THE COVENANT Chart

COVENANT HealthCare

COVENANT MEDICAL STAFF NEWSLETTER | DECEMBER 2012

CONTENTS

2, 3 & 4
A Culture of Safety = A Culture of Respect

5
Thoughts on Physician Patient Satisfaction

6 & 7
Endometriosis and Fertility

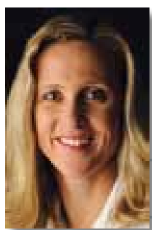
8, 9 & 10
Commentary on Choosing Wisely® Recommendations

11
A New Cancer Weapon: Antibody-Drug Conjugates

12 & 13
Pelvic Floor Disorders
Fighting the "Taboo"

14 & 15
Surgical Outcomes Research
Aiming For Better Patient Care

16
Taking Action on Physician Engagement



Treating Cancer
It's More than Medicine

Dr. Kristin M. Nelsen, Covenant HealthCare Chief of Staff

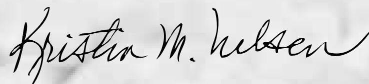
Cancer touches us all, whether it is our patients, family, friends or ourselves. It is a psychological battle as well as a physical one.

One of my high school classmates became a gifted surgeon and was diagnosed with pancreatic cancer, a tumor on which he had frequently operated on others. During his illness, he recommended a book, *Cancer: 50 Essential Things To Do*, by Greg Anderson which describes recovery from cancer by taking on a lifestyle of wellness – not just fighting an illness. He recommends paying attention to nutrition, exercise and attitude as well as emotional and spiritual support.

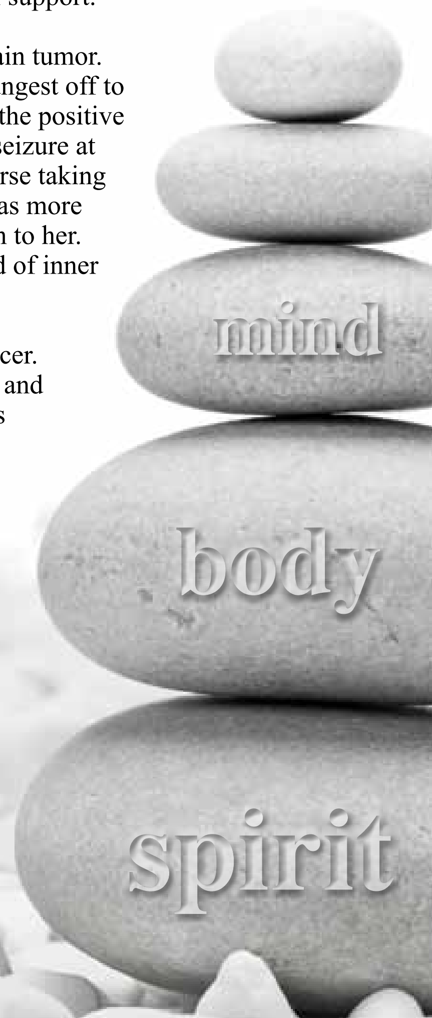
Yet another friend of mine was diagnosed with an inoperable brain tumor. She is a young mother of five children, and had just sent her youngest off to kindergarten. I am amazed by her strength and the ability to see the positive in life, despite her diagnosis. She was thankful that she had her seizure at night and not while driving her children, and grateful that the nurse taking care of her after her brain biopsy was someone she knew. She was more concerned with what to tell her children than what would happen to her. She had faith in her care team. I hope that I would have that kind of inner strength.

Jimmy Valvano won the ESPY award in 1993 while battling cancer. He mentioned three things we should do every day: laugh, think and have emotions that bring us to tears. Having a positive attitude is so important. We can live in the moment and find time to play and find joy.

As physicians, we must remember we are healing partners. We can have empathy with our patients and in the process, we may learn something about ourselves. Contact is comforting. Laughter is good medicine. Love, kindness and concern are essential. The journey of wellness is much more than medicine: it involves the body, mind and spirit.



Dr. Kristin M. Nelsen, Chief of Staff



A Culture of Safety = A Culture of Respect

GUEST AUTHOR
Dr. Peter Bistolarides, Surgeon Champion for the Michigan Surgical Quality Collaborative, CMU College of Medicine – Department of Surgery

Recently, the Covenant HealthCare Surgical Quality Improvement Committee (SQIC) – which participates in the Michigan Surgical Quality Collaborative (MSQC) – commenced participation in MSQC's Peri-Operative Initiative (POI). The POI is an initiative to look at peri-operative procedures and processes, identify areas of improvement based on evidence and best practices, and validate by improved outcomes. While secondary goals such as patient experience, satisfaction and even cost are important, the POI and MSQC programs are anchored by a higher purpose – **the improvement of patient safety**. The inaugural meeting of the hospital's POI group, whose membership includes surgeons, OR nursing staff, administration, and safety and quality staff, was held on October 16, 2012.

The source of the quote below is open to debate: it has been attributed to the 1st century philosopher Philo of Alexandria as well as a 19th century pastor, John Watson, in addition to Plato and others. It is true to say that the sentiment – or some variation of it – can be found in many of the world's religious and philosophical traditions. So, what does this quote have to do with the POI, MSQC or patient safety?

The Great Paradox

In April 2012, the MSQC held its first annual conference in Detroit. The keynote speaker was Dr. Lucian Leape, former professor of surgery at Tufts University, a member of the Institute of Medicine (IOM), and co-author of the 1999 IOM report "To Err is Human: Building a Safer Health Care System." In it, the IOM addressed errors and patient safety in the health care system. The report revealed that the U.S. health care system had a problem – a disturbing amount of errors and inefficiency – and that the technology existed to address this. The goal: a reduction of errors in the system by 50% within five years.

Leape described how there was great enthusiasm – and still is – in implementing all manner of procedures, tools and mechanisms to address this problem. Yet, the early gains seemed to have leveled off and 13 years after the IOM report, there is still a lot of opportunity for improvement. This is the paradox: more systems and efforts in place to improve patient safety than existed in 1999, definite improvement in many systems and processes, and the desire and commitment to continue to improve – yet efforts have stalled. Clearly, an improvement of systems is not enough. There is a piece of the puzzle that is missing.

A Dysfunctional Culture

Leape presented the results of various surveys of nurses, medical students and patients, which paint a picture of a high degree of dysfunction in health care, citing findings such as verbal abuse of nurses and other health care workers, dissatisfaction by patients of care received, and disturbingly – looking at the entry point of the health care system – a high rate of burnout in a survey of medical students (plus another that showed 4.4% of respondents have seriously considered suicide). Physicians surveyed about disruptive behavior were equally revealing – 11% reported witnessing this type of behavior daily. A full literature search of similar surveys will demonstrate that these findings are only the tip of the iceberg.

"Be kind to all, for everyone you meet is fighting a great battle."

In looking at the stalled rate of improvement in care, Leape proposed a hypothesis: *disrespectful behavior is the root cause of the dysfunctional culture of health care.*

It is important to point out that the concept of **disrespectful** behavior includes what most people readily identify as **disruptive** behavior. Besides **active** disruptive behavior (including verbal abuse, humiliation, put-downs and similar acts), there is **passive** disrespectful behavior (acts such as ignoring calls, dismissive attitudes, non-compliance, refusal to cooperate or communicate). There is also system-related disrespect (hours, workload, conditions, non-participatory environment and so on).

There are very few among us that can claim to demonstrate exemplary behavior at all times and in all situations. Note that disruptive or disrespectful behavior is not the sole purview of physicians. It can be displayed by ANY member of the health care team. There is a tendency to dismiss or even accept disrespectful behaviors, and to look at them as transient "incidents." Yet, this only introduces or perpetuates dysfunction in the overall system and affects people in profound ways – acutely and chronically.

When a Crisis Hits

In August 2005, Air France Flight 368 was carrying 309 passengers and crew. It made a hard landing in Toronto during a violent storm, skidding off the runway into a ravine, crashing and bursting into flames. In January 2012, the cruise ship Costa Concordia, carrying 4,252 passengers and crew, ran aground off the coast of Italy and capsized within hours.

How many people perished in each accident – absolutely or proportionately? Thirty-two people perished in the Costa Concordia disaster and given the nature of the Air France crash, you would expect an even greater loss. Surprisingly, all 309 passengers and crew of the Air France crash survived with only a few minor injuries – all evacuated *within 90 seconds of the crash and with the aircraft actively on fire!*

In the Costa Concordia case, the order to abandon ship did not come until an hour after the accident – even with evidence that the ship was starting to list, and then it took nearly *6 hours* to complete evacuation.

Why the difference? Was it a matter of training? Perhaps, but there was an even greater issue: the lack of communication and coordination from the Costa Concordia's command and a disregard of duty and mission. What has been well publicized

Continued on page 4

Standards of behavior and performance, and principles of good communication, will need to be applied across the board and find a home at all levels of the hospital.

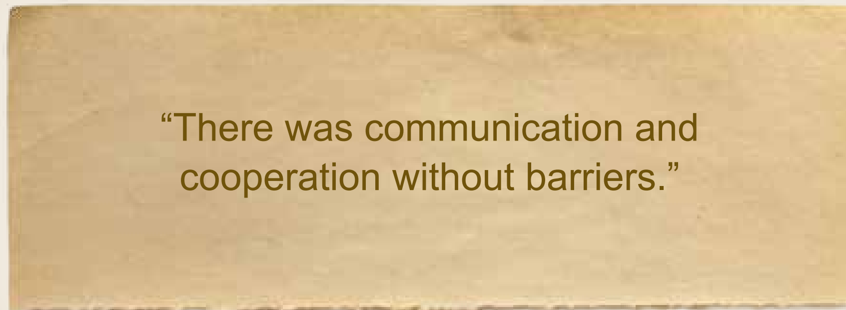
A Culture of Safety continued from page 3

is the fact that the captain of the Costa Concordia was already off the ship before serious rescue efforts were underway.

While one can call it a miracle on a number of levels, at the most fundamental level the Air France crew executed their training and their roles as expected – even in the cramped confines of a burning airliner – with the pilot and co-pilot being the last to leave.

The Adverse Effects of Disrespectful Behavior

What if the crew of Air France 368 refused to communicate with each other or follow procedures? With only seconds to make decisions and react, the result could have been catastrophic. We know nothing about the individual crew members of the Air France flight, any more than we know about the people we work with on a daily basis. Perhaps they had their disagreements – or even hated each other. Even if this were true, what is important is that the mission was kept in mind, the objective of the moment was the only thing that mattered, and everyone performed as they had been trained. *There was communication and cooperation without barriers.*



Leape describes acute reactions to disrespectful behavior (psychological distress such as fear, anger, shame and confusion), which also clouds judgment and impairs thinking. Long term, there is the maladaptive behavior of avoidance (minimizing contact with the source; calling only when necessary). ALL of these reactions increase barriers to good communication. More importantly, ALL of these may have a direct, negative effect on patient safety by hindering efforts to identify system problems and make meaningful improvements. This is the hidden cost of disrespectful behavior and dysfunction in the health care system.

The Challenge

The POI's over-arching goal is simple: to improve the care of the surgical patient. As part of the initiative, data-driven and methodical examination of our procedures and processes will certainly occur. Addressing the missing piece of the puzzle – communication and a culture of respect – must be addressed. This, without doubt, will be the most challenging part of the initiative. There are many factors to be considered, such as working conditions, team relationships, economic imperatives and personalities. A careful examination of team relationships and communication will take time and honesty. The process may even be uncomfortable at times. It will not be a simple matter of "being nice" to each other (though that doesn't hurt). It is much more than that.

This challenge is not limited to surgical services. It is not an "asymmetric" issue limited to one profession, one department or even one hospital. Standards of behavior and performance, and principles of good communication, will need to be applied across the board and find a home at all levels of the hospital.

As Covenant HealthCare, along with other hospitals, embarks on the journey to being a High Reliability Organization – and especially in its increasing role as a major teaching facility for physicians and health care personnel of all kinds – addressing team communication, disrespectful behavior and communication will be a critical part of those efforts.

Patients expect the team caring for them at some of the most critical moments in their lives to communicate with each other effectively and efficiently – without fail. As physicians, we must model that behavior to others and to those who are depending on our leadership and mentorship. We should expect no less than this when we ourselves become the "passengers" in the system.

For more information, please contact Dr. Bistolarides at 989.583.6993 or peter.bistolarides@cmich.edu. Sources are also available upon request.

Thoughts on Physician Patient Satisfaction

Dr. Noel Lucas, Hospitalist and Chair of the Physician Patient Satisfaction Committee, Covenant HealthCare

Dr. Noel Lucas, a hospitalist at Covenant HealthCare, has participated on physician patient satisfaction committees at various hospitals. In the interview below, he shares his thoughts about how and why physicians can make a difference.

If physicians could change one thing to improve physician patient satisfaction, what would it be?

At the very least, we need to remember to stop, sit and talk to our patients to reinforce the perception that we truly care – which we do. It's why we sacrificed all those years to go to medical school and residency. Sometimes, we just forget or we get hardened emotionally, so we breeze through our rounds but in the process – if we don't give our patients quality time – we can leave behind a wake of confusion, hurt, anger or feelings of abandonment.

Adjusting our behavior doesn't always require spending more time with the patient. It does, however, require spending "quality" time to increase the perception of care. For example, instead of standing up to talk to a patient, pull up a chair, have a conversation, listen and give them your undivided attention. This is the one behavior that can make a world of difference in physician patient satisfaction.

Why is physician patient satisfaction such a hot topic?

Because our top priority should always be the patient – they deserve a good health care experience regardless of prognosis. However, patient satisfaction is also critical to a hospital's financial viability. Hospitals have known for quite some time that Medicare would start withholding up to 1% of reimbursement payments based on their quality scores, 30% of which is based on physician patient satisfaction. The policy was implemented this past October, and equates to around $850 million per year in total withheld reimbursements to hospitals across the United States – or $255 million for just the physician patient satisfaction component. For an individual hospital, not meeting standards can add up to millions of dollars per year in withheld reimbursements.

What is the trickle-down effect of losing money?

It's like running a household – when you bring home less money, you don't have as much to spend – so maybe you don't buy that iPhone or extra car, or take that vacation. A hospital is no different. Anything that affects the long-term financial viability of a hospital can affect decisions on everything from technology, innovation and equipment, to recruiting and retaining top talent, to calibrating employee bonuses. It can also affect the health of local practices – many of which are attached to the success of area hospitals. The financial viability of a hospital also contributes to the economic success of the local community since quality healthcare is an important criterion for business investment. Plus, there is the element of employee morale too – we all want to be associated with a hospital and colleagues that we are proud of.

How else can physicians help?

We need to examine our behavior toward patients and adjust it when necessary, which is always easier said than done. You'll often hear that it takes 21 days to form a new habit (behavior), but there is no magic number. What it takes is constant dedication to do the right thing – which is to respect patients and give them the time of day. That's what they are paying for and what they expect, not just a successful procedure.

In her article in this issue of The Chart, Dr. Nelsen said, "As physicians, we must remember we are healing partners," – and she is absolutely right. Part of the problem we are facing right now is that we aren't always taught in medical school how to be respectful to our patients. More schools are starting to integrate this idea into their programs, but for those of us who are already practicing, we may need to rethink and recalibrate our approach to patients.

For more information, or to join the Physician Patient Satisfaction Committee, please contact Dr. Lucas at 248.219.6805 or noellucas@chs-mi.com.

Endometriosis and Fertility

GUEST AUTHOR
Dr. Steven Fettinger, Obstetrician and Gynecologist, Women's OB-GYN, PC

Physicians treating women in their reproductive ages must be mindful of the symptoms of endometriosis. Early diagnosis and treatment may prevent loss of fertility and avoid unnecessary pain. Relief of symptoms can be achieved by multiple medical and surgical interventions, but often requires definitive surgery after childbearing is completed.

Below is a primer on endometriosis – along with some useful updates – to ensure the proper care of women during and after their reproductive years.

The Disease Defined

Endometriosis is a common disease that affects 5 to 10% of reproductive age women. It involves the presence of endometrial tissue in an abnormal location (outside of the uterine cavity). These endometriosis "implants" can invade normal tissue under the influence of menstrual cycle hormones. Each month, inflammation from this ectopic endometrium causes pain and reactive scarring of the affected tissue. This invading tissue, although acting malignant, is totally benign but can cause significant pain and problems with fertility if not caught early.

Many women use medication to deal with their pain, and may also lose several days of work each month due to the disabling pain. The loss of productivity and income is enormous, plus the medical costs are substantial. Endometriosis is responsible for:

- 8% of all gynecologic hospital discharges
- Hospitalizing four out of every thousand women
- Up to 40% of all infertility

Symptoms & History

The risk of endometriosis is doubled for patients who have a family history of endometriosis. If your patients have a history or show the following symptoms, be on the alert:

- Dysmenorrhea
- Pelvic pain
- Dyspareunia
- Infertility

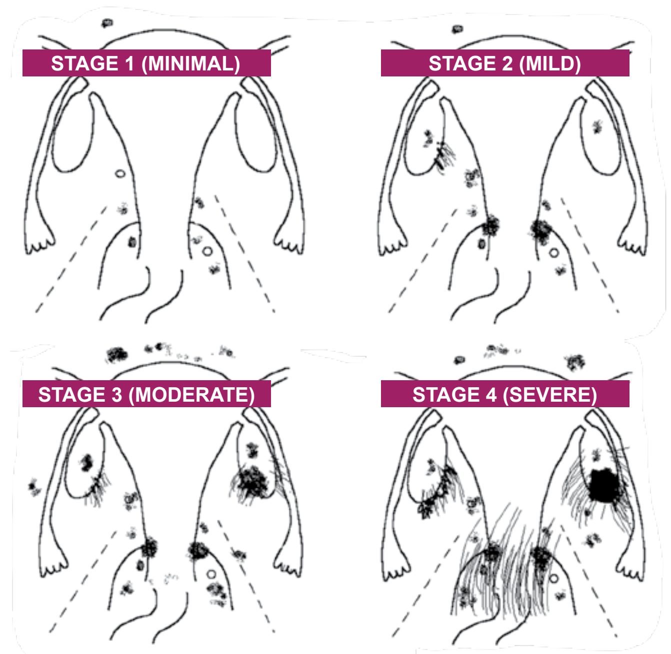
Endometriosis should also be suspected for patients who display those symptoms and fail to respond to non-steroidal anti-inflammatory drugs and birth control pills.

Diagnosis & Stages

Endometriosis typically involves the ovaries and uterus sacral ligaments but can occur in other tissues, such as lung, breast and C-section incisions. There are many theories regarding cause, but the predominant theory is retrograde menstruation with implantation of viable endometrial cells in the pelvis region.

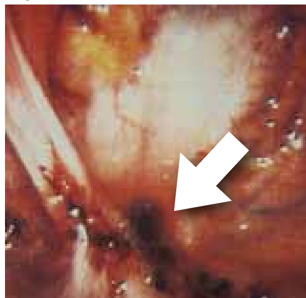
As with many diseases, endometriosis is classified into one of four stages as shown in the illustrations below.*

The stage depends on the location, extent and depth of endometriosis implants, the presence and severity of adhesions, and the presence and size of ovarian endometriomas.



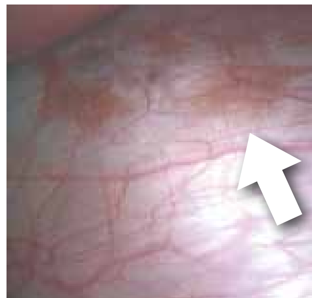
Illustrations developed by S. Fettinger to document findings.

Typical Lesion
Powder-burn in a Utero-sacral Ligament Nodule

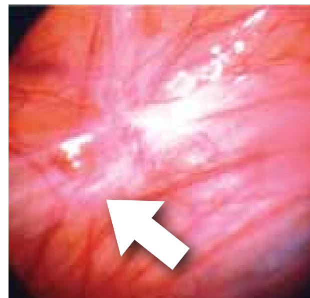


Atypical Forms of Endometriosis Lesions

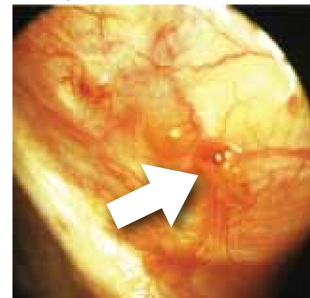
Tobacco Stain



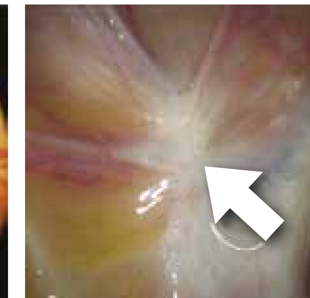
Clear Bleb



Fleshy



Stellate Formation



Two-thirds of endometriosis is diagnosed in Stages I and II, 24% in stage III and only 10% in stage IV. Severe involvement of other organs, such as bowel or bladder, usually occurs in stage IV and may require extensive surgeries.

The clinical course of the progression of disease is highly variable with the majority of patients remaining at Stage I and II throughout their menstrual years and remitting in menopause. Note that a variation of endometriosis is adenomyosis. This is endometriosis within the wall of the uterus causing the same pain symptoms but without the destructive properties of pelvic endometriosis. Ovarian endometriosis (endometrioma) is also common and can be suspected when seen on pelvic ultrasound.

The cyclical nature of the symptoms differentiates endometriosis from many other pelvic disorders such as pelvic inflammatory disease, appendicitis, ovarian torsion, ectopic pregnancy, inflammatory bowel disease and renal stones. Upon physical examination, pelvic tenderness, scarring of the uterus sacral ligaments or enlarged ovaries are often seen.

Definitive diagnosis usually requires laparoscopy with a finding of endometriosis lesions present within the pelvis. The typical powder-burn and utero-sacral ligaments nodule are the classic endometriosis lesion, but **many atypical forms are now recognized as endometriosis**. These include; tobacco stained lesions, bleb or clear lesions, fleshy lesions, stellate formations, spider webbing and peritoneal defects. Surgeons should familiarize themselves with these newly recognized forms, especially for patients having pain (see photos below).

Infertility Treatment Success

Infertility may be the only symptom of endometriosis for some patients. Most theories of how it causes infertility relate to inflammatory substances within the pelvis and distortion of pelvic anatomy secondary to scarring.

The four-stage classification system helps predict the success of traditional infertility treatments for endometriosis.

Stage I and II: **70%** success rate of pregnancy
Stage III: **50%** success rate of pregnancy
Stage IV: **30%** success rate of pregnancy

In-vitro fertilization for endometriosis has a 60-80% success range for all stages. The range of in-vitro success is more related to the patient's age than the extent of disease.

For more information, please contact Dr. Fettinger at 989.792.3100 or sfettinger@aol.com.

Treatment

Early treatment and intervention, of course, is always essential to preserve fertility.

Treatment modalities include conservative observation, surgical management and medical management. After identifying the lesions, most energy sources, including cautery, KTP laser, CO_2 laser and harmonic scalpel, can be used to cauterize or vaporize endometrial implants.

- The use of the daVinci Robotic System's improved 3-D optics may help identify early atypical lesions.
- The use of computer image enhancement, such as Olympus narrow band imaging, also aids in the identification of endometriosis.

Both of these modalities are currently available at Covenant HealthCare to identify endometriosis. Two different fiber-delivered CO_2 lasers are currently being evaluated for use at Covenant HealthCare as well.

When future childbearing is of concern, laparoscopic cautery of endometriosis lesions or excision of lesions may give symptom relief and improved fertility. Suppressive medical therapy is used after surgery when childbearing is postponed or when the patient wishes to preserve the option of having additional children.

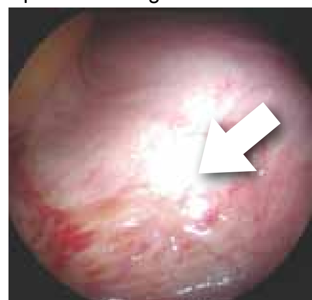
Birth control pills (in a continuous regime) and Depo-Provera are used to suppress menstruation using hormones to mimic pregnancy (pseudo-pregnancy). GRNH analogues/antagonist (Depo-Lupron) may be used to turn off hormones, preventing menstruation (pseudo-menopause). Research using anti-estrogens, such as those drugs used to treat breast cancer (Letrazole) is currently underway.

When childbearing is not of concern, a hysterectomy with bilateral salpingo-oophorectomy may be indicated for extensive disease. In the less severe cases, when conservative management (medical or previous laparoscopic cautery) fail, a hysterectomy with conservation of one or both ovaries may suffice.

Call to Action

Endometriosis is a disease that afflicts millions of women in our country, so most of us know someone afflicted with this disease. The tragedy is when the disease goes untreated, as it can result in unnecessary pain and/or infertility. As physicians, let's be mindful and ask the right questions, recognize the symptoms and be proactive in our approach.

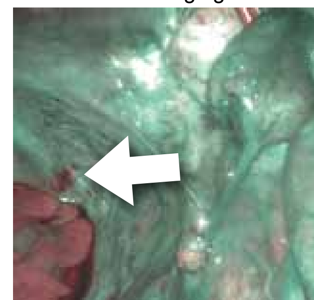
Spider-webbing



Peritoneal Defect

Peritoneal Defect

Endometriosis with Olympus Narrow Band Imaging



da Vinci Robot System with CO_2 Laser Through Fiber

Commentary on Choosing Wisely® Recommendations

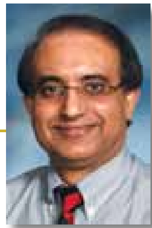
Dr. Michael Schultz, Vice President of Medical Affairs

In the September issue of *The Chart*, Dr. Schultz, Vice President of Medical Affairs, shared his thoughts about health care reform in an article, "Of Rationing and Waste." This article also summarized the Choosing Wisely initiative of the ABIM Foundation to improve patient care and eliminate unnecessary tests and procedures, and provided examples of waste reduction for nine medical societies. Schultz has subsequently asked key medical experts to comment on each of the Choosing Wisely recommendations for each society. This is the first in a two-part series of "Commentary" articles reflecting physicians' opinions.

NOTE: Choosing Wisely recommendations appear in black, expert's opinions appear in blue.

American Society of Nephrology

MOHAMMAD A. BASHIR, MD



Don't perform routine cancer screening for dialysis patients with limited life expectancies without signs or symptoms.

In general, the younger dialysis patient who lacks significant comorbid disease and is a good transplant candidate will likely benefit from a screening mammography and the colonoscopy, particularly if there are significant family or personal risk factors for those cancers. In specific other cases, a dialysis patient at high risk of breast or colon cancer and at low risk of mortality with end-stage renal disease (ESRD) may also benefit from a mammography and colonoscopy. For the most part, however, screening mammograms and colonoscopies are not recommended as routine procedures for dialysis patients.

Don't administer erythropoiesis-stimulating agents (ESAs) to chronic kidney disease (CKD) patients with hemoglobin levels greater than or equal to 10 g/dL without symptoms of anemia.

I agree with this recommendation.

Avoid nonsteroidal anti-inflammatory drugs (NSAIDS) in individuals with hypertension or heart failure or CKD of all causes, including diabetes.

In cases where patients have to take NSAIDS, they need to keep well hydrated.

Don't place peripherally inserted central catheters (PICC) in stage III–V CKD patients without consulting nephrology.

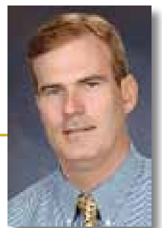
I agree with the recommendation, but keep in mind that patients with CKD may need dialysis access in the future. For that reason, I suggest protecting their blood vessels by using only hand veins for blood draws and IVs. For the same reason it is advisable to also use the dominant arm for taking blood pressure.

Don't initiate chronic dialysis without ensuring a shared decision-making process between patients, their families, and their physicians.

It is imperative that patients with CKD or ESRD be informed and educated about treatment options. Treatment options include transplant, in-center hemodialysis, peritoneal dialysis or no form of treatment. Various dialysis companies provide treatment option training for patients and their families. For more information, contact a nephrologist.

American Academy of Allergy, Asthma & Immunology

MICHAEL McAVOY, MD



Don't perform unproven diagnostic tests, such as immunoglobulin G (IgG) testing or an indiscriminate battery of immunoglobulin E (IgE) tests, in the evaluation of allergy.

Some of our nation's best food allergists who wrote the 2010 National Food Allergy Guidelines for NIH stated that allergen-specific IgG4 is a "nonstandardized and unproven procedure."

Don't order sinus computed tomography (CT) or indiscriminately prescribe antibiotics for uncomplicated acute rhinosinusitis.

Most acute rhinosinusitis is viral and most will resolve in two weeks without treatment.

Don't routinely do diagnostic testing in patients with chronic urticaria.

Unfortunately, a lot of patients think that if they have chronic urticaria they must have an allergic trigger. Most chronic urticaria is non-allergic and patient education is paramount. IgE testing is not recommended unless their history implicates a specific allergen.

Don't recommend replacement immunoglobulin therapy for recurrent infections unless impaired antibody responses to vaccines are demonstrated.

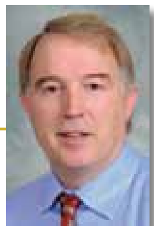
If IgG level is not <150mg/dl and genetically defined or a suspected disorder, IgG replacement does not improve outcomes unless there is impairment of antigen-specific IgG antibody responses to vaccine immunizations or natural infections.

Don't diagnose or manage asthma without spirometry.

Guidelines stress spirometry is essential in asthma diagnosis, stratifying disease severity and monitoring control.

American College of Physicians

GREGG MCLEAN, MD



Don't obtain screening exercise electrocardiogram testing in individuals who are asymptomatic and at low risk for coronary heart disease.

A positive test result in a patient at low risk for coronary artery disease (CAD) represents a greater likelihood of being a false-positive study. The United States Preventative Service Task Force recommends against screening for CAD in low-risk adults.

Don't obtain imaging studies in patients with non-specific low back pain.

- *Provide a trial of conservative treatment first.*
- *Most episodes of back pain are mechanical in nature and self-limited in duration.*
- *Consider earlier imaging for suspected fracture (trauma) neoplasm, infection or neurologic deficits.*

In the evaluation of simple syncope and a normal neurological examination, don't obtain brain imaging studies (CT or MRI).

A detailed history and physical examination are important in establishing a cause of syncope. Patients with true syncope have prompt return to baseline function. Consider further testing for suspected TIA, stroke and seizure.

In patients with low pretest probability of venous thromboembolism (VTE), obtain a high-sensitive D-dimer measurement as the initial diagnostic test; don't obtain imaging studies as the initial diagnostic test.

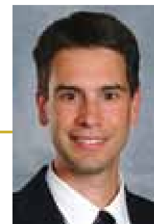
A negative D-dimer study is diagnostically useful in excluding VTE. The likelihood of VTE is low even in high-risk patients when the D-dimer is low (favorable and negative predictive value).

Don't obtain preoperative chest radiography in the absence of a clinical suspicion for intrathoracic pathology.

Most professional organizations recommend against routine chest x-rays in healthy patients. Consider a study in older patients undergoing major abdominal surgery or patients with cardiopulmonary disease.

American Academy of Family Physicians

ANDREW LaFLEUR, MD



Don't do imaging for low back pain within the first six weeks, unless red flags are present.

There are a couple of published guidelines, based on numerous studies, which recommend no imaging for acute low back pain within 4-6 weeks of onset. The vast majority of these patients (some 90%) will improve within this time frame with conservative measures alone.

Continued on page 10

Choosing Wisely recommendations continued from page 9

Don't routinely prescribe antibiotics for acute mild-to-moderate sinusitis unless symptoms last for seven or more days, or symptoms worsen after initial clinical improvement.

I agree with this recommendation. The Infectious Disease Society of America guidelines delineate the specific symptoms suggestive of bacterial rhinosinusitis, which may require antibiotic therapy.

Don't use dual-energy x-ray absorptiometry (DEXA) screening for osteoporosis in women younger than 65 or men younger than 70 with no risk factors.

I agree with this recommendation; however, keep in mind that assessing each adult patient for fracture risk is important. The major risk factors are advanced age, prior fracture, long-term steroid use, low body weight, family history of hip fracture, smoking and excess alcohol intake.

Don't order annual electrocardiograms (EKGs) or any other cardiac screening for low-risk patients without symptoms.

There is no convincing evidence that routine cardiac screening in low-risk, asymptomatic patients is of any benefit. Performing cardiac screening tests on these patients leads to harm (cost, overtreatment, invasive procedures, etc.).

Don't perform Pap smears on women younger than 21 or who have had a hysterectomy for non-cancer disease.

I agree with this recommendation. The 2006 American Society of Colposcopy and Cervical Pathology consensus guidelines led to major changes in the management of cervical disease in adolescents (minimal or no intervention). Subsequently, numerous specialty societies jointly recommended routine cervical cancer screening to begin at age 21.

American College of Radiology

SANJAY J. TALATI, MD

Don't do imaging for uncomplicated headaches.

It is unnecessary and less likely to change the management or outcome. Of course, incidental findings will lead to additional imaging and cost.

Don't image for suspected pulmonary embolism (PE) without moderate or high pre-test probability of PE.

CTA is very sensitive and specific for PE and moderate to high pretest probability adds to the diagnosis and management of patient. Low pretest probability unnecessarily adds radiation and radiographic contrast exposure to the patients.

Avoid admission or preoperative chest x-rays for ambulatory patients with unremarkable history and physical exam.

This is helpful only in patients with known chronic cardiopulmonary diseases or acute cardiopulmonary. The ACR recommends in patients older than 70 years who have not had a chest radiograph within the last six months.

Don't do computed tomography (CT) for the evaluation of suspected appendicitis in children until after ultrasound has been considered as an option.

Ultrasound is good in experienced hands and – only if it is equivocal – a CT should be done. This reduces CT radiation exposure in the pediatric population.

Don't recommend follow-up imaging for clinically inconsequential adnexal cysts.

Depending on the reproductive age or post-menopausal age, adnexal cysts should be followed up on depending on their size. ACR recommends 1cm as a threshold for simple cysts in post-menopausal women.

American Society of Clinical Oncology

BEI LIU, MD

Don't use cancer-directed therapy for solid tumor patients with the following characteristics: low performance status (3 or 4), no benefit from prior evidence-based interventions, not eligible for a clinical trial, and no strong evidence supporting the clinical value of further anti-cancer treatment.

This is standard practice. The exception: for some patients with a poor performance status due to cancer-related symptoms, and there is a chance to cure the cancer (such as lymphatic), we still give chemotherapy.

Don't perform PET, CT and radionuclide bone scans in the staging of early prostate cancer at low risk for metastasis.

I agree with this recommendation.

Don't perform PET, CT, and radionuclide bone scans in the staging of early breast cancer at low risk for metastasis.

I agree with this recommendation.

Don't perform surveillance testing (biomarkers) or imaging (PET, CT and radionuclide bone scans) for asymptomatic individuals who have been treated for breast cancer with curative intent.

Some high-risk patients do want doctors to perform imaging studies for surveillance despite it not being recommended by the ASCO.

Don't use white cell stimulating factors for primary prevention of febrile neutropenia for patients with less than 20 percent risk for this complication.

I agree with this recommendation.

Please go to www.choosingwisely.org for specific information about the Choosing Wisely initiative, or go directly to http://choosingwisely.org/?page_id=13 for the full list of recommendations. You can also contact Dr. Schultz at 989.583.4103 or mschultz@chs-mi.com.

This is the first in a two-part series of "Commentary" articles reflecting physicians' opinions. Part two will be published in the next issue of *The Chart.*

A New Cancer Weapon
Antibody-Drug Conjugates

GUEST AUTHOR
Dr. Jacob C. Ninan, Oncology/Hematology, Covenant HealthCare

The Holy Grail of cancer treatment is to kill cancer cells quickly and effectively with minimal collateral damage and side effects. A new cancer weapon, antibody-drug conjugates (ADCs), is bringing us closer to that objective.

The Potential of ADCs

ADCs combine the selective power of antibodies – which are the fastest growing class of targeted therapeutics, with the termination power of highly potent chemotherapeutic (cytotoxic) agents – which are more effective at killing cancer cells but lack the selectivity. ADCs are designed to guide the delivery of cancer-killing drugs to a precise location, maximizing their impact without adversely affecting normal tissues.

ADCs are comprised of three elements: a monoclonal antibody, a cytotoxic agent and a linker that connects the two together. The antibody is directed toward tumor cell antigens or overexpressed proteins on the tumor cell, binding to the cell surface antigen. The ADC then enters the cell, releasing the cytotoxic drug to kill the cell. Importantly, the drug is not released until it is in the cell where it can do its job and maximize its impact without compromising other areas of the body.

Key Areas of Progress

While initial ADC trials had disappointing results, the past 25 years of technology development in every facet of research is yielding excellent discoveries. Recent generations of ADCs are showing more promise in treating both earlier and later stage tumors. This is largely due to:

- **The selection of well-characterized antigens that serve as the target for the antibody.** These antigens should be well-expressed on tumor cells when compared to healthy cells. Blood cell cancers are often selected for study since malignant blood cells are more accessible to antibodies than solid tumors. B-and T-cell surface proteins are typical target antigens as they are often widely expressed. Other promising targets include the growth of new blood vessels (angiogenesis) since it is a key symptom of invasive cancers.
- **Maximizing the killing potential of cytotoxic agents.** ADCs enable the use of more potent doses of drugs than used in standard chemotherapy, since the targeted cell can accept a higher dose.
- **Improving the stability of the linker to keep the ADC stable in the bloodstream, releasing the drug within the targeted cell and not prematurely.** Hydrazone linkers were the initial linker of choice. To improve stability, other chemistries have been developed, such as disulfide-based linkers and peptide linkers, with some companies using noncleavable linkers such as thioether linkers. Each linker is suited to different types of cancer.

The best ADC protein targets have abundant expression on the cancer cells and very limited expression on other cells. Patients whose tumors express high target levels are most likely to benefit from ADC treatment.

Promising ADC Trials

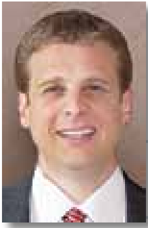
Currently, there are approximately 25 ADCs in oncology clinical trials and even more in preclinical development.

A few examples of ADC advances in the news include:

- **Brentuximab vedotin** (Adcetris; Seattle Genetics) was FDA-approved in 2011 for the treatment of Hodgkin Lymphoma and systemic anaplastic large cell lymphoma, representing the first new drug for Hodgkin Lymphoma in more than 30 years. The recipe includes an anti-CD30 antibody conjugated to the antimitotic agent monomethyl auristatin E (MMAE).
- **Trastuzumab emtansine** (T-DM1; Genentech) combines the anti-HER2 antibody trastuzumab (Herceptin) with a derivative of the cytotoxin, maytansine (DM1) to treat aggressive HER2+ breast cancer. It is currently under review by the FDA for women with advanced breast cancer that has progressed after treatment with trastuzumab. T-DM1 selectively binds to HER2 receptors that are often overexpressed on tumor cells. Positive Phase II trials and one positive Phase III trial were recently reported. At one year, T-DM1 had better response and survival rates than capecitabine plus lapatinib. It shows significantly prolonged progression-free survival with less toxicity and side effects. It is considered generally safer, despite producing higher rates of thrombocytopenia and liver enzyme abnormalities. Given the positive results of many studies, a major shift in the treatment of HER2 cancers is imminent.

Many ADCs are in various stages of trials for a wide range of cancers, and research continues to optimize the success rates of this very promising therapy.

For more information, please contact Dr. Ninan at 989.799.6110 or jac2nin@gmail.com. Source information is also available upon request.



Pelvic Floor Disorders
Fighting the "Taboo"

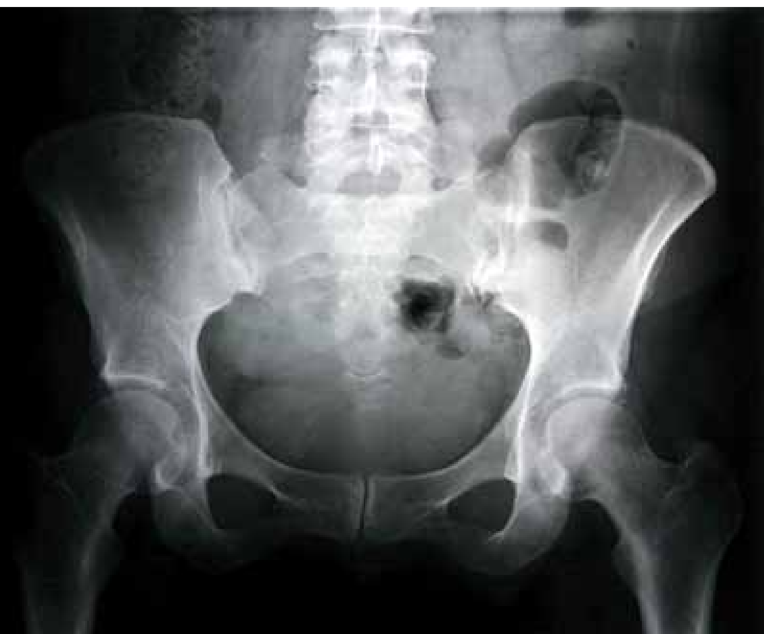
GUEST AUTHOR
Dr. Thomas Minnec, Gynecologist, Women's OB/GYN, PC

An estimated one-third to one-quarter of women in the United States will suffer from a Pelvic Floor Disorder (PFD) in their lifetime. As defined by the International Continence Society, PFDs include pelvic organ prolapse and urinary incontinence.

While PFD was often considered a taboo topic to discuss, more women today are seeking help earlier than in the past. Despite this trend, many still hesitate to broach the topic with their physician so it's important to empower adult female patients to speak up.

This is critical not only because quality of life is at stake, but also because age increases the likelihood of getting a PFD, and the population of women age 65 and older will double by 2030 according to the U.S. Census Bureau. However, pre-menopausal women can acquire the condition too.

While PFDs are rarely life threatening, they can lead to chronic pain and significant emotional and social consequences. Because the pelvic floor supports reproduction, urination and defecation, PFDs often affect urinary, colorectal and sexual functions, causing embarrassing situations.



PFD Causes

Normal anatomic support of the pelvic floor structures is provided by the interaction between the bony skeleton, intact neuromuscular function, and adequate ligamentous and fibromuscular fascial support structures. Pathologic loss of that support may occur with damage to the pelvic muscles, connective tissue attachments or both.

Pelvic organ prolapse (POP) can result from pregnancy, labor, vaginal childbirth, advancing age, variations in skeletal structure, neuromuscular compromise, racial and genetic factors, and connective tissue disease. COPD, obesity, constipation, estrogen deficiency, malnutrition and anemia may also play a role. Lifestyle issues such as work environment, heavy lifting and tobacco usage, and previous pelvic surgery also may contribute.

Anterior vaginal wall prolapse (cystocele) is a bulging of the anterior vaginal wall and overlying bladder. Posterior vaginal wall prolapse (rectocele) is a bulging of the anterior wall of the rectum into the vagina. Apical prolapse can consist of either the uterus/cervix descending into the vagina or the top of the vagina prolapsing down (uterine prolapse or vaginal vault prolapse respectively).

Management of POP and urinary incontinence (UI) includes both non-surgical and surgical options.

Non-surgical Management

Non-surgical management techniques may start with a simple observation for the asymptomatic or mildly symptomatic patient. Use of vaginal estrogen cream/tablets can help fortify vaginal tissue and alleviate irritative symptoms.

Pelvic floor muscle strengthening exercises (Kegel), biofeedback (beyond Kegel), weighted vaginal cones or electric stimulation may be utilized in an office setting. For patients whose symptoms are more prominent, have not completed childbearing, decline surgical options, or are poor surgical candidates, the use of vaginal pessaries – which are diaphragm-like devices – remains an excellent alternative to surgical repair.

The American Congress of Obstetricians and Gynecologists (ACOG) practice bulletin recommends pessary trial use prior to surgical management in patients. The use of pessaries dates back as early as the 5th century BC. They are generally made of an inert plastic or silicone and are either supportive or space-occupying, with some designed to address urinary incontinence, all with their own advantages and disadvantages.

Surgical Management

For patients who have failed conservative non-surgical management, the final option is surgical. Women have an 11%

Age increases the likelihood of getting a PFD, and the population of women age 65 and older will double by 2030.

lifetime risk of undergoing surgery for pelvic organ prolapse or urinary incontinence by the age of 80, with a 30% risk of a repeat operation over a four-year period.

Surgical correction approaches have evolved through a series of steps beginning with traditional reparative techniques and progressing to the development of specific tools and minimally invasive techniques, the increased acceptance of biologic and synthetic grafts, and the subsequent development of surgical kits that can be applicable to patients with prolapse.

This evolution of surgical approaches has been swift, owing primarily to technological advances in materials and techniques. As a result, new potential complications, such as graft-related healing difficulties have become apparent. Being prepared to address these and other surgical complications is of great importance to the reconstructive surgeon.

Specialized Care

For specialized treatment, it is recommended that women consult with a gynecologist who specializes in PFDs. Physical therapists may also be called upon for pelvic floor strengthening exercises. While women are the primary sufferers of PFDs, men can contract the disorder too and should visit their urologist.

The primary line of defense, however, is the primary care physician. It is important to engage, diagnose and start a course of action as early as possible, before symptoms become worse or irreversible.

For more information, please contact Dr. Minnec at 989.792.3100. Sources are also available upon request.

Surgical Outcomes Research
Aiming For Better Patient Care

GUEST AUTHOR
Dr. Aziz M. Merchant, Director of Surgical Research, CMU College of Medicine – Department of Surgery

In 2009, the Institute of Medicine (IOM) identified health delivery and outcomes research as one of their top priorities for investigation in the upcoming decades. These initiatives, referred to as Comparative Effectiveness Research (CER), can take a number of forms, including systematic reviews and meta-analysis, data analysis of administrative databases, establishment of prospective clinical databases and registries, and randomized controlled trials.

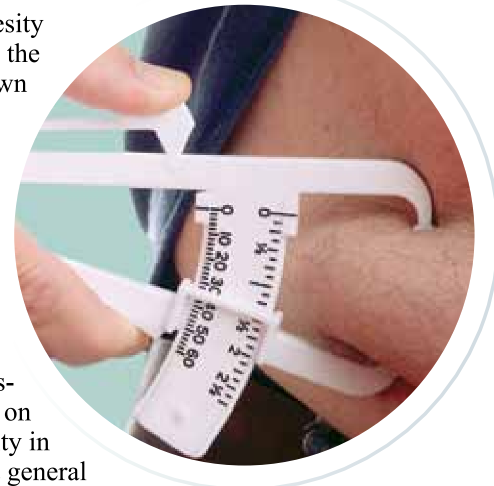
The IOM defines CER as "the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers and policy makers to make informed decisions that will improve health care at both the individual and population levels."

In addition to CER, another type of outcomes research was identified as being vital to furthering the cause of evidence-based medicine: Patient-Centered Outcomes Research (PCOR). This research involves looking at the outcomes of individual patients and establishing the best management and treatment based on individual patient characteristics.

The Central Michigan University Surgery Program, in addition to resident training, is engaged in surgical outcome and quality improvement research efforts as part of its mandated educational and scholarly activity mission. The Surgery Program has undertaken serious efforts to increase the amount of scholarly activity through the assignment of a director of surgical research, collaboration with the CMU College of Medicine, and participation with the Covenant HealthCare Surgical Care and Quality Review (SCQR) Committee.

Following is a sampling of projects that have been completed by CMU faculty and residents, in collaboration with Covenant HealthCare.

Effect of Age and BMI on Mortality and Morbidity in Elective and Emergent General Surgery



The prevalence of obesity and morbid obesity in the United States has grown exponentially. In addition, the elderly population is expected to be the dominant age group by the year 2030. We hypothesized that increasing age and body mass index (BMI) have a synergistically negative effect on morbidity and mortality in elective and emergent general surgery (in other words, increasing patient risk). Patient data from the Michigan Surgical Quality Collaborative (MSQC), encompassing almost 150,000 patients, was analyzed. Patients underwent general surgery, general anesthetic, were over 18 years of age and had a body mass index (BMI) between 19 and 60. A regression analyses of 30-day mortality revealed that the interaction of BMI with age is positively associated with higher mortality with the combination of higher BMIs and age above 70. Models to predict morbidity revealed that age alone is a predictor of morbidity, and that the general trend of increased BMI being predictive of morbidity is present predominantly after age 50. It was found that increasing age and a higher American Society of Anesthesiologists (ASA) class were the highest predictors of mortality.

Analysis of Outcomes of Diabetic and Non-diabetic General and Vascular Surgery Patients

Pre-operative diabetic and glucose screening is becoming routine in many centers and may or may not be cost effective. The true effect of diabetes on surgical outcomes is really not known. This study was conducted to assess the effect of diabetes on outcomes for general and vascular surgery patients. The MSQC was utilized to analyze data for 141,000 patients who had undergone elective or emergent general or vascular surgery and had a documented diabetes status (non-insulin dependent with or without oral medication; insulin-dependent). Analysis of overall 30-day mortality for the entire sample revealed that neither non-insulin dependent diabetics (with or without oral medication) nor insulin-dependent diabetics were at

increased mortality risk. However, when looking at 30-day overall morbidity, insulin-dependent diabetics undergoing general or vascular surgery are at increased risk compared to non-diabetics. Ventilator dependence, weight loss, emergency case and a higher ASA class were most predictive of morbidity and mortality. This data will form the basis of efforts to reduce adverse surgical outcomes in diabetic patients and the cost-effectiveness of preoperative diabetic screening.

Arms: The Forgotten Extremity

Many of the surgical quality indicators and collaborative improvement processes have focused on prevention of Venous Thromboembolism (VTE). The main focus, however, has been the prevention of VTE in the lower extremity, and little if any targeting the upper extremity. Covenant HealthCare SQRC and MSQC data, along with National Surgical Quality Improvement Program (NSQIP) data, clearly demonstrated that there was an opportunity to decrease our VTE O/E (Observed/Expected) ratio in this study.

A multi-disciplinary team was assembled to analyze the MSQC/NSQIP data, and Six Sigma process improvement tools were utilized to develop and implement a plan to decrease the number of Upper Extremity VTEs (UEVTEs). Improvement strategies included education of the staff on the importance of Range of Motion (ROM) for patients with a central line or long-term venous access device (such as PICC lines). This included mandatory nursing in-service "Venous Access Education" training, which included IV insertion, dressing changes, line trouble shooting, and partial occlusion declotting.

Since the process improvement education, the global MSQC UEVTE rate decreased by 16% and for all of Covenant HealthCare, a 37% decrease was noted in the first three months after education and other measures were implemented. To ensure the continued success of this project, the team continues to closely monitor the strategies implemented. Also, Venous Access Education has been added to Covenant HealthCare's nursing core education program to ensure that new employees receive this valuable education.

Surgical outcomes research is here to stay, and will inform much of the evidence-based approach that will guide the management of our surgical patients.

Summary

Using the MSQC administrative database does have its drawbacks. First, it is a completely retrospective approach to study design, and therefore will contain a certain amount of study bias. Second, the data is collected in block samples from a number of different hospitals; therefore the interpretation of data may not be appropriate for all populations. However, in terms of its advantages, large study sample sizes can be analyzed, thereby helping offset some of the inherent bias. It also allows us to ask and answer clinical questions that many times cannot be answered through a clinical trial.

Besides addressing patient care and quality issues, the projects noted above have involved residents and medical students, enhancing participation of residents in patient safety and outcome efforts at clinical sites of training – a major direction being taken by the Accreditation Council for Graduate Medical Education (ACGME). Furthermore, Covenant HealthCare's profile as a teaching institution and as a High Reliability Organization is raised through presentation and publication of these studies. The first two projects listed have been accepted for presentation at the Association for Academic Surgery in February 2013, while Dawn Grauf, CSCQR, of Covenant HealthCare, presented her work at the annual meeting of the MSQC in Detroit last April.

In summary, surgical outcomes research is here to stay, and will inform much of the evidence-based approach that will guide the management of our surgical patients. In addition, outcomes analysis will become an increasingly important process for determining quality of the care provided by healthcare entities, and will play a large role in forging healthcare policy in the future.

For more information, please contact Dr. Merchant at 989.583.6993 or aziz.merchant@cmich.edu. Sources are also available upon request.

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Taking Action on Physician Engagement

Dr. John Kosanovich, Vice President, Covenant HealthCare; CEO, Covenant Medical Group

After sharing the results of the Physician Engagement Survey at several physician meetings this Fall, a decision has been made to address the following improvement opportunities identified by our physicians:

- Disruptive behavior is not tolerated at my organization.
- I am kept informed of the organization’s strategic plans and direction.
- This organization makes patient safety a priority.

Our goal at Covenant HealthCare is to create the most attractive environment for physicians to practice medicine.

You will be hearing more about how we plan to address these specific opportunities as action plans are developed and implemented.

For more information, contact Dr. Kosanovich at 989.583.7555 or jkosanovich@chs-mi.com.