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In 2012, the Department of Medicine (DOM) continued to pursue excellence in its clinical and academic aspirations. During this year, the Hospital Medicine program expanded to recruit a number of wonderful physicians. Our Hospital Medicine division has been leading a number of projects related to quality (core measures and clinical effectiveness) and efficiency (length of stay and discharge clinic) that will lead to the best value for our patients and community. The division has also developed a close relationship with other specialties (orthopedics, cardiac services, neuroscience, diabetes program, palliative medicine, transitional care program) to deliver seamless and efficient care. In 2012, our Critical Care Program also expanded their role, not only to the Medical-Surgical ICUs and Neuro-ICU, but also to the CVICU and CCU. Again, the team is leading a number of quality and clinical effectiveness projects for critically ill patients. In 2012, our Rheumatology program expanded to provide both inpatient and outpatient practices and more recently, Palliative Medicine program is being developed as a collaboration between the hospital administration and the Department of Medicine (DOM).

In 2012, DOM, as a member of Inova Fairfax Medical Campus community, implemented EPIC as its Electronic Health Record. In fact, the department team has been instrumental in the successful launch and adoption of EPIC. Finally, last year, we continued to expand our academic aspirations. The application for Inova-sponsored Residency Program in Internal Medicine has been completed. Our research portfolio has been expanded not only to include Liver, Obesity, Advanced Lung Disease, Infectious Diseases, but also Health Services Research. Our faculty has been tremendously productive with dozens of peer-reviewed articles and national and international presentations. As we have move in to 2013, I am confident that DOM will remain a leader in the pursuit of excellence in clinical, quality, and academic aspirations for our institution. In these efforts, your active participation and support remain critical and will be greatly appreciated.
ACADEMIC AFFAIRS AND MEDICAL SUBSPECIALTIES

This year, we have focused on further developing our specialty programs along with our academic programs. One specific area which we have addressed is Dermatology services. The department leadership has worked closely with Dr. Amir Bajoghli, Dermatology Section Chief, to ensure adequate dermatology coverage for patients at Inova Fairfax Medical Campus. Dr. Bajoghli has created a consultation service with approximately 5 other dermatologists who will each be available for one week at a time for dermatology consults. In addition, the Department of Medicine has hired a physician extender to assist the dermatologists in providing care for our patients. Another specialty area of concentration has been Rheumatology Service. The service expanded with the addition of a Rheumatologist. This will allow for clinical coverage here at Inova Fairfax Medical Campus but also enable both physicians to begin seeing patients in the outpatient setting. Work continues with our section chiefs in Endocrinology, Gastrointestinal Diseases and Geriatrics to further develop these areas as patient needs continue to expand.

On the academic side, we continue to educate numerous students and residents with the talented faculty. Our faculty members continue to grow as academic mentors and many are actively involved in research activities under Dr. Younossi’s leadership. With Institutional support, we have been able to put the necessary components in place to apply for Inova-sponsored Internal Medicine Residency. The Residency application has been submitted to the ACGME and the site visit was scheduled on May 29, 2013. The department is very excited to begin its residency program and greatful to all of the department members who have continued to support this mission throughout the years.

QUALITY AND GENERAL MEDICINE

In 2012, there were many important accomplishments in the Department of Medicine quality arena. First off, we hardwired our peer review and focused review process. Now, at the time of re-credentialing, all individuals with a peer review fallout have received education as well as the focused review to facilitate a smooth and transparent re-credentialing process – without any surprises. Secondly, the successful hospitalist subsection CME series which is devoted to discussing high-yield Internal Medicine inpatient topics - bringing up to date evidence to the bedside, continued with effective results. Finally, we have become more savvy in utilizing quality and performance databases which will eventually allow us to measure our performance in key areas. We will be able to transmit this information to physicians to allow for improvements when appropriate.

In 2013, we hope to see continued gains in our quality program. Furthermore, we plan to implement pathways to improve clinical effectiveness for common disease processes we treat such as hip fracture, pneumonia, COPD, and heart failure. Subsequently, we are engaged with hospital administration to devise strategies to improve physician to patient communication. We are looking forward to reporting on our progress throughout the year and we thank you for your dedication in delivering excellent care to our patients.
VISION
The Department of Medicine at Inova Fairfax Hospital Campus will be recognized as a leader in delivering compassionate and personalized patient care by ensuring innovative and superior medical services for its patients and community. We will continue to train future physicians and create an environment that will attract and retain highly talented physicians and staff. We will integrate cutting-edge research into our clinical practice and educational activities.

GOALS
2. Education – develop top-tier Internal Medicine Residency Program and fellowship programs to ensure the development and retention of highly qualified physicians.
3. Research – develop a patient-focused research portfolio including clinical, translational, and health services research.
4. Reputation, Growth, and Development – expand depth and reputation of Department of Medicine programs and services to better integrate and support Inova’s vision and to be recognized for clinical excellence by patients, physicians, staff, and the community.
5. Physician Relations - Develop the best physician team which will provide collaborative opportunities with hospital and community-based physicians allowing us to develop and achieve quality and growth objectives despite location of employment.
6. Fundraising and Philanthropy - collaborate and enhance philanthropic efforts for the Department of Medicine in order to fund research, education, and clinical programs.
DEPARTMENT OF MEDICINE OVERVIEW

CLINICAL CARE
- Over 1,000 physicians on staff across 14 sections
- COE in Cardiovascular Disease, Chronic Lung Disease, Liver Disease, and Medical Cancer
- Co-manage patients across hospital including Surgery, Orthopedics, and Neuroscience
- Medicine Hospitalist - 24/7 coverage for inpatient units as well as the Emergency Department
- Intensivists - 24/7 onsite coverage at critical care units

EDUCATION
- Medical students from VCU-Inova Campus, Georgetown, and George Washington
- Georgetown and George Washington Medicine Residency Affiliations (150 residents)
- Top tier Transitional Year Residency Program (12 students)
- George Washington University Fellowship in Cardiology, Gastroenterology, and Renal
- National level grand rounds and conferences

RESEARCH
- Translational Research
- Clinical Research
- Health Services Research
- Epidemiologic Research
- Functional Assessment Research

QUALITY
- Evidence Based Practice
- Early Discharge (LOS)
- Multidisciplinary Teams
- Documentation/Coding
We are pleased to announce the approval of Inova Fairfax Internal Medicine Residency Program by the Accreditation Council for Graduate Medical Education (ACGME). Medical education has been a long standing tradition of the Department of Medicine at Inova Fairfax Hospital. Both our employed and community faculty members have been voted as top educators by students and residents from VCU, Georgetown and George Washington Universities. We are very excited as this new residency program will further our departmental and organizational efforts in medical education.

Our Director of Medical Education, Dr. Alita Mishra, will serve as the program director for the new residency program. We plan to recruit for our first intern class starting in July 2014 through ERAS, Electronic Residency Application Service.

Ambulatory training for our residents will occur in Inova Medical Group’s Internal Medicine clinics led by Dr. Z. Chris. We will also be sending our residents to our faculty partners in community practices for sub-specialty ambulatory experience. We eagerly look forward to working with our departmental members to further develop and enhance our Internal Medicine Residency curriculum.

Our new Internal Medicine residency program will complement our commitment to high quality-high value patient care and our efforts to develop a well-integrated cutting-edge program in clinical, translational and outcomes research. All of these efforts will certainly place our department and our institution as leaders in the future of health care and medical education.

We are thankful to all of our Department of Medicine’s hospital-based and private practice faculty members. We also greatly appreciate Inova’s administrative leadership for their support and help in this process.
In 2012, the Department of Medicine’s Inpatient Service was evaluated by the Nelson Flores consultative group. Dr. John Nelson is a pre-eminent leader in the field, and one of its most recognizable founding members of this speciality. Their summary report was very positive with the following comments for the report:

“Truly top tier group of doctors who are very engaged in things beyond direct patient care”

“Highly professional; well integrated into the broader medical staff”

“Strong culture of ‘yes’”

“Highly engaged in organizational performance improvement and teaching”

“Excellent clinical reputation, good esprit de corps, strong internal cohesion and high affinity to Inova Fairfax Medical Campus.”

“When compared with other hospitalist practices, the DOM hospitalists are in the top 10% with regard to engagement and responsiveness to organizational needs”

In pursuit of excellence for our institution and members of the hospitalist team are involved in a number of campus wide as well as system-wide committees. The team has tremendous involvement in hospital committees and initiatives including:

- Clinical competency committee
- Fall committee
- Pressure ulcer committee
- Blood usage committee
- Emergency management committee
- Green Team
- Peer Review

The physicians are also active in multiple scholarly projects, including:

- Case reports
- Clinical lectures/workshops

In addition, many of the physicians are engaged in community initiatives, including:

- Association of Physicians of Indian Origin
- Anahata International
- Virginia ACPAC

Members of the hospitalist team provide leadership roles in important system-wide initiatives including:

- Georgetown University, George Washington University residents
- Virginia Commonwealth University students
- Observation Unit
- Transitional Care Program
- Rheumatology Program
- Physician Case Management advisors
- Epic implementation
- Clinical Documentation
- Quality Initiatives

In 2012, many clinical initiatives and objectives were met including the harm avoidance targets, exceeding the core measure targets, and the mortality data ranks among the best in the country. While providing this degree of leadership, education, and quality care, the team still managed to exceed the 2012 productivity targets.

For 2013, focus will continue on growth and innovation of new initiatives and processes. Our goal is to create a program with the ability to quickly adapt to the needs of the patient, hospital, system, and community. We are creating three tracks within our program to better serve this goal, each providing dedicated resources and skills.

The Clinical/Quality track will focus on patient safety, quality, and outcomes initiatives. This will be built around optimizing Epic reporting, standardization of key clinical pathways, and protocols, focusing on the continuum of care, along with continued committee participation and leadership.

The hospitalist track will focus on internal operations allowing us to better align itself with the hospital’s needs. We have created an internal operations committee that reviews key metrics and re-assesses performance improvements. These physicians will serve as multi-disciplinary leaders to optimize care, and participate on the resulting committees to ensure their success.
The academic track will focus on promoting the departments academic goals which serve as a great source for attracting high-quality physicians and providing excellent care. They will work on scholarly projects under Dr. Younossi’s and the department’s research team guidance. They will provide internal performance improvement as both teachers and bedside caregivers, along with exploring innovative teaching methods.

Growth provides more opportunity to work together, innovate, and support our peers with patient care initiatives. In 2013, we will merge with a private hospitalist practice. Dr. Alarif and his group have provided excellent care and served the Inova community and patients very well over the years. We expect through this merger, we can create an even more dynamic program from the department’s inpatient services. We have also added Physician Assistants to grow our consultative services, specifically, Dermatology and ED liaison. Lastly, as the clinical landscape changes for all clinicians, we are excited to provide more medical co-management for our specialty colleagues’ patients to help ensure efficient care.
DEPARTMENT OF MEDICINE INITIATIVES

THE DEPARTMENT OF MEDICINE AND TRANSITIONS OF CARE

The Department of Medicine has joined forces with Inova Health System in enhancing transitions of care as one of their hospitalists, John Paul Verderese, MD, FACP, assumed the Medical Directorship of Inova Transitional Services (ITS) in September of 2012.

In 2011, Inova Health System, in response to current Medicare non-payment for select hospital re-admissions, instituted the Inova Transitional Care Management Division. This case management-based service continues to refer all uninsured or unmanaged Medicare and Medicaid patients with high-readmission diagnoses.

Patients with CHF, diabetes, pneumonia, asthma, and COPD, are referred to an intense 30 day program with the explicit goals of finding them physician follow-up in 7 days, educating them about their diagnoses, helping them learn to self manage their conditions, and placing them into permanent medical homes. Those who do not have access to a medical home for insurance reasons are referred to ITS for further clinical care until a permanent medial home can be secured.

Under the department’s guidance, ITS staff is now better equipped to help manage their patients' chronic diseases as the clinic's nurse practitioners, nurses, pharmacist, and LPNs have been provided with enhanced support in the form of educational sessions and frequent clinical supervision. The department’s assumption of the directorship role has also made it possible for highly complex patients to be seen by a hospitalist who is adept at managing their care and who can more easily coordinate with in-hospital providers and services that may be critical for after-hospital care. ITS is currently developing pathways of care and disease management models for patients with the hope to ultimately partner with inpatient services, in particular those managing CHF, COPD, and Diabetes, with the end goal to create comprehensive and seamless care and education plans that span the whole continuum of care, from the hospital to the home.

ITS is currently piloting a program that offers physicians the ability to directly refer their patients who may have other chronic conditions, need immediate ER or hospital follow-up that is not available to them, or who need more comprehensive review of their after-care plan and/or medication reconciliation. These expanded services will hopefully serve to: 1) decrease hospital and ER readmissions, 2) decrease after-hospital medication errors, 3) decrease in-hospital length of stay, 4) improve patient and physician satisfaction, and 5) decrease “over-utilization” of acute care for patients that could be more efficiently and cost-effectively serviced in outpatient settings.

Overtime, we are hoping to show that our interventions will improve such metrics. Our goal will be to use ITS as a “hub” for all Inova Health System transitions of care from the hospital or ED back into the community to a permanent medical home.

ITS currently sees patients from all of the five Inova Health System hospitals. Patients are seen either at our main site in Springfield (with plans to relocate to a larger, improved office site in Fairfax by late spring of 2013), and two satellite sites; one in Herndon and one in Leesburg. Aside from general medical care, Stephen Stern, DPM, Director of the Inova Podiatry Residency Program, with the assistance of his residents, offers Podiatry services to those patients in need, which has been very helpful in particular for our diabetic patients. We routinely send our patients with Diabetes to the Inova Diabetes Center for increased enhanced diabetic education and look forward to continued collaboration. Beginning with this upcoming academic year, we are also planning to host psychiatry residents and fellows from the Department of Psychiatry’s training program under the guidance of Catherine Crone, MD, with the hopes of having them evaluate and treat our patients that do, understandably, have a higher rate of co-morbid psychiatric illnesses than most populations. In the future, we hope to include other specialists and more hospitalists in this growing program.

The field of transitions of care is quite new, and it is therefore an exciting time for the department to include this as one of its main focuses. With the rapid changes and growing complexities of the delivery of healthcare, solid transitions of care will be critical to success. We ultimately hope to create a robust program that can serve as a model for other departments and health systems nationwide.
Inova Fairfax Hospital Department of Medicine (DOM) has provided successful consultative services since the establishment of the hospitalist program. Co-management services with Orthopedic, Cardiothoracic, Cardiology, Psychiatry, and Gynecology teams are currently ongoing at Inova Fairfax Hospital. Since 2008, the Department of Medicine has created and implemented a successful specialized Inpatient Diabetes consult service that provides therapeutic management, patient education, and resource referrals for hyperglycemic inpatients. With a dedicated lead Hospitalist, Shirley Kalwaney, MD, and members of Endocrinology Section, the DOM has provided inpatient diabetes and hyperglycemia treatment for patients and educational resources to the physician and healthcare staff at Inova Fairfax Hospital.

Using a multidisciplinary approach with pharmacy, nursing leaders, and specialized physician extenders, the Inova Fairfax Hospital Diabetes Service has focused efforts to improve utilization of evidence-based protocols for insulin therapy and diabetes patient and family education in the hospital setting. Since 2008, insulin order-set utilization has increased 12 fold and patient satisfaction scores for our consultative services have consistently been reported as very good to excellent. In addition, ongoing partnership with Translational Care Management services has been associated with improved continuity of care and reduced hospital readmission rates for patients with limited resources in our community.

**DIABETES CONSULTATION SERVICES - FUTURE DIRECTION**

The Department of Medicine plans to continue expansion of Inpatient Diabetes services to meet the needs of the community relating to the increasing incidence of new diabetes diagnosis and their complications. Providing consultative services by senior hospitalist physicians, physician extenders and medical residents, we plan to implement more effective quality improvement initiatives in order to affect inpatient and post-discharge patient outcomes. This includes the impact of implementing validated clinical pathways, advancement of our insulin order sets in the Electronic Medical Record (EPIC), and patient safety protocols. We will continue to work collectively with outpatient education (Inova Diabetes Centers) and clinical centers (Inova Medical Group) to ensure adequate transitions of care.

**INOVA PALLIATIVE CARE SERVICES**

Palliative care is a comprehensive coordinated approach to serious illness which aims to improve quality of life by focusing on:

- Prognosis
- Goals of care and advance care planning
- Treatment options
- Physical, emotional, and psychological suffering
- Functional capacity
- Bereavement needs

With advances in medical care and technology, people are living longer with complex and progressive illness. Meeting the unique needs of this evolving population includes ensuring access to excellence in comprehensive and coordinated palliative care. The goal of Inova Health System Palliative Care initiative is to transform health care delivery for these individuals by clinically integrating palliative care tenets into standard practice which will enable and support patient-centered care.

There is increasing local and national evidence supporting the effectiveness of early integration of palliative care including patient, family, and caregiver satisfaction, improved symptom control and emotional well-being in addition to reduction in hospital length of stay, costs, and readmissions.

As understanding and acceptance of the benefits of palliative care has grown on the part of patients, families, and health care providers, hospital-based Palliative Care services have increased exponentially in recent years due to this rising demand. The task now is to meet the need for subspecialty based palliative care within our hospitals as well as working to
clinically integrate palliative care best practices into all our care delivery models; including our community endeavors such as Home Health, PACE, transitional care and our ambulatory practices.

At Inova Fairfax Hospital, we are performing a formal needs assessment and planning to expand an expert interdisciplinary Palliative Care team. This team will work with the other divisions in the DOM as well as other departments throughout the hospital to optimize palliative care delivery for all patients. We will achieve this by:

- Formalizing processes and expectations for palliative care consultation
- Working with our Electronic Medical Record to ensure preferences for care are effectively communicated, including family meeting documentation tools and Advance directive tools
- Establishing evidence based protocols for comfort driven care
- Establishing a web based educational series to increase knowledge for all providers on palliative care fundamentals in order to incorporate palliative care best practices seamlessly and effectively within care delivery.

**DEPARTMENT OF MEDICINE INITIATIVES**

**DEPARTMENT OF MEDICINE AND INOVA GERIATRIC PROGRAM**

Inova Fairfax Hospital was the first hospital in Northern Virginia to recognize and develop geriatrics as a service to our older adult patients. Geriatrics at Inova Fairfax Hospital (IFH) consists of five programs.

1. The Geriatrics Consult Service or Geriatrics Team has offered hospitalized older adults, free comprehensive geriatrics assessment since 1987. The team consulted on twelve hundred and ninety nine patients in 2012.

2. The Nurses Improving the Care of Hospital Elders (NICHE) program was initiated at IFH in 2001. This program is an initiative designed and developed by New York University and funded by the John Hartford Geriatrics Initiative. This nurse driven program improves care of the older adult using evidence based practice using protocols, guidelines, modifications of order sets and geriatrics resource nurses.

3. The Hospital Elder Life Program (HELP), a volunteer based program was begun in 2006 and now offers services to older adults hospitalized on Tower 8 Medicine, Tower 10 Medical Telemetry and Tower 2 Stroke. This program decreases functional decline and incidence of delirium in the hospitalized older adult.

4. Joanne G. Crantz, M.D. Geriatrics Resource Center was established in 2010 as a result of a generous donation. It is housed in the Medical Library and offers current geriatrics resources to medical professionals, staff, and patients and families.

5. Geriatric section of Department of Medicine was established.

**Geriatrics Team (Inpatient Geriatrics Consult Service)**

The Geriatrics Consultative Team, multidisciplinary team, led by Dr. Joanne G. Crantz, MD, an internist with added qualifications in geriatrics and run by Deirdre Carolan, Ph.D., ANP,BC,GNP,BC, completes a comprehensive geriatrics assessment on referred patients. Based on a comprehensive assessment and team input, recommendations are made to the nursing,
DEPARTMENT OF MEDICINE INITIATIVES

medicine and rehab therapists. Support is also provided to the family or caregivers. Continuity of care and open communication with the entire health care team is ensured by interdisciplinary collaborative discussions and the provision of a complete report of the assessment to the older adult’s primary care physician. Together, the primary care physician, the attending medical team and geriatrics team will collaborate to develop approaches which address the older adult’s hospital challenges. Follow up visits are provided to evaluate intervention effectiveness, modify the plan, address emerging issues and enhance transitions to different care settings. Since 1987, the team has grown from consulting on 89 hospitalized older adults to currently seeing approximately 1300 patients per year for the past three years. Twelve hundred and ninety nine patients received services from the consult service in 2012.

Patients seen by the consult service have documented improvement of functional level, lower incidence of delirium and shorter duration of delirium, reduced readmissions and increased continuity of care when readmitted. Geriatrics Team intervention has averted at least 438 unreimbursed days in 2012 by educating patients and families on realistic expectations, planning and advocating for appropriate discharge plans using community services and collaborating with outside agencies to facilitate transitions to the next level of care.

Nurses Improving the Care of Healthsystem Elders (NICHE): A National Nursing Led Initiative to Improve Care for Older Adult Patients

NICHE is a program of the Hartford Institute for Geriatric Nursing at the New York University College of Nursing, the only national nursing led program designed to improve the care of hospitalized older adult patients. The NICHE program provides tools and resources to increase geriatric nurse competence as well as healthcare system principles, processes, and structures that support continued learning and the application of specialized knowledge into practice (Fulmer et al., 2002; Mezey et al., 2004).

Inova Fairfax Hospital geriatrics leadership identified the need for improved nursing care of the older adult in 2000 and began the process of becoming a NICHE best practice site. This cause was championed and funded by the Gala 2001. Inova Fairfax Hospital has been an active NICHE site since that time, attaining annual credentialing. Deirdre Carolan is active NICHE faculty since 2006 and works actively on the development of new programs and the refinement/revision of existing programs. Outcomes have included improved nursing knowledge on all aspects of care of the older adults. We are the benchmark for low restraint rates in non ICU settings across the country. Twenty nine RNs, one MSW and RPT have obtained advanced recognition in Geriatrics by achieving certification from their discipline.

Hospital Elder Life Program (HELP)

HELP is a program, developed by Sharon Inouye, MD, which uses specially trained volunteers to assist the hospitalized older adult at risk for delirium and functional decline by visiting the patient three to four times a day. Assistance with the patient’s hearing and vision devices or provision of HELP equipment, assist with hydration and nutrition and assisted ambulation are provided within the parameters of patient orders. Re-orientation activities and non pharmacologic sleep protocol and other interventions improve the patient’s hospital experience and maintain function. Here at Fairfax we have 49 active HELP volunteers ranging in age form 16 years to 79 years old. The program volunteers made over 2200 visits in 2012 to over 400 hospital inpatients. IFH HELP is a HELP site of excellence.

The Geriatric Resource Center

The Geriatric Resource Center is an innovative and interactive addition to the Inova Fairfax Hospital Health Sciences Library. The center provides valuable healthcare information to seniors and their caregivers and serves as a source for geriatric community resources. The Geriatric Resource Center also provides educational programs to the community. Through the Geriatric Resource Center, seniors and their caregivers will access valuable information and education to ease the process of making difficult decisions and dealing with daily life. They may also try out various assistive devices for hearing and reading prior to purchasing them for private use. The Geriatric Resource Center is made possible by a generous gift to the Hospital Elder Life Program (HELP) in honor of Dr. Joanne G. Crantz.
DEPARTMENT OF MEDICINE INITIATIVES

DEPARTMENT OF MEDICINE AND ACUTE PULMONARY UNIT

In 2012, the Acute Pulmonary Unit (APU) at Inova Fairfax Medical Campus continued to be an important priority for the department. In collaboration with hospital senior leadership, Eric Libre, MD, the Chief of the Pulmonary Section and Medical Director of the APU, continued to raise the standard of care through protocols, research, and education. The management of the APU revolves around quality and safety aspects of patient care. These include in-services, creation, and follow-up of protocols for pulmonary topics, in particular, those addressing core measures such as venous thromboembolism prophylaxis, venous thromboembolism discharge instructions, antibiotics and blood cultures in pneumonia patients, vaccine administration for S. Pneumonia and Influenza, as well as appropriate therapy for COPD.

In addition, the APU leadership works to assure both patients’ and physicians’ satisfaction. Some other issues that continue to be followed closely by the leadership and staff of APU include:

- Pulmonary Readmission Tracking in APU determining opportunities for improvement
- Monitor length of stay in APU
- Regular review and monitoring of resource utilization
- Ongoing efficient utilization of EPIC by APU staff
- Pulmonary teaching rounds in the APU
- Teaching students, residents, and hospitalists staff by giving them dedicated sub-specialty pulmonary lectures.
- Multidisciplinary rounds in the APU to facilitate care and coordinate timely discharges.
- Working with APU staff on initiatives to improve patient satisfaction – to include excellent physician and nurse interactions, physician and patient communication, explanation of medication side effects, management of quite at night, and frequency of visits from care team.
- Improved communication with both community physicians as well as employed physician colleagues to ensure excellent physician satisfaction with the unit and the surrounding care.

We look forward to a wonderful 2013, as we strive to provide best in class pulmonary care for our APU patients.

DEPARTMENT OF MEDICINE AND CYSTIC FIBROSIS PROGRAM

As a collaborative effort between the Pediatric Center, Northern Virginia Pulmonary and Critical Care Associates, and Inova Advanced Lung Disease and Lung Transplant Program, DOM and hospital leadership are in the process of assessing the possibilities of an accredited Cystic Fibrosis (CF) center based at Inova Fairfax Medical Campus. This center will encompass both adult and pediatric CF programs with a clinical infrastructure to support multidisciplinary team care provided by nurses, dieticians, respiratory therapists, social workers, hospitalists, pulmonologists and other specialists with expertise in Cystic Fibrosis. This CF program will be led by a collaborative team including Drs. Whitney Brown and Matthew Williams, two pulmonologists with interest and experience with CF. As an established CF center of excellence, the program will be able to provide spectrum of care to these patients, including lung transplantation. This program will provide enhanced training opportunities in the care of patients with CF for medical students, residents, and fellows. The program also has potential for involvement in clinical research and drug trials through the CF Foundation Therapeutics Development Network as well as other extramural research funding sources. The program will apply for formal accreditation by the Cystic Fibrosis Foundation. Ultimately, the program will provide an option for CF patients in the community to receive excellent care at an accredited program without having to travel out of our community.
RHEUMATOLOGY CONSULT SERVICE

Ramona Raya, MD

Rheumatology is an important subspecialty of medicine. Although the vast majority of patients with rheumatologic disorders are cared for in the outpatient setting, a number of critical and life threatening rheumatologic conditions can bring patients to the hospital. In 2011, the Rheumatology Consult service was established at Inova Fairfax Hospital with close collaboration with members of the Rheumatology Section.

In 2012, Dr. Ramona Raya joined as a Rheumatologist. Dr. Raya attended medical school at the University of Nebraska Medical Center, then completed her Internal Medicine residency at Georgetown University Hospital. She went on to do her Rheumatology fellowship at the National Institutes of Health. Since 2008, she has served as an assistant professor of medicine for the Rheumatology department at the Medical College of Wisconsin and has been awarded multiple teaching awards. Dr. Raya is board certified in both Internal Medicine and Rheumatology. Dr. Raya has already established an excellent inpatient consultation service for Rheumatology. She is also involved in teaching and has started a few research projects in collaboration with other members of the department and George Mason University faculty.

AMBULATORY MEDICINE

Z. Chris, MD

Dr. Z Chris is the Medical Director of Ambulatory Medicine for the Department of Medicine as well as for the Inova Medical Group (IMG) Primary Care. In this capacity, Dr. Chris has been working closely with the leadership of the department around projects related to graduate medical education, research, and quality improvement. He is coordinating the future rotation of house staff through IMG primary care offices and providing trainees a “real world” experience in primary care medicine. Dr. Chris graduated from the University of Virginia School of Medicine in 1986 and completed a post-doctoral fellowship in pharmacology at the University of Virginia in 1988, residency in internal medicine at the University of California, San Francisco, in 1991, and a general internal medicine fellowship at Georgetown University in 1993. He has served on the faculty of Georgetown, Duke, and Emory Universities. He was the director of resident ambulatory education at Georgetown and the medical director of a primary care site at Duke, where he also completed the Duke Physician Executive Leadership Program and the Stanford Faculty Development Programs in Clinical Teaching and Medical Decision Making. Dr. Chris joined the Inova Medical Group in Alexandria, VA, in July 2010, and has worked closely with Inova leadership to help build a primary care network of internal medicine and family physicians that now has 16 locations from Gainesville to Alexandria, all linked to our five Inova Hospitals and IMG specialist physicians by Epic, the recently implemented electronic health record system. Dr. Chris's goals for 2013-2014 are that IMG-Primary Care will become a patient-centered medical home (PCMH), a world class destination service for primary care, a recognized ambulatory teaching site for Inova Fairfax’s internal medicine residency program, and a model for quality improvement and research programs linking the inpatient and outpatient populations at Inova.

DEPARTMENT OF MEDICINE AND ADULT OBSERVATION UNIT

Joann Pfundstein, MD

The Adult Observation Unit was planned in 2012 to become operational at Inova Fairfax Medical Campus in April 2013. The unit was created to serve an adult population with symptoms in which a complete evaluation and/or treatment can potentially be accomplished within 24 hours. Maintaining best practices within the unit will be a priority for the Medical Director, Dr. Joann Pfundstein, who is board-certified in both internal medicine and infectious diseases. Over three decades ago, the concept of observation units emerged as an alternative pathway for the disposition of emergency room patients. However, the proliferation of these units resulted from changes in
reimbursement models created by The Centers for Medicaid and Medicare Services (CMS). Most healthcare payers now mandate observation services as a way to avoid costly one-day admissions. These services differ from inpatient services in that they have focused patient care goals with a lower intensity of care for a limited duration of time.

The unit will provide service-oriented, patient-centered, and efficient care to ensure streamlined delivery for patients with a defined set of conditions (see chart). Nurse practitioners, who have been oriented with a focus on observation medicine, make up the backbone of the unit. These mid-level providers will assess as to whether the patient is appropriate for observation services based on strict criteria and ensure the appropriate status is ordered. The nurse practitioners perform timely history and physical exams, round frequently in compliance with CMS regulations, and document care in a manner to avoid non-payments. From the time of their first contact with the patient, they prepare the patient for discharge, and ultimately provide education, medication reconciliation, follow-up and advice on health maintenance. For those patients requiring admission to the hospital, the unit team ensures an order for inpatient status is entered and that transfer to the appropriate unit is expedited.

One of the goals of the unit is to improve hospital throughput. Currently, many patients are kept waiting in the emergency room for a bed. The unit will strive to improve ER throughput by keeping inpatient beds open for acutely ill patients and the observation unit beds for high-turnover observation patients. Data is being collected on utilization to ensure the proper use of limited resources. Various metrics will be followed in order to improve average length of stay, allocate resources efficiently, and improve patient satisfaction.

It is now estimated that up to 25% of hospitalized patients are under observation status. There are challenges and opportunities that abound in this evolving and growing area of observation medicine. The hospital’s decision to invest in managing and operating an effective and efficient observation unit is a huge step forward in negotiating our ever-changing healthcare arena.
The Center for Medicare and Medicaid Services (CMS) defines critical care as the “direct delivery of medical care for a critically ill or critically injured patient,” when “…there is a high probability of imminent or life threatening deterioration in the patient’s condition.” While we most often associate critical care with the ICU, in reality critical care can be and is delivered anywhere in the hospital. So what is the composition of the Medical Critical Care (MCC) Section and how does it support the needs of our critically ill patients?

Historically, per our institutional bylaws, a section within a department is composed of the physician medical staff of that department. Yet, critical care by its very nature is a broad, multidisciplinary, and collaborative specialty that requires the input of multiple patient care experts each with niche expertise in order to best meet the needs of our patients. As a result, we have expanded our MCC section meeting to include our allied partners in critical care: hospital administration, infection control, nursing, respiratory therapy, palliative medicine, pharmacy, physical therapy, dietary, and social work. Only by working together with the patient and patient care at the center of this diverse group of providers, do we fully meet our patient needs. Subsequently, we can take the care processes that we develop through these partnerships and expand them throughout Inova Health System, as a means to ensure that all patients receive the best care.

In November 2012, we implemented Epic as our electronic health record. In January 2013, we moved into the South Patient Tower - 54 brand new, beautiful, and expansive ICU beds spread across 3 floors!

What are the initiatives on which we are working and where do we still have room to improve? In the specialty ICUs such as the Neuroscience and Cardiovascular, we continue to build and enhance our partnerships with our colleagues from Neurosurgery and Cardiac Surgery; respectively. Likewise, in the Coronary Care Unit, we are building a multidisciplinary team with Cardiology to ensure, per the recently released American Heart Association guidelines, that cardiac patients receive the best care.

Also in the spirit of partnership, there is greater unity of the community based critical care providers and the Inova Medical Group providers. Drs. Jim Lamberti and Svet Djurkovic are leading our organizational efforts to improve the care of mechanical ventilation patients through efforts aimed at reducing sedation, increasing patient activity and mobility even while on the ventilator, and ultimately reducing time on the ventilator. We are working with our Lung Transplant team and Cardiac Surgery on the development of protocols for respiratory ECMO – a temporary form of cardiopulmonary bypass that is instituted and managed in the ICU. As a means to expand the talent, breadth, and depth of the section, we have expanded eligibility criteria for critical care physician providers so that doctors who have completed anesthesiology, surgery, or neurocritical based critical care fellowships can be members of our section. Administratively, Critical Care is supported by an expanding leadership group. Dr. Laith Altaweel serves as Medical Director of the Neuroscience ICU; Dr. Svet Djurkovic of the Medical-Surgical ICU; Dr. Jim Lamberti continues to serve as Director, Respiratory Therapy; Dr. Steve Nathan chairs the Pulmonary-Critical Care Collaborative Task Force; and I humbly, serve as both Director of Medical Critical Care and Medical Critical Care Section Chief.

On the education front, Medical Critical Care continues to receive excellent evaluations from students and residents alike. This year, we started an elective rotation in Neuroscience ICU for critical care fellows which we are expanding to the transitional interns. Research wise, the productivity of the section is increasing with more abstracts and posters being presented at national meetings. Drs. Svet Djurkovic and Joanne Ondrush won a specialty award for their oral presentation entitled, “How do size, location, and organizational characteristics impact outcomes and costs in patients with sepsis, NIS Database 2005-2009” at the annual Society of Critical Care Medicine Congress.

What are the challenges moving forward? Five years ago, we invested in a nonphysician provider service composed of both nurse practitioners and physician assistants. Originally we hired 7 midlevel providers, which increased
to ten. Recognizing that they constitute a vital part of our future, we have developed a more formal educational curriculum for them led by Dr. Nitin Puri. We also need to be cognizant of the changing landscape of healthcare. How do we provide maximal value to our customers, namely patients and their families? What are the things that really matter to them; especially if we cannot improve their health? We are working with our new system Palliative Care Medical Director, Dr. Jessica Heintz, to address this issue – beyond excellent medical care, what are the requisite services that our critically ill patients deserve? Other issues concern how we stay fresh as providers. How do we incorporate new technology into our practice? How do we meet the changing face of healthcare? We are fortunate in many ways as we are required to examine our practices, assumptions, and values around healthcare. It makes the current times exciting.
There were many highlights in the realms of Quality and General Medicine in the past year. First and foremost, with the assistance of frontline physicians and our Health IT lead, Dr. Maruf Haider, we were able to adjust to EPIC and still provide the highest level of care for our patients. Also, an independent consultant in hospital medicine conducted a site visit to evaluate our employed hospitalist program. We are proud to report that our program was ranked in the top ten percent in terms of engagement with hospital initiatives and team culture. We have continued to engage our community physicians by creating a distinct and high-level hospital medicine lecture series addressing common topics for hospitalists – who typically care for over 200 patients in our hospital at any given time. General medicine physician, community and employed, have been engaged in quality initiatives related to hospital throughput. In terms of the Quality Assurance program, we have experienced success after streamlining our peer review processes to follow up on error reports and patient grievances. In terms of Quality Improvement, Dr. John Paul Verderese has become the Medical Director of the Inova Transitional Care Clinics and has started seeing patients after hospital discharge. This program focuses on improving the transition from hospital discharge to home and has already demonstrated a positive impact on outcomes; including 30 day re-admission rates. Also, Dr. JoAnn Pfundstein has designed the infrastructure for the Adult Observation Unit. The goal of this unit is to standardize care for patients in observation status by implementing care pathways driven by nurse practitioners. In terms of clinical documentation improvement, Dr. Rishi Garg has created a coding clarity tool that has been disseminated to departmental physicians to improve the accuracy of our documentation in order to reflect true severity of illness and risk of mortality. In 2013, we hope to see continued gains in these areas. Furthermore, we plan to implement pathways to improve clinical effectiveness for common disease processes we treat such as hip fracture, pneumonia, COPD, and heart failure. An additional focus will be to implement initiatives aimed at improving value of care for our patients. Finally, we are engaged with hospital administration to devise strategies to improve physician to patient communication. We are looking forward to reporting on our progress throughout the year and thank you for your dedication to delivering excellent care to our patients.

**DOCUMENTATION OVERSIGHT PROGRAM**

Spearheaded by leaders within the Department of Medicine, the Clinical Documentation Improvement program has made great strides over the past year. This, in no small part, has been a direct result of early physician buy-in and engagement from the entire medical staff and from senior leadership. Through various educational endeavors, including one-on-one sessions, group meetings and lectures, our physicians have realized the impact that accurate and complete clinical documentation can have. With this, and high quality medical care, we have seen significant improvements in scores for severity of illness and mortality variance outcomes; not just in the General Medicine population, but also in various medical sub-specialties such as Pulmonology.

With the EPIC implementation in November 2012, there was an obvious learning curve that took place for the entire medical staff, documentation nurses, and Health Information Management (HIM) department. With this, not unexpectedly, clinical documentation was affected as staff and practitioners learned how to navigate the new EMR. However, as comfort and maneuverability with the new system have improved, we have started to see the same progress in documentation improvement that was achieved earlier in the year. The new EMR has provided various modalities for documentation nurses and the HIM department to communicate with practitioners when documentation requires more clarity or specificity. With further educational efforts, and partnering with our physicians, this process will become even more streamlined as everyone gains more experience with the new EMR.
In the near future, our goal will be to start implementing language and documentation specificity and clarity tools that will make the transition to ICD-10 as seamless as possible. Continued engagement from our physicians, and a close working relationship with our colleagues in the HIM department, will be vital to our continued success. Following are examples of reporting for our quality metrics.

**QUALITY METRICS**

**Risk-Adjusted In-Hospital Mortality**

- We are outperforming the top quartile of similar hospitals.
- Our actual mortality rates are approximately 50% lower than what is expected based on risk of patients.

**Risk-Adjusted 30 Day Readmission Rate**

- We are outperforming the top quartile of similar hospitals.
- Our actual readmission rates are approximately 25% lower than what is expected based on risk of patients.
The Department of Medicine continues to be a leader in providing medical education to students, residents and fellows. For decades, Internal Medicine residents from Georgetown University, and more recently from George Washington University, have been receiving their inpatient Internal Medicine training at Inova Fairfax Hospital. Our Inova faculty as well as Inova affiliated private practice colleagues have been instrumental in carrying our longstanding tradition of medical education. Our hospitalists, intensivists, and subspecialty consultants in pulmonary medicine, infectious diseases, cardiology, nephrology, rheumatology, gastroenterology, hematology, and oncology groups work alongside residents and students on a daily basis. Inova faculty members have received multiple awards and are often commended for their dedication to teaching. They are the reason why many of our local graduates from Internal Medicine programs choose to come to Inova to practice medicine. In addition to GME and UME, the department has been a leader in providing high caliber CME programs.

GRADUATE MEDICAL EDUCATION (GME)

Graduate Medical Education has been an important part of the Department of Medicine. We submitted an application to the Accreditation Council for Graduate Medical Education (ACGME) for Inova-sponsored Internal Medicine Program and had our site visit in May, 2013 and we are eagerly awaiting the approval from ACGME. Having our own Internal Medicine training program will be a capstone to our longstanding tradition of teaching excellence. Depending upon the timing of ACGME accreditation, we hope to start recruiting Internal Medicine residents to our program either at the end of 2013 or in 2014. Each month we have about sixteen rotating residents from Georgetown and George Washington Universities’ Internal Medicine Residency programs throughout the inpatient clinical wards on campus each month. The teaching teams are complemented by Georgetown Inova Fairfax Transitional program and Fairfax Family practice interns. Dr. Alita Mishra, as the Director of Education for the department, oversees educational programs and collaborates with program directors across campus to ensure that innovative and high quality curriculum is delivered in our department. Dr. Mishra, with guidance from Dr. Erario, Vice-Chair for Academic Affairs and Designated Institutional Officer (DIO) for Inova Fairfax Medical Campus will be leading efforts towards securing successful ACGME accreditation and subsequent implementation of the new Internal Medicine Program. Our departmental colleagues and sub-specialty faculty partners have been extremely supportive of our efforts and we appreciate their hard work and dedication immensely.

TRANSITIONAL YEAR RESIDENCY PROGRAM

The Department of Medicine has had a very sought after Transitional Year (TY) Residency Program for over a decade. The Transitional Year residents spend their first year training at Inova Fairfax Hospital through our department before moving on to highly competitive residencies in radiology, ophthalmology, anesthesiology etc. Once again, we had a very successful match of incoming residents into this program. This is a testament to the top notch training that residents receive in our department. Our incoming class for the 2013-2014 academic year come from renowned medical schools such as Mayo Medical School, Yale University, New York University, University of Virginia, Georgetown and George Washington Universities. Dr. Shirley Kalwaney is the Program Director of the TY Residency Program and will serve as the Associate Program Director for the Inova Internal Medicine Residency Program.

UNDERGRADUATE MEDICAL EDUCATION

The Inova Fairfax Department of Medicine continues to host third and fourth year medical students from Georgetown, George Washington, and Virginia Commonwealth University for their clerkship experiences. Dr. Gregory Trimble serves as the Clerkship Director and Dr. Homan Wai serves as the Associate Clerkship Director and Director of the Acting Internship. This year, VCU renewed its relationship
DEPARTMENT OF MEDICINE EDUCATION PROGRAMS

with Inova Fairfax as a satellite campus for third and fourth year students. Overall, there are approximately 25 students per month that rotate through the inpatient wards, ICUs, and outpatient clinics. The Department is fortunate to have dedicated faculty in both the inpatient and outpatient environments that take time to provide excellent clinical education for our students.

In 2012, the VCU School of Medicine and the Department of Medicine supported Dr. Trimble to attend the four-week long Stanford Faculty Development course. He is now trained to deliver a series of seven seminars to colleagues and to residents that focus on improvement in teaching skills. He has completed his first training session and will continue to offer the seminar on a biannual basis to all interested faculty members in the department.

CONTINUING MEDICAL EDUCATION (CME)
The Department of Medicine continues on the tradition of sponsoring national level speakers for the Medical Grand Rounds (MGR) series. In 2012, we were fortunate to bring a number of expert speakers to provide grand rounds and also to interact with our faculty and residents. In addition, the Department of Medicine sponsors a number of CME programs in Cardiology, Pulmonary, Oncology, and Critical Care.
The following were some of the nationally and internationally renowned external speakers for MGR (2012):

- Len Nichols, PhD, Director of the Center for Health Policy Research and Ethics at George Mason University
- Virginia Steen, MD, Professor of Medicine, Georgetown University Medical Center
- Lynn Gerber, MD, Director of Research, Department of Medicine, Inova Fairfax Medical Campus, Professor of Rehabilitation Science at George Mason University
- James Udelson, MD, Chief, Division of Cardiology, The Cardiovascular Center, Division of Cardiology, Tufts Medical Center.
- Rachel Gafni, MD, National Institute of Health
- John Nestler, MD, Chair, Department of Internal Medicine, Virginia Commonwealth University
- James O’Brien, Jr., MD, Associate Director of Medical ICU, Ohio State University State Medical Center.
- Gary Falk, MD, Professor of Medicine, University of Pennsylvania
- Roberto Salvatori, MD, Medical Director, Pituitary Center, Johns Hopkins University School of Medicine
- James Stoller, MD, MS, Chairman, Education Institute, Cleveland Clinic
- Angelike Liappis, MD, FIDSA, Medical Service, Section of Infectious Diseases Veterans Affairs Medical Center, Washington DC
- Bret Lashner, MD, Director of Inflammatory Bowel Disease Center, Cleveland Clinic
- Lenard Seeff, MD, Consultant in Hepatology, CDER, OSE, FDA
- Timothy Quill, MD, Center for Ethics, Humanities and Palliative Care, University of Rochester School of Medicine
- Kenneth Burman, MD, Chief, Endocrine Section, Washington Hospital Center
- Jeffrey Ponsky, MD, Chairman, Department of Surgery, CWRU School of Medicine
- Gordon Guyatt, MD, Distinguished Professor of Medicine and Clinical Epidemiology and Biostatistics at McMaster University
- Dr. Kenneth Olivier, MD, Staff Clinician in the Immunopathogenesis Section of the Laboratory of Clinical Infectious Diseases at the National Institute of Allergy & Infectious Diseases.
Clinical informatics (Health Information Technology) affect nearly all aspects of the Department of Medicine’s daily life from clinical decision support, clinical images (e.g., radiological, pathological, etc), clinical documentation to computer provider order entry. This year, in particular, we have had large change in our operating culture due to the EpicCare implementation and adoption throughout the organization. Through the leadership of or Section Chiefs and Dr. Younossi, the Department of Medicine is successfully operational with Epic. There have been many examples of collaboration within the Department from the initial Fairfax Medical Campus go-live date including the Department of Medicine Patient Safety meetings led by Dr. Venkatesan where he led systematic evaluation of how the department was working with our new electronic medical records (EMR) system. These meetings allowed for sharing efficiencies and identifying potential pitfalls in the education and technical aspects of our new EMR. Our attending and residents have worked together to share smart phrases, order preference lists, and have contributed to order set creation and management. These practices exemplify the Department’s commitment to their patients and optimizing care. However, the work is not done. In 2013, we need to maximize our efforts to improve the clinician’s experience and assist in providing care in a meaningful way. The mission for this department’s clinical informatics will include:

1. Promote and support Epic optimization with focus on:
   a. Documentation efficiency and proper EMR etiquette to foster excellent communication
   b. Increase the department’s collaborative footprint on clinical decision support by contributing to clinical content meetings
   c. Utilize Lean concepts to analyze and improve workflow
   d. Optimize multi-disciplinary rounding using EpicCare tools
   e. Continue to support clinical providers’ needs in their daily workflow
   f. Leverage EpicCare’s mobile applications for patient care.

2. Explore and create a strategy for analyzing and potentially creating registries to improve quality of care

3. Continue to provide standard operating procedures and create a collaborative environment to empower and promote departmental initiatives.

**PHYSICIAN LIAISON PROGRAM-DOM**

The physician liaison program has continued to interface with the practicing physicians both in the community practice as well as those employed by Inova Fairfax Medical Campus. The goal of this program is to be a better and more responsive Department of Medicine. An example of this responsiveness was changing Medical Grand Rounds back to Tuesday noon. The department sensed the concern of the practicing community physicians and responded accordingly and as a result, the attendance has increased.

Approximately one million dollars has been raised for the Inova simulation center, which will be housed in the Claude Moore Health Education and Research Building. Once additional funding goals are met, outfitting of the facility will begin and once the unit is operational, physicians and other medical personnel will be able to refresh and enhance their skills as well as learn and apply new ones.

The planning for a free standing Internal Medicine Residency Program has overcome many problems and obstacles that has blocked the process in the past. The residency review committee will be visiting Inova Fairfax Medical Campus in May 2013 to assess the application.

A major effort over the past several months has been designing a program that improves patient experience at the hospital and in the process enhancing the medical experience of all care givers, physicians, nurses etc. The areas included in the design are physician communication, service excellence training for the entire hospital staff, as well as physician recognition. Although on the surface this seems simple, it will require the energy and participation of all individuals involved in patient care.
This section consists of over 130 cardiologists with superb expertise in cardiac sub-specialties. Members of the section provide inpatient and outpatient diagnostic testing, sophisticated interventional cardiac catheterization and intervention, interventional services, and highly specialized electrophysiology testing, and arrhythmia treatment. Additionally, this section provides an adult congenital heart clinic and a cardiac rehabilitation program. Furthermore, the advanced heart failure program, which was initiated in 2011, is a superb, high-quality collaborative program. It also provides the advanced heart disease program, cardiology expertise for left ventricular assistive device placement, and supports a very successful heart transplant program. Research is being done in all of the above programs.

Physicians in the dermatology section specialize in micrographic and laser cutaneous surgery and photophoresis. The section of Dermatology is well recognized for teaching medical students and residents as well as for their clinical expertise. In 2012, a consultative service for inpatient Dermatology was established by members of the section to provide efficient care to our patients. Also, plans to use of Telemedicine in dermatology consult (Teledermatology) has been started which may facilitate high-quality efficient care for patients.

The endocrinology section at Inova Fairfax Hospital continue to provide high quality consultative services and support the inpatient diabetes services. Establishing initiatives to provide not only the spectrum of care for diabetes but also multi-disciplinary services for other endocrine disorders will continue to be important priorities of the department.

The section offers the full spectrum of diagnostic and therapeutic gastrointestinal modalities for both in and outpatients. Our services parallel those provided by tertiary care centers across the region. Our highly qualified physicians draw hospital referrals from across the region. To the benefit of our inpatients, we are the only hospital in the region to have two, exclusively hospital-based, gastroenterologists.

Academically, members participate in a multi-disciplinary tumor conference as well as resident morning report. Several are engaged in gastrointestinal research. Many of the gastroenterologists hold academic positions in George Washington, Virginia Commonwealth, and Howard Universities. A physician director of education coordinates resident training in gastroenterology. An ongoing collaboration with George Washington University affords fellows in gastroenterology the opportunity to rotate through the service; a position that has been full for many years.

A comprehensive, multidisciplinary program provides advanced endoscopic services, including minimally invasive techniques to stage and treat cancers of the esophagus, stomach, bile ducts, pancreas, and rectum. The program’s features include:

- Photodynamic therapy for ablation for Barrett’s esophagus with dysplasia, intramucosal esophageal cancer, and cholangiocarcinoma
- Radiofrequency ablation of Barrett’s esophagus (Barrx Halo)
- Endoscopic mucosectomy for the resection of Barrett’s esophagus with high grade dysplasia and intramucosal esophageal carcinoma
- Endoscopic ampulllectomy for resection of ampullary neoplasia
- ERCP with Sphincter of Oddi manometry
- Endoscopic stenting of the biliary tree, pancreas, esophagus, duodenum, and colon.
- Endoscopic ultrasound for the diagnosis and staging of mediastinal and gastrointestinal tumors, as well as the evaluation and treatment of pancreatic lesions.
- Endoscopic management of complex pancreatic disorders; including celiac nerve block, pancreatic duct disease, and transgastric pseudocyst drainage.
CLINICAL SECTIONS FOR DEPARTMENT OF MEDICINE

- Cholangioscopy for visualization and management of bile duct lesions (SpyGlass system)
- Videocapsule Endoscopy for obscure bleeding and small bowel lesions
- The groundwork for establishing Inova Fairfax Medical Campus as a Digestive Health Center of Excellence is underway.

MEDICAL HEMATOLOGY/ONCOLOGY—N. Robert, MD

The section of hematology/oncology is active in providing care for patients with malignancies and as well as consultation services in non-neoplastic hematology. Members of the section are active in stem cell transplants program providing both auto and allo transplants and have the longest operating program in the Washington, D.C. area. In addition to our interest in hematology malignancies, members of the section are involved in multi-disciplinary programs of the major solid tumors sites. These include breast, head and neck, GI, thoracic, and urologic malignancies. Members of the section meet regularly with members of the surgical and radiation modalities as well as with the radiology and pathology diagnostic services. This will allow the patients to have the benefit of obtaining an in depth review of their cases as well as treatment options. Members of the section work closely with he palliative care service to optimize patient care. The section also has an extensive portfolio of research studies working with both the NCI sponsored cooperative groups (CALGB and ECOG) and studies sponsored by US Oncology. Some members of the section have recently joined the Multiple Myeloma Research Foundation. They are involved in novel studies in breast cancer (neoadjuvant setting and metastatic disease using assay directed therapy e.g. personalized medicine; a study in collaboration with George Mason University). Regarding teaching, members of the section continue to participate in regional and national conferences as well as teaching the medical students and residents.

NEPHROLOGY—R. Cheriyan, MD

Members of nephrology section participate in inpatient consultative services and conduct a large number of dialysis procedures a year and offer continuous renal replacement therapy. The section also actively participates in supporting our kidney transplant program. Currently, section’s clinical research includes studies on hypertension and retarding the progression of renal disease.

ALLERGY - R. Rosenthal, MD

Section of Allergy is involved with the care of important allergic and immunologic disorders. Most of their experts provide outpatient care for our community and they also provide excellent inpatient consults. Members are also involved in important research in the outpatient setting.

PULMONARY— E. Libre, MD

The Pulmonary section, led by section Chief Eric Libre, MD, is made up of approximately 20 active and numerous associate and courtesy members. The members of the section are some of the most active clinical staff at the hospital, involved in not only consultative pulmonary work, but also performing pulmonary procedures, research, and teaching. Our team meets monthly for section meetings. The meetings cover not only ongoing pulmonary issues at the hospital but also include an educational component where we discuss either a recent pulmonary article or receive an update from Dr. Nathan of the Advanced Lung Disease clinic on the status of current research projects. The section also has a quarterly QI meeting which is made up of members from the section and is headed by Matthew Williams, MD.

The section is actively involved in research and teaching, and collaboratively working to enroll patients in numerous research studies through the Advanced Lung Clinic as well as refer patients to the lung transplant program. The relationship is truly collaborative and several section members are actively involved in co-managing complex transplant, pulmonary hypertension, IPF and Cystic Fibrosis patients with the hospital- based physicians in the Advanced Lung Disease and Transplant Clinic. Whitney Brown, MD and Matthew Williams, MD are working with the leadership to develop a dedicated Cystic Fibrosis Clinic.

The teaching role involves not only working with residents and fellows on the wards and in the transplant clinic, but also formal didactic rounds in the Acute Pulmonary Unit and bi-weekly lectures on core pulmonary topics. Daily multi-disciplinary rounds take place in the Acute Pulmonary Unit to help facilitate best practices.
The section is currently working with colleagues in Radiology, Oncology, and Thoracic Surgery to set up an Inova Lung Cancer Screening Program; whereby, based on research from the National Lung Screening Trial, high-risk patients undergo screening (chest CT scans) to evaluate for possible lung cancer lesions. Our facility has state-of-the-art bronchoscopy equipment and will soon offer Bronchial Thermoplasty for the treatment of severe asthma.

RHEUMATOLOGY - J. Wilkenfeld, MD
Rheumatology section is involved in outpatient care and inpatient care of patients with arthritic, musculoskeletal, and immunologic disorders. Member of the section actively participate in outpatient clinical research related to the role of new medical therapies involved in the suppression of the body's immune system. These research efforts involve fairly sophisticated biologic medications and their effects on the body's immune status. Hopefully, these efforts will provide meaningful clinical data for the care of patients in the future.

In 2011, the section Rheumatology and section Department of Medicine were able to recruit Dr. Ramona Raya as an attending physician at Inova Fairfax Hospital. Dr. Raya will primarily be engaged with inpatient rheumatology consultations. It has been gratifying to see that a physician with Dr. Raya's experience and clinical abilities is now a member of the hospital staff and capable of performing rheumatological consultations; some of whom have severe and life threatening rheumatological illnesses. She will also have extensive teaching responsibilities for house staff and medical students, and will soon see patients in hospital affiliated outpatient settings.

INFECTIOUS DISEASE — S. Ambardar, MD
The Infectious Diseases Section at Inova Fairfax Medical Campus is comprised of several groups that provide consultative services. A broad scope of illnesses are treated including septic shock, meningitis, skin and soft tissue infections, and pneumonia. Infectious Diseases physicians are instrumental in diagnosing complex conditions, assessing their microbiologic features, and recommending treatment. Other areas of expertise include antibiotic selection as antibiotic resistance becomes a growing problem and guidance related to infection control and epidemiology. In addition, infectious disease consultants manage HIV care in both outpatient and inpatient settings. Several in the department are involved on clinical research and most participate in the teaching program with medical students, residents and fellows.

GERENTOLOGY - J. Crantz, MD
Aging is a natural part of life — a process to be respected, celebrated, and also better understood. Inova Health System is committed to providing the senior population of Northern Virginia and the greater D.C. metro area with quality medical care and support programs that ensure older individuals' comfort, wellness, dignity, and independence. We are here for seniors' families, too. Our services are available to elders and their caregivers at all stages of health and illness; including during and after a hospital stay. Inova also offers a wide variety of health classes and community resources to enhance and improve seniors' health status. In 2012, Section of Geriatric Medicine has developed a comprehensive plan to provide the spectrum of Geriatric services. Under the leadership of Dr. Crantz, an associate director will be recruited to enhance clinical care, quality, teaching, and research for the section.

HOSPITAL AND GENERAL INTERNAL MEDICINE
John Paul Verderese, MD, S. Oshry, MD
The section of General Internal Medicine of the Department of Medicine is comprised of both community primary care physicians and hospital based Internal Medicine Physicians known as "hospitalists." For details about the hospitalist program, please see previous paragraphs. The outstanding clinicians within the Internal Medicine Section receive privileges at Inova Fairfax
Hospital because of their commitment to excellence in the areas of patient care and education. The section is comprised of over 300 Internists of which approximately 200 have either solo or group practices within the Northern Virginia region.

**OCCUPATIONAL HEALTH - E. Kessler, MD**

Occupational Health Section of Department of Medicine is led by Dr. Ellen Kessler who is also the Medical Director of Inova Occupational Health Services. Inova Occupational Health provides workplace health services to over 1,100 diverse businesses, government, and county agencies with staff size ranging from 10 to 17,000 employees. Along with the medical surveillance programs to support over 800 organizations, Inova Occupational Health Services touches the lives of many in Northern Virginia. Patient satisfaction rate for this program is consistently in the 94th percentile. There are over 33,000 occupational health visits each year. For more details about the program, please see Inova Occupational Health website.
Over the past year, an Administrative Team has been developed to align with the clinical needs of the department. The focus has, primarily, been to ensure the needs of the clinicians and the objectives of the department are met through a qualified and talented team of professionals with diverse skills set. Each administrative member of the divisions has worked closely with their respective Medical Directors and leaders to develop opportunities for program initiatives and process improvement. As such, efficient processes and procedures have been developed; which have contributed to the department’s excellent customer service and timely management of important initiatives. There has been significant focus on the physician billing processes of the department (Hospital Medicine and MCCS Divisions) to develop not only effective systems and steps for physicians to bill, but also to ensure appropriate billing compliance. This effort has been managed with support from the Inova Medical Group; financial/billing team. The team will continue to support the department in meeting its goals and objectives to ensure the department is able to continue to provide excellent service to both its internal and external customers.

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<td>Gity Porjosh, MPH, MBA</td>
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<td>Operations</td>
<td>Mansoor Hallaji, MBA, HCM</td>
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<td>Critical Care</td>
<td>Priscilla Jang</td>
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<td>Michael Hendricks, MHA</td>
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As one of the most critical departments at Inova Fairfax Hospital, the Department of Medicine boasts a comprehensive and innovative research program. The connection between the bedside and the bench allows our investigators to bring together cutting-edge personalized research protocols to our patients, our institution and our community as well as offer essential support to the VCU School of Medicine. The Department of Medicine research program consists of many active areas. First, the Beatty Liver & Obesity Research Program has pioneered clinical and translational research in chronic liver diseases and obesity. This team generates original discoveries and pursues development of novel biomarkers for the diagnosis and treatment of non-alcoholic liver disease. In collaboration with global biotechnology and pharmaceutical companies, this Program is also able to offer cutting-edge protocols and treatment regimens for viral hepatitis.

Second, the Advanced Lung Disease Program, focuses on offering treatment options for the most serious respiratory diseases including pulmonary hypertension, idiopathic pulmonary fibrosis, and interstitial lung disease. Not only did this Program pioneer lung transplantation in the DC metropolitan area, it continues to be the sole provider of the region’s lung transplant option. Third, the Health Services Research Program support projects related to health care quality, cost effectiveness as well as quality of life research. Closely collaborating with the Beatty Liver and Obesity Research program, its primary goals are to identify the most effective ways to manage and deliver high quality care, reduce medical errors, and improve patient safety and quality of life. With access to several large, national databases they are able to provide local as well as national insight into health related issues. Finally, our new research initiatives for the Department of Medicine Research Program includes an expansion of program development by collaborating with five medical subspecialties: Infectious Diseases, Nephrology, Gastroenterology, Cardiology and Endocrinology. It will be through the combination of these research programs that the Department of Medicine can enhance its great clinical reputation and become a world-class leader in patient-oriented research, medical education and clinical care.
In 2011, the research program for the Department of Medicine was established by integrating a number of existing programs and developing a new area for health services research. The research teams from the Center for Liver Disease, Beatty Liver and Obesity Research Program, and the Advanced Lung Program came together to make up the new Department of Medicine research team.

The Beatty Liver and Obesity Research program includes a number of teams, including HCV clinical trial team, Laboratory-translational research team, clinical-translational research team, and functional assessment-outcomes research team. The Beatty program also has database expertise as well as statisticians who are well trained in data analysis; including large publically available databases. The advanced lung research team carries out clinical trials as well as original translational research projects. In addition to these two programs, the Health Services Research team for DOM has been established to conduct research using large databases such as National Inpatient Survey, NHANES, and Medicine economic analyses. In addition to these research programs, members of DOM sections are encouraged to carry out original research and will be supported by the department.

Currently, Department of Medicine Research Spoke carries out 90 research protocols within the various departments including Beatty Liver and Obesity Research Program, Liver Pathology, Infectious Diseases and Advanced Lung. The department’s research in all have been funded for a total of $3,271,497. In addition, the Beatty Liver and Obesity Program has received a pledge for $10 million in philanthropy funding in 2010 and 2012. Also, the Advanced Lung department was awarded an NIH Grant with pledge of $1,589,678 over 5 years. The number of active protocols and research funds make the Department of Medicine Research program the most active and well funded department.
DEPARTMENT OF MEDICINE RESEARCH PROGRAMS

Vice President for Research
Inova Health System

Assistant Vice President
For Research

IRC
- Business Office
- Database Admin & Support
- Epidemiology & Biostatistics
- Research Training & Education Office
- Research Quality Improvement
- Technology Transfer Office

Human Research Protection Program

Dept of Medicine

Dept of Neurosciences

Dept of Ob/Gyn

Dept of Surgery

Dept of Pediatrics

IHVI

Dept of Psychiatry

Comprehensive Cancer Services

ITMI

NCU Program

Peds Oncology

Peds Gastrointestinal

Rx Trials

CV Surgery Research

Advanced Heart Failure

Cardiology

CATS

Predictive Medicine Clinic

Advanced Lung Disease

Medical Effectiveness Research

Boaty Liver/Obesity Research Program

Advanced Lung Disease

ImVH

IAH

IMVH Research

Inova Nursing Research

ILH

IFOH

Clinical Trials

WHIRC

Trauma

Ortho Trauma

Kidney/Pancreas Transplant

Anderson Orthopaedic Research Institute

Biomechanical Lab

Grants Management Office

Radiation Oncology

Inova Alexandria Hospital

Inova Fair Oaks Hospital

Inova Loudoun Hospital

Inova Mount Vernon Hospital

Dept of Orthopedics

Dept of Surgery

Human Research Protection Program

IRL

Dept of Medicine
As a part of Betty and Guy Beatty Center for Integrated Research, the Beatty Liver and Obesity Program includes a basic science laboratory (including a Cell Culture Lab for advanced molecular experimentation), a clinical trial team, a data management team, and a Health Services Research team. Additionally, the program has a large specimen bio-repository. The staff includes PhD-trained scientists, data analysts, clinical trialists, and other research staff. A large number of graduate and undergraduate students are trained at the center.

The research portfolio includes development of diagnostic tests (called biomarkers) to predict an individual's predisposition to disease and targeted therapies for those affected.

The urgency for this obesity research is clear. Obesity-related liver disease currently affects about 30 percent of the U.S. population and that number is expected to climb dramatically in the years ahead. Our investigators are shedding new light on this insidious disease and sharing their findings on the world stage. In the last few years, they have presented at numerous international conferences and written articles which have been published in important peer-reviewed journals. Such exposure adds to the body of research and positions Inova as a major player in this critical area of investigation.
As previously noted, the Liver and Obesity Research Team as the Administrative Offices of the Inova Research Center and the Human Protective Research program specializes in investigating the intersection between obesity related metabolic disorders and chronic liver diseases.

The basic science laboratory has the capacity to utilize gene expression technologies, ELISA-based protein assays, as well as our newly established cell culture facility, and immunology lab. These technologies are used for biomarker validation and the implementation of novel clinical trial protocols related to liver and obesity. The research specimen storage facility is specifically designed to house minus 80°C freezers in a temperature controlled environment with backup electricity and a sophisticated electronic freezer temperature monitoring system. Currently, thousands of specimens from the Center for Liver Diseases are stored in seven freezers. All freezers are centrally monitored to ensure that research specimens are stored at optimal temperatures, providing important quality control for specimen integrity. Additional component of the program is its functional assessment laboratory. This laboratory is designed to implement research protocols that assess activity of daily living and other functional assessment measures of patients with chronic diseases. Finally, the outpatient clinic of the program is designed to provide the infrastructure for advanced clinical trials and biomarker validation protocols.

Our team is continuously developing better (more accurate and less invasive) biomarkers for staging and grading of obesity-related NAFLD; hence, adding to the understanding of the pathogenesis of NAFLD. Specifically, we have looked at the cascade of molecular signaling events that begin with expression and regulation of miRNA in visceral adipose tissue but ultimately lead to the apoptosis of hepatocytes and the development of non-alcoholic steatohepatitis (NASH). We have measured the contribution of specific nutrients, such as vitamin D, inflammatory cytokines, dyslipidemia, and appetite regulating hormones to the development NASH in obese and morbidly obese patients. We have proposed the use of specific molecules as biomarker candidates for NASH, and assessed the “normal” range for enzymes like aspartate aminotransferase (AST) and alanine aminotransferase (ALT) in an obese patient population.
Our translational research for 2012 has brought us a few steps closer to the age of personalized medicine. In the field of chronic hepatitis C, for instance, our laboratory has associated patient genotypes for specific genes, such as IL28B and ITPA, with important outcomes for patients such as the chances of treatment efficacy or the possibility of negative side effects. Additionally, investigation into the genomics and proteomics of these same patients has enabled us to propose mechanistic hypotheses that could one day lead to refinements in diagnosis and treatment.

As noted previously, our laboratory is also performing exciting research in the fields of Obesity, Metabolic Syndrome and Non-Alcoholic Fatty Liver Disease (NAFLD). Investigations can be generalized as being in the service of developing better (more accurate and less invasive) staging and grading tools for NAFLD, and adding to the understanding of the pathogenesis of NAFLD specifically as it relates to the contributions of the components of metabolic syndrome. Specifically, we have looked at the cascade of molecular signaling events that begin with expression and regulation of miRNA in visceral adipose tissue but ultimately lead to the apoptosis of hepatocytes and the development of non-alcoholic steatohepatitis (NASH). We have measured the contribution of specific nutrients, such as vitamin D, inflammatory cytokines, dyslipidemia, and appetite regulating hormones to the development of NASH in obese and morbidly obese patients. We have proposed the use of specific molecules as biomarker candidates for NASH, and assessed the “normal” range for enzymes like aspartate aminotransferase (AST) and alanine aminotransferase (ALT) in an obese patient population.

All of this work has yielded information worth reporting to various national and international conferences, including the American Association for the Study of Liver Disease (AASLD), Digestive Disease Week (DDW), the American College of Gastroenterology (ACG), and the European Association for the Study of the Liver (EASL) Annual Meetings. Additionally, our team had high-impact publications in esteemed journals such as New England Journal of Medicine, Hepatology, ATP, Liver International, Medicine, Clinical Gastroenterology and Hepatology, Obesity Surgery, Current Molecular Medicine, Journal of Hepatology, Journal of Viral Hepatitis, Gastroenterology and others.

We have been able to accomplish this level of productivity in the past year partially though the efforts of our research scientists, but also though our partnership with George Mason University and the many fine students that do their graduate research here.

We anticipate our team will move forward to another productive and rewarding year at the Beatty Liver and Obesity Research Program laboratory. As noted previously, we have recently expanded our capabilities by building a state-of-the-art cell culture facility. This facility will enable us to refine our hypotheses through experimentation on primary tissue cultures and established model cell lines.

Our team includes six PhD-level scientists: Dr. Ancha Baranova, Dr. Aybike Birerdinc, Dr. Elzafir Elsheikh, Dr. J Michael Estep, Dr. Azza Karrar, and Dr. Rohini Mehta. They have extensive experience in immunology, proteomics, genomics, cell culture and other biomarker development. In addition, we have expanded our teaching practices by developing an internship program for exceptional George Mason University undergraduates.

Our future projects include protocols addressing fatty liver and obesity as well as other co-morbidities involved in the metabolic syndrome such as PCOS and heart disease. Our aim is to continue to conduct high quality research into the diagnosis, treatment, and pathogenesis of liver and obesity diseases, and to provide valuable hands-on training opportunities for the next generation of young researchers.

**CLINICAL, TRANSLATIONAL, AND BASIC SCIENCE RESEARCH IN CHRONIC LIVER DISEASES, OBESITY AND OBESITY-RELATED LIVER DISEASE**

**A Role of IL28B Genotype and other Confounding Factors in Hepatitis C Treatment Response:** IL28B genotype is an important predictor of the single nucleotide polymorphisms (SNP) rs12980275 and the SNP rs8099917 are both located within a few thousand bases of the IL28B gene and are strongly and ribavirin treatment. Complications to HCV infection such as insulin resistance and
Proteomic and Genomic Analysis of ITPA SNP rs1127354 Undergoing Treatment for Chronic Hepatitis C (CH-C): Anemia is an important and common side effect of pegylated interferon alfa and ribavirin (PEG-IFN+RBV). The ITPA SNP rs1127354 “T” allele confers protection against RBV-induced anemia in CH-C patients undergoing PEG-IFN/RBV treatment compared to the more common “C” allele. The BLORP laboratory is conducting studies on the differences in both gene and protein expression between the “T” and the “C” groups, specifically focusing on entire cellular pathways that are divergent during treatment of CH-C.

Vitamin D Levels in Obesity-related NASH and NAFLD: Vitamin D is known to be a steroid hormone involved in the intestinal absorption of calcium and the regulation of calcium homeostasis. Recent evidence suggest that Vitamin D deficiency may have a potential role in the inflammatory processes and there is an ever increasing body of literature indicating that low vitamin D levels may play an instrumental role in the development of both hypertension and metabolic syndrome (MS) Pertinent to NAFLD and NASH, a significant inverse relationship between serum vitamin D levels and unexplained elevation in ALT was observed in NHANES III cohort recently. Consequently, the examination of vitamin D levels in patients with NASH with various degrees of liver involvement, may lead to a better understanding of the relationship between liver disease and vitamin D. In addition, if vitamin D is found to be intimately involved in the pathogenesis and progression of NASH, it may prove to be a reliable and non-invasive biomarker of severity of the disease and its propensity for progression.

Agouti-related protein (AgRP) RNA expression in the visceral adipose tissue of obese patients with non-alcoholic fatty liver disease (NAFLD): NAFLD begins as a dysregulation of fat metabolism (fatty acid production) and is closely associated with obesity; some have even considered it the hepatic manifestation of the metabolic syndrome. Since AgRP is an appetite regulating protein that suppresses metabolism and is regulated by circulating free fatty acids, it could be reasonably hypothesized to play a central role in the pathogenesis of NAFLD. Several proteins of this functional type have been associated with NAFLD severity in obese populations including leptin and des-acyl ghrelin.
AgRP, however, has the distinction of being regulated in part by circulating free fatty acids, high concentrations of which are central to the onset of NAFLD. Furthermore, AgRP is also central component of melanogensis. Melanogensis in adipose tissue has been proposed as a compensatory mechanism in obesity related inflammation – a key ingredient in the progression of NALFD to its most serious form Non-alcoholic steatohepatitis (NASH). Our laboratory is using a variety of techniques to measure AgRP expression as it relates to metabolic syndrome and NAFLD in an obese patient population.

**Association of Obesatin, Ghrelin, and Inflammatory Cytokinesin Obese Patients with Non-alcoholic Fatty Liver Disease:** The three protein products of ghrelin gene (acylated ghrelin, desacylated ghrelin and obestatin) are involved in appetite stimulation and suppression. There is increasing evidence that products of this gene may play important roles in metabolic processes such as adipogenesis, lipid mobilization, and insulin secretion. The Beatty Liver and Obesity laboratory has implicated the products of the ghrelin gene as being potentially significant in the pathogenesis of NASH by associating their circulating concentration with important aspects of the disease. We continue to investigate the activity and regulation of these molecules.

**Contributions of Omental Adipose Tissue to the pathogenesis of NAFLD:** This study began as an investigation of molecules that are differentially expressed in the omental adipose tissue of obese patients by the stage of NAFLD - specifically the expression of miRNA, a special type of regulatory molecule that coordinates the expression of many other genes, including those for several important cytokines and adipokines. This study has now matured to examining the expression in the omental adipose of the specific cytokines regulated by these miRNA as well as the expression in the liver of those cytokine’s receptors. Preliminary results for this study are promising, as they show concomitant expression of cytokine and receptor for several pathways known or suspected to be involved in the progression of NAFLD.

**Gene Expression Profiling of Inflammatory Cytokine Targets and Obesity related mRNA in Gastric Tissue:** Current understanding of the mechanisms underlying the development of obesity and NAFLD are poorly understood. The discovery of importance of gastric hormone, ghrelin in food intake has shifted the focus on gastric tissue as a peripheral tissue with important role in food intake and energy metabolism. This study attempts to explore the gene expression profile of cytokine and obesity related genes in gastric tissue using RT-PCR arrays. Energy sensing by the gastric tissue may help better understand the regulation of food intake and energy metabolism.

**TH1/TH2/TH17 Cytokine and TGF-β1 Profiles in Serum Samples of Depressed Patients with BMI-Matched Controls:** Depression is a frequent co-morbidity observed with chronic diseases, including chronic liver disease. An imbalance of the T-helper (Th1/Th2 cytokines in brain tissue can be involved in psychological stress or psychiatric disorders (Anisman and Merali, 2003; Dubas-Slep et al., 2003; Guereno and Diez, 2002). Major depression has been linked to increased levels of Th1 cytokine levels as compared to Th2 cytokine levels, thus activating the TH1 pathway inflammatory response (Maes M., 1995). This deregulation of the immune system has been shown to have a profound impact on major depression (Myint and Kim, 2003; Schiepers et al., 2005) and in fact there are studies that show a direct correlation between the onset of depression and an activated immune system including the increase in pro-inflammatory cytokines (Capuron and Dantzer, 2003; Connor and Leonard, 1998; Maes et al., 1995; Yirmiya, 2000). In addition to the Th1/Th2 cytokines TGF-β1 is a cytokine that may be crucial in regulating the proinflammatory/anti-inflammatory cytokine imbalance that is seen in major depression (Myint et al., 2005; Lee and Kim, 2006). On its own, TGF -β1 values are low in depressed patients and show a marked increase during anti-depressant therapy (Myint AM et al. 2005). This suggests that patients with naturally low levels of TGF-β1 may be more vulnerable to depression due to the lack of stimulation to the Th2 pathway by TGF-β1. We will test this hypothesis on a cohort of morbidly obese NAFLD patients.

**RT-qPCR Profiling of Mitochondrial and Genomic DNA in Visceral Adipose Tissue of NASH and non-NASH Patients:** Morbid obesity has been linked to a variety of severe, progressively degeneratgin conditions such as NASH NAFLD, reproductive and cardiovascular discoveries indicating that white adipose tissue (WAT) may not be the only player in this complex metabolic
condition. The discovery of metabolically active brown fat (BAT) is gaining the attention of researchers in numerous disciplines, including liver disease. The emerging data suggests that BAT not only plays a role in adult body weight homeostasis, but may also contribute to the regulatory mechanisms of obesity. Brown adipose tissue (BAT) works to control of body temperature in hibernating animals and newborn infants and until recently was believed to decrease with age in adults. One of the major limitations of gene expression studies in the determination of the presence of BAT is that its very definition, the BAT related genes must be active. Recent research has suggested however, that BAT cells can remain “dormant” under certain conditions, therefore the detection of total BAT content can not be achieved by gene expression analysis. One of the distinguishing factors of BAT is the large number of mitochondria found in this type of cell. Indeed, these mitochondria are what gives BAT its “brown” appearance. In this study we propose to quantify both mitochondria specific DNA and total DNA in order to obtain a ratio indicative of the total BAT cells in NASH and non-NASH subjects, irrespective of the “activation” status of the BAT cells.

**NON-ALCOHOLIC FATTY LIVER DISEASE IMMUNOPATHOGENESIS STUDIES AND ASSOCIATION TO OBESITY**

Immunopathogenesis of Non alcoholic fatty liver (NAFLD) is a relatively new area of research which will be led by Azza Karrar. Dr. Karrar has several years of experience working on immunopathology of liver disease. Non alcoholic fatty liver disease (NAFLD) is a chronic liver disease with an increasing prevalence of 75% along with an increasing prevalence of obesity. The etiology of the disease is so far unknown and the pathogenesis is poorly understood. No specific therapies for NAFLD exist today.

The immunopathogenesis of NAFLD is thought to be strongly associated to obesity. Infiltrating macrophage and T lymphocytes in the adipose tissue produce pro-inflammatory cytokines that contribute to the inflammatory status in the adipose tissue as well as in the liver in patients with NAFLD. Toll like receptors (TLR) are innate immune recognition markers and their activation mediates steatosis, inflammation and hence fibrosis. TLR molecules are potential targets for therapy therefore better understanding of TLR signaling and blockade is necessary for therapy options for patients with NAFLD.

The Human Leukocyte Antigen (HLA) is a genetic marker which may be implicated in the pathogenesis of or may contribute to disease susceptibility to Non Alcoholic Fatty Liver Disease (NAFLD). Previously immunogenetic studies on NAFLD revealed that HLA B65 was found to be significantly more present in NAFLD patients. The overall aim of our study is to study further the immunogenetics of NAFLD and to determine if there is any association between HLA Class I and II Antigens polymorphism and the sever form of the disease, Non Alcoholic Steatohepatitis (NASH).

Twenty percent of patients with NAFLD were found to have anti-nuclear and anti-muscle antibodies. Autoantibodies can serve as disease markers and are of diagnostic value and play a role in the pathogenesis of the disease. We are interested in studying more disease specific antibodies anti-adipocyte antibodies that have functional capacity and may explain the correlation between NAFLD and obesity. The cross talk between the liver and adipose tissue in patients with NAFLD needs to be addressed more. Studies on the immunopathogenesis of NAFLD may not only improve our understanding of the mechanisms involved in NAFLD progression but also, may lead to novel therapeutic strategies to treat this condition. Our studies will focus on identifying the underlying immunological mechanisms involved in disease injury with the aim of revealing better diagnostic and therapeutic approaches.

**SPECIFIC PROJECTS RELATED TO IMMUNOPATHOGENESIS OF NAFLD**

- Phenotyping of Inflammatory Cell Infiltrate in adipose and liver tissue of Patients with NAFLD.
- In Vitro Analysis of Adipocytes Damage by Inflammatory Mediators in Patients with NAFLD.
- Characterization of Immunomodulatory and Signaling Pathways up Regulated by Adipocytes (TLR/MAPK/ NFκB /SMAD).
- Profiling of Circulating Inflammatory Cell in Patients with NAFLD. (Circulating Inflammatory Adipocytes, T-helper cells and their subsets, T-cytotoxic and T-regulatory cells).
- Anti-adipocyte antibodies detection in patients with NAFLD.
  1. To study inflammatory migrating cells in the adipose tissue in patients with NAFLD and matched control groups. To correlate the presence of these inflammatory cells in other related organs liver, gastric tissue and
skeletal muscles.
2. To characterize the innate immune response markers expressed by adipocytes in patients with NAFLD and matched controls.
3. To characterize the presence of circulating inflammatory adipocytes in the peripheral blood in patients with NAFLD and matched controls.
4. To detect the presence of anti-adipocyte antibodies in sera and adipose tissue of patients with NAFLD. To study the functional immunomodulatory capacity of anti-adipocyte antibodies and to investigate their role in inducing adipocyte hypertrophy, proliferation and apoptosis.
5. HLA Class I, HLA Class II and the Major Histocompatibility Complex (MHC) class I polypeptide-related sequence A Antigen (MICA) and The Killer Cell Immunoglobulin-like Receptors KIR domain genotyping.

SIGNIFICANCE
The molecular pathogenic mechanisms underlying NAFLD is poorly understood. Our projects are addressing an important research area in the immunopathogenesis of NAFLD. These projects will shed the light on targeted molecules that could be of diagnostic and therapeutic potential. We at Inova health system, Centre for Integrated Research, have long experience in working with NAFLD research. We have generated strong foundation of clinical and genetic data for patients that can be used to build many research projects. We are currently building/establishing an immunology lab that focuses on studying the immune response NAFLD patients. We have good access to patients’ records and have strong collaboration with GMU.

STUDY DESIGN AND METHODOLOGY
Blood samples, liver biopsies and visceral adipose tissue will be obtained from patients with NAFLD. Liver tissues will be collected whenever a biopsy is made for clinical reasons. All clinical parameters will be obtained and correlated with the experimental data and will be used for statistical analysis. Patients’ informed consent and ethical approval is of course a prerequisite.

Different immunoassays will be used for immunophenotyping and profiling of cells, and immune recognition markers. The assays used are but not limited to cell culturing, magnetic cell isolation of the different subsets of the cells, flow Cytometry, immunoflorescent and enzymatic immunohistochemistry, electron microscopy, Polymerase Chain Reaction Sequence Specific Oligonucleotide method (PCR-SSO), Multiplex ELISA and western blots a, 2 D gels and proteome arrays.

Profiling Circulating miRNA in Obese Patients: miRNAs are highly conserved small non-coding RNAs of 19–25 nt in length that constitute a new layer of regulatory control over gene expression programs. Most of the DNA and RNA in the human body are located within cells, but small physiologic amounts of nucleic acids can also be found circulating freely in the blood. These molecules may enter circulation from both: i) active release of nucleic acids from living cells, or ii) break down of dying cells that release their contents into the blood. Among the various classes of circulating nucleic acids – miRNAs, are particularly attractive candidates. Approximately 940 mature miRNAs have been characterized to date in humans The concept that miRNA are also shed into circulation and can act as hormones affecting distant sites in the body is particularly appealing especially for complex diseases like obesity and NAFLD. This study attempts to investigate the presence of tissue and pathway specific circulating miRNA levels using LNA enhanced PCR primers.

Role of NACHT, LRR, and PYD domains-containing proteins (NALPs) in Obesity and associated non-alcoholic fatty liver disease (NAFLD): Inflammasomes are large caspase-1–activating multiprotein complexes that sense both exogenous and endogenous danger signals. The activated caspase-1 then promote the cleavage and, therefore, activation of proinflammatory cytokines such as IL-1β, IL-18, and IL-33, which then trigger a cascade of inflammatory response. In addition to tightly controlling the activation of IL-1β and IL-18, inflammasome signaling can also influence other important biological processes including autophagy and cell death. Low grade chronic inflammation is a hallmark of obesity and associated metabolic syndrome. The expression of the inflammasome components and targets in multiple tissues may contribute to increased inflammation and other pathogenic aspects of obesity. Thus, it is attractive to speculate that inflammasomes play an early role in inflammation by activating and contributing to the circulating proinflammatory cytokines.
Mitochondrial Genotype as a predisposing factor for progressive Non-Alcoholic Fatty Liver Disease (NAFLD): mtDNA represents one of the most informative systems for inter- and intra-specific study of human genetic diversity. The existence of hypervariable sites (sites that evolve at a rate much faster than average) in the non-coding human mtDNA control region has been well documented via various analyses of human mtDNA variation. Both germline and somatic mtDNA mutations occur preferentially at hypervariable sites, which supports the view that hypervariable sites are indeed mutational hotspots. Given the role of mitochondria in metabolic pathways, we are investigating the variation in mitochondrial sequence as a predisposing factor in metabolic diseases especially NAFLD.

Mechanism of fatty acid metabolism in obesity and associated NAFLD: An important component of energy homeostasis is regulation of fatty acid metabolism. In the presence of massive influx of lipids, adipocytes and hepatocytes are expected to upregulate LD biogenesis, as a mechanism of defense against the toxicity of FA. However, in order to prevent uncontrolled expansion of LDs, lipolysis activation also occurs concurrently under these conditions and contributes to maintain LD size. The catabolic process of lipolysis is dynamic and was until recently thought to be mediated by cytoplasmic lipases only. The clearance of lipid droplets (LDs) mediated by lipid specific autophagy (lipophagy) has been shown only recently. Given the increased circulation of free fatty acids in obesity, it is highly plausible that this leads to upregulation of fatty acid uptake and inhibition of lipolysis. This altered fatty acid flux contributes to the expansion of adipocytes. Once the capacity of adipocytes to store fat is exceeded, there is spillover of fat into ectopic sites such as liver culminating in steatosis and steatohepatitis. This study aims to explore fatty acid metabolism in vitro using primary cell culture.

Markers of Endothelial dysfunction in Patients with Nonalcoholic Fatty Liver Disease (NAFLD) and Coronary Artery Disease (CAD): NAFLD is independently associated with an increased risk of diabetes mellitus and cardiovascular disease (CVD). Furthermore, CVD is the most common cause of death among NAFLD patients. When the endothelium is injured, the regulatory functions become altered and the endothelium loses its specialized properties, resulting in “endothelial cell dysfunction”, which is a hallmark of vascular diseases. Activation and damage of the endothelial monolayer seem to trigger the development of the atherosclerotic lesions. Once the integrity of endothelium is interrupted, lipid penetration and mononuclear-cell adhesion might be initiated. Atherosclerosis risk factors such as hyperlipidemia, hypertension, diabetes mellitus, smoking and infections, can directly or indirectly stress the arterial endothelium, resulting in its dysfunction, damage or both. The aim of this study was to investigate endothelial dysfunction as the possible link between the NAFLD and CAD risk using some endothelial dysfunction markers. These markers include Endocan (Endothelial Cell-specific Molecule-1), which is released by damaged vascular endothelium in response to inflammatory cytokines and angiogenic stimuli. In addition, we studied High mobility group box 1 (HMGB1), which is known to induce inflammatory responses and promote tissue repair and angiogenesis. Finally, we assessed Anti-endothelial cell antibodies (AECA) that is increased in patients with previous myocardial infarction.

Serum Heat shock proteins; a possible mechanism linking nonalcoholic fatty liver disease with coronary artery disease: Heat shock proteins (Hsps) are highly conserved families of proteins found in the cells of all organisms. Several Hsps are known to function as molecular chaperones. However, in addition to their roles as molecular chaperones, they have other putative roles especially in cardiovascular tissue. Heat shock proteins may stimulate autoimmune responses, causing the production of antibody against them. An immune response to Hsps, either endogenously derived from cells involved in atherogenesis, or exogenously, from microorganisms, may lead to endothelial injury and subsequent atherosclerosis. In this study we hypothesized that, necrotic hepatocytes in NAFLD/NASH release Hsps which may magnitudes the risk of CAD. We specifically measured serum levels of Hsp 27, Hsp 60 and Hsp 70 in NAFLD patients with or without CAD. The results are under analysis.

Angiogenic growth factors as independent biomarkers of future major adverse cardiovascular Events in NAFLD: In response to vascular injury or physiological stress, stem cells have to be rapidly mobilized and recruited to the damaged area (e.g. coronary artery). The recruitment of stem cells from the bone marrow to homing sites of vasculogenesis is regulated by Angiogenic
growth factors (AGF). The chronic exposure to risk factors continuously damages endothelial cells and requires their intensive replacement. Conversely, risk factors possibly affect stem cells mobilization, integration in injured vascular sites, and angiogenic capacity. Reduced levels of AGF have been related to impairment of stem cells mobilization in vivo. In this study we hypothesized that, angiogenic properties are impaired in NAFLD, leading to increase prevalence of CAD. We assessed serum levels of Angiopoietin-2, BMP-9, FGF-2, G-CSF, PLGF, VEGF-A, VEGF-B and VEGF-C by Multiplex assay. This study will be finalized by end of October 2013.

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DATABASE MANAGEMENT AND ANALYSIS TEAM:

The data management and analysis team is led by Sharon Hunt, MBA and includes two database administrators, three statisticians and a research investigator. Sharon has recently designed a clinical data system that integrates the clinical data for research studies with the genomics specimen inventory, so that one central source of information can provide core data for all Beatty Liver and Obesity Program clinical and scientific research analysis projects. Within the last year, Sharon and database administrators Yun Fang, M.S. and Andrei Racila, B.S. have initiated collaborative work with Inova Fairfax Medical Campus administrators to develop applications that the administrators, clinicians, and staff might utilize for quality or research. In addition, the team developed an application that supports hospital quality assurance at the department or physician level by dynamically evaluating department and physicians’ performance based on stream data. This enables the physicians to develop appropriate benchmarks and identify abnormal epidemiological events or issues as they occur. Yun has specialized in working with the critical care team to build applications that support their clinical research studies, while providing the system infrastructure for new research study development. Andre has developed the research specimen inventory database for the genomics team, which tracks the availability, specimen usage and specimen integrity for BLORP. In addition he developed a database that supports the Inova Research auditing process to ease compliance monitoring for the many Inova research spokes.

Our biostatistics specialists, Munkhzul Otgonsuren, MS, Lin Zheng, PhD, and Maria Stepanova, PhD, provide data analysis support for both BLORP and DOM. Our statisticians are responsible for validating, processing, analyzing and reporting against a wide range of biomedical datasets. They also Interface with the scientists to develop data analysis protocols and methods; designing and applying knowledge management as well as quality check protocols. They are responsible for development of statistical analysis methods, bioinformatics algorithms, data mining techniques, design, implementation and annotation of programming code for data analysis along with interpretation and presentation of the results of analysis of biomedical data. Furthermore, they each specialize in epidemiological research using national health survey or health care data such as National Health and Nutrition Examination Survey (NHANES), Nationwide Inpatient Sample( NIS) and Medicare databases. In collaboration with the statisticians, our research investigator, Linda Henry PH.D., works with the physicians in designing research studies, analyzing the clinical data and describing the results.

In addition, the data management team support the efforts of students who are interested in learning how to manage or analyze data, or want to better understand the data research process by providing opportunities for participation in grants and various studies. This last summer Keanu Lee worked with our team on a data initiative that explored the impact of statins on patients with both coronary artery and non fatty alcoholic liver disease.
The mission of this program is to conduct and support research that results in a better understanding of quality and effectiveness of treatment. It also seeks to answer questions about function, performance, and factors leading to disability and people with chronic liver disease. The program is designed to assist Inova researchers in their efforts to develop and select appropriate outcome measures that will inform practicing physicians and care providers about comparative effectiveness, quality, and life satisfaction. The program is a collaboration between Inova Health System and George Mason University (GMU); and in this capacity, it acts as a liaison between investigators from both institutions to promote clinical research, develop, and support the inclusion of functional outcome measures. The members of this program provide consultative support to all Inova/Mason clinical investigators on the appropriate selection of outcomes for their research. Toward this aim, the program operates in a state-of-the-art functional assessment laboratory with equipment designed to measure aerobic capacity using gas exchange methods and measures of cardiac performance, ambulation patterns, and grip strength patterns using in-shoe and in-glove pressure measures to assess mobility and fine motor function. A simulated kitchen environment is used to determine if patients have the ability to return to the community and function independently and what is needed to accomplish this; a major concern for patients who are about to be discharged from the hospital. This type of evaluation can identify needs for assistance with adaptive technology and personal assistants. It is important to learn about individual levels of function with evaluation tools that meet requirements for sensitivity, validity, and reliability. The program is able to perform this type of instrumentation testing and development.

Through the use of metabolic assessment tools and blood-based biomarkers, researchers can determine how much energy is needed to function and whether a patient has the cardiorespiratory reserve, strength, and processing skills to perform activities of daily living (ADL). The measurements reliably predict the potential for independence in the community environment. Collaborating with faculty from Mason has been another way that the Outcomes Research Program has had the opportunity to perform studies that can benefit the local community. One of these studies assessed consumption of different food types that subjects with chronic liver disease consumed and whether this could be, in part, attributable to where they resided. Another study examined the relationships among different liver diagnostic groups, their level of fatigue and the distance they were able to walk in 6 minutes. Another study evaluated aspects of depression in people with chronic liver disease. These are just a few examples of how our program has been able to help others.

The program has completed its fourth year of operation in the Center for Integrated Research. The members of the program have assisted researchers from a wide variety of disciplines in their submission of research grants. This has set the course for excellence in providing support for researchers and investigators interested in measuring human capacity or limitations and level of satisfaction.

During 2012, the program continued its collaborations with the liver research team to assess the relationships between functional outcomes and biological markers. These investigations have demonstrated patterns of inflammation and
metabolic abnormalities that are present in the patients with liver disease. The results of these observations have suggested avenues for future treatment options for functional loss and distressing symptoms that often contribute to disability.

Naomi Lynn Gerber, MD, internationally renowned physician-investigator, leads the Center as the Medical Director of the Functional Assessment Laboratory. Dr. Gerber is the current Medical Director of research for the Department of Medicine. She has been the Director of the Center for the Study of Chronic Illness and Disability (CCID) at George Mason University. She brings her vast knowledge and experience as former Chief of the Rehabilitation Medicine Department at The National Institute of Health. Members of the functional assessment lab supervise and mentor students who are pursuing careers in rehabilitation science. In addition to Dr. Gerber, Jillian Price, MS, previous Program Manager of the lab, and now a Mason PhD student, provides an administrative base for the program, along with years of clinical research protocol development, grant and publication submission support, education and training on the inclusion and implementation of outcomes measures in research studies within Inova Health System. Carey Escheik, BS, took over as Program Manager in 2012. Patrice Winter, DPT, MS, also a George Mason faculty member, brings over thirty-five years of experience as a physical therapist to the team. Dr. Ali Weinstein, PhD, Assistant Professor and Deputy Director of CCID, brings experience as an investigator examining biobehavioral aspects of chronic illness and is collaborating on studies evaluating the relationship between psychological symptoms, function, and compliance in clinical trials in patients with chronic liver disease. Mani Srishord, RN, BSN, Administrative Director, assists and supports all aspects of the clinical operation as well as research projects.

**OUTCOMES RESEARCH STUDENTS**

- LAUREN ROVER (GRADUATE)
- ANTHONY LORIA, BS (PRE-MED)
- HABIB ZIAI, MD (PHYSICIAN)
- ZAREEN ARSALLA (UNDERGRADUATE)
- YUSUF AZIM (MEDICAL STUDENT)
- ALEX SAFFRAN (PRE-MED)
- ARADHIKA SHRESTHA (PRE-MED)
- AREEG ELAYAN (PRE-MED)
BEATTY LIVER AND OBESITY CLINICAL RESEARCH TEAM

Back Row Left to Right: Mani Srishord, BS, RN, Mariam Afendy, BS, Becky Cable, BS, Fatema Nader, MSBM, Front Row Left to Right: Hesham Mir, MD, Brian Lam, PA

CLINICAL TRIALS RESEARCH TEAM (CRT)
Under the oversight of the Administrative Director, Mani Srishord RN, BSN, the CRT is led by Fatema Nader, MSBM. Implementation of clinical trials is conducted by Study Coordinators: Becky Cable, CCRC, and Mariam Afendy, BS. Becky and Mariam have 8 years of combined experience executing protocols at the patient level. Medical management of the patients is directed by principal investigators (Dr. Younssi and Dr. James Cooper). Sub-investigators are Alita Mishra, MD and Brian Lam, PA. Together, these sub-investigators provide extensive liver-specific expertise combined with comprehensive internal medicine proficiency.

The mission of the Clinical Research Team (CRT) is to provide the most promising and innovative treatment options to our patients. Similar to other areas of research, primary areas of clinical trial research focus are on hepatitis C and obesity-related fatty liver disease. In collaboration with global biotechnology and pharmaceutical companies, the CRT is able to offer cutting-edge protocols and treatment regimens beyond the standard of care. It is because of these partnerships that the CRT has become a tertiary care center accepting referrals from gastroenterologists in the Washington metropolitan area and beyond. Since its inception, the CRT has conducted Phase 2, 3, and 4 clinical trials investigating medications for the treatment of an array of liver diseases. In 2011, as the prevalence of certain diseases increased, the team’s research focused on two primary areas: chronic hepatitis C and non-alcoholic steatohepatitis.

CHRONIC HEPATITIS C (CHC)
CHC is an infectious disease that leads to scarring and ultimately cirrhosis of the liver. An estimated 150 million people are affected worldwide and CHC is the leading cause of liver transplantation in the U.S. Since 2002, the standard of care for CHC remained unchanged until May 2011 when two new medications were approved for use to treat the disease. These medications not only can reduce the duration of treatment but can significantly increase the rates of treatment success. The CRT conducted several key Phase 3 clinical trials that one of these medications needed for the US Food & Drug Administration (FDA) approval and registration. In 2011, the team conducted 12 industry-sponsored clinical trials for CHC and was the global leader for patient enrollment for one these studies. In 2012, industry focused on all-oral treatment regimens using direct anti-viral agents (DAAs) for the treatment of CHC. Because of its reputation as a center for excellence, the CRT has again been selected as a site to manage these ground-breaking studies. The following is a selection of some of the clinical trials currently being conducted by the CRT:

1. A Phase 3, Multicenter, Open-Label Study to Investigate the Efficacy and Safety of GS-7977 with Peginterferon Alfa 2a and Ribavirin for 12 Weeks in Treatment-Naive Subjects with Chronic Genotype 1, 4, 5, or 6 HCV
2. A Phase 3, Multicenter, Randomized, Double-Blind, Study to Investigate the Efficacy and Safety of GS-7977 + Ribavirin for 12 or 16 Weeks in Treatment Experienced Subjects with Chronic Genotype 2 or 3 HCV
3. A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of GS-7977 + Ribavirin for 12 Weeks in Subjects with Chronic Genotype 2 or 3 HCV Infection who are Interferon Intolerant, Interferon Ineligible or Unwilling to Take IFN
4. A Phase III, randomized, double-blind trial to evaluate the efficacy, safety and tolerability of TMC435 vs. telaprevir, both in combination with PegIFNα-2a and ribavirin, in chronic hepatitis C genotype-1 infected subjects who were null or partial responders to prior PEG-RBV.

5. A Phase 2 Randomized, Double-Blind, Placebo-Controlled Study of GS-5885, GS-9451, Tegobuvir and Ribavirin; GS-5885, GS-9451 and Tegobuvir; GS-5885, GS-9451 and Ribavirin in Interferon Ineligible or Intolerant Subjects with Chronic Genotype 1a or lb HCV Infection.

6. An exploratory Phase Ila, randomized, open-label trial to investigate the efficacy and safety of 12 weeks or 24 weeks of TMC435 in combination with PSI-7977 with or without ribavirin in chronic hepatitis C genotype 1-infected prior null responders to peginterferon/ribavirin.

7. A Phase 3b Study of 2 Treatment Durations of Telaprevir, Peg-IFN (Pegasys®), and Ribavirin (Copegus®) in Treatment-Naïve and Prior Relapser Subjects With Genotype 1 Hepatitis C and IL28B CC Genotype.

8. A Phase II, Randomized, Double-blind, Multi-center, Placebo-controlled Study of the Safety and Efficacy of INX-08189 in Adjunctive Treatment with Peginterferon alfa-2a (Pegasys®) and Ribavirin (Copegus®) in Chronically-infected HCV Genotype 2 and 3 Treatment-naïve Subjects.

9. A Phase III, randomized, double-blind, placebo-controlled study to investigate the efficacy, safety and tolerability of TMC435 versus placebo as part of a treatment regimen including peginterferon α-2a (Pegasys®) and ribavirin (Copegus®) or peginterferon α-2b (Pegltron®) and ribavirin (Rebetol®) in treatment-naïve, genotype 1, hepatitis C-infected

10. A randomized, open-label, Phase 3 study of telaprevir administered twice daily or every 8 hours in combination with pegylated interferon alfa-2a and ribavirin in treatment-naïve subjects with genotype 1 chronic hepatitis C virus infection.

NON-ALCOHOLIC STEATOHEPATITIS (NASH)

NASH is a disease characterized by inflammation of the liver due to excessive fat accumulation. It is a progressive condition that ultimately can lead to cirrhosis of the liver. At present, there is no FDA approved treatment for NASH; and because its pathogenesis is currently unknown, therapeutic strategies have been chiefly empirical. In 2011, the CRT completed an investigator-initiated clinical trial for NASH with external support but with its own Investigational New Drug (IND) obtained from FDA (Open Label Clinical Trial of High Dose URSO with or without Vit E in Severely Obese Persons with Non-Alcoholic Steatohepatitis (NASH) Undergoing Bariatric Surgery).

LIVER PATHOLOGY RESEARCH

Zachary Goodman, MD, PhD is the Director of Hepatic Pathology Research at Inova Fairfax Hospital and leads the Liver Pathology Team for the Beatty Liver and Obesity Research Program. Dr. Goodman is an internationally renowned hepatopathologist who was the Chairman of the Department of Hepatic and Gastrointestinal Pathology at the Armed Forces Institute of Pathology. He has been the main study pathologist for numerous multicenter clinical trials for the treatment of chronic hepatitis B and C, as well as for the treatment of hepatic fibrosis and non-alcoholic fatty liver disease. Ongoing and planned studies include several clinical trials in which computerized image analysis will be used to assess outcomes of potential antifibrotic therapy in liver diseases.

CLINICAL AND TRANSLATIONAL RESEARCH TEAM

The most important component of the clinical and translational research is collection of clinical data and biological specimens that are used for ongoing projects in our labs. There are a number of ongoing projects including translational research in chronic diseases which collect samples from obese patients undergoing bariatric surgery and patients with chronic liver diseases such as hepatitis C virus (HCV) and Non-alcoholic fatty liver disease (NAFLD). We also have protocols assessing the molecular relationship between NAFLD and coronary artery disease. These samples are processed and frozen at –80 °C for future use. Each patient has 40 - 50 clinical variables collected. We have currently collected 1900 patients in all protocols and have over 22,000 samples in 10 freezers located in our specimen room. This program is led by Program Manager, Zahra Younouszai BS, and members include Spencer Frost, and Tom Jeffers both Research Assistant and Keanu Lee, our summer student.
patients. Indeed, we appear to be transplanting a sicker group of patients with our average LAS score this year of 47 (range: 35-95) vs. the national average of ~37.

We continue to welcome and encourage the referral of any patients with all forms of advanced lung disease; including the spectrum of interstitial lung diseases (especially IPF), COPD, cystic fibrosis, sarcoidosis, and pulmonary hypertension. From January 1\(^{st}\) 2012 to December 18\(^{th}\), 2012, we received ~500 new referrals and evaluated 372 new patients (vs. 356 in 2011). The average wait time for an appointment for a new patient in 2012 was 47 days (range: 0-174 days).

The program remained at 4.5 FTE Pulmonologists (Steve Nathan, MD, Shahzad Ahmad, MD, Oksana Shlobin, MD, Whitney Brown, MD, and Nargues Weir, MD). On the clinical side, in addition to the administrative support personnel, we have 3 Nurse Coordinators, and 3 Nurse Practitioners to help the physicians. We have 5 Clinical Research Coordinators and 1 Research Assistant who enable the implementation of our clinical trials. Our research is multifaceted with opportunities for involvement in one or more clinical studies or registries for most of the patients (refer to flow diagram of our research “network” on the next page).

The combined NIH-Inova Advanced Lung Disease Program continues to thrive with Dr. Nargues Weir providing the personnel bridge between our campus and the NIH. Continuation of this partnership in these uncertain times and federal funding cutbacks is an attestation to the success and value of this collaboration.

In 2012, the program had 8 original research manuscripts published in the peer review literature. In addition, there were 5 review papers authored and 17 abstract presentations at International and National meetings.
CURRENT ENROLLING TRIALS

- **Protocol BIPF 1199.32**
  Disease: Idiopathic Pulmonary Fibrosis (IPF)
  Study Name: BIBF-1120
  Title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multi-Center, Parallel-Group Study to Evaluate the Efficacy and Safety of BIBF-1120 in Subjects with Idiopathic Pulmonary Fibrosis and Pulmonary Hypertension
  Status: Closed to enrollment. 4 patients in follow-up.

- **Protocol PIPF-016 (Pirfenidone Study)**
  Disease: Idiopathic Pulmonary Fibrosis (IPF)
  Study Name: ASCEND Study
  Title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multi-Center, Parallel-Group, Event-Driven Study to Evaluate the Efficacy and Safety of Pirfenidone in Subjects with Early Idiopathic Pulmonary Fibrosis (IPF)
  Status: Closed to enrollment. 3 patients in follow-up, 5 in screening

- **Protocol ASY12295**
  Disease: Idiopathic Pulmonary Fibrosis (IPF)
  Title: A prospective, longitudinal, non-pharmacological, case-controlled study to evaluate longitudinal disease behavior and biomarker data over a 52-week period in idiopathic pulmonary fibrosis patients.
  Status: Closed to enrollment. 5 patients in follow-up

- **Protocol AC-052-414**
  Disease: Pulmonary Arterial Hypertension (PAH)
  Study Name: COMPASS 2
  Title: Effects of combination of bosentan and sildenafil versus sildenafil monotherapy on morbidity and mortality in symptomatic patients with pulmonary arterial hypertension - A multicenter, double-blind, randomized, placebo-controlled, parallel group, prospective, event driven Phase IV study
  Status: Closed to enrollment. 1 patient in follow-up

- **Protocol CHRC-002**
  Disease: Pulmonary Arterial Hypertension (PAH)
  Study Name: QUERI Study
  Title: A prospective, multi-center knowledge translation program collecting information on the management of PAH patients over three years.
  Status: Closed to enrollment. 10 patients in follow-up

- **Protocol GS-US-219-0101**
  Disease: Bronchiectasis
  Study Name: AIRBX-1
  Title: A Phase 3, Double-Blind, Multicenter, Randomized, Placebo-Controlled Trial Evaluating Repeated Courses of Aztreonam for Inhalation Solution in Subjects with non-CF Bronchiectasis and Gram-Negative Endobronchial Infection (AIR-BX1)
  Status: Closed to enrollment. 1 patient in follow-up

- **Blood/Biospecimens Bank**
  Study Name: Blood Bank Study
  Title: Collection and Storage of Blood/Biospecimens for Research in Patients Referred to the Advanced Lung Diseases Program
  Summary: Blood will be procured and stored at Inova to evaluate the role of
Current and future blood markers such as inflammatory mediators biomarkers and circulating cells in the progression and deterioration of advanced lung diseases.

**Select Inclusion:** Must be 18 years and above; patients referred to the Inova Advanced Lung Disease Program.

- **Exercise Test Study**
  - **Study Name:** Six minute walk study
  - **Title:** The six minute walk test: reproducibility and comparison with variable instructions.
  - **Select Inclusion:** Must be 18 years and above; patients referred to the Inova Advanced Lung Disease

- **Protocol RIN-PH-403**
  - **Disease:** Pulmonary Arterial Hypertension (PAH)
  - **Title:** A Postmarketing Observational Study to Assess Respiratory Tract Adverse Events in Pulmonary Arterial Hypertension Patients Treated with Tyvaso® (treprostinil) Inhalation Solution
  - **Select Inclusion:** Patients with a diagnosis of PAH (WHO Group 1) who have been prescribed and are currently receiving Tyvaso.

- **Registry**
  - **Disease:** Sarcoidosis associated pulmonary hypertension (SAPH)
  - **Title:** Multi center registry of patients with sarcoidosis associated pulmonary hypertension
  - **Select Inclusion:** Patients with known SAPH who are under care at the study center; newly diagnosed cases of SAPH.
One of the most important outcomes of an academically active department is the number of high caliber publications and presentations that are generated by the members of the department. Authorship, especially first or senior authorship of articles published in peer-reviewed, high-impact journals, provide validity of the academic standing of the department and its members. Additionally, research presentations to national and international scientific meetings will bring immense recognition to the department, its faculty, and the institution. Finally, delivering faculty lectures during these international meetings is a great honor that recognizes our faculty as the top leaders in their fields. This productivity is not only valuable to the department, but also brings great value to Inova Health System.

In 2012, members of the Department of Medicine enjoyed tremendous success and academic productivity by publishing articles in high impact journals and presenting their research to a number of international meetings. Furthermore, our faculty has had a number of opportunities to discuss their research findings in the media. Finally, in 2012, a number of members of our department were listed as top doctors in their fields by the U.S. News and World Report.
DEPARTMENT OF MEDICINE PRESENTATIONS AND PUBLICATIONS


GASTROENTEROLOGY:
Adams, Tonya, MD
Garone, Michael, MD
Scudera, Peter, MD
Prosky, Martin, MD
Younossi, Zobair, MD (Hepatology)

CARDIOLOGY
Kiernan, Joseph, MD
Nayak, Pradeep, MD
Rogan, Kevin, MD
Summers, Anne, MD

ALLERGY AND IMMUNOLOGY
Rosenthal, Richard, MD

INFECTIOUS DISEASES
Morrison, Allan, MD

PULMONARY
Lamberti, James, MD
Vaughey, Ellen, MD

MEDICAL ONCOLOGY/HEMATOLOGY
Feigert, John, MD
Heyer, David, MD
Orloff, Gregory, MD
Patel-Donnelly, Dipti, MD
Robert, Nicholas, MD
Spira, Alexander, MD
Wilkinson, Mary, MD

DERMATOLOGY
Albert, Moses, MD
Bajoghli, Amir, MD
Kim, Ho Jin, MD
Kravitz, Paul, MD
Sawchuk, William, MD

GENERAL INTERNAL MEDICINE
Andrawis, Nabil, MD
Fagan, Lynne, MD
Hoyle, Kelly, MD
Oshry, Stacy, MD
Pontz, Bradford, MD

ENDOCRINOLOGY
Crantz, Frank, MD
Rogacz, Suzanne, MD
Ross, Peter, MD
Tanen, S. Mark, MD

GERENTOLOGY
Crantz, Joanne, MD

RHEUMATOLOGY
Wilkenfeld, M. Jack, MD

Nephrology
Assefi, Ali, MD
Mackow, Robert, MD
Rakowski, Thomas, MD
BEATTY LIVER AND OBESITY PROGRAM
BOOKS, BOOK CHAPTERS AND JOURNAL ARTICLES


36. ZM. Younossi, Aybike Birerdinc, Mike Estep’ Maria Stepanova, Arian Afendy, Ancha Baranova. The Impact of IL28B Genotype on the Gene Expression Profile of Patients with Chronic Hepatitis C (CH-C) Treated with Pegylated Interferon Alpha and Ribavirin (PEG-IFN/RBV). J of Translational Medicine 2012 Feb 7;10:25.


ABSTRACTS AND PRESENTATION TO NATIONAL AND INTERNATIONAL MEETING


2. A Mishra, M Otgonsuren, C Escheik, L Gerber, ZM Younossi. Non-alcoholic Fatty Liver Disease (NAFLD) with Type 2 Diabetes have the Lowest Level of Physical Activity. Digestive Disease Week 2012, San Diego, CA.

3. A Baranova, M Abawi, L Wang, Z Goodman, V Chandhoke, M Estep, ZM Younossi. Alpha Melanocyte-stimulating Hormone (MSH), Melanin-concentrating Hormone (MCH), and Obestatin are Associated with Hepatic Inflammation in Morbidly Obese Non-alcoholic Fatty Liver Disease (NAFLD) Patients. Digestive Disease Week 2012, San Diego, CA.


30. Z Younossi, E Elsheikh, Z Younoszai, M Otgonsuren, S Hunt, B Raybuck. High Serum Endocan is a Marker of Endothelial Dysfunction in Patients with Non-Alcoholic Fatty Liver Disease (NAFLD) and Coronary Artery Disease (CAD). European Association for the Study of the Liver, Amsterdam, Netherlands, April 2013.

31. Z Younossi, K Doyle, A Birerdinc, L Wang, R Mehta, Z Younoszai, Z Goodman, A Baranova. The Levels of TGFb1 Production in Adipose Indicate the
Complexity of the Relationship Between Depression and Anxiety Disorders in Obese Patients with Non-Alcoholic Fatty Liver Disease (NAFLD). Digestive Disease Week, Orlando, FL, May 2013.


65. A Mishra, M Stepanova, M Afendy, B Lam, Z Younossi. Knowledge about infection is the only predictor of treatment in patients with chronic hepatitis C (CH-C). American Association for the Study of Liver Disease Annual Meeting, November 2012, Boston, MA.


67. Z Younossi, A Mishra, M Otgonsuren, C Venkatesan. Resource Utilization,


100. A Birerdinc, Q Tran, R Mehta, A Baranova. Role of Chemokine ligand 21 (CCL21) and Macrophage Inflammatory protein 1 Beta (MIP-1 beta) in NF-kB mediated Fas Signaling. Virginia Academy of Science, May 2012, Norfolk, VA.


103. A Birerdinc, J Frost, R Mehta, R Tran. Design and validation of primers
for quantitative analysis of the role of chemokines CCL4 and CCL21 in Fas mediated NF-kB pathway. Virginia Academy of Science, May 2012, Norfolk, VA.


105. Z Younossi, M Stepanova, A Mishra, H Mir. Is Healthcare Spending Increased in the Last Year of Life for Patients with Chronic Liver Disease? European Association for the Study of Liver Diseases, Amsterdam, Netherlands, April 2013.


LECTURES AND FACULTY PRESENTATIONS TO NATIONAL AND INTERNATIONAL MEETINGS - LECTURES BY DR. ZOBAIR YOUNOSSI


3. Non-alcoholic Fatty Liver Disease Treatment in 2013, 9th Biennial Meeting of Turkish Association for the Study of Liver Disease, Istanbul, Turkey, May 2013.
4. Non-alcoholic Fatty Liver Disease and Coronary Artery Disease, 9th Biennial Meeting of Turkish Association for the Study of Liver Disease, Istanbul, Turkey, May 2013.
6. HCV Quality of Life and Pro-burden, Chronic Liver Disease Foundation Evidence Based Analysis Workshop Washington, DC, May 2013.
7. Quality of Life in Decompensated Cirrhosis Journey, 9th Biennial Meeting of Turkish Association for the Study of Liver Disease, Istanbul, Turkey, May 2013.
8. Current Breakthroughs in the Management of Chronic Hepatitis C. CLDF, Falls Church VA. Jan 2012
9. Hepatitis B and associated liver cancer and cirrhosis. CHIP Program, Falls Church, VA, Jan 2012
10. New Management Paradigm for Chronic Hepatitis C. MGR, IFH, Feb 2012
13. Hepatitis C Treater Advisory Board Meeting, Dallas, TX, June 2013.
14. Chronic Liver Disease Foundation HCV Alliance Program, Falls Church, VA, June 2013.
17. Chronic Hepatitis B-ChiP Program, McLean VA, January 2012
18. Diabetes: Unlocking the Mysteries 3rd Annual Symposium, Winthrop University Hospital, Garden City, NY, May 2013.

LECTURES AND FACULTY PRESENTATIONS TO NATIONAL AND INTERNATIONAL MEETINGS - LECTURES BY DR. ZACHARY GOODMAN
1. Introduction to Liver Disease” (3 lectures) – Sophomore Pathology Course, Georgetown University School of Medicine, Washington, DC March 14-15, 2012
2. Combined hepatocellular-cholangiocarcinoma”, presented at annual meeting of the Laennec Liver Pathology Society, Heidelberg, Germany May 17, 2012
3. Liver biopsy in the assessment of hepatic fibrosis”, presented at the Gnomes’ Satellite Symposium, Bugando Medical Center, Mwanza, Tanzania July 2, 2012
4. Cells of the sinusoids”, presented at annual meeting of International Liver Study Group, Mwanza, Tanzania July 4, 2012
5. Liver Pathology in HIV”, presented at “HIV & Liver Disease 2012”, sponsored by the University of Cincinnati, Jackson Hole, WY Sept 6, 2012
7. Role of the Pathologist in Liver Disease Research”, presented at Inova Department of Medicine Research Day, Inova Fairfax Hospital, Falls Church, VA Nov 6, 2012
8. Inflammatory Diseases of the Liver”, presented to Walter Reed National Military Medical Center, Department of Pathology, Bethesda, MD Nov 16, 2012
9. Tumors of the Liver”, presented to Walter Reed National Military Medical Center, Department of Pathology, Bethesda, MD Nov 30, 2012
10. Introduction to Liver Disease” (3 lectures) – Sophomore Pathology Course, Georgetown University School of Medicine, Washington, DC March 13-14, 2013
11. Well differentiated hepatocellular neoplasms”, presented at annual meeting of International Liver Study Group, Noosa, Australia May 10, 2013
12. Unusual infections of the liver”, presented at annual meeting of the Laennec Liver Pathology Society, Singapore May 17, 2013

ADVANCED LUNG PROGRAM
BOOKS, BOOK CHAPTERS, AND JOURNAL ARTICLES


**ABSTRACTS AND PRESENTATIONS TO NATIONAL/INTERNATIONAL MEETINGS**


Vision 2015

Community-Based Coordinated Care

Destination Clinical Services

Hospital-Based Care
A health system based in Northern Virginia that consists of hospitals and other health services including emergency and urgent care centers, home care, nursing homes, mental health and blood donor services, and wellness classes. Governed by a voluntary board of community members, Inova’s mission is to improve the health of the diverse community we serve through excellence in patient care, education and research.