - patient comments
 - quality improvement data
- 3) Information about a resident's abilities shall be provided to all supervisory physicians to which the resident is assigned so that the resident receives appropriate assignments and levels of responsibility.
- 4) Residents shall be informed of the criteria used to evaluate their performance and shall be given ongoing, specific feedback about their progress by supervisory physicians. It is recommended that a resident complete a self assessment for the purposes of discussion. This presents an opportunity to identify and address any discrepancies between a resident's own perceived abilities and those observed by supervisory physicians.

Supervisory MD Interaction

- 1) Physicians with responsibility for supervising residents shall create an environment in which residents are encouraged to discuss patient management and to seek advice and assistance when appropriate. The extent to which attendings act as role models in discussing patient management will influence the success of such an effort.
- 2) A supervisory surgeon shall be readily available to provide sufficient support to residents in all aspects of patient care. In addition to the usual areas of care, this support should extend to talking with patients/families during difficult or complex situations such as: when the patient is dying, has experienced an untoward event, or when the patient/family is difficult.
- 3) A system shall be established for contacting supervisory physicians when their assistance is perceived necessary by appropriate hospital personnel.
- 4) Specific programs for faculty training shall be developed and provided to all physicians who will be supervising residents. The elements of such programs shall include instruction on:
 - assessing resident performance
 - effective methods for providing feedback
 - appropriate steps in handling residents experiencing difficulties in their performance
- 5) Mechanisms shall be established, consistent with Residency Review Committee requirements, by which the performance of physicians in their supervisory role is evaluated. One component of this process shall be the solicitation of feedback from residents about the performance of physicians in their supervisory role.

Moonlighting Within and Outside the Harvard Institutions

- 1) Moonlighting, in any setting, shall not interfere with the educational activities of resident training and shall be consistent with guidelines for work hours.
- 2) Residents and fellows shall consult with a designated physician at their parent institutions regarding appropriate settings in which to moonlight based on the resident's and fellow's experience and skill level.
- 3) The Chief and/or Director of Residency Program at the parent institution shall assess the adequacy of systems in place at the moonlighting institution to provide needed support for residents and fellows.
- 4) Periodic communication between the parent institution and moonlighting institution shall occur regarding the environment in which the residents and fellows will be practicing.

Web Site Address

www.rm.f.harvard.edu/rmLibrary/clinical-guidelines/supervision

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Contact RMF (617-495-5100, ext. 255)

For all physicians

Sample CRICO Case

A patient who underwent exploratory abdominal surgery for symptoms of a possible bowel obstruction claimed the surgery was unnecessary, and that no one in the institution had made any disclosures about the need for, or risks of, the planned procedure. The Massachusetts Appeals Court upheld the summary judgment of the lower court on the basis that the consent forms for surgery and anesthesia signed by the patient made reference to discussions between the physician(s) and patient, and the patient had presented no credible evidence to dispute that finding.

Background

A 1982 ruling by the Massachusetts Supreme Judicial Court (SJC) in a malpractice case [*HARNISH V. CHILDREN'S HOSPITAL MEDICAL CENTER*, 387 MASS 152 (1982)] involving CRICO-insureds established the basic framework for the doctrine of informed consent in the Commonwealth. Additional opinions from Massachusetts' courts in 1985, '93, '94, '97, and '99 provided further clarification.

RMF coordinated development of the initial *Informed Consent Guideline* based on the criteria set out by SJC's 1982 opinion. In 1987, the Massachusetts Board of Registration in Medicine adopted the same language for its Patient Care Assessment regulations mandating formal risk management programs in health care facilities.

Using the Guidelines

RMF coordinated development of the *Informed Consent Guidelines* to assist CRICO-insured institutions in reviewing policies, procedures, and forms related to the process of obtaining and documenting a patient's informed decision and consent to undergo a proposed medical intervention or procedure. These include the:

- ◆ nature of the patient's condition and procedures to be performed;
- ◆ type of and probability of the material risks involved;
- ◆ benefits to be reasonably expected from the procedure;
- ◆ inability of the physician to predict results;
- ◆ irreversibility of the procedure, if applicable;
- ◆ likely result of no intervention or procedure; and
- ◆ available alternatives, with their risks and benefits.

In 1983, the initial *Informed Consent Guidelines* were adopted as a loss control requirement by the CRICO Board of Directors. The guidelines were reviewed, updated, and again affirmed as loss control requirements by CRICO in 1990.

The *Informed Consent Guidelines*, as revised in 1990, delegate responsibility to each institution for periodic review/ updating, and determining the appropriate implementation processes and scope of procedures requiring informed consent in their particular setting. Given the range of institutions insured through CRICO, the content of institutional informed consent policies varies.

The guidelines provide a framework for institutional policies and procedures, and have also been successfully used as a defense tool in medical malpractice cases where lack of informed consent has been part of the claimant's allegations. They have also served as a model for other institutions developing informed consent processes.

Next Steps

Revision of the generic *RMF Informed Consent Guidelines* is not planned for the immediate future. Insured institutions are not required to file their current informed consent policy or forms with RMF in order to obtain insurance coverage. **For more information or to offer feedback**, contact RMF Director of Regulatory Services, Sally Trombly, at (617) 495-5100, ext. 243, or by e-mail to strombly@rmf.harvard.edu ■

Developed by Risk Management Foundation (1983)

The *Informed Consent Guidelines* are not to be construed or to serve as a standard of care. This model should be considered only as a guideline. Adherence to it will not ensure a successful outcome in every case.

Web Site Address

www.rmfm.harvard.edu/rmLibrary/clinical-guidelines/informed-consent

For Paper Copies

Contact RMF (617-495-5100, ext. 255)

RMF Informed Consent Guidelines

Full text

The following guidelines have been prepared to assist institutions in reviewing policies, procedures and forms relative to obtaining and documenting informed consent. The guidelines are based in part of opinions and advice of malpractice defense attorneys in Massachusetts. RMF recognizes that institutions should continue to have the flexibility to respond to such recommendations in a manner that will least disrupt the orderly provision of health care at the facility.

- 1) Written policies and procedures should be developed by each institution designed to address all aspects of the informed consent process. At a minimum, policies should address: a) Medical procedures and treatments for which informed consent is required; b) Persons responsible for obtaining the consent of the patient; c) Manner of documentation of consent; and d) Appropriate persons, other than the patient, from whom consent may be obtained.
- 2) Consent should be obtained for all major therapeutic and diagnostic procedures where disclosure of significant medical information, including major risks involved, would assist a patient in making an intelligent decision whether to undergo the proposed procedure. Such procedures include:
 - a) All surgical procedures performed under general/spinal anesthesia and selected procedures under local anesthesia
 - b) Selected biopsies and excisions (including bone marrow)
 - c) Cardiac catheterization and angiography
 - d) All major endoscopies
 - e) Bronchograms, lymphangiograms, myelograms, pneumoencephalograms, splenograms, ventriculograms, and radiation therapy
 - f) Extracorporeal and peritoneal dialysis
 - g) Cancer chemotherapy
 - h) Electroconvulsive therapy
 - i) Testing for human immunodeficiency virus (HIV)
 - j) Blood and blood product use (including blood donation and autologous and other blood transfusions)
 - k) Major radiologic and/or imaging procedures involving the use of contrast media (as per specific recommendations anticipated from the Loss Control Committee's Radiology Advisory Committee)
 - l) Medications and/or other therapeutics with the potential for particularly severe side effects
- 3) A separate written consent should be obtained for the use of general, spinal and/or epidural anesthesia by the clinician administering and/or responsible for the anesthesia.
- 4) It is the physician's responsibility to obtain the informed consent of his patient, and to discuss sufficient medical information to enable the patient to decide whether to submit to treatment. Although the physician is responsible for informing the patient, hospital personnel may assist in the completion of documentation.
- 5) The type of information to be disclosed and discussed with the patient includes:
 - a) Nature of patient's condition and procedures to be performed
 - b) Nature and probability of material risks involved
 - c) Benefits to be reasonably expected of the procedure
 - d) Inability of the physician to predict results
 - e) Irreversibility of the procedure, if that is the case
 - f) The likely result of no treatment or procedure
 - g) Available alternatives, including their risks and benefits
- 6) The type and the number of risks to be disclosed should depend on the significance the doctor's patient would attach to such risks in deciding whether to consent to the procedure or treatment. (The court recognizes that such disclosure does not apply to all "remotely possible risks of proposed treatment" which may be "almost without limit.")
- 7) A patient's consent should be documented with sufficient clarity and detail so as to satisfy the reader that the patient was given and understood the medical information listed in Item 5 above. Such documentation should include:
 - a) A statement that the information listed in Item 5 above was imparted to the patient
 - b) A specific listing of some of the more major material risks disclosed including, but not limited to, loss of life, loss of limb function, brain damage, paralysis, hemorrhage, allergic reactions, nerve injury and blood clots
 - c) General information such as the patient's name, contemplated procedure, and provision for the disposal and/or use of tissue necessarily removed during surgery
 - d) The date the patient expressly gave his/her consent
 - e) The date the documentation was recorded (if different than the date of consent)
 - f) Signature of the physician disclosing the information and obtaining consent
 - g) Signature of the patient
- 8) The patient's informed refusal of recommended diagnostic and therapeutic interventions, particularly when the decisions involve potentially life-threatening conditions, should also be documented.
- 9) Institutional policies should delineate the process to be followed, including required documentation, when it appears likely that tissue obtained by a procedure will be used in commercial development.
- 10) The potential use of tissue obtained by a procedure in research (of a non-commercial nature) and/or training should be documented on consent forms, as applicable.
- 11) Consent forms should contain language addressing the participation of physicians-in-training and/or other allied health practitioners in the procedure, as applicable.
- 12) Medical services and departments should develop brief lists of procedures, performed frequently within the specialty involved, which require written informed consent. Additionally, major material risks for each procedure should be identified. These lists should be appended to the institutional informed consent policy to provide clearer guidance for physicians on institutional requirements for informed consent.
- 13) Institutional informed consent policy and forms should undergo periodic review and update by the institution, as indicated, and should be submitted as requested to the Loss Control Committee of the CRICO shareholders for endorsement.

Approved by CRICO, March 12, 1990 as Loss Control Requirements of Shareholder Institutions

The RMF Guidelines for Responding to an Adverse Event

For all clinicians and health care administrators

Case Study

After undergoing the resection of an arterial venous malformation, a patient had a stroke with resulting left side paralysis and seizure activity. The patient alleged that the stroke was caused by damage to an artery during the surgery. The surgery had been performed by a chief resident after she consulted with the attending physician. However, in a written response to a note from the patient inquiring about his involvement, the attending tried to distance himself from the case. In addition, review of the record indicated correction fluid had been placed over the attending's name on the operative report.

Background

Most patients who experience an adverse event or poor clinical outcome do not sue their clinicians. But, many claims of malpractice are exacerbated by how things were handled *after* an unexpected outcome. The vast majority of providers know how to handle the medical aftermath of an adverse event, but because such events are infrequent, many are less clear about what to say and to whom; what to write down and what not to.

In an effort to help health care providers focus on the patient's ongoing care and needs, RMF, in 1997, recognized the value of offering guidelines on communicating and documenting bad news following an adverse medical event. Consultation with risk managers and legal counsel from the CRICO-insured institutions led to publication of RMF's *Guidelines for Responding to an Adverse Event*.

Using the Guidelines

RMF created these guidelines to assist CRICO-insured institutions in reviewing their own policies and procedures. They serve to identify the sequence of post-event steps as well as the institutional contacts and information that a department or clinic should have readily available.

Next Steps

The *RMF Guidelines for Responding to an Adverse Event* were written in 1997. As with any risk management guideline, the practical application and benefit analysis is best determined by the clinicians asked to employ it over time. RMF is keenly interested in your feedback related to understanding and referencing these guidelines. **For more information or to offer feedback**, contact RMF Communications Director, Jock Hoffman, at (617) 495-5100, ext. 240, or by e-mail to jhoffman@rmf.harvard.edu ■

Web Site Address

www.rmfm.harvard.edu/rmLibrary/legal-claims/adverse-event

For Paper Copies

Contact RMF (617-495-5100, ext. 255)

Developed by Risk Management Foundation (1997)

The *Guidelines for Responding to an Adverse Event* are not to be construed or to serve as a standard of care. This model should be considered only as a guideline. Adherence to it will not ensure a successful outcome in every case.

Full text

What To Do After An Adverse Event

The following checklist covers a range of actions to consider after an unexpected outcome. The seriousness of the event and the relationship between the parties involved will dictate which steps need to be carried out in full, and their sequence. Running through the list will help organize thorough, appropriate, and consistent responses.

Attend to the Patient's Medical Needs

When appropriate, obtain medical consultation and arrange for consultants to forward necessary follow-up information.

Talk to the Patient or Family

- 1 As soon as possible after an adverse event occurs, try to speak with the patient and family members to apprise them of the situation and to help them understand the implications.
- 2 Answer questions factually and directly.
- 3 Offer emotional support.
- 4 Do not blame other clinicians.
- 5 Do not speculate about what *might* have gone awry. While early speculation might restore trust, it will have a damaging effect if it proves incorrect later on.

Confer with Other Providers

- 1 Meet with the rest of patient's health care team. Clarify the factual details and sequence of what occurred, as well as what needs to be done in response. A group discussion can resolve information gaps and dispel potential conflicts among providers.
- 2 Identify which clinician will assume primary responsibility for communicating with the patient or family.

Contact the Risk Manager

Contact your organization's risk manager. Complete other reports (e.g., potential claims to insurer, medical device failures to FDA) as needed.

Talk to the Patient or Family *Again*

- 1 Organize a family meeting if several relatives are involved in the patient's care or if treatment decisions are complicated. Consider inviting the primary care or referring physician. A group meeting can help generate a common understanding of the situation among family members and facilitate coordinated decision making.
- 2 Communicate the sequence of events, outcome, and care plan to the patient and family.
- 3 Be accessible for follow-up questions or further explanations. As patients and family members begin to understand the significance of information previously communicated, they may think of new questions or ask providers to re-explain the event.
- 4 Try not to be defensive when speaking with patients and families, even if their remarks are accusatory. If appropriate, acknowledge and apologize for the patient's distress.
- 5 Accept responsibility for follow-up of serious complaints, but do not accept blame or assign blame to others. Do not criticize the care or responses of other providers.

The Medical Record

- 1 Assign the most involved and knowledgeable member(s) of the health care team to record factual statements of the event in the patient's record. Also record any medical follow-up completed, planned, or needed.
- 2 Avoid writing information in the medical record which is unrelated to the care of the patient (e.g., "incident report filed," "legal office notified").
- 3 Avoid writing derisive comments about other providers. If you disagree with another clinician, document the basis for your treatment recommendations but do not use the medical record for peer performance evaluations.
- 4 If you add information to the patient's record after an adverse event has occurred (particularly if your notation relates to treatment decisions made prior to the event):
 - Mark your entry with the actual date it is written; do not "backdate" any entries.
 - Beware of creating entries which appear self-serving, especially explanations intended solely to justify your actions. Taken out of context later, these entries can make you look defensive and can give the impression you thought you were at fault.

Writing off Bills

Disagreements about the patient's bill commonly arise in the same cases in which patients or family members seek legal advice. To address this dissatisfaction, the clinician or entity may want to consider "free servicing" all or a portion of a patient's bill on a case-by-case basis. Some patients will see this as a gesture of goodwill and will be satisfied to resolve the problem this way. Others, who may be inclined to sue, will do so regardless of any billing adjustments.

The National Practitioner Data Bank does not consider waivers of debt to be reportable and courts do not consider them admissions of liability. However, because billing issues can both identify and precipitate problems with patients, physicians should coordinate offers to write off care with individuals who would normally be involved in resolving a potential claim or suit (e.g., risk managers, billing departments, and professional liability insurers).

The Media

Media queries related to adverse events are best handled via institutional protocols for responding to press contacts. This will avert complications related to patient confidentiality, legal discovery, and heat-of-the-moment coverage.

Conclusion

This list is premised on the belief that clinicians should do what is best for their patients, after adverse events or otherwise. These actions will not prevent all claims and suits, but will prevent some, mitigate others, and ensure that risk management is aligned with good medicine.

Receiving a Summons & Complaint

On occasion, the first evidence a clinician receives of connection to an "adverse event" is delivery of legal papers known as a Summons & Complaint. Immediately upon receipt of these documents, the clinician should contact his or her institutional risk manager, who will contact the professional liability insurer. Failure to respond can result in serious penalties for the defaulting clinician.

FORUM

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

**Risk Management
Foundation
101 Main Street
Cambridge, MA 02142**

E-mail:
Forum@RMF.Harvard.edu

Fax: 617-495-9711.

Editor
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Alice Fritz

This issue introduces some changes to the look and layout of *Forum*. These enhancements are designed to improve our ability to present timely and practical health care risk management information in a clear and concise format. We would appreciate any feedback on these adjustments.

FALL 2000

Volume 20

Number 5



RISK MANAGEMENT FOUNDATION HARVARD MEDICAL INSTITUTIONS

Review of Risk Management Guidelines

Issue Editor: Jock Hoffman

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