the JOURNAL of East Jefferson General Hospital

VOLUME 6, NUMBER 1 • FIRST QUARTER 2018

A PUBLICATION FOR THE MEDICAL STAFF

The Journal of East Jefferson General Hospital
Volume 4, Number 2 • Third Quarter 2016

INDEX

CLINICAL ARTICLES

QUALITY CORNER

the JOURNAL of East Jefferson General Hospital

Chief of Staff Report

Jeffrey J. Sketchler, MD
Chief of Staff
East Jefferson General Hospital

East Jefferson General Hospital has been providing top-notch, patient-centered health care to our region for approximately a half a century. For decades we have existed as an independent service district hospital. As the health care industry has been turned upside-down over the last several years, it has become impossible for our institution to continue to operate on its own. Despite being ranked as the #1 hospital in Louisiana for the 3rd consecutive year, EJGH continues to be reimbursed by insurers and government alike as a 2nd or 3rd tier institution.

Being part of a network is a matter of survival in this modern day health care environment.

Throughout my tenure in 2017, your Medical Executive Committee, along with our partners in the hospital administration, has been working tirelessly to continue to improve revenue and efficiencies throughout the hospital. We thank the leaders and participants of numerous committees such as the Utilization Review Committee, the Pharmacy and Therapeutics Committee, and many others that have spent countless hours to improve the care delivered at our hospital and to allow us to thrive during this recent fiscally challenging era. As you know, the Board of Directors has agreed to a letter of intent for a partnership lease with HCA-Tulane. HCA is in the process of "due diligence" in this transfer. Our "due diligence" as a medical staff is to preserve top-ranked patient-centered health care for all of our patients.

We have already communicated with HCA that as we move forward, less disruption equals more production. Our present medical staff is the main driver in the top-ranked care that the hospital has delivered year after year. We want to preserve what our patients have become accustomed to. Preserving our medical staff and preserving the hospital's identity is paramount. We feel that our expertise in health care delivery, along with HCA's economy of scale, mixed with an infusion of Tulane University's history of academic excellence bodes well for East Jefferson General Hospital's future.

A Transition Committee has been formed. This committee as well as your Medical Executive Committee will assist in this transition and will represent you, the medical staff, as we move forward. Employed, contracted, and independent physicians have legitimate concerns regarding their future. We will be open to the medical staff in our discussions with the new entity. Many details are yet to be determined. Many questions have been asked. HCA has stated their intent to preserve EJGH's identity and their desire to not disrupt our tradition of excellence. As details become available, we will communicate them with you.

Organizational structural changes, medical staff bylaws, board representation, and other details will be worked out as we move forward. As we do so, we must remember who the most important person in the hospital is. As always, the most important person at EJGH is the patient.

The Journal of East Jefferson General Hospital

Information for Authors

This publication is a peer-reviewed medical journal published quarterly for the benefit of the East Jefferson General Hospital medical staff, under the direction of the EJGH Continuing Medical Education Committee. Original scientific studies as well as articles addressing pertinent medical topics, the practice of medicine, medicolegal issues and medical informatics will be considered for publication. Submissions should be approximately 2500 words or less and referenced. Submissions will be reviewed by the editorial staff and at least one peer reviewer, selected by the CME committee. Manuscripts are subject to editorial revision for elements of grammar, style and format. Authors should follow the following guidelines when submitting a paper for publication.

PARTS OF MANUSCRIPT:

Title page: Please include the title of the manuscript, the full name and title of each author, the institutional affiliation of each author, and contact information for the corresponding author.

Abstract and Keywords: The abstract should be a brief summary of the paper in 150 words or less. Three to five keywords should be selected for assistance in indexing the article.

Text: Every manuscript should include an introduction and a summary/conclusion. Scientific studies should include subsections addressing materials and methods as well as results. Abbreviations should be spelled out the first time they are used. Reference citations in the text should be Arabic numerals in parentheses placed at the end of the sentence, before the end punctuation.

Acknowledgements: Financial assistance pertinent to the topic of the article must be disclosed. Individuals contributing to the content of the work, but who are not listed as authors, may be acknowledged in this section.

References: References should be numbered consecutively in the order in which they are first cited in the text. For journal articles, the authors' names should be followed by the title of the article. The journal, year of publication, volume, number and inclusive page numbers should follow. When there are six or less authors, all should be listed. For reference publications with seven or more authors, only the first three need be listed, followed by "et al." For references to books, the authors of the chapter, title of the chapter, editor(s), title of the book, edition, city, publisher, year and chapter pages should be given. References to web-based material should include the authors' names; title of the article, journal or web page title; the year, volume and issue of publication (if applicable); the URL for the document; and the date the document was accessed.

Figures/Tables: Images used for publication should be in JPEG or TIFF format. All figures should be numbered consecutively in the order in which they are first mentioned in the text. All figures should be accompanied by a concise legend explaining the figure. Tables should be numbered consecutively in the order in which they are first mentioned in the text. All tables should have a title. Previously published figures/tables cannot be reproduced by this journal without the written consent of the original author and publisher.

The Relationship between Emergency Department Length of Stay and the Development of Pressure Injuries in the Vulnerable Adult Patient

Victoria Johnson RN, BSN, PCCN, Krystal Raphael RN, BSN, CMSRN. East Jefferson General Hospital.

ABSTRACT & KEYWORDS:

A team of nurses on the Skin Wound Assessment Team (SWAT) questioned the best practice of preventing pressure injuries in the Emergency Department. After a literature search and gathering data on pressure injuries in the hospital, the team decided to develop a better workflow in the Emergency Department. Emergency Department, Pressure Injury, Preventative Dressings

INTRODUCTION & PURPOSE:

Hospitals no longer receive reimbursement from Centers for Medicare and Medicaid Services (CMS) for pressure injuries that develop during hospitalization, and approximately $11 billion is spent nationally to treat acquired pressure injuries on an annual basis. A higher incidence of pressure injuries was found to occur in the Emergency Departments (ED) when length of stay was greater than 2 hours. Because there was no ED standardized protocol regarding pressure risk assessment or prevention, the impact of length of stay in the ED on the development of pressure injuries in the vulnerable adult patient was investigated as a component of a continuous quality improvement process (1,2).

METHODOLOGY:

Along with the National Database of Nursing Quality Indicators (NDNQI), the hospital-acquired pressure injury rates in 2016, and the current hospital policy regarding acquired pressure injuries were reviewed. Next, a current literature search involving emergency department patients' risk for pressure injuries using EBSCO, OVID, CINAHL, and the Cochrane databases revealed the following essential points: 1) Of hospital acquired pressure injuries, 53% occurred on heels, and 29% occurred on the sacrum. 2) Costs for prevention and treatment of unavoidable pressure injuries that occur in acute care facilities in the USA are not reimbursed.

The risk factors for ED patients developing hospital-acquired pressure injuries are numerous. Some risk factors include age greater than 65 years, altered mental status, trauma, comorbidities such as diabetes, obesity, pulmonary and cardiac disease, impaired regulation of body temperature, and altered nutrition. Additional risk factors involve hemodynamic factors such as hypotension, mechanical ventilation, blood loss, immobility, contractures, impaired sensation, incontinence of bowel and bladder, time spent on the emergency department stretcher, positioning (intensity and duration of pressure), and history of previous pressure injuries (3).

RESULTS:

During 2016, the Skin and Wound Assessment Team (SWAT) identified 60 Hospital Acquired Pressure Injuries (HAPI) when performing quarterly audits for National Database of Nursing Quality Indicators (NDNQI). The two most common wounds identified were Stage 2 (partial-tissue skin loss) and DTIs (Deep Tissue Injury). There were 27 Stage 2 pressure injuries and 13 DTIs. Of the 60 patients who developed HAPI in 2016, fifty-five were admitted through the ED with a 5.8-hour average length of stay.

CONCLUSION:

Research supports the use of risk assessment upon admission to EDs as an adjunct to pressure injury prevention, with the initiation of pressure injury prevention practices when indicated. Evidence supports the application of absorbent, soft silicone dressings to aid in the prevention of pressure ulcer development. Therefore, ED admits at risk for pressure injury should have a five layer silicone border dressing applied to the sacrum and heels.

Additionally, application of a dressing to the sacrum and heels is recommended for patients admitted with prolonged immobilization such as hip fractures. When patients are identified at high risk, preventative measures should be initiated including offloading heels with pillows and turning/repositioning every two hours. For documentation, the creation of a flow sheet within the chart to identify at-risk patients is essential.

To ensure quality improvement, these evidenced-based changes in patient care are critical to roll out in a widespread education program to all nursing staff, especially the ED staff, to incorporate skin care/pressure injury prevention as part of the ABC'S (skin).

ACKNOWLEDGEMENTS:

Skin Wound Assessment Team Project Team - Victoria Johnson RN,BSN, PCCN; Krystal Raphael RN, BSN, CMSRN; Denise Abadie RN, CWCN; Darlene Elmer RN, BSN, CCRN; Laura Braud RN; Karina Estrada RN; Amber Hamilton RN, BSN, PCCN; Nina Joseph LPN; Sara Luce RN, BSN; Tanya Solly RN, CMSRN; Karen Vix RN, CMSRN; Angela Whitbrodt RN; Tracey Galassi RN, and Jane Savage PhD, RN, CNE, LCCE, FACCE for her clinical expertise and sincere collaboration on this project.

REFERENCES:

1. Black, J., Clark, M., Dealey, C., Brindle, C.T., Alves, P., Santamaria, N., & Call, E. Dressings as an adjunct to pressure ulcer prevention: consensus panel recommendations, *Interventional Wound Journal*, 2014: 12, 484 – 488.

2. Blenman, J. and Maran, D. Pressure ulcer prevention is everyone's business: the PUPS project. *British Journal of Nursing*, 2017: 26(6), 516-526.

3. Fagan, M. Early Prevention of Pressure Ulcers in the Emergency Department. Seton Hall University DNP Final Projects, 2015: Paper 10.

the JOURNAL of East Jefferson General Hospital

Routine Measurement and Replacement of Magnesium to Decrease the Risk of Dysrhythmias in the Adult Cardiac Patient

Bridget Boogaerts, BSN, RN-BC, CRRN, ONC, PCCN, 2 East, East Jefferson General Hospital.

INTRODUCTION & PURPOSE:

A current review of the literature was examined to evaluate the effectiveness of IV magnesium in minimizing the risk of dysrhythmia in hospitalized adult patients with hypomagnesemia. With routine serum magnesium monitoring orders for the convergent maze surgical patients, East Jefferson General Hospital (EJGH) nurses on 2 East often called physicians to determine the need for magnesium replacement in hypomagnesemic patients because of increased risk for dysrhythmias.

Some physicians questioned the need for IV magnesium replacement if the patient was not demonstrating clinical manifestations, such as prolonged QTc, or ventricular dysrhythmias, including Torsades de Pointes or ventricular tachycardia.

The purpose of the project was to determine if IV magnesium replacement is a more effective method than oral magnesium replacement to decrease the incidence of dysrhythmias.

METHODOLOGY:

A critical review was conducted of the current, relevant East Jefferson General Hospital policies, National Clinical Practice Guidelines, EBSCO, Medline, CINAHL, and Cochrane databases to determine what evidence exists regarding the use of IV magnesium to treat hospitalized adult patients with hypomagnesemia. Additional hospital resources for EBP were utilized, including Up-to-Date and Lexicomp.

RESULTS:

Scientific resources yielded data on IV and oral magnesium replacement. The method of replacement of magnesium depended on the patient's condition and the critical value of the lab. IV magnesium replacement should be reserved for patients with severe symptoms such as seizures, or life-threatening arrhythmias such as Torsades de Pointes. The rate of administration depended on the hemodynamic stability of the patient. Due to the mechanism of absorption of magnesium in the kidney, up to 50% of the magnesium dose that is infused IV will be excreted by the kidneys.

Oral magnesium replacement should be administered whenever it can be tolerated. Magnesium chloride is preferable to magnesium oxide for an oral replacement for the following reasons: (a) Sustained-release preparation results in slower absorption and less renal excretion; (b) Lower dose results in less GI discomfort and diarrhea, which is the primary cause of intolerance with oral magnesium replacement; therefore (c) Caution should be used in patients taking laxatives, with diarrhea, or with compromised skin integrity.

Special treatment considerations include suspected hypomagnesemia in patients with chronic diarrhea, PPI therapy, alcoholism, diuretic use, refractory hypokalemia, unexplained hypocalcemia, or ventricular arrhythmias. Caution must also be used when prescribing magnesium replacement to patients with impaired renal function. For patients who must remain on thiazide or loop diuretic therapy and remain hypomagnesemic, the addition of a potassium-sparing diuretic may be helpful.

Those patients taking PPI and concomitant diuretic therapy are at higher risk for hypomagnesemia. Ranitidine or Maalox may be considered as alternatives for gastric acid suppression. Monitoring for signs of hypomagnesemia when administering magnesium replacement is essential. Those signs include facial flushing, hypotension, and AV Blocks.

Additionally, collaboration with Dr. Zhen Jiao and Pillie Morrison, R.Ph. prompted the team to reconsider the original clinical question. A revised question was developed: In hospitalized cardiac patients, does routine measurement and replacement of magnesium decrease the risk of dysrhythmias? However, a secondary literature review returned no evidence to support routine monitoring of magnesium levels in patients without clinical manifestations of hypomagnesemia.

CONCLUSION:

Maintaining normal ranges of magnesium in the adult patient is an essential role of the cardiac care nurse. The review of current evidence supports:

- removing routine magnesium monitoring on convergent maze order sets.

- assessing serum magnesium when clinically indicated (e.g. Prolonged QTc, ventricular dysrhythmias).

- administering oral magnesium replacement is best practice in the stable patient.

These EBP findings will be disseminated to 2 East nursing staff via The Pulse, unit newsletter. Also, the team recommends a sustained-release oral magnesium replacement option be considered for stable hypomagnesemic cardiac patients. The availability of magnesium chloride will be verified on the formulary. Finally, the development of a magnesium replacement powerplan/guideline in collaboration with a clinical pharmacist and electrophysiologist to reflect current recommendations is the next essential step to improve patient outcomes.

A Q&A about Hyperbaric Oxygen Therapy

John V. Capotorto, MD, Restorix Health, Inc.

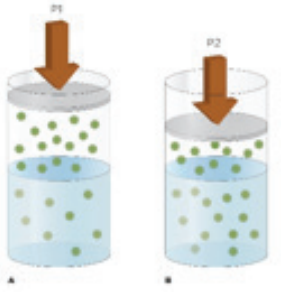
WHAT IS HYPERBARIC OXYGEN THERAPY?

Hyperbaric oxygen therapy (HBOT) is a medical treatment used to treat a number of diseases and conditions, some with little or no hope of healing without increased oxygen. When a patient is given 100% oxygen under pressure, hemoglobin is saturated, but the plasma is not. The blood can be hyperoxygenated by dissolving oxygen within the plasma.

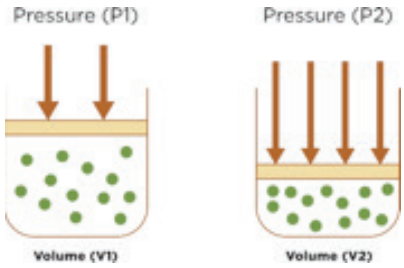
The science of hyperbaric oxygen therapy is based upon gas laws of physics, including Henry's Law and Boyle's Law.

WHAT IS THE SCIENCE OF HBOT?

Henry's Law states that the amount of gas dissolved in a liquid is equal to the partial pressure of the gas exerted on the surface of the liquid. By increasing the atmospheric pressure in the chamber, more oxygen can be dissolved into the plasma than would be seen at surface pressure.



Boyle's Law (p1 v1 = p2 v2) states that the pressure and volume of a gas have an inverse relationship, when temperature is held constant. If volume increases, then pressure decreases and vice versa, when temperature is held constant. This principle can help explain the mechanism of action of HBOT on problems such as decompression sickness (DCS) or arterial gas embolism (AGE). As the pressure is increased, the volume of the bubble decreases. This also becomes important when the hyperbaric nurse or technician decompresses a patient in the chamber; if a patient holds his/her breath, the volume of the gas trapped in the lungs over-expands and may cause a pneumothorax.



HOW IS HBOT ADMINISTERED?

Patients receive hyperbaric oxygen via one of two types of chambers: Type A, or multiplace chambers; and Type B, or monoplace chambers. Both types can be used for routine wound care, treatment of most dive injuries, and treatment of patients with conditions such as arterial gas embolism or late effects of radiation.

Multiplace chambers treat multiple patients at the same time, generally with a nurse or another inside observer who monitors the patients and any associated equipment brought into the chamber (anything brought into the chamber must be approved). Multiplace chambers are also utilized to treat emergencies (see image A). Patients in multiplace chambers breathe 100% oxygen via a mask or close-fitting plastic hood. Multiplace chambers can usually be pressurized to the equivalent of about six atmospheres of pressure. Equipment such as ventilators and intravenous lines is put into the chamber with the patient. The nurse or attendant is inside the chamber with the patient, and therefore there is a risk of decompression sickness as seen in SCUBA divers.

A monoplace chamber compresses one person at a time, usually in a reclining position. The gas used to pressurize the vessel is usually 100% oxygen. Some chambers have masks available to provide an alternate breathing gas (such as air). Employees tend to the patient from outside of the chamber and equipment remains outside the chamber. There are also chambers that hold two patients sitting up, called duoplace chambers.

Two other types of chambers have gotten press lately, but they do NOT deliver HBOT. Those are: 1) Topox, in which topical oxygen is delivered through a small chamber that is placed over the extremity with the wound, and 2) soft vessels, which are billed as "portable" or "mild" and are currently only approved for altitude sickness. They are the types of chambers seen frequently in medical spas, or in private homes and should not be utilized for the conditions described herein.

WHAT ARE THE TREATMENT GUIDELINES?

The usual pressure for a hyperbaric treatment is between 2.0 and 2.8 ATA (atmospheres absolute). Depending on the condition and associated protocol, the patient may receive anywhere from one to thirty treatments or more, typically lasting from 60-90 minutes with additional time for the descent and ascent portions of the dive. They may also take air breaks during the treatment to avoid oxygen toxicity.

ARE HYPERBARIC TREATMENTS APPROVED BY THE FDA?

Hyperbaric chambers are regulated and registered by the US Food and Drug Administration (FDA) in order to protect the safety of these medical devices for their "intended use," which includes the specific conditions and diseases that will be treated using HBOT.

WHAT ARE THE INDICATIONS FOR HBOT?

The Hyperbaric Oxygen Therapy Committee of the Undersea and Hyperbaric Medical Society (UHMS) issues a report of the indications for which HBOT is deemed safe and effective. Payors such as Medicare conduct literature reviews and then make their own determination on which conditions/diseases are or are not covered. While HBOT is considered a primary treatment for a few conditions, such as decompression sickness, in most cases it is an adjunctive therapy. This means that it is added to the standard of care and not a stand-alone treatment. For example, with diabetic foot ulcers, there must still be offloading, debridement, infection control and reperfusion. As of this

writing, the following conditions were approved by the UHMS:

1. Air or gas embolism*
2. Carbon monoxide poisoning*
a. Carbon monoxide poisoning complicated by cyanide poisoning
3. Clostridial myositis and myonecrosis (gas gangrene)
4. Crush injury, compartment syndrome and other acute traumatic ischemias
5. Decompression sickness*
6. Arterial insufficiencies
a. Central retinal artery occlusion*
b. Enhanced healing in select problem wounds (including diabetic foot ulcers, Wagner grade 3 or higher)
7. Severe anemia
8. Intracranial abscess
9. Necrotizing soft tissue infections
10. Osteomyelitis (refractory)
11. Delayed radiation injury (soft tissue and bony necrosis)
12. Compromised grafts and flaps
13. Thermal burn injury
14. Idiopathic sudden sensorineural hearing loss

*HBOT is a primary treatment

WHAT ARE THE CONTRAINDICATIONS AND COMPLICATIONS OF HBOT?

HBOT can be safely administered safely in a hospital setting, with physician or other qualified healthcare provider supervision. In monoplace chambers, patients cannot be safely extracted in less than 5 minutes, although in non-medical emergencies requiring evacuation (e.g., fire, tornado, gun violence) an emergency ascent can be performed which will result in decompression sickness. Therefore, it is important to safely assess the patient for potential risks prior to HBOT. There are absolute contraindications and relative contraindications which are presented in Table 1. The most common complications are middle ear barotrauma (with or without tympanic membrane rupture), sinus pain, and hypoglycemia. All can be managed without discontinuing HBOT. More serious complications of HBOT that are extremely rare but can be life-threatening, are also listed in Table 2.

Table 1

Absolute Contraindications	Relative Contraindications
• Untreated pneumothorax • Concurrent administration of Antabuse (Disulfuram) • Concurrent administration of cisplatin, doxorubicin • Premature infants • Certain implants (check with manufacturer)	• Prior chest surgery • Lung disease • Optic neuritis • Seizure disorders • Recent middle ear surgery • Viral infections • High fever • Congenital spherocytosis • Claustrophobia

Table 2

Possible Complications of HBOT
• Middle ear barotrauma • Sinus pain • Hypoglycemia • Claustrophobia • Transient myopia and/or early cataract formation • Oxygen toxicity seizures • Pulmonary barotrauma • Decompression sickness • Spontaneous tension pneumothorax *Potentially life-threatening

IS THERE EVIDENCE FOR HBOT?

Levels of evidence for specific, accepted indications fall into Level B (double-blind RCTs but with small sample or one study) and Level C (consensus opinion of experts). With the devastating consequences of failed conventional therapies for many of the accepted conditions, such as major amputation, or painful and debilitating late effects of radiation, it would be unethical to withhold treatment with expert consensus from ample documented cases. In addition, the great number of variables and complex nature of some of the cases makes study design difficult. However, research is ongoing and promising for other conditions arising from ischemia, such as coronary ischemia, stroke and traumatic brain injury.

COMMENTS:

Thousands of patients have had dramatic and positive results from hyperbaric oxygen treatments. The science is well documented, but there is still confusion over the indications, efficacy and evidence. Multiple studies of various quality have been conducted, but some are contradictory. However, in the last ten years, there have been efforts to review the literature, critique studies, and design new studies. Overall, the evidence suggests the benefits outweigh the risks, but there is still a need for further study and current consensus guidelines.

If you have a patient who might benefit from HBOT, contact an expert who can advise whether the patient meets the approved indication criteria. Hospital-based centers are established to follow strict procedures surrounding safety and best practices. In some cases, hyperbaric oxygen therapy needs to be administered in a time-sensitive manner, as with central retinal artery occlusion, and in other cases, it can offer hope for patients who are experiencing devastating late effects from radiation and have failed other treatments, such as radiation cystitis or enteritis.

Insurance coverage varies from payer to payer, but most accepted conditions are covered. When utilized for the appropriate conditions, hyperbaric oxygen therapy can be a vital adjunct or a first-line treatment that improves the quality of life for patients with the specific indications as set forth by the UHMS.

REFERENCES AND SUGGESTED READING:

1. Jain KK. Textbook of Hyperbaric Medicine. Springer; 2016.

2. The Hyperbaric Oxygen Committee Report. Hyperbaric Oxygen Therapy Indications, 13th Edition. The Undersea and Hyperbaric Medical Society. 2014. https://www.uhms.org/images/indications/UHMS_HBO2_Indications_13th_Ed._Front_Matter__References.pdf Accessed on July 24, 2017.

3. Mathieu D, Marroni A, Kot J. Tenth European Consensus Conference on Hyperbaric Medicine: recommendations for accepted and non-accepted clinical indications and practice of hyperbaric oxygen treatment. Diving Hyperb Med. 2017;47(1):24-32.

4 Fife CE, Eckert KA, Carter MJ. An Update on the Appropriate Role for Hyperbaric Oxygen: Indications and Evidence. Plast Reconstr Surg. 2016;138(3 Suppl):107S - 16S.

High Frequency Spinal Cord Stimulation for Complex Regional Pain Syndrome: A Case Report

Joseph T. Capanzano, MD[1,4], Lisa M. Harrison-Bernard, PhD[2,3], Mark R. Jones, MD[2,4], Alan D. Kaye, MD, PhD[2,4], Erich O. Richter, MD[2,5], Mordeci N. Potash, MD[6]
East Jefferson General Hospital

Abstract

Complex regional pain syndrome (CRPS) is a chronic, debilitating, neuropathic pain condition which is often misdiagnosed, difficult to manage, and lacks proven methods for remission. Most available methods provide some relief to a small percentage of patients. Recent FDA approval and superiority of the Nevro Senza 10-kHz high frequency (HF10) spinal cord stimulation (SCS) therapy over tradional low-frequency spinal cord stimulation for treatment of chronic back and leg pain may provide a new interventional therapeutic option for patients suffering from CRPS. We provide a case report of a 54-year-old Caucasian female who suffered with CRPS in the right knee and thigh for over 7 years. Implantation of the HF10 device provided over 90% relief of pain, erythema, heat, swelling, and tissue necrosis to the entire region within 1 month of treatment. Becuase the HP10 therapy provides pain relief without paresthesia typical of traditional low-frequency, this system may provide relief for patients suffering from chronic pain.

Introduction

Complex Regional Pain Syndrome (CRPS) is a chronic pain condition characterized by spontaneous and evoked regional pain, usually beginning in a distal extremity, that is disproportionate in magnitude or duration to the typical course of pain after similar tissue trauma. (1) CRPS differs from other chronic pain conditions with regard to the presence of pronounced inflammatory and autonomic changes in the pain-afflicted region. With varying severity, patients suffering from CRPS may exhibit hyperalgesia and allodynia; frank changes in skin color, temperature, and diaphoretic tendencies; edema and altered hair, skin, or nail growth to the affected area; reduced strength; tremors; and dystonia. (2) Patients may present with further symptomology including altered body perception and proprioreception. (3) CRPS may inflict significant impairments in a patient's ability to function and complete activities associated with daily living, which creates a huge burden to the patient and family. (4) CRPS affects an estimated 200,000 people per year in the United States, occurring approximately three to four times more often in women than men. (5) The disease arises most frequently after injury, with fractures responsible for >40% of cases. The underlying pathophysiology of CRPS involves a multifactorial process of both peripheral and central mechanisms. (6,7) Possible factors involved in the development of CRPS include nerve injury, ischemic reperfusion injury or oxidative stress, central and peripheral sensitization, altered sympathetic nervous system function or sympatho-afferent coupling, inflammatory and immune related factors, changes in the brain, as well as genetic, psychological, and disuse factors. (8-20) Taken together it is clear to see that effective management of CRPS requires a wide variety of pharmacological (21), behavioral, and interventional strategies. In addition, a systematic review of clinical trials for the treatment of CRPS from 2000 to 2010 indicated that there was weak evidence for effective treatment of CRPS (22), emphasizing the need for more effective therapies for patients suffering with CRPS.

Bruehl's description of CRPS pathophysiology offers an explanation of the observed complex symptom and physical findings in this classic, albeit severe case of CRPS. Initiating injuries may be severe, but are often relatively minor and typically afflict an extremity. Genetic factors appear to play a role with higher prevalence of the disease noted in family members of patients with CRPS. Peripheral sensitization occurs with the release of neuropeptides (substance P, calcitonin gene-related peptide (CRGP) and bradykinin) at the injury site. A red, hot, edematous extremity is the result of plasma extravasation of neuropeptides and vasodilation. Bradykinin is thought to contribute to the release of proinflammatory cytokines such as TNF-a, as well as Interleukin-1B,-2,-6 from lymphocytes and mast cell. Proinflammatory cytokines are found in the fluid of skin blisters, plasma and cerebrospinal fluid. There is a decrease in nociceptive fibers in the afflicted region of the body with increased expression of adrenergic receptors. Sympathetic nervous system outflow of catecholamines may exacerbate symptoms related to nococeptive nerves developing adrenergic receptor expression. CRPS mediated central sensitization, mediated by the release of neuropeptides such as bradykinin and substance P, results in increased windup phenomenon in the cortical region supplying the affected limb. The associated somatosensory cortex of the brain demonstrates a decrease in size of the area representing the CRPS afflicted limb. There is expansion of the adjacent unaffected cortical regions into the somatosensory areas of the brain that have lost afferent input. Somatotrophic changes in the brain likely contribute to associated nondermatomal skin abnormalities resulting in the area afflicted being a regional rather than dermatomal distribution. CRPS pain and hyperalgesia demonstrate a significant correlation with degree of somatotrphic change (23).

Pain is commonly described as burning, constant and severe. The skin may demonstrate hard brawny edema (peau d orange) with associated rashes, ulcers, and blisters sharply demarcated along a clear line. The symptoms may spread and become diffuse occurring in distant areas of the trunk, other extremities, or on the side of the face. Treatment involves addressing the psychosocial issues, medication management, physical / occupational therapy, as well as procedures such as sympathetic blocks and sympathectomy after successful sympathetic blocks. When conservative measures fail spinal cord stimulator therapy may be of benefit (24).

Case Report

The patient in question is a 54-year-old Caucasian female with a professional career who has CRPS of her right knee and thigh. She previously had four arthroscopic surgeries on the right knee. The first surgery in April 1983 was performed related to a developmental defect which had resulted in a misaligned right patella. A second surgery was performed in April 2008 secondary to gradual worsening of right knee function, swelling, and fatigue. During her recovery from this surgery, the patient and her family were forced to evacuate emergently because Hurricane Gustav threatened New Orleans in August, 2008. During the evacuation, her vehicle was severely rear ended in a motor vehicle accident and her right knee was slammed into the car's dashboard area.

At this point after the rear-end motor vehicle accident, the patient began to experience intense pain in the right knee and thigh with associated redness and swelling. Unfortunately, one week later she was misdiagnosed by an orthopedist with cellulitis for which she was unsuccessfully treated with antibiotics. The patient underwent a third right knee surgery in December, 2008. Nine months later in September, 2009 she was finally diagnosed with CRPS by a neurologist. A final, fourth right knee surgery was performed in May, 2010, consisting of a partial medial meniscectomy, synovectomy, abrasion arthroplasty, chondroplasty, repeated repair of the anterior cruciate ligament, and excision of scarring throughout the knee capsule and severe synovitis. This fourth knee surgery successfully restored the biomechanics of the right knee; however, over time the CRPS migrated to include the entire right knee and thigh, and left and right shoulders and upper arms. The patient's CRPS symptom complex began on the evening of the motor vehicle accident in August, 2008. The severity of the patient's symptoms increased after the 3rd and 4th knee surgeries. The patient described intense 8/10, constant, and unbearable deep bone pain, as well as sharp and hot pain sensation to the associated muscle and skin. The right knee frequently erupted in painful and weeping blisters which were slow to respond to topical steroids or other topical treatment interventions. On examination, the knee appeared warm, with the anterior right thigh exhibiting a peau d'orange appearance. Erythema as well as multiple blisters and bullae in different stages of healing were evident across her right thigh. Additionally, the affected area continued to grow gradually over time, especially proximally, medially, and laterally. Also, pain and stiffness of the left and right shoulders and upper arms became increasingly evident.

The patient was prescribed an extensive list of medications owing to the variety of her symptomology, including but not limited to opiates (fentanyl, Butrans, oxycodone, Percocet, codeine), NSAIDs (ibuprofen, naproxen), antidepressants (venlafaxine, paroxetine, aripiprazole), anticonvulsants (gabapentin, pregabalin), several different topical agents and lidocaine patches, hydrochlorothiazide for swelling, methylphenidate for fatigue, and stool softeners and laxatives for constipation. No analgesic provided her more than temporary partial relief. Opioid analgesics were partially effective, but suboptimal doses were required since therapeutic doses rendered the patient overly sedated. The patient also relied on application of frozen gel packs to the affected areas throughout the day and an electric thermo-cooling circulating water wrap at night in order to cool the affected area. In addition to pharmacologic management, the patient received a single lumbar sympathetic block in 2013, which provided minimal relief for less than twelve hours. Physical therapy was unsuccessful and any standing, walking, or exercise induced swelling, increased pain, and heat at the affected region.

When evaluating the patient in the clinic, the patient offered a compelling history documenting the impact of CRPS upon her life in her own words:

"I suffer with excruciating pain, depression and fatigue. I often feel sad, anxious, overwhelmed, irritable, hopeless, helpless, and a complete loss of self. Simple daily tasks, such as walking, showering, and cooking dinner, are difficult due to the pain and minimal energy reserves. I suffer from severe stiffness, inflammation, redness, heat and swelling of the entire right knee and thigh. The affected area continues to enlarge distally, proximally, laterally, and medially. Because of the inflammation the affected area is hot to the touch and I've relied on the use of research laboratory grade frozen gel packs for the past 5 years, 24 hours/day, 7-days/ week. I also use an electric thermo-cooling circulating water wrap to sleep since the gel packs do not stay cold for 7-8 hours. As the CRPS has continued, it has had a greater impact on reducing my quality of life and interfering in my performing important roles as a researcher, teacher, mentor, spouse, mother, and community member. I am unable to drive and walk even moderate distances. My ability to travel for business and pleasure has severely and negatively impacted my professional and personal life. My social life is minimal to nonexistent. Since starting the medications for CRPS my body weight has increased by 25 percent which contributes to low self-esteem and tremendous sadness. My pain experience is exhausting, exasperating and has had a negative impact on my family." Initially the patient was averse to spinal cord stimulation (SCS). After nearly a decade of failed treatments, however, the decision was made to proceed with a SCS trial. The patient was offered a traditional SCS trial vs. high frequency SCS trial. Traditional SCS operates in a range of 2 to 1,200 Hz, with typical pulse frequencies of 40 to 60 Hz. High Frequency (HF) SCS delivers electrical stimulation pulses at 10,000 Hz for a short duration (30μs). This novel method of stimulation does not rely on producing paresthesia, as does traditional SCS. The SENZA-RCT randomized control trial of 2015 demonstrated significant superiority of HF over traditional SCS, with 67% of HF patients experiencing pain relief at 12 months vs. 35% of traditional SCS patients. [25] In light of this information, the patient opted for a trial of HF SCS.

After a successful HF trial of one week, a permanent implantation was performed two months later. The patient has been seen four times for follow up evaluation since the procedure. She endorses marked pain relief, and no longer relies on any ice packs or cooling blankets being applied to the knee and thigh. The skin on the affected area has returned to a normal appearance. There are no weeping bullae, and the erythematous, peau d'orange appearance has completely resolved. The pain and stiffness of the shoulders and upper arms has also resolved. The patient enjoys a much more active and enthusiastic life without pain in the knee and thigh region. Within 4 months of the permanent HF SCS implant, the patient has discontinued use of all anticonvulsants and reduced opiates by 75%. It is anticipated that there will be a reduction in the use of the other pharmacological therapies used to treat the CRPS over the coming months.

Results

Figure 1a & 2a. Before HF SCS. The right knee and thigh were hot to the touch, with the anterior right thigh exhibiting a peau d'orange ppearance. Erythema, as well as, multiple blisters and bullae in different stages of healing were evident across her right thigh. Figure 1b & 2b. Four Months After HF SCS. The signs and symptoms of CRPS have resolved.

Figure 1a

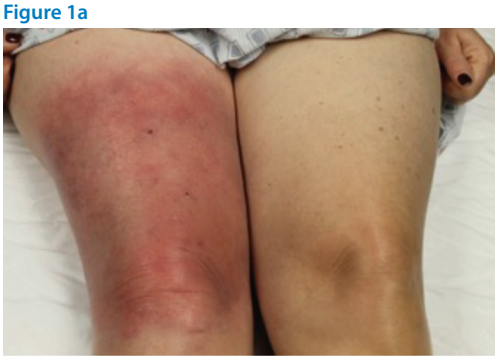


Figure 1b

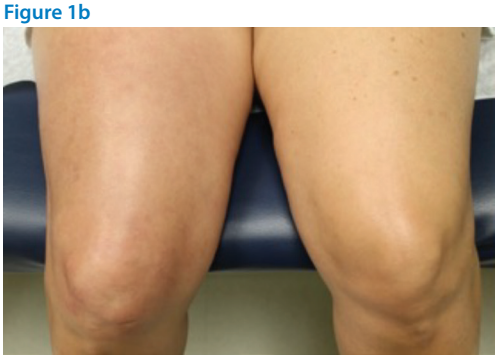


Figure 2a

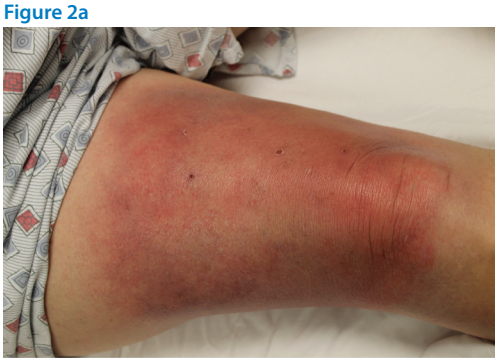
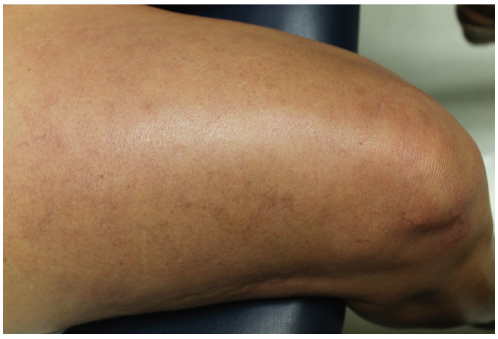


Figure 2b



Conclusion

The role of neuromodulation in chronic pain conditions continues to evolve. SCS have proven to be an effective means of treating a variety of these conditions. As the devices and technology continue to evolve, added benefits are being revealed. The rapid, dramatic response of our patient's myriad of symptomology to HF SCS is promising. Further investigation into the mechanism of action of HF SCS in the treatment of CRPS is warranted in the future.

References

International Association for the Study of Pain. Classification of chronic pain. 2nd edition (revised). www.iasppain.org/files/Content/ContentFolders/Publications2/ClassificationofChronicPain/Part_II-A.pdf.

Bruehl S. Complex regional pain syndrome. BMJ. 2015 Jul 29; 351:h2730.

Lewis JS, Kersten P, McCabe CS, et al. Body perception disturbance: a contribution to pain in complex regional pain syndrome (CRPS). Pain. 2007;133:111-9.

Van Velzen GA, Perez RS, van Gestel MA, et al. Health-related quality of life in 975 patients with complex regional pain syndrome type 1. Pain. 2014;155:629-34.

De Mos M, de Bruijn AG, Huygen FJ, et al. The incidence of complex regional pain syndrome: a population based study. Pain. 2007;129:12-20.

Jänig W, Baron R. Complex regional pain syndrome: mystery explained? Lancet Neurol. 2003;2:687-97.

Jänig W, Baron R. Complex regional pain syndrome is a disease of the central nervous system. Clin Auton Res. 2002;12:150-64

Oaklander AL, Fields HL. Is reflex sympathetic dystrophy/complex regional pain syndrome type I a smallfiber neuropathy? Ann Neurol. 2009;65:629-38.

Ross-Huot MC, Laferrière A, Khorashadi M, et al. Glycemia-dependent nuclear factor κB activation contributes to mechanical allodynia in rats with chronic postischemia pain. Anesthesiology. 2013;119:687-97.

Eisenberg E, Chistyakov AV, Yudashkin M, et al. Evidence for cortical hyperexcitability of the affected limb representation area in CRPS: a psychophysical and transcranial magnetic stimulation study. Pain. 2005;113:99-105.

Cheng JK, Ji RR. Intracellular signaling in primary sensory neurons and persistent pain. Neurochem Res. 2008;33:1970-8.

Drummond PD, Finch PM, Skipworth S, et al. Pain increases during sympathetic arousal in patients with complex regional pain syndrome. Neurol. 2001;57:1296-303.

Schinkel C, Scherens A, Köller M, et al. Systemic inflammatory mediators in post-traumatic complex regional pain syndrome (CRPS I)—longitudinal investigations and differences to control groups. Eur J Med Res. 2009;14:130-5.

Uçeyler N, Eberle T, Rolke R, et al. Differential expression patterns of cytokines in complex regional pain syndrome. Pain. 2007;132:195-205.

Goebel A, Blaes F. Complex regional pain syndrome, prototype of a novel kind of autoimmune disease. Autoimmune Rev. 2013;12:682-6.

Barad MJ, Ueno T, Younger J, et al. Complex regional pain syndrome is associated with structural abnormalities in pain-related regions of the human brain. J Pain. 2014;15:197-203.

Maihöfner C, Handwerker HO, Neundörfer B, et al. Cortical reorganization during recovery from complex regional pain syndrome. Neurology. 2004;63:693-701.

Van Rooijen DE, Roelen DL, Verduijn W, et al. Genetic HLA associations in complex regional pain syndrome with and without dystonia. J Pain. 2012;13:784-9.

De Jong JR, Vlaeyen JW, de Gelder JM, et al. Pain-related fear, perceived harmfulness of activities, and functional limitations in complex regional pain syndrome type I. J Pain. 2011;12:1209-18.

Beerthuizen A, Stronks DL, Huygen FJ, et al. The association between psychological factors and the development of complex regional pain syndrome type 1 (CRPS1)—a prospective multicenter study. Eur J Pain. 2011;15:971-5.

Potash M. Common sense in prescribing pain medications for the Louisiana physician. J La State Med Soc. 2010 Nov/Dec 162:317-324

Cossins L, Okell RW, Cameron H, Simpson B, Poole HM, Gobel A. Treatment of complex regional pain syndrome in adults: a systematic review of randomized controlled trials published from June 2000 to April 2010. Eur J Pain. 2013 Feb; 17(2) 158-173.

Bruehl: An Update on the Pathophysiology of Complex Regional Pain Syndrome. Anesthesiology 2010; 113:713-25

Kirkpatrick: International Update on Reflex Sympathetic Dystrophy/Complex Regional Pain Syndrome (RSD/ CRPS). Feb 1&2, 2002

Kapural L, Burgher AH, et al. Novel 10-kHz High-frequency Therapy (HF10 Therapy) Is Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: The SENZA-RCT Randomized Controlled Trial. Anesthesiology. 2015 Oct;123(4):851-60.

Stanton-Hicks MD, Burton AW, Bruehl SP, et al. An updated interdisciplinary clinical pathway for CRPS: report of an expert panel. Pain Pract. 2002;2:1-16.

Van de Vusse AC, Stomp-van den Berg SG, Kessels AH, et al. Randomised controlled trial of gabapentin in complex regional pain syndrome type 1 (ISRCTN84121379). BMC Neurol. 2004;4:13.

Harke H, Gretenkort P, Ladleif HU, et al. The response of neuropathic pain and pain in complex regional pain syndrome I to carbamazepine and sustained-release morphine in patients pretreated with spinal cord stimulation: a double-blinded randomized study. Anesth Analg. 2001;92:488-95.

O'Connell NE, Wand BM, McAuley J, et al. Interventions for treating pain and disability in adults with complex regional pain syndrome. Cochrane Database Syst Rev. 2013;4:CD009416

Al-Kaisy A, Van Buyten JP, Smet I, Palmisani S, Pang D, Smith T. Sustained effectiveness of 10 kHz highfrequency spinal cord stimulation for patients with chronic, low back pain: 24-month results of a prospective multicenter study. Pain Med. 2014 Mar;15(3):347-54.

Kemler MA, Barendse GA, van Kleef M, et al. Spinal cord stimulation in patients with chronic reflex sympathetic dystrophy. N Engl J Med. 2000;343:618-24.

Grider JS, Manchikanti L, Carayannopoulos A, Sharma ML, Balog CC, Harned ME, Grami V, Justiz R, Nouri KH, Hayek SM, Vallejo R, Christo PJ. Effectiveness of Spinal Cord Stimulation in Chronic Spinal Pain: A Systematic Review. Pain Physician. 2016 Jan;19(1):E33-54.

van Bussel CM, Stronks DL, Huygen FJPM. Complex regional pain syndrome type I of the knee: A systematic literature review. Eur J Pain. 2014;18(6):766-773,

the JOURNAL of East Jefferson General Hospital

Endoscopic Treatment of Reflux

Melissa Spera, M.D. Section of Gastroenterology, Department of Medicine, Louisiana State University Health Sciences Center School of Medicine, New Orleans, La, USA.
Gary Reiss, M.D. Section of Gastroenterology, Department of Medicine, Louisiana State University Health Sciences Center School of Medicine, New Orleans, La, USA.

Abstract

Gastroesophageal reflux disease (GERD) is one of the most common diseases encountered by a gastroenterologist and can have a significant effect on the quality of life of a patient. Treatment of GERD includes medical, surgical and endoscopic therapy. The goal of this paper is to review the currently available endoscopic therapies for GERD including Stretta, EsophyX™, MUSE™ and anti-reflux mucosectomy.

Key Words

GERD, Stretta, EsophyX™, MUSE™, anti-reflux mucosectomy.

Financial Disclosures

Dr. Reiss has received training grants / honoraria from Boston Scientific, Mederi, and Medtronic.

Introduction

Gastroesophageal reflux disease (GERD) is one of the most common diseases encountered with approximately nine million outpatient visits per year. GERD diminishes patients' quality of life with symptoms that occur daily to weekly, often resulting in decreased productivity and missed work(1-2). The prevalence of GERD in the Western world is estimated to be between 10-20% (1). Current treatment options include medical, surgical and endoscopic therapies. Proton pump inhibitor (PPI) therapy has been a mainstay in the medical management of GERD but it has been estimated that PPI therapy fails to control GERD symptoms in up to 40% of patients (1,3). In recent years, there has been concern about the safety and potential side effects of long term PPI use which has renewed interest in alternative treatment options(4).There are surgical options for the treatment of GERD including laparoscopic fundoplication or bariatric surgery in obese patients(1). Laparoscopic fundoplication is considered to be a gold standard of surgical treatment in patients with poorly controlled GERD symptoms on PPI therapy (5). Patients who undergo laparoscopic fundoplication have a re-intervention rate of about 15% and other possible adverse events including dysphagia, gas bloat syndrome and the inability to belch (3).

Several effective endoscopic techniques have been developed as alternatives to medical and surgical treatment of GERD (4, 5). These endoscopic therapies may be ideal for patients who seek a non-surgical, less invasive treatment option for their GERD or for those who do not respond to or are unwilling to continue long term PPI therapy. The following review will further discuss four endoscopic therapies for GERD including radio frequency energy ablation utilizing Stretta system, transoral incisionless fundoplication (TIF) using the Esophyx™ device and MUSE™ system, and anti-reflux mucosectomy (ARMS) procedure.

Endoscopic Radiofrequency Ablation

Stretta

The Stretta procedure applies radiofrequency energy to the lower esophageal sphincter (LES) and the gastric cardia for the treatment of GERD (6, 7). The Stretta system (Mederi Therapeutics, Greenwich, CT) was introduced in 2000 as an alternative to chronic medical therapy or surgical intervention for GERD (7). The procedure is performed on an outpatient basis and can be performed in an endoscopy suite using conscious sedation or monitored anesthesia care. Endoscopy is performed to document the distance from the bite block to the squamocolumnar junction (Z-line). The Stretta catheter is passed transorally over a guidewire and positioned 1 cm above the Z-line. The Stretta catheter is made up of a soft, flexible bougie tip and a balloon basket assembly with four nickel-titanium needle electrodes that are positioned radially around the balloon. A four-channel generator then delivers temperature controlled non-ablative radiofrequency (NARF) energy to the smooth muscle of the gastroesophageal junction via the needle electrodes (8). Stretta is thought to treat GERD by increasing LES pressure secondary to tissue hypertrophy, decreasing esophagogastric junction compliance, reducing transient LES relaxation by neural modulation of the distal esophagus or by improving gastric emptying (9).

The Stretta procedure has been extensively studied over the past 15 years including a recent systematic review and meta-analysis by Fass et al. The meta-analysis included 28 studies involving 2468 Stretta patients. The outcomes of interest were the relief of symptoms associated with GERD. Three symptom variables and three physiological markers were used in the meta-analysis including: PPI use, GERD-health related quality of life scores (HRQL), heartburn score, presence of erosive esophagitis, esophageal acid exposure and LES basal pressure. Prior to Stretta, 97.1% of patients were using PPI for GERD therapy. Following Stretta, only 49% of patients were still using PPI therapy. Stretta reduced (improved) the HRQL score by a mean of -14.60 ($P<0.001$). Stretta treatment reduced (improved) the heartburn standardized score significantly ($P<0.001$, N=12 studies) by -1.53, statistically better than the control subgroup ($P=0.01$). The Stretta treatment reduced the incidence of erosive esophagitis by 24% ($p<0.001$) and reduced esophageal acid exposure by a mean of -3.01 ($P<0.001$). Stretta treatment increased (improved) the pooled estimate of LES basal pressure by +1.73mmHg ($P=0.09$, N=9 studies) but this was not significantly different than sham. This study concluded that the Stretta procedure significantly improved subjective and objective clinical endpoints as discussed above with the exception of LES basal pressure and should be considered as a viable addition to GERD management (7). Adverse events of Stretta were infrequent and typically minor. The Stretta procedure appears to relieve GERD symptoms for up to 10 years in the majority of patients (10).

The Stretta procedure may be recommended as an appropriate therapeutic option in GERD patients, eighteen years old or older, who chose endoluminal therapy over laparoscopic fundoplication with symptoms of heartburn, regurgitation or both for 6 months or more who have been partially or completely responsive to antisecretory pharmacologic therapy (11). Other potential candidates for Stretta are those who cannot tolerate PPI therapy, those who desire to stop drug therapy, those who do not wish to undergo anti-reflux surgery and those who are considered to be poor surgical candidates. Stretta may also be used to treat GERD in patients who have undergone prior gastric bypass or subtotal gastrectomy (6).

Transoral Incisionless Fundoplication (TIF)

EsophyX™ Device

Transoral incisionless fundoplication (TIF) using the EsophyX™ device (Endogastric Solutions, Redmond, Washington, USA) is an endoscopic treatment for GERD that uses an endoscopic approach to repair the anatomical defects of the LES by creating a gastric fundal wrap and plication, similar to a laparoscopic fundoplication (9). This procedure has undergone several modifications since it was originally introduced in 2007 (3, 10). TIF 1.0 was initially a gastro-gastric stapling technique which later evolved into TIF 2.0 creating an esophagogastric plication (12). The TIF procedure using the EsophyX™ (TIF 2.0) device is performed under general anesthesia. The device is inserted transorally with an endoscope into the stomach and the procedure is performed under endoscopic visualization. Using the EsophyX™ device the fundus is folded and wrapped around the distal esophagus with fasteners placed through the apposed walls of the esophagus and stomach. This maneuver is repeated until it creates a full thickness, esophagogastric fundoplication above the Z-line. The fundoplication may extend up to 3.5 cm long and between 270° and 330° circumferentially (13).

Studies have shown that TIF using the EsophyX™ device is efficacious in treating GERD. Hunter et al performed a sham controlled randomized controlled trial of TIF plus placebo vs sham plus PPI which showed by intention to treat analysis that TIF eliminated regurgitation symptoms in a larger amount of patients (67%) than PPIs (45%) (P=.023) (14). A recent systematic review and meta-analysis by Huang et al showed the pooled relative risk of response rate to TIF vs PPI/sham was 2.44 (95% CI 1.25-4.79, p=0.0009) in randomized controlled trials in the intention to treat analysis. Patients who underwent TIF showed a significant decrease in episodes of reflux compared to those who did not undergo TIF but there was no difference in acid reflux episodes between the two groups. The total satisfaction rate after TIF in this study was 69.15% six months after the procedure. A limitation of this meta-analysis was the high degree of heterogeneity among the studies included (12). The TEMPO trial from Trad et al showed a three year follow up study in which symptoms of regurgitation (88%) and atypical GERD symptoms (88%) resolved following TIF. This study also showed the mean Reflux Symptom Index score (RSI) of patients improved from 22.2 (9.2) on PPIs down to 4 (7.1) off PPIs three years later following TIF. GERD-HRQL improved from 26.4 (9.4) on PPIs at initial screening to 5.0 (9.2) off PPIs three years post TIF, p<0.0001. Trad et al also showed that previously noted esophagitis had healed in 86% of patients and at the end of the study 71% of patients had discontinued use of their PPIs (13). Testoni et al showed that TIF by the EsophyX™ device achieved elimination of daily PPI use in 75-80% of patients for up to six years. This study also noted that factors that predict good long term outcomes of TIF include: pre procedure Hill's grade I-II gastroesophageal valve, no hiatal hernia or hernia≤ 2cm (p=0.03), absence of ineffective esophageal motility (p<0.0001), and number of fasteners deployed (p=0.01) (15). Based on the results of several case studies and registry reports both the TIF technique and EsophyX™ device have undergone modifications and have evolved to improve outcomes and decrease procedure related complications (15). This evolution of the technique and the device complicate interpretations of the data relating to TIF and EsophyX™.

The TIF procedure with the EsophyX™ device is recommended as a therapeutic option in select GERD patients with a small (<2cm) or absent hiatal hernia who have incomplete control of their symptoms on PPI therapy and those do not wish to undergo laparoscopic anti-reflux surgery (13). The overall complication rate ranges from 3-10%. Possible complications include bleeding, mucosal tears, perforation, pneumothorax and mediastinal abscess (15).

Medigus Ultrasonic Surgical Endostapler (MUSE™)

The MUSE™ system (Medigus, Omer, Israel) is a transoral endoscopic stapling device that is used to create an anterior or partial fundoplication as a treatment for GERD (16). MUSE™ is performed under general anesthesia. A flexible stapler is passed trans orally into the stomach and used to place two or three quintuplets of titanium staples attaching the fundus of the stomach to the esophagus about 3cm above the gastroesophageal junction to create a wrap covering 180 ° of the esophagus (17). This anterior fundoplication is functionally similar to the surgical Dor-Thal operation (4).

A pilot study of this device was initiated in 2007 and included 13 patients. Efficacy data was shown by 6 weeks following the procedure. GERD-HRQL scores in these patients improved by 50% off of PPI therapy. Mean total acid exposure was significantly reduced (p<0.002) from 16.3 to 8.6. Fifty four percent of patients had normalized acid exposure post procedure as defined by a total time pH< 4 or 5% or less. Daily PPI use was eliminated in 92% of patients. Five year data in the thirteen patients showed that 3 patients had resumed PPI therapy but with a dose reduction of > 50%. All patients reported satisfaction with their symptom elimination from the procedure and would undergo the MUSE™ procedure again (17). Zacherl et al performed a multicenter, prospective trial of sixty six patients with GERD who underwent MUSE™ at six international sites between 2008 and 2010. The primary endpoint of this study was met and showed at least a 50% reduction in GERD-HRQL score off PPI from pre procedure values in 48 out of 66 patients (73, 95% CI 60-83%) at 6 months following the procedure. Eighty five percent of patients (55/65) who were taking a PPI prior to the procedure showed a reduced dose or frequency by 50% post procedure. There was a statistically significant reduction in total acid exposure on esophageal pH monitoring six months following the procedure. However, in the first twenty four patients, there were eight serious adverse events (SAE), two were severe and included an empyema with pneumothorax and upper gastrointestinal hemorrhage. A review was performed following these SAE which resulted in protocol and device changes. Following these changes there were no further SAE in the next forty eight cases (16). Long term follow up results of the same cohort of patients were evaluated by Kim et al looking at the efficacy and safety data for 37 of 66 patients who underwent MUSE™ in the study by Zacherl et al (16, 18). Kim et al showed that 83.8 % (31/37) patients remained off PPI following MUSE™ at 6 months and 69.4 % (25/36) remained off PPI at 4 years after MUSE™. GERD-HRQL scores off PPI improved from 29.1 to 8.9 at 6 months (P<0.01, compared to baseline) and to 5.3 at 4 years post procedure (P<0.01, compared to baseline and 6 months). No new SAE were reported beyond the initial 6 month follow up (16, 18). A limitation to the MUSE™ system is that there are a limited number of studies evaluating efficacy. More long term studies, ideally randomized controlled trials, are needed to further assess the long term efficacy of MUSE™ (4).

The MUSE™ system is FDA approved in the United States as an endoscopic device to create an anterior fundoplication for the treatment of symptomatic GERD. This procedure is a treatment option for patients who are seeking to reduce or discontinue use of medical therapy for

GERD or those looking to avoid incisional therapies like laparoscopic fundoplication to treat their GERD (16).

Anti-reflux mucosectomy (ARMS)

In 2003, Inoue et al reported a case of circumferential endoscopic mucosal resection (EMR) of the distal esophagus and gastric cardia which was performed as a treatment for high grade dysplasia in short segment Barrett's esophagus. This treatment for Barrett's esophagus also resulted in improvement in the patients' GERD symptoms and was termed anti-reflux mucosectomy. Stricture formation was a complication of the first two procedures performed due to the circumferential nature of the EMR and required multiple balloon dilation procedures to resolve this issue. The procedure was then changed to a subtotal dissection of the distal esophagus or crescentic ARMS (5).

This pilot study consisted of ten patients with refractory GERD who underwent ARMS. The first two patients had circumferential ARMS performed then the subsequent eight patients had crescentic ARMS. Symptoms of GERD significantly improved following the ARMS procedure. DeMeester score mean heartburn score decreased from 2.7 to 0.3 (P=0.0011), regurgitation score from 2.5 to 0.3 (P=0.0022) and the total DeMeester score decreased from 5.2 to 0.67 (P=0.0011). Esophageal pH monitoring post ARMS showed the percent of time at a pH< 4 improved from 29.1% to 3.1% (P=0.01). PPI therapy was continued for forty days post procedure but then discontinued without issues in all ten patients (5).

This study suggests a possible anti reflux effect of the ARMS procedure. The mechanism of action is thought to be due to scar formation in the lower esophagus and a narrowing of the opening of the gastric cardia. Possible complications of this technique are similar to other EMR procedures and include bleeding, stricture, and perforation. A possible advantage of this procedure over other endoscopic anti reflux procedures is that ARMS does not require the use of proprietary equipment and no artificial prostheses like staples or sutures are left in place. ARMS is a promising endoscopic treatment for GERD but larger studies are needed to further assess these results (5).

Conclusion

Endoscopic therapies are an option in the treatment of GERD in well selected patients. The Stretta procedure has been shown to be a safe and effective anti-reflux procedure in adult patients with poorly controlled reflux despite medical therapy and in those who do not wish to pursue surgical therapy. EsophyX™ and MUSE™ are two examples of transoral fundoplication which are minimally invasive, compared to traditional laparoscopic fundoplication, and have been shown to reduce GERD symptoms and PPI use. ARMS is a promising upcoming endoscopic treatment for GERD. While more studies are needed to fully evaluate ARMS as a treatment for GERD, a variety of endoscopic treatments are now available for patients suffering from GERD.

References

1. Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease. *Am J Gastroenterol*. 2013 Mar; 108(3):308-28; doi: 10.1038/ajg.2012.444.

2. Peery AF, Dellon ES, Lund J, et al. Burden of gastrointestinal disease in the United States: 2012 update. Gastroenterology. 2012 Nov; 143(5):1179-87.e1-3. doi: 10.1053/j.gastro.2012.08.002.

3. Nabi Z, Reddy DN. Endoscopic Management of Gastroesophageal Reflux Disease: Revisited. *Clin Endosc*. 2016 Sep; 49(5):408-416.

4. Testoni PA, Mazzoleni G, Testoni SG. Transoral incisionless fundoplication for gastro-esophageal reflux disease: Techniques and outcomes. *World J Gastrointest Pharmacol Ther*. 2016 May 6; 7(2):179-89. doi: 10.4292/wjgpt.v7.i2.179.

5. Inoue H, Ito H, Ikeda H, et al. Anti-reflux mucosectomy for gastroesophageal reflux disease in the absence of hiatus hernia: a pilot study. Ann Gastroenterol. 2014; 27(4):346-351.

6. Triadafilopoulos G. Stretta: a valuable endoscopic treatment modality for gastroesophageal reflux disease. *World J Gastroenterol*. 2014 Jun 28; 20(24):7730-8. doi: 10.3748/wjg.v20.i24.7730.

7. Fass R, Cahn F, Scotti D, Gregory D. Systematic review and meta-analysis of controlled and prospective cohort efficacy studies of endoscopic radiofrequency for treatment of gastroesophageal reflux disease. *Surg Endosc*. 2017 Feb 23. doi: 10.1007/s00464-017-5431-2.

8. Richards WO, Houston HL, Torquati A, Khaitan L, Holzman MD, Sharp KW. Paradigm shift in the management of gastroesophageal reflux disease. *Ann Surg*. 2003 May; 237(5):638-47; discussion 648-9.

9. Hillman L, Yadlapati R, Whitsett M, Thuluvath AJ, Berendsen MA, Pandolfino JE. Review of antireflux procedures for proton pump inhibitor nonresponsive gastroesophageal reflux disease. *Dis Esophagus*. 2017 Sep 1; 30(9):1-14. doi: 10.1093/dote/dox054.

10. ASGE Standards of Practice Committee, Muthusamy VR, Lightdale JR, et al. The role of endoscopy in the management of GERD. *Gastrointest Endosc*. 2015; 81(6):1305-10. doi: 10.1016/j.gie.2015.02.021.

11. Auyang ED, Carter P, Rauth T, Fanelli RD; SAGES Guidelines Committee. SAGES clinical spotlight review: endoluminal treatments for gastroesophageal reflux disease (GERD). *Surg Endosc*. 2013 Aug; 27(8):2658-72. doi: 10.1007/s00464-013-3010-8.

12. Huang X, Chen S, Zhao H, et al. Efficacy of transoral incisionless fundoplication (TIF) for the treatment of GERD: a systematic review with meta-analysis. *Surg Endosc*. 2017 Mar; 31(3):1032-1044. doi: 10.1007/s00464-016-5111-7.

13. Trad KS, Fox MA, Simoni G, et al. Transoral fundoplication offers durable symptom control for chronic GERD: 3-year report from the TEMPO randomized trial with a crossover arm. *Surg Endosc*. 2017 Jun; 31(6):2498-2508. doi: 10.1007/s00464-016-5252-8.

14. Hunter JG, Kahrilas PJ, Bell RC, et al. Efficacy of transoral fundoplication vs omeprazole for treatment of regurgitation in a randomized controlled trial. *Gastroenterology*. 2015 Feb; 148(2):324-333.e5. doi: 10.1053/j.gastro.2014.10.009.

15. Testoni PA, Testoni S, Mazzoleni G, Vailati C, Passaretti S. Long-term efficacy of transoral incisionless fundoplication with Esophyx (Tif 2.0) and factors affecting outcomes in GERD patients followed for up to 6 years: a prospective single-center study. *Surg Endosc*. 2015 Sep; 29(9):2770-80. doi: 10.1007/s00464-014-4008-6.

16. Zacherl J, Roy-Shapira A, Bonavina L, et al. Endoscopic anterior fundoplication with the Medigus Ultrasonic Surgical Endostapler (MUSE™) for gastroesophageal reflux disease: 6-month results from a multi-center prospective trial. *Surg Endosc*. 2015 Jan; 29(1):220-9. doi: 10.1007/s00464-014-3731-3.

17. Roy-Shapira A, Bapaye A, Date S, Pujari R, Dorwat S. Trans-oral anterior fundoplication: 5-year follow-up of pilot study. *Surg Endosc*. 2015 Dec; 29(12):3717-21. doi: 10.1007/s00464-015-4142-9.

18. Kim HJ, Kwon CI, Kessler WR, et al. Long-term follow-up results of endoscopic treatment of gastroesophageal reflux disease with the MUSE™ endoscopic stapling device. *Surg Endosc*. 2016 Aug; 30(8):3402-8. doi: 10.1007/s00464-015-4622-y.

Joint Commission Survey: A Physicians' Guide

Ruby Brewer, RN, MSN/MBA, Chief Nurse Executive/Chief Quality Officer, East Jefferson General Hospital
Donna M. Carbajal RN, RRT, RRT-NPS, MBA, CJCP, Senior Director of Quality/Organizational Effectiveness

Joint Commission Survey: What to Expect

Joint Commission is coming! EJGH is currently in our Joint Commission triennial "survey window" for Acute and Skilled Units, including Family Practice and offsite clinical areas. As a reminder, the survey is unannounced; therefore, we are focused on compliance every day. We expect a four day survey with at least 4 surveyors, including a Physician. Medical Staff will be notified of surveyor arrival via overhead paging system, notification on Cerner sign on box and an all user emails. During the evaluation, the surveyors will trace patient care from entry to discharge as well as interview staff and physicians during tracers and special session interviews to assess EJGH's compliance with Joint Commission standards and CMS (Centers for Medicare and Medicaid) conditions of participation.

Special sessions in which physicians may be asked to participate include the following:

- **Medical Staff Credentialing and Privileging** (30-60 minutes)
  - Learn about the process used to collect data relevant to granting and delineating privileges.
  - Evaluate FPPE (Focused Professional Practice Evaluation) and OPPE (Ongoing Professional Practice Evaluation), credentialing process, and determining if practitioners are practicing within the scope of delineated privileges.
- **Emergency Management** (60-90 minutes)
  - Planning performance for the six critical functions:
  - Communication (including backup communications capabilities)
  - Resources and assets
  - Safety and Security
  - Staff responsibilities (including orientation/ competency training of staff
  - Utilities management
  - Patient and clinical support activities
  - Disaster privileging process
- **Data Use/Management** (60 minutes)
  - How is data used in the organization to drive improvement
  - Examples of EJGH process improvement and dashboards will be presented
  - Opportunity for to highlight our best improvement projects
- **Infection Control** (60 minutes)
  - Learn about the planning, implementation, and evaluation of your organization's infection control program.
- **Leadership Session** (60 minutes)

  During this session, surveyors will explore, through organization-specific examples:
  - Leadership commitment to improvement of quality and safety
  - Creating a culture of safety
  - Robust process improvement
  - Observations that may be indicative of system-level concerns
  - Leadership's awareness of successes and opportunities along with support for improvement.

Commitment to excellence and involvement in quality, safety and performance improvement initiatives is an EJGH physician specialty. Let's make sure we highlight our many successes during the Joint Commission survey.

Antibiotic Stewardship: New Medication Standard for Joint Commission

Current scientific literature emphasizes the need to reduce the use of inappropriate antimicrobials in all health care settings due to antimicrobial resistance. The Centers for Disease Control and Prevention (CDC) identified that 20%–50% of all antibiotics prescribed in US acute care hospitals are either unnecessary or inappropriate. In January 2017, the Joint Commission added a new Medication Management (MM) standard for hospitals and nursing care centers. The standard addresses antimicrobial stewardship. Surveyors will include review of this standard during tracers and medication management and leadership session interviews.

EJGH's Quality Council established a multidisciplinary Performance Improvement team to conduct a gap analysis and establish a process to ensure compliance.

- **Project Purpose**: The team will focus on improving appropriate use of antimicrobials by promoting the selection of optimal drug regimens, dose, duration and route of administration. Achieve optimal clinical outcomes related to antimicrobial use, minimize toxicity and other adverse events, and improve antibiotic susceptibility rates.

Recent literature suggests up to 50% antibiotic over use may exist. In addition, EJGH's antibiogram does reveal some resistance trends and C-diff rates are above expected national SIR.

- **AIM Statement**: Achieve 20% reduction in overall ABX utilization as measured by decrease expenditures (DOT/1000 Pt. Days).

CDC (Centers for Disease Control) Summary of Core Elements of Hospital Antibiotic Stewardship Programs

- **Leadership Commitment**: Dedicating necessary human, financial and information technology resources.
- **Accountability**: Appointing a single leader responsible for program outcomes. Experience with successful programs show that a physician leader is effective.
- **Drug Expertise**: Appointing a single pharmacist leader responsible for working to improve antibiotic use.
- **Action**: Implementing at least one recommended action, such as systemic evaluation of ongoing treatment need after a set period of initial treatment (i.e. "antibiotic time out" after 48 hours).
- **Tracking**: Monitoring antibiotic prescribing and resistance patterns.
- **Reporting**: Regular reporting information on antibiotic use and resistance to doctors, nurses and relevant staff.
- **Education**: Educating clinicians about resistance and optimal prescribing

Core elements of hospital antibiotic stewardship programs: Pharmacist Interventions

- Changes from intravenous to oral antibiotic therapy in appropriate situations and for antibiotics with good absorption which improves patient safety by reducing the need for intravenous access.
- Dose adjustments in cases of organ dysfunction (e.g. renal adjustment).
- Dose optimization including dose adjustments based on therapeutic

drug monitoring, optimizing therapy for highly drug-resistant bacteria, achieving central nervous system penetration, extended-infusion administration of beta lactams, etc.
• Alerts in situations where therapy might be unnecessarily duplicative including simultaneous use of multiple agents with overlapping spectra e.g. anaerobic activity, atypical activity, Gram-negative activity and resistant Gram-positive activity.
• Time-sensitive automatic stop orders for specified antibiotic prescriptions, especially antibiotics administered for surgical prophylaxis.
• Detection and prevention of antibiotic-related drug-drug interactions e.g. interactions between some orally administered fluoroquinolones and certain vitamins.

Focus on HAI (Hospital Acquired Infection) Prevention

As hand hygiene is widely known to be the most important intervention for preventing HAIs, The Joint Commission requires organizations to implement a hand hygiene program, set goals for improving compliance with the program, monitor the success of those plans, and steadily improve the results through appropriate actions. Surveyors will conduct observations of staff and physicians' compliance with hand hygiene and isolation compliance during the various tracers conducted in clinical areas.

In addition, observation of pre-cleaning instruments, sterilization process, high level disinfection and appropriate surgical attire will assist surveyors in scoring EJGH's compliance with standards. Appropriate surgical attire includes full coverage of hair and beard during surgery / procedures and removal of surgical mask, shoe covers, etc. outside of the surgical/procedure area. Full hair covering has been fiercely debated as to whether or not it actually contributes to SSI (surgical site infection); however, Joint Commission and CMS stand firm on their interpretation of this standard. Failure to comply with this standard will result in a citation for EJGH.

Infection Prevention is a hot topic for the Joint Commission due to the national increase of HAI and impact on the risk for patients. Thus, non-compliance with standards may result immediate jeopardy. Immediate jeopardy means a direct threat to patient safety has been observed and will require an urgent response or risk preliminary denial of Joint Commission Accreditation and possibly a CMS survey.

Handoff Communication

A patient's journey through a care setting can be enormously complex and is ripe for critical communication breakdowns, presenting a clear and present threat to his or her safety. The Risk Management Foundation of Harvard Medical Institutions survey found communication failures in hospitals and medical practices were at least in part for 30 percent of all malpractice claims, resulting in 1,744 deaths and $1.7 million dollars in malpractice costs over five years[1].

Joint Commission will survey handoff communication while tracing patient care throughout the organization. Eight Tips for Quality Hand-Offs was produced by Joint Commission (graphic 1).

Physicians should be able to discuss hand-off communication during transitions from ED to Unit, Attending to Consultant, Attending to Cross-covering physician, etc. Although face-to-face is the most useful hand-off, electronic methods are valuable as well. Cerner physician M-Page offers a one page review of the patient's current status. In addition, several physicians have developed forms in Cerner to allow more standardized hand-off communication.

Physician Specific Hot Topics

Time Out: Time Out is part of the Joint Commission's Universal Protocol. In the past, we were cited for lack of suspending all activity during the time out. Remember to use the Safe Surgery Checklist posted in every OR and Procedure room and stop all activity during the time out to ensure compliance with Joint Commission standards. Using the checklist on every patient every time will make complying with this standard easy.

Alarm Management: Joint Commission standards require the organization review alarms and establish standardized settings as well as the process for adjusting settings according to individual patient needs. EJGH has a policy for setting initial alarms on selected critical equipment. Clinicians should contact the physician if standard settings are not meeting the patient needs to allow adjustments to alarms and documentation of discussion (i.e. order).

Critical Drip Titration: Patients require immediate adjustments to critical drips; therefore, standard protocols and orders have been established to ensure nurses are following physician protocols. Joint Commission will survey this standard by comparing the physician's titration and clinical parameter order details, patient vital signs and nurses' adjust of the critical drip. Variation from order or lack of clinical parameter to support critical drip changes will result in non-compliance. Physicians can assist by using the established order sets for critical drips which have all order elements required by Joint Commission.

Consents: Patient consents are the focus for Joint Commission and CMS. Elements required for a complete consent are: procedure name, physician/proceduralist, material risks, patient information, and signatures of the proceduralist/patient/witness with date of signature. Completed consent must be available prior to the start of surgery or procedure.

H&P and addendums: A history and physical is due within 24 hours after inpatient admission. However, an H&P must be completed after registration but prior to the surgery/procedure. Addendums are acceptable if the H&P is completed within 30 days prior to surgery/ procedure otherwise a new H&P is required. Addendums must include an attestation a physical exam was completed as well as any pertinent changes from the prior H&P. EJGH H&P addendum has the preferred language listed for the physician.

Pain Orders and Therapeutic Duplication: Patient pain orders must address all levels of the pain scale. An order addressing only 1-3 or mild pain creates a challenge if the patient states pain level is above 4. Technically, the pain order does not address the medication to be administered for the patient's pain; therefore, the nurse would have to call the physician for instruction.

Inclusion of patient choice in your pain orders will allow the nurse to administer a pain medication for a lower level of pain even though the patient's stated pain level is higher.

Let's review the following scenario:

Pain orders list Tylenol for pain level 1-3 and IV Dilaudid for 4-7. Patient states pain level is 5. The nurse informs the patient the physician has ordered IV Dilaudid for their pain level. However, the patient states they want the Tylenol not Dilaudid. Under the current orders, the nurse would have to contact the physician for authorization to give a pain medication outside the ordered pain level.

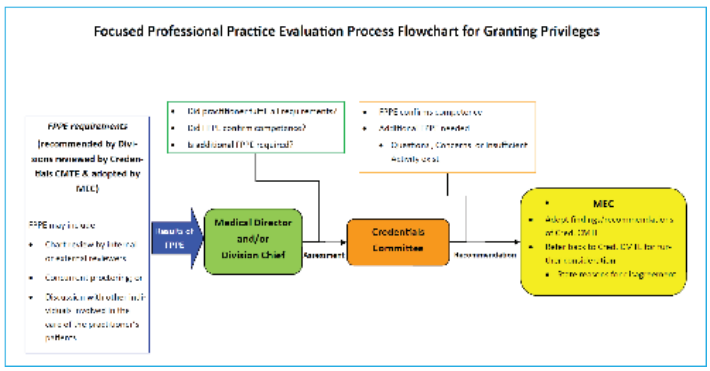
Ordering of multiple medications for the same indication can result in therapeutic duplication. For example, ordering Zofran and Phenergan for nausea without any further clarification would be cited by Joint Commission. Order must be clear and distinct enough for any nurse (expert or novice) to follow without confusion or miscommunication. Including more instruction within the order would resolve this issue: i.e. Zofran times two doses; if no relief, administer Phenergan.

FPPE/OPPE

Since the continuation of clinicians' privileges at a hospital hinges on the quality and safety of care delivered to patients, the review of privileges is a critical – and sensitive – process. This responsibility falls on the medical staff, which monitors the performance of all practitioners who are granted privileges and makes recommendations to the governing body of the hospital concerning which medical staff members should receive new or maintain existing privileges.

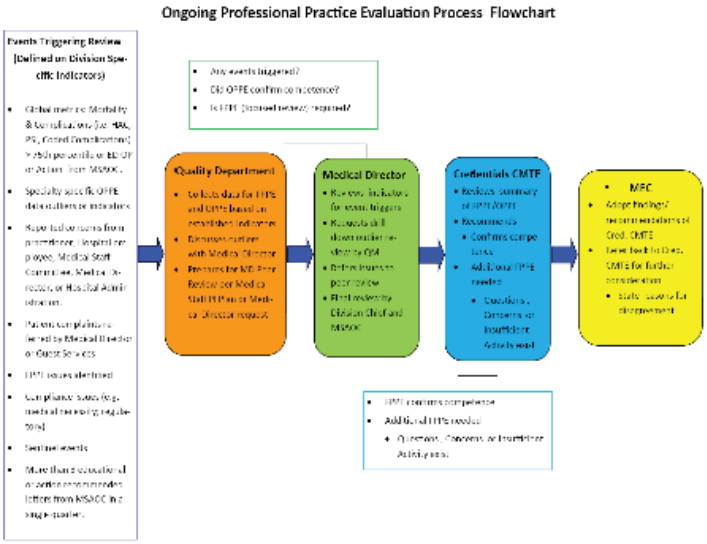
In order to make the decision of privileging more objective and continuous, in 2007 The Joint Commission introduced its Ongoing Professional Practice Evaluation (OPPE) and Focused Professional Practice Evaluation (FPPE) processes. These tools were created to work together to help determine if the care delivered by a practitioner falls below an acceptable level of performance. It is important to note that neither FPPE nor OPPE on its own is capable of making an adequate assessment, but instead it is the thoughtful and judicious use of both that is required.

FPPE: Focused professional practice evaluation is a process whereby the organization evaluates the privilege-specific competence of the practitioner who does not have documented evidence of competently performing the requested privilege at the organization. The below figure outlines EJGH's process and flow of information regarding FPPE.



OPPE: Ongoing professional practice evaluation is a process to evaluate privilege-specific competence of the practitioner more frequently than the every 2 year credentialing cycle and identify clinicians who might be delivering an unacceptable quality of care. OPPE indicators serve as a screening tool with established thresholds for each indicator. Therefore, prior to concluding the physician or AHP quality issue based on non-compliance with the indicator threshold, a drill down into the data is required.

EJGH conducts reviews every eight months for physicians and allied health professionals credentialed through the medical staff office. The below figure outlines EJGH's process and flow of information regarding OPPE.



During the Credential Session, Joint Commission surveyors will review credential and quality files for compliance with Medical Staff standards.

References

1. CRICO Strategies. Malpractice risk in communication failures; 2015 Annual Benchmarking Report. Boston, Massachusetts: The Risk Management Foundation of the Harvard Medical Institutions, Inc., 2015 (registration required for download)

In order to increase Medical Staff awareness of the clinical research taking place at EJGH, the open clinical trials at our institution are listed below. For more information regarding a particular study, please contact Mr. David Potter at 504-503-4283/dpotter@ejgh.org or the principal investigator.

Open Studies January 2018

NAME OF STUDY	PRINCIPAL INVESTIGATOR Date Approved
EJ-BB-0703 The Pattern of Colonic Bacterial Flora in Infants with Necrotizing Entercolitis (Institute of Research at Children's Hospital/LSUHSC)	Dr. Raegan Wetzel Gupta, Principal Investigator Dr. Brian Barkemeyer, Dr. Michael Ferris, Dr. Duna Penn, and Valerie McMurtry, Co-Investigators 03/06/07 EJGH 2007-03 **Annual report expires May 2, 2018**
EJ-GM-0902 Validation of a Screening Questionnaire for Androgen Deficiency in a Family Practice Setting (EJGH Internal Study)	Gordon Magonet, MD, Principal Investigator, EJGH Paula Rhode, Ph.D., Co-Investigator Linda Collings, Ph.D., Co-Investigator Ka-Yan Tong, MD, Co-Investigator 03/03/09 EJGH 2009-02 **Annual report expires May 2, 2018**
EJ-AC-1303 **Chart Review:** The Pregnancy Outcomes in Patients Carrying Fetuses with Thickened Nuchal Translucency in the United States Diversified Population	Dr. Ann Chau, Principal Investigator Dr. David Goodyear, Co-Investigator 05/07/2013 EJGH 2013-03 **Annual report expires May 2, 2018**
EJ-AC-1304 **Chart Review:** Prenatal and Postnatal Course of Isolated Ventricular Septal Diagnosed by Color Doppler Sonography	Dr. Ann Chau, Principal Investigator Dr. Christian Lilje, Co-Investigator Dr. Nancy Ross-Ascuitto, Co-Investigator Mr. Andrew Jones, Co-Investigator 05/07/2013 EJGH 2013-04 **Annual report expires May 2, 2018**
EJ-AC-1501 **Chart Review:** The Comparison of the Transabdominal Ultrasound Versus the Transvaginal Ultrasound of the Cervical Evaluation Among the Obstetric Patients with and Without the History of a Previous Preterm Delivery	Dr. Ann Chau, Principal Investigator, EJGH Dr. Adriana Luciano, Co-Investigator Dr. Jay Davis, Co-Investigator 03/03/2015 EJGH 2015-01 **Annual report expires March 7, 2018**
EJ-LH-1601 **Nursing Research Study:** Does the Use of a Peanut Ball, to Facilitate Positioning to Widen the Pelvic Outlet, Reduce Length of Labor and Cesarean Section Rate in Women Laboring with an Epidural? **(Closed to Further Patient Enrollment)**	Lisa Hickey, RNC, Principal Investigator Jane Savage, RN, PhD, CNE, Co-Investigator 09/13/2016 EJGH 2016-01 **Annual report expires November 7, 2018**
EJ-JL-1604 **Data Collection Study:** Ultrasound-Assisted Planning in Plastic and Reconstructive Surgery: Visualization of Perforators and the Superficial Fascial System	Dr. John Lindsey, Principal Investigator Dr. Radbeh Torabi, Co-Investigator, LSUHSC Martin Carney, Soobin Lim, John Miller, Research Assistants 11/01/2016 EJGH 2016-04 **Annual report expires November 7, 2018**
EJ-RV-1701 **Patient Chart Review Study:** Family Study of IgM-mediated Cold Agglutinin Disease	Principal Investigator: Dr. Robert Veith Co-Investigator: Jacob Veith, BS 01/10/2017 EJGH 2017-01 **Annual report expires January 10, 2018**

NAME OF STUDY	PRINCIPAL INVESTIGATOR Date Approved/Date Waived Jurisdiction
EJ-BG-1702 **Chart Review Study:** De-escalation of Empirically Broad Spectrum Antibiotics in Hospital-Acquired Pneumonia, Ventilator-Assisted Pneumonia and Community-Acquired Pneumonia patients at EJGH	Brittany Guillory, PharmD. Principal Investigator Anh Le, PharmD and Taraya Gerard, PharmD. 09/12/2017 EJGH 2017-02 **Annual report expires September 12, 2018**
EJ-FA-1703 **Chart Review Study:** SGLT2 Inhibitors as Adjunct to Insulin therapy in Type 2 Diabetes	Principal Investigators: Fahamina Ahmed, PharmD & Taraya Gerard, PharmD Co-Primary Investigator: Candace Hopgood, PharmD 09/12/2017 EJGH 2017-03 **Annual report expires September 12, 2018**
EJ-TZ-1704 **Nursing Survey:** Survey to Examine Barriers to Compliance with Sequential Compression Device Use in Bedside Nurses	Primary Investigator: Tara Zaabel, RN, BSN, EJGH and Southeastern University College of Nursing and Health Sciences 09/12/2017 EJGH 2017-04 **Annual report expires September 12, 2018**
EJ-AC-1705 **Chart Review Study:** The Comparison of the 3D (three dimensional) Transabdominal Cervical Ultrasound Versus the 2D (two dimensional) Transabdominal and 2D Transvaginal Cervical Ultrasounds in Pregnant Women High-Risk for Pre-Term Births	Dr. Ann Chau, Principal Investigator, EJGH Dr. Barbara Neuhoff, Co-Investigator 11/7/2017 EJGH 2017-05 **Annual report expires November 7, 2018**
Protocol: CA209141: *An Open Label, Randomized Phase 3 Clinical Trial of Nivolumab vs. Therapy of Investigator's Choice in Recurrent or Metastatic Platinum-refractory Squamous Cell Carcinoma of the Head and Neck (SCCHN) (Bristol-Myers Squibb)*	Dr. Thomas Cosgriff, Principal Investigator **Western Institutional Review Board, Puyallup, Washington** Date EJGH IRB Waived Jurisdiction 07/01/2014
Southern Area Patient Oriented Research Organization (SAPORO)	Dr. Clarissa Hoff, MD, Ph.D., Principal Investigator, Tulane Department of Family and Community Medicine Dr. Patrick O'Callaghan, Ph.D., EJGH Family Medicine Residency Program **Tulane IRB, New Orleans , LA** Date EJGH IRB Waived Jurisdiction 09/09/2014
Louisiana Cancer Research Consortium: Biospecimen Core Laboratory	Dr. Arnold Zea, Co-Investigator, LSUHS Dr. Krzysztof, Co-Investigator, Tulane **LSUHSC IRB, New Orleans, LA** Date EJGH IRB Waived Jurisdiction 01/06/2015
Protocol H05001 - Human Device Exemption (HUD) 03-0101 Wingspan® Stent System with Gateway® PTA Balloon Catheter (Stryker Neurovascular)	Dr. Aaron Dumont, Principal Investigator **Western Institutional Review Board, Puyallup, Washington*** Date EJGH IRB Waived Jurisdiction 01/06/2015 * EJGH IRB office awaiting IRB approval Documentation from WIRB
Protocol H020002/A009 - Human Device Exemption (HUD) 2000-0059 Neuroform® Microdelivery Stent System (Stryker Neurovascular)	Dr. Aaron Dumont, Principal Investigator **Western Institutional Review Board, Puyallup, Washington*** Date EJGH IRB Waived Jurisdiction 01/06/2015 * EJGH IRB office awaiting IRB approval Documentation from WIRB
Protocol EKOS-12: Study of the OPTimum Duration of Acoustic Pulse ThromboLYSis ProcEdure in the Treatment of Acute Submassive Pulmonary Embolism - OPTALYSE PE (EKOS)	Dr. Tod Engelhardt, Principal Investigator: **Western Institutional Review Board, (WIRB) Puyallup, Washington** Date EJGH IRB Waived Jurisdiction 05/05/2015
Humanitarian Use Device (HUD) Jostent Coronary Stent Graft System (Abbott Vascular)	Dr. Gregory Tilton, Principal Investigator **Western Institutional Review Board, (WIRB) Puyallup, Washington** Date EJGH IRB Waived Jurisdiction 05/05/2015

NAME OF STUDY	PRINCIPAL INVESTIGATOR Date Approved/Date Waived Jurisdiction
SAPORO: Southern Area Patient Oriented Research Organization Survey: A Study of Clinics Populations and Clinicians Participating in a Practice-based Research Network **(Overall SAPORO Project reviewed and approved by EJGH IRB on September 9, 2014)**	Clarissa Hoff, MD, MPH, Tulane, Principal Investigator Patrick O'Callaghan PhD, EJGH Family Medicine, Co-Investigator **Tulane University IRB, New Orleans, Louisiana** Date EJGH IRB Waived Jurisdiction 05/05/2015
Humanitarian Use Device (HUD) Wingspan® Stent System with Gateway® PTA Balloon Catheter (Human Device Exemption H05001 – HUD Number: 03-0101)	Dr. Aaron Dumont, Principal Investigator EJGH IRB previously waived oversight of Humanitarian Use Device to Western IRB in January 13, 2015. IRB oversight now through **Tulane IRB, New Orleans, LA** Date EJGH IRB Waived Jurisdiction 09/01/2015
Humanitarian Use Device (HUD) Neuroform® Microdelivery Stent System – Human Device Exemption (Human Device Exemption H020002/A009 – HUD Number: 2000-0059)	Dr. Aaron Dumont, Principal Investigator EJGH IRB previously waived oversight of Humanitarian Use Device to Western IRB in January 13, 2015. **IRB oversight now through** **Tulane IRB, New Orleans, LA** Date EJGH IRB Waived Jurisdiction 09/01/2015
Humanitarian Use Device (HUD) MicroVention Low-profile Visualized Intraluminal Support (LVIS®) or LVIS Jr. Humanitarian Use Device ("LVIS HUD") (H130005/S001 - HUD Designation # 09-0222)	Dr. Aaron Dumont, Principal Investigator Tulane IRB, New Orleans, LA Date EJGH IRB Waived Jurisdiction 09/01/2015
Tissue Collection Study: Collection of aneurysm dome tissue for gene expression profiles and angiogenic protein analysis (data collection study)	Dr. Aaron Dumont, Principal Investigator **Tulane IRB, New Orleans, LA** Date EJGH IRB Waived Jurisdiction 09/01/2015
Study: The Relationship between Nursing Specialty Certification and Surgical Site Infection Rates in U.S. Acute Care Hospitals (data files submission)	Kim Schroeder, EJGH Site Coordinators, Performance Improvement, EJGH Carol Scioneaux, Infection Control, EJGH **Kansas University Medical Center (KUMC) IRB)** Date EJGH IRB Waived Jurisdiction 09/01/2015

NIH Clinical Trials Conducted at EJGH	
(All Tumors) ECOG 1AY13 **(NCT02465060)** Phase II trial studies how well treatment that is directed by genetic testing works in patients with solid tumors or lymphomas that have progressed following at least one line of standard treatment or for which no agreed upon treatment approach exists. **(Colon)** SWOG 0820 **(NCT01349881)** Phase III Stage 0-III Colon Cancer A Double Blind Placebo-Controlled Trial of Eflornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers **(Head and Neck)** RTOG 0920 **(NCT00956007)** A Phase II study of Postoperative Radiation Therapy (IMRT) +/- Cetuximab for Locally Advanced Resected Head and Neck Cancer **(Lung)** SWOG 1400 **(NCT02154490)** Phase II/III Biomarker-Driven Master Protocol for Second Line Therapy of Squamous Cell Lung Cancer A081105 **(NCT02193282)** Randomized Double Blind Placebo Controlled Study of Erlotinib or Placebo in Patients with Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-small Cell Lung Cancer (NSCLC) A151216 **(NCT02194738)** Genetic Testing For Patients with Resectable or Resected Lung Cancer: Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST) NRG LU001 **(NCT02186847)** Randomized Phase II Trial Of Concurrent Chemoradiotherapy +/- Metformin HCL In Locally Advanced NSCLC	Dr. Augusto Ochoa, Principal Investigator, LSUHSC Dr. Thomas Cosgriff, Dr. Paul Page, Dr. Siddhartha Padmanabha, and Dr. Paul Monsour, Sub-Investigators **LSUHSC IRB, New Orleans, Louisiana** Date EJGH IRB Waived Jurisdiction 07/01/2014
(Prostate) RTOG 0924 **(NCT01368588)** Phase III Randomized Trial: Androgen Deprivation and High dose Radiation With or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer RTOG 0815 **(NCT00936390)** Phase III Prospective Randomized Trial of Dose-Escalated Radiotherapy With or Without Short-Term Androgen Deprivation Therapy for Patients With Intermediate-Risk Prostate Cancer A031201 **(NCT01949337)** Phase III Trial of ENZALUTAMIDE (NSC # 766085) VERSUS ENZALUTAMIDE, ABIRATERONE AND PREDNISONE For Castration Resistant Metastatic Prostate Cancer **(Renal)** SWOG 0931 **(NCT01120249)** A Randomized Study of Everolimus Versus Placebo in Patients with Renal Cell Carcinoma who have Undergone Nephrectomy or Partial Nephrectomy EA8143 A Phase 3 Randomized Study Comparing Perioperative Nivolumab versus Observation in Patients with Localized Renal Cell Carcinoma Undergoing Nephrectomy	Date EJGH IRB Waived Jurisdiction 01/10/2017

NIH Clinical Trials Conducted at EJGH	
Protocol: Collection of Specimens Used for Vitro Diagnostic Studies for Oncology and Hematology Diseases (Dx Biosamples, LLC) **DXBIO-1012** Protocol is to obtain whole blood, serum, plasma, buffy coat, bone marrow, urine, saliva, oral swabs, nasal swabs, anogenital swabs, stool, surgical tissues and other specimens with associated data from consented study subjects. There are no investigational drugs or devices used in this study. The specimens will be for the use in development and testing of existing or future in vitro diagnostic assays.	Dr. Ashish Udhrain, Principal Investigator. **Diagnostics IRB, Cummaquid, Massachusetts** Date EJGH IRB Waived Jurisdiction 11/03/2015
Protocol: B9991003: A Phase 3, Multinational, Randomized, Open-Label, Parallel-Arm Study of Avelumab (MSB0010718C) in Combination with Axitinib (Inlyta®) Versus Sinitinib (Sutent®) Monotherapy in the First-Line Treatment of Patients with Advanced Renal Cell Carcinoma (Pfizer, Inc.)	Dr. Thomas Cosgriff, Principal Investigator **Western Institutional Review Board, (WIRB) Puyallup, Washington** Date EJGH IRB Waived Jurisdiction 01/05/2016
Protocol CA209370: A Master Protocol of Phase 1/2 Studies of Nivolumab in Advanced NSCLC Using Nivolumab as Maintenance after Induction Chemotherapy or as First-line Treatment Alone or in Combination with Standard of Care Therapies (Bristol-Myers Squibb)	Dr. Thomas Cosgriff, Principal Investigator **Quorum Review Institutional Review Board, Seattle, Washington** Date EJGH IRB Waived Jurisdiction 03/01/2016
Protocol MK3475-185-00: A phase III study of Lenalidomide and low-dose Dexamethasone with or without Pembrolizumab (MK3475) in newly diagnosed and treatment naïve Multiple Myeloma (Merck)	Dr. Thomas Cosgriff, Principal Investigator **Copernicus Group IRB, Durham, North Carolina** Date EJGH IRB Waived Jurisdiction 05/03/2016
Protocol: PCYC.1128.CA: A Phase 1b/2 Study of Ibrutinib Combination Therapy in Selected Advanced Gastrointestinal And Genitourinary Tumors (Pharmacyclics)	Dr. Thomas Cosgriff, Principal Investigator **Western Institutional Review Board, (WIRB) Puyallup, Washington** Date EJGH IRB Waived Jurisdiction 05/03/2016
Protocol 15-001: FlowTrie Pulmonary Embolectomy Clinical Study (FLARE) (Inari)	Dr. Todd Engelhardt, Principal Investigator **Western Institutional Review Board, (WIRB) Puyallup, Washington** Date EJGH IRB Waived Jurisdiction 05/03/2016
Patient Chart Review Study: Anterior, Posterior and Central Placenta Previa; Does Location Impact Resolution?	Dr. Asha Heard, Principal Investigator Dr. Megan Savage, Dr. Tabitha Quibedeaux and Ms. Ashley Meyn, Co-Investigators **LSUHSC IRB, New Orleans, LA** Date EJGH IRB Waived Jurisdiction 05/03/2016
Protocol SCMP-8811-202: A Multicenter, Randomized, Placebo-controlled, Double-blinded Study of the Efficacy, Safety, and Pharmacokinetics of Cobiprostone for the Prevention of Severe Oral Mucositis in Subjects with Head and Neck Cancer (HNC) Receiving Concurrent Radiation and Chemotherapy (Sucampo AG)	Dr. Siddhartha Padmanabha, Principal Investigator **Copernicus Group IRB, Durham, North Carolina** Date EJGH IRB Waived Jurisdiction 05/03/2016
Humanitarian Use Device (HUD) **Protocol H010001:** Stryker MCP Joint Implant Finger Prosthesis (Stryker Orthopedics)	Dr. Nicholas Pappas, III, Principal Investigator **Western Institutional Review Board, (WIRB) Puyallup, Washington** Date EJGH IRB Waived Jurisdiction 05/03/2016
Humanitarian Use Device (HUD) **Protocol H980002:** Stryker PIP Joint Implant Finger Prosthesis (Stryker Orthopedics)	Dr. Nicholas Pappas, III, Principal Investigator **Western Institutional Review Board, (WIRB) Puyallup, Washington** Date EJGH IRB Waived Jurisdiction 05/03/2016
Clinical Study: Vaginal Microbiota Phylotypes During Pregnancy	Dr. Emily Harville, Principal Investigator, Tulane School of Public Health and Tropical Medicine Dr. Katherine Malczewski, Co-Investigator: Tulane OB/GYN Resident **Tulane IRB, New Orleans, LA** Date EJGH IRB Waived Jurisdiction 05/03/2016

NIH Clinical Trials Conducted at EJGH	
RSV-M-301 - Protocol: A Phase 3, Randomized, Observer-Blind, Placebo-Controlled, Group-Sequential Study to Determine the Immunogenicity and Safety of a Respiratory Syncytial Virus (RSV) F Nanoparticle Vaccine with Aluminum in Healthy Third-Trimester Pregnant Women; and Safety and Efficacy of Maternally Transferred Antibodies in Preventing RSV Disease in Their Infants (Novavax)	Dr. Robert Jeanfreau, Principal Investigator **Copernicus Group IRB, Durham, North Carolina** Date EJGH IRB Waived Jurisdiction 09/13/2016
Patient interview Study (SAPORO project): Investigation into Our Patient Population's Health Literacy, Smartphone Health Application Use and Their Correlation with Weight Loss over a One Year Period.	Dr. Kiernan Smith, Principal Investigator Clarissa Hoff, MD, MPH, Tulane, Patrick O'Callaghan PhD, EJGH Family Medicine, Co-Investigators **Tulane University IRB, New Orleans, Louisiana** Date EJGH IRB Waived Jurisdiction 09/13/2016
Protocol: cX8-ZIKA-412: A Prospective Study to Evaluate the Specificity of the cobas® Zika Test for use with the cobas® 6800/8800 System for Screening of Blood Donations for the Presence of Zika Virus RNA	The Blood Center, Principal Investigator Dr. Barry Sartin, Co-Investigator **Copernicus Group IRB, Durham, North Carolina** Date EJGH IRB Waived Jurisdiction 11/01/2016
Protocol GV29893: A Phase 2 Randomized, Double-Blind, Placebo-Controlled Trial of MHAA4549A, a Monoclonal Antibody Administered as Monotherapy for the Treatment of Acute Uncomplicated Seasonal Influenza A Infection in Otherwise Healthy Adults (Genentech)	Dr. Robert Jeanfreau, Principal Investigator **Chesapeake IRB, Columbia, Maryland** Date EJGH IRB Waived Jurisdiction 11/01/2016
Research Interview Study: Fathers Matter: Social Support Perceptions of Fathers at Two Months after Their Infants' Birth	Debra Copeland, Principal Investigator **Loyola University-New Orleans IRB** Date EJGH IRB Waived Jurisdiction 11/01/2016
Questionnaire Study: Development of the patient Turnover Indicator: A Pilot Study of the National Database of Nursing Quality Indicators (NDNQI)	Shin Hye Park, Principal Investigator Donna Carbajal, EJGH Study Coordinator **University of Kansas Medical Center IRB** Date EJGH IRB Waived Jurisdiction 11/01/2016
Protocol MK-3475-355: A Randomized, Double-Blind, Phase III Study of Pembrolizumab (MK-3475) plus Chemotherapy versus Placebo plus Chemotherapy for Previously Untreated Locally Recurrent Inoperable or Metastatic Triple Negative Breast Cancer – (KEYNOTE-355)	Dr. Thomas Cosgriff, Principal Investigator **Copernicus Group IRB, Durham, North Carolina** Date EJGH IRB Waived Jurisdiction 01/10/2017
Protocol PM1183-C-003-14: A Phase III Randomized Clinical Trial of Lurbinectedin/Doxorubicin versus Cyclophosphamide, Doxorubicin and Vincristine or Topetecan as treatment in patients with Small Cell Lung Cancer who failed one prior platinum containing line (Atlantis Trial)	Dr. Thomas Cosgriff, Principal Investigator **Copernicus Group IRB, Durham, North Carolina** Date EJGH IRB Waived Jurisdiction 01/10/2017
Protocol B9991016: A Randomized Double-Blind Phase 3 Study of Avelumab in Combination with Standard of Care Chemoradiotherapy (Cisplatin plus Definitive Radiation Therapy) Versus Standard of Care Chemoradiotherapy in the Front-Line Treatment of Patients with Locally Advanced Squamous Cell Carcinoma of the Head and Neck	Dr. Siddhartha Padmanabha, Principal Investigator **Copernicus Group IRB, Durham, North Carolina** Date EJGH IRB Waived Jurisdiction 01/10/2017
Protocol 2013-0609: Biospecimen Banking and Biomarker Validation for Lung Cancer Early Detection in Cohort Receiving Low-Dose Helical Computed Tomography Screening	Dr. Thomas Cosgriff and Dr. Mary Beth Lobrano, Principal Investigators **MD Anderson IRB, Houston, Texas** Date EJGH IRB Waived Jurisdiction 01/10/2017
Protocol PA11-1087: Prospective Registry of Breast Cancer Patients with Axillary Nodal Metastases Identified During Ultrasound Staging	Dr. Thomas Cosgriff and Dr. Mary Beth Lobrano, Principal Investigators **MD Anderson IRB, Houston, Texas** Date EJGH IRB Waived Jurisdiction 01/10/2017

NIH Clinical Trials Conducted at EJGH	
Protocol NSMM-5001: A global, prospective, non-interventional, observational study of presentation, treatment patterns, and outcomes in multiple myeloma patients – the INSIGHT-MM study (non-interventional observation study) Millennium Pharmaceuticals (Takeda)	Dr. Ashish Udhrain, Principal Investigator. **Schulman IRB, Cincinnati, Ohio** Date EJGH IRB Waived Jurisdiction 01/10/2017
Research Study: Active Versus Passive Post-Operative Voiding Trials in Women Undergoing Surgery for Pelvic Organ Prolapse	Barry Hallner, MD, LSUHSC and EJGH Principal Investigator Co-Investigators: Drs. Diane Thomas, Erin Dougher, Gillian Wolff, Ralph Chesson, Lisa Peacock, Ryan Krlin and J. Christian Winters **LSUHSC IRB, New Orleans, LA** Date EJGH IRB Waived Jurisdiction 01/10/2017
Chart Review Study: A Retrospective Chart Review Study to Develop an Evidence-Based Scale to Identify Newborns at Greatest Risk of Falling (SINGR F) (Questionnaire)	Rose Ainsworth, RN, MSN, Principal Investigator Paula Adamcewicz, Local (EJGH) Study Coordinator: EJGH Woman and Newborn Services **Exemption of Review from Huntsville Hospital (Alabama) Institutional Review Committee)** Date EJGH IRB Waived Jurisdiction 01/10/2017
Protocol S1605: Phase II Trial of Atezolizumab in BCG-Unresponsive Non-Muscle Invasive Bladder Cancer	Thomas Cosgriff, MD, Principal Investigator/EJGH Faculty **LSUHSC IRB, New Orleans, LA** **(NIH Trials)** Date EJGH IRB Waived Jurisdiction 03/07/2017
Research Study: Prevention of Chemotherapy-Induced Oral Mucositis Using Cryotherapy along with MuGard	Principal Investigator: Tracy Garrett, MSN, FNP-C, Oncology Services, EJGH University of **South Alabama (USA) IRB, Mobile, Alabama** Date EJGH IRB Waived Jurisdiction 03/07/2017
Protocol NRG-GY005: A Randomized Phase II/III Study of the Combination of Cediranib and Olaparib Compared to Cediranib or Olaparib alone, or Standard of Care Chemotherapy in Women with Recurrent Platinum-Resistant or -Refractory Ovarian, Fallopian Tube or Primary Peritoneal Cancer (COCOS)	Amelia Jernigan, MD, Principal Investigator/EJGH Faculty **LSUHSC IRB, New Orleans, LA** **(NIH Trials)** Date EJGH IRB Waived Jurisdiction 03/07/2017
Protocol NRG-GY006: A Randomized Phase II Trial of Radiation Therapy and Cisplatin Alone or in Combination with Intravenous Triapine in Women with Newly Diagnosed Bulky Stage IB2, Stage II, IIIB, or IVA Cancer of the Uterine Cervix or Stage II-IVA Vaginal Cancer. S1605: Phase II Trial of Atezolizumab in BCG-Unresponsive Non-Muscle Invasive Bladder Cancer	Amelia Jernigan, MD, Principal Investigator/EJGH Faculty **LSUHSC IRB, New Orleans, LA** **(NIH Trials)** Date EJGH IRB Waived Jurisdiction 03/07/2017
Protocol S1605: Phase II Trial of Atezolizumab in BCG-Unresponsive Non-Muscle Invasive Bladder Cancer	Thomas Cosgriff, MD, Principal Investigator/EJGH Faculty **LSUHSC IRB, New Orleans, LA** **(NIH Trials)** Date EJGH IRB Waived Jurisdiction 05/02/2017
Protocol BDR 080316: A Retrospective, Multi-Center Study to Evaluate the Clinical Effectiveness of the OmniSeq Immune Advance Test to Predict Response to Checkpoint Inhibitors	Principal Investigator (National): Carl Morrison, MD EJGH Study Investigator: Khawaja Jahangir, MD **Roswell Park Cancer Institute IRB, Buffalo, New York** Date EJGH IRB Waived Jurisdiction 05/02/2017
Retrospective Chart Review Study: An evaluation of the effects of vaginal packing at the time of vaginal surgery	Principal Investigator Lisa Peacock, MD Department of Obstetrics & Gynecology, LSUHSC Sub-Investigators: Amanda Thomas, MD - Department of Obstetrics & Gynecology, LSUHSC and Joseph Hagan, ScD - Department of Obstetrics and Gynecology, LSUHSC **LSUHSC IRB, New Orleans, LA** Date EJGH IRB Waived Jurisdiction 07/11/2017

NIH Clinical Trials Conducted at EJGH	
Protocol: EA8141: A Prospective Phase II Trial of Neoadjuvant Systemic Chemotherapy Followed by Extirpative Surgery for Patients with High Grade Upper Tract Urothelial Carcinoma	Dr. Augusto Ochoa, Principal Investigator, LSUHSC Dr. Thomas Cosgriff, Sub-Investigator, EJGH **LSUHSC IRB, New Orleans, LA** Date EJGH IRB Waived Jurisdiction 07/11/2017
Patient Specimen Collection Study Toxic and Essential Metals and Leukemia in Louisiana; Metallomics and Genomics in Acute Leukemia	Principal Investigator: Maro Ohanian, MD, Hematology/Oncology, MD Anderson, Houston, Texas Specimen Collection Faculty: Jayne Gurtler, MD, Robert Veith, MD and Barry Sartin, MD, EJGH **MD Anderson IRB, Houston, Texas** Date EJGH IRB Waived Jurisdiction 09/12/2017
EOMI Tissue Procurement Protocol	Thomas Cosgriff, MD, Hematology/Oncology, EJGH Site Investigator **CIRB - National Cancer Institute, Rockville, MD** Date EJGH IRB Waived Jurisdiction 09/12/2017
Protocol: HPV-301 REVEAL 1 Trial: REVEAL 1 Trial (Randomized Evaluation of VGX-3100 and Electroporation for the treatment of Cervical HSIL)	Robert Jeanfreau, MD, Principal Investigator, EJGH **Copernicus IRB, Durham, North Carolina** Date EJGH IRB Waived Jurisdiction 09/12/2017
Protocol: POLARIS: Palbociclib in Hormone Receptor Positive Advanced Breast Cancer: A Prospective Multicenter Non-Interventional Study	Thomas Cosgriff, MD, Hematology/Oncology, EJGH Site Investigator **Schulman IRB, Cincinnati, Ohio** Date EJGH IRB Waived Jurisdiction 09/12/2017
Chart Review Study: Utilization of a NICU Feeding Protocol for Neonates </=34 WGA or BW </=2000 Grams	Raegan Gupta, MD, EJGH, Principal Investigator Michelle Knecht, MD; Jeffrey Surcouf, MD, Co-Investigators **LSUHSC IRB, New Orleans, Louisiana** Date EJGH IRB Waived Jurisdiction 09/12/2017
Chart Review Study: Neonatal Abstinence Syndrome: Implementation of a Standardized Treatment Protocol	Staci Olister, MD, EJGH, Principal Investigator Danielle Eggie Thompson, MD, Anne Nuttli, MD, Dana Rivera, MD **LSUHSC IRB, New Orleans, Louisiana** Date EJGH IRB Waived Jurisdiction 09/12/2017
Protocol: ALLIANCE A031501 - Phase III Randomized Adjuvant Study of MK-3475 (Pembrolizumab) in Muscle-Invasive and Locally Advanced Urothelial Carcinoma (Ambassador) Versus Observation	Thomas Cosgriff, MD, Principal Investigator: **CIRB-National Cancer Institute, Rockville, Maryland** Date EJGH IRB Waived Jurisdiction 11/07/2017
Protocol: 54767414SMM3001 - A Phase 3 Randomized, Multicenter Study of Subcutaneous Daratumumab Versus Active Monitoring in Subjects with High-Risk Smoldering Multiple Myeloma	Thomas Cosgriff, MD, Principal Investigator **Sterling IRB, Atlanta, Georgia** Date EJGH IRB Waived Jurisdiction 11/07/2017
Protocol PA11-1087: Prospective Registry of Breast Cancer Patients with Axillary Nodal Metastases Identified During Ultrasound Staging	Dr. Thomas Cosgriff and Dr. Mary Beth Lobrano, Principal Investigators **MD Anderson IRB, Houston, Texas** Date EJGH IRB Waived Jurisdiction 01/10/2017
Protocol: NRG-GU003 - A Randomized Phase III Trial of Hypofractionated Post-Prostatectomy Radiation Therapy (HYPORT) Versus Conventional Post-Prostatectomy Radiation Therapy (COPORT)	Augusto Ochoa, MD, LSUHSC, Principal Investigator Thomas Cosgriff, MD, EJGH Site Faculty **CIRB-National Cancer Institute, Rockville, Maryland** Date EJGH IRB Waived Jurisdiction 11/07/2017
Protocol: WO30070 - A Phase III, Multicenter, Randomized, Placebo-Controlled Study of Atezolizumab (Anti-PD-L1 Antibody) as Monotherapy and in Combination with Platinum-Based Chemotherapy in Patients with Untreated Locally Advanced or Metastatic Urothelial Carcinoma	Khawaja Jahangir, MD, EJGH, Principal Investigator **CIRB-National Cancer Institute, Rockville, Maryland** Date EJGH IRB Waived Jurisdiction 11/07/2017

Medical Staff Grand Rounds

Schedule for January – July 2018 • Tuesdays at 12 Noon to 1pm • Esplanade Room 1

JAN 9
Quality/Core Measures Presentation
Ruby Brewer, RN, Senior Vice President, Chief Quality Officer, and Interim Chief Nurse Executive

JAN 16
Open Date

JAN 23
Opiate Addiction
A. Kenison Roy, MD

JAN 30
To Close or Not to Close A Patent Foramen Ovale
Fortune Dugan, MD

FEB 6
Transplant Topic
Mary T. Killackey, MD
Chair, Department of Surgery, Associate Professor of Surgery and Pediatrics
Tulane University School of Medicine

FEB 13
Mardi Gras (No Session)

FEB 20
Evidence-Based Research Presentations
(November 2017 Winners)

FEB 27
Interventional Radiology Topic
Benjamin Henderson, MD

MAR 6
Genital Skin Diseases
Andrea Murina, MD
Assistant Professor, Department of Dermatology
Tulane University School of Medicine

MAR 13
HPV-Related Disease and Anal Cancer
Michael Hagensee, MD

MAR 20
Internal Medicine Topic
David Bateman, MD

MAR 27
Video-Assisted Thoracoscopic Surgery (VATS) and Lung Cancer
Michael Brothers, MD

APR 3
Interaction of Chaplains and the Healthcare Team
(Speakers TBA)

APR 10
Disorder of the Thyroid
Escipion Pedroza, MD

APR 17
Interesting CVT Cases
Harry Roach, MD

APR 24
Osteoporosis of the Spine – Diagnoses and Treatment
Manish Singh, MD

MAY 1
Melanoma and Non-Melanoma Skin Cancer of the Head and Neck
Paul Spring, MD

MAY 8
Hypertension Update
Pedro Romaguera, MD

MAY 15
Supportive Care/Facilitating Shared Decision Making
Kenneth Smith, MD

MAY 22
WHY Breastfeeding Course for Providers
Lisa Credo, MD, Pediatrician, Louisiana Department of Health

MAY 29
Orthopedic Topic
Joseph Finstein, MD

JUN 5
Continuous Renal Replacement Therapy
Ashwin P. Jaikishen, MD

Use of Antibiotics in Colorectal Surgery
Matthew Zelhart, MD

Interesting Infectious Disease Cases
Frank Rabito, MD

Update on Limb Salvage
Amber Poirot, DPM
and Henry Pretus, MD

Syncope Update
David Snyder, MD

Updates in Transfusion Medicine
Tim Peterson, MD
Assistant Professor, Pathology
Tulane School of Medicine

Internal Medicine Topic
Ahmed Mohiuddin, MD

the JOURNAL of East Jefferson General Hospital

Medical Staff Services
4200 Houma Boulevard • Metairie • Louisiana 70006