



## Cancer Clinical Trials – Access & Barriers – July 2008

This month we will continue our informative series on clinical trials with a discussion on "Access & Barriers," again spearheaded by Dr Grant Harrer, MD, Principal Investigator of the Montana Cancer Consortium and Medical Director of the Sletten Cancer Institute in Great Falls. Future topics will be Ethics & Safety in August, Funding & Finances in September, and Education & Advocacy in October.

### **July 2008: Cancer Clinical Trials - Access & Barriers "Systems Barriers to Cancer Clinical Research" By Benjamin Marchello, MD, Principal Investigator, Montana Cancer Consortium, Billings, MT**

There are a number of barriers built into the performance of clinical trials that restrict opportunities to our cancer patients to participate in research. First, there is a bottleneck in the scientific process of developing new treatments. Second, the process of review of research is onerous. Third, our local cancer care specialists must be educated in the promise of specific new treatments. And finally, there must be enough money to pay for research.

Scientific barriers are many. With rare diseases there may not be enough experience with any treatment to know what is promising to test. On the other hand there are so many promising new drugs in this era of cancer genetics and targeted therapy that there can be disagreement about what is best to test. No consensus means no trial at all. Then come the delays in results. It may take years to treat enough cancers to get a valid answer and years to see if patients have fewer relapses or live longer. While we wait it is difficult to develop a new treatment without knowing if a new standard has emerged with the previous study.

To win approval of a new study is challenging. A scientist must prove the merit of his idea to his peers and prove the ethics of his method to his peers. Then the coordinating research group needs to review everything again and plan for the actual treatment and monitoring of patients. Then layers of federal government committees review and criticize and review and make a budget decision about what is feasible. Then when all is ready our local Institutional Review Board (IRB) must rule whether we can do this in Montana. This process takes years and hundreds of steps of proposal, criticism, revision, re-review, re-revision to ensure feasibility both scientifically and monetarily and to ensure patient safety.

Our cancer specialists in Montana and Wyoming are some of the best and are up to date with the latest therapies. However, many of the new ideas have not been published so cannot be known in detail. Explaining to our doctors why a new treatment is worthwhile remains an important step. We have up to ten research meetings a year

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associated with our  
The information is

over the country, and we encourage all our doctors to attend conferences to learn about the latest laboratory ideas that will develop into the best new treatments for our patients. Finally comes one. The National Cancer Institute (NCI) has had no increase in funding since 2002 and none is in sight. We all know that with the inflation factor added, this means we actually have fewer dollars to help with research. Right here in Montana our finances are the same, no increase in funding to support research. With rent, utilities, mailing, and computer costs all up we rely heavily on donation of time and resources by our hospitals and doctors, whose reward is knowledge that our cancer patients will be the winners if we find better treatments.

national clinical trials.  
brought back from all

So how do we address these issues? First, more national and international cooperation as well as more of our patients participating in research will give us answers faster and more certainly. Second, efforts are underway for a more centralized review process to speed new ideas to testing. Third, we use phone, email, regular mail, and personal visits to educate our doctors and pay their travel to meetings. And last, we try to get funds from drug companies, private foundations, and other sources for research. But the bottom line is that to get unbiased study of all cancers our tax dollars must be spent in a proportion that recognizes the priority of cancer research to save lives right here in our home states. Yes, politics will ultimately be the difficult path to our success in cancer clinical trials.

## **Cancer Connections Online Monthly Forum July 2008: Cancer Clinical Trials - Access and Barriers to Clinical Trials "Patient/Participant Barriers"**

**By Amanda R. Dinsdale, CCRC, Program Coordinator, Montana  
Cancer Consortium**

Only 3 percent of U.S. adults with cancer participate in clinical trials. In one survey by Harris Interactive, 85 percent of cancer patients were either unaware or unsure at the time of their diagnosis that participation in clinical trials was an option. Of those, 75 percent said they would have been willing to enroll had they known it was possible. However, this enthusiasm did not carry over to patients facing real-life treatment decisions. Of those patients who knew about clinical trials, 71 percent chose not to participate.

There are valid reasons why people do not participate in clinical trials. Patients may not meet the eligibility criteria outlined in the protocol. There may also be practical reasons such as the distance one must travel for the closest available trial.

The following is a list of some common barriers that may prevent patients from participating in clinical trials:

- \* Don't know about clinical trials
- \* Don't know how to find clinical trials

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- \* Fear or suspicion of
- \* Concerns about treatment and/or procedures
- \* Fear that quality of life will be reduced
- \* Fear of receiving a placebo in place of actual treatment
- \* Belief that standard treatment is better than what is offered on a trial
- \* Cultural barriers
- \* Financial barriers (see essay this month by Patrick Beatty, MD)

research  
side effects of

Many of these barriers are misperceptions which can be cleared up with some basic education on clinical trials. Other barriers, such as financial, are a real barrier not only for clinical trial participation but for cancer care in general.

One specific financial barrier is the fact that some insurance providers do not pay for patients' routine care costs if enrolled on a clinical trial. Routine care costs include doctor visits, laboratory tests, scans, etc., that patients would receive whether or not they were enrolled on a clinical trial. What is covered varies by health plans. It is important for potential clinical trial participants to discuss this with their physicians and to contact their insurance provider to determine what the insurance plan will cover. A growing number of states have passed legislation or instituted voluntary agreements requiring health plans to pay the costs of routine care for patients participating in clinical trials. The state of Wyoming recently passed legislation and the state of Montana is currently working on a voluntary agreement.

The idea that placebos are given instead of standard treatment or that clinical trials do not offer the best treatment is a myth. Placebos are occasionally used in cancer clinical trials but not in lieu of an active standard treatment (unless there is no standard treatment or if standard treatment is observation). Placebos are more often used as an addition to the standard treatment (as a means to test if the addition of a new drug to standard treatment is helpful). Clinical trials offer cutting-edge treatment options not readily available to the public. The National Comprehensive Cancer Network believes that "The Best Management for Any Cancer Patient is In a Clinical Trial".

Education programs are needed to raise awareness, reduce fears, and dispel myths about clinical trial participation. Forums such as this and the works of the Montana Cancer Control Coalition help to fill this need.

There are a number of ways to find information about participating in a clinical trial. The best first step is to consult with your physician. Ask your physician "Are there clinical trials that might be right for me?"

In addition there are a number of clinical trials websites you can search to find clinical trials available in your area.

Web site: [www.clinicaltrials.com](http://www.clinicaltrials.com)

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finding clinical trials in  
Canada.



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an internet resource for  
the United States and

Web site: [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

ClinicalTrials.gov provides regularly updated information about federally and privately supported clinical research in human volunteers. ClinicalTrials.gov gives information about a trial's purpose, who may participate, locations, and phone numbers for more details. The information provided on ClinicalTrials.gov should be used in conjunction with advice from health care professionals.

Web site: [www.mtcancer.org](http://www.mtcancer.org)

Montana Cancer Consortium is a nonprofit organization whose mission is to bring state-of-the-art cancer treatment and prevention to Montana and Northern Wyoming through clinical trials sponsored by the National Cancer Institute.

## **July 2008: Cancer Clinical Trials - Access and Barriers to Clinical Trials**

**"Financial Barriers" by Patrick G. Beatty, MD, PhD; Medical Oncologist, Montana Cancer Specialists; President, Montana Cancer Institute Foundation; Missoula, MT**

A key issue for a patient contemplating entrance into a clinical trial is 'what might it cost me?'

This has been an important issue over the last several years. Even if patients have excellent insurance, many policies have clauses which ban coverage of care that the insurance company deems to be 'experimental'. How the word 'experimental' is interpreted can vary considerably. For instance, how might it apply to a Phase III clinical trial, where two previously tested treatment regimens are being compared one to the other? If each of the regimens would qualify individually as non-experimental, would the simple entry of a patient onto a trial comparing them allow the insurance company to deny coverage? The answer is sometimes a company would disqualify the patient from receiving coverage. What if the trial had each arm receiving a non-experimental standard of care treatment, with the patients being randomized between receiving or not receiving a new treatment, free of charge. Again, sometimes this would disqualify the patient from receiving coverage.

Even more difficult are Phase I or II trials, where a new treatment is being used? Even if the drug is provided free of charge, the patient could be denied coverage for the care necessary for any cancer patient undergoing treatment: laboratory testing, X-ray tests, physician fees, etc.



All of these issues are being addressed. For instance, for most federally funded insurance programs, there is a mandate that clinical trials approved by a federal agency such as the National Cancer Institute be funded by federally funded insurance programs, as if the treatment was standard of care. The rationale should be that participation in cancer clinical trials IS the standard of care! For non-federal insurance programs, the policy is variable. Some states have mandated that any insurance company doing business in that state follow federal insurance guidelines with respect to coverage of patients on clinical trials. Some insurance companies have established the federal type guidelines into their own policies.

For the patient, and treating physician, it is important that these issues be understood before the patient enters upon a clinical trial. For physicians involved in clinical trials, it remains important to continue to educate legislators and insurance companies in the necessity to allow coverage for patients entering into well-designed clinical trials.

On a perhaps more mundane level, but also of crucial importance, is to make sure a clinical trial does not make extra financial demands upon a patient above what would incur with non-trial treatments. As one example, will the trial mandate the patient travel to the treatment center more often than clinically necessary, in order to meet the requirements of the trial? Particularly in a large state, with high costs of travel, there needs to be financial support available to a patient to defray such expenses. The physician proposing the trial must review each trial, asking the question not only as to the possible scientific and clinical value of the trial, but also whether the trial might have hidden financial costs for the patient.

**Cancer Connections Online Monthly Forum  
July 2008: Cancer Clinical Trials - Access & Barriers  
"Provider Barriers to Cancer Clinical Research"  
by Grant W. Harrer, MD, Co-Principal Investigator of the Montana  
Cancer Consortium and Medical Director of the Sletten Cancer  
Institute, Great Falls, MT**

**THE DEMANDS ON PROVIDERS' TIME ARE A DISINCENTIVE TO OFFER CLINICAL TRIAL PARTICIPATION TO THEIR PATIENTS!**

To participate in clinical trials, a provider must devote significant administrative, scientific, regulatory, and clinical time to do so. Time must be available to establish and maintain an infrastructure within the providers' clinic to deal with the massive amount of information associated with each trial. That doesn't include the time to actually read and digest the scientific information itself. Additional time is needed to go through all the regulatory hoops that exist for each trial. This especially involves IRB (Institutional Review Board) approval and ongoing review.



It takes far more of the provider's time to treat a patient on a clinical trial than it does to simply provide a "standard therapy" without the trial. The explanation of the clinical trials process to the patient takes additional time. Not to mention, thorough discussion of the pros and cons of each possible treatment on a given study. One of the strengths of the clinical trials process is that it lends itself to much more complete informed consent compared to even the same treatment provided without the trial. Although a plus for the individual patient, it is a balancing act given many other demands on provider time.

**THERE ARE DIRECT AND INDIRECT EXPENSES FOR PROVIDERS THAT ARE A DISINCENTIVE TO OFFER CLINICAL TRIAL PARTICIPATION TO THEIR PATIENTS!**

- Direct costs (staff expenses) include:
  - Clinical research staff hiring and training
  - Clinical research staff salary and benefits
  - Office space rent, computers, other office supplies
  - Transportation, food, and room expenses for attending clinical trials-related conferences
- Indirect costs (for the provider himself or herself) include:
  - Additional time spent with potential and actual clinical trials participants
  - Time spent administering clinical trials
  - Time spent on clinical trial regulatory activities
  - Time spent in studying, phone conferences, meetings, and conferences relating to clinical trials.

This is all time when providers who are not providing clinical trials to their patients are seeing more patients, spending time with their families, and so forth . the point being that it takes real commitment on the part of providers to do this. We are particularly blessed in Montana in that the vast majority of oncology providers in this state have made personal commitments to provide clinical trials to their patients. We far surpass the national averages for clinical trial participation.

To be complete, some trials (typically industry-sponsored ones) provide additional provider income for participation. Such trials can be conducted very well, both scientifically and ethically, though they deserve greater scrutiny to ensure this. However, the typical "cooperative oncology group" trials that are NCI-approved provide little or no monies to the provider. Total payments to the providers amount to coverage for a fraction of the administrative costs of doing the trials only (and sometimes travel expenses).



## SO WHY DO PROVIDERS PARTICIPATE IN CLINICAL TRIALS AT ALL?

Simply stated, for many oncology providers in Montana, it is a professional commitment to provide the best in care for our individual patients and to make a personal contribution to our world. Participation in clinical trials is considered a stamp of quality on any cancer program and one that most of us must have for "job satisfaction" when dealing with morbid and mortal diseases.

## WHAT CAN BE DONE TO MINIMIZE THE DISINCENTIVES FOR PROVIDERS TO PARTICIPATE IN CLINICAL TRIALS?

This is a complex issue that this paragraph does not do justice. The short answer is that all involved must recognize the value of clinical trials and to provide the infrastructure to make them available. Sponsors of the trials must cover added costs, direct and indirect. Hospitals must recognize that they benefit from their physicians participating in clinical trials directly by better patient care and indirectly by the ability to recruit higher quality physicians by offering this great community.

### Clinical Trials Information (Provided by the Montana Cancer Control Coalition)

Web site: [www.cancertrialshelp.org](http://www.cancertrialshelp.org)

A non-profit organization founded in 1997, the Coalition was chartered to increase participation in high-quality cancer clinical trials, thereby accelerating development of new cancer therapies. Today the Coalition offers a full suite of programs and services designed to increase the understanding of cancer clinical trials and boost participation. Close-knit collaborative relationships with healthcare industry partners concentrate on streamlining and promoting cancer clinical trials in both the public and private sectors, enhancing the clinical trials experience for physicians and patients alike.

Web site: [www.clinicaltrials.com](http://www.clinicaltrials.com)

Clinicaltrials.com is an internet resource for finding clinical trials in the United States and Canada.

Web site: [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

ClinicalTrials.gov provides regularly updated information about federally and privately supported clinical research in human volunteers.

ClinicalTrials.gov gives information about a trial's purpose, who may participate, locations, and phone numbers for more details. The information provided on ClinicalTrials.gov should be used in conjunction with advice from health care professionals.

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Website: <http://ctep.cancer.gov>

Cancer Therapy Evaluation Program (CTEP)

Website: <http://integratedtrials.nci.nih.gov>

Clinical Trials Working Group (CTWG)

Website: [www.cancer.gov/clinicaltrials/developments/ncd179n](http://www.cancer.gov/clinicaltrials/developments/ncd179n)

Centers for Medicare and Medicaid Services (CMS)

Website: [www.ctsu.org](http://www.ctsu.org)

Clinical Trials Support Unit