Nation’s First Successful Implantation of New Intracranial Aneurysm Device Performed in State-of-the-Art Neuroendovascular Suite at BWH

In February 2015, Ali Aziz-Sultan, MD, Chief of Vascular/Endovascular Neurosurgery at Brigham and Women’s Hospital performed the nation’s first successful implantation of the WEB™ SL device, an intra-aneurysmal device that enables endovascular embolization of intracranial aneurysms.

Compound Found to Protect the Kidney Filter and Prevent Proteinuric Kidney Disease

Groundbreaking work by researchers at Brigham and Women’s Hospital have identified a small-molecule compound which in pre-clinical models has been shown to protect podocytes and preserve the kidney filter, thereby preventing or ameliorating proteinuric kidney disease.

Diabetes Experts Deliver Evidence-based Precision Medicine for Patients with Complex Disease

Specialists in the Diabetes Management Program at Brigham and Women’s Hospital (BWH) are delivering a wide range of specialized integrated services and tailored therapy designed to improve care for patients with poorly controlled diabetes and complex conditions.

Trial Investigates Novel Approach to Pancreatic Cancer; Researchers Identify Early Sign of the Disease

Medical oncologists in the Pancreaticobiliary Tumor Center at Dana-Farber/Brigham and Women’s Cancer Center are leading a novel clinical trial targeting KRAS mutations in pancreatic cancer and have discovered a new sign of the early development of the disease.
Nation’s First Successful Implantation of New Intracranial Aneurysm Device Performed in State-of-the-Art Neuroendovascular Suite at BWH

In February 2015, Ali Aziz-Sultan, MD, Chief of Vascular/Endovascular Neurosurgery at Brigham and Women’s Hospital (BWH), performed the nation’s first successful implantation of the WEB™ SL device, an intra-aneurysmal device that enables endovascular embolization of intracranial aneurysms.

The procedure was performed in the recently opened hybrid neuroendovascular suite at BWH as part of an international clinical study. The WEB Intrasaccular Therapy (WEB-IT) study is evaluating the WEB SL device for both unruptured and ruptured wide neck intracranial bifurcation aneurysms and will enroll 150 patients at 25 sites in the United States, Canada, and Europe. BWH is one of only two sites in New England offering enrollment in this study, which builds upon previous experience with the device in European studies.

“This is among a number of new innovative endovascular approaches that we are offering for the minimally invasive treatment of aneurysms, including challenging cases where traditional approaches are not ideal due to structure or risks,” said Dr. Aziz-Sultan, the BWH Site Principal Investigator for the WEB-IT study. (For more information on this study and enrollment, please contact Bianca Belcher, MPH, PA-C, at bbelcher1@partners.org)

First Case Employs Personalized Approach

The procedure was performed in a 63-year-old woman with an unruptured aneurysm and difficult anatomy (Image 1). Prior to the procedure, 3D printing based on computed tomography and angiography was employed to create a model of the patient’s brain, including her aneurysm. Dr. Aziz-Sultan used the model to practice the procedure and prepare a personalized approach for the patient. The WEB SL device bridges the neck of an intracranial aneurysm and disrupts the inflow of blood, causing hemostasis within the aneurysm sac and leading to thrombus formation within the implant (Image 2).

Benefits of a Hybrid Suite

The state-of-the-art hybrid neuroendovascular suite at BWH, one of the first of its kind in the U.S., provides the flexibility to perform minimally invasive neurointerventional approaches and open neurosurgical procedures in the same setting for a wide range of cerebrovascular diseases and conditions. Treatment teams are able to quickly change direction if a different approach is needed during an individual case. The suite is particularly useful in treatment of patients with stroke and other emergent cases.

“Traditionally, endovascular and open neurosurgical procedures are performed in entirely different environments, resulting in significant time delays if both approaches are required for a patient,” said Dr. Aziz-Sultan. “The time saved in a hybrid suite can make a significant difference in the patient’s outcome.”

Access to Our Neurosurgical Services

To refer a patient, please call our Referral Coordinators at (617) 732-9894 or email bwhreferrals@partners.org. For more information regarding our neurosurgical services, please contact our Physician Liaison, Tom Anderson, at (617) 582-4760 or tanderson0@partners.org.

Image 1

![Aneurysm](Image 1)

Image 2

![Aneurysm with WEB™ device](Image 2)
The initiating event in many chronic and progressive kidney diseases is the breakdown of the kidney filtration barrier, leading to abnormal protein loss in the urine called proteinuria.

Decades ago, investigators speculated that disruption of calcium signaling might be one of the early events leading to kidney disease through damage of podocytes, specialized kidney cells that mediate an essential filtration barrier function. Podocyte injury is thought to be the predominant – and potentially reversible – mechanism in the nephrotic syndrome and related proteinuric kidney diseases.

There are currently few therapies to protect the kidney’s essential filtration barrier. However, groundbreaking work by Anna Greka, MD, PhD, and colleagues in their lab at Brigham and Women’s Hospital (BWH) have identified a small-molecule compound which in pre-clinical models has been shown to protect podocytes and preserve the kidney filter, thereby preventing or ameliorating proteinuric kidney disease.

**Novel Therapeutics**

Dr. Greka is the director of the new Center for Glomerular Kidney Disease and Novel Experimental Therapeutics (Glom-NExT) at BWH, which is dedicated to the discovery of personalized and targeted treatments to cure kidney disease.

As Dr. Greka and colleagues reported in the *Journal of Clinical Investigation* (2013;123(12):5298–5309), the calcium-permeable ion channel TRPC5 is a mediator of filtration barrier injury: when induced to become overactive, TRPC5 leads to damage of the actin cytoskeleton and podocyte injury.

The Greka laboratory also showed that blocking TRPC5 with the small molecule inhibitor ML204 rescues podocytes from cytoskeletal remodeling in vitro, thereby preserving podocyte function and maintaining the integrity of the kidney filtration barrier. Furthermore, they showed that the molecule protects against TRPC5-mediated podocyte injury in models of kidney disease.

“We were able to find a potential therapeutic importance for this small molecule inhibitor, by showing that it can be used for the targeted treatment of kidney disease,” Dr. Greka said. “For the past few decades there has been little progress in therapies for kidney disease, an area of tremendous unmet need.”

**Podocyte Targeted Therapeutics in Development**

Dr. Greka added, “Much excitement at this time also comes from the fact that we are starting to develop podocyte-targeted treatments for patients.”

One of the other therapies in development for the treatment of patients with proteinuric kidney disease is abatacept, a drug currently on the market for treatment of rheumatoid arthritis. As Dr. Greka and Peter Mundel, MD, of Massachusetts General Hospital and colleagues reported in 2013 in *The New England Journal of Medicine* (369:2416-23), abatacept induced complete or partial remissions in patients with proteinuric kidney disease where biopsies showed podocyte expression of B7-1, also known as CD80. Successfully treated patients included four individuals with focal segmental glomerulosclerosis (FSGS) resistant to the CD20 inhibitor rituximab, and one with primary FSGS resistant to the glucocorticoid prednisone.

Normally, podocytes do not express B7-1, but detailed mechanistic work in Dr. Mundel’s laboratory had revealed B7-1 induction in many models of podocyte injury. Furthermore, immunostaining in randomly selected biopsy specimens from patients with proteinuric kidney diseases was positive for B7-1. These findings suggest that B7-1 is induced in the course of disease, and point to B7-1/CD80 as a possible biomarker for the targeted treatment of proteinuric kidney diseases.

Dr. Greka and colleagues are now planning for a multicenter randomized controlled clinical trial of the drug in patients with refractory nephrotic syndrome. For more information on enrolling a patient, contact Dr. Greka at agreka@partners.org.

**Specialty Clinic for Patients with Proteinuric Kidney Diseases**

In weekly clinics, Glom-NExT staff provide consultations and specialty care for patients with the most common proteinuric kidney diseases (such as diabetic and hypertensive kidney disease), in addition to those with more complex conditions such as focal segmental glomerulosclerosis (FSGS), minimal change disease, membranous nephropathy, IgA nephropathy, lupus and inflammatory glomerulonephritis and vasculitis.

Anna Greka, MD, PhD
Center for Glomerular Kidney Disease and Novel Experimental Therapeutics
Brigham and Women’s Hospital

**Access to Our Nephrology Services**

At Brigham and Women’s Hospital, our nephrologists are available for timely consultations and will work with you to develop treatment plans for your patients. Our Physician Liaison Ellen Steward can provide direct assistance with patient referrals and consultations. Ellen can be reached at (617) 582-4733 or via email at esteward@partners.org.
Diabetes Experts Deliver Evidence-based Precision Medicine for Patients with Complex Disease

Specialists in the Diabetes Program at Brigham and Women’s Hospital (BWH) are delivering a wide range of specialized integrated services and tailored therapy designed to improve care for patients with diabetes, especially those with complex conditions.

“With the increasing prevalence of diabetes, we are dedicated to providing referring physicians and patients with expert specialty care and personalized approaches to treatment in order to better manage this disease across the lifespan,” said Marie E. McDonnell, MD, Director of the Diabetes Program.

Optimizing Medications for Diabetes Patients
Endocrinologists at BWH are working to determine the most precise medication for subgroups of patients with diabetes through funded research. Alexander Turchin, MD, and Donald Simonson, MD, are collaborating on a Patient-Centered Outcomes Research Institute (PCORI) grant to identify patient characteristics from a BWH database of 20 randomized trials with almost 7,000 patients to ascertain which treatment is likely to work best in a specific patient population (See Figures 1 and 2). Dr. Turchin also has published a retrospective study of 107,000 patients with dyslipidemia that showed that even though 17 percent of patients reported adverse reactions to statins, many of them could ultimately tolerate statin therapy (Annals of Internal Medicine, 2013;158:526-534).

The diabetes research team is also conducting an investigator-initiated clinical trial (Safety and Efficacy of Saxagliptin for Glycemic Control in Non-Critically Ill Hospitalized Patient) studying the use of a low-risk diabetes drug in hospitalized patients with diabetes, who are typically only given insulin therapy. The ongoing study, led by principle investigator Rajesh Garg, MD, is evaluating the effect of saxagliptin, a DPP4 inhibitor, on glycemic control in non-critically ill hospitalized patients with type 2 diabetes.

Integrated Diabetes Care
Program specialists, including an endocrinologist and diabetes educators, are embedded in a variety of locations and practices throughout BWH. These include the Endocrinology Center at 221 Longwood Avenue in Boston, the Watkins Cardiovascular Center, the Fish Center for Women’s Health in Chestnut Hill, OB/GYN and Maternal Fetal Medicine (MFM) services at the Center for Women and Newborns at the main BWH campus, and Brigham and Women’s/Mass General Health Care Center in Foxborough, Massachusetts. Specialists in the Diabetes Program also work closely with bariatric surgeons and pancreas and renal transplantation experts at BWH for patients who require or may benefit from weight loss surgery or transplantation. For pregnant women with diabetes, care is provided through a close collaboration with MFM specialists (See Case Study).

“Our team delivered specialized care for this patient from pre-conception through the post-partum period, working

### Comprehensive Services

Diabetes Program specialists work with referring physicians and patients to determine which therapies best meet each patient’s needs, including:

- Intensive insulin therapy
- Insulin pump therapy
- Continuous glucose monitoring
- Novel non-insulin therapies
- Lipid management
- Patient education, nutrition, and weight management
- Access to specialty care including podiatry, ophthalmology and nephrology
- Access to metabolic surgery, vascular/endovascular surgery, or transplantation consultations

### Figure 1

**Personalizing Diabetes Treatment**

**Logistic Regression Model**

<table>
<thead>
<tr>
<th>Demographic and Clinical Characteristics</th>
<th>Patient Example</th>
<th>Treatment</th>
<th>Probability of Achieving HbA1c &lt; 7.0%</th>
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<td>Age (yrs.)</td>
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<td>Drug A</td>
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<td>Race/Ethnicity</td>
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<td>BMI (kg/m²)</td>
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<td>Drug D</td>
<td>0.33</td>
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<tr>
<td>Fasting Glucose (mg/dl)</td>
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</tr>
<tr>
<td>HbA1c (%)</td>
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<td>Diabetes Duration (yrs.)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Previous Treatment</td>
<td>No</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

HSPH – Marcia A. Testa, MPH, PhD  
BWH – Donald C. Simonson, MD, MPH, ScD; and Alexander Turchin, MD, MS  
Funded by: Patient Centered Outcomes Research Institute (PCORI)
Case Study: Diabetes in Pregnancy

Background:
A 38-year-old woman (G4P0) with a history of recurrent miscarriage, obesity, and type 2 diabetes presented to BWH for preconception counseling. Thorough evaluation for etiology of recurrent miscarriage was unremarkable. Medications included statin therapy, metformin, insulin glargine, and an antidepressant. At her initial visit, she was found to be mildly hypertensive and with a BMI of 38. Exam was otherwise unremarkable. Hemoglobin A1C was 7.6 %; TSH was 5.1 with FT4 0.8.

Approach:
The patient met monthly with a BWH team including an endocrinologist, nurse practitioner, and nutritionist with a goal of A1C <6.5% (<6.0% as possible without hypoglycemia). Metformin was continued and glargine transitioned to NPH in preparation for pregnancy. Lispro insulin was started with meals, and a detailed exercise and weight loss plan was initiated. Labetolol was started for blood pressure control, and levothyroxine initiated for a goal TSH of 1-2. Progress between visits was tracked with weekly team communication via the electronic patient portal. The patient’s husband also was engaged by the team in her care and dietary and exercise approach. The patient began using a lifestyle and glucose tracking phone app, and a meditation app for daily meditation for stress management.

The patient lost 20 pounds over the course of six months. Insulin was sequentially titrated upward and hemoglobin A1C decreased to 5.8% prior to conception without significant hypoglycemia. TSH and blood pressure were at goal. In addition to her endocrinologist and nutrition specialist, an MFM specialist was added to her team when she conceived. Throughout her pregnancy, she was seen on the same day by her joint endocrine and MFM team. Insulin requirements increased significantly over the course of her pregnancy, however, glycemia remained well controlled with her continued lifestyle efforts and glycemic tracking. The patient developed preeclampsia at 37 weeks. Via induction, she delivered a healthy baby boy at 6 lbs, 11 oz. The baby required a brief NICU stay for monitoring.

Follow up:
Post-partum, the patient has maintained her lifestyle. At her one year post-partum visit, her weight was 40 pounds less than her pre-pregnancy weight, and she required a regimen of metformin and low-dose glargine only to maintain A1C <6.5%.

The concept of precision medicine can also entail using available medications that have a more targeted effect instead of older, more known medications that can pose unique risks. Rajesh Garg, MD, is currently evaluating patients who have high blood glucose in the hospital to see if there is a more precise and potentially more effective alternative to insulin injections.
Medical oncologists in the Pancreaticobiliary Tumor Center, part of the Center for Gastrointestinal Oncology and the Robert T. and Judith B. Hale Center for Pancreatic Cancer at Dana-Farber/Brigham and Women’s Cancer Center, are leading a novel clinical trial for pancreatic cancer and have recently discovered a new sign of early development of the disease.

**Identifying Key Genes Downstream of KRAS**

The trial is based on pioneering research performed by David Barbie, MD, a medical oncologist in the Lowe Center for Thoracic Oncology, and William C. Hahn, MD, PhD, Deputy Chief Scientific Officer and Director, Center for Genome Discovery. After conducting systematic screens of genes in KRAS mutant and wild-type cell lines, they discovered that the kinase TBK1 was selectively essential in cells that harbor mutant KRAS (Nature. 2009 November 5; 462(7269): 108-112). Through further testing in human and murine lung cancers, they confirmed that tumors that depend on oncogenic KRAS require TBK1 activity and inhibition of this activity leads to tumor regression.

“Finding drugs that effectively target KRAS, which is mutated in a wide range of cancers, has been an extremely difficult challenge,” said Dr. Barbie. “We developed a novel approach to targeting KRAS mutant tumors by examining signaling downstream from KRAS.”

Building on these earlier findings, researchers in the Pancreaticobiliary Tumor Center are now conducting studies to investigate a novel approach to target KRAS mutations.

**Combination Trial for Advanced Pancreatic Ductal Adenocarcinoma**

The Gemcitabine and Nab-paclitaxel Combined with Momelotinib in Participants with Previously Untreated Metastatic Pancreatic Ductal Adenocarcinoma trial is a two-phase study evaluating a combination therapy that is designed to interrupt TBK1 signaling in KRAS mutant pancreatic tumors. Following a lead-in phase to evaluate safety and define the maximum tolerated dose, participants are being randomized to receive nab-paclitaxel and gemcitabine, the standard-of-care for advanced pancreatic cancer, with either momelotinib or placebo. The study, which will measure overall survival, progression-free survival, and response rate, could lead to expedited review and approval of the therapy, if it is shown to be effective. For more information regarding this trial, please contact Principal Investigator Kimmie Ng, MD, MPH, at (617) 632-4150 or knge@partners.org.

“With KRAS mutations present in over 90 percent of all pancreatic tumors, this approach has the potential to benefit many patients,” said Kimmie Ng, MD, MPH, a medical oncologist in the Pancreaticobiliary Center.

**Early Sign of Pancreatic Cancer**

Dana-Farber/Brigham and Women’s Cancer Center medical oncologist Brian Wolpin, MD, MPH, recently led a study examining metabolic changes that occur before pancreatic cancer is diagnosed. Using plasma samples derived from the Brigham and Women’s Hospital Nurses’ Health Study and other large studies, the researchers profiled metabolites in prediagnostic plasma from individuals with pancreatic cancer, along with matched controls. They found that elevated plasma levels of branched-chain amino acids (BCAAs) were associated with a greater than two-fold increased risk of future pancreatic cancer diagnosis, with the strongest association observed two-to-five years before diagnosis. (Nat Med. 2014 Oct;20(10):1193-8.)

“The majority of patients with pancreatic ductal adenocarcinoma are diagnosed in an advanced stage of the disease and survive less than 12 months following diagnosis,” said Dr. Wolpin. “Our findings suggest that, together with genetic and other risk factors, elevated levels of branched-chain amino acids may serve as a useful marker for diagnosing pancreatic cancer earlier in the disease process.”

Using pre-clinical models in collaboration with Matthew Vander Heiden, MD, PhD, a medical oncologist in the Center for Genitourinary Oncology, the researchers also showed that plasma BCAAs were elevated in early-stage pancreatic cancers driven by mutant KRAS expression (but not in KRAS-driven tumors in other tissues) and that breakdown of tissue protein accounts for the increase in plasma BCAAs that accompanies early-stage disease. These findings point to increased...
whole-body protein breakdown as an early event in development of pancreatic cancer, similar to what is seen in cancer cachexia.

“By uncovering key elements in the underlying biology of pancreatic cancer, our team is introducing new approaches to the treatment and earlier detection of this disease,” said Charles S. Fuchs, MD, MPH, Director of the Center for Gastrointestinal Oncology and the Robert T. and Judith B. Hale Chair in Pancreatic Cancer.

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Leadership Announcements

New Chair of Anesthesiology, Perioperative and Pain Medicine

James P. Rathmell, MD, MS, has been appointed Chair of the Department of Anesthesiology, Perioperative and Pain Medicine at Brigham and Women’s Hospital (BWH), effective June 1, 2015. Dr. Rathmell joins BWH from Massachusetts General Hospital, where he served as Executive Vice Chair and Chief of the Division of Pain Medicine. He has been at the forefront of outstanding patient care as a devoted clinician, directing much of his time to patients with acute, chronic, and cancer-related pain. His research has focused on emerging treatments for pain, and he has published widely on the safety and effectiveness of specific interventions used in pain medicine. Dr. Rathmell also serves as a director for the American Board of Anesthesiology and recently served on the National Institutes of Health (NIH) Interagency Pain Research Coordinating Committee’s National Pain Strategy taskforce.

New Chief of Cardiac Surgery

Prem S. Shekar, MD, has been appointed Chief of the Division of Cardiac Surgery and Surgical Director of the Heart & Vascular Center at BWH. Dr. Shekar joined BWH in 2001 as a cardiothoracic surgical fellow and became a faculty member in 2004. A highly-skilled, respected, collaborative, and caring surgeon, Dr. Shekar’s clinical and research interests include surgery for hypertrophic cardiomyopathy, surgical correction of aortic root and mitral valve pathologies in patients with Marfan’s syndrome and other connective tissue disorders, minimally invasive valve surgery and radiation induced heart disease aside from conventional surgery. He is well known among his colleagues for his thoughtful approach to complex cases. Dr. Shekar received his medical degree from Bangalore University, India, completed his postgraduate training at the Command Hospital – Indian Air Force and Jawaharlal Institute of Postgraduate Medical Education and Research, India and advanced cardiothoracic fellowships at the Fremantle Hospital and Royal Adelaide Hospital in Australia and the Brigham and Women’s Hospital. He is also the Fellow of the Royal College of Surgeons of Edinburgh.
Alzheimer’s Research Update

Landmark Clinical Trial Expanded

The landmark Anti-Amyloid Treatment in Asymptomatic Alzheimer’s (A4) study, led by Reisa A. Sperling, MD, Director of the Center for Alzheimer’s Research and Treatment at Brigham and Women’s Hospital (BWH), is being expanded to include a new tau imaging agent for use in the PET scans as part of the A4 study and its companion Longitudinal Evaluation of Amyloid Risk and Neurodegeneration (LEARN) study.

The PET tau imaging pilot substudy will include up to 500 individuals from the A4 study (and 50 from the LEARN study) with the aim of clarifying the role of tau in tracking progression toward Alzheimer’s disease dementia. Researchers are hoping to discover whether tau is suitable as a biological marker of disease progression from the preclinical to the early symptomatic stages of Alzheimer’s and investigate whether the build-up of tau in the brain is altered in response to anti-amyloid treatment. The study’s expansion is being supported by a grant from the Alzheimer’s Association and the NIH Accelerating Medicines Partnership.

To refer someone for consideration for the A4 study, the LEARN study, or other AD clinical trials at Brigham and Women’s Hospital, please contact Alison Pietras at (617) 278-0379 or apiertas@partners.org.

Referring Physicians: Access to clinical information

Would you like to easily access the status of your patients who are also receiving care from physicians at Brigham and Women’s Hospital and other Partners HealthCare hospitals and affiliates? Partners Physician Gateway enables referring physicians to view the medical records of their patients at Brigham and Women’s Hospital (BWH), Brigham and Women’s Faulkner Hospital, Dana-Farber Cancer Institute, Massachusetts General Hospital, Newton-Wellesley Hospital, and North Shore Medical Center. To find out more and request your User ID and Password, please visit www.physiciangateway.org. If you have any questions or would like assistance, please contact BWH Physician Liaison Ellen Steward at (617) 582-4733 or esteward@partners.org.

Surgical Services South of Boston

Neurosurgeon Tracy L. Ansay, MD, recently joined Brigham and Women’s Neurosurgery of South Weymouth. She treats a wide range of neurological diseases and specializes in the latest surgical techniques for the treatment of spine conditions and brain cancers. Dr. Ansay is on the medical staffs of South Shore Hospital and Brigham and Women’s Hospital and sees patients in South Weymouth, Massachusetts. To refer a patient, please call (781) 331-4923.

GI and bariatric surgeon Neil Ghushe, MD, has joined Brigham and Women’s Surgical Associates at South Shore Hospital, and has started a clinic for the evaluation and post-surgical follow-up of bariatric surgery patients. Surgery will take place at Brigham and Women’s and Brigham and Women’s Faulkner Hospitals in Boston. The clinic is located in South Weymouth, Massachusetts. To refer a patient, please call our Referral Coordinators at (617) 732-9894.

Access to Brigham and Women’s Hospital

Physician Referral Service
(617) 732-9894 or 1-800-MD-TO-BWH (1-800-638-6294)

Experienced referral coordinators assist with outpatient appointments, access to our physicians, and information regarding our specialists and services.

Physician Liaisons

Our Physician Liaisons provide direct assistance with patient referrals and consultations with our specialists.

Ellen Steward
(617) 582-4733 | esteward@partners.org

Tom Anderson
(617) 582-4760 | tanderson0@partners.org

MD Connect

(inpatient transfers and transportation services)
1-877-637-3337