This issue of SCI access focuses on clinical research and highlights some of the research projects conducted by the researchers at the UM Model SCI Care System (UM MSCICS). With the dramatic rise of national media coverage of new studies in spinal cord regeneration in the United States and abroad, we are getting many more questions about research from the patients seen here at the University of Michigan Health System. Therefore, we wanted to focus this issue of our newsletter on clinical research to educate consumers and their families. But first, let’s start with a brief overview of the Model SCI Care System Program.

The Research Program of the Model SCI Care Systems

What is a “Model SCI Care System”?  
As its name suggests, the network of 16 Model SCI Care System Programs in the United States provides comprehensive clinical services and conducts and disseminates research to both consumers with SCI and professionals. By coordinating clinical care and research in collaboration with consumers, these programs provide the most comprehensive care to patients and their families. The Model SCI Care System Program sets the standard of SCI care, not only in the United States, but worldwide. One of the most important things each of the Model SCI Care System programs does is collect data from people with SCI. This data collection covers a variety of topics such as health, mood, level of independence, the barriers in the community, and the kinds of assistive technology that people use.

What Happens to the Data once its collected?  
For the last 30 years, the National Model SCI Care System Program has gathered information from over 29,000 individuals who have had traumatic SCI, making it the world's largest SCI database. This national database, housed at the University of Alabama at Birmingham, provides a “benchmark” for all SCI health care providers to improve clinical care and the quality of life of people with SCI.
Since 1985, the UM MSCICS has provided care to over 875 people with SCI and contributed its information to the Model SCI Care System National Database.

Does Consumer Participation matter?  
Since its beginning, the research program of the Model SCI Care System has grown from learning the basics about SCI to addressing more complicated health and psychological issues. Without the generous participation of the thousands of individuals with SCI across the United States, our understanding of SCI would simply not be where it is today. The continued partnership of researchers and consumers is essential as we face the 21st century challenges of limits in funding and rapidly advancing technology to serve the needs of people with SCI.
The advancement of clinical research in spinal cord regeneration has led to greater interest in SCI research being conducted in the United States and around the world. For this issue, we have put together some information (courtesy of the National Institutes of Health) about clinical research to help consumers better understand the basics.

What is a clinical trial?
A clinical trial or clinical research is a research study utilizing human volunteers to answer specific health questions. A clinical trial compares the effectiveness of a new treatment to a current treatment or to the body’s natural healing capability. Clinical trials are the fastest and safest way to find out if treatments really work or work better than current treatments.

What are some of the benefits and risks of a clinical trial?

Benefits
- Playing an active role in one’s own health care.
- Involvement in research treatments before they are widely available.
- Expert medical care at leading health care facilities.
- Contributing to medical research.

Risks
- Though designed to minimize such, there may still be unpleasant, serious or even life-threatening side effects to treatment.
- The experimental treatment may not work, with worsening of the disease or condition.
- The study may require more time than originally planned.

What should people consider before participating in a trial?
People should know as much as possible about the clinical trial and feel comfortable asking the members of the research team questions about it, the care expected while in a trial, and the cost of the trial. Some useful questions to ask are:
- What is the purpose of the study?
- Who is going to be in the study?
- Why do researchers believe the new treatment being tested may be effective? Has it been tested before?
- What kinds of tests and treatments are involved?
- How do the possible risks, side effects, and benefits in the study compare with my current treatment?

How is the safety of the participant protected?
Most clinical research is federally regulated with built-in safeguards to protect the participants. The trial follows a carefully controlled plan. Before it can start, the plan must be reviewed by an Institutional Review Board (see below). As a clinical trial progresses, researchers keep close watch over the safety of the subjects.

What is an Institutional Review Board (IRB)?
An IRB is a committee of physicians, statisticians, researchers, community advocates, and others that makes sure that a clinical trial is ethical and the safety and rights of the study participants are protected. All clinical trials in the U.S. must be approved by an IRB before they begin. This is not necessarily the case with clinical research conducted in other countries.

What is Informed Consent?
This is a process where the potential participant learns about the project from the researchers. The Informed Consent Document discusses the purpose of the study, required procedures, risks and benefits, duration of the study, key contacts and other important details of the study. The researchers should discuss this document and any other questions about the study that the participant might have before the participant signs the agreement to be in the study. Informed consent, however, is not a contract, and the participant may withdraw from the trial at any time without penalty.


“The most exciting phrase to hear in science, the one that heralds new discoveries, is not 'Eureka!' (I found it!) but 'That's funny ...”“
— Isaac Asimov
Consumer advocacy and the Internet have opened the doors for people with SCI to more easily than ever access information about clinical trials, participate in research and even drive research agendas. So we called on some experts—consumers with SCI who also have experience in research—and got their take on the current state of clinical research in the area of SCI.

Where do you learn about the latest in clinical research in SCI?

Eric Appleberry, D.D.S., is a retired Periodontist and has served on the UM Medical School IRB. He has lived with an SCI for 6 years.

Eric Appleberry: Mostly it's been magazines like New Mobility, Paraplegia News, science articles and occasionally from PM&R doctors that I see or know.

Maurice Jordan: I get a large majority of my information from the Internet. It is often a challenge to find current research information and more often than not it is written medical language that does not translate well to the typical SCI person.

Barbara Schoen: Work, news bureaus and newspapers, and Internet headlines. Also quite often from family friends.

William Scelza: Being in the health field and a physician I know exactly where to go for information. My one concern is the Internet. It is a great way to disseminate information for any one to review. The problem is that there is no regulation in place and accuracy and reliability of information may be suspect. Consumers should be very cautious when reading information on the Internet and review it with their doctor.

What is your take on clinical research in SCI – do you believe that researchers are asking the right questions?

EA: Yes and no. For instance, the why? and how? of motivation to do things the right way in health.

MJ: Because the individual uniqueness of each person SCI, the answer to this question is often predicated on the individual and where they perceive themselves to be in the "recovery phase" as it relates to the direction that the SCI research community should be going in. Personally I would like to see more in gait training for people with incomplete, partially ambulatory SCI.

BS: I do now. For the first time since my injury I have genuine faith that I may see “a cure” in my lifetime, that I may eventually walk or at least regain some additional functioning.

WS: Consumers want questions that will impact them directly now and they want good results. It may help if they understood the constraints of studies and briefly how the scientific process works.

How, if at all, does clinical research impact your life?

EA: Greatly!! It is the method whereby it’s determined what works reliably and not just “sometimes.”

MJ: I think overall that clinical trials have a positive impact on all of us living with an SCI and I would encourage the continued exploration toward one day finding a cure for SCI through these controlled research trials.

BS: It certainly has impact—who wouldn’t want recovery? But it is the background—I’m keeping track while I am living my life. I can also say that the recent research has made me MUCH MORE health conscious. I’m trying to get myself in better shape because I know any recovery will require personal and physical commitment.

WS: It does in the treatments that we do or do not prescribe based on the research and trials that are done.
Update on UM MSCICS Projects
By Martin B. Forchheimer, M.P.P.

In addition to the research that we do by our participation with the other 15 Model SCI Care Systems throughout the country for the National Model SCI Care System Database, the UM MSCICS is engaged in five projects that are considered “local.”

Alcohol Consumption and Severity of SCI

Study #1 looks at the relationship between alcohol consumption and severity of trauma. This study is led by Ronald Maio, D.O., from the Department of Emergency Medicine. While it is well known that people who are intoxicated are more likely to have accidents resulting in SCI, only laboratory studies had been done looking to see if alcohol has an impact on the severity of impairments among those having injuries. The findings of this study suggest that people who were drinking at the time of their injuries tend to have more severe impairments than those who were not. Also, this greater severity was not limited to those who had been drinking heavily. Even low levels of alcohol consumption may be associated more severe neurological impairments. This has important implications for public health campaigns and drivers’ training because the current emphasis on not driving while drunk may give the inaccurate impression that driving after consuming small amounts of alcohol is safe. This study’s findings will be presented at the American Association of SCI Psychologists and Social Workers Conference in Las Vegas, Nevada this September and a manuscript is now being written.

Quality of Life and Ventilator Assistance

Study #2 looks at the factors explaining differences in quality of life among people with tetraplegia who use a ventilator for breathing, those who have tetraplegia but do not use a ventilator and those who use ventilators but do not have a SCI. This study is led by Seth Warschausky, Ph.D. While data collection is still on-going, initial analyses have been done that suggest that people in all three groups are similar in terms of how many medical complications they have and how satisfied they are with their lives. People with SCI who use a ventilator tend to receive more of their care from unpaid family members than do people in the other two groups. When people were asked to identify what was most important to their life satisfaction, 60% said their relationship with their family or spouse which highlights the central role of social relationship among all three of these groups. These preliminary findings will be published in a special issue of Topics in Spinal Cord Injury Rehabilitation.

Wellness and Spinal Cord Injury

Study #3 evaluates the long-term impact of a two-year wellness program that was conducted as part of an earlier study. This study is led by Denise Tate, Ph.D. The wellness study was a randomized clinical trial, in which half of the subjects received counseling on nutrition, stress management and exercise while the other group did not. One year later, this intervention showed some modest benefits, particularly in the area of behaviors and attitudes, but not in terms of other health parameters, like cholesterol and weight. This suggests that the benefits of the program were not maintained over time for there to be long-term benefits and, as such, more follow-up and/or an intervention would be needed.

Knowledge of Employment Policies

Study #4 is a descriptive study, looking at what people with SCI know about employment-related public policies. It is being led by Martin Forchheimer, M.P.P. During recent years, there have been several public policy changes with the goal of making it easier for people with SCI to become em-

(Continued on page 7)
Altho[00]ugh more and more money funding rehabilitation research goes to “basic science” work in neuroscience and nerve regeneration, many studies continue to focus on “restoration” and rehabilitation. Significant progress has been made in gait rehabilitation. And some of that progress has taken place right here at the University of Michigan. It was gravity that started Dan Ferris, Ph.D. on the road that led him to the University of Michigan and his Human Neuro-mechanics Laboratory. Recently Ferris, Assistant Professor in the Departments of Movement Science and Biomedical Engineering at the University of Michigan since 2001, gave a tour of his laboratory where gait rehabilitation after SCI is making strides. Upon entering his laboratory, it is clear there is some serious engineering is going on. The lab, occupying 1,200 square feet, has 10 computers, a tool bench, electronics station, and outlets aplenty – in fact, there is one every foot along the walls.

Ferris’ work is based on a simple principle: when a spinal cord injury occurs, the body does what it was designed to do – it adapts. In other words, it forgets walking and adapts to sitting. Gait retraining helps the body to remember how to walk.

Although standing frames can have a number of health benefits, they do not let the body practice walking. Locomotor training was first tested in the 1980’s on cats whose spinal cords had been cut. It turned out that gait retraining was relatively easy in cats (and rats) because locomotor control is more centralized in their spinal cords. But for humans, locomotor control is more distributed in the brain and spinal cord, making gait retraining a more difficult task.

So Ferris took two old ideas – artificial pneumatic muscles and orthoses – and combined them in a unique way to create pneumatically powered lower limb exoskeletons. In other words, robotic braces for the legs. Pneumatic muscles are like specialized balloons. When you pump air into them, they inflate and contract like human muscles. The hope is that these will help train the muscles to work on their own again.

Ferris says that his work in gait training is a natural extension of the work being done in spinal cord regeneration because once those nerve connections are re-established, the body must re-learn how to walk.

From a rehabilitation perspective, one of the most important ideas driving Ferris’ work is empowerment. The exoskeletons and exercise machines that Ferris works on in his lab are designed to let the user have control over the rehabilitation. An added bonus of the exercise machines is that people can use them independently at home.

Ferris has three important points for people with SCI to keep in mind when thinking about his and others’ research in gait retraining:

1. Few clinics have the equipment and specially trained staff that are necessary to produce good results. Until rehabilitation practice and insurance join in these efforts, widespread use of this technology will not occur.

2. Research in gait training is (Continued on page 6)
positive overall, but there have been some results showing little benefit. This may be because therapists are not always similarly trained in a highly specialized technique. As such, different results can occur between studies.

3. Knowledge learned from these studies can be used not only to help people right now, but also those who will benefit from advances in molecular biology and spinal cord regeneration in the future.

Ferris’ lab boasts two engineers, two physical therapists and two kinesiologists (those who study human movement). Their mission is to understand the complexities of physiology and technology—not an easy job. But Ferris is optimistic that one day people with SCI and clinicians will have a wide array of devices and exercise machines that will greatly improve the rehabilitation process.

Therapists Assisting in Gait Training
To learn more, visit http://www-personal.umich.edu/~ferrisdp/UMHNL.html.

Your Bottom Line...Ask the Doctor By David R. Gater, Jr., M.D., Ph.D.

Why is it so difficult to keep my weight under control?

Calories. Calories represent fuel in the body, and are stored as fat when your food intake is greater than your energy expenditure. After an SCI, almost all people will lose muscle and have a lower metabolism. Muscles are the primary part of our metabolism. Since muscle mass is lost in SCI, metabolism is lower. Therefore, this means you will burn fewer calories even if you do the same amount of work! Depending on the level of your SCI, resting metabolism may decrease by as little as 12% (low paraplegia) or by as much as 54% (high tetraplegia). Most people with SCI won’t burn enough calories in their daily activities to compensate for this lower metabolism, and will need to incorporate exercise into their daily habits. Aerobic (endurance) exercise burns more calories during the activity itself, whereas anaerobic exercise (lifting weights) builds more muscle mass, which burns more calories at rest. Both types of exercise are important for your health, community mobility and keeping excess weight (fat) under control.

Food contains calories (fuel) in the form of fats, carbohydrates and proteins. Per unit of weight, fat has twice the calories as a similar amount of carbohydrate or protein. So, even if you reduce the fat in your diet, you may still gain body fat if you are eating too many carbohydrates and proteins. The type of carbohydrate is also important, because ones causing a higher blood sugar response (high glycemic index) generally increases fat storage. Carbohydrates with high glycemic indexes include white bread, pasta, potatoes, full fat ice cream and (sorry!) chocolate bars. This doesn’t mean that all carbohydrates are bad, however!

Carbohydrates are an essential part of the diet, and those with low glycemic index (including whole-grain cereals, fruits, lentils and low fat fruit yogurt) are especially good for you. You should also be aware that most of the high protein/low carbohydrate diets can cause constipation, dehydration and kidney stress, and the initial weight loss is hard to maintain since it is mostly just lost water weight. Essential nutrients and minerals must also be maintained at appropriate levels to ensure optimal health.

Most of us could do with smaller portion sizes and a little more exercise. This is especially important if you have an SCI.
Forgiveness and Spinal Cord Injury  By Claire Z. Kalpakjian, Ph.D.

Since 2002, two studies examining the role of forgiveness in health after SCI have been conducted by UM MSCICS investigators Denise G. Tate, Ph.D. and Claire Z. Kalpakjian, Ph.D. in collaboration with Jon R. Webb, Ph.D. (University of Oklahoma) and Loren L. Toussaint, Ph.D. (Luther College). Jane Walters, Database Coordinator for the UM MSCICS also assisted with data collection for these projects.

What does Forgiveness mean?
Decreasing or releasing negative thoughts about and/or actions towards an offender without relieving them of responsibility.

Motor vehicle accidents and violence cause the majority of SCI sustained in the United States. As such, issues of blame and forgiveness may be very important in the adjustment process, but we do not know much about this in SCI.

The first study found that in general, people who were more forgiving of themselves and other people were more satisfied with their lives and reported being in better health than those who were more unforgiving. For outpatients, being younger at the time of injury was related to being more forgiving.

We also found that the people who abused alcohol were more likely to blame other people for their injuries instead of blaming themselves. Finally, how much people blamed themselves or others for their injury was not related to how much forgiveness they felt in general.

The second study looked at the relationship of forgiveness and health over time. Although we expected that people who were more forgiving would be healthier, we also found that people who were healthier were in general more forgiving.

And of course people who blamed others tended to blame themselves less and vice versa. People who blamed others for their injury also had poorer sleep and rated their overall health lower. Finally, the more angry people were, the less forgiving they were of either themselves or others.

It would seem that, indeed, forgiveness is good for your health!

Some Thoughts on Forgiveness

• “It [forgiveness] just makes you feel better, you know. ... you’re not always carrying that baggage around.”

• “I guess I started to realize that she didn’t do it on purpose...she didn’t, you know, hurt me or say ‘I’m going to go out and hit X today,’ and it just swelled in my mind and I just realized, “Hey, this is my life. I’ve done well so far, in the first couple years, I’m just going to let this go...”

• “You know, it makes it a lot easier to move on if you just take responsibility for it, hold yourself accountable for what you did, move on and try to make things better...”

Update on UM MSCICS Projects (continued)

(Continued from page 4)

ployed. The impact of these policies has not been great, but we do not know whether this may be at least in part due to people being uninformed about these policy changes. By looking at people’s knowledge of these policies, this study will help us to determine how extensive a problem lack of information is among people who want to return to work. Based on this, we can develop better education programs. We expect to complete this study early next year.

Societal Participation and Independent Living

Study #5 explores the factors that explain societal participation among people with SCI. It is being led by Martin Forchheimer, M.P.P. In particular, the study focuses on the interaction of knowledge of independent living skills, interpersonal support, environmental barriers and physical functioning as explanatory factors. We expect to complete this study by the end of
The information consumers generously contribute to the Model SCI Care System has been used extensively this year. So far in 2004, seven articles have either been published or accepted for publication. Here are some highlights from a few of them.

**Patterns of Alcohol and Substance Use and Abuse in Persons with Spinal Cord Injury: Risk Factors and Correlates.** Authors: Denise G. Tate, Martin B. Forchheimer, James S. Krause, Michelle A. Meade, and Charles H. Bombardier. Accepted for publication in the Archives of Physical Medicine and Rehabilitation.

This study evaluated the relationship between alcohol and substance use and abuse and number of adverse outcomes using data from all 16 Model SCI Care Systems. Key findings were that at-risk drinkers and substance users tended to be younger, single, male and less educated. They also tended to have more pain and lower life satisfaction. Moderate drinkers tended to have better outcomes than either heavy drinkers or those who said that they did not drink at all. Finally, there were indications that alcohol and substance use may be underreported in the sample.

**Enhancing Community Integration Following Spinal Cord Injury.** Authors: Martin B. Forchheimer and Denise G. Tate. Published in NeuroRehabilitation, Vol. 19, No. 2, pp 103 – 113.

This paper evaluated the effectiveness of a community-based program to provide independent living services to people during the two years after their discharge from inpatient rehabilitation. The project was conducted by the UM MSCICS along with the Ann Arbor Center for Independent Living (CIL), together with four other Model Systems and their neighboring CILs. At each site, some subjects received periodic phone calls from CIL staff members to do goal setting and problem solving while others did not.

While the study found that people receiving these calls were similar to those who did not in terms of the number of independent living services that they received, their quality of life or activity level, the Model System Programs and the CILs who had not worked together previously, found this collaboration increased their mutual understanding.

**Psychological Well-Being and Intensity of Employment in Individuals with a Spinal Cord Injury.** Authors: David W. Hess, Michelle A. Meade, Martin B. Forchheimer and Denise G. Tate. Published in: Topics in Spinal Cord Injury Rehabilitation, Vol. 9, No. 4, pp 1-10.

This paper used data from all 16 of the SCI Model Systems. It compared people who were unemployed, employed part-time and employed full-time in terms of their life satisfaction, level of social integration and depression. For all three of these, the findings were the same: people who were unemployed had the poorest life satisfaction, social integration and highest depression.

**Grant Awarded for Rural SCI Health Education in Michigan**

In June 2004, Claire Z. Kalpakjian, Ph.D. and Barbara Schoen, M.S. were awarded a Christopher Reeve Paralysis Foundation Quality of Life Grant to support the University of Michigan Spinal Cord Injury Rural Health Education Initiative Project (UMSCI-RHEI).

Nearly 70% of the 83 Michigan counties are considered to be rural and it is estimated that approximately 400 individuals sustain SCI in Michigan each year, many of whom return to rural communities. To better meet their needs, the UM SCI-RHEI will disseminate educational materials to health care providers, community-based agencies, and consumers in an effort to enhance their health, independent living and quality.

The ultimate objective of this project, which will begin in August 2004, is to educate and empower people with SCI living in rural Michigan communities and to lay an important foundation for future, larger outreach efforts to individuals with SCI living in rural communities throughout the Midwest.

Want to get involved? Have suggestions for outreach in your community? Let us know by emailing us at ruralsci@med.umich.edu or give us a call 734.763.0971!
Life can be filled with traumatic events. Annick Hivert-Carthew's story of survival is proof that seemingly insurmountable grief and depression can eventually be overcome. The author, normally competent and in control of her life, was sent reeling when she was diagnosed with breast cancer. While dealing with the fear and uncertainty of this disease she became increasingly depressed until one morning she was unable to get out of bed, move, eat or even respond to simple suggestions. With suicidal thoughts mounting she realized she needed professional help. This step was just the beginning.

Her voyage, captured in her latest book, Strategies to Overcome Depression, A Survivor Shares 150 Tips for Sufferers, Families, and Advocates includes insight into depression, along with effective skills, tools and resources.

As Annick navigated her path to recovery she discovered there were countless choices and decisions she needed to make. Should she seek treatment by her family doctor, a psychologist or psychiatrist? What types of questions should she ask her physician, what questions would they have for her? As an author of many non-fiction works, Annick was used to finding answers in books. However, when she sought out simple answers in the available books on depression she found these books were highly technical or just too difficult to read.

Initially terrified and ashamed of her depression, she now realizes depression is not a character flaw, nor a lack of personal strength or self-control. It is an illness and is highly treatable. In addressing her depression, she was also able to get rid of unnecessary baggage, break away from restrictive situations and eventually grab life with both hands. Having almost lost life and joy she “found how precious these gifts are.”

Combining her strengths as an author and her experience, Strategies to Overcome Depression, is written in brief, easy to read chapters. Each one includes practical tips and simple things one can do to negotiate through the stages of recovery. Annick urges readers to understand that while depression can be extremely debilitating it is also highly treatable. She stresses that if you or someone you know is depressed or suicidal please urge them to seek medical attention and help them learn all they can to aide in their recovery.

If you feel stuck in a dark tunnel of depression, let me tell you – there is plenty of sunshine at the end of the tunnel.”

— Annick Hivert-Carthew


Book Review

By Barbara Schoen, M.S.

Kudos Corner

This spring, two of the University of Michigan Health System SCI Physicians, Drs. David R. Gater and Lisa A. DiPonio jointly received the Margaret Weber Provider of Choice Award awarded by the Veteran’s Administration for best service delivery providers within the VA Midwest Region (VISN 11).

The Margaret Epp Weber Provider of Choice Award, first instituted in February 1999, acknowledges “the actions, teams, or individuals who contributed significantly to the well-being of a patient or group of patients as demonstrated through individualized services and/or caring interactions.”

Congratulations to Drs. Gater and DiPonio!

Lisa A. DiPonio, M.D.

David R. Gater, M.D., Ph.D.
The University of Michigan Spinal Cord Injury Care System publishes SCI access twice annually. This newsletter is designed to provide information on research, treatment, and social issues related to rehabilitative care, spinal cord injury and disability. Established in 1985, the UM Model SCI System receives funding from the National Institute on Disability and Rehabilitation Research (Award #H133N00009). It is one of 16 Model SCI Systems in the United States. The purpose of this research and demonstration project is to improve outcomes of medical and rehabilitative care provided to individuals with spinal cord injury.

Denise G. Tate, Ph.D.
Co-Director, Co-Principal Investigator
David R. Gater, M.D., Ph.D.
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Want to get the latest news fast? Join our new email list by sending us your email address to spinalcordinjury@med.umich.edu. This will give us an opportunity to pass along any news to consumers quickly and cost effectively. As with any personal information, your email address will not be shared with any other organization.

Also, keep an eye out for our newly designed website. We are in the process of revamping the look and content of our website and expect to have this completed by the end of the summer. The address remains http://www.med.umich.edu/pmr/model_sci/.

We welcome any feedback or comments you may have about our website, newsletter or any other aspect of our program. You may contact our Project Manager, Claire Kalpakjian, Ph.D. directly.

Save the Date! September 17-19, 2004
Abilities Expo is the nation’s leading consumer show for people with a disability, their family members, caregivers, and healthcare professionals.
Abilities Expo has been successfully running for 20 years and each year delivers the latest in assistive technology, durable medical equipment, daily living aids, adaptive vehicles as well as service organizations and rehabilitation facilities. Free consumer and professional workshops and seminars are also offered throughout the weekend.
On-site admission to Abilities Expo is $5; children under 12 are free.
We will be distributing free tickets so email us at spinalcordinjury@med.umich.edu or give us a call at 734.763.0971 and reserve your tickets!

For more information, visit their website at http://www.abilitysexpo.com.