Reliant
Medical Group

The Reliant Medical Group
Research Department

ROUNDUP

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In this issue...

CONDUIT: A Study that Actively Engages Patients in Their Blood Pressure Care

By Peggy Preusse, RN and Larry Garber, MD

Drs. Maryanne Bombaugh, executive Medical Director of Population Health and Larry Garber, Medical Director for Informatics, have been working with UMass Medical School and Dr. Barry Saver on an Agency for Healthcare Research and Quality (AHRQ) funded study looking to see if patients' use of home blood pressure monitors linked to their Epic Electronic Health Record (EHR) and monitored by nurses can improve blood pressure control in both the pre-diabetic and diabetic populations.

Eligible patients have been assigned by a computer program to one of two study arms, either an intervention or control. Control subjects continue with their usual care and are not given a blood pressure cuff until they exit the study after one year. Intervention subjects were given an off-the-shelf, validated blood pressure cuff that has a USB computer connector, along with a free Microsoft® personal health record application called HealthVault® to automatically load their home blood pressure readings into their Epic EHR. Patients in the CONDUIT research study are having their home blood pressure readings seamlessly flow directly into their Epic medical record and be visible in a flow sheet called "BLOOD

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The Division of Rheumatology Pilots TSP

By Peggy Preusse, RN and Robert Yood, MD

The Division of Rheumatology and UV Therapeutics have teamed up to study the safety and feasibility of exposure to a specific narrow band of ultraviolet (UV) light in reducing disease severity in patients with systemic lupus erythematosus (SLE). Dr. Robert Yood is the Primary Investigator. Drs. John Reed, John Hosey and Maria Abruzzo as well as Janice Lewis NP are sub-investigators.

SLE patients traditionally have been advised to avoid sun exposure, but several studies have indicated that a specific band of targeted light exposure (UVA) may actually have beneficial effects on the immune system with the potential to reduce disease severity activity. There is evidence to suggest that the harmful effects of sunlight in patients with SLE are due to the presence of UVB.

This particular treatment is known as trans-cutaneous systemic photoimmunemodulation or TSP. The technology uses light – emitting diodes (or LED's) to provide a targeted trans-cutaneous wavelength range of UVA that induces immune system changes. Preliminary human clinical studies on over 90 patients have demonstrated an effective reduction in disease activity and symptoms greater than 30% within 3 to 4 weeks of initial treatment and over 70% following 2 months of treatment.

The study procedures consist of exposure to the TSP system for 25 minutes. The light –emitting device, which looks like a tanning booth is set up at the Reliant Medical Group site located on North Lake Avenue. A previously used space for radiology has been converted to house the machine and provide space for the research physicians' and nurses to see study subjects and perform all study procedures. We will first conduct a pilot study of 10-15 patients, with plans to conduct a larger study in the future. The Department of Research will be coordinating the study. For more information about the study contact the study nurses, Marcy Kirkpatrick, Candace LeBlanc or Peggy Preusse at (508) 595-2195.

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Identifying Genetic Factors Associated with COPD

By Diane Kirk, RN

Although smoking is the number one risk factor for developing Chronic Obstructive Pulmonary Disease (COPD), not all smokers develop the disease and the reason why is unknown. Some develop COPD because of their genetic make-up, making them either more or less sensitive to, or affected by, the effects of smoking. COPD is the third leading cause of mortality in the United States. COPD is heterogeneous, with varying contributions of emphysema and airway disease.

Over 430 participants from Reliant Medical Group completed the first phase of the COPDGene study, with enrollment of 10,300 subjects nationwide. The goal of this project was to create a large cohort of participants, identify and correlate the genetic risk factors, and confirm the features that underlie COPD. Over time the data collected can be used to identify factors that control progression of the disease.

All participants from phase one are being invited to return for a second evaluation five years after their initial visit. Phenotyping, pathophysiologics and genetic data from the first phase will be compared to the data collected in phase 2. This will determine which COPD risk factors and subtypes are associated with the disease progression. Ultimately, the data collected may lead to the development of effective therapies, prevention, and refining diagnostic criteria for a new treatment approach.

Those returning will have repeated imaging, genetics, pulmonary function tests, clinical and physiologic characteristics identified, as well as longitudinal progression for long-term outcomes. Subjects will continue to be contacted up to four times per year by telephone, mail, or email for up to ten years. Patients will be asked about current health status, exacerbations, cancer, new illnesses or medical conditions and current smoking status.

We will also recruit (nationwide) 1,500 non-smokers without lung disease, from two racial groups, non-Hispanic Whites and African Americans. Genetic, epidemiologic, and natural history studies will provide insight on healthy subjects. Healthy aging lungs are associated with loss of lung elasticity, a characteristic feature of emphysema. The five-year natural history and progression for non-smokers provides the basic information needed for comparison with smokers.

Diane Kirk, RN, lead coordinator, has worked closely with Richard Rosiello, MD (Chief of Pulmonary and Critical Care Medicine) on this study. She has worked for Reliant Medical Group for over 25 years, seven of them in the Research Department. Other studies include the use and response of combining inhalers for those with COPD and a home blood pressure study involving patients with diabetes.

Study to Improve Influenza and Pneumococcal Vaccination Rates

By Peggy Preusse, RN

Meyers Primary Care Institute (MPCI) and Reliant Medical Group (RMG) recently received funding to undertake a project with the goal to improve appropriate influenza and pneumococcal vaccine rates among adults who receive care at RMG. Dr. Sarah Cutrona (MCPI) will be working closely with Dr. Larry Garber (RMG Medical Director for Informatics) and Dr. Lloyd Fisher (RMG Assistant Medical Director for Informatics). The study is funded by Pfizer Inc.

The study will fund development and integration of the currently used reminder call system ELIZA to also include messaging to patients in need of immunization. This messaging will allow for patient responses and these will be integrated back into the electronic health record to allow for a more complete picture of a patients' vaccine status. For those patients who use the MyChart patient portal, this additional method of communicating with the patient will be leveraged.

Secure messaging will be sent to patients overdue for immunization that will include dates of upcoming flu clinics as well as a questionnaire enabling on line self-reporting of vaccination completions done outside of RMG.

Peggy Preusse, RN will coordinate research activities at RMG. Devi Sundaresan, MS will be responsible for data analysis. Dr. Garber will oversee the integration of Eliza and EPIC, and Dr. Lloyd Fisher will use his expertise in immunization decision support and IT infrastructure to provide education to providers and staff and identify the appropriate patients for the intervention. The project will also include development of educational communications for providers and for patients. Technology system support will be provided by Carlo Vivenzio and Donna Curboy, who are responsible for development of the interface and data base queries, key to study success.

Reliant Medical Group Plays a Leading Role in Improving Massachusetts Post-Acute Care Transfers (IMPACT)

By Peggy Preusse, RN and Larry Garber, MD

The Office of the National Coordinator for Health Information Technology (ONC) awarded Massachusetts a $1.7 million "Challenge Grant" to encourage breakthrough innovations for health information exchange (HIE). This project, known as **IMPACT – I**mproving **M**assachusetts **P**ost-**A**cute **C**are **T**ransfers, will implement a HIE in Worcester County that interconnects Reliant Medical Group, Family Health Center of Worcester, Saint Vincent Hospital, UMass Memorial Medical Center, two home health agencies, an inpatient rehab facility, eight skilled nursing facilities (SNFs), and Fallon Health. Reliant Medical Group, under the guidance of Larry Garber MD, has taken a leadership role in the design, implementation and evaluation of the IMPACT project which has spanned three years.

The Reliant Medical Group IT and Research Departments, in particular, have played critical roles to assure the success of this project. Carlo Vivenzio, Paul Barnes and Paul Lavallee from our IT department have successfully connected Epic to the state's new HIE called the "Mass HIway." Our Research Department's Peggy Preusse, RN and Judy Gilmore have assisted with research coordination and site training, Devi Sundaresan, MS has extracted evaluation data, and Susan Sama, ScD has coordinated the analysis of cost savings as a result of the IMPACT project.

Over the last two years, IMPACT members analyzed the data elements in the current paper-based Massachusetts Department of Public Health three-page Hospital Discharge Form that has been used for decades at the time of patient discharge from the hospital. IMPACT surveyed numerous health care providers, nurses, therapists, social workers, care managers, and ward clerks, identifying what information was actually required when they receive patients for care. Over 1000 survey responses were received from physician practices, ERs, hospitals, nursing facilities, home health agencies, community-based organizations and patients. It was determined that for some transfers, three-times more information is needed than is currently covered on the three-page paper forms. Simple things such as documentation that an X-ray had been performed to confirmation of proper placement of a central IV line can delay important medications for hours or necessitate another placement. Home Health agencies have the greatest data requirements, needing for instance, the name and contact information of DME vendors so that when oxygen, a walker or dressing supplies were not delivered to the patient's home, they know who to call.

One of the goals of this project was to create a new national standard to support the full set of information needed by recipients of patients during transfers and care coordination. In order to accomplish this, Dr. Garber helped start the ONC's Standards & Interoperability Framework's Longitudinal Coordination of Care Workgroup and he co-chairs its Long Term and Post-Acute Care Transitions Sub-workgroup. This workgroup had clinical and technical representatives from around the world fine tuning the data requirements and proposed standards. These were subsequently brought to HL7, the international standards organization that all HIE and electronic health record (EHR) vendors follow. New transfer summary document and care plan standards based on the IMPACT project's work was successfully balloted and will be published by HL7 for use by all EHR vendors in July of 2014.

One of the other goals of IMPACT was to create software tools called "LAND and SEE" to allow any healthcare organization to participate in HIEs, regardless of whether or not they had a sophisticated EHR. Massachusetts, always a leader in innovation, developed a secure network specific to health care information exchange. Cleverly called the "Mass HIway," it gives healthcare organizations the ability to send and receive patient healthcare information securely from one institution to another with the consent of patients. IMPACT created LAND to make it easier for healthcare institutions with existing EHRs to connect to the HIway. The first live connections took place in October of 2012 with our Governor Deval Patrick sending his electronic medical record to Bay State Medical in Springfield from Boston's Massachusetts General Hospital using LAND and the HIway. Currently there are over 50 institutions live on the HIway with hundreds more about to connect.

One of the other problems that IMPACT is addressing is that some of the most complex care with the sickest patients takes place in skilled nursing facilities, which do not have the infrastructure or financial resources that are required to implement an EHR. But without an EHR, how can they send or receive electronic transfer summary documents? IMPACT answers that need by providing a secure "mailbox on steroids" known as SEE (a Surrogate EHR Environment). Using SEE, nursing facilities, behavioral health providers, community-based organizations, insurers, and any other healthcare organization that doesn't have an EHR can connect to the HIway securely using a simple web browser. They can receive electronic documents as well as create and send new ones. SEE training has been completed at all Worcester pilot sites and

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Newsworthy

Mammography Reminder Study

Reliant Medical Group is collaborating with UMass and Fallon Health on a mammogram reminder study. Drs. Robert Yood, Medical Director of Research, Daniel Roswig, Chair of Radiology, and Susan Sama, Research Epidemiologist, are overseeing study activities at Reliant Medical Group. The goal of this study is to determine the most effective way to encourage non-adherent women to get their screening mammograms. Mammography can detect breast cancer at an early stage. When detected early, breast cancer can typically be treated more successfully.

Study enrollment began in July 2010 and included FCHP patients ages 51-84. In July 2011 women ages 40-50 were also enrolled for study. In 2012 the study was expanded to include women insured by Blue Cross Blue Shield, Tufts and Harvard Pilgrim. Women that are determined to be overdue (those that have not had a mammogram in eighteen months or more) received a letter reminding them to schedule. Some also received a follow-up call from a scheduler and others received a follow-up call from a health educator. Patient and PCP acceptance was very high. Over 12,000 letters have gone out to women reminding them to schedule mammograms. Patient enrollment has been completed. Data collection for this study will end in August of this year. Data are currently being collected and prepared for analysis. We expect to submit results for publication this year. For more information, please contact Dr. Susan Sama at (508) 595-2220.

For additional information on design methods: Costanza ME, Luckmann R, White MJ, Rosal MC, Cranos C, Reed G, Clark R, Sama S, Yood R. Design and methods for a randomized clinical trial comparing three outreach efforts to improve screening mammography adherence. BMC Health Serv Res. 2011 Jun 3;11:145. doi: 10.1186/1472-6963-11-145.

Sputum PGP, a Biomarker for COPD Exacerbations

The Research and Pulmonary departments participated in a large, randomized clinical trial, funded by NIH, that looked at the impact of azithromycin treatment on patients with Chronis Obstructive Pulmonary Disease (COPD). As previously reported in a prior issue of this newsletter, patients who took azithromycin for one year had decreased exacerbations and improved quality of life.

Investigators took a closer look at the sputum levels of these patients. The results showed that azithromycin treatment significantly reduced sputum levels of Proline-Glycine-Proline (PGP) in patients with COPD, especially with increased duration of macrolide therapy. Sputum PGP levels were highest around the time of an exacerbation and with successful treatment, levels decreased.

Investigators concluded: "These data support a role for PGP in the airway and parenchymal neutrophilic inflammation that drives COPD progression and exacerbations, and provide new information on the anti-inflammatory properties of macrolides. PGP may have potential as a target for novel anti-inflammatory therapies in COPD and as a biomarker for clinical trials."

More detailed information is available online: *http://bmjopen.bmj.com/content/3/12/e004140.full*

CONDUIT

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PRESSURES (HOME)". This flow sheet shows not only the blood pressure and pulse, but also the date and time the reading was obtained, thus allowing for a trended graph of blood pressure management. Patients using the MyChart patient portal can also view this same flow sheet online from home.

Each patient's blood pressure results are batched together over a multi-week period of time regardless of how often they upload readings, and then sent as a single Epic InBasket message to a team of Diabetes Disease Management nurses along with the Epic-calculated mean blood pressure. If any of the readings are critically abnormal, the result is sent to the nurse within seconds of a patient plugging their home blood pressure monitor into their computer.

For over a year, patients enrolled in the Intervention arm of the CONDUIT study have been followed by the High Risk Diabetes Disease Management nurses, Madelyn Wronski and Lin Holton. These nurses can titrate doses of the patient's current anti-hypertensive medications using strictly defined protocols based on the mean blood pressure reading, but must have provider approval prior to adding any new medications. The objective is to find a convenient and efficient way to help pre-diabetic and diabetic patients take an active role in reaching and maintaining their blood pressure goals. Each primary care practitioner has been notified when their patient enrolls in the program and is given the opportunity to decide how much responsibility to give to the nurses.

Enrollment of eligible patients was completed in October 2013 with 197 patients enrolled. Those who received the usual care arm (control participants) are given the opportunity to join the intervention group at their exit visit one year after enrollment. If the intervention results in improved blood pressure control, Reliant Medical Group patients outside of this study will also be able to use this system, first for home blood pressure monitoring, and eventually for monitoring home blood sugars, weights, pulse oximetry, peak flows, and other health measures. Preliminary results should be available in October 2014.

(IMPACT)

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exchange of summary documents will occur starting in August of this year!

Massachusetts hopes to use the IMPACT project to demonstrate how multiple healthcare organizations and the state's HIE can be integrated to improve healthcare quality and safety while reducing cost, and to use this as a model for the rest of the state. Indeed, several other states are considering using LAND & SEE, and ONC desires to spread LAND & SEE throughout the rest of the country!

"Massachusetts is a national leader in healthcare reform and home to some of the best health care institutions and most innovative health technology companies in the world," said Governor Deval Patrick. "This federal funding [for IMPACT] will help reduce healthcare costs and improve patient care using proven technologies, many of which are developed right here in Massachusetts."

"Healthcare provider organizations throughout the nation have a wide disparity in the use of information technology," said Dr. Garber. "The IMPACT project's LAND & SEE applications will enable all organizations and their patients to immediately participate in, and realize the benefits of, secure electronic health information exchange."

Larry Garber, MD is a practicing Internist and Medical Director for Informatics at Reliant Medical Group. He was principal investigator (PI) for the SAFEHealth HIE and is currently the PI for the IMPACT project.

Peggy Preusse, RN is a research nurse at Reliant Medical Group, participating in numerous research projects including SAFEHealth and IMPACT.

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What's Involved in an Institutional Review Board Review (excerpted from the Code of Federal Regulations)

By Mary Charpentier, BS, CIM

Institutional Review Board Reviews (IRBs) are mandated by federal law (Food and Drug Administration and the Office for Human Research Protections) to ensure that human subjects research is conducted with the following three ethical principles in mind:

Respect for Persons – consent to participate in research must be voluntary. Subjects must be adequately and thoroughly informed about the research and what is required of them. Additionally, their privacy and confidentiality must be protected.

Beneficence – the risks of research are justified by potential benefits to the individual or society and that those risks are minimized as much as possible.

Justice – this is the equitable distribution of both risks and benefits among those who may benefit from the research.

In order to fulfill our mandate, human subject research studies at Reliant Medical Group must be thoroughly reviewed by the IRB prior to beginning enrollment. The elements that will be considered are listed below.

A) Risk/Benefit Analysis:

Identification and Assessment of Risks:
The risks will be identified and classified as physical, psychological, social, and economic.

Minimal Risk vs. Greater Than Minimal Risk:
The IRB will assess whether the research presents greater than minimal risk.

Determination That Risks Are Minimized:
Risks should be reduced or managed. Researchers should use procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever possible, use procedures already being performed on the subjects for diagnostic or treatment purposes.

Assessment of Anticipated Benefits:
The IRB should assure that the anticipated benefits to research subjects and the knowledge researchers expect to gain are clearly identified.

Determination That the Risks Are Reasonable in Relation to Anticipated Benefits:
Evaluation of the risk/benefit ratio is the major ethical judgment that IRBs must make in reviewing research proposals. This determination should be based solely on the risks and benefits to the potential subjects of the proposed research study.

B) Informed Consent:
Informed consent is one of the primary ethical requirements underpinning research with human subjects; it reflects the basic principle of respect for persons. Consent must also be properly documented.

C) Selection of Subjects:
IRBs are required to make a specific determination that the selection of subjects is equitable. In making this assessment, the IRB will consider the purpose of the research. In addition, the IRB will pay particular attention to special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.

D) Privacy and Confidentiality:
When information linked to individuals will be recorded IRBs should assure that adequate precautions will be taken to safeguard the confidentiality of the information.

E) Monitoring and Observation:
The protocol must, when appropriate, include plans for monitoring the data collected to ensure the safety of subjects.

F) Additional Safeguards:
Each project is reviewed to determine whether some or all of the subjects are likely to be vulnerable to coercion or undue influence to participate.

G) Incentives for Participation:
IRBs must consider whether paid participants in research are recruited fairly, informed adequately, and compensated appropriately.

H) Continuing Review:
At the time of its initial review, the IRB must determine how often it should reevaluate the research project. The reevaluations must occur no less than annually.

The IRB is committed to assure, both in advance and by periodic (continuing) review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in a research study.

Mary Charpentier has worked for Reliant Medical Group since 1994. She has been the IRB Administrator since 1999.

Simvastatin: No Beneficial Effect for COPD Patients

By Anne McDonald, RN and Richard Rosiello, MD

Retrospective studies have suggested that statins (such as simvastatin) decrease the rate and severity of exacerbations, the rate of hospitalization, and mortality in chronic obstructive pulmonary disease (COPD).

COPD exacerbation is a common complication that significantly contributes to the high morbidity, mortality and costs associated with COPD. In search of new treatments that can effectively lessen the prevalence and severity of COPD exacerbations, Reliant Medical Group participated in a Prospective Randomized Placebo-Controlled Trial of Simvastatin in the Prevention of COPD Exacerbations (STATCOPE).

This large, multicenter study was a randomized, controlled trial of simvastatin (at a daily dose of 40 mg) versus placebo, with annual exacerbation rates as the primary outcome. Eligible patients with moderate to severe COPD (defined by a forced expiratory volume in one second [FEV1] of less than 80% and a ratio of FEV1 to forced vital capacity of less than 70%) were recruited. Patients with diabetes, cardiovascular disease, taking a statin or should be taking a statin for cholesterol or cardiovascular conditions were excluded. A total of 885 participants with COPD were enrolled for approximately 641 days; 44% of the patients were women.

The results of this prospective study showed that simvastatin at a daily dose of 40 mg did not improve exacerbation rates or the time to a first exacerbation in patients with COPD who were at high risk for exacerbations. Furthermore, simvastatin had no effect on lung function, quality of life, the rate of severe adverse events, or mortality. Thus, the data did not show a therapeutic benefit of statins in patients with moderate-to-severe COPD.

The full article was published on May 18, 2014, at NEJM.org.

(Funded by the National Heart, Lung, and Blood Institute and the Canadian Institutes Of Health Research; STATCOPE ClinicalTrials.gov number, NCT01061671.)

Anne McDonald, RN has been with Reliant Medical Group for 27 years and with the Research Department for 12 years. Anne's first studies focused on outdoor allergens and asthma, collecting local air samples from the rooftop of Worcester Medical Center. Subsequent studies were related to Chronic Obstructive Pulmonary Disease (COPD) and the effects of certain medications in patients with COPD, such as macrolide, an antibiotic and simvastatin. Currently, Anne is working on two Multiple Sclerosis studies that enable patients to take an oral pill in place of injectable medications, which has been the standard of care for many years. Previous to joining Research, Anne worked at Reliant Medical Group in Urgent Care, Orthopedics and Surgery.

Dr. Richard Rosiello is the chief of Pulmonary and Critical Care Medicine at Reliant Medical Group and the division director of Pulmonary Medicine at Saint Vincent Hospital. He is also the medical director of the nationally recognized COPD Disease Management Program at Reliant Medical Group. He is an author of many articles in the medical literature on the topic of COPD recognition and treatment.

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Research Recap

Cardiovascular Inflammation Reduction Trial (CIRT).

The primary aim is to test the inflammatory hypothesis of atherothrombosis. Investigators will evaluate whether low-dose methotrexate will reduce rates of myocardial infarction, stroke, or cardiovascular death among patients with a recent history of coronary artery disease and either type II diabetes or metabolic syndrome.
Luigi Pacifico, MD (Cardiology), Peggy Preusse, RN, Anne McDonald, RN and Kathy Allain, LPN (Research).
National Institutes of Health.
May 2014 – Active.

Genetic Epidemiology of COPD; Phase II

Investigators will continue to follow the 400+ patients enrolled in phase one of the study. The aims are to identify new genetic loci that influence the development and/or progression of chronic obstructive pulmonary disease (COPD) and COPD-related phenotypes, and 2) to reclassify COPD into subtypes that can ultimately be used to develop effective subtype-specific therapies and prevention. We will also enroll additional non-smoking subjects.
Richard Rosiello, MD (Pulmonary), Diane Kirk, RN and Diane Gannon, RN (Research)
National Institutes of Health.
September 2013 – Active.

Prospective registry of mamma print in breast cancer patients with an intermediate recurrence score

The purpose of this registry study is to assess information obtained from a breast cancer suite of diagnostic tests and other clinical information to study ways to assist in breast cancer diagnosis and treatment decisions.
Kerri Bennett, MD (Surgery), James Rooney, MD and Tony Samaha, MD (Oncology). Marcia Kirkpatrick RN, CCRN and Candace LeBlanc, RN, CCRN (Research).
Agendia.
1/2013 – Active.

A 12-month, prospective, randomized, active-controlled, open-label study to evaluate the patient retention of fingolimod vs. approved first-line disease modifying therapies in adults who are in early stages of treatment for relapsing remitting multiple sclerosis

To evaluate the retention rate of different therapies for patients diagnosed with relapsing remitting MS.
Gary Keilson, MD (Neurology), Anne McDonald, RN and Kathy Allain, LPN (Research).
Novartis Pharmaceuticals.
11/2012 – Active.

A multicenter, randomized, double-blind, parallel-group, placebo-controlled variable treatment duration study evaluating the efficacy and safety of siponimod (BAF312) in patients with secondary progressive multiple sclerosis.

The primary objective is to demonstrate the efficacy of BAF312 relative to placebo in delaying the time to 3-month confirmed disability progression in patients with SPMS as measured by EDSS.
Gary Keilson, MD (Neurology, Anne McDonald, RN and Kathy Allain, LPN (Research)
Novartis Pharmaceuticals.
September 2013 – Active.

A randomized, double-blind trial assessing the impact of methotrexate discontinuation on the efficacy of subcutaneous tocilizumab with methotrexate therapy.

The purpose of this study is to observe the effects of subcutaneous tocilizumab plus methotrexate on patients with rheumatoid arthritis. Investigators will also see whether stopping or continuing the methotrexate once patients responded to the two together has an influence on their RA.
John Hosey, MD (Rheumatology), Candace LeBlanc, RN and Marcia Kirkpatrick, RN (Research)
Genentech.
December 2013 – Active.

A multicenter, randomized, double-blind, placebo controlled phase III trial of tecemotide versus placebo in subjects with completed concurrent chemo radiotherapy for unresectable stage III non-small cell lung cancer (NSCLC).

This is an international, multi-center, double-blind, placebo-controlled, randomized, phase III trial of subjects with unresectable stage III NSCLC who have demonstrated either stable disease or objective response following primary concurrent CRT, comparing OS time in subjects treated with tecemotide versus subjects treated with tecemotide-matching placebo.
Saleem Khanani, MD (Oncology), Candace LeBlanc, RN and Marcia Kirkpatrick, RN (Research)
EMD Serono.
April 2014 – Active.

A double-blind, randomized, placebo-controlled, dose-escalation, multi-center study of a single intravenous infusion of allogeneic mesenchymal precursor cells (MPCs) in patients with rheumatoid arthritis and incomplete response to at least one TNF∝ inhibitor.

To evaluate the safety, tolerability and feasibility of a single intravenous (IV) infusion of allogeneic mesenchymal precursor cells (MPCs) compared to placebo at 12 weeks post-infusion in the treatment of patients with active rheumatoid arthritis (RA) who have received methotrexate +/- other oral DMARDs for at least 6 months and who have had an incomplete response to at least one course of a TNF∝ inhibitor.
John Hosey, MD (Rheumatology), Diane Kirk, RN and Diane Gannon, RN (Research)
Mesoblast Inc.
February 2014 – Active.

A Phase Ib/II study of docetaxel with or without buparlisib as second line therapy for patients with advanced or metastatic squamous non-small cell lung cancer

The purpose of the Phase Ib part of this study is to determine the MTD/RP2D of buparlisib plus every-three-week docetaxel in patients with previously treated advanced/metastatic squamous NSCLC.
The purpose of the Phase II part of this study is to assess the treatment effect of adding buparlisib versus buparlisib matching placebo to every-three-week docetaxel in patients with previously treated advanced metastatic squamous NSCLC.
Saleem Khanani, MD, James Rooney, MD and Tony Samaha, MD (Oncology); Marcia Kirkpatrick RN, CCRN and Candace LeBlanc, RN, CCRN (Research).
Novartis Pharmaceuticals.
October 2013 – Active.

A randomized, double-blind, parallel-group, multi-center, phase III study to compare the efficacy and tolerability of fulvestrant (Faslodex) 500 mg with anastrozole (Arimidex) 1 mg as hormonal treatment for postmenopausal women with hormone receptor-positive locally advanced or metastatic breast cancer who have not previously been treated with any hormonal therapy.

To compare two approved medications, fulvestrant and anastrozole, in approximately 450 postmenopausal women with hormone receptor-positive, locally advanced or metastatic breast cancer.
Saleem Khanani, MD, James Rooney, MD and Tony Samaha, MD (Oncology); Marcia Kirkpatrick RN, CCRN and Candace LeBlanc, RN, CCRN (Research).
AstraZeneca.
8/2012 – Active.

A multicenter, randomized, active-control, phase 3b study to evaluate the cardiovascular safety of febuxostat and allopurinol in subjects with gout and cardiovascular comorbidities.

The purpose of this study is to see whether gout patients treated with febuxostat for a long time (5 years or more) have a different rate of serious heart and blood vessel complications than patients treated with allopurinol.
Robert Yood, MD, Maria Abruzzo, MD, John Hosey, MD, John Reed, MD, Janice Lewis, NP and Alice Williams, MD (Rheumatology), Marcia Kirkpatrick RN, CCRN and Candace LeBlanc, RN, CCRN (Research).
Takeda Pharmaceuticals.
9/2010 – Active.

A double-masked, randomized, multi-center, active-controlled, parallel, 12-month study assessing the safety and ocular hypotensive efficacy of AR-13324 Ophthalmic Solution, 0.02% q.d. and b.i.d. compared to Timolol Maleate Ophthalmic Solution, 0.5% b.i.d. in patients with elevated intraocular pressure; Rho Kinase Elevated Intraocular Pressure Treatment Trial (ROCKET-2)

To evaluate the ocular hypotensive efficacy of AR-13324 Ophthalmic Solution, 0.02% q.d. and AR-13324 Ophthalmic Solution, 0.02%, b.i.d., compared to the active comparator Timolol Maleate Ophthalmic Solution, 0.5% over a 3 month period).
Bradley Daines, MD (Ophthalmology), Diane Gannon, RN and Diane Kirk, RN (Research).
Aeries Research.
August 2014 – Active.

A phase III, 52-week, randomized, double-blind, 3-arm parallel group study, comparing the efficacy, safety and tolerability of the fixed dose triple combination [Fluticasone furoate (FF)/Umeclidinium UMEC)/Vilanterol (VI)] FF/UMEC/VI with the fixed dose dual combinations of FF/VI and UMEC/VI, all administered once-daily in the morning via a dry powder inhaler in subjects with chronic obstructive pulmonary disease.

To evaluate the efficacy of FF/UMEC/VI (3 medications at once) to reduce the annual rate of moderate and severe exacerbations compared with dual therapy of FF/VI or UMEC/VI (two medications) in subjects with COPD.
Daniel Steigman, MD (Pulmonary), Anne McDonald, RN and Kathy Allain LPN (Research).
GlaxoSmithKline Pharmaceuticals.
August 2014 – Active.

ROUNDUP

Presented & Published

Publications

- Lafeuille, MH, Grittner AM, Gravel J, Bailey RA, Martin SC, Garber L (Reliant Medical Group Informatics), Duh MS, Lefebvre P. Opportunities for improving attainment of quality measures in patients with type 2 diabetes mellitus. American Journal of Managed Care. 2014;20(1):S5-S24.
- Rapose A (Reliant Medical Group Infectious Disease). Measles & pertussis outbreaks: an important role for travel clinics. American Journal of Infection Control. Letters to the editor. 2013;41:1140.
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The Reliant Medical Group Research Department provides valuable assistance to Reliant Medical Group physicians and other providers interested in participating in research studies. For studies originating outside Reliant Medical Group, the provider must contact the Research Department early in the discussions to assure that organization policies including those concerning access to data, privacy, budgeting and submission to the Institutional Review Board (IRB) are followed. For studies generated within the organization, the Research Department can help with the study design and budgeting and the Department can assist with the application to the IRB. The Department has a group of specially trained research nurses who can perform the nursing responsibilities required for most studies.

In all cases, the Research Department must be contacted early in the process, even if the Research Department will not be involved in actually conducting the study. The Department will help you avoid pitfalls involving performance of the project later on.

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