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COVENANT HealthCare

COVENANT MEDICAL STAFF NEWSLETTER | SEPTEMBER 2018

Impact of Childhood Traumas on Long-Term Health

Dr. Michael Fiore
Covenant HealthCare Chief of Staff

Much of our medical education focuses on understanding discrete disease conditions, with an emphasis on physiology, pharmacology, and utilization of technology. We address acute problems (or acute exacerbations of chronic problems) and evaluate, diagnose, and treat. The added consideration of family stressors and psychosocial dynamics are often considered secondary, yet are serious issues that pose complications to medical care.

As health professionals, we cannot simply treat acute problems without some consideration of implications to the long-term health and well-being of our patients. We have long understood that many adult-based disease processes have roots in early childhood. What happens during childhood does not necessarily stay in childhood.

Landmark Study on Childhood Stress

The landmark Adverse Childhood Experiences (ACE) study is one of the largest investigations of childhood abuse and neglect and their impact on later-life health and well-being. The study evaluated childhood exposures to potentially adverse experiences such as abuse, witnessing domestic violence, household substance abuse, parental separation, and neglect. There is a clear, significant, and graded relationship between the number of childhood adversities and a wide array of adult onset disease (e.g., ischemic heart disease, chronic lung disease, liver disease and diabetes) as well as mental illness, social dysfunction, academic failure, and economic hardship.

Scientists have long debated, but at least acknowledged, the relative contribution of genes and environment on a child's development. This is the age-old nature versus nurture debate, with evidence that both are important. It has not been until recently, however, that we have learned how this occurs biologically. Advances in the field of epigenetics provides evidence of environmental influences of genetic expression at a molecular level.

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What happens during childhood does not necessarily stay in childhood.

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Epigenetics

Epigenetics refers to the alterations in gene expression in response to external stimuli, without changes in the DNA sequence itself. The path from genotype to phenotype is complex, affected by random events and environmental stressors. Modification of histones with DNA methylation or acetylation can alter gene activation or deactivation, resulting in genes being turned on or off.

One implicated pathway has demonstrated early stress-causing alterations in expression of genes related to the glucocorticoid receptors, with subsequent modulation of the hypothalamic-pituitary-adrenal axis, leading to an altered stress response. These epigenetic changes validate that genes are not destiny, and early childhood ecology and subsequent events can alter the way the genetic blueprint is used.

Fortunately, as a corollary, enriched childhood experiences can improve or even reverse these biological processes. Attentive caregivers, adequate nutrition, early education services, access to healthcare, opportunity for play, and parental presence allow for a positive stress response.

Adult Stress Implications

The impacts of adverse stress exposure are not limited to early childhood. There is a growing body of literature highlighting the long-term health impacts of acute illness and hospitalizations in both children and adults. These concerns extend beyond pulmonary, renal, and cardiac manifestations. Longitudinal studies have recognized an increased risk for life-altering delirium, depression, and anxiety after acute hospitalizations.

As care providers, this should serve as a reminder to measure success not in the short term but over the life course of our patients. A great example is the Intensive Care Unit (ICU) liberation collaborative, a multidisciplinary effort to reduce delirium, improve pain management, and reduce long-term consequences for ICU patients.

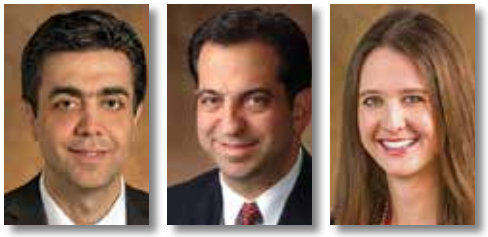
Broadening Our Medical Thinking

Our evolving understanding of epigenetic principles is one of the most exciting areas of developmental science. Predictably, as with many evolving fields of study, gaps of knowledge are rapidly filled with pseudoscience and unfounded quackery. Despite alternate claims, harnessing the power of epigenetics is not as simple as thinking your way to health, developing a “curative” diet, or with the correction of subluxations. It is left to the educated physician to separate fact from magic.

As medical providers, we will need to broaden our medical thinking about wellness beyond the immediate problem and think longitudinally about the life-long implications of our care. We are left with the challenge of applying developmental research to our practice in pragmatic ways, in addition to incorporating the principles of patient-centered, even community-centered, care. This, in turn, will help create a strong foundation for life-long health and wellness.

Sincerely,

Dr. Michael Fiore
Chief of Staff



Advanced Robotic-Assisted Pancreatic and Liver Surgery Now Available

GUEST AUTHORS
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Patients in the Great Lakes Bay Region requiring complex pancreatic surgery for oncologic or non-oncologic reasons now have the option to reduce hospitalization, recovery and travel time through three advanced robotic-assisted procedures: pancreaticoduodenectomy (RPD) known as the robotic Whipple procedure, distal (subtotal) pancreatectomy (RDP) and liver resection.

These minimally-invasive procedures are now available at Covenant HealthCare, which continues to build tertiary care capabilities as part of its comprehensive Cancer Care Center and collaboration with the University of Texas MD Anderson Cancer Center.

The Procedures

The robotic Whipple, RDP and robotic liver resection procedures are only available at a limited number of facilities nationwide due to the intense surgical training that is required to master the procedure. The surgical goal is to remove benign or malignant tumors through major liver and pancreatic resections via ultrasound (US)-guided microwave ablations and via computed tomography (CT) imaging for primary and metastatic liver lesions.

The primary differences between the robotic Whipple and RDP are:

- The robotic Whipple is a five- to six-hour procedure, which typically involves removing cancerous tumors from the head of the pancreas, duodenum and bile duct.
- RDP is a two- to three-hour procedure which typically involves removing the body and tail of the pancreas, but can also require removal of most of the pancreas and the spleen.

The Benefits of Robotics

Since the mid-1990s, the conventional laparoscopic approach has been favored over open surgery, however technical barriers have been a major disadvantage – especially in more complex vascular and tissue dissections.

The three robotic-assisted procedures, enabled via the da Vinci® surgical system, help overcome this hurdle, opening the door to:

- A more favorable safety profile
- Higher rates of margin-negative resections
- Improved lymph node yield
- Increased spleen salvation
- Shorter hospital stays
- Fewer complications
- Improved patient outcomes

The Team Approach

Successful patient outcomes require a multi-disciplinary team approach across disciplines, including oncology, radiology, pathology, gastroenterology, surgery and the primary care physician (PCP).

Pancreatic and liver conditions are often revealed through annual or biannual surveillance US and CT scans for high-risk patients with hepatitis C, cirrhosis of the liver or a history of cancer. Typically, jaundice or weight loss are initial symptoms. The sooner patients are diagnosed with a condition, the more likely they are a candidate for the robotic Whipple or RDP procedures.

To date, approximately 30 of these procedures have been performed at Covenant HealthCare with very good success. Referrals can be made by calling the Covenant Cancer Care Center at 989.583.5060 or CMU Department of Surgery at 989.790.1001.

For more information, contact Dr. Ghanem at 313.618.2948 (cell), 989.790.1001 (office) or maher.ghanem@cmich.edu, or contact Dr. Paulus at 989.790.1001 or elizabeth.paulus@cmich.edu.

Update: Current and Future Influenza Vaccines

GUEST AUTHOR
Dr. Palaniandy Kogulan, Infectious Disease Specialist

Vaccination against influenza is the most effective method to prevent influenza infections. Yet influenza is the most frequent cause of death among all vaccine-preventable diseases in the United States.

About 5-20% of the U.S. population is diagnosed with influenza during the influenza season each year, resulting in an estimated total economic burden of more than $87 billion, and an annual average of more than 200,000 hospitalizations and 23,610 related deaths. During the aggressive 2017-2018 flu season, hospital admissions might have actually exceeded 700,000 and sadly during 2018 alone, 174 pediatric deaths were documented.

It is therefore imperative for all physicians to understand the influenza virus and vaccines – including those on the horizon – that can save lives and improve community health.

Influenza Pandemics

Influenza is a virus that has RNA as its genetic material. Influenza A, B and C are capable of infecting humans, with influenza A and B the most common circulating types.

Prior to the 1930s, there was no vaccine protection against the influenza virus. In 1933, the first human influenza virus was isolated and by the 1940s, the first approved inactivated vaccine was developed. Even so, influenza pandemics continue to occur, hitting hard and fast. Below are four pandemic stand-outs worldwide and the estimated number of deaths:

- Spanish Flu of 1918 (HINI)– 50 million deaths
- Asian Flu of 1957 (H2N2) – 1.1 million deaths
- Hong Kong Flu of 1968 (H3N2) – 1 million deaths
- Swine Flu (H1N1) of 2009 – 151,700-575,400 deaths

Current influenza vaccines can be inactivated or a live-attenuated intranasal vaccine. During the 2017-2018 season, the live attenuated vaccine was not approved, but during the 2018-19 season, the live attenuated vaccine will likely be available again with a different H1N1 type virus.

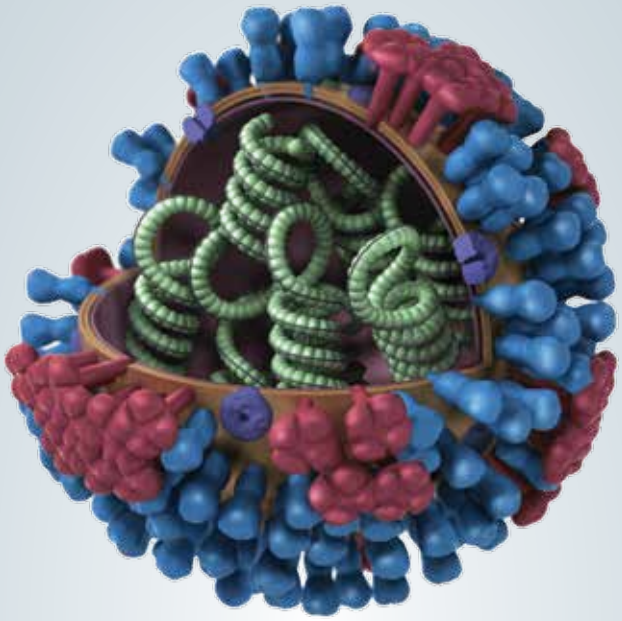
Getting the Drift and Shift

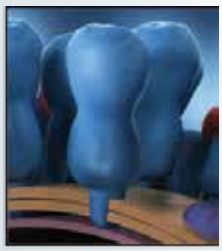
Influenza viruses are constantly adapting and changing. These changes can be minor which is known as “drift,” or major which is known as “shift.” Antigens on the virus’ surface can trigger the body’s immune response to produce specific antibodies to fight that virus by binding to antigenic sites.

The influenza virus’ outer membrane surface contains two important glycoproteins (see image on right).

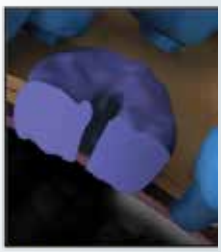
- The hemagglutinin (HA) is the viral attachment protein that mediates the virus’ entry into cells by fusion. The antibody against HA is neutralizing and very protective against infection and illness.
- The neuraminidase (NA) is an enzyme that enables the cell-to-cell spread of the virus. The antibody against NA can reduce the severity of the illness.
- Other parts of the virus that can be used as targets for vaccine productions are the outer membrane matrix protein M2, cellular proteins such as matrix protein 1 (M1) and ribonucleoprotein (RNP).

Features of an Influenza Virus

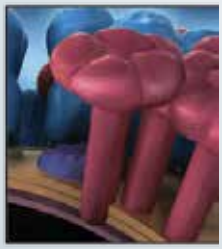




Hemagglutinin



M2 Ion Channel



Neuraminidase

RNP

Source: CDC website

Table 1: Vaccine Production Technologies

TECHNOLOGY	FAST FACTS
1.Egg-Based Flu Vaccine	• This technique has been in use for more than 70 years. • It requires a large supply of chicken eggs and thus takes longer to produce vaccine than other methods.
2.Cell-Based Flu Vaccine	• This technique was approved in 2012. • Vaccine virus are grown in animal mammalian cells instead of chicken eggs, however, the original virus is grown in egg prior to transferring to the mammalian cells so there is a small amount of egg protein. • Avoiding the use of eggs allows a faster start-up of the flu vaccine manufacturing process. • The first FDA-approved cell-based influenza vaccine was produced in May 2016, known as Flucelvax®, an inactivated quadrivalent vaccine for people aged 4 and older.
3.Recombinant Flu Vaccine	• This technique was approved in 2013. • It contains purified HA proteins produced in a continuous insect cell line using recombinant technology. HAs are expressed in this cell line using a baculovirus vector. • It can produce vaccine in the shortest amount of time as it does not depend on egg supply nor is it limited by the selection of vaccine viruses that are adopted for growth in eggs. • As the first and only FDA-approved recombinant vaccine, it was first produced in 2013 as Flublok®. • It is the only 100% egg-free vaccine on the U.S. market.

An antigenic **shift,** which is only seen with influenza A virus, results from replacement of the HA and sometimes NA with novel virus subtypes that have not been present in human viruses for a very long time. The H1N1 virus in 2009 is an excellent example of an antigenic shift that created a new pandemic.

Antigenic **drift** is a subtler process than shift, involving the accumulation of minor mutations within the antibody-binding sites in the HA, NA or both. Because of these mutations, the resulting virus cannot be inhibited well by the antibodies used to fight previous strains. Antigenic drift occurs in both influenza A and B viruses. In the influenza A (H3) virus, antigenic drift variants occur more quickly than in influenza A (H1) or B.

Vaccine Strains

The selection of influenza vaccine strains is an ongoing and complex process involving Centers for Disease Control (CDC) and World Health Organization (WHO) surveillance systems. Every February, the U.S. Food and Drug Administration (FDA) decides the final strains of the influenza vaccine for the upcoming season, based on CDC and WHO recommendations. This is timed to allow at least six months for manufacturers to produce large quantities of vaccine for distribution.

Currently, three production technologies are approved by the FDA, as shown in Table 1 above.

Variations in Vaccine Effectiveness

Seasonal influenza vaccine effectiveness varies from year to year. Overall influenza vaccine effectiveness was only 36% in the 2017-2018 season: 25% against H3N2, 42% against influenza B and 67% against H1N1.

The lower overall effectiveness occurs because:

- The H3N2 virus mutates at a faster rate than other flu viruses. Mutation of the virus after the vaccine strain is selected could result in a less effective vaccine.
- It is difficult to grow H3N2 virus in eggs due to “egg-adapted changes” that occur when growing the culture in the egg, which can likely result in further antigenic change. This was the main reason for the lower vaccine effectiveness against the H3N2 strain in 2017-2018.

For the upcoming 2018-2019 season, vaccine strains are slightly different from the 2017-2018 vaccine, specifically those for H3N2 and influenza B.

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Universal Vaccines on the Horizon

Current vaccines produce antibodies against the head domain of the HA, which is highly variable due to antigenic drift. The good news is that scientists engaged in universal flu vaccine research have located the conserved sites of the influenza virus against which the immunity can be targeted. In this way, a universal vaccine can be created to provide long-lasting protection against ALL influenza viruses, regardless of antigenic shifts or drifts.

Vaccines in development include:

- Vaccine against conserved stalk domain of the HA.
- Matrix protein 2 ectodomain (M2e)-specific antibodies.
- DNA vaccine technology – plasmids that carry genes for HA, NP and matrix protein 1 (M1) could protect against influenza.
- Influenza virus peptides used for induction of the influenza-specific immune B cell and T cell response, such as HA, NP and M1.

These universal vaccines are in early development and will take several years for approvals and clinical use.

2018-2019 Vaccine Recommendations

Until there is a universal vaccine, the best way to protect patients from the influenza is by administering a yearly influenza vaccine. Table 2 below shows current available vaccines, including options in cell-based or recombinant vaccines that are also available, especially for people with egg allergies (recombinant) or needle aversions (intradermal and intranasal).

Important Note about Egg Allergies: The CDC recommends the following: "People with a history of egg allergy of any severity should receive any licensed, recommended and age-appropriate influenza vaccine. Those who have a history of severe allergic reaction to egg (i.e., any symptom other than hives) should be vaccinated in an inpatient or outpatient medical setting (including but not necessarily limited to hospitals, clinics, health departments, and physician offices), under the supervision of a healthcare provider who is able to recognize and manage severe allergic conditions."

While most flu shots and nasal sprays contain a small amount of egg proteins, studies indicate that severe allergic reactions in people with egg allergies are unlikely, and a CDC study found the rate of anaphylaxis is 1.31 per one million vaccine doses given. See https://www.cdc.gov/flu/protect/vaccine/egg-allergies.htm for details.

Again, as mentioned, if anyone still refuses to take the flu vaccine because of an egg allergy, they have the option of the egg-free recombinant flu vaccine.

For more information, contact Dr. Kogulan at 989.791.7085.

Table 2: Current Approved Influenza Vaccines

CATEGORY	CURRENT VACCINES
Inactivated, Trivalent	• Standard-dose trivalent vaccine virus grown in egg – Afluria™ for age 5 and older and Fluvirin™ for age 4 and older • High-dose trivalent vaccine approved for age 65 and older – Fluzone® high dose (four times the antigen of regular flu shots) • Recombinant trivalent egg-free vaccine approved for age 18 and older – Flublok® • Trivalent vaccine, a standard-dose vaccine made with an adjuvant approved for age 65 and older – FLUAD™
Inactivated, Quadrivalent	• Quadrivalent flu vaccine virus grown in egg – approved for patients age 6 months and older • Intradermal quadrivalent flu vaccine that uses a needle 90% smaller than a regular needle, and is approved for ages 18-64 – Fluzone® intradermal • Quadrivalent flu vaccine virus grown in cell culture approved for age 4 and older – Flucelvax® quadrivalent • Recombinant quadrivalent vaccine approved for age 18 and older – Flublok quadrivalent
Live Attenuated Influenza Vaccine, Quadrivalent	• Needle-free nasal spray vaccine grown in egg approved for ages 2-49 without contraindication – FluMist® quadrivalent

Hip Replacement Surgical Procedures Keep Getting Better

GUEST AUTHOR
Dr. Adam Cote, Orthopaedic Surgeon, Covenant Medical Group

Approximately 27 million Americans have osteoarthritis due to wear-and-tear, and one in four people will likely develop this condition, often in the hip or knee. Most patients opting for total hip replacement surgery (THR) are middle-aged between the ages of 50 to 80 and have reached the point where walking is difficult and the pain is unbearable. In addition, they are unwilling to sacrifice an active lifestyle for a sedentary way of life.

With the advent of THR, they don't need to make that sacrifice. In fact, about 300,000 THRs are performed annually. THR replaces damaged bone ends of the femur, acetabulum and cartilage with hip implants that replicate the hip joint. Implants commonly consist of a metal stem and ball with a polyethylene socket/liner.

Surgical Approaches

Surgical approaches to THR continue to advance. Traditionally, surgeons have approached from the lateral or posterior side of the hip, but a newer minimally-invasive technique using a direct anterior approach (DAA) offers several benefits to surgeons and patients alike. In simple terms, here is how the two approaches stack up:

- **Traditional approaches:** Incision of 8-12 inches, but these approaches often detach or disrupt muscle/tendon attachments which can take a significantly longer time to heal.
- **DAA:** Incision of only 3-4 inches at the front of the hip where there are fewer muscles. This can reduce muscle damage and have fewer recovery restrictions.

Operative times are comparable – typically about two hours. In some cases, DAA can be performed as an outpatient surgery.

Benefits of DAA

Because the DAA splits muscle planes, the muscles and tendons do not need to be detached as with lateral, posterior or direct lateral approaches; consequently there is less muscle and soft tissue damage. Studies have shown that the DAA procedure significantly decreases length of stay in the hospital and allows for quicker recovery and discharge to home. In addition, postoperative pain is notably decreased as is scarring. Short-term functional outcome is also substantially improved.

Covenant HealthCare has been successfully performing the DAA procedure since January 2018 using advanced technology. This includes a special Hana Table for precise positioning and an intraoperative C-arm X-ray for real-time imaging.

"The hip surgery I had was fast and efficient. I was only in the hospital one night and was up the same day. It's only been two weeks since surgery and I'm walking around with a cane with no problem and no pain. I would recommend this surgery for anyone that is having problems with their hip."

–Brenda Holland

Summary

If you have patients with significant hip pain or degenerative joint disease of the hip and are candidates for THR, they may want to consider an accelerated, less painful recovery with the DAA. Success will depend on the type of joint disease, anatomy, body habitus and overall health of the patient.

As with all surgical procedures, there are risks involved – such as potential nerve damage – that should be discussed with the surgeon along with the potential advantages and disadvantages of the various surgical approaches. This will help the patient make an informed choice.

Meanwhile, a few useful resources for both patients and physicians include:

- Video simulation of procedure: https://www.youtube.com/watch?v=q4rF13tdK20
- General background: https://patients.stryker.com/hip-replacement/procedures/direct-anterior-approach

For more information, contact Dr. Cote at 989.583.7450 or adam.cote@chs-mi.com.

Children and Food Allergies: What To Eat, When and How To Test

GUEST AUTHOR
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Fussy babies, tummy aches, burping, spitting, crying – it must be a food allergy, right? This is not necessarily true, especially when other symptoms are not present. Unfortunately, there are a lot of misconceptions about food allergies that can create unnecessary worry among parents and in some cases, malnourishment and inadvertent testing (see Table 1 below).

That said, food allergies are quite common and can be serious. About 4-6% of children and adolescents in the United States have a food allergy; about 40% of those have experienced a severe reaction such as anaphylaxis. Of particular concern is that food allergies are on the rise, increasing about 50% between 1997 and 2011.

A proper diagnosis and treatment plan requires an accurate medical history, including information on the type of food implicated and the severity of reaction. It also requires consultation with an experienced allergist-immunologist, and a strong commitment by the patient and parent to identify the possible allergen.

This will help avoid two negative outcomes:

1) The inadvertent elimination of important nutritional foods and in rare cases,
2) Life-threatening food-related anaphylaxis.

Food Introduction

Technically, a food allergy is defined as an immune-mediated adverse reaction to a certain food that can cause symptoms affecting the skin, gastrointestinal (GI) tract or respiratory system. The reactions can be immunoglobulin E (IgE)-mediated and non-IgE-mediated processes.

When introducing new foods to babies in the first year of life, it is best to introduce just ONE new food item at a time and observe the child for three to five days for any food reaction. If the child does well, then the child can be given a second new food, and so on.

Table 2 on the far right provides a basic guide on what should be introduced at various ages, based on the American Academy of Pediatrics recommendations. A food diary to track potential reactions is only necessary if the child has shown reactions, as it is very useful during diagnosis.

Key Culprits

The most common food allergens involve eight food groups: milk, eggs, fish, crustacean shellfish, wheat, soy, peanuts, and tree nuts. More specifically:

- The pediatric population is most affected by peanuts, cow's milk, eggs, tree nuts, soy and wheat.
- The adult population is most affected by peanuts, tree nuts, fish, and shellfish.

The **good news** is that some allergies can be outgrown, including milk, soy, egg and wheat. The bad news is that those that persist tend to be peanuts, tree nuts and shellfish allergies.

Most food allergies can be managed by simple avoidance, and not all have serious concerns. An example is Oral Allergy Syndrome (OAS) – also known as pollen-food allergy

Continued on page 9

Table 1: Common Misconceptions about Food Allergies

MISCONCEPTIONS	FACTS
Birth – 4 Months	
Lactose intolerance is common.	Primary (congenital) lactose intolerance is rare.
Milk protein allergies are common.	Only 2-5% of children are allergic to cow's milk protein.
Breast milk allergies are common.	This is the extremely rarest-of-rare allergy, when an allergy is passed onto the baby from mom's oral diet ingredient. One should never diagnose this unless everything else has been ruled out.
4 Months – 1 Year	
When any new food is introduced and the child spits it out, it must be an allergy.	It is NOT an allergy unless the child develops a typical rash and/or has trouble breathing.
1 Year and Above	
After the intake of any new food and the child complains of tummy aches, it must be an allergy.	It is NOT an allergy unless the child develops a typical rash and/or has trouble breathing.

syndrome. OAS patients experience mild symptoms involving tingling around the mouth after handling fresh fruits or vegetables. Different fruits and vegetables that are implicated in OAS are grouped as those cross-reacting with:

- The birch family, e.g. apples, plums, peaches, nectarines, cherries and almonds
- The ragweed family, e.g. melons, bananas and tomatoes
- The grass family, e.g. melons and kiwi fruit
- The mugwort family, e.g. celery, spices and carrots

Diagnosis and Testing

The range of food allergy symptoms varies widely, from just simple mouth tingling to life-threatening anaphylaxis. Diagnosis is difficult as it is not always easy to pinpoint the exact food allergen, and testing does not always provide clear-cut answers.

It is therefore best to seek medical attention with an experienced allergist-immunologist when:

- There is a family history of severe life-threatening food reactions, as a proactive measure.
- A child develops any symptoms within minutes to hours after ingesting a new food. Symptoms include those that affect the:
  - Skin, such as a rash, tingling around mouth or swelling of lips.
  - Respiratory system, such as wheezing, respiratory distress or the feeling of impending doom.
  - GI system, such as vomiting, diarrhea and cramps.

Key diagnostic tests **performed by the allergist-immunologist** may include:

- **Skin-prick tests** (SPTs) to see the local skin reaction to the suspect food are the preferred method of testing. Patients should NOT be on any antihistamines or steroids at least three to four weeks prior to the scheduled SPTs. Results take about 30 minutes, but about 50-60% of SPTs yield false-positive results due to the impact of digestion on proteins. Also, the possibility of cross-reactivity can occur, in which a positive response may actually be to another member of the same food family sharing a similar protein.
- **Blood tests** (also known as RASTS) measure IgE antibodies and can be performed when the patient is on antihistamines or has an existing rash. However, results take several days to arrive and are not helpful in gauging severity, plus the same issue with false-positive described above occurs. These tests should not be ordered unless absolutely necessary.
- **A trial elimination diet** may be prescribed for two to four weeks in which suspect foods are eliminated and then gradually reintroduced. This can help diagnose IgE-mediated food allergies in addition to other food disorders. The elimination diet should be avoided without a concrete diagnosis, due to the risk of inadvertent avoidance of a nutritional diet eventually leading to compromised nutrition.
- If more information is needed, an **oral food challenge** (OFC) can also be performed in the office with suspected foods at increasing doses until a reaction occurs. These are known as the single-, open-, or double-blind placebo-controlled food challenge. However, they rarely confirm an actual food allergy.

The allergist-immunologist will also examine related conditions for potential linkages. About 35% of children who have moderate-to-severe eczema (atopic dermatitis), for example, have IgE-mediated food allergies, and about 6% of children who have asthma have food-induced wheezing.

Table 2: Food Introduction Schedule

AGE	FOOD INTRODUCTION
Infants	• Infants at high risk for atopy – a genetic tendency toward, for example, allergic rhinitis, asthma and atopic dermatitis – should be breastfed exclusively. • Introduction of solid foods should be delayed until 6 months of age. • If exclusively breast-fed infants develop significant eczema, only then should lactating mothers avoid cow's milk, peanuts, other nuts and high-risk allergens (wheat, soy, fish, seafood) in their diets as a precaution.
1 year	Dairy products should be delayed until age 1.
2 years	Eggs should be delayed until age 2.
3 years	Peanuts, nuts and fish should be delayed until age 3.

Treatments

Once a food allergen has been identified and depending on the severity of reaction, further action will be determined in consultation with the patient's physician. While there is no cure for food allergies, the following treatments are recommended:

- Food that induced severe anaphylaxis should be diagnosed immediately and completely avoided. Peanuts, tree nuts, fish and seafood are commonly implicated. Parents and patients should be educated immediately on the use of EpiPen®, an epinephrine injection, which can be life-saving.
- Foods that cause less severe reactions can be avoided.
- Oral Allergy Syndrome (OAS) can be handled by proper washing of the fruits/vegetables prior to consumption or by cooking or peeling them prior to consumption.
- Medications will also be discussed as necessary to manage food allergies. These range from antihistamines and steroids to alpha-agonists and EpiPens.
- Patients should be advised to go to the emergency room upon onset of severe symptoms.

Key Take-Aways

As physicians, it is vitally important to diagnose life-threatening food-related anaphylaxis as quickly as possible, and to consult with an experienced allergy-immunologist for diagnostic evaluation and management of patients suffering from food allergies.

This collaboration will help identify the best and safest tests for that specific patient, avoid unnecessary tests and diets, help rule out or diagnose other conditions, and define a meaningful treatment plan. A strong course of action will also help alleviate anxiety and restore quality of life.

For more information, contact Dr. Vaniawala at 972.765.5739 or vishwas.vaniawala@cmich.edu.

Xofigo®: A Novel Treatment for Advanced Prostate Cancer

GUEST AUTHOR
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After skin cancer, prostate cancer is the most common cancer in American men. According to the American Cancer Society, in 2018 there will be about 165,000 new cases of prostate cancer and about 29,500 deaths.

Caught early, prostate cancer is very treatable. In some cases, however, it can spread to the bone. This is also referred to as metastatic castration (or hormone-resistant prostate cancer [mCRPC]), or advanced prostate cancer. For these patients, there is new hope in the form of Xofigo® (pronounced zo-FEEG-oh).

Xofigo Treatment

Xofigo is a radioactive injection (Radium-223) that is absorbed by the bone, and an alpha-emitter that targets cancer cells in bone with minimal collateral damage. It is used to treat prostate cancer patients with painful, widespread bone metastasis who are no longer responding to hormonal or surgical treatment to lower testosterone. This condition is typically diagnosed via bone scan or PSA tests.

In a randomized clinical trial of over 900 patients, Xofigo was shown to:

- Significantly decrease bone pain and reduce the time to skeletal events, such as broken bones, spinal cord compression and surgical intervention.
- Improve median overall survival by more than 30% from 11.3 months to 14.9 months, which is statistically significant.

Xofigo is not for patients with existing bone marrow problems or who have organ involvement – although this latter situation is rare in prostate cancer.

Procedure and Side Effects

For most patients, Xofigo is extremely safe, effective and well-tolerated. Eligible patients receive a monthly IV injection for six consecutive months. The injection only takes minutes to deliver and there is minimal to no recovery needed.

There are also minimal but important radiation precautions. These include hygiene protocols such as wearing gloves and handwashing during and after fluid handling, and practicing safe sex by using condoms and other methods of birth control.

Major side effects of Xofigo may include pain flares and bone marrow suppression, requiring close monthly monitoring of blood counts. Other side effects can include nausea, diarrhea and peripheral edema.

What Physicians Can Do

Xofigo is a cutting-edge treatment that is gaining traction in the medical community. Because of its improved survival rate and other benefits, physicians should help ensure that their mCRPC patients know about this option, and collaborate with the oncology team accordingly.

Xofigo has been available at Covenant HealthCare since early 2018 and has had good success. In one patient, for example, body-wide bone pain nearly subsided allowing him to use minimal narcotic medications – significantly improving his quality of life. Depending on the treatment plan, Covenant can also:

- Deliver external beam treatments to various bone sites before, during or after Xofigo.
- Offer a spectrum of other prostate cancer treatments, before or after Xofigo. These range from hormone therapy and chemotherapy to a vaccine therapy called Provenge®. Provenge is a cell-based cancer immunotherapy and personalized treatment that programs each patient's immune system to seek out and destroy the cancer.

Eventually, Xofigo may also qualify to treat other cancers, such as women with bone-only breast cancer experiencing significant pain. See www.xofigo-us.com for further treatment details about this innovative and promising treatment.

For more information, contact Dr. Fugazzi at 989.583.5250 or james.fugazzi@chs-mi.com.

Heart Failure Clinics Offer Convenient Access to Host of Cardiac Services

GUEST AUTHOR
Dr. Mayar Jundi, Cardiologist, Covenant Medical Group

Heart failure (HF) continues to be an epidemic with a 50 percent mortality rate in the first five years. It also poses a potential strain to medical resources and the economy. According to the American Heart Association, by 2035, nearly half of Americans will have some form of cardiovascular disease and the related cost of care will have soared to $1.1 trillion (up from $555 billion in 2016).

Heart Failure Clinic Growth

The good news is that treatments for HF have significantly advanced and today's heart failure guidelines are calling for more and better care. However, there are growing penalties for hospital readmission that can affect practice and hospital ratings, and where patients go for care. The Centers for Medicare & Medicaid Services (CMS), for example, is tying the bulk of traditional Medicare payments to quality or value, and phasing in new payment models to hold providers more accountable for patient outcomes and satisfaction.

In response, a growing number of specialized HF clinics are being established to better serve patients with cardiomyopathy regardless of the etiology. HF clinics are designed to provide faster and more convenient access to a host of cardiac care services, beyond what a normal cardiology office can provide. The goal is to improve the morbidity and mortality of patients, specifically for those who require more frequent outpatient care and close attention to their symptoms.

Heart Failure Clinic Capabilities

Patients are typically referred to HF clinics by their cardiologists and PCPs for further care, especially when they cannot be seen within seven days after inpatient discharge from the hospital – a vulnerable period of time for the patient. The HF clinic:

- Supports the cardiologist by handling acute events and developing an integrated care plan that goes beyond medication therapies, including patient education, self-management and lifestyle goals.
- Will recommend any additional procedures for the patient's cardiologist to perform.
- Will share progress notes to delineate the care plan and course of action. Physicians can help adjust the plan as the patient's situation evolves.
- Deploys a highly experienced multidisciplinary team, ranging from cardiologists to nutritionists, transition coaches, dedicated nurse practitioners, physical therapists and for inpatients, visiting nurses if needed.
- Meets and tracks patient progress via face-to-face visits and telemonitoring as needed.

Covenant HealthCare Heart Failure Clinic

Covenant HealthCare opened a heart failure clinic in May 2018 after significant planning and piloting. Located at 900 Cooper, the Covenant HF clinic:

- Has a team of multidisciplinary cardiac experts that currently sees up to 35 outpatients weekly and approximately 10 inpatients daily.
- Has seen a 46% reduction in all-cause readmission rates for heart failure patients over the 2017 average.

The sooner that cardiac patients are referred to the HF clinic, preferably prior to hospital discharge, the more they can benefit from the full realm of cardiac resources.

For more information, contact Dr. Mayar Jundi at 989.583.4700 or mjundi@chs-mi.com.

By 2035, nearly half of Americans will have some form of cardiovascular disease and the related cost of care will have soared to $1.1 trillion.

– American Heart Association

Long-Term Follow-Up of Bariatric Patients

GUEST AUTHOR
Dr. Chad Ringley, Bariatric Program Medical Director, Covenant HealthCare

Obesity is a significant illness affecting 35% of the population of the United States, and the problem is only growing. While diet and exercise remain the cornerstone for treatment, bariatric operations are proven to be powerful, life-altering procedures that can deliver rapid and effective results in correcting metabolic dysfunction and decreasing lifetime risks in morbidly obese patients.

Successful outcomes, however, require long-term follow-up – a fact that cannot be overstated. The fundamental reason is that in addition to weight loss, there are significant changes in the hormonal signaling and overall metabolism that must be monitored not just during recovery, but also over the patient's lifetime since these changes are ongoing.

In the past, post-bariatric surgical follow-up has been sporadic. In the U.S., for example, only 10 to 15% of patients have been followed by the bariatric surgical team for 10 years or more. This shortcoming not only affects the ability to track outcomes but also fails the patient and can lead to an unsuccessful therapy for their morbid obesity. This is namely because bariatric surgery can:

- Result in progressive nutritional deficiencies.
- Lead to weight regain and the return of the comorbid obesity conditions.
- Give rise to rare, late and sporadic complications.

The Follow-Up Team

A multidisciplinary team approach is the best way to optimize outcomes for post-bariatric patients.

- **Primary care physicians (PCPs)** play a critical if not dominant role in health maintenance and comorbidity management. The vast majority of bariatric surgeons do not feel comfortable adjusting medications for other conditions like hypertension or diabetes. They typically require bariatric patients to be seen by their PCP in the first week after surgery to establish their new baseline and make medication adjustments based on metabolic changes.
- **The bariatric team** also must be seen by bariatric patients for the remainder of their lives. It is the belief of this author that "once a bariatric patient, always a bariatric patient." Continued care by the bariatric team – which includes the surgeon and a registered dietician – will help identify and manage any delayed complications.
- **Bariatric patients** themselves must make a lifelong commitment to their new lifestyle with dedicated follow-ups with their bariatric team and PCP, and with attendance to bariatric support groups.

The Follow-Up Process

The typical post-bariatric follow-up process is shown below:

- **About 10 days to two weeks following surgery,** the patient sees the bariatric surgeon and a registered dietician. The goals are to ensure surgical site healing and adequate hydration and nutrition. During this time, a new baseline is also established with the PCP for ongoing support, and the patient is encouraged to attend a monthly bariatric support group.
- **Three months after surgery,** the patient sees the bariatric surgeon for weight-check in and consults with the dietician. Full labs are done, and the patient is encouraged to join a gym and return to full activity. The PCP is also very instrumental in medication titration since some of the baseline medications can be decreased at this time.
- **Six months after surgery,** the patient sees the surgeon and dietitian, and full labs are done. Adjustments to diet, calorie requirements, protein goals and supplements are made.
- **One year after surgery,** the patient sees the surgeon and dietician again, and another full set of labs is obtained. Vitamin and mineral deficiencies are addressed and supplements added as needed. The patient should also meet with their PCP following this visit.

During all visits, the patient is encouraged to attend bariatric support groups, a cornerstone of treatment that is proven to help avoid weight regain.

Follow-Up Benefits

Multiple longitudinal studies have shown that bariatric patients who do NOT receive consistent follow-up care will regain a significant amount of weight versus those who are well-engaged with their bariatric team and PCP. The latter group copes much better with their physical and psychological changes, and therefore tend to stay on track with their treatment plan.

It is also imperative that a registered dietician be involved at all clinic visits to ensure a meaningful dialogue and review of the patient's eating routine. In this way, intervention can be delivered as needed with nutritional supplements and changes in eating habits, especially if maladaptive eating behaviors have occurred.

Weight Regain

The regaining of weight post-bariatric surgery is emerging as the most feared complication and long-term threat to patient success. It is estimated that about 20% of bariatric patients will regain the weight they initially lost and re-enter the BMI description of morbid obesity.

In general, weight regain is due to:

- Potential surgical and mechanical factors associated with the surgery.
- Behavioral factors, including lack of adherence to lifestyle changes in diet and exercise, and the patient's unwillingness to attend group support programs.

As far as the surgical factors go, the most pronounced issue is NOT "pouch dilation" but rather dilation of the gastrojejunal anastomosis when referring to Roux-en-Y gastric bypass patients. In this situation, the gastrojejunal anastomosis becomes wider as food travels through it, into the pouch, and then to the small intestine – negating any restrictive affect that this patient might have. This can be addressed in two key ways:

- Surgically revise the gastrojejunal anastomosis in its entirety, but this is a significant revisional gastric surgery which carries risk.
- Use endoscopic suturing devices to tighten up the gastric jejunal anastomosis for patients who are candidates.

As mentioned, behavioral factors can significantly lead to weight regain too. Patients who do not adhere to recommended lifestyle eating and exercise changes in the first year, or who "honeymoon" at any time, typically gain weight back when the significant restriction from the initial surgery has worn off.

Eating issues range from the consumption of high-calorie liquids to constant day-long snacking, also known as grazing. For this reason, all patients should be strongly encouraged by all members of the follow-up team to participate in support groups upon discharge from the hospital as it is proven to make a difference.

Other Potential Complications

Other potential long-term complications are marginal ulcerations and reactive hypoglycemia.

- Marginal ulcerations can happen in Roux-en-Y patients which typically occurs on the jejunum mucosa:
  - After ingestion of significant NSAIDs.
  - If the patient is smoking or exposed to second-hand smoke for a significant amount of time.

  It is important to recognize these ulcerations early so they do not progress into an anastomotic stricture or gastro-gastric fistula.
- Reactive hypoglycemia is associated with the increase in insulin secretions after bariatric surgery, mostly in Roux-en-Y patients but also with those having sleeve surgery. While most can be treated with dietary modifications alone, a small percentage may require oral medications in the form of acarbose, verapamil or diazoxide.

Conclusion

Lifelong follow-up with bariatric patients via a multidisciplinary team approach requires diligence, communication and commitment. The PCP plays a pivotal role in patient outcomes, as do the bariatric team and patients themselves.

Although the bariatric team takes extra steps pre-surgery to educate patients about the longitudinal effects of bariatric surgery and required lifestyle changes, getting the patient to stay on track post-surgery requires everyone's engagement. In this way, the patient has a more seamless experience, is on the right medications and is better able to cope with ongoing changes in lifestyle and metabolism. Most importantly, this approach helps ensure a better quality of life by preventing a return to obesity.

For more information, contact Dr. Ringley at 989.790.4855 or mmssurgery@mmssurgery.com.

Obesity is a significant illness affecting 35% of the population of the United States.

How Physicians Can Share in Cost Savings

Dr. Michael Sullivan, Vice President, Performance Improvement and Chief Medical Officer, Covenant HealthCare

As a federally recognized Accountable Care Organization (ACO), Covenant HealthCare is actively participating in Hospital Quality and Efficiency Programs (HQEPs). These programs help drive cost savings and ensure quality of care that can benefit physicians, the hospital and patients alike, and also allow some of the cost savings to be shared directly with physicians.

Background

For the past three years, Covenant HealthCare has been a partner in Affirmant Health, a clinically-integrated network striving to improve the health of Michigan citizens at an affordable cost. With our partners at Bronson Methodist, Lakeland Health, MidMichigan Health, Sparrow and Henry Ford Health System, Covenant has been collaborating to define best practices, care coordination models, EMR connectivity, data-sharing and risk-sharing models of care. The engine of this work is driven by our local clinically-integrated network (LCIN) which is run through our Physician Hospital Organization (PHO), Covenant HealthCare Partners (CHP).

Through the work of CHP, physicians and the hospital are collaborating in new and exciting ways as we strive to drive extraordinary care and value for our patients and community. As a member of Affirmant, CHP is a member of the Federation ACO, a care model that allows participants to share risk for the care of those patients.

Benefits of Cost Savings

The overall goal of the LCIN, Covenant HealthCare, CHP and physicians is to provide the highest quality of care at the best value for our patients. When we can accomplish this goal and remove waste from the system, we can cut costs.

HQEPs allow the hospital and CHP to share these cost savings directly with physicians. The LCIN, in our case CHP, contracts with the hospital to identify and run these programs. Physicians who are members of the LCIN can then engage in these programs and subsequently share in any savings generated. Therefore, both the hospital as well as physicians benefit in the cost savings and quality of care driven through these programs, and of course, patients reap the benefits of improved quality too – such as enhanced safety and outcomes. This is also an excellent example of working together to further our "Shared Vision" and strengthen our collaboration.

Sharing of Cost Savings

HQEPs are not primarily about cost savings. Quality metrics are chosen and must be maintained or improved. Only then can any cost savings be shared and distributed, with a portion of the savings:

- Utilized by the LCIN to reward all its members for citizenship metrics and to continue to build the infrastructure of the LCIN.
- Kept and utilized by the hospital for various needs.
- Distributed to those engaged in the clinical improvement work. This portion is primarily shared with those directly involved in the work: the responsible pool. The remainder is shared with those who have a secondary role in the work: the coordinating pool. For example, in an orthopaedic HQEP, the surgeon would be in the responsible pool and a consulting hospitalist would be in the coordinating pool.

For each HQEP, specific metrics are established which measure cost reductions in addition to the quality metrics mentioned previously. The distributions to physicians fall within fair market value appraisal which is a provision of the Federal ACO guidelines.

Five Areas of Opportunity

An in-depth analysis by CHP has identified five areas of opportunity where we have elected to start HQEP:

- Orthopaedic care, specifically total hip replacement, total knee replacement, and total shoulder replacement
- Cardiology care, specifically interventional cardiology procedures including electrophysiology interventions
- Length of stay, including medical and surgical DRG's
- Readmissions
- Blood utilization

Each of these five programs is in various stages of being implemented at Covenant. Many of you have been involved in this work either directly or indirectly. Once the program has started, strategies to improve quality and reduce costs will be implemented. Typically, these programs run for two to three years with defined performance periods lasting six to 12 months with distributions of the savings.

Metrics and dashboards will be used to track and assess performance and identify further areas of opportunity. The greater the cost savings, the greater the amount that can be shared directly with physicians. See Dr. Smith's sidebar article (at right) for a closer look at the blood utilization initiative.

HQEP on the Move

As we strive to collaborate and become more clinically integrated at the hospital-physician level, as well as at the larger population health level, HQEPs are an exciting way to improve the health of our patients, to create more value for not only them but also for the institution and physicians, and to share in the cost savings that HQEP can produce. You will be hearing more about these programs in different forums as we launch these initiatives.

For more information or to get involved, contact Dr. Sullivan at 989.583.7351 or msullivan@chs-mi.com, or Dr. Smith at 989.583.6256 or aaron.smith@chs-mi.com.

Blood Utilization Initiative Drives Safety, Access and Cost Reduction

Dr. Aaron Smith, Chief Medical Information Officer, Covenant HealthCare

The Covenant HealthCare Blood Utilization Initiative is one of the first Hospital Quality and Efficiency Programs (HQEPs) at Covenant that allows multiple medical specialties to participate. Launched in 2018, it is focused on driving quality and using best demonstrated practices regarding blood product utilization.

Eight physicians representing eight different areas of specialty have joined the Blood Utilization Initiative work group. The goal of this multidisciplinary team is to address patient safety, resource access and cost effectiveness of blood products usage at Covenant.

Blood products transfusion is a high-risk procedure leading to a variety of potentially serious complications. It is estimated that 5-6% of blood recipients suffer adverse effects to transfusion via both non-infectious and infectious hazards. Blood products are also a precious resource. At times, we have seen critically low levels of supply that could potentially hamper our ability to care for our patients. In addition, this limited resource has an ever-increasing cost associated with the price of the product itself, administration (such as supplies and nursing labor) and adverse effects of transfusion.

The Blood Utilization Initiative work group has made great strides. For example:

- It has reviewed current industry best practices and Covenant Blood Products Utilization guidelines, updating the guidelines with minor changes.
- It will be modifying product ordering within Epic to align with this initiative, and is set to launch with Beaker, the Epic Lab module that will go live in early August.
- It has reviewed educational materials and strategy with the goal of spreading awareness. This will include distributing fliers throughout Covenant and educating nurses about Beaker.

Such changes will allow accurate data to be collected for blood product utilization and ongoing utilization review. This data will be provided to the Medical Section Chairs for distribution to its members. It will also allow us to focus on areas of potential improvement regarding blood products. Future areas of focus could range from peri-operative anemia management strategies to optimizing coagulation status to minimize blood loss.

Review of our historical blood utilization has identified a potential savings of nearly $600,000. Through HQEP and utilization guidelines, we can achieve improved quality and patient safety while sharing in these savings. Potential savings that could be shared with the medical staff could amount to nearly $200,000. These efforts will allow us to successfully move ever-closer to patient-centered, high-quality care and pay-for-performance. Your questions and support are welcome. Please see the contact information at the end of Dr. Sullivan's article (on page 14 to the left).

THE CHART SPOTLIGHTS

Survey Heads Up

Please look for the Physician/Nurse Practitioner/ Physician Assistant survey coming your way by email. The survey period runs from Monday, October 8, to Monday, November 5. Your feedback is critical to creating an extraordinary care environment for patients and physicians alike, so please take the time to complete and submit. We appreciate your participation.

Congratulations Physicians of the Month!

Your patients and colleagues are saying extraordinary things…

JULY

Dr. Umesh Badami

INTERVENTIONAL CARDIOLOGY

"Dr. Badami is a good, caring doctor who knows his stuff. His staff are a plus and he takes the time to answer all my concerns and questions."

"Dr. Badami and his staff were very compassionate, professional and addressed all my concerns."

"Dr. Badami and his team do a great job every time I see them; I enjoy going to see him."

"Dr. Badami is very engaged in ensuring not only that his patients are having a great experience, but that Covenant is a leader in healthcare for the region."

AUGUST

Dr. Theresa Matzura

HOSPITAL MEDICINE

"Dr. Matzura was fantastic. She asked me questions and listened intently. I could tell that she really cares about her patients!"

"Dr. Matzura works great with the team. She is always looking for ways to help patients."

"Dr Matzura went unit by unit throughout the hospital to assure that person-to-person communication was uninterrupted and that extraordinary patient care continued during the extended Epic downtime."

"Dr. Matzura is always helpful and clinically astute. She is well-loved by students."

COVENANT HealthCare

Extraordinary care for every generation.

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