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# ◆ THE DERBY CITY NSCIA NEWSLETTER ◆

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APRIL 2005

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*The Derby City Chapter of the National Spinal Cord Injury Association Network- Serving Kentuckiana.*

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## Message From the President

*Dear Members & Friends-*

*At press time we have not received information regarding our speaker for the March meeting. We will likely have a speaker, but if not, a video will be shown. Food and drink will be provided at the meeting.*

*April's meeting will be held at Frazier Rehab; 6:30; 4th floor dining hall.*

*- David Allgood*

*The following is from AAPD News, Summer 2004—ed*

### **What You Need to Know About the Medicare-Approved Drug Discount Card Program By Ernest Haskell**

The enactment of the Medicare Modernization Act is an important step toward increasing the quality of healthcare for Medicare beneficiaries. The law creates a significant benefit for many patients who need help to secure access to life-saving and life-improving medicines. That is particularly true for the most vulnerable of Medicare beneficiaries—those with limited incomes.

The most talked about part of Medicare reform has been the Medicare-Approved Drug Discount Card Program. This new program officially launched on June 1, but millions of eligible Medicare beneficiaries, including people with disabilities, may be missing out on significant prescription drug savings.

Far too often, discussion of the new Medicare-Approved Drug Discount Card have focused on seniors and neglect to mention that Medicare beneficiaries with disabilities can also take advantage of the program.

While there has been some confusion about the Medicare-Approved Drug Discount program, people with disabilities need to know about the significant savings that many pharmaceutical companies are offering to those most in need through these discount cards. For millions of people with Medicare coverage, not signing up for a card means leaving money on the

The good news is that enrolling in the Medicare drug discount program, while confusing, can be easy once one selects the right program for their needs. Beneficiaries only need three pieces of information to find the right card for them. You need to know your zip code, know your drugs and dosages, and know your income if you are interested in transitional assistance and the added savings provided by some pharmaceutical companies.

The new program also gives Medicare beneficiaries the flexibility and the options they need to decide the best approach to their healthcare needs. For the first time, they have the opportunity to make a choice that will help reduce their drug costs and provide more coverage.

By enrolling in the Medicare-Approved Drug Discount Card program, Medicare beneficiaries with disabilities can save 10-20 percent on prescription drug purchases. One of the intents of the program was to make sure that those in the greatest need received the largest benefit. Under the new program, people with Medicare under certain income limits without drug coverage may be eligible for \$600 in drug benefits (those that earn less than 135 percent Federal Poverty Line—\$12,569 for a single and \$16,862 for a married couple), no premiums or deductibles, and co-payments as low as \$1 (those that earn less than the 100 percent Federal Poverty Line).

For example, one of the cards that provides significant savings is the U-Share card, a Medicare-Approved Drug Discount Card sponsored and managed by the United Health Group. Through the U Share Card, Pfizer and other pharmaceutical companies will provide even greater savings

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**Derby City Area Chapter  
*of the*  
National Spinal Cord Injury  
Association**

**ABOUT THE ORGANIZATION**

The Derby City Area Chapter of the N.S.C.I.A. is a membership organization for individuals with spinal cord injuries, their families, and health professionals. Founded in 1984 as a Charter Member of the N.S.C.I.A., it was incorporated under IRS Section 501 (c) 3 as a not for profit organization. The Board of Directors consists of the Officers, Past President and the Board Members At Large.

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**NSCIA  
DERBY CITY CHAPTER  
NEWSLETTER**

Editor- Barbara Davis

Contributor- David Allgood

**Medicare-Approved Discount Cards, Cont'd**

to Medicare beneficiaries with low income. For those who qualify, Medicare beneficiaries will pay only a \$15 flat fee per prescription for up to a 30-day supply of many Pfizer medicines. For medicines made by Pfizer and the other participating companies, income can be up to \$18,620 for a single person and up to \$24,980 for a couple to qualify for the additional savings.

The U Share Card is just one of many discount cards currently available to people with Medicare. Because of the potential discounts and added savings provided by pharmaceutical companies, it is important that all Medicare beneficiaries are aware of the program and enroll in the card that is best for them. Not choosing a card is the wrong choice because Medicare beneficiaries may be missing out on real savings.

For more information on the U Share Card, call 1-800-707-3914 or 1-866-234-4138 (TTY) or visit [www.usharex.com](http://www.usharex.com).

*The following is from The Miami Project to Cure Paralysis newsletter.*

**CLINICAL STUDIES ABROAD: WHAT CAN WE LEARN?**

Recently there has been news from various countries of the effects of transplanting olfactory ensheathing cells (OECs) into people with spinal cord injury (SCI). Of note to the scientific community are anecdotal reports that people who have undergone these procedures have had improvements in sensory and motor function within the first days after the procedures. While there is interest within the scientific community, these reports are leading to more questions than scientific answers.

Several studies in animals support the idea that OEC transplants may increase function, thus leading some doctors in other countries to offer such treatments. Because these experimental surgical procedures are both invasive and permanent, many scientists feel that transplanting these cells in humans is premature. There are numerous questions about the effectiveness of the procedures and concerns about potential adverse effects. The Miami Project has taken the position that there may be an opportunity to advance scientific knowledge from these clinical experiences if more comprehensive information can be obtained. The following explains this position in relation to one of these experimental procedures.

One experimental transplant that has gained the attention of people with SCI, the media, and scientists is that of Dr. Hongyun Huang in Beijing, China. In February 2004, representatives from the Miami Project had attended the Clinical Trials Workshop sponsored by the International Campaign for Cures of Spinal Cord Paralysis (ICCP) where Dr. Huang was among several clinicians who presented their

**(Continued On Page Four)**

# **Refrigerator Calendar**

## **\*2005**

### **APRIL**

**4th - Elderly & Disabled Advisory Council Meeting**

**Mon 1:00-2:30 p.m.; TARC; 1000 W. Broadway; Board Room.**

**18th - NSCIA Derby City Area Chapter meeting, 6:30 p.m., Frazier Rehab.**

**Mon 4th floor dining hall; speaker to be announced. Call David or Barb at 589-6620.**

**16th - Metro disAbility Coalition Meeting; 1 p.m. – 3 p.m.; PVA Office on Goss Avenue.**

**Sat Speaker to be announced; if questions, contact Terri Leasor at 589-6620 or at mdclouky.org**

### **MAY**

**2nd - Elderly & Disabled Advisory Council Meeting**

**Mon 1:00-2:30 p.m.; TARC; 1000 W. Broadway; Board Room.**

**16th - NSCIA Derby City Area Chapter meeting, 6:30 p.m., Frazier Rehab.**

**Mon 4th floor dining hall; speaker to be announced.**

**21st - Metro disAbility Coalition Meeting; 1 p.m. – 3 p.m.; PVA Office on Goss Avenue.**

**Sat Speaker to be announced; if questions contact Terri Leasor at 589-6620 or mdclouky.org**

**For More Information Call**  
**David Allgood, 502-589-6620**

**CLINICAL STUDIES ABROAD: Cont'd**

experiences with experimental treatments in humans with SCI. The Miami Project decided to initiate open communication with Dr. Huang to more completely understand his transplant procedure using olfactory bulb-derived fetal cells as a means to promote recovery of function following SCI. Miami Project scientists and other researchers have been experimenting with OECs as a potential cell therapy in experimental modes of SCI, however, limited data were available concerning the clinical use of these cells.

A first step in this information-gathering effort was to invite Dr. Huang to the Miami Project to present a lecture summarizing his clinical experiences. Dr. Huang presented a lecture entitled *Transplantation of Olfactory Ensheathing Glia in Patients with Spinal Cord Injury*, where scientists and clinicians had the opportunity to listen to his presentation and ask specific questions regarding procedures and outcome measures. Although this presentation provided new information, including the suggestion that some patients experienced functional benefit, many important scientific questions were left unanswered and led to various concerns. One concern was the lack of appropriate outcome measures that would adequately assess any long term benefits. Another was the lack of follow-up information that would help determine the incidence of adverse effects of the procedure.

Large numbers of individuals have undergone these procedures in Beijing. In an effort to obtain better scientific data, The Miami Project faculty decided it would be important to obtain first-hand information concerning the procedures and the clinical effects. To this end, two scientists/clinicians within The Miami Project traveled to Beijing and, over a ten-day period, had the opportunity to observe twelve patients, evaluating six of them for neurological function before and after surgery. It is important to note that several patients demonstrated a modest degree of improvement in motor and sensory function. Interestingly, this improvement in neurological status occurred immediately after the surgical procedure. In addition to these positive findings, some adverse effects were also observed. For example, wound breakdowns were noted in two patients, one of whom had a reduction in leg function after surgery. Meningitis occurred in another, however, the Chinese doctors did not record these complications in the patients' medical records.

The Miami Project's representatives had the opportunity to observe what they describe as a

procedures and examine some patients, they were not permitted access to the laboratory where the cells for transplantation were prepared. Therefore, little information is currently available concerning the cellular content of these human fetal olfactory bulb cultures. One cell preparation, however, that was not transplanted into a patient was provided to The Miami Project for analysis. This analysis has been initiated and is ongoing. At this time, apart from descriptions from Dr. Huang, researchers can only guess at the important aspects of the preparation such as: What method of cell processing was used? Does the transplant tissue actually contain OECs? In what stage of development are the cells?

Even after having the opportunity to directly observe patients and the procedure, there are still many important questions that need to be answered that are critical for scientific understanding. A major limitation of Dr. Huang's work is lack of long-term assessment of neurological function. It appears that patients who undergo the surgery do not have a set schedule to return for follow-up assessments. Apparently, the only data collected is obtained immediately following the surgery, therefore, it is unclear if the benefits experienced in the short-term are maintained over time. Without consistent follow-up data in all patients, few conclusions regarding the long-term benefits and safety of this surgical procedure can be made.

Additionally, when considering invasive surgical procedures in people with SCI, it is of utmost importance to understand the potential complications and risks of the procedure. The detection of adverse effects requires careful and consistent documentation. Presently, it does not appear that data related to adverse effects are being systematically collected and documented by the Chinese group. Therefore, if adverse effects such as neuropathic pain or tumor formation are occurring in this group of patients, these effects may not be detected and reported.

While questions remain about the benefits and potential risks of this procedure, the observation that some functional improvements occur soon after the surgery is intriguing. The reason for these early improvements is unknown. One explanation for rapid neurological improvements in some patients may be a trophic or nourishing effect. The transplanted tissue may be secreting growth factors that enhance nerve signal conduction in the synapses or along the axons. To better understand if a trophic effect is responsible for the functional improvements, researchers will need to conduct studies on the cells used for transplantation to determine if they actually release neuropathic (nerve nourishing) factors. If this can be confirmed, it would provide a clear rationale for their use.

Because accurate and conclusive information concerning the surgical protocol, methods of cell processing, and the long-term safety of this procedure is lacking, The Miami Project's

**(Continued On Page Five)**

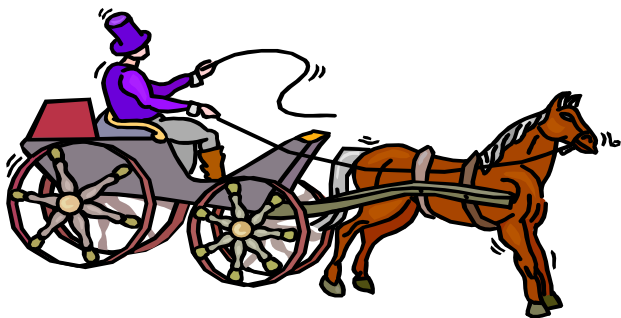
**CLINICAL STUDIES ABROAD: Cont'd**

faculty do not endorse this procedure and at this time would not advise individuals to undergo this surgical transplantation strategy. While some people with SCI will view current experimental procedures abroad as their only hope, by participating they may be putting themselves at risk as well as potentially disqualifying themselves from participating in future more promising and well-designed clinical trials.

Presently, Dr. Huang's work would meet the standard for clinical trials set by the FDA or European regulatory agencies. His work should therefore be viewed as a series of clinical treatments rather than a clinical trial. This is a very important distinction since a clinical trial would allow for definitive conclusions while a treatment series cannot. To properly assess this treatment, a more rigorous clinical trial is required; one that includes specific outcome measures and comparisons to a control group. It would also include accurate documentation of whether adverse effects occur over the long-term.

While there may be disagreement among clinicians and researchers as to when and which promising pre-clinical strategies should be advanced to clinical trials, it is important to emphasize that scientists all over the world are coming together to develop valid clinical trial guidelines for treatments targeting SCI. ICCP supported and funded the International Clinical Trials Workshop on SCI in Vancouver that brought a varied team of researchers and clinicians together to discuss progress in clinical trials and the complexities involved in effective clinical trial design. A report of this meeting was peer-reviewed and published by J. Steeves, J. Fawcett, and M. Tuszynski in 2004 (*Spinal Cord* 42:591-597). As a result of this meeting, an international advisory panel was created to develop more detailed guidelines on how to conduct future SCI clinical trials in the most accurate and effective manner.

It is hoped that further information coming from individual clinical studies as well as continued research into this into this important and exciting field will stimulate well-controlled multi-center trials utilizing the appropriate safety and outcome measures. Well-designed FDA-approved clinical trials will minimize the chances of a procedure being harmful to the patient and will maximize the opportunity to document long-lasting improvements in the future. Only through a strategy such as this can evidence-based medicine be advanced, and the safest and most effective treatments be

**FOR SALE!!!!**

**\*Chair Topper & Hand Control;** price negotiable; Call Greg @ 968-4630.

**\*2003 Ford F-250 lift-equipped green/gray van;** leather seats, TV, DVD player. Playstation hookup, am-fm radio. Rick Miller, 937-2245.

**\*Shower Chair; 2 yrs old, negotiable; 2 RoHo cushions; low profile; \$150 each; Invacare 900 Action Power Chair; 4 yrs. Old; \$600. Call 448-5296.**

**\*RoHo High Profile 16x16 cushions; \$160; 589-6620.**

**\*Ford 1997 Econoline Van;** 100,140 mi; \$16,000. Hunter Green-gray; new tires & brakes; "loaded"; call 270-786-4547; ask for Dale.

**\*Cookbooks for Sale:** Recipes compiled by Chapter members; \$10:00. Call David @ 589-6620.

**\*Video tapes for sale.** Various topics related to spinal cord injuries. Call David Allgood or Buddy Lawson.

**\*\*\*If assistance is needed to pay for any of the above items, contact Kentucky Assistive Technology Loan Corporation at 1-800-327-5287 for information on loans at 5% interest to qualified candidates.**

**IF YOU WOULD LIKE TO PLACE AN AD IN FOR SALES, CALL 589-6620. ASK FOR BARB OR DAVID.**

