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PRF NEWS

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Covering Practice and Risk Management Issues for Physicians

Informed Consent

BY JUNE RILEY

Informed consent is the formal process by which patients participate in decisions about their health care. This means that the patient not only has the right to refuse any recommended medical procedure, but that the physician has the obligation to provide sufficient information to make the consent meaningful. Yet the ambiguity of what is "sufficient information" can be an issue when the recommended procedure gives rise to complications. Although the following paragraphs highlight some basic guidelines, keep in mind that taking care to communicate thoroughly and thoughtfully with your patients (and documenting that communication) serves both the patient's and physician's best interests.

➤ **A pre-printed consent form used alone does not satisfy a physician's responsibility for obtaining informed consent**

A printed informed consent form should only be used in *conjunction* with a discussion between the physician and patient (or the patient's legal representative) about the recommended treatment. Although many physicians believe that forms provide tangible evidence that the patient has had the chance to review the appropriate information before giving consent, others voice the concern that forms are inflexible and may actually harm the physician in court if information later deemed "material" was not included. The solution is to place a note in your chart documenting that you discussed issues *specific* to the patient's decision in addition to the general factors on the written form. A copy of the signed consent form should be placed in the patient's medical record. Remember that proper documentation is your best defense to a later claim that the consent was not adequate.

➤ **Certain procedures have special informed consent requirements**

Certain procedures are governed by laws that require physicians to obtain specific uniform acknowledgements in addition to obtaining verbal informed consent. However, despite the requirement for the signing of mandated forms, documenting the informed consent discussion with the patient is especially important in these clinical circumstances.

Some of the procedures that are governed by special rules include:

- Sterilization
- Hysterectomy
- Treatment of breast, prostate and gynecological cancers
- Infertility treatments
- Certain experimental procedures

➤ **It is the physician's personal responsibility to obtain the patient's informed consent.**

The duty to inform and explain is the responsibility of the physician who will be performing the procedure. Generally, the physician should not delegate this duty to a nurse or any other non-physician.

➤ **Emergency medical situations may modify informed consent requirements**

In the case of a true emergency, the informed consent requirement may be waived. However, the "emergency" exception is narrowly defined. For example, discovering an unexpected condition during the course of performing a procedure for which informed consent has been obtained does not necessarily constitute an "emergency" that would relieve the physician of his or her duty to obtain the patient's informed consent for further treatment. The "emergency" exception would apply only if a physician encounters a truly unexpected condition that must be remedied immediately. If the unanticipated condition does not pose a danger of immediate harm to the patient, the physician would be well advised to postpone additional surgery until such time as he is able to obtain the patient's informed consent. You may also consider obtaining specific consent in advance for additional surgery to remedy conditions you may encounter and which can and should be dealt with in the same surgery.

➤ **For an informed consent to be valid the patient's consent must be voluntary and the patient must have the capacity to make decisions.**

In general, the responsibility for determining whether a patient possesses the capacity to make health care decisions lies with the physician. It is up to the physician to determine whether a patient is capable of understanding the treatment information being offered, and of the patient's ability to communicate his or

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Inside PRF News

Early Diagnosis of Colorectal Conditions

STEPHEN J. SCHEIFELE, M.D.

Although colorectal cancer has become the second leading cause of cancer-related death in the United States, patients can expect a high survival rate if the malignancy is detected early.

Table 1 on page 3 several different clinically valid screening modalities for colorectal complaints, yet it is clear that these tests have a wide variation in detection sensitivity and cancer mortality reduction. Although many Bay Area physicians are recommending colonoscopy as the primary screening method, patient compliance in following through with the recommended test is a factor in physician test selection. Recent data suggest virtual colonoscopy carried out using specialized techniques may be equivalent to standard colonoscopy. Further study is ongoing. Table 2 outlines current screening recommendations.

Delays in colorectal cancer diagnosis are an increasing cause for failure to diagnose (FTD) malpractice lawsuits. The following factors have been identified as contributing to these claims:

- **Failure to perform an endoscopic exam.** The most common cause for a colorectal cancer FTD lawsuit is the failure to obtain a consultation or order an appropriate diagnostic procedure.
- **Inadequate history.** Although colorectal cancer affects men and women equally, the 1 in 16 lifetime risk of developing colorectal cancer increases significantly with a positive family history. Also cited is the inadequacy of noting certain nonspecific symptoms such as "gas" without attempting to differentiate belching from flatulence.
- **Physician complacency.** Assuming a positive fecal occult blood test (FOBT) is due to a benign condition, e.g. hemorrhoids, without follow-up.
- **Misleading barium enema.** X-rays should be reviewed with the radiologist to assess the quality and completeness of the films and to discuss questionable findings. PCPs should insist on a repeat procedure if the patient had an inadequate prep.
- **Patient lost to follow-up.** Make sure that your office has an appropriate tracking system in place. ■

LEGAL HANDBOOK

The California Physician's Legal Handbook (CPLH) is available through the California Medical Association (CMA). The six-volume set is updated and published annually in print and as a CD ROM. Call the CMA's publications line at (800) 882-1262 to order the 2003 CPLH and to find out the current price for a CMA member and the expected availability date for the 2004 edition. ■

Informed Consent *(continued from page 1)*

her views regarding the health care decision. If the patient has the capacity to give a knowing and informed consent, his or her wishes must be honored.

However, conditions such as medication, emotional turmoil, or a mental disorder may render a patient temporarily "incompetent." If the situation permits, the physician should delay and discuss the matter again when the patient regains his or her decision making capacity.

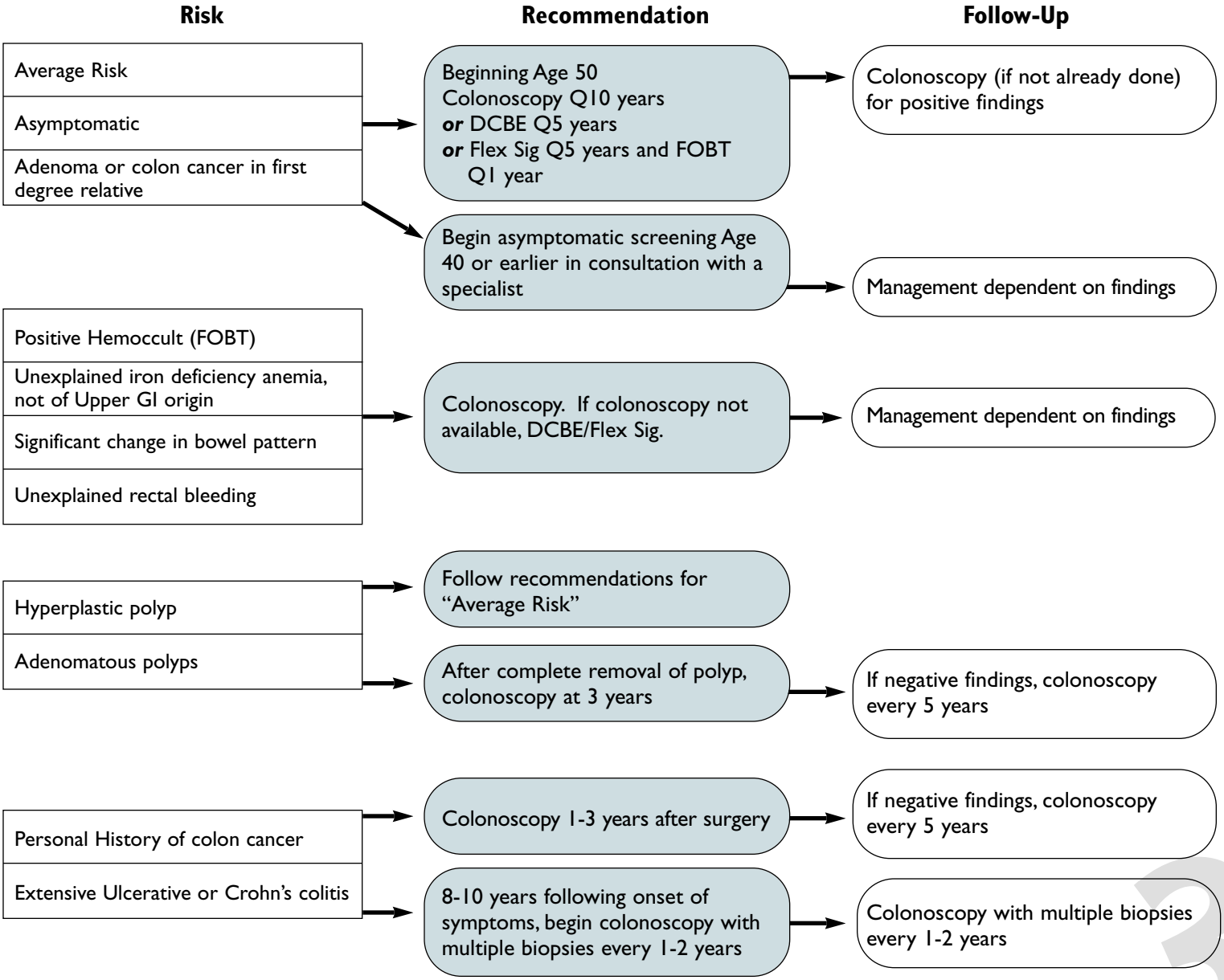
Although these guidelines are presented as a reminder of the importance of the informed consent process, this subject is too complex to be fully covered in a PRF News article. There are many sources to consult for a more complete discussion on informed consent. One very good source is the *California Physician's Legal Handbook*, available from the California Medical Association. (See Briefcase item above.) ■

June Riley is executive director of Physicians Reimbursement Fund, Inc.

Table 1. Colon Cancer Screening Tests

	Periodic Screening	Sensitivity for Polyps >1.0cm	Sensitivity for Cancer	Mortality Reduction from Colon Cancer	Comments
Fecal Occult Blood Test (FOBT)	Yearly	10%	45%	30%	Requires 3 consecutive hemoccults yearly
Flexible Sigmoidoscopy	5 Years	50%	50%	40-50%	Misses 30-40% polyps in proximal colon
Colonoscopy	10 Years	90%	95%	65-80%	Entire colon visualized
Double Contrast Barium Enema (DCBE)	5 Years	50-80%	70-75%	Unknown	Misses 30% polyps and 10% cancers

Table 2. Colorectal Cancer Screening Recommendations



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Responding to Patient Requests for Medical Records

BY ALAN W. SPARER, JD

Although most medical offices receive patient requests for records on a daily basis, physicians and office staff may still be uncertain as to the required response to these requests. The take-home-message is that the medical information contained in your records belongs to the patient, and with few exceptions, patients have nearly an absolute right to access that information. Requests for access by other parties is a different matter and will be discussed in a future article. When responding to patients' requests to inspect or copy their own records, we suggest following these simple guidelines:

- **The request to inspect or copy records must be in writing and signed by the patient or the patient's representative** (a parent or the guardian of a minor, the guardian or conservator of an adult patient, or the beneficiary or personal representative of a deceased patient).
- **Unless the request is limited to specific subjects or time periods, you must respond by providing access to ALL records in the patient's medical file *except* for privileged communications with your attorney or insurer (which do not belong in that file to begin with).** "All records" includes lab reports (including HIV test reports if they are maintained in the file), x-rays, notes, billing and collection records, and correspondence to and from the patient. "All records" includes hospital records, reports received from other physicians, and even materials that may be very old and unrelated to the patient's recent treatment. If the volume is large or you think the patient wants something more specific, discuss it with the patient and document in writing that the request has been narrowed. This documentation itself becomes part of the patient's file.
- **Unless other arrangements are made, the patient must be allowed to inspect the medical file within five days after receipt of the patient's written request. If copies are requested, the copies must be delivered no later than 10 days after receipt of both a written request and payment for copying charges.**
- **It is permissible to charge for the reasonable costs of duplicating the patient's file, although the CMA encourages physicians to waive these charges where the patient is unable to pay.** By law you may charge up to $.25 per page ($.50 per page for records copied from microfilm) or actual costs for reproduction of documents that require special processing. You may also charge reasonable clerical costs incurred in making records available. It is good practice to advise the patient in advance of the charges, because these costs can add up, and the patient may decide to narrow the request.
- **The law allows you to provide the patient with a detailed, written summary instead of a copy of the medical file, but this practice should be avoided.** Record requests are often a signal of dissatisfaction and can be preliminary to legal action. If the patient has questions about your treatment, these are better handled in person. Written summaries are not required and may be viewed merely as an effort to conceal something that would be disclosed in the records.
- **Finally, when in doubt about how to respond, consult with a staff member of the PRF or the Chair of the PRF's Patient Care and Management Committee.** They have plenty of experience to draw upon, and they are ready to assist you. ■

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