

Seen or Not Seen: That Is the Question in Appropriate Liver Transplant Allocation

ACRIN 6690: Comparing Computed Tomography and Magnetic Resonance Imaging for the Diagnosis of Liver Cancer and Liver Transplant Allocation

By Martha Heckel, BA
ACRIN Headquarters

Scientific Background

The United Network for Organ Sharing (UNOS) and national liver-transplant experts have acknowledged that current guidelines used to determine patient waitlist status for liver transplantation are in need of improvement. Experts agreed, in particular, that a high rate of false-positive image-based diagnoses of liver cancer have often resulted in ineffective treatment decisions and inappropriate donor organ allocation.

Therefore, UNOS convened an interdisciplinary team to develop new policy recommendations for the accurate staging of hepatocellular carcinoma (HCC)—a liver disease assigned priority in the placement of patients on the liver transplant waitlist—using magnetic resonance imaging (MRI) and computed tomography (CT) technology.

The resulting recommendations include updated imaging protocol parameters and a revised system for diagnosis, classification, and reporting of liver lesions. Due to the lack of robust clinical trial data, this proposed policy is based upon expert consensus rather than scientific evidence. The ACRIN 6690 trial, endorsed by UNOS, addresses the critical need to evaluate the efficacy of the new policy guidelines in clinical practice.

It is hypothesized that the combination of state-of-the-art multidetector MRI or CT equipment, contemporary multiphase contrast-enhanced imaging protocols, and new diagnostic criteria will reduce false-positive image-based diagnoses of liver cancer and ultimately lead to more informed treatment decisions and appropriate organ allocation.

Objectives and Design

“Liver transplantation can save a patient’s life, especially after a liver cancer is diagnosed correctly and in time,” says Dr. Christoph Wald, principal investigator for ACRIN 6690. “More and more patients suffer from this disease, but there is a shortage of available transplant organs in many parts of the United States. We have assembled a national team of expert doctors to conduct ACRIN 6690 and carefully study which imaging method [MRI or CT] is the best and most accurate



Christoph Wald, MD, principal investigator for ACRIN 6690

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Join Us: Education Session Slated for September 29, 2010

The next RA education session will be held Wednesday, September 29, 2010 at the Ritz-Carlton, Pentagon City, in Arlington, VA. The session will be held in conjunction with the 2010 ACRIN Annual Meeting.

This is an opportunity for RAs to come together as a team dedicated to their research and the ACRIN mission. RAs will share their experiences, learn something new, and meet with old and new friends. The day-long meeting will feature:

- Working groups; the challenges of participant accrual
- The RA's roles and responsibilities for recruitment
- RA boot camp (basic training for new RAs)
- An update on the Centers for Quantitative Imaging Excellence Initiative of the National Cancer Institute
- Roundtable discussions of new and ongoing ACRIN trials

ACRIN leadership will join the luncheon and will provide an update on what's new at ACRIN, and the Jo-Ann D'Amato Award of Excellence will be presented.

Register at
<https://registrations.acr.org/acrin/>.

See page 2 for SoCRA Exam News.

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AccrualNet: A Resource and Professional Community for Clinical Trial Accrual

By Suzanne Lenz, MA-CCRP
Dartmouth Hitchcock Medical Center

In late April of this year, the National Cancer Institute (NCI) launched AccrualNet, a Web site designed to serve as “a resource and professional community for clinical trial accrual.” The purpose of the Web site is “to open channels to the literature among people who conduct clinical trials” and “to provide health care providers with a single source for clinical trials recruitment resources, strategies and tools.”

The Web site seeks to provide accrual support at each stage of a clinical trial:

- Prestudy stage (developing a protocol, selecting a trial, preparing to open the trial)
- Active study stage (recruiting and enrolling participants, managing the trial, retaining participants)
- Active study stage (recruiting and poststudy stage [evaluating accrual and lessons learned])

For each of the above stages, the site provides a link to tools and materials, a list of published journal articles, a place to ask questions, post tips, and share information, and a variety of training resources.

“The site is designed to be interactive; posting comments, and sharing tips and experiences are encouraged.”

Suzanne Lenz, MA-CCRP

The site is very easy to view and navigate. Although experienced coordinators may find that some of the tools and materials contain information they already possess, most would find the posting of articles and resources very impressive

and a great help in researching specific topics, such as minority recruitment. The site is designed to be interactive; posting comments, and sharing tips and experiences are encouraged. Group registration is possible so that postings can be viewed only among registered group members as opposed to being visible to all site members.

AccrualNet is still quite new (a recent visit to the site did not show a large number of postings), but this should improve as awareness increases. The direct, hard work involved in recruiting participants for clinical trials will always be up to us; however, AccrualNet appears to have the potential to be a valuable tool to make this work more effective, or at least a little easier.

Check out the NCI's new accrual resource, AccrualNet, at <http://accrualnet.acscreativeclients.com/>

Contribute Your Ideas

The ACRIN Research Associate Newsletter provides a means to keep in touch with one another. To improve that process, we are requesting information from each of you that can be shared. The contribution can be a few lines or an article you have written. If the resource is properly cited, we can also reprint information from other sources. Please forward all contributions by e-mail to taylor@acr-arrrs.org for review by the RA Executive Committee. We look forward to hearing from you.

A few suggestions follow:

- A day in the life of an RA
- Human interest story (no names please)
- New technology
- Recruitment challenges and difficulties
- Ideas to boost recruitment
- Ideas to facilitate retention
- Helpful tips, shortcuts, and suggestions

Be creative! Other topics welcome.

SoCRA Examination Scheduled!

The RA Executive Committee has again made arrangements for the Society of Clinical Research Associates (SoCRA) certification examination to be offered in conjunction with the ACRIN Annual Meeting. The examination will take place on Tuesday, September 28, 2010 from 2:00 - 6:00 PM at the Ritz Carlton, Pentagon City, in Arlington, VA. The registration deadline is August 17. For more information, visit SoCRA's Web site at <http://www.socra.org/>.

Tips from the RA Mentors: Organization and Consistency Are Key to Success

By Monene Kamm, AS
University of Connecticut Physicians

Finding the time to keep clinical research study records orderly can be difficult. The initial organization of charts, case report forms, binders, etc., although time consuming, contributes to the long-term success of the study. Strive to create a comprehensive system for organization and follow it consistently. The following are some tips for setting up a new study or organizing an ongoing study:

- Keep copies of informed consents in convenient locations to make it easy to hand them out to potential study participants to review at home. Don't assume he or she will bring the consent back at the time of the signing; always provide a fresh copy for signing. You may want to include a business card with the consent so the potential participant has easy access to your phone number.
- Use only institutional review board (IRB)-approved consents. File all original copies of approved consents in the regulatory binder. Be sure to hand out and distribute the correct version of the consent. Establish a system for marking previous versions or expired consents as such. This can be accomplished by using a tab in the binder for expired or previous consent versions or by flagging the current copy. When a new consent is released by the IRB, be sure that all previous versions are removed from the access places.
- Maintain copies of the study consent, HIPAA authorization, source documents, and case report forms in packets for easy access.
- When organizing participant charts, maintain consistency. File the study paperwork in the same order in every chart. Doing this will allow you to easily access any of the paperwork and will make your charts easy to follow when you are monitored or audited.
- If something is included in one chart (e.g., a patient history form), include it in all charts; again, be consistent.
- Make sure that all needed source documents are either in the study chart or easily accessed.
- If multiple research associates are working on a study, be sure that all are in agreement as to how the chart should be organized.
- Talk with other RAs about how they organize their study documents. It is often helpful to bounce ideas off one another to fine-tune systems already in place.

More Acronyms

New acronyms continue to make their way into the vernacular of imaging research. Following are a few that may be new to some RAs. A complete list of acronyms presented in the RA Newsletter in the past several years can be found on the ACRIN Web site at www.acrin.org/RA_Materials.aspx.

ARRS

American Roentgen Ray Society

CER

Comparative effectiveness research

CR

Computed radiography

DR

Direct radiography

EISC

Experimental Imaging Sciences Committee

ICP

Institute for Clinical PET

IR

Interventional radiology

PACS

Picture Archival Communication System

RFP

Request for proposal

RIS

Radiology Information System

SR

Speech recognition (dictation/transcription systems)

New Subcommittee Members Assist with RA Support Activities

The RA Committee is pleased to present information to the community about new volunteers who stepped forward to serve on RA subcommittees. For a list of all subcommittees and their members, visit http://www.acrin.org/RA_Committee.aspx.

Mentorship Subcommittee

Kathleen Thomas, BS, is the clinical research operations manager in the Department of Radiology at the University of Pennsylvania. She began her career there as a clinical research coordinator several months after college and has enjoyed every moment. Thomas sees this new role as an opportunity to help mentor RAs working on ACRIN trials. Currently enrolled in the Master of Organizational Dynamics program at the University of Pennsylvania, she hopes to receive her degree by the spring of 2012. In her spare time, Thomas enjoys baking and decorating.



Kathleen Thomas, clinical research operations manager, University of Pennsylvania



Anna Fagan, radiology research coordinator, University of Pennsylvania

Quality Assurance Subcommittee

Anna Fagan, BS, joined the University of Pennsylvania's radiology research coordinator team in November 2008.

Since then, she has been involved with ACRIN PA 4002 and ACRIN 6657. She is a graduate of the University of Rochester with a BS in Brain and Cognitive Science. In her free time, she enjoys reading and participating in local theatre productions. Fagan looks forward to working with the RA Quality Assurance subcommittee.

Networking and Communications Subcommittee

Martha Heckel, BA, appreciates the opportunity to work more closely with the RAs who so wonderfully support ACRIN trials. She is a protocol associate in ACRIN's

Protocol Development and Regulatory Compliance Department. She is responsible for the development and amendment of the majority of currently active ACRIN trial protocols. Heckel looks forward to putting her medical writer/editor background to good use in RA-driven networking and communications, including updating the RA section of the ACRIN Web site. Heckel loves spending time with her family, listening to live music, being active in her church community, growing fruits and vegetables in her New Jersey home garden, and traveling the world.



Martha Heckel, protocol associate, ACRIN Headquarters

Cheryl Noller, RT(R)(M), CPC, entered the "world of radiology" during high school, when, as a radiology aide, she helped with dictation, transported patients, and cleaned film processors. She graduated from Lincoln Land Community College with an Associate of Applied Science and from St. John's School of Radiology, both in Springfield, IL. Although she worked for 30 years primarily in CT and mammography, Noller is also a Certified Professional Coder® with experience coding radiology reports. In addition, she has served as vice president of her district's radiology society. Having joined the Research/Quality Assurance Department at Clinical Radiologists, S.C., in Springfield last July, Noller is excited to now be involved in the research aspect of radiology. She is looking forward to her new role on the subcommittee. In her spare time, she loves family time, reading, camping, fishing, a "little" gardening, and playing with her new puppy, Alvin.



Cheryl Noller, research technologist, Clinical Radiologists, S.C.

Welcome new subcommittee members! To learn how you can participate on an ACRIN RA subcommittee, visit http://www.acrin.org/RA_Subcommittees.aspx.

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to diagnose liver cancer in an effort to make good future choices regarding who is best suited for liver transplantation.”

Scheduled to begin recruitment in fall 2010, this multicenter trial will evaluate the new policy guidelines for classifying HCC. A total of 440 participants who are on the liver transplantation waitlist with HCC will be recruited from U.S. transplantation centers accredited by UNOS. According to Donna Hartfeil, ACRIN 6690 project manager, “This trial has been met with such interest and support. The response signifies the importance of the trial.” Participants will undergo MRI and CT as part of the 90-day UNOS updates required to maintain their waitlist status. Although patients usually undergo only one of the two modalities to update UNOS, the

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**Christoph Wald, MD
ACRIN 6690
Principal Investigator**

study is requiring both a CT and MRI scan to be completed. The radiologists' interpretations of baseline images and those taken immediately prior to transplant will be evaluated against the pathology assessment of the explant liver (the liver removed from the participant at the time of transplantation) to see how well the images identify HCC found in the explant liver.

“This study presents a real opportunity to make progress in the difficult area of accurately determining the extent of liver cancer in an individual.”

**Michael Nalesnik, MD
ACRIN 6690
Co-Principal Investigator**

Status and Challenges

The success of this trial will depend largely on the sites' ability to coordinate multidisciplinary teams—radiologists, surgeons, hepatologists, pathologists, research associates, and other research staff—to ensure that scheduling, and assessment and coordination of data and images are completed according to protocol specifications.

One of the greatest challenges for ACRIN in developing this trial has been determining how to ensure that lesions identified on imaging or pathology are verified as “the same lesion” across platforms. ACRIN is developing tools to help sites facilitate appropriate lesion identification, including formulaic labeling and consistency in lesion naming conventions between modalities and over time, and guidelines encouraging radiologists to be present during macroscopic explant pathology analysis.

According to Dr. Michael Nalesnik, ACRIN 6690 co-principal investigator and pathology expert, “This study presents a real opportunity to make progress in the difficult area of accurately determining the extent of liver cancer in an individual. The results will not only aid in allocating scarce transplant organs, but will also lead to more precise diagnosis and follow-up for these patients.

Participation of pathologists in performing exhaustive diagnostic assessments of the explant livers in close coordination with radiologists is absolutely critical in providing ‘gold standard’ diagnoses. This will allow us to evolve from collective opinion to solid data as the basis on which decisions are made regarding treatment for patients with liver cancer.”

In order to reach trial target accrual, approximately 20 to 30 sites across the 11 regions will be asked to participate. Participant enrollment in each of the 11 regions will be proportional to the overall contribution of the region to the national total of patients receiving a liver transplant based upon historical data.

Thank you to all of the site personnel who are working to activate the ACRIN 6690 trial at their centers!

The ACRIN Research Associate Newsletter is developed in cooperation with the RA Executive Committee and ACRIN Headquarters and distributed to ACRIN's research community.

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