CCRP Community

Our annual newsletter to the Colorado Cancer Research Program community 2005

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CCRP: From Revolutionary to Relevant

An interview with CCRP Founder Robert F. Berris, MD

Although Dr. Robert Berris takes pains to emphasize that he was far from alone in pioneering the concept of community-based cancer research, the fact remains that Berris was instrumental in founding the Colorado Cancer Research Program (CCRP). A recent interview with Berris — a retired clinical oncologist who remains very active in Denver's cancer research community — sheds light on why and how this organization was created and why community research and CCRP remain more relevant than ever in today's world.

What did cancer research look like before the advent of community-based programs?

Prior to the 1980s, cancer research programs were largely the province of the National Cancer Institute (NCI) and the programs they supported in certain key cancer institutes. These institutes gradually amalgamated themselves into several large, nationwide (but still university based) cooperative research groups that designed and developed clinical trials, such as ECOG, SWOG and others. These cooperatives in turn ran very limited outreach programs allowing community physicians to enroll a small number of patients in clinical trials coordinated by a university.

How did you get involved in questioning the status quo?

In 1970, I wrote a letter to the head of NCI stating that the majority of cancer patients were being treated by community physicians (rather than university based doctors), and that the current system did not contribute to medical science or new cancer treatments as effectively as it should. I suggested that they develop a new system that encouraged doctors to enroll patients in formal cancer research programs within the community. Around the same time, President Nixon pushed a bill through Congress to fund the war on cancer, with one goal being to accelerate the progress of cancer research by encouraging more formal research programs.

In response to these and many other calls for change, NCI put out an RFP for what would come to be known as Community Clinical Oncology Programs (CCOPs). The RFP stated that the CCOPs would agree to enroll a specified number of patients in clinical trials each year, and that they would have to belong to one of the national cooperative research groups as a community member. As a result of that initial RFP, 21 programs throughout the U.S. were approved for the purpose of conducting cancer clinical trials in the community.

And CCRP was one of those?

Yes. CCRP was founded under the name Hematology Oncology Association of Denver in 1983 by Presbyterian Medical Center and myself. We had a very supportive CEO at the hospital who wrote the grant, myself as principal investigator, a staff of one researcher, and contributions by many other people. After a while, St. Joseph's wanted to join us, then eventually Swedish and Porter and the American Medical Center, and we were off and running.

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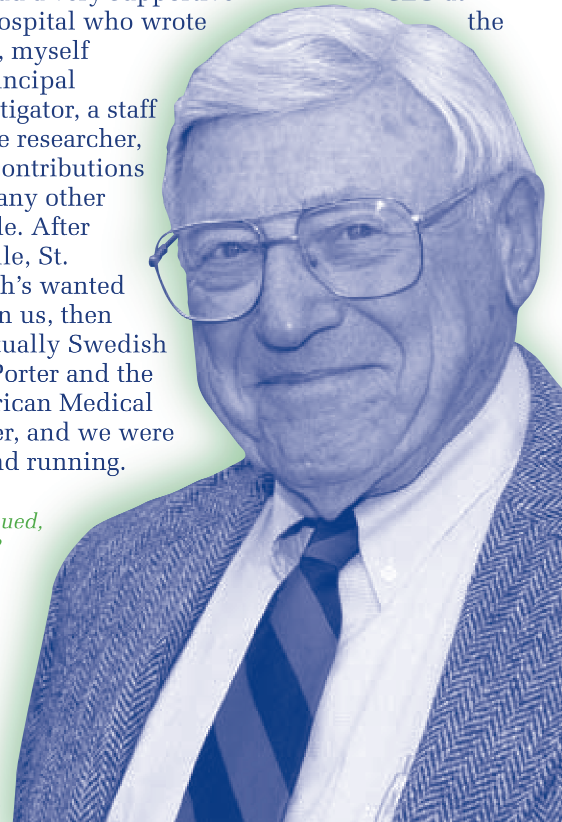

Robert Berris, MD, Medical Oncologist & Founder of CCRP

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CCRP: From Revolutionary to Relevant
continued

What was the goal of these early CCOPs?
Our founding principles were, first of all, to increase the rate of accrual of patients to cancer research programs so that studies could be finished in a reasonable length of time. And second, to promote education regarding recent advances in cancer treatment and allow importation into the community of these advanced cancer techniques.

Why was that emphasis on community research so important?
As community-based programs, CCRP and our fellow CCOPs have been instrumental in allowing the more rapid dissemination of cancer knowledge and techniques into community cancer practice. Our cancer patients get all the benefits of cutting-edge medical technology while being allowed to stay in their homes and their community. Cancer patients typically have particularly close relationships with cancer doctors in their community, so continuity of that relationship and care is vitally important.

Why do you believe CCRP's work is relevant today?
We are relevant because we have survived…and we would not have survived for more than 20 years if we hadn't been useful. We are proud of the fact that many 10- and 20-year results that you see reported in the media are a direct result of CCRP's contributions to research protocols. Through our clinical trials, we are helping to answer important questions: Can we give medications, in addition to surgery and therapy, that will benefit our patients? Are we merely adding days to patients' lives or are we curing them? What are the long-term costs and benefits of treatment? Can you eliminate surgery or radiation as part of treatment and use chemotherapy or hormones exclusively? Most important, there are a lot of people alive today as a result of the successful completion of these protocols. Cancer research is a progressive evolution, and CCRP is proud to be a part of that evolution.

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continued...

L-R: Sami Diab, MD, Susan Freeman, MD, Eduardo Pajon, MD, and Nicholas DiBella, MD

Molecular Fingerprinting Points to Promising Cancer Treatments

by Eduardo R. Pajon, MD, Principal Investigator, CCRP

When people ask me what is new and promising in oncology trials and drug development, the answer is as amazing as it is exciting. A new era in cancer treatment has truly begun with the unraveling of the genetic code in humans and the subsequent ability to start studying the genetic abnormalities found in cancers.

We now have the technology in the lab to do molecular fingerprinting of tumors. This means we can check inside these beautiful little gene-chip arrays within the tumor for the presence or activity of any proteins or enzymes expressed in that tissue, allowing us to essentially 'fingerprint' cancer patterns. As a result, we can now see how different cancers differ molecularly, even if they look similar under a microscope.

We are also learning about the chemical pathways inside cancer cells and how the activation of various chemical processes causes cells to grow and divide more rapidly. This has given us a much better idea of which molecules and enzymes switch cancers on and off, so that we are better able to design specific molecules to block some of these processes.

This greater understanding of the inner workings of cells through studying molecular structure has provided us with better-targeted drugs to attack malignant cells. We can now go back to patients and determine that people with one particular gene-chip array respond to a specific drug and people with a different array do not.

To that end, some drug companies and labs are now coming up with designer molecules that will inactivate bad genes or find growth-controlling genes that cancer has 'switched off' and switch them on again. As an example, Avastin is a designer drug that targets a chemical interaction to prevent the formation of new blood vessels that may feed the development of cancer cells. Other drugs — some of which are currently in the pipeline and some of which have already been released — target other growth factors, and these drugs will revolutionize the treatment of colorectal, breast, leukemia and other cancers.

Because CCRP is actively involved in the clinical testing of several of these new agents, our patients are afforded access to state-of-the-art cancer therapies. And the best news of all is that some of these new drugs offer improved response rates when combined with standard chemotherapy, sometimes with lesser toxicity.

It is this kind of scientific progress that makes our work at CCRP so valuable to both our community physicians and to the patients participating in clinical trials within our community. We look forward to sharing further advances with you as they develop.

Eduardo Pajon, MD, CCRP Principal Investigator and Nicholas DiBella, MD, CCRP Board Chairman

Fund Development Key to CCRP's Financial Future

How do you take 65% and try to make it meet 100% of CCRP's needs? Finding that additional (and elusive) 35% is the ever-growing challenge that CCRP faces when seeking funds for its research.

CCRP is about a mission delivered since 1983 — ensuring Colorado physicians local access to large national and international cancer clinical trials. What this means is that for more than 20 years, Colorado cancer patients have benefited from having medical research locally available through their physician. Participation in this research also means that local cancer doctors and their patients have helped accelerate the advancement of cancer science for all mankind.

Delivery of CCRP's mission requires adequate income. Our two major sources of income cannot fill CCRP's 35% revenue short fall. Our 12 consortium hospitals contribute approximately 15% of CCRP's total annual budget, and the National Cancer Institute (NCI) contribution adds an additional 50%. NCI's support provides approximately $1,200 for each patient enrolled; CCRP's actual cost is about $4,200 per patient.

For the first time in this organization's history, CCRP is actively turning to individuals to contribute to and assist with ensuring CCRP's financial future. Individuals — not corporations and community foundations — are the most affected if we cannot ensure the delivery of life-improving, life-saving research. At present, contributions from individuals total less than 5% of CCRP's annual income. We ask for your help.

Additional funding crucial to long-term follow-up for patients

Increased income is critical to offsetting increased operational costs. CCRP's cost increases include expected costs, including salary increases for nurse and non-medical personnel and lease increases for CCRP's office space.

There are also increases, such as "lifetime follow-up," that most people do not associate with the cost of research. NCI requires that CCRP provide long-term, *lifetime* follow-up on all its patients who enter clinical trials. Long-term follow-up is critical so that science can gather information about the long-term effects of a study drug over time. This requirement, however, means that CCRP adds another 100 or so patients each year to its follow-up level, creating a progressive accumulation of patients without any financial support to CCRP for this vital activity. To date, approximately 900 patients require long-term follow-up.

Board focused on tapping new funding sources for future

The bottom line for a for-profit organization is fiscal profitability. The bottom line for CCRP, as a non-profit, is financial assurance to continue the delivery of its mission. Funding from individuals, both from the medical community as well as the community at large, is necessary to continue our responsibilities to past, current and future patients.

In 2004, the Board of Trustees initiated actions to help ensure the organization's financial stability and viability. The development of an infrastructure, including practices and policies for receiving major gifts and the development of an Endowment Fund, was important for setting the foundation.

In 2005, we seek to build on this strategy of engaging the community and asking individuals to support CCRP's community-benefiting endeavor through community grants and major gifts from individuals and patients who have benefited from our clinical trials.

Together, we can ensure CCRP's continued ability to pursue its mission of bringing new drugs and interventions to better treat, control and cure cancer. Every day we are seeing advances being made. We must not stop now.

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please contact Tomiko Takeda, CCRP Executive Director, at 303.777.2663

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Quality Assurance Aims for Correct Data and Credible Research
by Sandy Paul, RN and Tomiko Takeda, M.Ed.

When an individual participates in a clinical trial at CCRP, our first priority is patient safety. Several protective mechanisms are put into place to monitor this, including the use of data. Though not commonly thought of as a safety measure, the proper processing of data is indeed in the best interest of the patient.

Results of laboratory and other diagnostic tests completed as part of a clinical trial become data. In the physician's office, this data is reviewed to determine how an individual responds medically to treatment. At the research level, this data is analyzed to determine how a large population responds to a particular drug or intervention being tested.

CCRP's patient data is reported to the national research group responsible for the design and development of that specific protocol. (A protocol is the 'recipe' of how to conduct a specific clinical trial.) It is critical that this data is accurate, backed by quality source documents (lab and/or test results), and timely. The composite results of research data enable scientists to determine the outcome of a clinical trial.

With high-quality and timely data, scientists can more accurately provide large-population feedback of the drug or intervention being tested. Without it, we are in danger of losing statistical accuracy and possibly losing the research altogether.

As a measure to ensure the accuracy of the data and overall integrity of the research, CCRP institutes quality assurance practices and procedures that meet Good Clinical Practice Guidelines and that adhere to regulatory standards and requirements.

Another essential element of our quality assurance program is QA auditing. CCRP undergoes formal external audits conducted by the national research groups. These audits help determine whether we have enrolled the appropriate patients, collected and reported accurate data and followed protocol in a trial. We also perform internal 'house' audits on an ongoing basis. These involve visits to our research offices to identify areas of strengths and weaknesses. We can then take corrective measures and implement new actions or standards to improve our studies when warranted.

Beyond contributing to the accuracy of research that may (or may not) lead to new cancer treatments, CCRP's quality assurance program has another important goal: to provide *reassurance* to our patients that they are receiving the best possible care under the safest possible conditions.

L-R: Sandy Paul, RN, Jatonya Turner, Patty Gibson, RN

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