Carle Strategic Plan 2013 consists of seven pillars that will guide our organization this year and into the future. Research will follow these principles, striving to provide value to our staff and physicians, patients, and our community.

Strategic Plan Pillars:

1. **Provide Value to Patients** – Archive the best outcomes by providing care at lower cost, higher quality, and with better access.
   
   **Research:** New research and clinical trials are ways for Carle to contribute to the development of new and improved standards of care, cutting edge treatments, as well as attracting and retaining valuable staff.

2. **Benefit the Community** – Help more people receive care and stay healthy by investing resources in patients, organizations, and local initiatives.
   
   **Research:** Carle is involved with many collaborative research projects with investigators from the local community. Being a clinical site involved in groundbreaking research is important for Carle’s relationship to our community. Carle Research enables investigators in the community to recruit patients, obtain human tissue, and medical data for their projects. Additionally, the goal of these research projects is to improve future patient care. Current research projects include determining how to provide faster access to Carle’s trauma center for the rural communities in central Illinois and an up-to-date surveillance of infectious disease outbreaks.

3. **Focus on our People** – Attract and retain the best people through empowerment, investment, and development.
   
   **Research:** Having research opportunities available at Carle assists in attracting the brightest clinicians to Carle and is an integral part of Carle’s Magnet status for nursing excellence.

4. **Make Care More Accessible** – Provide our patients and members with timely and convenient access to Carle providers and services.
   
   **Research:** Carle administration is committed to providing an extensive research support infrastructure for Carle clinicians allowing them to focus on both patient care and research.

5. **Grow and Partner Regionally** – Collaborate with regional providers to expand quality care to a broader geographic area.
   
   **Research:** Research provides numerous opportunities for clinicians to collaborate with other health care facilities as well as the University of Illinois. Carle Research also holds monthly educational research seminars such as Lunch ’N’ Learns, which are open to the public.

6. **Deliver Integrated Care** – Create innovative models for delivering care that improve coordination, enhance patient experience, encourage wellness, and improve health management.
   
   **Research:** At least two active nursing research projects at Carle directly involve improving the delivery of care. The goal is to improve patient outcomes and contribute to the scientific knowledge by publishing their findings.

7. **Use Financial Resources Wisely** – Maintain strong financial position to support the communities we serve and fund strategic initiatives.
   
   **Research:** Carle Research has recently consolidated the use of space and is moving towards revenue enhancement initiatives through submission of more grant proposals.

For more information regarding research at Carle, please visit carle.org/research.
CANCER RESEARCH UPDATE

Nearly all colon cancers begin as benign polyps, which slowly develop into cancer. There is no single cause, yet it remains the second most fatal cancer. Although screening has reduced colon cancer mortality, the decrease has not been great. It is estimated that more than half of the adults in the United States have never received screening. There is a need for more accurate, less costly and easy to use methods to increase screening effectiveness, acceptability and access.

In 2002, Carle Cancer Center began enrolling in a clinical trial lead by Mayo Clinic. MC9944, also called the EXACT Trial, sought to compare different methods of stool analysis as a way to detect precancerous lesions and early stage cancer. Participants submitted three stool samples for two different types of DNA (genetic material) and three samples for blood testing as smeared fecal blood cards (Hemoccult and HemoccultSensa). The samples were shipped overnight to a central lab facility. All participants received a colonoscopy as the final step. A total of 132 patients from central Illinois participated in this trial at Carle.

The results of MC9944 trial were published in 2008 and found that the first stool DNA test showed no improvement over the HemoccultSensa fecal blood test for detection of cancer or abnormal cells. However, the second DNA test detected significantly more cancers than the Hemoccult or HemoccultSensa but showed a higher number of false positive results in patients with a normal colonoscopy. In addition, the stool DNA test results were not affected by the distance of the lesion from the rectum, as is common in the blood in hemocult.

To continue the goal of finding a more accurate method for colon cancer detection using stool samples, Carle Cancer Center will soon participate in a new study lead by the Great Lakes New England Clinical Validation Center and Mayo Clinic. This study will evaluate stool samples from 6,000 participants nationwide in the hopes of increasing the reliability of stool DNA testing. This study will be available to the community sometime this spring.

PUBLICATIONS


CARLE IRB - NEW RESEARCH STUDIES

Role of Microbial Hydrogen Metabolism in Chronic Constipation and Constipation-Predominant Irritable Bowel
PI: Rex Gaskins, PhD

Left Ventricular Diastolic Dysfunction as a Prognostic Factor in Acute Pulmonary Embolism
PI: Abraham Kocheril, MD

For more information regarding research at Carle, please visit carle.org/research.
Investigator Profile: Dr. Daniel Picchietti

Daniel Picchietti, MD, attended medical school at the University of Chicago. He completed his pediatric residency at St. Louis Children’s Hospital and neurology fellowship at the University of Chicago. Dr. Picchietti joined Carle in 1984 and is certified in sleep disorders medicine, neurology, and pediatrics.

Although he trained in research techniques while in medical school and during his fellowship, he focused on clinical practice until the late 1990s when he became interested in sleep-related research.

Dr. Picchietti has produced a steady stream of publications since 2003. His 2003 NIH workshop article has been cited in medical literature over 850 times. His most recent publications discuss periodic limb movement disorder (PLMD) and restless legs syndrome (RLS) in the pediatric population. While PLMD and RLS are his primary research topics, he also focuses his efforts on attention-deficit/hyperactivity disorder (ADHD), neuropsychiatric disorders and other sleep disorders. He has collaborated with research teams at the University of Illinois for two major projects: an NIH-SBIR funded study with Dr. Antonios Michalos on Absolute Near-Infrared Brain Oximetry in Obstructive Sleep Apnea and The Effect of Physical Activity on ADHD with Dr. Charles Hillman.

Other projects have included collaboration with investigators at Johns Hopkins University, Stanford University, Mayo Clinic, Harvard Medical School and Vanderbilt University. His publications have appeared in highly regarded peer-reviewed journals, including Sleep, Sleep Medicine, Pediatrics, Neurology, Movement Disorders and Archives of Neurology.

When he’s not seeing patients or working on his research, it is likely Dr. Picchietti is teaching students at College of Medicine, University of Illinois. He began teaching at the University in 1988 and has been a clinical associate professor since 1996. Dr. Picchietti enjoys working with and mentoring students. In addition to the Hillman study, he’s also conducted three other research projects with MD/PhD students. Furthermore, he has been active on nearly 20 national and international committees, task forces and boards. These include the Diagnostic and Statistical Manual of Mental Disorders, fifth edition sleep section, the International Classification of Sleep Disorders task force and the American Board of Sleep Medicine. In his free time, Dr. Picchietti enjoys rebuilding computers and traveling with his sons.
Protecting Subject Privacy and Confidentiality

Investigators have a duty to protect subject privacy and to maintain the confidentiality of subject data. In turn, the IRB is responsible for reviewing a research protocol to ensure an investigator has adequate measures in place to accomplish those tasks [45 CFR 46.111(7)]. It is important to remember that privacy and confidentiality — though related — are not identical. Simply put, privacy is about people; confidentiality is about data. Privacy relates to a person’s sense of being in control of others’ access to herself and her information. On the other hand, confidentiality deals with how identifiable information that has been disclosed will be treated. Subject privacy and confidentiality should be protected out of a general respect for research subjects, but also because these protections help shield subjects from potential psychological harms (embarrassment, distress), social harms (if sensitive information is released), as well as potential civil or criminal liabilities.

Every study is unique, so privacy and confidentiality concerns will vary. However, here are a few considerations as you develop your protocol:

1. Who are the subjects? If your project involves vulnerable populations, such as children, the elderly, or employees, then perhaps special precautions may need to be put in place.

2. What kind of information will you be collecting? In general, the more sensitive the information, the greater the need for measures to protect data confidentiality. For example, if you want to interview subjects about alcohol use or sexual practices, you’ll want to record as little identifiable information as necessary. Any data you collect will still need to be covered by layers of protection. In addition, collection of protected health information (PHI) will be subject to HIPAA rules regarding PHI use and disclosure.

3. How will recruitment take place? Will subjects feel comfortable being approached about a potential study just moments prior to an extensive surgery? Who will conduct the consent process? Will potential subjects question whether their privacy is protected if they are approached by a total stranger?

4. How will data be stored? Whenever possible, store study data in restricted areas. If the study records are paper-based, keep them in a place where only qualified investigators have access (perhaps in a locked cabinet accessible only to the research team). If the study data is electronic, it may be a good idea to keep the data on a password-protected database. If identifiable information will be transmitted via email, use encryption software so that only the intended recipient(s) can access the data.