THE COVENANT Chart

COVENANT HealthCare

COVENANT MEDICAL STAFF NEWSLETTER | JUNE 2013

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The Intersection of Social Media and Medicine: *Keeping It Professional*

Dr. Sara Rivette, Covenant HealthCare Chief of Staff

In the past decade, communications have changed dramatically with the emergence of social media in our personal and professional lives. Facebook, LinkedIn, Twitter, YouTube, blogs, office websites and other venues provide a unique model of interaction that can strengthen relationships with colleagues and patients as we engage in meaningful conversations.

In addition, Smartphones, iPads and other tools allow us to record and share information with large communities of people at the push of a button.

However, while social media is exciting, physicians should be cautious in how they interact. Is it prudent, for example, to answer patient questions via Twitter? Should patients be allowed to be your friends on Facebook? Is it legal to share patient images even without personal details? What if patients see a questionable picture of YOU on line (remember Prince Harry)? Is your staff saying things about patients on their personal posts that could have repercussions? Are HIPAA rules being violated?

Those and other questions are the topic of a growing number of articles about the intersection of social media and medicine. One article I read is about nurses and doctors who got fired due to the "perception" of violating patient confidentiality online, even though personal details were not shared. Another is about a study that shows a high degree of consensus among state medical boards about the likelihood to investigate questionable online behaviors among physicians, possibly even reviewing their Facebook pages.

My advice? Make sure you have a comprehensive social media policy for your office to avoid HIPAA violations. Have your staff read and sign it, and hold a group meeting to clarify the rules of engagement that guide professional conduct. To get started, go to the AMA website, search for Opinion 9.124 and select *Professionalism in the Use of Social Media*. Also identify a social media leader on your team who can field questions and stay on top of trends and tools, like the HIPAA-compliant site for exchanging patient images that I recently received (DocBookMD).

Meanwhile, advise your staff to never discuss or identify patients in any personal or professional posts – even "friending" patients can violate HIPAA. Also, they should never answer questions online that patients post, and they should never share photos of patients or their body parts. Institutions have strict rules about taking and sharing photos.

At the end of the day, we need to remember our oath to "First, Do No Harm" as we navigate the exciting world of social media. Used properly, social media can be a great way to disseminate useful information and build brands. A successful experience, however, requires ethics and professionalism both online and off. It also means remembering one simple fact ... the best way to communicate with patients is often the old-fashioned way: face-to-face.

Sincerely,

Sara L Rivette MD

Dr. Sara Rivette, Chief of Staff


Cancer Staging: *What Physicians Need To Know*

GUEST AUTHORS
Dr. Sussan Bays, Medical Director, Covenant Breast Health Program, and
Dr. Ernie. P. Balcueva, Medical Oncology and Hematology

When patients have cancer, it is not always their oncologist or surgeon to whom they turn. Patients may also ask questions of their primary care physicians and other specialists. In addition, many groups of physicians are responsible for completing working and/or clinical staging documentation. For these reasons, it helps to understand the basics and importance of staging, which are covered in this article.

What Is the Purpose of Staging?

Staging is a way to describe the extent of cancer at the time of diagnosis. It is critical in defining the prognosis and appropriate treatment based on the outcomes of patients in a similar stage. Staging is also used to evaluate the results of treatments and clinical trials; accuracy is essential. This facilitates the exchange of information among treatment centers and can help advance clinical and translational cancer research.

What Is Clinical Staging?

Clinical staging (or working stage) includes any information obtained about the extent of cancer either before a definitive treatment is initiated (such as surgery, systemic or radiation therapy, active surveillance, or palliative care) or within four months after the date of diagnosis, whichever is shorter – as long as the cancer has not clearly progressed during that time.

Clinical staging incorporates information obtained from the following symptoms:

- Physical examination
- Endoscopic examinations
- Imaging studies of the tumor, regional lymph nodes and metastases
- Biopsies of the primary tumor
- Surgical exploration without resection

When a primary tumor (T) is classified only clinically (cT), information from a biopsy of single or sentinel lymph nodes may be included in clinical node staging (cN). Occasionally, information obtained at the time of surgery may be classified as clinical, such as liver metastases (M) that are identified clinically but not biopsied during a surgical resection of an abdominal tumor.

What Is Pathologic Staging?

Pathologic staging is defined by the same diagnostic studies used for clinical staging, but is supported by histological examination from surgical resections. Pathologic diagnosis adds significant prognostic information that may not have been clinically recognized before surgery.

Cancer protocols from the College of American Pathologists (CAP) are used as an important resource for pathologists to effectively report surgical pathology results. These protocols are specific to the primary cancer site and/or type of histology. The American College of Surgeons – Commission on Cancer (ACoS-CoC) has recognized the importance of CAP protocols and in 2004, mandated pathologists at CoC-approved cancer programs to develop scientifically validated or regularly used data elements for protocols on all surgical pathology cancer reports.

How Does Staging Affect Patient Outcomes?

According to the American Joint Commission on Cancer (AJCC) Cancer Staging Manual, 7th Edition, all staging classifications, and most importantly clinical and pathologic T, N, M and stage grouping, should be recorded in the medical record. Clinical staging is used to define the primary therapy (including surgery if performed). When surgery is the initial treatment, subsequent systemic or radiation treatment is based on the pathologic stage. Recording the clinical stage is also important because it may be the only common denominator among all cancers of a certain anatomic site and histology.

Essential Elements of Staging

Below is a summary of essential elements to staging. Please refer to Table 1 on page 3 for details.

- Site of the primary tumor
- Tumor size and number of tumors
- Lymph node involvement (spread of cancer into lymph nodes)
- Cell type and tumor grade (how closely the cancer cells resemble normal tissue cells)
- The presence or absence of metastasis

TNM Classification Rules

The Tumor-Nodes-Metastasis (TNM) system classifies and groups cancers primarily by the anatomic extent of the primary tumor, the status of regional draining lymph nodes, and the presence or absence of distant metastases. The system is a shorthand notation for describing the clinical and pathologic anatomic extent of a tumor. For some disease sites, subdivisions of the main designators are used to provide more specific prognostic information. For each designator, the prefix of c, p, yc, yp, r or a, may be applied to denote the classifications stage. Please refer to Table 2 on page 3.

What Are Physicians' Responsibilities?

All physicians should have a basic understanding of cancer staging, not only to answer patient questions but also to ensure proper documentation.

The following groups of physicians are responsible for clinical and/or working stage documentation:

- Colorectal Surgeons
- General Surgeons
- Gynecologic Oncologists
- Ophthalmologists
- Oral/Maxillofacial Surgeons
- Orthopaedic Surgeons
- Thoracic Surgeons
- Otolaryngologists
- Plastic and Reconstructive Surgeons
- Surgical Oncologists
- Pulmonologists
- Urologists
- Medical Oncologists
- Radiation Oncologists

When completing the electronic staging form (E-staging) for cancer patients, **only the clinical and/or working stage** is necessary prior to definitive treatment, such as surgery, neoadjuvant radiation or systemic chemotherapy.

Physicians do not need to document pathologic staging. At Covenant HealthCare, for example, all malignant pathology reports contain a cancer diagnosis and the required CAP protocol elements.

All staging classifications, and most importantly clinical and pathologic T, N, M and stage grouping, should be recorded in the medical record.

For questions or assistance on how to use E-staging, please contact Maryln Kapala, Health Information Management Department, at 989.583.4181 or mkapala@chs-mi.com.

Table 1: TNM System

PRIMARY TUMOR (T)

T	DEFINITION
TX	Primary tumor cannot be evaluated.
T0	No evidence of primary tumor.
Tis	Carcinoma in situ (CIS). Abnormal cells are present but have not spread to neighboring tissue; although not cancer, CIS may become cancer and is sometimes called pre-invasive cancer.
T1, T2, T3, T4	Size and/or extent of the primary tumor.

REGIONAL LYMPH NODES (N)

N	DESCRIPTION
NX	Regional lymph nodes cannot be evaluated.
N0	No regional lymph node involvement.
N1, N2, N3	Involvement of regional lymph nodes (number of lymph nodes and/or extent of spread).

DISTANT METASTASIS (M)

M	DESCRIPTION
MX	Distant metastasis cannot be evaluated.
M0	No distant metastasis.
M1	Distant metastasis is present.

STAGE

STAGE GROUP	DESCRIPTION
Stage 0	Carcinoma in situ.
Stage I	Higher numbers indicate more extensive disease: larger tumor size.
Stage II and Stage III	Spread of the cancer beyond the organ in which it first developed to nearby lymph nodes and/or organs adjacent to the location of the primary tumors.
Stage IV	The cancer has spread to another organ(s).

Table 2: Prefix Definitions

STAGE	PREFIX	DEFINITION
Clinical	**c**	Pretreatment stage: It is the extent of disease defined by diagnostic study before information is available from surgical resection or initiation of neoadjuvant therapy, within the required time frame.
Pathologic	**p**	Is defined by the same diagnostic studies used for clinical staging supplemented by findings from surgical resection and histologic examination of the surgically removed tissues.
Recurrent	**r**	Is used because information gleaned from therapeutic procedures and from the extent of disease defined clinically may be prognostic for patients with recurrent cancer after a disease-free interval. Clearly, the extent of recurrent disease guides therapy and this should be recorded in the medical record using the TNM classification. It is important to understand that the rTNM classification does not change the original clinical or pathologic staging of the case.
Post treatment	**y**	Post-therapy stage: Documents the extent of the disease for patients whose first course of therapy includes systemic or radiation treatment prior to surgical resection or when systemic therapy or radiation is the primary treatment with no surgical resection.
Autopsy	**a**	Is used to stage cases of cancer not identified during life and only identified postmortem.

Alert! West Nile Virus

GUEST AUTHOR
Dr. Muhammad Umar Khan, General Medicine Section Chief and Infectious Diseases Physician

As you treat patients throughout the summer, look for symptoms of the mosquito-borne West Nile Virus (WNV), which can sometimes be confused with the flu or other illnesses.

WNV is a threatening seasonal epidemic in North America that begins in April and flares up throughout the summer, becoming less prominent during early fall. Since December 2012, 5,387 cases of human WNV infections and 243 related deaths were reported to the Centers for Disease Control (CDC). This is the highest number of cases reported in the U.S. through December since 2002. Eighty percent of the cases occurred in 13 states, including Michigan, with approximately 33% occurring in Texas (see figures at right). Michigan had 202 cases or about 4%.

As the virus becomes increasingly active in Michigan in the coming months, it is important to know the protocols for diagnosis and treatment, and to remind patients to take preventive measures.

SERIOUS SYMPTOMS OCCUR IN
1 out of 150
OF INFECTED INDIVIDUALS

Modes of Spread

Mild winters, early springs and hot summers create ideal conditions for breeding of the Culex mosquito from Africa, which carries WNV. It first appeared in New York City in 1999 and has since spread across the nation in the following ways:

- Infected mosquitoes acquire the virus by feeding on infected birds and transmit the disease to humans through bites. Incubation time is 3-15 days.
- Blood transfusions, organ transplantation and rare cases of transplacental mother to fetus transmission.

Symptoms

Although a large percentage of people infected with WNV do not experience any symptoms, the virus has the potential to cause life-threatening complications.

- Serious symptoms occur in 1 out of 150 of infected individuals (mostly elderly and immunocompromised individuals). Symptoms include high fever, neck stiffness, meningitis and paralysis, and may cause permanent neurological damage.

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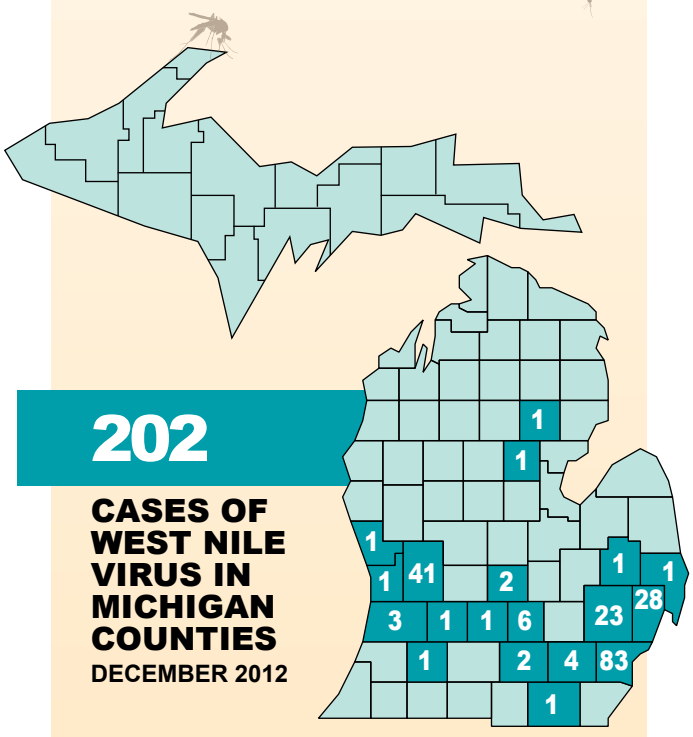
2012 WEST NILE VIRUS CASES
5,387

Non-Neuroinvasive	49%
Neuroinvasive *e.g. meningitis or encephalitis*	51%
Occurred in 13 States*	80%

** Texas, California, Louisiana, Illinois, Mississippi, South Dakota, Michigan, Oklahoma, Nebraska, Colorado, Arizona, Ohio and New York*



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CASES OF WEST NILE VIRUS IN MICHIGAN COUNTIES
DECEMBER 2012

Cumulative 2012 data as of December 11, 2012; data are provisional. Source: CDC. See http://diseasemaps.usgs.gov/wnv_mi_human.html.

Physician Engagement Ramps Up

Dr. Michael Schultz, Vice President of Medical Affairs

After carefully evaluating the results of the 2012 Physician Engagement survey, Covenant HealthCare is ramping things up with a clear action plan for three improvement opportunities designed to help create the most attractive environment for practicing medicine.

As shown in the table below, improvement opportunities identified by physicians are as follows:

- Disruptive behavior is not tolerated at Covenant HealthCare.
- Covenant HealthCare makes patient safety a priority.
- I am kept informed of Covenant HealthCare's strategic plans and direction.

Results and action plans have been shared at several physician meetings. Feedback has been positive and action plans are now being implemented. A few examples are highlighted below.

Disruptive Behavior Training

Addressing disruptive behavior was not only identified as a key improvement opportunity in the 2012 Physician Engagement survey but also in the 2012 Employee Engagement survey, underscoring the importance of resolving issues among clinical staff, non-clinical staff, leaders and physicians.

Hopefully, you were able to attend one of five, four-hour Managing Disruptive Behavior learning sessions scheduled in April and May, which were also eligible for CME credit. These sessions were structured to show how all people involved in a disruptive situation have a role and obligation to fulfill in driving positive change. The goal is to create a self-correcting culture regarding disruptive behavior before resorting to formal corrective action measures.

To date, 20 doctors and 17 residents have participated in Managing Disruptive Behavior learning sessions.

Volunteer opportunities are also available. If you have a particular interest in this issue, please consider volunteering as a peer advisor for managing disruptive behavior, working with Medical Affairs and physicians to make a difference.

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ACTION PLAN FOR PHYSICIAN ENGAGEMENT

TOP IMPROVEMENT OPPORTUNITIES	KEY ACTIONS	ACTION PLAN OWNER
Disruptive behavior is not tolerated at Covenant HealthCare.	• Pursue use of Physician Safety Leadership Team (HRO*) as a vehicle to address the situation. • Improve utilization of current disruptive physician behavior policy; improve timeliness of actions. • Provide script to ECC physicians/Hospital Medicine in dealing with disruptive specialists/others.	Dr. Michael Schultz
Covenant HealthCare makes patient safety a priority.	• Continue roll-out of HRO initiative, involving physicians where indicated. • Utilize all physician communication vehicles to educate/update physicians on HRO initiative.	Dr. Michael Schultz
I am kept informed of Covenant HealthCare's strategic plans and direction.	• CEO/Administration to routinely update medical staff on strategic plans and direction. • Send email blasts from Administration with strategic updates; strive to offer video broadcasts/webinars of active medical staff meetings.	Spence Maidlow

**High Reliability Organization*

Saving the Shoulder

GUEST AUTHOR
Dr. Colleen Linehan, Orthopaedic Surgeon, Covenant Center for Advanced Orthopaedics

Shoulder pain is a common malady that afflicts most people at some point in their lives, prompting them to seek treatment from their physician. To save the shoulder from further damage and ensure an effective recovery, it is important to properly diagnose and treat the condition as soon as possible.

The best question to ask when facilitating diagnosis and treatment is, "what is the hardest thing for you to do?" If a patient had an injury, be sure to ask about the specific mechanism, keeping in mind that patients are often unable to recall a specific injury, or the injury is minor in nature. Their answers and symptoms, however, will help you diagnose one of four basic conditions, each with its own treatment approach:

- Frozen shoulder
- Rotator cuff tear
- Impingement
- Arthritis

Fortunately, most shoulder issues can be treated conservatively, but some will require surgical intervention.

Frozen Shoulder

Frozen shoulder or adhesive capsulitis often presents itself insidiously. A patient may have frozen shoulder when the hardest movement to perform is reaching behind the back. For example, women will often have problems fastening their bra, whereas men have difficulty when they reach back to pull up their pants or put on a jacket.

The most common patient population affected is females 40-60 years old, but frozen shoulder can affect anyone. Diabetics tend to develop recalcitrant adhesive capsulitis that often takes much longer to resolve. It is important to check HbA1c in this population, and if patients have a significant family history.

The three phases of frozen shoulder are: freezing, frozen and thawing. Each can last many months. Physical therapy is the most effective treatment in each phase, either at home or via practitioner. Below are a few tips:

- Encourage patients to stretch the shoulder at least five times a day at home to prevent freeze-up between stretches, but 10 times a day is best. Exercises generally involve walking fingers up the wall, and the sleeper stretch for internal rotation. Heat can help loosen the soft tissues for a more productive stretch.
- Physical therapy should be ordered if patients can't perform stretches on their own.
- Steroid injections are not recommended. They have not proven to be helpful, other than slightly decreasing pain within the first month.

The majority of patients are able to resolve frozen shoulder issues on their own. Therefore, it is rare to take the patient to the operating room for manipulation under anesthesia.

Impingement

As the second most common shoulder diagnosis, impingement generally includes the spectrum of bursitis and rotator cuff tendinitis—problems in the subacromial space. Patients complain of a painful arc of motion that involves pain from just below, to just above, shoulder height. Their pain is often diminished when they use their unaffected arm to assist the injured arm in overhead range of motion.

Treatment is on the conservative side. Patients with impingement respond well to a subacromial steroid or Toradol injection in combination with physical therapy, which primarily involves rotator cuff and periscapular strengthening. If the injection works well, but is too short in duration (pain returns quickly), the patient is an excellent candidate for arthroscopic decompression. This involves removing the bone spurs and bursal tissue which affect the function of the rotator cuff.

Rotator Cuff Tears

This condition can be the result of an acute injury or chronic wear and tear. Patients with a rotator cuff tear tend to experience weakness with overhead lifting; MRIs are essential for a proper diagnosis. Treatment options include:

- **Conservative.** If the tear is only partial thickness, initial treatment with an injection and physical therapy is often proven to be effective. If the patient continues to complain of weakness after injection, it may be necessary to proceed with surgical repair.
- **Surgical Repair.** For patients with full-thickness rotator cuff tears, immediate surgery is recommended as the tear can progress, leading to tendon retraction and muscle atrophy. The muscle atrophy does not reverse with rotator cuff repair. Although the procedure is completed in 1 hour, the recovery period is 4-6 months. As tendon tears become more chronic or if the patient is advanced in years, the success rate of rotator cuff repair declines significantly.

Shoulder Arthritis

Shoulder arthritis generally occurs in the glenohumeral joint. It may be post-traumatic or the result of chronic wear and tear at the articular surface. These patients tend to have

Shoulder pain is a common malady that afflicts most people at some point in their lives.

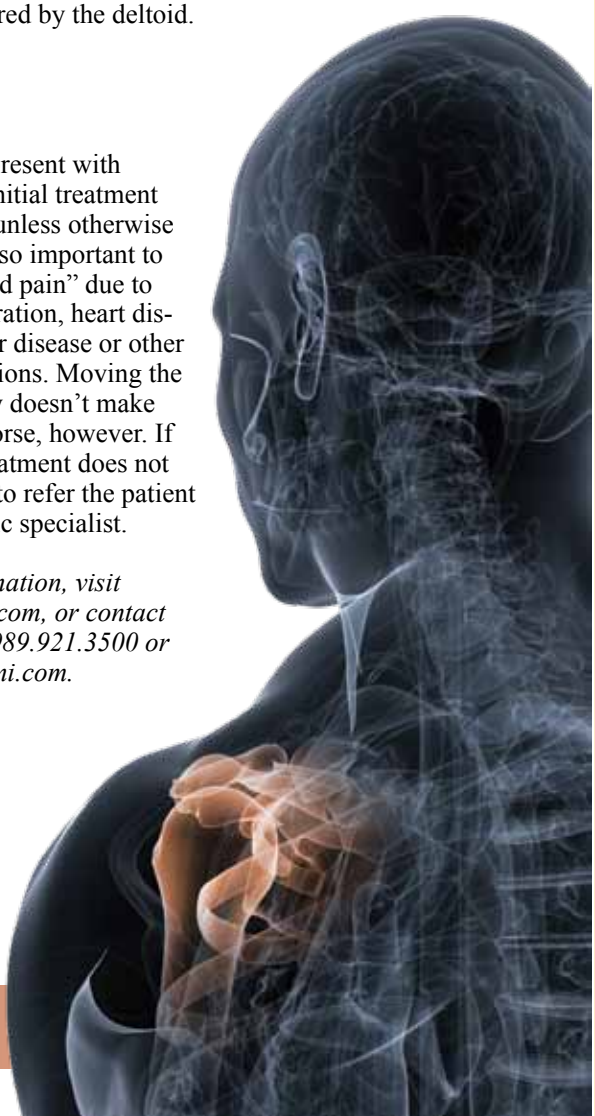
difficulty at the extreme ranges of motion and suffer from a chronic ache that increases in pain after activity. Two treatment options are available:

- **Conservative.** Initially, the pain resolves with over-the-counter anti-inflammatories, but as the arthritis progresses, these medications are no longer helpful. Steroid injections have proven to be beneficial when placed directly into the glenohumeral space. Physical therapy is usually not recommended as increased activity often exacerbates the irritation. Instead, patients are encouraged to maintain whatever activity level they can tolerate at home. Transcutaneous Electrical Nerve Stimulation (TENS) units can also be helpful in reducing arthritic pain.
- **Total Shoulder Replacement.** When conservative pain management fails, most specialists proceed with total shoulder replacement. Partial shoulder replacement is inferior with regard to pain relief as only half of the arthritis is treated. The recovery from shoulder replacement is often faster than joint replacements in the lower extremities. Surgery is about 1.5 hours and usually involves an overnight stay in the hospital. Although maximal recovery may require two years, the majority of the recovery occurs within the first three months. It is standard to obtain pre-operative MRIs in all patients to assess the rotator cuff integrity and for three-dimensional pre-operative planning. If the rotator cuff is torn, a reverse total shoulder is used. This style of prosthesis changes the biomechanics of the shoulder and is powered by the deltoid.

Summary

When patients present with shoulder pain, initial treatment is conservative unless otherwise indicated. It's also important to rule out "referred pain" due to cervical degeneration, heart disease, gallbladder disease or other localized conditions. Moving the shoulder usually doesn't make referred pain worse, however. If conservative treatment does not work, it is time to refer the patient to an orthopaedic specialist.

For more information, visit www.drlinehan.com, or contact Dr. Linehan at 989.921.3500 or clinehan@chs-mi.com.



Alert! West Nile Virus — continued from page 4

- Milder symptoms occur in approximately 20% of infected individuals. They may develop muscle aches, swollen glands and skin rash. These symptoms may last several days to a few weeks.
- No symptoms occur in 80% of infected patients.

Prevention

While community-based mosquito control programs help reduce exposure, the following preventive approaches add an extra layer of protection:

- When outdoors, use mosquito control products.
- Wear long-sleeve shirts and pants at dusk and dawn, when mosquito activity is at its highest.
- Drain standing water in the yard and outdoor containers weekly; avoid traps like tire swings.
- Install and repair window screens to prevent mosquitoes from entering the home.
- Never handle a dead bird with bare hands; report it to the local health department and get instructions for disposal.

Treatment & Research

Unfortunately, there is no "magic pill" to treat WNV. Current treatment includes supportive measures such as hydration, intubation, fever control and treatment of secondary infections. Earlier diagnosis, of course, increases positive outcomes.

However, according to the National Institute of Allergies & Infectious Diseases (NIAID), progress is being made to become more proactive with this disease. For example, in the **diagnosis and treatment** area, research is underway to develop simple devices for a rapid point-of-care diagnosis of arboviruses, including WNV. The goal is to offer cost-effective, rapid diagnostic techniques that could eventually be performed in a physician's office or even at home, to administer treatment as soon as possible.

In the area of **prevention**, NIAID is supporting research into a variety of vaccines. Approaches include vaccines comprised of WNV proteins and chimeric vaccines, where the proteins from more than one virus are combined into a single vaccine. DNA vaccines are also being explored, in which the DNA for a particular virus protein is combined with bacterial DNA and then injected into the skin. Studies are being conducted at numerous institutions and are at various stages of research and trials (for NIAID details, see http://www.niaid.nih.gov/topics/westnile/Pages/default.aspx).

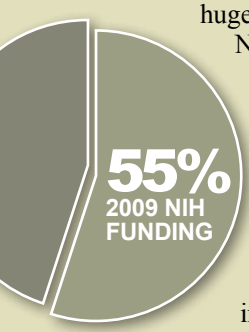
For more information, contact Dr. M.Umar Khan at 989.791.4100 or mukhan1@hotmail.com, or any Infectious Disease physician at Covenant HealthCare.

Cardiac Research: *The Value and the Promise*

GUEST AUTHOR
Dr. Firas Alani, Interventional Cardiologist, Covenant Center for the Heart Physician Group

The goals of any cardiac research program are clear: to prevent cardiac problems, reduce mortality and improve the quality of life for cardiac patients.

New solutions don't happen overnight, however. It takes time to investigate, evaluate and approve new technologies, therapies and procedures, and to educate experts in the field. Eventually – if all goes well – the initial medical discovery becomes an accepted practice.

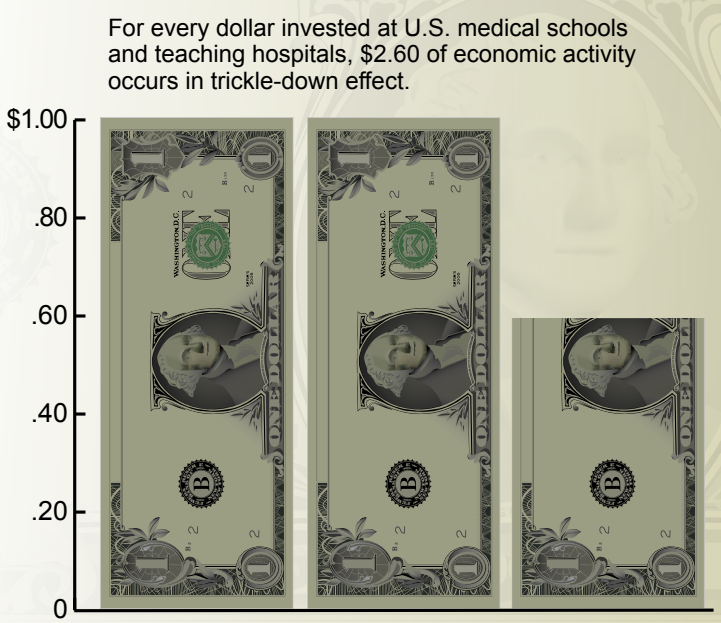


Success requires perseverance and dedication, and a huge amount of funding. In 2009, about 55% of National Institute of Health (NIH) funding went to medical schools and teaching hospitals, a highly productive research environment where physicians and scientists not only deliver care to patients but also conduct vital medical research and help train the next generation of physicians and researchers.

Without this funding, our pipeline of innovative solutions will be interrupted. So will the benefits that cardiac research brings to the national economy. Federal- and state-funded research at medical schools and teaching hospitals in 2009 added close to $45 billion to the U.S. economy. The data show that for every dollar invested, $2.60 of economic activity occurs in trickle-down effect. Furthermore, while cardiac research costs money initially, it can actually save money in the long run by turning out cost-effective solutions that prevent problems and hospitalization in the first place.

As medical professionals, let's remember to advocate at every turn for continued funding, especially in the current climate of deep budget cuts. Together, we must reinforce not only the health benefits of research, but also its economic value to our nation.

Below are just a few examples of promising cardiac solutions, still in the research phase, which can make a difference for patients everywhere – including yours.



CIRT: New Era for Anti-Inflammatory Drugs

Problem: Patients suffering from cardiovascular disease and Type 2 diabetes are prone to pro-inflammatory response, a condition that inflames the cardiac tissue and contributes significantly to atherothrombosis (blood clots). It is unknown whether inhibition of inflammation will lower vascular event rates.

Research Solution: To address this issue, a Cardiovascular Inflammation Reduction Trial (CIRT) is being sponsored by Brigham and Women's Hospital and funded by the National Heart, Lung and Blood Institute. The clinical impact of this study is broad, with the power to directly address core issues regarding atherothrombosis and open major new directions for cardiovascular treatment. The official title of the study is, *"A Randomized, Double-blind, Placebo-controlled, Event-driven Trial of Weekly Low-dose Methotrexate (LDM) in the Prevention of Recurrent Cardiovascular Events Among Stable Post-myocardial Infarction Patients With Type 2 Diabetes or Metabolic Syndrome."* The study is not yet open for participant recruitment.

Overview: The primary aim of the CIRT is to directly test the inflammatory hypothesis of atherothrombosis by evaluating whether or not low-dose LDM will reduce rates of recurrent myocardial infarction, stroke, and cardiovascular death among stable, post-myocardial infarction patients with Type 2 diabetes or metabolic syndrome. The study will be conducted from March 2013 through December 2018 and include approximately 7,000 men and women from the United States and Canada. Eligible participants who have suffered documented myocardial infarction in the past five years will be randomly allocated over a three- to four-year period to a usual-care-plus-placebo regimen or usual-care-plus-LDM. The target methotrexate dose among those allocated to active therapy is within the range of that commonly used for the treatment of rheumatoid arthritis. LDM complications will be minimized through education programs and other approaches.

Details: Please see http://clinicaltrials.gov/show/NCT01594333 for specifics about the trial including participant recruitment status.

> **"Governments will always play a huge part in solving big problems. They set public policy and are uniquely able to provide the resources to make sure solutions reach everyone who needs them. They also fund basic research, which is a crucial component of the innovation that improves life for everyone."**
>
> *–Bill Gates*

Takeda: Reducing Cardio Complications in Diabetics

Problem: Patients who have Type 2 diabetes and cardiovascular disease are at a higher risk for cardiovascular complications due to the toll that diabetes takes on the heart. In particular, patients who have taken ACTOS, a diabetic drug, have suffered sudden death as a side effect.

Research Solution: To better control diabetes and avoid Major Adverse Cardiovascular and Cerebrovascular Effects (MACCE), a new class of diabetic drug, TAK-875, is being tested. The Takeda Global Research and Development Center initiated a study entitled, *"Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 3 Study to Evaluate Cardiovascular Outcomes of TAK-875, 50 mg, in Addition to Standard of Care in Subjects With Type 2 Diabetes and With Cardiovascular Disease or Multiple Risk Factors for Cardiovascular Events."* The study is testing TAK-875 on diabetic patients with cardiovascular disease to determine its effectiveness in controlling diabetes and reducing the number cardiovascular events such as heart attacks. TAK-875 works by increasing insulin secretion in a glucose-dependent manner, which is different from other mechanisms. The TAK-875 study will also evaluate standard of care. It is currently recruiting participants.

Overview: This trial is being conducted worldwide from June 2012 to December 2018 at approximately 700 sites. The study will enroll approximately 5,000 patients randomly assigned to one of two treatment groups, one that is prescribed the TAK-875 and one that is prescribed a placebo. These participants all have Type 2 diabetes and fall into one of three cardiovascular risk categories: myocardial infarction, peripheral arterial disease or intermittent claudication. Participants must take one tablet daily at the same time throughout the study, and will need to record when they have low blood sugar symptoms in a diary. They must also commit to multiple clinic and telephone visits for additional data gathering.

Details: Please see http://clinicaltrials.gov/show/NCT01609582 for specifics about the trial, including how to participate.

For more information, please contact Hafsa Aba Ali, Research Assistant, at 989.583.6494 or habaali@chs-mi.com.

Physician Engagement Ramps Up — continued from page 5

Patient Safety

In 2012, Covenant HealthCare began developing our infrastructure to become a High Reliability Organization (HRO). We now have in place an Executive Leadership Team, the Safety Leadership Team, and the Physician Safety Leadership Team. Many individuals have already received in-depth training in HRO science, cause analysis and how to train others on HRO principles.

Both the infrastructure and our growing expertise are enabling Covenant HealthCare to develop a culture that will dramatically reduce the incidence of serious safety events. With this transformation, disruptive behavior fades away as we show deference to expertise rather than positional authority, and safety becomes 'The Core Value.' We will develop mindsets that make us situationally aware with the hope of avoiding failure, but at the same time being able to effectively deal with serious events when they occur while maintaining the resilience to continually improve. We will become reluctant to simplify (i.e., accepting the easy answer) and will be very mindful of front-end operations (the "sharp end" of medicine).

Stop by the Bickel/Geyer Conference Room at Cooper, Monday through Friday at 10:30 am, to see one of our HRO tools in action: the Daily Check-In for Safety. **You will become a believer in less than 15 minutes!**

Strategic Direction

To increase outreach and attendance, we are striving to make Active Medical Staff meetings available as video broadcasts/webinars in the future. Spence Maidlow routinely provides updates on strategy and related matters at these meetings. Video broadcasts/webinars would make them readily available to physicians who are unable to attend in person. You can expect to see more details as logistics are finalized.

For more information or to sign up for volunteer activities, please contact Dr. Schultz at 989.583.4103 or mschultz@chs-mi.com.

When Should You Transfuse Your Patients?

GUEST AUTHOR
Dr. Omer Mirza, Internal Medicine, Northeast Michigan Pulmonary Associates

Transfusions are integral to the practice of medicine and saving lives. Annually, about 15 million red blood cell (RBC) units are transfused in the United States and about 85 million are transfused worldwide. However, clinical decisions are not standardized, likely due to limited, high-quality evidence of the benefits versus harm of RBC transfusions.

If you were to review opinions between hospitals or physicians, you would find different transfusion triggers. Hemoglobin (Hgb) concentration is the most common transfusion trigger point and hospitals often have protocols to give blood to patients having an Hgb count of 7, 8 or 9, no matter what. This varies by hospital.

Consequently, there are two types of transfusion strategies: the liberal versus the restrictive.

1. The **liberal strategy** is to automatically transfuse at a certain Hgb count, even if the patient is not bleeding acutely, not complaining of fatigue, or has the bone marrow to replenish their own blood supply – the goal is to usually keep Hgb >9.
2. The **restrictive strategy**, on the other hand, considers both the Hgb count and the symptoms, in addition to comorbid conditions like Coronary Artery Disease (CAD). Most guidelines recommend this approach – with the typical triggers of Hgb <7 or 8.

The Optimal Approach

The optimal approach to transfusions is to do what is best for the patient. Physicians should:

- Transfuse only enough RBCs to maximize clinical outcomes, one unit at a time.
- Avoid unnecessary transfusions that expose patients to potential infectious and non-infectious risk (e.g. lung injury or allergic reaction) which can affect outcomes and increase costs.

Doing anything more liberal is preferable only if evidence supports it. In terms of patient safety, sometimes the best thing is to do nothing – just treat with a saline solution and iron supplements and give the body time to heal itself.

There are exceptions, of course. Excessive blood loss due to trauma is an obvious example. Less obvious is the fact that oxygen delivery from RBC to the heart may be reduced by obstructed CAD or anemia. Evidence suggests a higher risk of death and complications associated with anemia in the presence of CAD, so withholding transfusions raises concerns in this patient population.

When to Intervene

So, where is the best intervention trigger? Below are some randomized studies that shed light on this issue.

TRICC Trial

A Transfusion Requirements in Critical Care (TRICC) trial randomly assigned 418 critically ill patients to a restrictive transfusion strategy (one unit transfused for Hgb <7 g/dL to maintain Hgb 7-9 g/dL). In addition, 420 patients were assigned to a liberal transfusion strategy (one unit transfused for Hgb <10 to maintain Hgb of 1-12 g/dL). Approximately 43% of patients had cardiovascular disease.

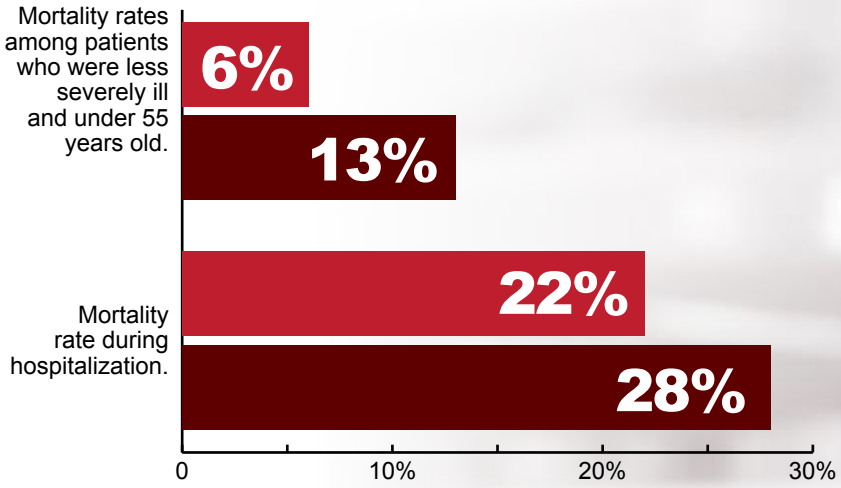
- **Mortality rates were significantly lower with the restrictive strategy** among patients who were less severely ill and among patients under 55 years old. Patients in the restrictive strategy group had a mortality rate of 6% versus 13% for the liberal strategy group. Among patients with clinically significant cardiac disease, the difference was not notably significant – 20% versus 23% respectively.
- **The overall mortality rate during hospitalization was significantly lower in the restrictive strategy group** versus the liberal strategy group, at 22% versus 28% respectively, although the 30-day mortality was similar.

These results suggest that a restrictive strategy of RBC transfusion is at least as effective as and possibly superior to a liberal transfusion strategy in critically ill patients. The possible exception to superiority would be in patients with acute myocardial infarction (MI) and unstable angina.

FOCUS Trial

FOCUS is a trial to study Functional Outcomes in Cardiovascular Patients Undergoing Surgical Repair of Hip Fracture. The FOCUS trial included post-operative patients with cardiovascular disease or cardiovascular risk factors. Overall there was no difference in functional recovery, mortality or hospital complications of myocardial infarction, congestive

RESTRICTIVE TRANSFUSION STRATEGY
VERSUS
LIBERAL TRANSFUSION STRATEGY



heart failure, stroke, infection or thromboembolism with liberal or restrictive transfusion strategies. Approximately 63% of patients had CAD or cardiovascular disease. The transfusion trigger in the FOCUS trial was <8 g/dL in the restrictive group and <10 g/dL in the liberal group.

- The TRICC trial found a slightly lower risk for MI in the restrictive group than in the liberal group (20% versus 23%). In contrast, FOCUS found a higher risk for MI in the restrictive group than in the liberal group, but it was not statistically significant.
- Also, combined data from eight trials that evaluated risk for MI did not find increased risk.

Due to statistical power and probability, however, a two-fold increased risk for MI could still have been missed.

Conclusions

Based on these studies of critical care patients, the recommendation favors a restrictive transfusion strategy as an integral part of the healthcare provider's toolbox. Note that:

- In critical care patients, an adequate consideration is to transfuse one unit of blood if Hgb is 7 or less. In the TRICC trial, patients with cardiovascular disease or cardiovascular risk factors did not have a statistically increased risk of complications. However, because of the power of the study, a question was raised in these patients: Would 8 have been a better transfusion trigger?
- In patients with significant cardiac disease and evidence of ischemia, the restrictive trigger would be >8 g/dL – this is because while TRICC suggests 7 as safe, the FOCUS used a trigger of 8. The sensitivity of the studies make this a bit of a grey area, so 8 is suggested in transfusion guidelines.
- The FOCUS trial suggested no added benefit from a liberal transfusion strategy.
- In both studies, protocols transfused one unit at a time; the practice of transfusing two units at a time is in decline.
- These findings are supported by a recent study of a patient with an upper GI bleed, which demonstrated improved outcomes with a restrictive transfusion strategy at a trigger at 7 g/dL.

Ongoing investigations will continue to improve our understanding and clinical best practices, enabling us to do what is best for the patient, and tailor our decisions to their specific situation.

For more information, contact Dr. Mirza at arrakis1971@hotmail.com or 989.583.9200.

15 million* RBC units are transfused in the U.S. and **85 million*** are transfused worldwide.

**Numbers are approximate.*

Identifying Hereditary Colorectal Cancer: *Get the Family History*

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The most important step in diagnosing hereditary colorectal cancers (CRC) is to ask patients about their family history of cancer – any cancer. CRC can be inherited, especially in patients with genetic syndromes that increase their risk for cancer or that increase the likelihood of getting cancer at a young age.

Although genetics play a role in only 5% of CRC syndromes, physicians should be on the alert to single out these patients early. This will enable you and a specialist to develop proactive screening strategies tailored to these patients and their families.

The two most common categories of CRC syndromes that affect both genders are:

1. Hereditary nonpolyposis colorectal cancer (HNPCC) – the most typical being Lynch syndrome.
2. Polyposis syndromes – the most typical being familial adenomatous polyposis (FAP).

People who carry the genes for these conditions should ***not*** be told to get their first colonoscopy at age 50; screening should begin before that. The children of these people have a 50% chance of inheriting the disease-causing gene.

CRC syndromes are usually diagnosed in one of two situations:

1. Learning the personal and family history for CRC, polyps and other cancers.
2. What is observed at the time of the screening colonoscopy – such as a few small bumps that turn out to be adenomas.

Situation 1 is the best, as it enables physicians to be more proactive in improving patient outcomes. Situation 2 leads to a more reactive treatment plan with potentially poorer outcomes.

HNPCC or "Lynch" Syndrome

Lynch cancer is the most common form of hereditary colon cancer, accounting for about 2-6% of all diagnoses each year. Patients who carry this gene have a family history of CRC and a 50-70% lifetime risk of getting CRC. They are also at higher risk of developing other cancers at a younger age than the normal population.

Lynch syndrome is caused by a germline mutation in one of the DNA mismatch repair genes. There are several gene mutations that may be responsible for the condition. Affected people have fewer polyps than FAP patients but when adenomas develop, the patient is on the fast-track to developing cancer. Equally bad, the extraintestinal manifestations tend to be malignant – including cancers of the uterus, ovaries, stomach, small bowel, hepatobiliary region, pancreas, upper genitourinary tract and brain.

Lynch is usually defined by the Amsterdam Criteria, which include Lynch cancers in at least three family members in two or more successive generations, and at least one person affected before age 50. Usually, all three criteria are not present in Lynch syndrome patients, so if it is still suspected, an immunohistochemical stain of the tumor can be ordered to determine expression of one of the DNA mismatch repair genes.

FAP Syndrome

In 1991, researchers identified the adenomatous polyposis coli (APC) gene, which is responsible for FAP. The APC mutation can be detected in 82% of patients with FAP, and their lifetime risk for developing CRC is about 100% unless the colon is surgically removed. FAP is estimated to represent about 1% of all CRC diagnoses, and while most cases are inherited, about one third may result from spontaneous gene mutation.

FAP is a rare condition in which patients have hundreds to thousands of adenomas in their colon, or growths in the large intestine. About 50% of FAP patients develop polyps by age 15 and 95% by age 35 – so the condition starts early in life with cancer potentially appearing by age 40. Because the APC gene is in every cell of the body, mutations can cause polyps and lesions elsewhere too, such as fundic gland polyps in the stomach or adenomas in the small intestine.

While extraintestinal malignancies are rare with FAP, they include medulloblastoma in the brain, hepatoblastoma in the liver and thyroid cancer. Benign conditions can include epidermoid cysts of the skin, desmoid tumors, congenital hypertrophy of the retinal pigment epithelium, osteomas and extra teeth.

Consider FAP when a patient has multiple adenomatous polyps, extraintestinal manifestations and a family history of CRC. Also note, however, that FAP appears as a *de novo* manifestation in 30% of people.

Summary

When seeing new or existing patients, it is always prudent to ask for their family history of CRC, endometrial cancer and other cancers. Look for patterns of CRC in relatives. If you suspect Lynch or FAP, consider talking to a specialist about a treatment plan for colorectal screening – not just for the patient, but for the entire family.

For more information, contact Dr. Mannam at 989.980.2212.

Physician or Healer?

GUEST AUTHOR
Dr. Gregg Stefanek, Gratiot Family Practice

Note: Dr. Stefanek, a primary care physician, shares his personal thoughts about the role of physicians and healers.

I recently saw an outdoor billboard for a hospital system claiming it had the best healers. I wasn't sure exactly why, but that claim struck me as arrogant. However, it did prompt me to think again about my role with patients, and to develop a Personal Philosophy of Care statement. I ignored the voice in my head that said it would be hard, and decided to put on paper what I believe.

Defining Our Role

I started by revisiting the oath I took upon becoming a physician. I promised to be loyal to my profession and always mindful of my great responsibility to preserve the health and life of my patients. I also promised to:

- Retain patients' confidence.
- Use only those recognized methods of treatment consistent with good judgment and my skills and ability.
- Keep in mind nature's laws and the body's inherent capacity for recovery.
- Help our community, retain good behaviors, and not purposefully hurt anyone.
- Work collegially – respecting our teachers and nurturing our students.

I then went to the Merriam-Webster dictionary for additional insights. It defines a physician as, "a person skilled in the art of healing; specifically: one educated, clinically experienced, and licensed to practice medicine." To heal is defined as, "to make sound or whole." Medicine is defined as, "the science and art of dealing with the maintenance of health and the prevention, alleviation or cure of disease."

When you combine these definitions, you get something like this: "A physician is a person who uses the science and art of dealing with the maintenance of health and the prevention, alleviation or cure of disease to make one sound or whole."

I was reminded that my job description is not limited to curing disease. To be healthy or whole means more than the absence of disease. We all have known patients who – though wracked with physical affliction – seem to transcend their illness, while those who may be cured for some reason are never truly healed. Unfortunately we have become better at curing disease than healing patients and actually, I don't think I heal anyone. The best I can do is use all of my abilities to **facilitate** healing in a willing patient.

Creating a "Healing" Interaction

I believe that focusing on healing is infinitely more rewarding than curing. It is also much more challenging. It takes more time and energy to focus on the person as a whole than it does to write a prescription. However, focusing on the person is what makes what we do worthwhile. Ironically, it is in truly giving our all that we receive the most. We receive satisfaction, protection, replenishment and enlightenment from patients who know we are treating them as a whole person, and not just their illness.

In the accompanying sidebar, I've identified seven guiding principles for creating a patient-physician interaction that is focused on healing.

Continued on page 16

Guiding Principles for Creating a "Healing" Interaction

Accept people for who they are. Do not pre-judge them.

Realize that death is not synonymous with failure, just the last part of living, and can be a tremendous healing opportunity.

Healing is often about helping people transcend their illness.

It is a privilege to do what we do.

Our patients do not exist for our benefit.

We are mandated by our Oath and by choosing to be physicians to help the whole person and not just their disease.

We have a tremendous responsibility to our patients for what they entrust to us.

Autism Spectrum Disorder: *A Treatable Disease*

GUEST AUTHOR
Dr. Marianne Majkowski, Pediatric Neurologist, Covenant Pediatric Neurology

Cases of Autism Spectrum Disorder (ASD) continue to increase nationwide, with 1.5 million Americans affected. The ripple effect of this condition impacts another 15 million individuals, including health care practitioners and families. There are many theories as to cause, but nothing conclusive and intense research is still underway. What experts do agree on, however, is the need to diagnose and treat the condition as soon as possible to minimize complications and maximize the quality of life for patients and families. It is proven that early intervention can make a world of difference – that there is hope after all.

Diagnosis and Treatment

ASD is characterized by two core areas of concern: social/communication challenges and repetitive behavior. The symptoms and severity are varied across these core areas, and can result in mild to severe complications.

High-intensity, consistently monitored and structured intervention at the earliest possible opportunity is the most effective treatment. Professional communities all agree that delaying diagnosis and treatment can result in devastating, life-long, irreversible effects to the patient and family.

This cogent understanding has spurred an association between the Centers for Disease Control and Prevention (CDC) and the National Center on Birth Defects and Developmental Disabilities in promoting awareness for early diagnosis and speedy access to intensive intervention. Campaigns like *"Learn the Signs. Act Early."* from the CDC are also actively underway to get the word out.

Early Warning Signs of Autism

Members of the healthcare community, especially primary care physicians, are in a unique position to observe developmental issues during well-child checks. It is important to keep complete records of the child's behavioral condition as well as their physical condition, and to ask parents relevant questions. Some parents may be unaware of the condition while others may be naturally hesitant to broach the topic.

While the list of ASD symptoms is extensive (see the CDC website), early warning signs include:

- No big smiles or other warm, joyful expressions by six months or thereafter.
- No back-and-forth sharing of sounds, smiles or other facial expressions by nine months.
- No babbling by 12 months.
- No back-and-forth gestures such as pointing, showing, reaching or waving by 12 months.
- No words by 16 months.
- No meaningful, two-word phrases (not including imitating or repeating) by 24 months.
- Any loss of speech, babbling or social skills at any age.

Complications of Autism

ASD is the fastest growing developmental delay in the country. Aside from the social ramifications of ASD, there are several associated co-morbid conditions as well. These include depression, Attention-Deficit/Hyperactivity Disorder (ADHD), gastrointestinal problems, sleep disturbances, obsessive-compulsive disorder, anxiety disorder and epilepsy.

Furthermore, the CDC has reported that children with autism or other developmental disorders have higher than expected rates of specific medical conditions. Children with ASD are:

- 1.8 times more likely than children without developmental disabilities to have asthma.
- 1.6 times more likely to have eczema or skin allergies.
- 1.8 times more likely to have food allergies.
- 2.2 times more likely to have chronic severe headaches.
- 3.5 times more likely to have chronic diarrhea or colitis.

Causes of Autism

There is no agreement as to what causes autism, nor is there a clear explanation behind the sharp rise in ASD cases. While part of the rise could be due to enhanced diagnostics and broader definitions, it is unlikely the sole reason. Consider

1.5 million Americans have autism, which affects another 15 million individuals, including families, health care practitioners, educators and caregivers.

Autism is more common than childhood cancer, cystic fibrosis and multiple sclerosis combined.

During the 1990s, the population in the United States increased by 13%, disabilities by 16%, and autism by 172%.

Autism treatments add up to $90 billion a year. In 10 years, the annual cost will rise to $200-$400 billion a year.

that 10 years ago, one in every 2,500 American children was diagnosed with autism. According to the CDC and as of March 2012, it is now one in every 88 children. It is estimated that the total number of Americans afflicted with autism will soon reach 4 million. For this reason, many studies are underway to understand potential triggers, be they genetic, environmental, biological or some combination.

Medicine and Autism

Unfortunately, few drugs effectively relieve ASD symptoms. There is no single medication that treats all the core symptoms, and none of the options most often prescribed by practitioners work well for every individual. Drugs can, however, have beneficial effects if they are constantly monitored and prescribed in the context of a consistent behavioral program and ongoing family education.

Two drugs are FDA-approved for the treatment of irritable behavior: risperidone and aripiprazole. Medications that reduce irritability, attention deficit and depression can have positive effects by improving the person's ability to socialize with others and reducing stereotypic behavior and aggression.

Advanced Treatment Programs

There is no cure for ASD. Meanwhile, to overcome the unique learning barriers of ASD children, new treatment approaches are necessary. Valid studies show that one early intervention technique – Applied Behavior Analysis (ABA) – is an effective approach for teaching new skills and reducing behavioral difficulties. ABA treatment for autism:

- Helps teach social, motor and verbal behaviors in addition to reasoning skills.
- Creates a learning environment focused on intensive practice of skills, continuous evaluation of success and challenges, and ongoing training to families and staff.
- Applies to all stages of child development and behavior management.
- Involves constant behavioral observation to determine and remove triggers.
- Includes positive reinforcement of desirable behaviors.

ABA is based on 30 years of empirical research that demonstrates how ASD children receiving early and intensive behavioral intervention make significant progress in all developmental domains, and that such progress is likely to be maintained over time.

Regional Treatment Program

In response to the growing need in the Great Lakes Bay Region for ASD treatment programs, Covenant HealthCare will be opening the Covenant Center for Autism. After thoroughly investigating autism services nationally, Covenant decided to mirror its diagnostic and treatment program after the Cleveland Clinic's autism program, working closely with the Cleveland Clinic Autism Consulting Group to make this happen.

Clinical services in the Covenant Center's **Diagnostic Clinic** will provide cutting-edge diagnostic evaluation, including neurological assessment, psychological evaluation, speech/language evaluations and behavioral assessment. It will also offer initial and second opinion evaluations.

Services in the **Treatment Center** will offer early intensive behavioral intervention to toddlers and preschoolers with a diagnosis of ASD up to age 7 years. The program will operate on a full-day schedule of intervention providing approximately 25-30 hours per week of intensive intervention to children enrolled in treatment. The treatment program will operate year-round.

For more information about ASD or the treatment program, contact Joseph Norcross at 989.671.5721 or jnorcross@chs-mi.com. Note: A special thanks is extended to a key contributor to this article; Leslie Sinclair, BCBA Program Director, Center for Autism, Cleveland Clinic.

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Physician or Healer — continued from page 13

Keeping the Focus

It is unfortunate that the business of running our practice can be an obstacle to the healing process. When our bottom line becomes our most important concern, consider it a red flag as it means we have lost what we are meant to be, and it's time to refocus. It means that we have forgotten that in giving our all, we receive the most.

When I look back on my most rewarding experiences, I am sometimes surprised that the people I have helped die are the experiences that come to mind first. While I have never witnessed a case of a miraculous physical cure, I've seen remarkable healing throughout an entire family when a dying loved one lets go of their earthly existence with peace and dignity. I couldn't exactly heal, but I could help.

Crafting the Statement

That voice in my head was right; creating a Personal Philosophy of Care statement is not easy. I have earned the right to be called a physician, but think it's self-important to call myself a healer like that hospital billboard did.

Given all my research and personal beliefs, this is the statement I crafted:

> "I believe in helping each person whom I have the privilege of serving, be as healthy and whole as possible. This includes maintaining their health, preventing illness, curing illness when possible, and helping people transcend their illness when we have to let go, to the limits of our knowledge and abilities. It is with awe and humility that I accept this great responsibility entrusted to me."

The process of writing this was enlightening. It has reminded me about my priorities and the rewards of working with patients to facilitate healing. Should you want to craft your own statement, feel free to use this as a starting point.

For more information, contact Dr. Stefanek at 989.285.4545 or gstefanek@chs-mi.com.