

Entry Level Clinical Nutrition May 2013 Update

Jeffrey Moss, DDS, CNS, DACBN
jeffmoss@mossnutrition.com

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What is Entry Level Clinical Nutrition?

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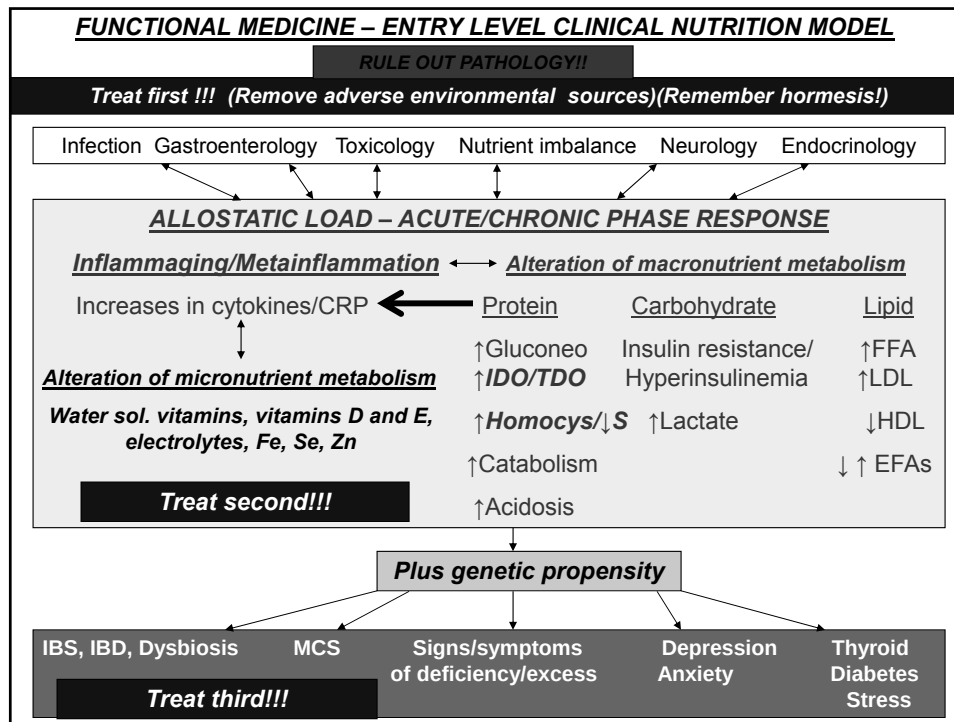
***This is a relatively easy,
inexpensive way to help
most patients feel better
early on during the course
of therapy no matter what
their “disease” or chief
complaint.***

3

A simplified approach to helping patients feel better

- Understanding the true nature of chronic illness: Excessive allostatic load
- Simple, cost effective diagnostic tools
- A simplified, cost effective menu to improve patient quality of life

4



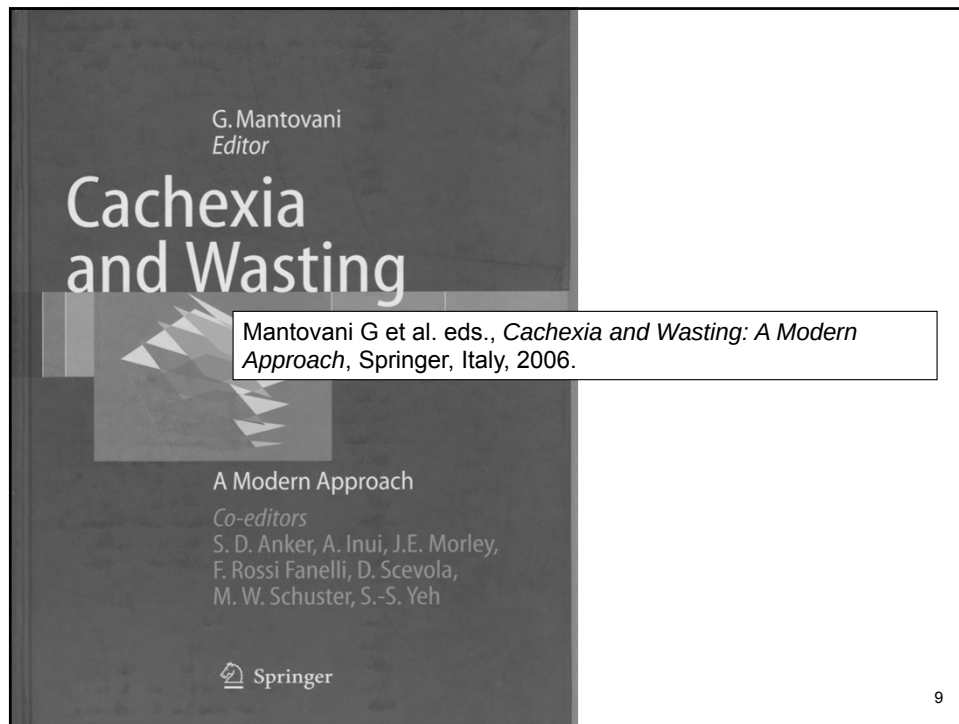
Is this alternative medicine?

No!!!

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It is the outpatient application
of decades of research in the
field of critical care nutrition

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- “Cachexia may well represent the devastating flip side of the tremendous achievements of modern medicine, as the incidence of cachexia is also a function of survival of chronic illness.”
- “Many diseases – which rapidly led to death only a few years ago – are now better controlled by new therapies. Even if we cannot cure and eradicate these diseases, their natural history has significantly increased by months and years. Although these new therapeutic strategies represent a remarkable advantage over the previous standards of care, ***it is impossible to ignore the fact that many more patients are now facing the nutritional and metabolic consequences of prolonged immunological and hormonal challenges due to both the illness process itself and the aggressive therapies.***”



Nestlé Nutrition Workshop Series
Clinical & Performance Program, Vol. 8

Nutrition and Critical Care

Luc Cynober
Frederick A. Moore

KARGER



Baracos VE. Overview on
metabolic adaptation to
stress, pp. 1-13.

"An understanding of the
nature of stress is
fundamental to the rational
design of nutrient mixtures to
feed patients whose
homeostasis has been altered
by one or more stressors."

"All stresses may be
presumed to be associated
with characteristic
modifications in the
metabolism of lipids,
carbohydrates, amino acids,
and micronutrients."

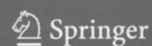
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Jesse B. Hall

Handbook of Critical Care

Third Edition

Hall JB. *Handbook of Critical Care*,
Third Edition, Springer-Verlag,
London, 2009



Chapter 11

Nutritional support

John Kress
University of Chicago, Chicago, IL, USA

Background

Cachexia is a common consequence of critical illness, and is characterized by marked muscle breakdown. It correlates with an increased susceptibility to infection, prolonged ventilatory requirements, and mortality. Causes include the following:

- pre-existing malnutrition prior to admission to the intensive care unit (ICU)
- hypercatabolic response to critical illness
- delayed introduction of nutritional support
- immobilization.

The hypercatabolic response that accompanies severe trauma, burns, sepsis, pancreatitis, etc differs significantly from the normal physiologic response to starvation (Figure 11.1).

Nutritional requirements

Energy

The total calorie intake should be approximately equivalent to normal resting energy requirements (ie, 25–30 kcal/kg per day), and for parenteral feeding regimens approximately one-third of this should be given as fat. Patients who are very hypercatabolic (eg, with severe burns) may require more than this; however, in general an excess of calories should be avoided.

Nitrogen

Nitrogen intake should be 1–2 g protein/kg per day (this should be reduced in cases of renal failure to minimize uremia). Approximately 150 kcal of non-protein energy source are required per gram of nitrogen to permit satisfactory protein synthesis. Glutamine supplementation (≥ 25 g/day) may help maintain

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How Does Critical Illness Change Metabolism?

Mark E. Nunnally

The evolution of a discrete injury into a syndrome that spans neurologic, endocrine, and metabolic systems, sometimes leading to radical changes in end-organ function, is one of the fundamental characteristics of the critically ill patient. Many metabolic changes in this syndrome have been described, but the meaning of these changes remains subject to interpretation. Without interpretation, the observations remain isolated facts unable to guide clinical management. Evidence-based management of critical illness, therefore, must rely on theoretical interpretation.

The relationship between tissue injury and total-body metabolic changes has been well evaluated. Cuthbertson was among the first to describe and explain the stress response, a pattern of metabolic changes in injured patients.¹ In his framework, the physiology of critical illness was an adaptive response. Metabolic changes from "normal" were necessary to heal serious injury. This concept informs the scientific inquiry into which processes are biologically helpful or harmful and which should be supplemented or suppressed. Such scientific debate extends to nutrition, care of endocrine systems, and intervention in immunologic signaling. In each case, there is usually a dearth of clear evidence, a glut of theory, and an absence of consensus. Nevertheless, good data do exist. This chapter considers the predictable pattern in response to injury, the role of interventions that depend on this pattern, and the diagnostic utility of comparing a patient's clinical data to the stress response pattern.

PATHOPHYSIOLOGY AND MECHANISM OF ACTION

Hypermetabolism is the trademark of critical illness, a phenomenon originally described as "ebb and flow,"² in which a period of hypoperfusion to maintain survival is followed by a healing period. As description in critical care evolved, these phases became shock and postresuscitation hypermetabolism, respectively. To these two phases was added a third phase. This anabolic phase follows resolution of the stress response and persists for weeks to months (Fig. 63-1). Changes affect the entire body, change activity in each organ system, and are reflected in secondary failures of these systems. Available evidence supports the theory that this adaptive response makes tissue healing possible.

Neurologic

Brain tissue uses a wide variety of metabolic fuel. During stress, glucose and lactate metabolism increases, but so does that of amino acids. The encephalopathy of critical illness is believed to be related to the presence of elevated levels of aromatic amino acids and their metabolites.³⁻⁵ In some cases, global cerebral function is impaired, as evidenced by alterations ranging from delirium to overt coma.

Cardiovascular

Stress increases the need for oxygen in the periphery. Cardiac output increases, and peripheral vascular tone decreases, augmenting blood flow to peripheral tissues, possibly at the expense of loss of flow to other vascular beds, to facilitate delivery. That oxygen consumption is highest in tissues with the highest levels of leukocytes suggests that delivery is increased to feed cells that repair tissue and control infection.^{6,7} Capillary beds leak because of the loss of tight junctions. The balance between fluid extravasation and reabsorption consequently favors the formation of edema because plasma proteins accumulate outside vessels walls, pulling fluid and electrolytes with them.

The result of these changes is circulatory hyperdynamics and edema, with increased peripheral delivery of oxygen and nutrients. In some patients, myocardial damage ensues. This may lead to a failure to supplement oxygen delivery that is associated with a high mortality in critical illness lung injury.⁸ Attempts to mediate this response through supplementation of oxygen delivery⁹⁻¹⁰ have been met with mixed and often detrimental results. With recovery, edema resolves, although reduced oncotic pressure in plasma may make the period of anabolism longer.

Fluids, Electrolytes, and Nutrition

Tissue edema and intravascular resuscitation increase body water, and patients characteristically gain weight. The distribution of water during the stress response was explored by Moore and colleagues.¹¹ The extracellular and vascular compartments expand,¹²⁻¹⁴ but intracellular water is lost. This suggests that water can actively shift from the intracellular space to the extracellular

Clifford S. Deutschman · Patrick J. Neligan

Evidence-Based Practice of Critical Care

Deutschman CS & Neligan PJ. Evidence-Based Practice of Critical Care, Saunders Philadelphia, PA, 2010

SAUNDERS ELSEVIER

Nutritional Deficiencies During Critical Illness

Nilesh M. Mehta, MD^{a,*}, Christopher P. Duggan, MD, MPH^b

KEYWORDS

Critical care • Children • Malnutrition • Deficiency • Nutrition

Awareness of the deleterious consequences of malnutrition during critical illness and the will to prioritize nutritional therapy are necessary first steps toward addressing this problem. Careful attention to preventing malnutrition, regular and accurate assessment of nutritional requirements, and accurate measurement of energy expenditure in some cases allow individually tailored nutritional prescriptions to be designed for critically ill children. A multidisciplinary effort at the bedside is required to overcome

Mehta NM & Duggan CP. Nutritional deficiencies during critical illness, *Pediatr Clin N Amer*, Vol. 56, pp. 1143-1160, 2009.

malnutrition, a longer length of hospital stay, and increased hospital costs.¹ In hospitalized children, malnutrition is associated with altered physiologic responses and increased resource use, and it influences outcome during critical illness.^{2,3} The prevalence of malnutrition in children admitted to the pediatric intensive care unit (PICU) has remained unchanged over the past 3 decades.^{4,5} Critical illness itself may increase metabolic demand on the host in the early stages of the stress response, and nutrient intake may be limited. Thus, children admitted to the PICU are at risk for worsening nutritional status and anthropometric changes with increased morbidity.⁶

"Critical illness itself may increase metabolic demand on the host in the early stages of the stress response, and nutrient intake may be limited."

Pediatr Clin N Am 56 (2009) 1143-1160

doi:10.1016/j.pcl.2009.06.007

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pediatric.theclinics.com

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REVIEW

Acute and “chronic” phase reaction—a mother of disease

Stig Bengmark

Department of Surgery and Liver Institute, UCL, London, UK

Received 23 July 2004

KEYWORDS

Acute phase response;
Chronic phase response;
Metabolic syndrome;
Cellular membranes;
Endothelial cells;
Abdominal obesity;
Insulin resistance;
Growth hormones;
Free fatty acids;
Alzheimer disease;
Parkinson disease;
Neurodegenerative diseases;
Arteriosclerosis;
Coronary-vascular diseases;
Cancer;
Breast cancer;
Colorectal cancer;
Prostatic cancer;
Diabetes;
Cirrhosis;
Fatty liver;
Gallbladder disease;
Chronic renal disease;

Summary The world is in diseases. Almost half of the mortality is due to these chronic diseases. And they are these diseases are associated consumption of calorie-cord also under-consumption of a function of the innate immune changes induced in response the subsequent development chronic diseases. The endot importance, and the function the function of the underlying cells; their ability to obtain nutrients and antioxidants and to eliminate waste products. The abdominal adipocytes seen to play a key role, as they have the ability to in stressful situations release much of proinflammatory cytokines, PAI-1 and free fatty acids compared to elsewhere in the body. The load on the liver of these various substances in often of greater magnitude than the liver can handle. Some of the most common chronic diseases and their potential association with acute and “chronic” phase response, and with metabolic syndrome are discussed separately. The need for studies with lifestyle modifications is especially emphasized.

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Bengmark S. Acute and “chronic” phase reaction – a mother of disease, *Clin Nutr*, Vol. 23, pp. 1256–66, 2004

E-mail address: S.bengmark@ucl.ac.uk (S. Bengmark).

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doi:10.1016/j.clnu.2004.07.016

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Drug Discovery Today: Disease Mechanisms

Vol. 1, No. 1, 2004

Editor-in-Chief
Toren Finkel – National Heart, Lung and Blood Institute, National Institutes of Health, USA
Tamas Bartal – Harold L. Dorris Neurological Research Center and The Scripps Research Institute, USA

Cardiovascular diseases

The acute phase response and atherosclerosis

Charles Lowenstein^a, Kenji Matsushita

The Johns Hopkins University School of Medicine, Baltimore, MD 21205, USA

The acute phase response (APR) is an acute systemic response to infection. Recent studies reveal that the APR is chronically atherosclerosis. Di cholesterol triggers release of hundred damage the endo driving the process molecules that med dates for anti-inflammatory therapy of patients with atherosclerosis.

Section Editor:
Pascale J. Goldschmidt-Clermont – Duke University Medical

Lowenstein C & Matsushita K. The acute phase response and atherosclerosis, *Drug Discovery Today: Disease Mechanisms*, Vol. 1, No. 1, pp. 17–24, 2004

Introduction

Atherosclerosis – fatty, fibrous thickening of the arteries – is the most common cause of death in the United States [1]. Out of the 11 million Americans who had atherosclerosis in 2003, 1.5 million had heart attacks, 750,000 had strokes, and 500,000 died from complications of heart attacks and strokes. Therapies for atherosclerosis have been evolved along with our understanding of the underlying causes of atherosclerosis. Discovery of the role of low-density lipoprotein (LDL) cholesterol in atherosclerosis led to the widespread use of statins (HMG-CoA reductase inhibitors) to decrease LDL cholesterol in patients with coronary artery disease. Characterization of the proteins that mediate reverse cholesterol transport has led to the development of drugs that increase high-density lipoprotein (HDL) cholesterol. Visualization of thrombotic (blood clots) in coronary arteries during heart

attacks led to the widespread use of thrombolytics. Recent studies that emphasize the inflammatory nature of atherosclerosis have raised hopes that anti-inflammatory drugs will be useful in inhibiting the development of atherosclerosis.

Inflammation is a risk for atherosclerosis

Elevated levels of inflammatory markers are associated with an increased risk of coronary artery disease in apparently healthy subjects. These markers include tumor necrosis factor alpha (TNF-α), interleukin-6 (IL-6), and C-reactive protein (CRP). In the Physicians' Health Study, baseline levels of IL-6 were higher in men who subsequently had a myocardial infarction than in men who did not, and elevated levels of

^aCorresponding author (C. Lowenstein) (clowen@jhmi.edu).

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- “The acute phase response (APR) is an acute systemic response to infection. Recent studies reveal that the APR is chronically activated in patients at risk for atherosclerosis. Diabetes, hypertension, and elevated cholesterol trigger the APR, leading to the systemic release of hundreds of effector molecules that might damage the endothelium and activate macrophages, driving the process of atherogenesis. The signaling molecules that mediate the APR are attractive candidates for anti-inflammatory therapy of patients with atherosclerosis.”
- “Many of the inflammatory markers elevated in patients at risk for atherosclerosis are part of the APR. The APR is an innate systemic inflammatory response to diverse injuries, such as infection and trauma. Although the APR is a beneficial short-term response to life threatening physiological challenges, the APR can harm the host if it is chronically activated. Elevation of APR markers in patients with heart disease suggests that the APR plays a role in atherogenesis.”

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- “Elevations in the APR markers in patients with atherosclerosis suggest that risk factors for heart disease – such as diabetes, mediators of hypertension, and LDL cholesterol – might trigger the APR.”
- “Normally, the APR is activated within hours by infection and then shuts down within two to three days. However, in patients with atherosclerosis the APR appears to be chronically activated at a low level for years. For example, elevated CRP levels predict the risk of atherosclerosis more than six years into the future. Perhaps the continued presence of atherosclerotic risk factors such as hypertension play a role in the persistent activation of the APR.”

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Why is entry level clinical
nutrition needed?

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Modern medicine tends to
define success in terms of
mortality rates and
optimization of lab values

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Poor Pain Control for Cancer Patients - NYTimes.com <http://well.blogs.nytimes.com/2012/09/20/poor-pain-control-for-canc...>

Well - Tara Parker-Pope on Health

SEPTEMBER 20, 2012, 10:17 AM

Poor Pain Control for Cancer Patients

By PAULINE W. CHEN, M.D.

Recounting her father's struggle with cancer was difficult for the young woman, even several years after his death. He'd endured first surgery and then chemotherapy and radiation, she told me, and the cancer had gone into remission. He was thrilled, but the aggressive treatment left him with chronic, debilitating pain. Once active, he struggled to get around in his own home.

"It wasn't the cancer that got him," the daughter said. "It was the pain."

His

op

res

co

He was no longer treating him and couldn't provide ongoing follow-up and dosing guidance. His primary care doctor listened intently to his descriptions of his limitations, but then prescribed only small amounts of pain meds that offered fleeting relief at best.

"I'll never forget what my father had to go through," she said, weeping. "I wouldn't wish this on anyone."

I wish I could have reassured her that her father's case was unusual. Sadly, according to a new study in *The Journal of Clinical Oncology*, a significant percentage of cancer patients continue to suffer from pain as her father did.

Researchers who surveyed more than 3,000 cancer patients found that nearly two-thirds said they were in pain or receiving pain medications. Roughly a third felt they needed more painkillers to fully treat their symptoms.

A month after the patients saw their oncologists, the researchers again asked the patients about their pain. Instead of showing improvement, the percentage of patients who continued to be in pain remained unchanged.

Their pain, in other words, had not been treated.

The findings are a sobering echo of research from nearly two decades ago that revealed that more than 40 percent of cancer patients did not receive adequate treatment for their pain. While patients were reluctant to ask for relief or to take prescribed pain medications, the researchers found that physicians were just as unwilling to prescribe the needed medications. Nearly a third of cancer specialists waited until the patient was only

Chen PW. Poor pain control for cancer patients, *The New York Times*, September 20, 2012

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- "‘It wasn’t the cancer that got him.’ the daughter said. ‘It was the pain.’"
- "Her father had turned to all of his doctors, with little relief. His surgeon had looked at his operative wounds, pronounced them well healed, then stated that they were in no way responsible for his disability."
- "Both his cancer doctor and his radiation doctor congratulated him on being in remission but then declined to prescribe pain medications since they were no longer treating him and couldn’t provide ongoing follow-up and dosing guidance."

National Institutes of Health State-of-the-Science
Conference Statement: Symptom Management in
Cancer: Pain, Depression, and Fatigue, July 15–17, 2002

National Institutes of Health State-of-the-Science Panel*

Background: Despite advances in early detection and effective treatment, cancer remains one of the most feared diseases. Among the most common side effects of cancer and treatments for cancer are pain, depression, and fatigue. Although research is producing increasingly hopeful insights into the causes and cures for cancer, efforts to manage the side effects of the disease and its treatments have not kept pace. The challenge that faces us is how to increase awareness of the importance of recognizing and actively addressing cancer-related distress. The National Institutes of Health (NIH) convened a State-of-the-Science Conference on Symptom Management in Cancer: Pain, Depression, and Fatigue to examine the current state of knowledge regarding the management of pain, depression, and fatigue in individuals with cancer and the difficulties that often accompany such

ers, a belief that such symptoms are simply a part of the cancer experience that must be tolerated, and inadequate coverage and reimbursement for some treatments. Additional research is needed on the definition, occurrence, the treatment of pain, depression, and fatigue, alone and in combination, in adequately funded prospective studies. The panel also concluded that the state of the science in cancer symptom management should be reassessed periodically. [*J Natl Cancer Inst Monogr* 2004;32:9–16]

Scientific discoveries have transformed the outcome of cancer from a usually fatal disease to a curable illness for some people and a chronic condition for many more. With this shift has come not only a growing optimism about the future but also an increasing appreciation for the human costs of cancer care. As

National Institutes of Health State-of-the-Science Panel, National Institutes of Health State-of-the-Science Conference Statement: Symptom management in cancer: Pain, depression, and fatigue, July 15–17, 2002. *J Natl Cancer Inst Monogr*, Vol. 32, pp. 9–16, 2004.

Specific individuals and/or for symptom delivery in of-the-Sci member, radiology, and epist experts in the confere. The panel was prepared to address, addressing the five predetermined questions and drawing on submitted literature, the speakers' presentations, and discussions held at the conference. The statement was presented to the conference audience, followed by a press conference to allow the panel to respond to questions from the media. After its release at the conference, the draft statement was made available on the Internet. The panel's final statement is available at <http://consensus.nih.gov>. **Conclusions:** The panel concluded that the available evidence supports a variety of interventions for treating cancer patients' pain, depression, and fatigue. Clinicians should routinely use brief assessment tools to ask patients about pain, depression, and fatigue and to initiate evidence-based treatments. Assessment should include discussion about common symptoms experienced by cancer patients, and these discussions should continue over the duration of the illness. Impediments to effective symptom management in cancer patients can arise from different sources and interactions among providers, patients and their families, and the health care system. Numerous factors could interfere with adequate symptom management. Among these factors are incomplete effectiveness of some treatments, a lack of sufficient knowledge regarding effective treatment strategies, patient reluctance to report symptoms to caregivers,

symptoms to cancer care providers, wariness to grow, or in these figures, addressing the effect of cancer symptoms on individuals' lives is becoming increasingly critical to efforts to reduce the burden of cancer and its treatment.

Despite advances in early detection and effective treatment, cancer remains one of the most feared diseases, because of its association not only with death but also with diminished quality of life. Among the most common symptoms of cancer and treatments for cancer are pain, depression, and fatigue. These symptoms may persist or appear, even after treatment ends.

Although research is producing new insights into the causes of and cures for cancer, efforts to manage the symptoms of the disease and its treatments have not kept pace. Evidence suggests that pain is frequently undertreated. Patients and health care

*The members of the National Institutes of Health State-of-the-Science Panel are the authors of this article (see page 15).
Correspondence to: Kelli K. Marsh, National Institute of Health Office of Medical Applications of Research, 6000 Executive Blvd., Rm. 2B01, Rockville, MD 20852 (e-mail: marshk@od.nih.gov).
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Journal of the National Cancer Institute Monographs No. 32, 2004

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- “Although research is producing new insights into the causes of and cures for cancer, efforts to manage the symptoms of the disease and its treatments have not kept pace. Evidence suggests that pain is frequently undertreated.”
- “Patients and health care providers have reported depression and persistent lack of energy as the aggressiveness of therapy has been increased and/or the underlying malignancy has worsened.”

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- “Providers barriers to effective pain management include the following factors: lack of awareness of patient’s pain, inadequate training and education on the management of cancer pain, lack of time and resources to address pain, a higher priority given to curing cancer than to treating symptoms...”

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The Cancer of Optimism - NYTimes.com <http://www.nytimes.com/2013/05/05/opinion/sunday/the-cancer-of-a...>

The New York Times

May 4, 2013

The Cancer of Optimism
By HAIDER JAVED WARRAICH
BOSTON

I MET her in 2011, during my first few weeks as an intern in internal medicine. She was not the kind of patient who had appeared in my textbooks. She had been admitted from rehab after expressing an intent to take her own life, and I soon learned that her body was as troubled as

Warraich HJ. The cancer of optimism, *The New York Times*, May 4, 2013.

She had been diagnosed with a condition called aortic stenosis, which an overgrown muscular wall keeps blood from properly flowing out of the heart. She might have been born with it, or acquired it from years of neglected high blood pressure. Her blood pooled in her swelling legs and seeped into her lungs, causing her to wheeze constantly.

“According to a study published in 2000 in the British medical journal BMJ, about two-thirds of doctors overestimate the survival of terminally ill patients.”

At this point, she wasn't a suitable candidate for heart surgery, but I felt there was some hope. A procedure called alcohol septal ablation could potentially reduce her symptoms. It involved injecting alcohol into a blood vessel to strangle the blood supply to the muscular part of the heart obstructing blood flow. The patient was desperate to have the procedure.

“Around 70 percent of the discrepant estimates were overly optimistic.”

days, I convinced the other doctors that, in spite of the risks, we should try it.

The procedure was uneventful, but when I was updated on the patient's condition the next morning, I was stunned. Overnight, she had gone into complete heart block: a failure of the heart's electrical system that kept it beating.

“This optimism is far from harmless. It drives doctors to endorse treatments that most likely won't save patients' lives, but may cause them unnecessary suffering and inch their families toward medical bankruptcy.”

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“Keeping the patient ‘alive’ became easier. And yet the definition of ‘alive’ suffered – with quality of life frequently being usurped by length of life.”

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HARD CASES | ABIGAIL ZUGER, M.D.

The Traps of Treating Pain

Doctors are rarely trained to manage discomfort, so they wind up following general guidelines.

I HADN'T SEEN LARRY in a dozen years when he reappeared in my office a few months ago, grinning. We were both grinning. I always liked Larry, even though he was a bit of a hustler, a little erratic in his appointments, a persistent dabbler in a variety of illegal substances. But he was always careful to avoid the hard stuff, he said he had a bad problem as a teenager and was going to stay clean.

It was to stay out of town all those years back, grayer and thinner. Then he pulled out a pill he needed, and we both took it.

According to Larry, taking giant quantities of one of the most addictive painkillers around, an immensely popular black-market drug most doctors automatically avoid prescribing except under the most exceptional circumstances.

"I got a bad back now, Doc," Larry said.

Doctors hate pain. Let me count the ways. We hate it because we are (mostly) kindhearted and hate to see people suffer. We hate it because it is invisible, cannot be

measured or monitored, and varies wildly and unpredictably from person to person. We hate it because it can drag us closer to the perilous zones of illegal practice than any other complaint.

And we hate it most of all because unless we specifically seek out training in how to manage pain, we get virtually none at all, and wind up flying over all kinds of scary territory absolutely solo, without a map or a net.

The events of the last few decades haven't helped much. First came a consumer-driven "pain power" movement – justified, for the most part – pointing out that pain was wildly undertreated by most doc-

guidelines and policy statements, even fatter than usual of vicious general principles, aren't of much help in figuring how to do any of this.

One of the most accurate, articulate and heartfelt reflections on the situation was written a few years ago in Archives of Internal Medicine by Dr. Mitchell Katz, who now directs the Los Angeles County health department. Dr. Katz described his slow disillusionment with the standard approach to pain control, which involves escalating from nonnarcotic to narcotic medication, then prescribing as much as needed to eradicate the pain, while deploying measures like written contracts, pill counts

without malignant diseases who are likely to be taking them long-term? Also, how about formally acknowledging that sometimes pain cannot be entirely eradicated? "Learning how to cope with pain can be more empowering for patients than trying to find a pill to completely eliminate it," he wrote.

Cheerily Larry's last doctor wasn't buying into these sentiments, given the quantities of medication Larry was asking for – assuming there actually was a previous doctor in Larry's life. All I had for evidence was a list, in Larry's handwriting. The pills themselves, the bottles? "They got stolen off me on the bus here," Larry said.

When was that?

"Last month," Larry said.

Ultimately, all careful nonograms fall aside in the face of the particular patient. I was lucky enough to know Larry pretty well, although in some ways that only made things more difficult. I knew he was a decent and intelligent guy, with a pretty sophisticated understanding of his own problems and a hard time keeping straight. I also knew he was clearly wailing with the careful "don't touch me" pain of someone with a really bad back.

And Larry, of course, knew me well, too – well enough not to be surprised when I sent him off with a sheet of referrals to evaluate his back, a weaker, nonnarcotic pain reliever, and not a single one of the requested pills. He just smiled and said, "I knew you wouldn't give them to me."

These decisions are always harder than hard; you have nothing but instinct and experience to guide you, and you never know if you've done the right thing. I think

Zuger A. The traps of treating pain, *The New York Times*, May 14, 2013

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- “Doctors hate pain. Let me count the ways. We hate it because we are (mostly) kindhearted and hate to see people suffer.”
- “We hate it because it is invisible, cannot be measured or monitored, and varies wildly and unpredictably from person to person.”
- “We hate it because it can drag us closer to the perilous zones of illegal practice than any other complaint.”

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“And we hate it most of all because unless we specifically seek out training in how to manage pain, we get virtually none at all, and wind up flying over all kinds of scary territory absolutely solo, without a map or a net.”

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Is there increased recognition for a need to change?

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EDITORIAL

Annals of Internal Medicine

Contextualizing Patient-Centered Care to Fulfill Its Promise of Better Health Outcomes: Beyond Who, What, and Why

Efforts to improve patient outcomes have focused, in large part, on technical processes of health care, which are ideally informed by the most up-to-date evidence on effective care practices. Technical quality is often viewed as the "science" of medicine as opposed to its "art," which involves such less tangible and potentially harder-to-capture aspects of care as the interpersonal and cognitive processes underlying patient-physician communication and decision-making.

Over the past decades, which recognize the importance of these processes, it is not surprising that the optimal ability to

technical care, which is often captured via medical record reviews. The past 2 decades have seen great strides toward improving our ability to measure the elements of interpersonal care. Several objective methods of analyzing patient-physician communication and describing the interpersonal process have been developed and are widely used in research settings (2). For example, the Roter Interaction Analysis System provides a quantitative analysis of patient-physician dialogue. It codes "utterances" in the dialogue into categories of talk that are combined into such composites as information exchange, rapport building, and facilitation or patient activation. A measure of patient-centered communication can be calculated as the ratio of psychosocial, rapport-building, and facilitative utterances to those that further only the biomedical agenda of the dialogue. There is ample evidence that patient-centered process of communication can influence patient satisfaction, perceptions of care, shared decision making, and health behavior (3, 4). The communication process can also have major implications on whether adherence to treatment—a critical pathway to improving outcomes—is achieved (5).

In this issue, Weiner and colleagues (6) offer a novel and in-depth approach to analyzing the content of patient-physician communication. To examine the relationship between patient-centered decision making and health outcomes, they used a systematic approach in which trained coders flagged visits with evidence of specific contextual "red flags" (for example, missed appointments or lack of control of hypertension or diabetes); coded whether underlying factors for the red flag surfaced during the visit; and measured whether physicians tailored patient care plans to address the underlying factors, which the authors referred to as "contextualizing" the care plan. The study provides

unique evidence for improved health outcomes among patients whose physicians contextualize care plans.

Contextualization represents a desirable blending of many of the concepts of patient-centeredness and cultural competence. Patient-centered care is "care that is respectful and responsive to individual patient preferences, needs and values, and ensures that patient values guide all clinical decisions" (7). Cultural competence in health care is the

Aboumatar HJ & Cooper LA. Contextualizing patient-centered care to fulfill its promise of better health outcomes: Beyond who, what, and why. *Ann Intern Med*. Vol. 158, pp. 628-9, 2013.

to improve patient-centeredness target patient-physician communication or coordination of health care services for patients. These interventions frequently take place within the walls of health care establishments rather than in patients' homes and communities, and they rarely adapt approaches to the context in which patients live or create solutions to specific challenges posed by that context. Not surprisingly, most interventions to improve patient-centeredness of clinical interactions show positive changes in patient-physician communication, patient behaviors, and perceptions of care; however, improvements in health outcomes are reported infrequently (2, 4, 5). Most interventions to improve cultural competence typically involve communication strategies tailored to the social and cultural needs of patients and are community-based; these studies have found early evidence for the effectiveness of contextualization in health care (10).

Interestingly, in the study by Weiner and colleagues (6), different contextual red flags received different levels of attention by physicians. For example, although lack of adherence to treatment plans frequently led to exploration of underlying factors and contextualized care plans to help address it, frequent emergency department visits or missed appointments received less exploration. This may reflect the hesitance of physicians to explore problems they feel unable to solve. Interventions, therefore, may need to focus not only on advancing physicians' attention to the "patient context" and their patient-centered decision-making skills but also on creating linkages to needed services and support systems that empower physicians to develop contextualized care plans that help to solve their patients' problems.

Public health interventions are increasingly using ecological models to address multilevel contributors to health

628 | © 2013 American College of Physicians

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- “Efforts to improve patient outcomes have focused, in large part, on technical processes of health care, which are ideally informed by the most up-to-date evidence on effective care practices.”
- “Technical quality is often viewed as the ‘science’ of medicine as opposed to its ‘art,’ which involves less tangible and potentially harder-to-capture aspects of care as the interpersonal and cognitive processes underlying patient-physician communication and decision making.”

33

- “Yet, as Donabedian said more than 2 decades ago, ‘The interpersonal process is the vehicle by which technical care is implemented and on which its success depends.’”
- “Therefore, to achieve desired health outcomes, it is essential to focus on optimizing both the technical and the interpersonal processes in care.”

34

The bottom line

- Allopathic practitioners have long assumed that, by curing “modern acute diseases” (Which are, more often than not, acute exacerbations of chronic illness) and by optimizing key lab values, patients will predictably see improvements in chief complaints.

35

The bottom line

This is not proving to be true for many patients.

36

Have alternative medicine practitioners also focused too much on the technical –
Treating diseases and optimizing lab values?

37

First, consider treating acute diseases

38

THE NEW ENGLAND JOURNAL OF MEDICINE

ORIGINAL ARTICLE

n-3 Fatty Acids in Patients with Multiple Cardiovascular Risk Factors

The Risk and Prevention Study Collaborative Group*

ABSTRACT

BACKGROUND
 Trials have shown a beneficial effect of n-3 polyunsaturated fatty acids in patients with a previous myocardial infarction or heart failure. We evaluated the potential benefit of such therapy in patients with multiple cardiovascular risk factors or ath-

The members of the writing group, who are listed in the Appendix, assume responsibility for the content and integrity of this article. Address reprint requests to the Risk and Prevention Study Collaborative Group, Mario Negri 20156 Milan.

*The intervention is listed in the available N Engl J Med DOI: 10.1056

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and nonfatal stroke. At 1 year, after the event rate was found to be lower than anticipated, the primary end point was revised as time to death from cardiovascular causes or admission to the hospital for cardiovascular causes.

RESULTS
 Of the 12,513 patients enrolled, 6244 were randomly assigned to n-3 fatty acids and 6269 to placebo. With a median of 5 years of follow-up, the primary end point oc-

The Risk and Prevention Study Collaborative Group, n-3 fatty acids in patients with multiple cardiovascular risk factors, *N Eng J Med*, Vol. 368, No. 19, pp. 1800-1808, May 9, 2013

"In a large general-practice cohort of patients with multiple cardiovascular risk factors, daily treatment with n-3 fatty acids did not reduce cardiovascular mortality and morbidity."

morbidity. (Funded by Società Prodotti Antibiotici and others; ClinicalTrials.gov number, NCT00317707)

1800 N. ENGL. J. MED. 368(19) NEJM.ORG MAY 9, 2013

39

Why do the epidemiologic studies look so good and the interventional studies look so bad?

What Do Scientific Studies Show? - NYTimes.com <http://opinionator.blogs.nytimes.com/2013/04/25/what-do-scientific-studies-show/>

The New York Times
Opinionator

APRIL 25, 2013, 8:00 PM
What Do Scientific Studies Show?
By GARY GUTTING

As any regular reader of news will know, popular media report "scientific results" nearly every day. They come delivered in news reports and opinion pieces, and are often used to make even

Gutting G. What do scientific studies show? *The New York Times*, April 25, 2013

For "vita

"During the past decade, there's been an explosion of research suggesting that vitamin D plays a significant role in joint health and that low levels may be a risk factor for rheumatologic conditions such as rheumatoid arthritis and osteoarthritis." However, in February 2013, a more rigorous study called the previous studies into serious question. Similarly, despite many studies suggesting that taking niacin to increase "good cholesterol" would decrease heart attacks, a more rigorous study showed the niacin to have no effect.

Such reports have led many readers to question the reliability of science. And given the way the news is often reported, they seem to have a point. What use are scientific results if they are so frequently reversed? But the problem is typically not with the science but with the reporting.

In both the above examples, earlier studies had shown a correlation but not a causal connection. They had not shown that, for example, taking vitamin D was the only relevant difference between those whose pain decreased and those whose pain did not decrease. Perhaps, for example, those taking vitamin D also exercised more, and this was the cause of the pain decrease. Typically, the best way to establish a cause rather than a correlation is to perform a randomized controlled experiment (R.C.T.), where we know that only one possibly relevant factor distinguishes the two groups. In both the vitamin D and the niacin cases, there was an R.C.T. that showed that the earlier results had been merely correlations.

R.C.T.s are often very difficult to set up properly and can take many years to carry out. As a result, most research we read about involves just correlational studies. John Ioannidis, in a series of highly regarded analyses, has shown that, in published medical research, 80 percent of non-randomized studies (by far the most common) are later

1 of 3 5/9/2013 3:04 PM 41

- "What use are scientific results if they are so frequently reversed? But the problem is typically not with the science but with the reporting."
- "...earlier studies have shown a correlation but not a causal connection."
- "Randomized controlled studies (R.C.T.s) are often very difficult to set up properly and can take many years to carry out. As a result, most research we read about involves just correlational studies."

- “John Ioannidis, in a series of highly regarded analyses, has shown that, in published medical research, 80 percent of non-randomized studies (by far the most common) are later found to be wrong.”
- “Even 25 percent of randomized studies and 15 percent of large randomized studies – the best of the best – turn out to be inadequate.”

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- “Media tend to present almost any scientific result they report as valuable for guiding our lives, with the entire series of reports accumulating a vast body of practical knowledge.”
- “In fact, most scientific results are of no immediate practical value; they merely move us one small step closer to a final result that may be truly useful.”
- “Too many news reports present experimental results as providing good advice on which we can reliably act.”
- “In most cases those results would be better viewed as mistakes pointing to a next step that will be a bit less mistaken.”

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***“Media reports saying ‘studies show...’
are most often giving us highly
tentative results – indeed, results that
are likely to be false. They need to be
labeled as such.”***

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OPEN ACCESS Freely available online

PLOS MEDICINE

Misrepresentation of Randomized Controlled Trials in Press Releases and News Coverage: A Cohort Study

Amélie Yavchitz^{1,2,3}, Isabelle Boutron^{1,2,3}, Aida Bafeta^{1,2,3}, Ibrahim Marroun⁴, Pierre Charles⁵, Jean Mantz⁶, Philippe Ravaut^{1,2,3}

1 INSERM, U758, Paris, France, **2** Centre d'Épidémiologie Clinique, AP-HP (Assistance Publique des Hôpitaux de Paris), Hôpital Hôtel Dieu, Paris, France, **3** Université Paris Descartes, Sorbonne Paris Cité, Faculté de Médecine, Paris, France, **4** Département de Médecine Interne, Hôpital Pitié, Sorbonne, France, **5** Département d'Anesthésiologie et Soins Intensifs, Hôpital Pitié, Sorbonne, France, **6** Département de Médecine Interne, Hôpital Pitié, Sorbonne, France

Abstract

Background: Previous studies indicate that in published reports, trial results can be distorted by the use of “spin” (specific report of results that is not based on the actual results of the study).

Methods:

Results:

Conclusion:

Abstract:

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Background:

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Background:

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Journal:

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Abstract:

Background:

Methods:

Results:

Conclusion:

Abstract:

Yavchitz A et al. Misrepresentation of randomized controlled trials in press releases and news coverage: A cohort study, *PLOS Medicine*, Vol. 9, No. 9, September 2012.

Conclusion: “Spin” was identified in about half of press releases and media coverage. In multivariable analysis, the main factor associated with “spin” in press releases was the presence of “spin” in the article abstract conclusion.

Please see later in the article for the Editors' Summary.

Citation: Yavchitz A, Boutron I, Bafeta A, Marroun I, Charles P, et al. (2012) Misrepresentation of Randomized Controlled Trials in Press Releases and News Coverage: A Cohort Study. *PLoS Med* 9(9): e1001308. doi:10.1371/journal.pmed.1001308

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Competing Interests: Isabelle Boutron is a member of PLOS Medicine Editorial Board. The authors have declared that no other competing interests exist.

“Spin” was identified in about half of press releases and media coverage. In multivariable analysis, the main factor associated with ‘spin’ in press releases was the presence of ‘spin’ in the article abstract conclusion.”

Next, consider treating lab values with the assumption that chief complaints will improve

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Clinical Chemistry 59:5
726-728 (2013)

Editorials

Vitamin D and Cancer: Can We Believe the Evidence from Observational Studies?

Nancy R. Cook^{1,*}

The article by Afari et al. in this issue of *Clinical Chemistry* (1) presents data showing an association of low concentrations of vitamin D with risk of tobacco-related can-

a wonder drug for cardiovascular disease. In trials, however, no effect was found, and a slight increase in mortality has even been suggested though not proven (2). Argu-

Cook NR. Vitamin D and cancer: Can we believe the evidence from observational studies? *Clin Chem*, Vol. 59, No. 5, pp. 726-728, May 2013.

remain suggestive rather than conclusive.

Science is rife with examples of promising hypotheses based on observational data that did not hold up under more rigorous randomized controlled trials. An early panacea was β -carotene, which was hypothesized to reduce cancer incidence (2). At the time, it was the exciting new theory and garnered much attention. When tested in randomized controlled trials, however, the promising hypothesis failed to hold up. The Physicians' Health Study, the Alpha-Tocopherol, Beta-Carotene Cancer Prevention (ATBC) trial, the Beta-Carotene and Retinol Efficacy Trial (CARET), and other trials found no

more vitamin D appears, one more suggestive of a possible protective effect for both cancer and cardiovascular disease. An effect on cancer has biologic plausibility on the basis of animal studies and studies of effects on cells. Residual confounding may still occur, however, since concentrations of 25(OH)D are related to factors such as obesity, physical activity, and diet (7). Reverse causation must also be considered when evaluating dietary exposures.

Data from trials of vitamin D so far have been limited. An early trial suggested a protective effect of a combination of vitamin D and calcium on total cancer (8) but was based on a relatively small number of events. There was also little difference between the

"Science is rife with examples of promising hypotheses based on observational data that did not hold up under more rigorous randomized controlled trials."

ture (9). As has been shown to be related to cancer of cardiovascular disease in observational data, but the results did not hold up to the more rigorous examination of a randomized trial. Vitamin E, in particular, enjoyed widespread public attention and was promoted as akin to

cluding cancer, was inconsistent and inconclusive. Several observational studies found an association between 25(OH)D concentrations and cancer risk, but these also were inconsistent and could not prove causality. Several new trials of vitamin D are now ongoing, however. One is the Vitamin D and Omega-3 Trial (VITAL) (10), which will include >20 000 men and women across the US. VITAL will test the effects of 2000 IU/day of vitamin D3 (cholecalciferol) over a 5-year follow-up period. Although this level has generally been recognized as safe, there must be careful monitoring for any adverse effects, especially among individuals with high baseline values of vitamin D.

Of course, not all questions can be answered with randomized trials. Trials are generally restrictive in their eligibility requirements and test a single dose or a

¹ Division of Preventive Medicine, Brigham & Women's Hospital, Harvard Medical School, Boston, MA.

* Address correspondence to the author at: Division of Preventive Medicine, Brigham and Women's Hospital, 500 Commonwealth Ave, East, Boston, MA 02115. Fax 617-354-0194; e-mail: ncook@rics.bwh.harvard.edu.

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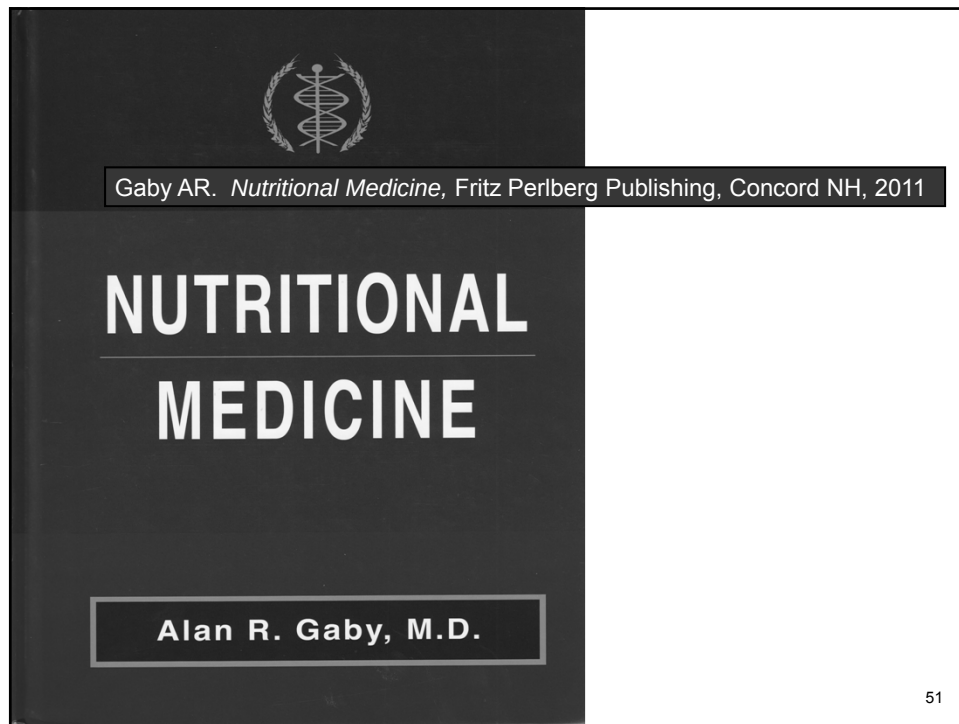
² Nonrandomized observations: 25(OH)D, 25-hydroxyvitamin D; ATBC, Alpha-Tocopherol, Beta-Carotene Cancer Prevention; CARET, Beta-Carotene and Retinol Efficacy Trial; VITAL, Vitamin D and Omega-3 Trial.

- “The same has occurred for various other dietary nutrients, including vitamin E, vitamin C, and the B vitamins.”
- “All had been shown to be related to cancer or cardiovascular disease in observational data, but the results did not hold up to the more rigorous examination of a randomized trial.”

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- “Several observational studies have now been conducted on vitamin D, the nutrient with the current most widespread appeal, that have suggested a possible protective effect for both cancer and cardiovascular disease.”
- “An effect on cancer has biologic plausibility on the basis of animal studies and studies of effects on cells.”
- “Residual confounding may still occur, however, since concentrations of 25(OH)D are related to factors such as obesity, physical activity, and diet.”

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- “Metallurgically speaking, however, the reliability of serum 25(OH)D as an indicator of vitamin D status might more aptly be characterized as bronze, rather than gold, even though it is currently the best assessment method available.”
- “One problem with this test is that substantial variations have been encountered from one laboratory to another and with the use of different methods of assessment.”

- “Another complicating factor is that 25(OH)D is only one of more than 50 vitamin D metabolites that have been identified.”
- “Although little is known about many of these metabolites, at least one (not including 1,25[OH]₂D) appears to have biological activity...”
- “It would not be surprising if some of these compounds were able to bind to vitamin D receptors or to compete with vitamin D, 25(OH)D, or 1,25 (OH)₂D as substrates for enzymes involved in vitamin D metabolism.”

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The New York Times

May 14, 2013

No Benefit Seen in Sharp Limits on Salt in Diet

By GINA KOLATA

In a report that undercuts years of public health warnings, a prestigious group convened by the government says there is no good reason based on health outcomes for many Americans to drive their sodium consumption down to the very low levels recommended in national dietary guidelines.

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Kolata G. No benefit seen in sharp limits on salt and diet, *The New York Times*, May 14, 2013

Some influential organizations, including the American Heart Association, have said that everyone, not just those at risk, should aim for that very low sodium level. The heart association reaffirmed that position in an interview with its spokesman on Monday, even in light of the new report.

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“But more recently, researchers began looking at the actual consequences of various levels of salt consumption, as found in rates of heart attacks, strokes and death, not just blood pressure readings. Some of what they found was troubling.”

possible harms included increased rates of heart attacks and an increased risk of death.

The committee was not asked to specify an optimal amount of sodium and did not make any recommendations about how much people should consume. Dr. Strom said people should not eat too much salt, but he also said that the data on the health effects of sodium were too inconsistent for the committee to say what the upper limit of sodium consumption should be.

Until about 2006, almost all studies on salt and health outcomes relied on the well-known fact that blood pressure can drop slightly when people eat less salt. From that, and from other studies linking blood pressure to risks of heart attacks and strokes, researchers created models showing how many lives could be saved if people ate less salt.

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- “One study the committee examined, for example, randomly assigned 232 Italian patients with aggressively treated moderate to severe congestive heart failure to consume either 2,760 or 1,840 milligrams of sodium a day, but otherwise to consume the same diet.”
- “Those consuming the lower level of sodium had more than three times the number of hospital admissions – 30 as compared with 9 in the higher-salt group – and more than twice as many deaths – 15 as compared with 6 in the higher-salt group.”

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Clinically insignificant effect of supplemental vitamin C on serum urate in patients with gout; A pilot ran... Page 1 of 4



Full Length

Clinically insignificant effect of supplemental vitamin C on serum urate in patients with gout; A pilot randomised controlled trial[†]

1. Lisa K Stamp FRACP, PhD^{1,2,*},
2. John L O'Donnell FRACP²,
3. Christopher Frampton PhD³,
4. Jill D...
5. Mei Z...
6. Peter...

DOI: 10.1002/

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Stamp LK et al. Clinically insignificant effect of supplemental vitamin c on serum urate in patients with gout; A pilot randomised controlled trial, *Arthritis & Rheumatism*, Published online ahead of print May 16, 2013.

“Modest dose vitamin C (500mg/d) for 8 weeks had no clinically significant urate lowering effect in patients with gout despite increasing plasma ascorbate. These results differ from findings in hyperuricaemic healthy controls. The uricosuric effect of modest dose vitamin C appears less in patients with gout as monotherapy, and in combination with allopurinol.”

Department of Medicine, University of Otago, Christchurch New Zealand

<http://onlinelibrary.wiley.com/doi/10.1002/art.37925/abstract>

5/17/2013

56

Overall, how well has allopathic medicine performed?

- Excellent concerning acute exacerbations of chronic diseases and related laboratory values.
- Not so good with overall chronic illness
- Not so good concerning outcome related issues such as “How do you feel?”

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25-Year summary of US malpractice claims for diagnostic errors 19... <http://qualitysafety.bmj.com/content/early/2013/03/27/bmjqs-2012-...>

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BMJ Quality & Safety

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bmjqs.bmj.com
BMJ Qual Saf doi:10.1136/bmjqs-2012-001550

Original research

25-Year summary of US malpractice claims for diagnostic errors 1986–2010: an analysis from the National Practitioner Data Bank

Tehrani A et al. 25-year summary of US malpractice claims for diagnostic errors 1986–2010: an analysis from the National Practitioner Data Bank, *BMJ Qual Saf*, Published online ahead of print April 2013.

Published Online First 22 April 2013

Abstract

Background We sought to characterise the frequency, health outcomes and economic consequences of diagnostic errors in the USA through analysis of closed, paid malpractice claims.

Methods We analysed diagnosis-related claims from the National Practitioner Data Bank (1986–2010). We describe error type, outcome severity and payments (in 2011 US dollars), comparing diagnostic errors to other malpractice allegation groups and inpatient to outpatient within diagnostic errors.

“Among malpractice claims, diagnostic errors appear to be the most common, most costly and most dangerous of medical mistakes. We found roughly equal numbers of lethal and non-lethal errors in our analysis, suggesting that the public health burden of diagnostic errors could be twice that previously estimated. Healthcare stakeholders should consider diagnostic safety a critical health policy issue.”

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Clinical Nutrition 30 (2011) 571–571

Contents lists available at ScienceDirect

Clinical Nutrition

journal homepage: <http://www.elsevier.com/locate/cn>

Original article

Effect of a high protein meat diet on muscle and cognitive functions: A randomised controlled dietary intervention trial in healthy men^a

lene H. Jakobsen^{a,b}, Jens Kondrup^{a,b}, Maria Zeller^a, Inge Tetens^a, Erich Roth^c

^aDepartment of Human Nutrition, Faculty of Life Sciences, University of Copenhagen, Denmark
^bClinical Nutrition Unit, Copenhagen, Denmark
^cSurgical Research, Medical University Vienna, Austria
^dDepartment of Nutrition, National Food Institute, Technical University of Denmark, Denmark

ARTICLE INFO

Article history:
 Received 16 July 2010
 Accepted 10 December 2010

Keywords:
 Protein
 Muscle function
 Cognitive function
 Plasma amino acids

SUMMARY

Background: Recommendations to use other criteria than N-balance for defining protein requirements have been proposed. However, little evidence to support other measures such as physiological functions is available.

Objective: To investigate the effects of a usual (UP) versus a high protein (HP) diet on muscle function, cognitive function, quality of life and biochemical regulators of protein metabolism.

Design: A randomised intervention study was conducted with 23 healthy males (aged 19–31 yrs). All subjects consumed a Usual Protein (UP) diet (1.5 g protein/kg BW) for a 1-week run-in period before the intervention period when they were assigned to either a UP or a high protein (HP) diet (3.0 g protein/kg BW) for 3-weeks with controlled intake of food and beverages. Blood and urine samples were taken along with measurements of physiological function as baseline and at the end of the intervention period.

Results: The HP group improved their reaction time significantly compared with the UP group. Blood cholestanol and creatinine in plasma were significantly increased following the HP diet, which may explain the improved reaction time.

Conclusion: Healthy young males fed a HP diet improved reaction time. No adverse effects of the HP diet were observed.

This trial was registered at www.clinicaltrials.gov NCT00122371.

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Clinical Nutrition 30 (2011) 571–571

Contents lists available at ScienceDirect

Clinical Nutrition

journal homepage: <http://www.elsevier.com/locate/cn>

Original article

Effect of essential amino acid supplementation on quality of life, Amino acid profile and strength in institutionalized elderly patients

Mariangela Rondanelli^{a,*}, Annalisa Opizzi^a, Nello Antonelli^a, Federico Roschi^a, Paolo Iadarola^a, Evasio Pisini^a, Roberto Aquilani^a, Francesco Saverio Dioguardi^a

^aDepartment of Applied Health Sciences, Section of Human Nutrition and Dietetics, Faculty of Medicine, Metabolic and Nutrition Unit, University of Ferrara, Italy
^bAcademia di Scienze della Medicina di Ferrara, Italy
^cDepartment of Experimental and Applied Pharmacology, University of Ferrara, Italy
^dDepartment of Biochemistry "A. Casati", University of Ferrara, Italy
^eCardiology Division, S. Margherita Foundation, IRCCS Scientific Institute of Lumezzane, Brescia, Italy
^fMetabolic Service and Nutrition Pathophysiology, S. Margherita Foundation, IRCCS Scientific Institute of Lumezzane, Brescia, Italy
^gDepartment of Internal Medicine, University of Milan, Italy

ARTICLE INFO

Article history:
 Received 11 August 2010
 Accepted 20 April 2011

Keywords:
 Elderly
 Disability
 Dietetic intervention
 Health-related quality of life
 Muscle strength

SUMMARY

Background & aims: This study assessed the effects of supplemented essential amino acids on depressive symptoms, nutrition, muscle function, daily physical activity, and health-related quality of life (HRQL) of institutionalized elderly patients.

Methods: Forty-nine patients (58.5% women, mean age 78.8 yrs) with sagittal of coronary artery disease (CAD), Senescent Factor (SF), were randomly assigned to receive oral essential amino acids (e.a.a.) 2 g twice a day for 8 weeks or placebo. Before randomization and 8 weeks after the protocol started, the following variables were measured: depressive symptoms (Geriatric Depression Scale, GDS), nutritional status (Mini Nutritional Assessment, MNA), serum albumin and prealbumin levels, muscle strength (Hand Grip, HG), Activity Daily Life (ADL), Quality of Life (QoL), and amino acid profile.

Results: Compared with the placebo group, EAA patients improved: nutrition (MNA score 22.6 ± 1.5 post vs 21.8 ± 1.5 pre; p < 0.04), albumin (g/dL 4.04 ± 0.2 post vs 3.88 ± 0.3 pre; p < 0.01), CDB score (83.3 ± 1.75 post vs 83.5 ± 1.77 pre; p < 0.001), HG (kg 18.73 ± 1.7 post vs 18.0 ± 1.38 pre; p < 0.001), ADL (p < 0.04) and both physical and mental components of SF-36 (p < 0.002).

Conclusion: Oral supplementation with essential amino acids improved several determinants of quality of life in institutionalized elderly patients, including depressive symptoms, nutrition, muscle function and daily life activity.

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Clinical Nutrition 31 (2012) 563–570

Contents lists available at ScienceDirect

Clinical Nutrition

journal homepage: <http://www.elsevier.com/locate/cn>

Original article

A nutritional program to improve outcome of very low birth weight infants

Niels Rødbow^{a,b}, Gerhard Fusch^{a,b}, Alexandra Mühlinghaus^a, Christian Nicysto^a, Sebastian Straube^a, Norbert Utzig^a, Christoph Fusch^{a,b,*}

^aDepartment of Pediatrics, University of Göttingen, Germany
^bDepartment of Pediatrics, MGH Hannover, Hannover, Germany
^cDepartment of Paediatrics, Social and Environmental Medicine, University Medical Center Göttingen, Göttingen, Germany

ARTICLE INFO

Article history:
 Received 19 January 2011
 Accepted 1 July 2011

Keywords:
 Catching growth
 Nutritional outcome
 Growth chart
 Protein intake

SUMMARY

Background & aims: The growth of very low birth weight infants does not match intruterine trajectories. They due to inappropriate caloric intake. We therefore investigated whether modification of the standard nutritional schedule can improve postnatal growth.

Methods: We conducted a set of evidence-based strategies in a study group of infants (n = 523): 1) higher maximum intake of intravenous amino acids and lipids; 2) prioritization of earlier enteral feeding; 3) faster attainment of full enteral feeds; 4) daily adjustment of enteral feeds according to growth trajectory; and 5) utilization of an electronic pre-structured prescription ordering system that tracks individual growth and energy intake. These effects were compared with a control group (n = 103), in a parallel retrospective cohort study.

Results: The study group achieved a higher caloric intake, attained full enteral feeds 5 days earlier, and returned to their birth weight more rapidly than the control group. At 36 weeks postmenstrual age, infants who had been born at < 28 weeks were 2.60 kg (95% CI 1.98–3.22) heavier and 1.5 g protein/kg BW (95% CI 1.04–1.96) higher than the control group. These birth of < 28 weeks had a larger head circumference (2.41 cm) and lower weight gain (1.83%).

Conclusions: Optimization of early postnatal nutrition and daily adjustment of milk intake according to weight gain improved growth, without any deleterious outcomes for body composition and neurodevelopmental follow-up.

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Clinical Nutrition 31 (2012) 563–569

Contents lists available at ScienceDirect

Clinical Nutrition

journal homepage: <http://www.elsevier.com/locate/cn>

Original article

Oral nutritional support in malnourished elderly decreases functional limitations with no extra costs

Floor Neelmaat^{a,*}, Judith E. Bosmans^a, Abel Thijs^a, Jaap C. Seidell^b, Marian A.E. van Bokhorst-de van der Schueren^a

^aDepartment of Nutrition and Dietetics, Internal Medicine and EMGO Institute for Health and Care Research, VU University Medical Center, Amsterdam, The Netherlands
^bDepartment of Health Sciences and EMGO Institute for Health and Care Research Faculty of Earth and Life Sciences, VU University De Boelelaan 1083, 1083 HX Amsterdam, The Netherlands
^cDepartment of Internal Medicine, VU University Medical Center, PO Box 7057, 1007 MB Amsterdam, The Netherlands

ARTICLE INFO

Article history:
 Received 24 February 2011
 Accepted 17 October 2011

Keywords:
 Cost-effectiveness
 Functional limitations
 Malnutrition
 Elderly
 Patients

SUMMARY

Background & aims: Older people are vulnerable to malnutrition which leads to increased health care costs. The aim of this study was to evaluate the cost-effectiveness of nutritional supplementation from a societal perspective.

Design: This randomized controlled trial included hospital admitted malnourished elderly (< 80 years) patients. Patients in the intervention group received nutritional supplementation (energy and protein enriched diet, oral nutritional support, calcium-vitamin D supplement, telephone counselling by a dietitian) and three months after discharge from hospital. Patients in the control group received usual care (control). Primary outcomes were Quality-Adjusted Life Years (QALYs), physical activities and functional limitations. Measurements were performed at hospital admission and three months after discharge. Data were analyzed according to the intention-to-treat principle and multiple imputation was used to impute missing data. Incremental cost-effectiveness ratios were calculated and bootstrapping was applied to evaluate cost-effectiveness. Cost-effectiveness was expressed in cost-effectiveness planes and cost-effectiveness acceptability curves.

Results: 290 patients were included, 905 in each group. After three months, no statistically significant differences in quality of life and physical activities were observed between groups. Functional limitations decreased significantly more in the intervention group (mean difference -0.72, 95% CI -1.15–-0.28). There were no differences in costs between groups. Cost-effectiveness for QALYs and physical activities could not be demonstrated. For functional limitations we found a 63% probability that the intervention is cost-effective in comparison with usual care for caring rates > €4500.

Conclusions: A multi-component nutritional intervention in malnourished elderly patients for three months after hospital discharge leads to significant improvement in functional limitations and is neutral to costs. A follow-up of three months is probably too short to detect changes in QALYs or physical activities.

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Original article

A nutritional program to improve outcome of very low birth weight infants

Niels Rødbow^{a,b}, Gerhard Fusch^{a,b}, Alexandra Mühlinghaus^a, Christian Nicysto^a, Sebastian Straube^a, Norbert Utzig^a, Christoph Fusch^{a,b,*}

^aDepartment of Pediatrics, University of Göttingen, Germany
^bDepartment of Pediatrics, MGH Hannover, Hannover, Germany
^cDepartment of Paediatrics, Social and Environmental Medicine, University Medical Center Göttingen, Göttingen, Germany

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SUMMARY

Background & aims: The growth of very low birth weight infants does not match intruterine trajectories. They due to inappropriate caloric intake. We therefore investigated whether modification of the standard nutritional schedule can improve postnatal growth.

Methods: We conducted a set of evidence-based strategies in a study group of infants (n = 523): 1) higher maximum intake of intravenous amino acids and lipids; 2) prioritization of earlier enteral feeding; 3) faster attainment of full enteral feeds; 4) daily adjustment of enteral feeds according to growth trajectory; and 5) utilization of an electronic pre-structured prescription ordering system that tracks individual growth and energy intake. These effects were compared with a control group (n = 103), in a parallel retrospective cohort study.

Results: The study group achieved a higher caloric intake, attained full enteral feeds 5 days earlier, and returned to their birth weight more rapidly than the control group. At 36 weeks postmenstrual age, infants who had been born at < 28 weeks were 2.60 kg (95% CI 1.98–3.22) heavier and 1.5 g protein/kg BW (95% CI 1.04–1.96) higher than the control group. These birth of < 28 weeks had a larger head circumference (2.41 cm) and lower weight gain (1.83%).

Conclusions: Optimization of early postnatal nutrition and daily adjustment of milk intake according to weight gain improved growth, without any deleterious outcomes for body composition and neurodevelopmental follow-up.

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Original article

Oral nutritional support in malnourished elderly decreases functional limitations with no extra costs

Floor Neelmaat^{a,*}, Judith E. Bosmans^a, Abel Thijs^a, Jaap C. Seidell^b, Marian A.E. van Bokhorst-de van der Schueren^a

^aDepartment of Nutrition and Dietetics, Internal Medicine and EMGO Institute for Health and Care Research, VU University Medical Center, Amsterdam, The Netherlands
^bDepartment of Health Sciences and EMGO Institute for Health and Care Research Faculty of Earth and Life Sciences, VU University De Boelelaan 1083, 1083 HX Amsterdam, The Netherlands
^cDepartment of Internal Medicine, VU University Medical Center, PO Box 7057, 1007 MB Amsterdam, The Netherlands

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SUMMARY

Background & aims: Older people are vulnerable to malnutrition which leads to increased health care costs. The aim of this study was to evaluate the cost-effectiveness of nutritional supplementation from a societal perspective.

Design: This randomized controlled trial included hospital admitted malnourished elderly (< 80 years) patients. Patients in the intervention group received nutritional supplementation (energy and protein enriched diet, oral nutritional support, calcium-vitamin D supplement, telephone counselling by a dietitian) and three months after discharge from hospital. Patients in the control group received usual care (control). Primary outcomes were Quality-Adjusted Life Years (QALYs), physical activities and functional limitations. Measurements were performed at hospital admission and three months after discharge. Data were analyzed according to the intention-to-treat principle and multiple imputation was used to impute missing data. Incremental cost-effectiveness ratios were calculated and bootstrapping was applied to evaluate cost-effectiveness. Cost-effectiveness was expressed in cost-effectiveness planes and cost-effectiveness acceptability curves.

Results: 290 patients were included, 905 in each group. After three months, no statistically significant differences in quality of life and physical activities were observed between groups. Functional limitations decreased significantly more in the intervention group (mean difference -0.72, 95% CI -1.15–-0.28). There were no differences in costs between groups. Cost-effectiveness for QALYs and physical activities could not be demonstrated. For functional limitations we found a 63% probability that the intervention is cost-effective in comparison with usual care for caring rates > €4500.

Conclusions: A multi-component nutritional intervention in malnourished elderly patients for three months after hospital discharge leads to significant improvement in functional limitations and is neutral to costs. A follow-up of three months is probably too short to detect changes in QALYs or physical activities.

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Cost!!

Every facet of Entry Level Clinical Nutrition revolves around the idea of cost effectiveness.

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IMPROVING PATIENT CARE

ORIGINAL RESEARCH

Patient-Centered Decision Making and Health Care Outcomes

An Observational Study

Saul J. Weiner, MD; Alan Schwartz, PhD; Gurjan Sharma, PhD; Amy Elms-Culvey, BA; Naomi Ashley, BA; Brendan Kelly, BA; Amit Dayal, MD; Sonal Patel, MD; Frances M. Weaver, PhD; and Rene Harris, PhD

Background: Patient-centered decision making (PCDM) is the process of identifying clinically relevant, patient-specific circumstances and behaviors to formulate a contextually appropriate care plan.

Objective: To ascertain whether encounters in which PCDM occurs are followed by improved health care outcomes compared with encounters where there is no attention to patient context.

Design: Patients' surreptitiously audio-recorded encounters with their physicians. Medical records of these encounters were then screened for "contextual red flags," such as deteriorating self-management of a chronic condition, that could reflect such underlying contextual factors as competing responsibilities or loss of social support. When a contextual factor was identified, either as a result of physician questioning or because a patient volunteered information, physicians were scored on the basis of whether they adopted

a patient presenting with hypertension and loss of medication coverage. Outcome scores were limited to physician performance.

Results: Among 548 contextual red flags, 208 contextual factors were confirmed, either when physicians probed or patients volunteered information. Physician attention to contextual factors (both probing for them and addressing them in care plans) varied according to the presenting contextual red flags. Outcome data were available for 157 contextual factors, of which PCDM was found to address 96. Of these, health care outcomes improved in 68 (71%), compared with 28 (46%) of the 61 that were not addressed by PCDM ($P = 0.002$).

Limitation: The extent to which the findings can be generalized to other clinical settings is unknown.

Conclusion: Attention to patient needs and circumstances when

Weiner SJ et al. Patient-centered decision making and health care outcomes, *Ann Intern Med*, Vol. 158, pp. 573-579, 2013.

Evidence-based medicine has been described as the "conscious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients" (1). The process of adapting best evidence to the care of the individual patient has been characterized as

"Attention to patient needs and circumstances when planning care is associated with improved health care outcomes."

circumstances and behaviors. For instance, failure to recognize when a worsening chronic condition, such as diabetes, is due to progressive cognitive disability and deteriorating medication adherence rather than a need for intensified medication therapy is a contextual error. Although dementia is a common cause of such errors, it is not the only one. Other causes include depression, loss of social support, and loss of skills and abilities. Addressing these contextual factors is a key component of patient-centered care.

Contextual factors include access to care, social support, competing responsibilities, relationship with health care providers, skills and abilities, emotional state, financial situation, cul-

tural beliefs, spiritual beliefs, and attitude toward illness (2). Contextualizing care involves identifying the relevance of one or more of these domains to a patient's care plan and adapting the plan accordingly (3). For instance, if a patient is unable to adhere to a twice-daily medication regimen because of work responsibilities, modification of

ing with common clinical problems, appropriate care was provided 73% of the time when adherence to research evidence (that is, guidelines and best practice recommendations) was all that was required. When contextual factors were introduced that required attention to avoid ineffective or potentially harmful care, appropriate care was not

"Although it may seem intuitive that addressing the patient's ability to pay for medication results in improved diabetes control..."

First editorial comment, ... 628

16 April 2013 | *Annals of Internal Medicine* | Volume 158 • Number 8 | 679

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A Hospital Says 'No' to an \$11,000-a-Month Cancer Drug - NYTimes... <http://www.nytimes.com/2012/10/15/opinion/a-hospital-says-no-to-...>

The New York Times

October 14, 2012

In Cancer Care, Cost Matters
 By PETER B. BACH, LEONARD B. SALTZ and ROBERT E. WITTES
 AT Memorial Sloan-Kettering Cancer Center, we recently made a decision that should have been a no-brainer: we are not going to give a phenomenally expensive new cancer drug to our patients.

The reasons are simple: The drug, Zaltrap, has proved to be no better than a similar medicine we already have for advanced colorectal cancer, while its price — at \$11,063 on average for a month of treatment — is more than twice as high.

In most cases, the new drug is no better than the old one. It does not consider what the relative costs might be once the new medicine is marketed.

By law, Medicare must cover every cancer drug the F.D.A. approves. (A 2003 law, moreover, mandates payment at the price the manufacturers charge, plus a 6 percent cushion.) In most states private insurers are held to this same standard. Physician guideline-setting organizations likewise focus on whether or not a treatment is effective, and rarely factor in cost in their determinations.

Ignoring the cost of care, though, is no longer tenable. Soaring spending has presented the medical community with a new obligation. When choosing treatments for a patient, we have to consider the financial strains they may cause alongside the benefits they might deliver.

This is particularly the case with cancer, where the cost of drugs, and of care over all, has risen precipitously. The typical new cancer drug coming on the market a decade ago cost about \$4,500 per month (in 2012 dollars); since 2010 the median price has been around \$10,000. Two of the new cancer drugs cost more than \$35,000 each per month of treatment.

The burden of this cost is borne, increasingly, by patients themselves — and the effects can be devastating. In 2006, one-quarter of cancer patients reported that they had used up all or most of their savings paying for care; a study last year reported that 2 percent of cancer

Bach PB et al. In cancer care, cost matters, *The New York Times*, October 14, 2012

1 of 3 5/13/2013 12:07 PM 65

- “At Memorial Sloan-Kettering Cancer Center, we recently made a decision that should have been a no-brainer: we are not going to give a phenomenally expensive new cancer drug to our patients.”
- “The reasons are simple: The drug, Zaltrap, has proved to be no better than a similar medicine we already have for advanced colorectal cancer, while its price – at \$11,063 on average for a month of treatment – is more than twice as high.”

- “In most industries something that offers no advantage over its competitors and yet sells for twice the price would never even get on the market. But that is not how things work for drugs. The Food and Drug Administration approves drugs if they are shown to be “safe and effective.” It does not consider what the relative cost might be once the new medicine is marketed.”
- “Ignoring the cost of care, though, is no longer tenable. Soaring spending has presented the medical community with a new obligation. When choosing treatments for a patient, we have to consider the financial strains they may cause alongside the benefits they might deliver.”

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CLINICAL PATHOPHYSIOLOGY

A FUNCTIONAL PERSPECTIVE

A systems approach to understanding and reversing disease processes

Joseph E. Pizzorno Jr., ND
Joseph Katzinger, ND

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EDITORIAL

FUNCTIONAL DIAGNOSTICS: REDEFINING DISEASE

Mark A. Hyman, MD

Mark A. Hyman, MD, is the editor in chief of *Alternative Therapies in Health and Medicine*. (*Alt Ther Health Med*, 2008;14(4):10-14.)

Functional medicine is a disruptive technology that will overthrow the tyranny of the diagnosis.
—Jeffrey Bland

Medical diagnosis has a storied and embarrasing past, as we not molecularly dissect the human mind. Hippocrates: black bile, yellow bile. 18th-century Swedish scientific classification of plant species, including painful disease, distinguishing 404 diseases originating in past lifetimes, disease resulting from influences in early life, disorders involving spirits, and superficial disorders resulting from diet and behavior.

In the late 19th and early 20th centuries, doctors and scientists shifted from a symptom-based diagnostic model to an anatomical view of disease, which led to the first international classification of disease in the 1850s and segregated disease into 140 categories, including "Visitation from God." The 10th edition of the ICD (International Classification of Diseases) published by the World Health Organization in 1993 contains 12,000 categories of disease. With the advent of the genomic revolution and personalized medicine, the next edition, due in 2015, may need a radically new system of classification.

Our current categorization of diseases has little to do with the meaning, myths, and metaphors we associate with them. Before Robert Koch discovered the "tubercle bacillus," medical textbooks unequivocally defined the cause of tuberculous leprosy: defective ventilation, unfavorable climate, sedentary indoor life, defective ventilation, deficiency of light, and depressing emotions. The microscope changed all that.

Disease is primarily defined in phenomenological, not etiological, terms. We describe what we see—histology under the

microscope or through more refined and sophisticated ways of seeing static pathology: the x-ray, ultrasound, computed tomography, magnetic resonance imaging, or other advanced imaging tools, or gross alterations in physiology such as elevated glucose or renal or liver function tests.

We struggle to accommodate new scientific understanding by creating new categories of "pre-disease"—pre-diabetes, pre-hypertension, pre-dementia (MCI), pre-autoimmune disease. But what has eluded us until now as we move away from the static, anatomically based categorization of disease divided into medical specialties is a dynamic functional model that can weave

ogy, necessarily transitional, can provide a more effective, specific, and accurate way of getting to the roots of illness.

I suggest we put aside the artifact of medical history that is our current ICD model of illness and replace it with a new framework of interpretation of clinical information. It is based on function rather than pathology, on networks of physiology rather than organ systems, on assessment of more subtle changes on the continuum of dysfunction rather than sharp lines marking the onset of "disease." The anatomical assessment of disease becomes less relevant as we assess the burden of functional illness in the 21st century: the functional somatic syndromes (eg, chronic fatigue and immune dysfunction syndrome, fibromyalgia syndrome, premenstrual syndrome, multiple chemical sensitivity syndrome), obesity, diabetes, cardiovascular disease, depression, autism, attention deficit disorder, allergies, asthma, respiratory disease, autoimmune disease, digestive disorders (gastroesophageal reflux disease, irritable bowel syndrome), migraines, back pain, and more.

In assessing a patient today a new roadmap is available, one based on networks of function and causality, on a new architecture of thinking and evaluation. It is a diagnostic medicine focused on patterns and disruptions in molecular pathways

Hyman MA. Functional diagnostics: Redefining disease, *Alt Ther Health Med*, Vol. 14, No. 4, pp. 10-14, Jul/Aug 2008

10 ALTERNATIVE THERAPIES, JUL/AUG 2008, VOL. 14, NO. 4

Functional Diagnostics: Redefining Disease

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- "JP was an 18-year-old man who presented fatigue, depression, anxiety, a 27-pound weight gain, and acne worsening over the 4 years prior to his visit."
- "His symptoms included cold intolerance; early morning fatigue; canker sores; chelosis (cracking at the corners of the mouth); acne on his face, chest, back and shoulders; and seasonal allergies."
- "He also complained of trouble falling asleep, increasing anxiety, and depression worsening during the winter, for which he had been on Paxil for 4 years, when he gained 27 pounds and had increased refined carbohydrate and sugar cravings. Other symptoms included itchy ears and white spots on his nails."

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Results

- “His clinical response included improved energy, depression, and cold intolerance. His acne, canker sores, and chelosis resolved. He lost 15 pounds in the first two months of treatment and eliminated his carbohydrate cravings.”

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Therapies

- “Based on these clinical markers we simply removed impediments to health – gluten, IgG food allergens, and antibiotics – treated yeast overgrowth with fluconazole. We removed processed food, junk food, and refined carbohydrates from his diet.”

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Therapies

- “Then we replaced what he was lacking and needed to thrive: a whole-foods, low-glycemic-load, high-phytonutrient, allergen-free diet, thyroid hormone (Armour thyroid), a multivitamin and mineral, vitamin D, zinc, methylation factors (5-methylfolate, pyridoxine, sublingual B₁₂), mitochondrial support (coenzyme Q₁₀, carnitine, lipoic acid), omega 3 fatty acids, detoxification support (N-acetylcysteine), probiotics, protein kinase modulators from hops to improve insulin sensitivity, as well as whole soy protein and plant sterols to improve lipid metabolism.”

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Diagnostic tests

- Serum 25 OH D
- Essential fatty acid analysis
- Organic acids
- Thyroid panel
- Basic blood chemistry
- Cardiac panel (lipoprotein-a)
- 2-hour glucose/insulin response test
- Celiac panel (antigliadin antibodies, tissue transglutaminase antibodies.
- IgG food allergy testing

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Diagnostic rationale

- “He was nutritionally depleted of vitamin D (seasonal depression and impaired immunity), as well as deficient in omega 3 fats (depression and acne), B₁₂ and B₆ (depression and fatigue), B vitamins (chelosis, B vitamin deficiency markers on organic acids), and zinc, based on his impaired immunity, acne, and the white spots on his nails.”

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Diagnostic rationale

- “His hormones and neurotransmitters were out of balance, causing the history of anxiety and depression. He had low body temperature (95.5 F), elevated thyroid antibodies, and low free T3 (depression, morning fatigue, hyperlipidemia, insulin resistance), he was severely hyperinsulinemic (acne, depression, weight gain, carbohydrate cravings), and he had dyslipidemia with low HDL, high triglycerides, and high LDL (from insulin resistance).”

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Diagnostic rationale

- “His immune imbalances included elevation of IgG antigliadin antibodies (fatigue, depression, hypothyroidism, acne) and IgG antibodies to dairy, wheat, and yeast. His canker sores supported the diagnosis of gluten intolerance.”

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Diagnostic rationale

- “Digestive imbalances were supported by his history of long term antibiotic use and dysbiosis markers on organic acids.”
- “Mitochondrial dysfunction was inferred from his fatigue and confirmed by significant abnormalities of fat, carbohydrate, and Krebs cycle metabolites. Deficiency of sulfate and abnormal glutathione markers indicated impaired detoxification and oxidative stress.”

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Why consider Entry Level Clinical Nutrition?

- Focused on outcome issues that are important to patients
- Focused on cost effectiveness
- Based on the work of critical care nutritionists who have been focusing on outcome and cost issues for years

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Clinical Nutrition

Journal homepage: <http://www.elsevier.com/locate/clinut>

Randomized control trials

Impact of protein pulse feeding on lean mass in malnourished and at-risk hospitalized elderly patients: A randomized controlled trial¹

Olivier Bouillanne^{a,b,*}, Emmanuel Curis^c, Brigitte Hamon-Vilcot^d, Ioannis Nicolis^e, Pascale Chretien^f, Nathalie Schauer^g, Jean-Pierre Vincent^g, Luc Cynober^{h,i}, Christian Ausseil^{c,d}

^aService de Geriatrie 2, AP-HP, Hôpital Saint-Antoine, France
^bService de Geriatrie 4, AP-HP, Hôpital Saint-Antoine, France
^cService de Nutrition, AP-HP, Hôpital Saint-Antoine, France
^dLaboratoire de Biologie de la Nutrition, UMR 4480, Université Paris-Descartes, Faculté de Pharmacie, France
^eLaboratoire de Biomechanique (UMR 4480), Université Paris-Descartes, Faculté de Pharmacie, France
^fService de Nutrition, AP-HP, Hôpital Saint-Antoine, France
^gService de Nutrition, AP-HP, Hôpital Saint-Antoine, France
^hService de Nutrition, AP-HP, Hôpital Saint-Antoine, France
ⁱService de Nutrition, AP-HP, Hôpital Saint-Antoine, France

Bouillanne O et al. Impact of protein pulse feeding on lean mass in malnourished and at-risk hospitalized elderly patients: A randomized controlled trial, *Clin Nutr*, Vol. 32, pp. 186-192, 2013

Abstract

Background: Protein pulse feeding is a nutritional strategy that aims to improve protein intake in malnourished and at-risk hospitalized elderly patients. The aim of this study was to evaluate the impact of protein pulse feeding on lean mass in malnourished and at-risk hospitalized elderly patients.

Methods: Sixty elderly malnourished or at-risk patients in an intensive rehabilitation unit. All were given a controlled diet for 6 weeks. In a pulse diet (PD) group (n = 30), dietary proteins were spread over the four daily meals. In a pulse diet (PD) group (n = 30), 75% of dietary proteins (1.33 g/kg weight on average) was consumed in one meal at noon. The patients were evaluated at admission and at 6 weeks for body composition (lean mass (LM), appendicular skeletal muscle mass (ASMM), and body cell mass (BCM) index, measured by X-ray absorptiometry combined with bioelectrical impedance analysis) (primary outcome), hand grip strength, and activities of daily living (ADL) score.

Results: Protein pulse feeding was significantly more efficacious than protein spread feeding in improving lean mass, ASMM, and BCM index.

Conclusion: Protein pulse feeding is a nutritional strategy that aims to improve protein intake in malnourished and at-risk hospitalized elderly patients. The aim of this study was to evaluate the impact of protein pulse feeding on lean mass in malnourished and at-risk hospitalized elderly patients.

Keywords: Protein pulse feeding, lean mass, appendicular muscle mass, body cell mass

“Aging per se is responsible for gradual loss of skeletal muscle mass (40% from 20 to 80 years of age) and muscle function, termed sarcopenia. Sarcopenia is a major cause of the increased prevalence of disability, falls, morbidity and mortality in elderly people.”

¹ The trial is registered at <http://clinicaltrials.gov> (study ID number NCT00100001).

Conference presentation: 21st congress of the European Society for Clinical Nutrition and Metabolism, August 29 – September 3, 2008, Torino, Italy. (Shawls: ESPEN Best Abstract 2008).

mass (40% from 20 to 80 years of age) and muscle function, termed sarcopenia.¹ Sarcopenia is a major cause of the increased prevalence of disability, falls, morbidity and mortality in elderly people.^{2,3} Malnutrition greatly accelerates sarcopenia in elderly

“This study demonstrates for the first time that protein pulse feeding has a positive, clinically relevant effect on lean mass in malnourished and at-risk hospitalized elderly patients.”

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Thank you!!

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