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For immediate release:

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Editors note: Research, new techniques and improved facilities by Philadelphia International Medicine hospitals and physicians may lead to new ways to treat some of our most challenging diseases. Below are just some examples from our hospitals.

**Protein Shows Promise for Spinal Cord Injury Patients Regaining Partial Movement
in Thomas Jefferson University Hospital Study**

Philadelphia – A study of a protein applied to the spinal cord for totally paralyzed patients during surgery shows some promise for spinal cord injury patients, with some regaining partial movement.

A one-year clinical study of Cethrin(R), performed by neurosurgeons at Thomas Jefferson University Hospital in Philadelphia and other medical centers in the United States and Canada, indicated positive interim results for the treatment of acute spinal cord injury (SCI). The study was designed to determine if the protein was safe and well tolerated by SCI patients.

In the trial, 31 percent of patients recovered some sensory and/or motor function below the level of their injury, going from a complete injury to an incomplete injury. In one case, a patient who participated in the study at Jefferson was able to regain movement in his previously paralyzed legs.

“It’s pretty exciting,” said neurosurgeon James Harrop, MD, assistant professor of Neurosurgery, Jefferson Medical College, the study’s primary investigator at Jefferson.

Dr. Harrop cautioned, however, that this is not a “panacea” and requires further study to determine if the protein can restore function. “But in a population that has seen no progress in the last decade in restoring spinal cord functions, this is a huge leap,” he said.

There are currently no effective therapies for spinal cord injury and the nearly 12,000 new patients each year in North America alone. Despite significant scientific breakthroughs, existing clinical interventions remain limited to reducing local inflammation of the spinal cord.

The 12-month study evaluated 37 patients from nine centers who suffered a complete thoracic or cervical injury (i.e. having no sensory or motor function below the level of the spinal cord injury). Five of the participants were seen at Jefferson.

“A complete injury means no sensation or movement below the lesion, while an incomplete injury means the patient has some neurologic function, either sensation or motor,” Dr. Harrop explained. “This is important because if they have any sensation or movement the chances for recovery are much improved.”

Cethrin(R) is topically applied to the dural sac (the membranous sac that encases the spinal cord within the bony structure of the vertebral column) during decompression/stabilization surgery. Cethrin(R) is the first of a new class of protein that is specifically designed to penetrate cells and inhibit Rho, a signaling master switch whose activation triggers cell death and exacerbates spinal cord damage following injury.

The trial was not placebo controlled but has an efficacy component based on the American Spinal Injury Association's (ASIA) scale that is designed to assess sensory and motor function in patients.

Children’s Hospital of Philadelphia is Increasing Its Capabilities To Conduct Cutting-Edge Research in Pediatric Nursing

The Children’s Hospital of Philadelphia is increasing its capabilities to conduct cutting-edge research in pediatric nursing, and has brought on four outstanding nursing leaders to lead and support the research program. Sharon Barton, APRN-BC, PhD, Kathleen Philbin, RN, PhD, Katherine Finn Davis, RN, PhD, and Elizabeth Ely, RN, PhD, have joined Children’s Hospital have recently joined Children’s Hospital. In addition, three more nurse researchers will be added in 2007.

These doctorally prepared nurses will bring their expertise and knowledge to enrich the world-renowned Children’s Hospital research enterprise.

“As Children’s Hospital nurses provide cutting-edge care in the clinical setting, questions naturally arise about the evidence supporting nursing practice and ways to improve patient care,” says Leslie Clarke, RN, MS, MBA, CNAA-BC, senior vice president and chief nursing officer at Children’s Hospital. “Nursing research is a way to answer questions specific to nursing clinical practice and patient outcomes as well as examine nursing education and leadership methodologies and results.”

Currently, there are approximately 85 research projects involving nurses at Children’s Hospital. Projects span multiple subspecialties and care methods including diabetes, HIV, patient safety, CPR, breastfeeding and end-of-life care. The addition of the new nurse researchers to Children’s Hospital will enhance the opportunity for all nurses to contribute to research and patient care innovation.

“As those at the bedside of our patients, nurses possess a deep understanding of a patient’s condition and how treatments and practice can evolve to meet their needs,” said Alan R. Cohen, MD, chief medical officer and

physician-in-chief at Children’s Hospital. “We look forward to the insight and pioneering ideas these highly trained nurse researchers will bring that will keep Children’s Hospital at the forefront of patient care.”

Dr. Barton, Dr. Philbin, and Dr. Ely will serve as leaders, mentors and consultants to current and future bedside nurse scholars, helping them develop research questions and guiding them through the process of inquiry. The nurse researchers also will evaluate the applicability of nursing research, while maintaining their own active research programs.

The newest members of the nursing research team: Dr. Barton has expertise in infant feeding, qualitative research, and evidence-based nursing. Dr. Barton’s recently completed NIH/NINR-funded study investigated family and cultural beliefs related to infant feeding practices. She has helped implement numerous clinical nursing research studies with practicing nurses.

Dr. Philbin is an internationally recognized expert on the effects of hospital noise on preterm infants, and translates research into practice by contributing to national standards for newborn ICU design. Dr. Philbin conducts both basic and clinical studies on the effects of unusual early experience on infant behavior and development.

Dr. Davis recently completed a National Institutes of Health/ National Institute of Nursing Research-funded study examining the effects of sleep on health outcomes in preschoolers attending daycare, and is currently researching sleep in hospitalized children.

Dr. Ely has expertise in pediatric pain assessment and management. Dr. Ely conducts clinical research with children who have sickle cell disease and their families. She also provides consultation to nurses regarding application of research findings to practice.

The Children’s Hospital of Philadelphia was founded in 1855 as the nation’s first pediatric hospital. Through its long-standing commitment to providing exceptional patient care, training new generations of pediatric healthcare professionals and pioneering major research initiatives.

Analysis by Fox Chase Oncologist, Others, Finds Older Men With Early Prostate Cancer Who Were Treated Lived Longer Than Those Who Were Not Treated

An analysis of Surveillance, Epidemiology and End Results (SEER)-Medicare records for 44,630 older men suggests surgery or radiation therapy for early-stage prostate cancer increased the lifespan of men between 65 and 80 years old compared to observation, sometimes known as “watch and wait.” Published in the Dec. 13 issue of *Journal of the American Medical Association*, the study supported a benefit of treatment even for men whose disease had a low risk of spreading, and even if they were elderly men (75 to 80 years old).

“Studies have shown that low- and intermediate-grade prostate cancers may grow slowly, and many patients may never suffer complications from their disease. This makes decisions regarding treatment complicated for patients and their families,” said lead author Yu-Ning Wong, MD, a medical oncologist at Fox Chase Cancer Center who authored the study with colleagues at the University of Pennsylvania. “In our

study, we looked back at existing data that tracked long term outcomes of elderly men whose cancer was at low and intermediate risk of spreading. After accounting for all of the observed differences between the groups, we found that men who had either a radical prostatectomy or radiation therapy within six months of their prostate cancer diagnosis were 30 percent less likely to die than those who did not undergo treatment during this time period,” she said.

Researchers confined the study sample to men with small tumors (clinically designated as T1 or T2) with well-differentiated (corresponding Gleason score 2 to 4) or moderately differentiated (corresponding Gleason score 5 to 7) prostate cancers, who were diagnosed between 1991 and 1999.

Of the 44,630 patients included in the study, 12,608 (28.3 percent) were not treated while 32,022 (71.8 percent) were actively treated. In the treatment group, 88 percent lived five years or longer and 66 percent lived 10 years or longer. In the non-treatment group, 78 percent lived five years or longer and 51 percent lived 10 years or longer. The benefit of treatment was still present after adjusting for differences between the treatment and non-treatment groups, including patient demographics and tumor characteristics.

Since the study was a retrospective analysis of existing data (observational) rather than a randomized controlled trial, the authors noted that treatment and non-treatment groups may differ in measured and unmeasured ways that are associated with differences in survival.

“Observational studies such as ours should be interpreted with caution, since men who were offered treatment, or specific types of treatment, may have been ‘healthier’ than men who were not offered treatment, which raises the possibility that the treatment benefit may be due to the selection of healthier men,” Wong noted. “We performed extensive statistical adjustments to account for these differences and still found that treatment was associated with longer survival.”

Wong emphasized that observation is a reasonable choice for many men since some prostate cancers grow slowly. Studies have shown that in recent years only between 7 and 17 percent of men in the U.S. with low-risk localized prostate cancer choose observation rather than treatment.

Longer survival alone is not the only factor in choosing treatment over observation, Wong pointed out. “The risks of treatment have decreased as options have improved including more targeted radiation therapy that reduce side effects and less invasive surgical techniques, but both may be associated with bowel, bladder and sexual dysfunction. Patients should talk to their doctors about their risks of side effects associated with radiation, surgery and observation before making treatment decisions.”

“Our study is just one piece of an extraordinarily complex puzzle, and many other researchers are examining different aspects of prostate cancer biology and treatment. Patients should consider enrolling in clinical trials and other research protocols to help us better understand how prostate cancer grows and which patients most likely to benefit.” Wong concluded.

While the study used the SEER-Medicare database, interpretation and reporting of these data are the

sole responsibility of the authors. They acknowledge the efforts of the National Cancer Institute's Applied Research Program, the Centers for Medicare and Medicaid Services' (CMS) Office of Research, Development and Information, Information Management Services, Inc., and the SEER Program tumor registries in creating the SEER-Medicare database.

Wong's co-authors include Fox Chase medical oncologist Gary R. Hudes, MD; Nandita Mitra, PhD, and Russell Localio, PhD, of the University of Pennsylvania's department of biostatistics and epidemiology; Fei Wan and Chantal Montagnet at the University of Pennsylvania's department of general internal medicine; as well as J. Sanford Schwartz, MD, and Katrina Armstrong, MD, of the University of Pennsylvania's department of general internal medicine, Abramson Cancer Center, and Leonard Davis Institute of Health Economics. The Center for Population Health and Health Disparities at the University of Pennsylvania sponsored the research.

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