

EDITORIAL BOARD

Chairman: Robert C. Young, MD

President, Fox Chase Cancer Center, Philadelphia

James O. Armitage, MD

Dean, University of Nebraska Medical Center College of Medicine

Joseph S. Bailes, MD

Executive Vice President of Clinical Affairs
US Oncology, Dallas

Paul A. Bunn, Jr., MD

Director, University of Colorado Cancer Center
Grohne/Stapp Chair in Cancer Research
University of Colorado Health Sciences Center, Denver
President, American Society of Clinical Oncology

Harold P. Freeman, MD

President and CEO, North General Hospital, New York City
Chairman, President's Cancer Panel
Director, Center for Reducing Health Disparities, NCI
Director, Ralph Lauren Center for Cancer Prevention and Care,
New York City

Joan Hermann, LSW

Director, Social Work Services, Fox Chase Cancer Center

Linda White Hilton, MSN, RN, FAAN

Director, Department of Patient Affairs
MD Anderson Cancer Center

Richard T. Hoppe, MD

Professor and Chairman, Department of Radiation Oncology
Stanford University School of Medicine

Robert J. Mayer, MD

Professor of Medicine, Harvard Medical School
Director, Center for Gastrointestinal Oncology
Dana-Farber Cancer Institute

Peggy A. Means, MHA

Executive Vice President and Chief Operating Officer
Fred Hutchinson Cancer Research Center

Frank L. Meyskens, Jr., MD

Director, Chao Family Comprehensive Cancer Center
Professor of Medicine and Biological Chemistry
University of California, Irvine

Joseph V. Simone, MD

President, Simone Consulting, Dunwoody, GA
Clinical Director Emeritus, Huntsman Cancer Institute

Ellen Stovall

President and CEO, National Coalition for Cancer Survivorship

Paul A. Valberding, MD

Professor of Medicine, University of California, San Francisco
Chief, Medical Service,
San Francisco Veterans Affairs Medical Center
Vice Chair, Department of Medicine, UCSF

Jane C. Weeks, MD, MSC

Director, Center for Outcomes & Policy Research
Dana-Farber Cancer Institute, Harvard Medical School

Norman Wolmark, MD

Chairman and Principal Investigator for Operations
National Surgical Adjuvant Breast and Bowel Project
Allegheny General Hospital Cancer Center, Pittsburgh

PUBLISHED BY LIPPINCOTT WILLIAMS & WILKINS

EDITOR: Sereno Stockwell

ART DIRECTOR: Ellen Oxild

ASSOCIATE EDITOR: Joan Klein

EDITORIAL ASSISTANT: Yesenia Maldonado

ASSOCIATE DIRECTOR OF PRODUCTION: Barbara Nakahara

DESKTOP MANAGER: Peter Castro

COVER ART: Kathleen Giarrano

MANAGER OF CIRCULATION: Deborah Benward

ASSISTANT MANAGER OF ELECTRONIC DEVELOPMENT: Esther Lerch

CONTRIBUTING WRITERS:

Charles Bankhead, Robert Carlson, Lilian Delmonte,
Peggy Eastman, Jane Erikson, Joyce Frieden, Margot Fromer,
Alice Goodman, Gretchen Henkel, Charlene Laino, Peggy Peck,
Naomi Pfeiffer, Eric Rosenthal, Ed Susman, Rabiya Tuma

PUBLISHER: Vickie Thaw

VICE PRESIDENT, ADVERTISING SALES: Ray Thibodeau

DIRECTOR OF ADVERTISING SALES: Paul Tucker

ADVERTISING REPRESENTATIVES:

Frank Cox, Gene Conselyea, Steve Close, Pharmaceutical Media, Inc.
30 East 33rd St., 4th FL NY, NY 10016, 212-685-5010EDITORIAL/PUBLISHING OFFICES: 345 Hudson St., 16th Fl., NY, NY
10014; 212-886-1244, fax 212-886-1209; e-mail: OT@LWW.com;
www.oncology-times.comCLASSIFIED ADS: Melissa Moody, Lippincott Williams & Wilkins,
351 West Camden St., Baltimore, MD 21201; 800-269-4339,
fax 410-528-4452; e-mail: mmoody@LWW.com

 Oncology Times (ISSN 0276-2234) is published twice a
month by Lippincott Williams & Wilkins, at 116522
Hunters Green Parkway, Hagerstown, MD 21740.

 Business, editorial, and production offices are at 345 Hudson St., 16th
Floor, NY, NY 10014. 212-886-1244, fax 212-886-1209, OT@LWW.com.
Printed in USA Copyright 2003 by Lippincott Williams & Wilkins.

 Indexed in the CINAHL® database of nursing and allied health
literature. Periodical postage rates paid at Hagerstown, MD, and at
additional mailing offices. SUBSCRIPTION INFORMATION,
ORDERS, OR CHANGES OF ADDRESS (exceptions listed below):
16522 Hunters Green Parkway, Hagerstown MD, 21740, 800-638-3030; in
Maryland, call collect 301-714-2300. ANNUAL SUBSCRIPTION
RATES: US \$160 individual, \$220 institution. All other countries except
Japan, \$220 individual, \$276 institution. Airfreight charges added for all
destinations outside of the United States, Canada, and Mexico. Single
copies \$22. In Japan, contact Igaku-Shoin, Ltd., 3-24-14 Hongo, Bunkyo-
Ku, Tokyo 113-0033, Japan. POSTMASTER: Send address changes to
Oncology Times, 7400 Linder Ave., Skokie, IL 60077-9819. No part of this
publication may be reproduced without the prior written permission of
the publisher. The appearance of advertising in Oncology Times does not
constitute on the part of Lippincott Williams & Wilkins a guarantee or
endorsement of the quality or value of the advertised product or services
or of the claims made for them by their advertisers.

Whole-Body CT Screening: Scanning or Scamming?

By Andrew Holtz, MPH

The opinions of expert bodies and medical societies are nearly unanimous: Individuals without symptoms or a family history or other specific risk factor should not get whole-body computed tomography screening scans, because there is no evidence there are any benefits that would outweigh the risks and costs. Yet newspapers, television and radio are filled with upbeat ads for CT screening.

When patients heed marketing over expert opinions, what can and should clinicians do?

One Scan Leads to Another

"We'll get a request from a physician saying, 'Patient had screening study. They recommended further scans. Please do what they said,'" says radiologist Kendall Barker, MD, Section Head for CT scanning for Kaiser Permanente's Northwest Region.

He doesn't see much leeway at that point. "I feel like we are pretty much forced to do that," he explained. "I guess there could be an occasional case where we could look at the scan and say, 'Well, we just don't agree with their interpretation. We don't think it was anything to begin with.'

"But a lot of times the findings are in fact indeterminate. We don't know for certain what they are, and so you may have to do something more to disprove disease."

In Dr. Barker's experience, the suspicious findings in CT screening scans usually turn out to be benign cysts or hemangiomas.

"We've seen only a modest number of cases to date, but I have the impression that it is gradually picking up," he said. While he says the health conse-

Increasingly the question for physicians is not whether CT screening is good or bad, but how to counsel curious patients, and then support and care for those patients who get screened...only to be given results that raise questions and fears.

quences of CT screening for an individual are almost always of no consequence, the potential cost and burden for the system are daunting.

At the most recent Radiological Society of North America Scientific Assembly and Annual Meeting in December, Dr. Barker heard a presentation by Giovanna Casola, MD, of the University of California, San Diego, on the results of 1,200 whole-body CT screening scans at a for-profit facility in Southern California.

Three out of four of the individuals screens had referred themselves to the scanning center. There was at least one

finding in 87% of the scans. Recommendations for further testing or other follow-up work were entered in 32% of the records.

"You can imagine if your entire adult population in a health plan over a couple of years all went and got a screening study, and a third of them needed more work-up, then you'd be working-up a third of your population for mostly benign disease. There's a big cost to that," Dr. Barker notes.

Proactive Approach

At the Be Well Body Scan facility in Chestnut Hill, MA, Medical Director Max Rosen, MD, urges physicians to take a proactive approach toward whole-body CT screening of individuals who do not have symptoms or other indications that might suggest disease.

Ideally, he says, physicians should communicate with radiologists at local facilities before patients undergo a screening scan.

"We have some doctors in the Boston area who are integrating this into their practice," Dr. Rosen said. "We had a couple come in, and their doctor happens to be across the street from me. He came over when I was ready to review the scan with them, sat with them for 10 or 15 minutes as we reviewed the scan, and was really part of the discussion and part of the process.

"Obviously that only works in certain situations, but I think it's very reasonable for patients to discuss with their doctors whether they should have the scan done, and then, with the patient's permission, have the radiologist call the primary care doctor."

Of course, everyday practice does not always match that ideal collaborative scenario. Dr. Rosen admits some

(continued on page 6)

On the Cover:

Artistic rendering of medical imaging composite of body, with x-rays, MRI, CT, and bone scan. © Scott Camazine/Photo Researchers, Inc.

Letters

continued from page 4

breast cancer, cardiac events, stroke, and clots among women who were assigned to the treatment group were small. They do not state that the risk, at least of breast cancer, was not statistically significant and was based on statistical assumptions that could render the conclusion invalid.

The piece in *Oncology Times* goes on to quote Dr. Robert Hoover, Director of NCI's Epidemiology and Biostatistics Program, who "noted that in 1989 a Swedish study suggested that combination HRT might not only not decrease the risk of breast cancer, but might in fact increase it."

That study, by Bergkvist et al, *The risk of breast cancer after estrogen and*

estrogen-progestin replacement (N Engl J Med 1989;321:293-297), reported a relative risk of 4.4 among women who used the combination for more than six years.

Two months after this article appeared in the *New England Journal of Medicine*, it was reviewed in the *Harvard Medical School Health Letter (October 1989;14[12]:1-3)*.

The reviewers commented: "There is a very important reason not to take this figure [RR=4.4] literally. There were only 10 women in this group, too few to provide a statistically stable result. Indeed, on the basis of these 10 cases, the true value had a 95% chance of being 10% below the average, as high as 22.4 times average or somewhere in between."

They go on to write: "Earlier research has given us no reason to expect

a strong association between estrogen replacement and breast cancer."

I fear the article in *Oncology Times* will validate the premature conclusions of the Women's Health Initiative, which has already generated headlines around the world warning women away from hormone-replacement therapy. This warning, which is generating a great deal of anxiety (not good) and discussion (good), may be incorrect.

After the headline fever abates, a better and continuing analysis of this issue would be appropriate. For now, any specific change in practice on the part of physicians or patients with regards to HRT should not be based on the results of this study.

Avrum Bluming, MD
Clinical Professor of Medicine
University of Southern California

Whole-Body CT

continued from page 5

physicians are less than pleased when they learn patients have been screened at his center.

"Sometimes when I've called doctors because one of their patients was here, the initial response has a bit of an edge to it," Dr. Rosen concedes.

"But I think because I am calling them and communicating with them directly, that edge disappears in about 10 seconds. And the conversation always finishes up with, 'Thank you very much for taking care of my patient, and thank you for calling me.' I can't stress enough how important that communication is."

One resource oncologists cannot easily turn to are practice guidelines for investigating findings on CT screening scans.

Be Well Body Scan is a not-for-profit operation affiliated with Beth Israel Deaconess Medical Center in Boston. "We feel that this is an extension of our academic department; so we would not do anything here that we would not feel comfortable doing at the hospital," Dr. Rosen said.

Unlike the marketing materials produced by some commercial, for-profit scanning centers, Be Well's Web

site emphasizes that CT screening is not for everyone.

Also, Dr. Rosen says there needs to be more awareness of the fact that "abnormalities" on a sophisticated scan image are indeed normal in healthy individuals.

'Something' is Almost Always Nothing

At Johns Hopkins Medical Institutions' Advanced Medical Imaging Laboratory, Elliot Fishman, MD, goes further to downplay the significance of "findings" on CT screening scans.

"Most of the time, and I mean 90% of the time, if there is 'something' seen on one of these studies, it is something that is of no significance or something that is not important," Dr. Fishman said.

Nevertheless, he strongly advocates CT as a useful tool in the context of a comprehensive medical care program. "If I do a study, and we do a great study, and we don't see anything, that's good. But realistically, if you are a male of a certain age, you need a PSA. If you are a woman, you need a mammogram. There are so many things you need that are part of the whole process."

However, self-referred whole-body CT screening scans lack the proper context, Dr. Fishman warns, urging physicians to be wary.

"My first word of advice is to proceed slowly, without going into the mega-work-up," he says. "Say a report comes back: 'possible metastasis in the liver or solitary mass right lobe.' Well, seven to 10 percent of women have lesions in the right lobe that are hemangiomas.

So before you start working up the



James Borgstede, MD:
"Physicians need to reassure their patients that they are going to take care of the person, whether they agreed or disagreed with the decision to get the initial scan. I think there is some value in reassurance of the patient that a lot of these findings are false positives, in some situations up to 90% of the lung scan findings, for example, are false positives."

patient and running their bowel and doing x, y, and z to look for the primary tumor, say, 'Wait a second, there's a good chance this could be a hemangioma.' Do not put the pedal to the metal. You are not dealing with a biopsy. I'm very, very cautious."

Dr. Fishman says the first step by a physician should be to consult a radiologist he or she regularly works with, in order to get an independent review of images taken at a scanning center.

If it were up to the leading professional organizations of radiologists, whole-body CT screening of asymptomatic individuals would not be done outside of clinical trials.

As a policy statement of the American College of Radiology (ACR) puts it, "To date, there is no evidence that total body CT screening is cost efficient or effective in prolonging life."

James Borgstede, MD, Vice Chair of the ACR Board of Chancellors and the Chair of ACR's Patient Safety Task Force, says the college issued its cautionary statement in response to a rising number of questions from members.

Despite the skeptical approach to CT screening, he recognizes that once a screening study has been done, the situation is changed. "Now we are dealing with the reality of a finding on an

examination, and while we may not have recommended that evaluation to begin with, we are confronted with the finding and we have to take the next step," Dr. Borgstede says.

The Scan Changes Everything

"Once you embark upon this course,

then you've got a commitment that you really have to evaluate, from an ethical point of view, from a medical-legal point of view, and from a purely health care point of view; you have to go ahead and find out what this abnormality is," Dr. Borgstede notes.

"First, physicians need to reassure their patient that they are going to take

Who Pays?

When individuals decide to get a CT screening scan, they usually pay out of pocket. A scan of the chest, abdomen, and pelvis in a mobile CT scanner can be had for \$398. At the other end of the scale, a Hawaiian resort spa and scanning center offers airport pick-up, lei greeting, spa treatments, meals, and two nights lodging, in addition to five imaging tests and other exams, all for \$4,000.

That hit to the wallet does dampen public enthusiasm for CT screening. According to a market survey performed by Be Well Body Scan in the Boston area, cost was the most common reason people cited for not wanting a CT scan.

Recognizing that an initial test often raises new questions, Be Well includes a limited amount of follow-up testing in the basic package.

"If somebody has something, particularly in the liver or the kidney, sometimes in the CT scan it looks like a cyst, but you just can't be 100% sure; we will do an ultrasound to clarify that finding or the abnormality in

the liver or the kidney, as part of the exam without charging extra for it. We are doing it so people leave with as few loose ends as possible," Be Well's Medical Director, Max Rosen, MD, says. But he concedes that scanning centers cannot offer a full work-up after every scan that shows some sort of abnormality.

Radiologist Jim Borgstede, MD, Vice Chair of the ACR Board of Chancellors, says the initial scans are not the problem—"The real problem is the false positives that come out of that screening scan. Who pays for those?" he asks.

"You know, the patients will come in and pay the money for the scan, but then as soon as something is found in the scan, which is typically a false-positive finding, then their insurance kicks in. And if you have a health care plan, now suddenly somebody in your plan gets one of these scans, that changes the profile of your health care plan, and that, in effect, changes your premiums. So I think we have to think about this from an

epidemiologic and a population basis."

Some experts go even farther, arguing that until CT screening proves its worth, individuals who opt for CT scans in the absence of symptoms or clear risk factors should bear the full cost of the consequences.

Elliot Fishman, MD, Head of the Advanced Medical Imaging Laboratory at Johns Hopkins Medical Institutions, notes that a positive scan often leads to a steady stream of regular follow-up scans, a cash cow for scanners, but a drain on health plans.

"As far as I'm concerned, they ought to do this: If you self-refer, you are responsible for everything," he argues. While he supports coverage of screening ordered by a physician as part of comprehensive care, Dr. Fishman warns about the cost to society of uncontrolled CT screening.

"Truthfully, it could break the system. You start running up these costs chasing nonsensical things," he predicts. "I'm not here to have my insurance rates go up because people

decide on their own they are going to go for studies at second-rate places and then get more studies to follow something that's of no importance."

The potential price tag for self-referred CT screening is as uncertain as potential health benefits. In a plenary session debate on CT screening at December's Radiological Society of North America Scientific Assembly and Annual Meeting, Bruce Hillman, MD, Chair of Radiology at the University of Virginia, said yet-to-be-published results of a study of CT scanning indicated that screening healthy 50-year-old individuals for key cancers, aneurysms, and heart disease could cost \$150,000 per year of life saved.

On the other hand, Michael Brant-Zawadzki, MD, Medical Director of Radiology at Hoag Memorial Hospital in Newport Beach, CA, pointed to other analyses of more limited screening for lung cancers that predict CT scanning might cost less than \$50,000 per year of life saved.

—AH

care of the patient, whether they agreed or disagreed with the decision to get the initial scan. I think there is some value in reassurance of the patient that a lot of these findings are false positives, in some situations up to 90% of the lung scan findings, for example, are false positives."

He also suggests that physicians consult with radiologists within their medical group or hospital to decide what, if any, steps should be taken to answer questions raised by the CT screening scan.

Guidelines Lacking

One resource oncologists cannot easily turn to are practice guidelines for investigating findings on CT screening scans.

At the American Society of Clinical Oncology, a spokesperson said that ASCO does not have a policy position or guidelines regarding body scans of asymptomatic individuals who do not have identifiable risk factors.

Meanwhile, some other specialty groups have taken steps to help their members navigate the aftermath of CT screening. In recently revised guidelines on the management of chronic stable angina, the American College of Cardiology and the American Heart Association included guidelines for workup of asymptomatic patients following CT screening, not as an endorsement of the screening, but merely acknowledgment of "the clinical reality that such patients often present for evaluation after such tests have been performed."

The guidelines go on to suggest which, if any, follow-up tests or procedures should be considered, based on the patient and the finding on the screening scan.

If it were up to the leading professional organizations of radiologists, whole-body CT screening of asymptomatic individuals would not be done outside of clinical trials.

For example, the updated guidelines point out in which circumstances a stress echocardiogram is preferable to an exercise electrocardiogram. That sort of specific consensus advice is not yet readily available to oncologists or other physicians faced with a mass on an abdominal CT image.

Is Resistance Futile?

In the absence of practice guidelines, oncologists are left to pick and choose from the advice offered by individuals in the field. Dr. Rosen at Be Well Body

Scan suggests physicians become familiar with the scanning centers in their area.

"Find out who is doing screening in their area, call up the medical director or one of the radiologists at the site, and say, 'I'd like to come see what you are doing, I'd like to talk with you, and I'd like to maybe start thinking about how, for my patients who want the service, how I can integrate this into my practice.'

"It doesn't have to be for all their patients. They don't have to be recommending it to everybody. But for the

The impact of screening CT on patient-physician relationship bears some similarity to issues relating to alternative or complementary medicine.

patients who are interested in it, I think it can actually be a very useful tool for

the clinician," he says.

Dr. Borgstede of the American College of Radiology agrees that local research, including tours of local scanning centers, can be useful; in part to help build a persuasive argument against screening CT.

"It's always better to have knowledge. If that gives the primary care physician some knowledge so they can comment to their patient, that's probably better, I think it will give them more credibility. I think it will also give them credibility with their patients if they

(continued on page 8)

for chemotherapy-induced anemia

Aranesp®: the next-generation molecule proven to power up erythropoiesis

Aranesp® is indicated for the treatment of chemotherapy-induced anemia in patients with nonmyeloid malignancies.

Aranesp® is contraindicated in patients with uncontrolled hypertension. Erythropoietic therapies may increase the risk of thrombotic and other serious events; dose reductions are recommended if the hemoglobin increase exceeds 1.0 g/dL in any 2-week period. The most commonly reported side effects in Aranesp® trials were fatigue, edema, nausea, vomiting, diarrhea, fever, and dyspnea; no important differences were observed between Aranesp® and Epoetin alfa.

Please refer to the accompanying brief summary of the Aranesp® prescribing information.

References: 1. Ego JC, Bunn JK. Development and characterization of novel erythropoiesis stimulating protein (NESP). *Dr J Cancer*. 2001;9(suppl 1):3-10.

An approximately 3-fold longer half-life powers...

- More red blood cell production over time*
- Early and sustained erythropoietic effect*
- Less-frequent dosing than Epoetin alfa for more treatment free-days

*The clinical benefit of the pharmaceutical data listed hereof have not been determined.



Aranesp®
(darbepoetin alfa)

Powering up erythropoiesis

