



THE ROCKEFELLER UNIVERSITY HOSPITAL

UPDATE

Winter • 2003

Recruiting and Orienting Research Nurses to The Rockefeller University Hospital

Kelly McClary, R.N., *Director of Nursing and Patient Care Services*

With the support and assistance of Dr. Barry Collier, Dr. Emil Gotschlich, Susan Richer, and the Human Resources Department, a major nurse recruitment initiative was undertaken this fall. I am pleased to report that recruitment for the nursing staff is nearly complete. Our new day shift nurses, Carlton Niven, R.N., and Victoria Clark, R.N., are in the midst of orientation, and our new evening shift nurse, Gretchen Fromm, R.N., started on December 1.

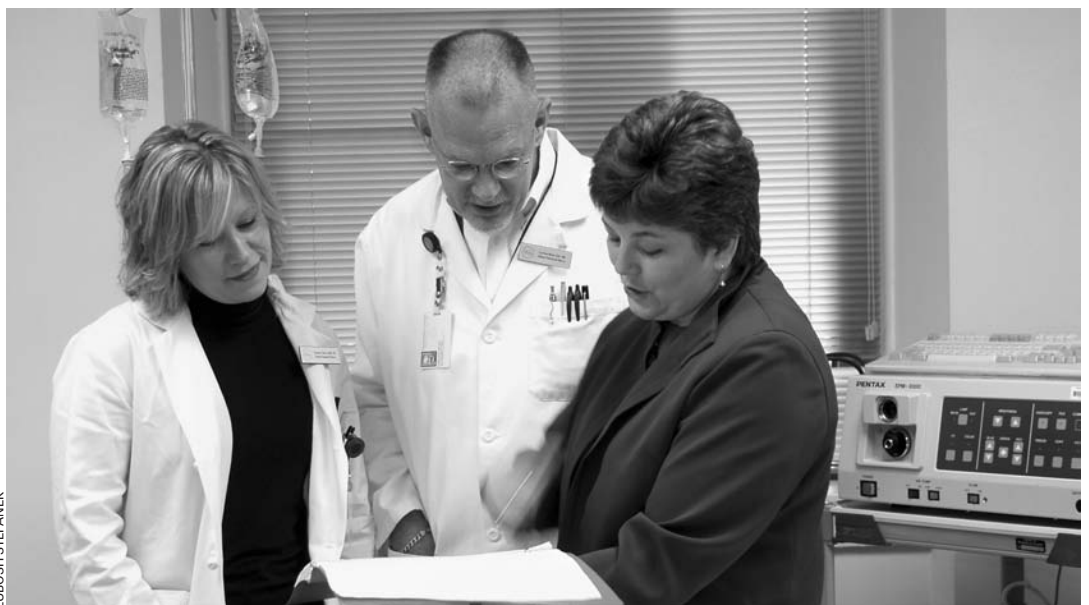
The role of the Clinical Research Nurse is unique and very specialized. Typically, a nurse coming to The Rockefeller University Hospital has extensive nursing expertise, but little or no research experience. To ensure excellent care of human subjects and protocol adherence, a thorough orientation period for nurses is essential.

Orientation begins with an introduction to the mission, vision, function, and history of the General Clinical Research Center as well as how it is funded. The unique ability of our investigators to carry out translational research is described through articles and regularly scheduled discussion sessions. Many investigators assist in the orientation and continuing education process by providing seminars; recent topics have included HIV vaccines, processing of research specimens, psoriasis, the phases of clinical research, and dealing with difficult patients.

Nurses are provided with opportunities to learn about the work of particular research scientists through various mechanisms, including “hands-on” rotations in research laboratories on campus. Proper specimen collection, processing, and storage techniques are a major component of the clinical research nurse training provided in large part by our very knowledgeable nursing assistants.

Human subjects protection and the informed consent process are reviewed in detail throughout the orientation period, and education on this important topic continues during the entire tenure of the clinical research nurse. Nurses learn how to handle issues that they confront when working with research volunteers (both healthy patients and individuals with one or more illnesses) by following the examples of their mentors and by participating in multidisciplinary discussion groups.

Upon completion of orientation, the nurse will have developed a foundation of knowledge in order to excel at research nursing and grow professionally at The Rockefeller University Hospital. In addition, the nurse will be able to provide the best nursing care to our research volunteers while ensuring successful completion of the research protocol. ♦



LUBOSH STEPANEK

To ensure the successful completion of research protocols, clinical research nurses Victoria Clark (left) and Carlton Niven (see related article on page 5) undergo a specialized orientation period. Kelly McClary (right), director of Nursing and Patient Care Services, participates in the nurses’ career-long education.

Hospital Website Gets a Make-Over A Boost for Investigators and for Study Recruitment

Rhonda G. Kost, M.D.

After months of careful design work and suspense, the significantly redesigned Rockefeller University Hospital website (<http://www.rucare.org>) – a successful collaboration between the hospital and the University IT Web Design Group – went live on October 21.

- Among the goals of the make-over were:
- to capture the professional look and feel of the University website for the hospital website
 - to increase the appeal to potential research volunteers

- to improve the ease of use and navigability of the site
- to provide a user-friendly directory to clinical protocols and studies, contact information, and eligibility information to enhance recruitment
- to expand the information provided about research groups, principal investigators, the hospital itself, and the General Clinical Research Center.

Investigators may add or alter clinical research study or lab group information on the website by

contacting Jane Berger, of the Clinical Research Office, Recruitment and Outreach, at 212-327-8610.

We also sought to separate the interface and content presented to users outside the University (such as potential subjects, referring physicians, collaborators, and sponsors) from the interface and con-

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Toward the Pursuit of a Vaccine Against the Human Immunodeficiency Virus

Sandhya Vasan, M.D.

Aaron Diamond AIDS Research Center

Drs. David Ho and Martin Markowitz, Heads



LUBOSH STEPANEK

Despite substantial advances in the treatment of the human immunodeficiency virus (HIV), new cases of HIV infection and inadequate access to treatment continue to devastate many areas of the world. In China, the incidence of new cases of HIV infection has skyrocketed since 2001, leading to estimates that 10 million people may be infected by the year 2010. Despite an effort by the Chinese government to provide prevention education and access to treatment, it is clear that a preventative vaccine is urgently needed, not only in China but around the world.

Over the past few years, Dr. Yaoxing Huang and his team have developed a DNA candidate vaccine in the laboratory of Dr. David Ho at the Aaron Diamond AIDS Research Center (ADARC). This potential vaccine expresses multiple gene products from the HIV genome, while retaining certain “safety” mutations to inactivate viral protein function and to ensure that live HIV cannot be made. The vaccine was developed based on a strain of HIV isolated from the Yunnan province in southern China. Given the significant genetic diversity of HIV, it remains unknown if a vaccine based on a particular strain can provide protection against other strains of HIV.

SANDHYA VASAN

Early preclinical tests have shown that this candidate vaccine produces strong immune responses in animals, without any toxicity. Because of these promising results, ADARC has formed a partnership with the International AIDS Vaccine Initiative (IAVI)

to further develop this potential vaccine for clinical testing both here at The Rockefeller University and subsequently in China. At the same time, a second candidate vaccine, developed by Dr. Zhiwei Chen and colleagues at the ADARC, uses the Modified Vaccinia Ankara (MVA) virus as a vector to deliver the same HIV gene products. This vaccine is also under development with IAVI, with plans to enter phase I clinical trials in mid-2004.

As a Clinical Scholar at The Rockefeller University and the ADARC, I have participated in developing our phase I clinical trial to assess the safety of our candidate vaccine, named ADVAX, in 45 healthy uninfected volunteers. This study is beginning this month at The Rockefeller University Hospital as well as the University of Rochester Medical Center. If the phase I trial proceeds successfully and demonstrates safety here in the United States, we will then move on to larger trials in the Yunnan province of China. Both ADARC and IAVI have been working closely with the national and local governments in China to provide education and technical training, and to develop laboratory and clinical facilities in preparation for future vaccine trials.

I am also working in Dr. Ho’s laboratory to develop a novel adenoviral vaccine vector to optimize gene expression, and therefore immunogenicity of future candidate vaccines. Current “first generation” adenoviral vaccine vectors are effective in producing an immune response, but are much less effective in persons with pre-existing immunity to adenovirus from prior natural infection(s). My work involves developing a “gutless” adenovirus vector that expresses the genes from the candidate vaccine without expressing genes from the vector itself; this approach should minimize the problems caused by pre-existing immunity to adenovirus. I am excited to be pursuing research that translates directly from the laboratory to the clinic, and which may ultimately have some impact on ameliorating the effects of HIV in the developing world.

Sandhya Vasan completed her undergraduate studies at the Massachusetts Institute of Technology, where she majored in mechanical engineering. She attended medical school at Harvard University in the Harvard-MIT Division of Health Sciences and Technology, a research-based medical education program. She completed a residency in pediatrics at Johns Hopkins University in Baltimore, after which she was awarded a Luce Foundation Scholarship to pursue research on HIV in Singapore as well as public health education in Indonesia. Her work in Southeast Asia heightened her interest to pursue preventative HIV research with an impact on the developing world. She decided to come to The Rockefeller University as a Clinical Scholar in the laboratories of Dr. David Ho and Dr. Martin Markowitz to pursue research on the development of vaccines to combat HIV infection. ♦

Rare Neurologic Disorders Provide a Glimpse into the Immune System

Athanasios Dousmanis, M.D., Ph.D.

Laboratory of Molecular Neuro-Oncology

Dr. Robert Darnell, Head

Patients with rare illnesses can sometimes provide an opportunity to study disease mechanisms in a unique and insightful way. Such has been the case with cancer patients (especially those with breast, ovarian, and small cell lung cancers) who develop *paraneoplastic neurologic disorders*. In these patients, neurologic problems arise that are not due to the spread of cancer cells to the nervous system, but rather to a case of immune “mistaken identity.” Instead of limiting its attack to cancer cells, the immune system also homes in on normal neurons that bear a protein identical to one found in cancer cells, destroying these nerve cells and causing characteristic and often devastating neurologic disability. It is often the relatively abrupt onset of the neurologic problem, in fact, that brings the person to medical attention and which prompts a search for the inciting cancer.

Our laboratory studies patients with such paraneoplastic disorders. Lately we have been focusing on patients with small cell lung cancer, especially a small

subset of patients who develop neurologic deficits because of this autoimmune assault. These patients can develop a variety of specific neurologic problems, depending on which neurons are being destroyed. Most commonly, they experience limb pain and a profound loss of sensation as sensory neurons are attacked and obliterated. But occasionally, other parts of the nervous system are targeted, causing severe memory loss, anxiety, and/or seizures if cells of the limbic system are destroyed; difficulty walking,

ATHANASIOS DOUSMANIS



LUBOSH STEPANEK

impaired control of the arms and legs, and/or vertigo if Purkinje cells in the cerebellum are damaged; or double vision and/or slurred speech if neurons in the brainstem are targeted.

In some instances, we offer an experimental treatment using tacrolimus, a phosphatase enzyme inhibitor that prevents the proliferation of the killer T lymphocytes that we believe are significant, if not the sole, mediators of the autoimmune destruction. We are also extremely interested in a related group of people – namely, those who are at risk for developing small cell lung cancer but who are healthy – to see if we can find electrophysiologic or immunologic evidence indicating that their immune systems have already mounted a successful “silent” attack against cancer cells, preventing them from growing into large tumors.

We see our patients in the Heilbrunn Outpatient Research Center and as inpatients at The Rockefeller University Hospital. Patients donate blood cells and spinal fluid, and we perform a series of detailed electrical neurophysiologic tests to determine to what extent individual components of their nervous system – peripheral nerves, sensory or motor neurons, spinal cord, and/or brainstem – are affected. We then correlate the particular problems that the patients experience and the deficits we find with the neurophysiologic deficits and the immune attack. The immune attack is assessed by examining the T lymphocytes in the spinal fluid and blood to determine which subtypes are in each location, and to what extent they are activated to destroy

particular neurons. We hope that measures of neurophysiologic dysfunction can serve as early indicators of the onset or progression of neuronal autoimmune damage.

If we can determine what allows the immune systems of these patients to recognize and combat their tumors, we may be able to harness the power of the immune assault to treat cancer. Additionally, by studying how the immune system in these rare patients causes such potent and specific autoimmune destruction, and by evaluating novel treatments to block it, we may shed light on other much more common diseases of neuronal autoimmunity such as multiple sclerosis.

Athanasios Dousmanis completed his undergraduate studies at the University of Toronto, where he majored in mathematics and physiology. He then moved to New York City to enter the Tri-Institutional M.D.-Ph.D. Program. At The Rockefeller University, he obtained his Ph.D. in the Laboratory of Cardiac/Membrane Physiology under Dr. David Gadsby. After a medicine internship at Mount Sinai Hospital, he pursued residency training in neurology and a fellowship in electromyography and neuromuscular diseases at the Neurological Institute of Columbia University College of Physicians & Surgeons. He then decided to return to The Rockefeller University as a Clinical Scholar in the Laboratory of Molecular Neuro-Oncology, headed by Dr. Robert Darnell, to pursue research into the mechanisms and treatment of neuronal autoimmune diseases. ♦

Harnessing the Immune System to Fight Brain Tumors

Kavita M. Dhodapkar, M.D.
Laboratory of Cellular Physiology and Immunology
Dr. Ralph M. Steinman, Head

Childhood cancers represent the success story of modern oncology, as several of these cancers can now be cured by current chemotherapies. There is, however, one glaring exception: brain tumors. These tumors are now the leading cause of cancer-related death in children, and are the subject of my clinical studies here at The Rockefeller University Hospital. Our goal is to learn to harness the power of the immune system to fight these tumors.

Brain tumors present an interesting challenge for immunotherapy. The brain is thought to be *immune-privileged*, or protected from the immune system. Yet this very property may make it particularly amenable to modern immunotherapeutic approaches, if robust and specific immunity to these tumors could be elicited in patients.

Our studies are aimed at targeting dendritic cells. Discovered here at Rockefeller by Dr. Ralph Steinman more than 30 years ago, dendritic cells are potent antigen-presenting cells specialized to initiate and regulate immunity. Prior studies in the Steinman lab have shown that these cells can be utilized to boost immunity to tumor antigens in healthy volunteers and in patients with cancer.

We have recently developed new methods to load dendritic cells with tumor antigens. These techniques take advantage of specific receptors (such as Fc receptors) expressed on dendritic cells. These approaches not only allow us to measure immunity to tumor antigens in patients with cancers such as brain tumors, but may also permit the development of new methods to boost immunity in these patients using such dendritic cell vaccines. Prior studies in the Steinman lab have identified several key aspects of the biology of these cells that are critical to the optimal development of this promising approach in the immune therapy of cancer.

More recently, we also identified a possible role for another less well-studied immune cell called the natural killer T cell. These cells recognize glycolipid antigens (as opposed to the protein or peptide antigens recognized by conventional T cells). Our recent studies suggest that this arm of the immune system is preserved in patients with glial tumors, providing an important target for immunotherapeutic approaches to treating glioma. Learning to harness the immune system against brain tumors and integrating immune approaches into the clinical management of these tumors may lead to improved survival of patients with these notoriously difficult-to-treat cancers.

Prior to coming to The Rockefeller University, Kavita Dhodapkar completed her pediatric residency at the Mayo Clinic, followed by fellowship training in hematology-oncology at the St. Jude Children's Research Hospital and New York University Medical Center. At NYU, Dr. Dhodapkar was an active member of the neuro-oncology unit, and helped develop novel treatment protocols for brain tumors, including the application of high-dose chemotherapy in patients with a common pediatric brain tumor called medulloblastoma. She is currently a Clinical Scholar in the Laboratory of Cellular Physiology and Immunology, headed by Dr. Ralph Steinman, and has an adjunct faculty appointment as an instructor at NYU. Dr. Dhodapkar recently received a three-year grant from the Program in Human Immunology of the Dana Foundation to pursue her studies of brain tumors. ♦



KAVITA M. DHODAPKAR



THE ROCKEFELLER UNIVERSITY HOSPITAL

General Clinical Research Center

Clinical Research at The Rockefeller University Hospital

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The Rockefeller University Hospital Update

[Spring 2003 Newsletter \(987 kb\)](#)

New Outpatient Research Center Opens

Patients, investigators, and staff of The Rockefeller University Hospital are all delighted with the new Outpatient Research Center, which opened this past January 22. The attractive, warm, and spacious facility conveys a friendly, yet professional first impression of the hospital and its research mission. The environment is truly commensurate with the quality of research that is carried out in the hospital.

[Read more \(download newsletter\)](#)

UPCOMING CLINICAL RESEARCH SEMINAR

[Future Seminars Schedule](#)

RECENT FACULTY HONORS

[Ho honored for HIV research](#)

[Osman receives ASCO award](#)

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The birthplace of American Biomedical Research

Rockefeller University Hospital Website continued from page 1

tent for internal University users (investigators, coordinators, nurses, administrators, and IRB members). Users who need internal resources can access them directly at <http://www.clinfo.edu>, or can access them from within the [rucres.org](http://www.rucres.org) website by using the Investigators' Log-In located in the upper right corner of each web page. No user id or password is actually required if accessing the site from within the University network or via vpn. Users who need internal resources but who are accessing the site from a non-University location can also use the Investigators' Log-In, and will be prompted to provide the user id "gcr" and the password "gcr" to enter the internal site at <http://www.clinfo.edu>.

Plans are under way for major reconstruction of the internal website in the near future, providing access to the many new modules under construction as part of the Hospital Information Technology Strategic Plan – such as scheduling, ADT (admissions/discharges/transfer), and clinical laboratory information – and in the future, protocol writing software, electronic IRB submission and tracking, study management, and much more.

Comments and feedback about the www.rucres.org site, and requests for features or other ideas about the make-over of the www.clinfo.edu internal site, are welcome and may be sent to Rhonda Kost, M.D., at kostr@rockefeller.edu. ♦

Rockefeller University Hospital Patient Recruitment

Jane Berger and Lanie Fleischer

The Patient Recruitment and Outreach Program's main goal is to provide centralized and organized recruitment and outreach efforts to Rockefeller University investigators and study coordinators. To achieve this goal, we present The Rockefeller University Hospital's clinical research studies in a positive way, with sensitivity to community concerns.

Specifically, we:

- Work with individual study coordinators to create and implement advertising strategies, including the choice of outside advertisers and recruitment specialists
- Collect monthly data as they pertain to responses to ads, including numbers of subjects pre-screened, eligible, and recruited
- Track the number of advertisements placed (where, when, and how much they cost)
- Integrate the presentation of clinical research on the hospital website
- Add studies to centerwatch.com and clinicaltrials.gov to increase recruitment via these websites
- Attend interdisciplinary medical study rounds to remain informed of clinical and research issues affecting recruitment
- Visit local constituencies in the community to describe our programs, including the Bronx Healthlink and Lower Manhattan Coalition
- Enhance the visibility of our clinical research studies by giving presentations and distributing handouts to community groups
- Ensure that advertising and handout information comply with institutional, Institutional Review Board, and National Institutes of Health guidelines
- Work with advertising specialists with extensive experience in patient recruitment



JANE BERGER AND LANIE FLEISCHER

- Forge alliances with local health facilities, including North General Hospital in Harlem

Some of our successful recruitment strategies have included:

- Ensuring that all recruitment strategies and documents comply with IRB and University regulations
- Targeting ads to newspapers read by perspective study populations
- Providing telephone screening of responders to ads to assess eligibility while assuring confidentiality
- Integrating recruitment activities and resources of the hospital under the leadership of the Clinical Research Officer
- Increasing the number of patients entered into protocols

Our future plans include monthly lunch meetings with study coordinators to discuss issues of mutual interest. If you would like the assistance of our program, please contact *Jane Berger* (by e-mail at bergerj@rockefeller.edu or by phone at 212-327-8610) or *Lanie Fleischer* (by e-mail at fleiscl@rockefeller.edu or by phone at 212-327-8415). ♦

New Nursing Personnel Announced

CARLTON E. NIVEN, R.N., B.A.,

joined The Rockefeller University Hospital staff as a clinical research nurse on October 1, 2003. He received his B.A. in English with a minor in psychology from Appalachian State University in Boone, North Carolina in 1975, and his nursing degree from Mercy School of Nursing in Charlotte, North Carolina in 1983. He comes to the hospital with 20 years of varied nursing experience, including both clinical and management positions. Prior to joining The Rockefeller University Hospital nursing staff, Mr. Niven worked as a quality assurance and improvement nurse specialist at NYU Medical Center. His other professional positions have included staff nurse in critical care, home infusion therapy nurse, home intake coordinator, and case manager for Oxford Health Plans. Prior to entering the nursing profession, he taught high school English for five years. He has been residing in New York since 1990, when he moved here from his home state of North Carolina.

Mr. Niven has always been interested in research nursing, and is very excited about the challenges of learning a new area of nursing. He believes his skills of organization, attention to detail, love of learning, and compassion for human beings – as well as his curiosity about life – will be an asset to the nursing department at The Rockefeller University Hospital. Mr. Niven is very excited to be a member of an investigative research team that will benefit mankind. Some of his interests include classical music, pipe organ, travel, reading, and skiing.

VICTORIA CLARK, B.S.N., R.N.,

came to The Rockefeller University on October 1, 2003. She has been interested in research since college, where she first acquired a B.A. with minors in biology and English, and then returned to earn her B.S. in nursing. The University's reputation notwithstanding, Ms. Clark sought a position at Rockefeller because she wanted a career that is both challenging and that affords her the opportunity to provide a high standard of patient care while putting her strong background in science to use. She hopes to embark on an M.A. nurse practitioner program.

Ms. Clark's experience during her ten years in practice included nursing related to orthopedics, rheumatology, and sports medicine at the Hospital for Special Surgery and Beth Israel Medical Center; neurologic oncology at Memorial Sloan-Kettering Cancer Center; and cardiac step-down, open-heart recovery and telemetry at New York Hospital and Lenox Hill Hospital. In addition, she spent five years of her career living in Germany and England. Ms. Clark has been a runner for many years. She completed two marathons while living overseas, and aspires to run in the New York City Marathon next fall. Her other interests include writing and photography.

GRETCHEN FROMM, B.S.N., R.N.,

received her B.S.N. from William Patterson College in 1993, where she was a member of the honor society and the dean's list. Her ten-year nursing career has focused on critical care at Lenox Hill Hospital and Beth Israel Medical Center. Ms. Fromm worked for many years on the burn unit at New York Hospital/Cornell Medical Center. She belongs to the American Association of Critical Care Nurses and Sigma Theta Tau International professional organizations.

Ms. Fromm is very excited about coming to Rockefeller; she has always been impressed with the biomedical advances made here. She looks forward to becoming part of a team that contributes to society in a meaningful way.

Ms. Fromm is also a personal trainer and believes in assisting people to achieve their personal best.

MARIAN O'ROURKE, R.N.,

joined The Rockefeller University Hospital as a clinical research nurse on March 31, 2003. Born in Tipperary, Ireland, she studied nursing in Dublin from 1974 to 1978 at the Richmond Hospital. She then left Ireland for London, where she completed a postgraduate course in neurology/neurosurgery at the National Hospital, Queens Square London, where she continued to work until 1981. Ms. O'Rourke continued her career in neurosurgery at the Prince of Wales hospital in Sydney, Australia, and then returned to Dublin. In 1988, she traveled to Dhahran, Saudi Arabia, where she worked in the fields of general medical surgery, ENT, orthopedics, and oncology. While in Saudi Arabia, Ms. O'Rourke met her husband (who is from Wisconsin), and they moved to the U.S. in 1997. Since arriving in the U.S., she has worked at the Hospital for Joint Diseases in New York.

When she first learned about The Rockefeller University Hospital at a job fair, Ms. O'Rourke immediately became intrigued with the concept of the nurse's role in research. The idea of being proactive in health issues as opposed to being reactive in understanding and treating human illness was particularly appealing to her. Ms. O'Rourke enjoys the city of New York, reading works by William Faulkner, and attending the opera. ♦

Medication Safety

Senior Staff and Pharmacy and Therapeutics (P&T) Committee

Johanne Andersen, Barbara O'Sullivan, M.D., and Barry S. Collier, M.D.

Errors within the medication use process have taken a front seat since the Institute of Medicine published their 1999 report *To Err is Human*. The report attributed 50,000 to 100,000 deaths annually in the United States to medication errors.

During the past six months, the Senior Staff of The Rockefeller University Hospital as a whole, in collaboration with the hospital Pharmacy and Therapeutics (P&T) Committee, has embarked on a comprehensive review of our medication use process, with a focus on system redesign to improve safety and reduce errors. The review included:

- 1) a systematic analysis of our medication errors since 2000
- 2) a criticality analysis of the ordering, transcribing, and dispensing systems to identify processes appropriate for pharmacy system redesign
- 3) a novel method for identifying *errors in waiting* and *near-misses* by capturing information shared at nursing report
- 4) new methods to monitor adverse events reports to analyze adverse drug reactions
- 5) the beginning of a criticality analysis of the dispensing process.

The Senior Staff also critically reviewed the advantages and disadvantages of the new information technology systems, documents management systems, and dispensing systems that are available. The diagram below outlines where information technology software can be applied to the medication use process.

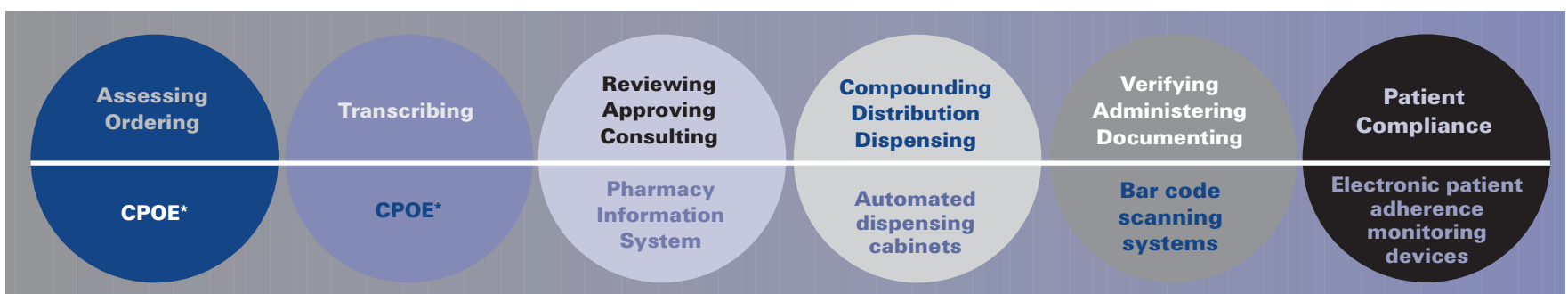
In response to the analysis, we have:

- 1) added the New York Presbyterian Hospital online formulary to assist physicians and others ordering medications

- 2) enhanced the information provided to the pharmacy to check the appropriateness of medication orders (e.g., patient height and weight)
- 3) updated and promulgated our list of acceptable and unacceptable abbreviations
- 4) developed novel methods to remind patients leaving the hospital on a pass to take their medications before departing
- 5) developed new computer education for the nursing staff to ensure adequate skill levels.

Over the next several months, we will upgrade our Pharmacy Information System to have more of the positive features of a computerized physician order entry (CPOE) system, but without the extraordinary financial costs and the need for extensive retraining required by a full CPOE system. At present, given the nature of our institution, we do not believe that a CPOE system will provide increased safety, and we fear that its introduction might create serious new errors. We anticipate that our upgraded Pharmacy Information System will overcome most of the limitations of our current system. It should also allow us to institute a more efficient medication administration record.

We are absolutely committed to constant, ongoing review of new technology to improve patient safety, and we are currently assessing the benefits, risks, and costs of bar code scanning systems, electronic patient-adherence monitoring devices, and automated dispensing cabinets. We also plan to conduct a new criticality analysis of drug administration, which will provide valuable information for making further recommendations for improving our processes. We welcome additional suggestions from the entire staff for improving medication safety at The Rockefeller University Hospital. ♦



*CPOE – Computerized Physician Order Entry

Infection Control Committee Sets New Policies for SARS and Needlestick Prophylaxis, Urges Use of Flu Vaccine

Christine Hogan, M.D.



JOHN SHOLTIS

The Infection Control and Transfusion Subcommittee of the Medical Staff Executive Committee is responsible for advising the Executive Committee about the prevention and control of infections within The Rockefeller University Hospital. Some of the committee's responsibilities include reviewing and approving policy and procedures for isolation, outbreak investigation, surveillance activities, reportable diseases, and environmental control; advising on products that affect infection control, such as cleaning products and safe-sharp devices; and educating hospital employees to understand and exercise good infection prevention techniques.

The committee has made several recommendations in the past year. Following CDC guidelines, we recommended the installation of Alcare Plus® antiseptic hand-rub dispensers in the hospital inpatient and outpatient units.

This alcohol-based alternative to hand-washing has broad-spectrum antimicrobial activity, and its use has been shown to decrease the incidence of nosocomial infections in hospital settings. We revised the protocol for post-exposure prophylaxis for health-care personnel who have sustained needlestick injuries in order to follow New York State guidelines that incorporate the use

of Tenofovir DF, a newly approved antiretroviral medication. We have also reviewed and revised the mechanism by which the occurrences of reportable illnesses in our volunteers are reported to the New York City Department of Health and Mental Hygiene.

With the advent of SARS, a worldwide outbreak of severe respiratory illness caused by a previously undescribed coronavirus, we drafted policies regarding the care and triage of patients presenting with symptoms suggestive of SARS, and procedures for the counseling and evaluation of hospital employees traveling to or returning from areas with current SARS transmission. We also responded to the Greater New York Hospital Association's call for hospitals to participate in the federal government's plan to initiate voluntary smallpox vaccination of health-care personnel. Because we are not an acute care hospital, however, our participation at this stage of the vaccination effort was not requested.

The day-to-day activities of the committee are overseen by Barbara Tiddens, R.N., the Nurse Coordinator for Infection Control. These activities include surveillance of nosocomial infections and review of antibiotic usage and transfusions, surveillance of the Bionutrition Department's food safety system and the pharmacy's mobile isolation chamber and laminar airflow hood, quality checks for the autoclave and the endoscope sterilizer, and oversight of construction site compliance with infection control standards (e.g., dust control). One of our main activities in the autumn and early winter is to work closely with Occupational Health Services to encourage all hospital employees with patient contact to receive an annual influenza vaccination in order to protect our study volunteers from acquiring influenza infection in our hospital. ♦

Clinical Research Office Announces Education Initiatives

Rhonda Kost, M.D., Clinical Research Officer



JOHN SHOLTIS

The Clinical Research Office has developed a new educational initiative to train investigators, research nurses and coordinators, clinical scholars, housestaff, and IRB members in the safe and ethical conduct of clinical research, addressing the six standards detailed in the Clinical Center's Guidelines and Standards for Clinical Investigative Research at the National Institutes of Health (NIH). The NIH standards describe the essential elements for institutions to oversee in conducting clinical research, including:

- 1) **Training and Education in human investigation and protection of human subjects**
- 2) **Biostatistics Support**
- 3) **Protocol Review**
- 4) **Clinical Informatics, Data Management, and Protocol Tracking**
- 5) **Quality Assurance and Quality Control**
- 6) **Human Resources and Physical Plant.**

RHONDA KOST

This new initiative is supported by a grant from the NIH as part of the Enhancement of Protections to Human Subjects program. The goal is to provide content in an online format that permits staff to complete required modules and receive certification to perform or continue human subjects research in a manner that is flexible, permits self-study, and facilitates research on the education process itself. Two community hospitals – Lutheran Medical Center and North General Hospital – will collaborate in this effort, and develop versions of the educational tools customized for their institutions as part of the initiative.

Topics covered in the educational initiative and training modules include:

1) Clinical Informatics, Data Management, and Protocol Tracking:

- a. **Clinical Informatics:** Identifying, reporting, and tracking adverse events (AE); how to use the online AE reporting system developed at The Rockefeller University; automated laboratory AE detection; and the physicians' desktop: its online resources and how to use them in your research practice.
- b. **Data Management:** How to create a data management plan for your protocol and your lab group: tools, process, and the Rockefeller Clinical Research Database; regulatory requirements: creating monitoring plans that ensure research integrity; understanding the elements in an external monitoring review.
- c. **Protocol Tracking:** Information technology to make the IRB more efficient: online protocol submission, review, stipulations, revisions, tracking, and notifications.

- 2) **Biostatistics Support:** Elements of study design; using analysis tools in the Rockefeller Clinical Research Database; embedding design elements of the study into the database structure so that data are stored in a more meaning-

ful manner; generalizing U-statistics to multivariate ordinal data, with examples in genetics, genomics, and response profiles research.

- 3) **Quality Assurance (QA) and Quality Control (QC):** Developing QA and QC practices in your lab group: understanding and ensuring compliance with Good Clinical Practice (GCP) standards; QA/QC in Good Tissue Practice; investigator self-assessment tool (audit in GCP); laboratory certification: Clinical Laboratory Evaluation Program.

- 4) **Protocol Review:** Training for new IRB members and continuing education for members.

- 5) **Human Resources and Physical Plant:** Recruitment, selection, and retention of outstanding research personnel; teamwork: optimizing communication for patient safety and data integrity.

6) Training and Education:

- a. **Introduction to Clinical Research:** History, research ethics (Belmont Report principles), international codes and standards, professional codes, conflict of interest, ethical conduct of research, and care versus research; workshop for nurses; workshop for new investigators; clinical coordinators' manual and toolkit.
- b. **Introduction to Informed Consent:** Elements of informed consent (45 CFR 46); how to write an informed consent form; readability; how to conduct an informed consent process; avoiding coercion; video and exercises.
- c. **Scientific Advisory Board:** Mission, study design issues, data and safety monitoring plans and boards, statistics, utilization.
- d. **ProtoType:** Protocol-writing software to write better protocols and streamline review. (Coming soon! Look for more information and a sneak peek in the next newsletter.)
- e. **Introduction to the Institutional Review Board:** Members, mission, levels and types of review, procedures, criteria for approval, preparation of protocols and presentations, investigator's assurance, HIPAA, delegation of authority, privacy, compensation, international research, record-keeping in research, specimen repositories.
- f. **Bioethics:** The Ethics Committee and how it differs from the Institutional Review Board; essential principles of ethics; teaching vignettes and case studies.

We will seek input from The Rockefeller University research community regarding these and other issues in education, areas of desired emphasis, format, presentation, testing and feedback on the modules, and other development issues as they arise. We are very excited at the opportunity to provide a novel, interactive and research-supporting platform for education in these essential topics in clinical research. We invite the community to join us in making these as meaningful and relevant as possible. Please e-mail your comments or recommendations to me at kostr@rockefeller.edu. ♦

Eamonn O'Donnell Joins IT Staff



LUBOSH STEPANEK

EAMONN O'DONNELL

Eamonn O'Donnell has joined The Rockefeller University as a Scientific Programmer. A native of Dublin, Ireland, he has been residing in the United States for nearly three years. He graduated from University College, Dublin with a pharmacology degree; he later completed a masters degree in biomedical science from King's College, London, and a Ph.D. in neuroscience from Trinity College, Dublin.

Dr. O'Donnell's thesis focused on the effects of diet on age-related changes in the rat hippocampus. During the course of his Ph.D. studies, he became

increasingly interested in the role of computers in biological research, and pursued a diploma in information technology at Dublin City University after the completion of his thesis.

After college, Dr. O'Donnell was employed by Ericsson Software Systems as a software designer. Following his move to the U.S., he became a software developer in the bioinformatics department of Curagen Corporation, a pharmaceutical company in Connecticut, where he helped develop an information management system for their laboratories. After Curagen, Dr. O'Donnell worked at Yale University in the emerging field of neuroinformatics, with Dr. Michael Hines. He was heavily involved in developing an open-source platform for the further development of a neural network simulator written over the course of many years by Dr. Hines.

Dr. O'Donnell will be working closely with Alex Peshansky to implement the Information Technology Strategic Plan for The Rockefeller University Hospital. This plan calls for enhanced integration and development of IT systems, with the goal of ultimately sustaining and improving the quality of clinical research being conducted at the hospital. One of his first tasks is to integrate the current medical credentialing software with the new admission/discharge/transfer system that was recently developed by the Rockefeller IT department. He also will be working closely with Biostatistics to implement various web interfaces to facilitate the upload and analysis of large data sets onto University servers.

Dr. O'Donnell lives in Westchester County with his wife. His interests include soccer, skiing, running, reading, writing, and playing bridge. ♦



GOOD NEWS

JOHN SHOLTIS



Dr. David Ho received the inaugural Lewis and Jack Rudin New York Prize for Medical Research from the Greater New York Hospital Association and The New York Academy of Medicine on October 30, 2003. As part of the award ceremony, he delivered a lecture entitled *HIV in 2010: What Will the Science Allow?* Dr. Ho also recently received Honorary Professorships from the Chinese Academy of Sciences and Fudan University, and the Friendship Award from the State Council of the People's Republic of China.

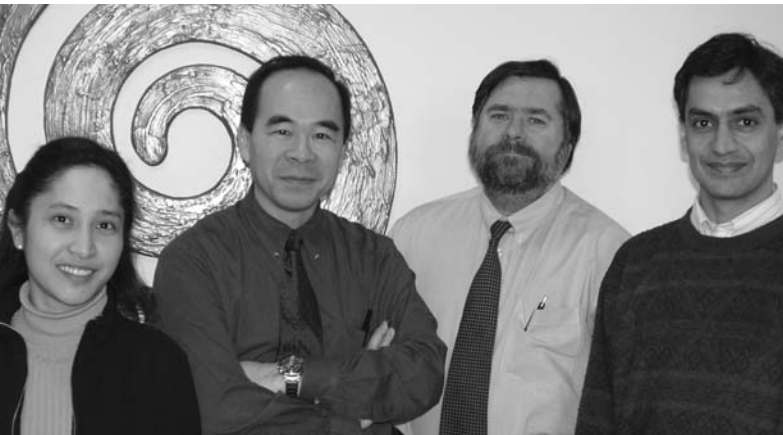


Dr. Barry S. Collier was elected to membership in the National Academy of Sciences in April 2003. In May 2003, Dr. Collier received an honorary Doctor of Science from the State University of New York at Stony Brook School of Medicine, where he delivered the commencement address, entitled *Science and Humanism: The Twin Pillars of Medicine*.

LUBOSH STEPANEK



Dr. Shao-lee Lin, Clinical Scholar, was awarded an Arthritis Foundation Postdoctoral Fellowship.



JOHN SHOLTIS

Dr. Edmund Lee, who just completed his term as a Clinical Scholar, will be first author of a paper scheduled for publication in early 2004 entitled *Increased Expression of IL-23, p19, and p40 in Lesional Skin of Patients with Psoriasis Vulgaris*. His coauthors are **William L. Trepicchio, Judith L. Oestreicher, Debra Pittman, Frank Wang, Maria F. Chamain, Madhav Dhodapkar, and James G. Krueger.**

(from left to right) Maria F. Chamain, Edmund Lee, James G. Krueger, and Madhav Dhodapkar

The Rockefeller University Hospital UPDATE

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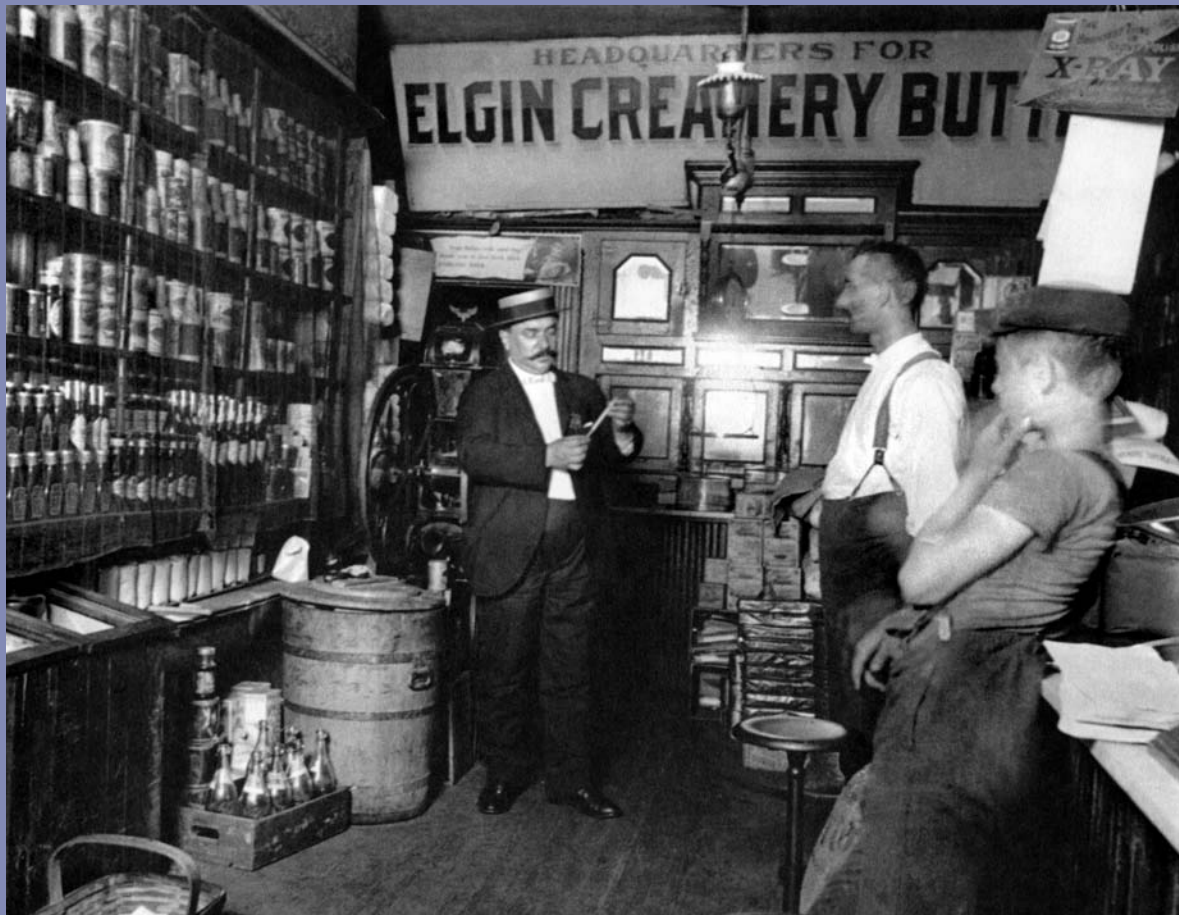
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Making New York's Milk Supply Safe



Epidemics of diarrhea among infants and toddlers swept into New York City each summer at the turn of the 20th century. Studies supported by The Rockefeller Institute on the bacterial contamination of milk prompted the New York City Department of Health to reform the handling and sale of milk. Pictured at left are inspectors from the health department taking samples of milk as it was delivered to the city and inside grocery stores.

