

# CareManagement

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## INSIDE THIS ISSUE

### CONTINUING EDUCATION ARTICLES:

#### 9 Care Management of UTI Caused by Gram-Negative Bacilli in Women and Children **CE**

by Puja Shahi, PhD

UTIs are the number 1 hospital-acquired infection in the US and can be the cause of ongoing acute problems such as pyelonephritis and cystitis. Case managers should be aware of the current trends in diagnosing and treating women and children with gram-negative bacilli UTIs to prevent further sequelae.

#### 15 Ethical Dilemmas in Case Management



By Elizabeth A. Dailey, MBA, HCM, MSN, RN;  
Mareesa Hopkins, MSN, RN; and  
David A. Zaworski, MSN, RN

Health and wellness cannot simply be defined as the absence of disease and disability. Quality of life is a patient-centric issue that often requires ethical decision making among clinicians and case managers to determine the best actions that will ensure positive outcomes.

#### 20 CE Exam **CE**

Members: Take exam [online](#) or print and mail.

Nonmembers: [Join ACCM to earn CE credits.](#)

### SPECIAL SECTIONS:

#### 22 *PharmaFacts for Case Managers*

Approvals, warnings and the latest information on clinical trials—timely drug information case managers can use.

#### 27 *LitScan for Case Managers*

The latest in medical literature and report abstracts for case managers.

### DEPARTMENTS:

#### 2 From the Editor-in-Chief

Ethics and the Case Managers

#### 3 News from CCMC

Focusing on the Case Management Process

#### 6 News from CARF

Document Management System

#### 8 Legal Update

Private Duty Home Care

#### 34 How to Contact Us

#### 34 ACCM Membership Benefits

#### 35 Membership Application

Join/renew  
ACCM online at  
[academyCCM.org](http://academyCCM.org)  
or use the application  
on page 35



Gary S. Wolfe

# Ethics and the Case Manager

**E**thics is the branch of philosophy that involves systematizing, defending, and recommending concepts of right and wrong conduct. The term ethics derives from the Ancient Greek word ἠθικός ethikos, which is derived from the word ἦθος ethos—habit or custom. As a branch of philosophy, ethics investigates the questions “What is the best way for people to live?” and “What actions are right or wrong in particular circumstances?” In practice, ethics seeks to resolve questions of human morality by defining concepts such as good and evil, right and wrong, virtue and vice, justice and crime.

Medical ethics is a system of moral principles that applies values and judgments to the practice of medicine. The first code of medical ethics was published in the 5th century. In the medieval and early modern periods, the field was indebted to religious teachings. By the 18th and 19th centuries, medical ethics emerged as a more self-conscious discourse. In 1847, the American Medical Association adopted its first code of ethics. While the secularized field borrowed largely from Catholic medical ethics, in the 20th century a distinctively liberal Protestant approach was articulated by thinkers. In the 1960s and 1970s, building upon liberal theory and procedural justice, much of the discourse of medical ethics went through a dramatic shift and largely reconfigured itself into bioethics. Now we are in the 21st century and medical ethics continues to evolve.

Today, the case manager is constantly faced with ethical dilemmas. Ethical dilemmas include access to care, withholding treatment, right to self-determination, informed consent, and the list goes on and on. The case manager is guided by their certification Code of

Conduct and the code of ethics governing the profession in which the individual’s eligibility for certification is based.

A common framework used in the analysis of medical ethics is the recognition of four basic moral principles, which are to be judged and weighed against each other, with attention given to the scope of their application. The four principles are:

- Respect for autonomy—the patient’s right to refuse or choose their treatment (Voluntas aegroti suprema lex.)
- Beneficence—acting in the best interest of the patient (Salus aegroti suprema lex.)
- Non-maleficence—“first, do no harm” (primum non nocere).
- Justice—the distribution of scarce health resources and the decision of who gets what treatment (fairness and equality). (Iustitia.)

Other values that are sometimes discussed include:

- Respect for persons—the patient (and the person treating the patient) have the right to be treated with dignity.
- Truthfulness and honesty—the concept of informed consent has increased in importance since the historical events of the Doctors’ Trial of the Nuremberg trials and Tuskegee syphilis experiment.

These values provide a useful framework for understanding conflicts, but they do not give answers about how to handle any particular situation. Sometimes, no good solution to a dilemma in medical ethics exists, and, on occasion, the values of the various participants also conflict. Sometimes the guiding values also are in conflict. These conflicts present additional challenges for the case manager.

For the case manager to effectively handle ethical dilemmas, they first must understand the Code of Conduct for their

*[continues on page 33](#)*

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# Focusing on the Case Management Process

By **Patrice V. Sminkey, RN, CEO, Commission for Case Manager Certification**

In the most recent role and function study conducted by the Commission for Case Manager Certification (CCMC), survey respondents reported more than 35 different job titles (as well as 30 work settings). Although care/case manager was the most frequently reported job title (nearly 54% of respondents), other titles included care/case coordinator, utilization reviewer, workers' compensation specialist, discharge planner, disease manager, and more. Titles sometimes referred directly to a professional discipline (eg, social worker or mental/behavioral health counselor); others reflected some primary aspect of the professional's responsibilities (eg, transitions of care).<sup>1</sup>

Case management spans professional backgrounds. Although the majority of case managers are nurses, others come from social work, rehabilitation, Workers' Compensation, mental and behavioral health, pharmacy, and more. They work in insurance, hospitals, ambulatory/outpatient, independent practice, government agencies, home care, and other settings.

Given such a range of professional diversity, what brings the practice together? It is the case management process—holistic, addressing the physical, psychosocial, and other needs of

the individual (the “client” receiving case management services). Rooted in advocacy, the case management process allows case managers to pursue goals that are focused on improving the client's clinical, functional, emotional, and psychosocial status. At every phase, the case manager educates and empowers the client and his/her support system or family to evaluate and understand options for care and treatment; determine what will best meet their needs; and take actions in pursuit of goals and to meet their interests and expectations.<sup>2</sup>

No matter how experienced they are or how long they've practiced, case managers should reflect on each of the nine phases of the case management process, to recognize that, no matter where or how one practices, this is the unifying force. Although described here in a linear fashion, the phases of the case management process are iterative, cyclical, and recursive—applied until the needs and interests of the individual are met.

The case management process begins with screening, focusing on the review of key information to identify the need for services. This is followed by assessing, to collect information in greater depth about the person's situation. The next phase is stratifying risk, to determine if the person is low, moderate, or high risk, in order to determine the appropriate level of intervention. The planning phase establishes objectives, short- and long-term goals, and actions. In the implementing or care coordination phase, specific case management activities and interventions are executed. The follow-up phase

focuses on review, evaluation, monitoring, and reassessment, which could result in a minor adjustment or complete change in the plan of care. The transitioning phase supports the client as he/she moves across the health and human services continuum, depending on health condition and need to access care and resource. This is followed by communicating post-transition with the client and/or the support system/family. The last phase is evaluating, to measure results of the case management plan of care, which also involves outcomes reports and findings disseminated to key stakeholders.

Given such emphases as identifying the individual's needs and goals, empowering decision making, coordinating care among multiple providers and facilitating communication among all stakeholders, and evaluating against specific goals and desired outcomes, the case management process enhances the delivery of care and resources across the health and human services spectrum. For this reason, in this era of post-health-care reform, case management is increasingly in the spotlight, particularly for its care coordination component. **CM**

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*Patrice V. Sminkey, RN, is CEO of the Commission for Case Manager Certification, the first and largest nationally accredited organization that certifies case managers. To date, more than 60,000 case managers have been certified, and currently more than 40,000 case managers are board certified as Certified Case Managers.*

# CCMC Shares Highlights of Its Successful First New World Symposium



**T**he Commission for Case Manager Certification (CCMC) celebrated a milestone January 21–23, 2016, in Las Vegas with a successful launch of the first-ever New World Symposium with nearly 600 people representing allied health in attendance.

Conference objectives included:

- **CREATE AWARENESS** of the current and future landscape influencing the patient, family and care provider(s) across the care continuum.
- **EMPOWER THE LEADERSHIP ROLE** of the case manager through education, advocacy and ethical practice.
- **ESTABLISH A FORUM** for discussion related to outcomes through research and evidence based practice.
- **PROVIDE RESOURCES**, knowledge and skill development related to the practice of case management across practice settings.
- **PROMOTE NETWORKING** with colleagues to establish a more integrated community of health care team members related to better care, lower cost

and healthier patient populations.

Sessions were filled with timely topics relevant to today's case management practice. A few speaker highlights were:

Keynote speaker Susan Dentzer "awakened the force" with a stirring presentation that made the case for

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**Excellent well-run conference. Looking forward to 2017!**

”

making “best the new norm” to achieve greater value in health care.

Dr. Kavita Patel drove home the Triple Aim with the session on exploring the cultural, technological, and workforce issues that contribute to optimizing a fully functioning team-based practice.

The conference sessions continued to inspire and entertain with David Rendal, leading author and

motivational speaker, who discussed learning how to improve your own productivity and performance by discovering uniqueness and flaunting weakness as a strength.

Attendees were greeted by a robust and diverse hall of nearly 50 exhibitors and sponsors representing multiple health care services, providers, and companies. Exhibitors and attendees were provided with multiple opportunities to network during receptions, events, and open exhibit hours.

In addition, Day 1 of the conference included pre-conference sessions highlighting the day-to-day practice of case management across practice settings. Topics covered Workers' Compensation, case management trends and awareness, and the wide world of professional case management.

On Day 2, the conference opened up with a Breakfast Symposia regarding the Science of Support Surfaces: Nomenclature, Design for Performance, and Selection. Hill Rom's Director of Case Management and Clinical Services, Tricia Litzinger, RN, BSN,

## Here's what the attendees and exhibitors had to say about CCMC's 2016 New World Symposium:

CCM, CDS, WCC, led the session about how to align the right level of care to improve outcomes while reducing costly complications and resource consumption using the knowledge of the science of surfaces.

Concurrent sessions for Day 2 included topics like motivating the unmotivated client with Dr. Judy Hibbard and client assessment tools and tips with Catherine Mullahy, RN, BS, CRRN, CCM, President, Mullahy & Associates. Day 2 concluded with



an exhilarating session on the topic of leadership for change management with former Under Secretary, Veterans Benefits Administration of Veterans Affairs, Allison Hickey.

On Day 3 of the event, the attendees took a humorous look at the excuses that get in the way of our success by examining the challenges of accountability and the practical approach of dealing with real-world scenarios with Donna Wright, MS, RN, President of Creative Healthcare Management.

The conference closed with

Alexandra Drane, Founder of the Eliza Corporation, who discussed the quality of working and personal relationships and the impact of stress on mind, body, and spirit. Drane shared creative ways to enable and support positive change.

Attendees had the opportunity to earn over 16 CE credits\* towards maintaining their CCM Certification, with the added benefit of earning credits towards licenses and certifications from multiple allied health organizations in nursing, social work,



and other related fields.

The Commission announced the 2017 New World Symposium will take place January 26–28, 2017, at the Gaylord Texan in Grapevine, TX (Dallas, TX). Registration for the 2017 conference will open in Spring 2016. Support opportunities are already available for the event. For more information on the conference, speakers, and presentations, [visit the symposium website](#).

**See You in 2017 in Dallas, TX!**

"The conference was a great experience. I was able to connect personally with many of my colleagues some of whom traveled to the conference from across the nation."

"I was very happy to have attended this inaugural conference and look forward to next year. The speakers were all stellar, the last being just as good as the first. Thank you very much."

"This was a wonderful experience. I left feeling energized and proud of what I do."

"Many new CMs really needed this information and it was a great reminder for the seasoned CMs too."

"I loved the level of intimacy the exhibit area was able to achieve."

"I was able to make a lot of professional contacts and have already gotten some good information from LinkedIn contacts."

"I was very impressed with the conference. I am really looking forward to seeing the videos uploaded so I can view the sessions I missed. "

"Overall I enjoyed the symposium and I especially enjoyed the opportunity to get to know some impressive CCMs! Thanks for putting on this event, I hope to attend others in the future."

"I brought back info to share with my supervisor."

"I loved the exhibits. I learned a lot and made some nice connections."

# Document Management System Allows Employees to Access Policies, Trainings, and Data Anytime, Anywhere

By **Howard M. Goldberg**, *Chief Quality and Compliance Officer, Institute for Community Living, Administrative Surveyor, CARF International*

In New York State, the behavioral health field is governed by a large assortment of laws and regulations to ensure that consumers are being treated in the best possible way and in accordance with government-approved practices. The amount of regulations, including their frequent updates, poses a challenge for organizations to ensure that employees are up-to-date on the latest rules and trainings and have access to the most current version of policies. This becomes especially difficult when a large portion of an organization's employees is rarely in an office and isn't readily able to log on to agency networks.

That was the challenge faced by ICL, a behavioral health agency that has more than 1,000 employees spread across the five boroughs of New York City and as far away as Montgomery County, Pennsylvania. In addition to a large number of remote employees, ICL offers many programs and services that each have their own set of policies that need ongoing review, updating, and cataloging. To address the issue of keeping remotely stationed employees up-to-date on regulations and policies relevant to these service areas, senior policy and compliance staff at ICL began to investigate document management systems.

After sifting through numerous requests for proposals (RFPs) and meeting with a number of different companies offering document management systems, ICL chose the

services of PowerDMS, which offers a system that meets most of ICL's needs. Other systems considered by the ICL team included NAVEX PolicyTech Software and Medworxx. The ICL team was looking for a solution that would enable essential documents to be organized, accessed remotely, and tracked to see who viewed them. ICL's criteria included having a repository where it could put content, including documents, trainings, procedure statements, contracts, and leases. ICL needed the content to be web based so that employees wouldn't have to log on to ICL's network to access it. ICL also wanted to be able to edit the documents online (rather than having to upload revised documents) and gather feedback from employees.

In addition to meeting the requirements listed above, the document management system enables ICL to create workgroups so that specific documents can be shown to select people. These workgroups allow participants to create workflows, edit drafts, and involve key people in the process. The ICL Board of Directors, for example, has its own dedicated section within the system that allows members to remain up-to-date on company activities. The system also offers the ability to create temporary access. This is helpful for CARF surveyors to access documents that ICL is using and sharing with its employees.

By implementing these processes, ICL has seen improvement in efficiency

as employees are able to retrieve policy and training information without having to contact a supervisor or the Department of Quality. ICL is also able to quantitatively measure how many employees access the system, allowing it to better hold them accountable. ICL continues to improve on the documents that it shares with employees, noting recently that hyperlinks can be added so staff can click to find explanations for specific policies. Even YouTube videos can be added into the system. ICL's document management system has become a vital tool that ICL uses to help people get better.

In 2015, ICL received exemplary recognition from CARF for its effective use of the document management system to improve communication, information sharing, and potential outcomes. The exemplary said, in part, that ICL's positive use of the "significantly increases the availability and accessibility of all business data, organizational information, policies, and procedures. This important investment helps to improve access to data for all staff members."

There are numerous off-the-shelf document management systems available for companies of different sizes. In addition to the options considered by ICL, others can be located quickly using an internet search. For further information about ICL's document management system, contact Howard Goldberg at [hgoldberg@iclinc.net](mailto:hgoldberg@iclinc.net) or (212) 385-3037. **CM**

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# What Hospital Discharge Planners Need to Know About Private Duty Home Care

By Elizabeth Hogue, Esq.

**H**ospital discharge planners and case managers need to know more about private duty home care.

In order to be appropriate for home health or hospice services paid for by any payor, including the Medicare Program, patients must either be able to care for themselves or they must have a primary caregiver. Patients' family members or others may be willing to fulfill this role on a voluntary basis. If not, discharge planners/case managers should offer patients and/or their family members the option to pay privately for a primary caregiver who can meet patients' needs in between visits from professional staff from home health agencies and hospices. These types of services may be referred to by post-acute providers as private duty home care services.

The option to pay for private duty home care services should be offered to all patients who cannot care for themselves and who have no voluntary primary caregivers. Patients who can care for themselves or have voluntary primary caregivers may also wish to contract for additional assistance, so discharge planners/case managers should offer this option to all patients who may benefit from these services.

Discharge planners/case managers may be reluctant to offer these services to patients and their families because

of the cost of such services. They may also erroneously conclude that patients and their families cannot afford these services. Discharge planners/case managers should not jump to conclusions about who can afford these services. Instead, private duty home care services

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**Instead, private duty home care services should be offered to every patient and family who may benefit from them.**

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should be offered to every patient and family who may benefit from them. This conclusion is consistent with legal and ethical requirements that govern the practice of case management.

From a legal point of view, discharge planners/case managers who work in hospitals must comply with Conditions of Participation (CoPs) that govern hospitals. Specifically, discharge planners/case managers are required to develop appropriate discharge plans, if necessary, for all patients. According to Interpretative Guidelines for the CoPs, development of appropriate discharge plans undoubtedly includes private duty home care services for patients who may benefit from them.

In addition, the [Case Management Society of America](#) (CMSA has published [national standards of care for case managers](#)). They are likely to apply to all case managers/ discharge

planners, regardless of whether they are certified as case managers, because they are practicing as case managers.

These standards make it clear that case managers have a duty to advocate on behalf of patients. As advocates for patients, discharge planners/case managers have an obligation to make sure that patients understand all of the options available to them, including the option to pay privately for home care services.

Case managers/discharge planners also have an ethical obligation to inform patients about the availability of private duty services. Autonomy is an important ethical principle applicable to the practice of case management/discharge planning. This ethical principle generally requires case managers to provide information to patients so that they can make informed choices.

Patients cannot make choices about the care they wish to receive unless they have information about all services available, including private duty services. Discharge planners/case managers, therefore, have a clear ethical obligation to provide information about private duty home care services to all patients who may benefit from them.

Patients are in the drivers' seat when it comes to decisions about their care, but they cannot make appropriate choices unless they have information about all of the types of care available to them. Consequently, discharge planners/case managers have legal and ethical obligations to make sure that patients have information about private duty home care services. **CM**

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*Elizabeth Hogue, Esquire, is an attorney who represents health care providers. She has published 11 books, hundreds of articles, and has spoken at conferences all over the country.*



# CE I Care Management of UTI Caused by Gram-Negative Bacilli in Women and Children

By Puja Shahi, PhD

*Urinary tract infections (UTI) in the US cause more than 1 million emergency department (ED) visits and 7 million outpatient visits every year. These account for one of the most frequent clinical indications for prescription of antibiotics and 6 billion health care expenditures.*

Urinary tract infections (UTIs) affect almost half the world's population and are more common among women in their reproductive years, children, and hospitalized patients. In fact, the number 1 infection acquired in the hospital setting is UTI (based on Jan 2015 data from the Centers for Disease Control and Prevention [CDC]).

## Causes

Ninety percent of the clinically presented cases of UTI are due to enteric Gram-negative bacilli (GNB). Studies performed over a period of 7 years identified *Escherichia coli* as the number 1 causative agent in these infections, followed by *Enterococcus*, *Klebsiella*, and *Proteus*.<sup>1,2</sup> Urine in normal healthy individual is sterile or free of any microorganism. The presence of bacteria in urine can be caused by either contamination during specimen collection or infection from colonization by microbes. Bacterial colonization, also known as *bacteriuria*, is confirmed by culturing urine sample from patients. A colony-forming unit (CFU) of  $\geq 10^5$ /mL of GNB is considered the standard for defining UTI.<sup>3</sup> Diagnosis is made

on the basis of clinical findings and the pathogen identified via urinalysis. The antibiotic course and specific case management depend on the site of infection, the type and degree of illness, and mostly importantly, the presence of other predisposing factors (which can lead to complicated infections).<sup>4</sup> Patients' outcomes can significantly affect use of health service resources; hence, it is imperative to understand categories of UTI and their care management guidelines.

## Infection Types

### *Asymptomatic Infection*

Asymptomatic bacteriuria (ABU) is characterized by the absence of usual symptoms of UTI (such as fever and frequent painful urination) and is more common in women than men. Studies show no significant improvement of clinical outcomes with use of antibiotics in overall healthy individuals. Thus, antibiotics are recommended only in pregnant women, children aged 5-6 years, and patients scheduled for invasive genitourinary procedures.<sup>5</sup>

### *Symptomatic and Complicated Infection*

Infections in the lower urinary system—urethritis (urethra) and cystitis (bladder)—are uncomplicated, but those associated with upper the urinary system—ureter (ureteritis) and

pyelonephritis (kidneys)—usually need immediate medical attention and are classified as complicated. Urethral or bladder infection cases, when presented clinically with general symptoms like fever and vomiting can often lead to inconclusive or incorrect diagnosis. The delay in proper antibiotic treatment allows bacteria to further multiply and migrate to upper parts of the urinary system, leading to complicated infections.<sup>6</sup> Patients with functional or anatomical abnormalities, where the urine path is not cleared properly, are at significantly higher risk of developing ureteritis and pyelonephritis from an uncomplicated infection.<sup>7</sup>

Appropriate care management can significantly decrease the occurrence of complicated infections in pregnant women, patients with urinary catheterization, and with anatomical obstruction (benign prostatic hypertrophy, abdominal or pelvic masses (cancer), and stones (in bladder, ureters, or kidneys)).

### *Acute or Chronic/Recurrent infection*

Acute infections are classified as one-time infections that can be resolved with antibiotic therapy. Usually, there is no damage to the kidneys, and patients do not develop pyelonephritis again. Chronic infections, on the other hand, are seen in patients with urinary

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birth defects. Anatomical blockages lead to abscess formation and require nephrostomy to drain the abscess. Recurrent UTI (rUTI), defined as two uncomplicated infections in 6 months or three infections within 1 year can occur because of inadequate antibiotic intake, noncompliance with medication regimens, drug resistant microbes, or reinfection by rectal flora.

**Current Trends in Treatment of GNB Infections in Women**

*The selected antibiotic should be effective for common uropathogens but should not expose patient to unwarranted risks.*

Most antibiotics like carbenicillin, ampicillin, trimethoprim/sulfamethoxazole (TMP-SMX), ciprofloxacin, and nitrofurantoin are very effective in clearing infections because they concentrate in the urine (Table 1). Empirical treatment for UTI infection involves treatment with ampicillin and aminoglycosides or a third-generation

cephalosporin to minimize side effects. The treatment is then modified to be case specific; for example, antibacterial treatment should be aggressive in patients who have a risk of developing multidrug-resistant (MDR) infections—those with a history of recent hospitalization, who reside in a nursing home/long-term care facility, with a urological procedure in the past 3 months, receiving hemodialysis, or with an indwelling catheter. Choice of antimicrobial agent also depends on local resistance patterns, patient-specific factors, including anatomical site of infection, severity of disease, pharmacokinetic and pharmacodynamic principles, and cost-effectiveness. European Association of Urology (EAU) 2013 guidelines recommend use of drugs like TMP-SMX (if local resistance is less than 20% for *E coli*), nitrofurantoin, fosfomycin trometamol, or pivmecillinam as first-line therapy. Fluoroquinolones may be used only as alternative therapy

because resistance to these first-line antimicrobial agents has become increasingly common.<sup>8</sup> The presence of extended-spectrum beta-lactamases (ESBLs) and carbapenemases in these pathogens is of great concern because these drugs are often the last line of treatment.

*Identifying patients at high risk for MDR UTIs is important for guiding empirical antimicrobial therapy and care management.*

**UTI in Women**

Cystitis is more common in women than men. Women have shorter urethras than do men; this facilitates easy migration of uropathogens like *E coli* up the urinary tract. Although bacteria like *Staphylococcus saprophyticus*, *Klebsiella species*, *Proteus mirabilis*, and *Enterococcus faecalis* can also cause infections, 80% of these infections are caused by uropathogenic *E coli* (UPEC). Nearly 50% of women develop UTIs during their lifetimes, and incidence increases with age. rUTI can occur even when women are treated with antibiotics—either because of independent inoculation of the urinary tract or establishment of latent bacterial cells. Bacteria can colonize the underlying or superficial bladder epithelial tissue, escaping the toxic effects of drugs (quiescent intracellular reservoirs) and increase the risk of acute uncomplicated/complicated cystitis or pyelonephritis. These infections commonly occur in healthy women with such factors as high blood sugar and pregnancy posing additional risk. Simple cases of UTI may also become complicated if the vaginal introitus is colonized by gastrointestinal (GI) pathogens and in women who use spermicides, have low estrogen levels, have intercourse during infection, or have a genetic predisposing factor.<sup>8</sup> Treatment recommendations are shown in Table 2.

*Acute cystitis/urethritis* cases manifest with symptoms such as urinary

**TABLE 1** COMMONLY USED ANTIBIOTICS FOR GNB AND CONSIDERATIONS IN USE OF THE SAME.<sup>7</sup>

Antibiotic	Active against	Considerations
Nitrofurantoin monohydrate/macrocystals	<i>Klebsiella</i> , <i>Enterobacter</i> , ESBL <i>Escherichia coli</i>	Bacteriostatic at low and bacteriocidal at high concentrations; used in pregnancy; low resistant rates; prophylactic use
Trimethoprim-sulfamethoxazole (TMP/SMX)	<i>Klebsiella</i> , <i>Enterobacter</i> , <i>Proteus</i> , <i>Escherichia coli</i>	First line of treatment; prophylactic; allergic reactions seen and high resistance rates
Fosfomycin trometamol	<i>Klebsiella</i> , <i>Proteus</i> , <i>Escherichia coli</i>	Lower efficacy than some other recommended agents; lower resistance rate
Pivmecillinam	General Gram-negative bacteria	Lower efficacy; lower resistance rate
Carbenicillin	<i>Pseudomonas aeruginosa</i> , <i>Escherichia coli</i> , some <i>Proteus species</i>	Can cause bleeding and hypokalemia, lower toxicity and resistance; higher stability and efficacy than ampicillin
Ciprofloxacin	<i>Pseudomonas aeruginosa</i> , <i>Klebsiella</i> , <i>Escherichia coli</i> , <i>Proteus species</i>	For acute pyelonephritis and nosocomial UTI, an increased risk of tendinitis and tendon rupture, especially in patients >60 years

**TABLE 2** RECOMMENDATIONS FROM INTERNATIONAL CLINICAL PRACTICE GUIDELINES FOR TREATMENT OF UTI IN WOMEN.<sup>4</sup>

Infection	Antibiotic/Dosage
Asymptomatic	No treatment unless pregnant or impending Antibiotic urologic procedure with bleeding anticipated
Acute Cystitis/Urethritis	<ul style="list-style-type: none"> <li>• Nitrofurantoin monohydrate/macrocrystals</li> <li>• 100 mg orally for 5 days</li> <li>• Trimethoprim-sulfamethoxazole (TMP-SMZ) 160/800 mg orally (one double-strength (DS) tablet) for 3 days</li> <li>• Fosfomycin trometamol 3 g single dose</li> <li>• Pivmecillinam 400 mg for 5 days</li> </ul>
Acute Pyelonephritis	An initial 400-mg dose of intravenous ciprofloxacin; oral ciprofloxacin (500 mg twice daily) for 7 days, ciprofloxacin (1000 mg once daily for 7 days), or levofloxacin (750 mg once daily for 5 days)

urgency and frequency, dysuria, lower abdominal discomfort, and cloudy urine. Initial diagnosis is based on past medical history—individual or family health issues, sexual activity, and current symptoms. Infection is confirmed by urinalysis—the causative agent and antimicrobial drug susceptibility are identified. Although the standard definition of GNB requires the load of uropathogens to be  $>10^5$  CFU/mL, recent case studies have shown clinical pathology in women with  $10^3$  CFU/mL. Current clinical practice guidelines recommend use of recommended antimicrobials based on local availability of the drug and cost, the patient's allergy and compliance history, tolerance levels, and local resistance rates. Fluoroquinolones (ciprofloxacin, ofloxacin) are highly efficacious in 3-day regimens but can have adverse side effects in some cases; hence, they are used only as alternative therapy. Nitrofurantoin, TMP-SMX, fosfomycin, and pivmecillinam are recommended because beta-lactams like amoxicillin or ampicillin have inferior efficacy and cause more adverse effects.

**Acute pyelonephritis** may start symptoms similar to those of lower UTI infections but progress into more severe symptoms like back pain, flank

pain, fever accompanied by chills, feelings of malaise, nausea and vomiting in certain cases, and confusion (especially in elderly women). Frequency of urination increases. Urine is cloudy and foul smelling, with or without hematuria. Diagnosis by blood testing for bacterial growth and ultrasound can help identify factors underlying disease progression such as abscesses, stones, and blockages. If the patient is able to get around and can consistently take oral antibiotics (is not confined to bed or regularly vomiting), oral ciprofloxacin (500 mg twice daily) for 7 days, with or without an initial 400-mg dose of intravenous ciprofloxacin or once-daily oral fluoroquinolone, including ciprofloxacin (1000 mg for 7 days) or levofloxacin (750 mg for 5 days), is the choice of therapy. If the uropathogen is susceptible to TMP-SMX, an oral dose of 60/800 mg of this antibiotic twice daily for 14 days is recommended. Beta-lactams are less effective in treating pyelonephritis. In all these cases, if the community resistance exceeds 10% for fluoroquinolone or if pathogen's susceptibility is unknown, 1 g of ceftriaxone or a consolidated 24-hour dose of an aminoglycoside is recommended.

Hospitalization is required to treat more severe pyelonephritis and

in some cases when local resistance is not known because pyelonephritis can lead to systemic infections. Empirical therapy in these patients should include intravenous long-acting parenteral antibiotics. Delivering antibiotics intravenously in the hospital ensures that the medicine is reaching the kidneys. The therapy starts with the use of a broader-spectrum agent such as a fluoroquinolone; an aminoglycoside, with or without ampicillin; an extended-spectrum cephalosporin/penicillin, with or without an aminoglycoside; or a carbapenem. Later, when laboratory results are available, therapy can be narrowed down to a pathogen-specific antimicrobial agent.<sup>9</sup>

### UTI in Pregnancy

The incidence of bacteriuria (ABU, symptomatic cystitis, or pyelonephritis) in pregnant women is slightly higher than among nonpregnant counterparts, and the consequences for both mother and baby in former case are more severe. During pregnancy, increased progesterone levels reduce smooth muscle tone, resulting in slow peristalsis and urethral relaxation causing hydro-nephroses. The pressure of the growing uterus on the bladder can also lead to vesicourethral reflux and an increase in urine pH (due to higher glucose, amino acid, and hormone levels). Diagnosis is more restrictive in this category because the potential risks concern both expectant mother and unborn child. The same applies to the use of antibiotics—nearly all antimicrobial drugs can cross the placenta, and some of them may trigger teratogenic effects. The most common UTI treatments during pregnancy are antibiotics such as penicillin or cephalosporins such as cephalexin.<sup>10</sup>

**ABU.** Studies of pregnant women with ABU have shown a high risk for acute pyelonephritis later in pregnancy or for preterm birth. Therefore, routine

**TABLE 3** TREATMENT OPTIONS FOR VARIOUS UTI INFECTIONS IN PREGNANT WOMEN

Infection	Antibiotic/Dosage
Asymptomatic bacteriuria (ABU)	<ul style="list-style-type: none"> <li>• Amoxicillin 500 mg twice a day for 3-7 days</li> <li>• Cephalexin 500 mg twice a day for 3-7 days</li> </ul>
Acute cystitis/urthritis	<ul style="list-style-type: none"> <li>• Amoxicillin 500 mg twice a day for 7 days</li> <li>• Cephalexin 500 mg twice a day for 7 days</li> </ul>
Mild or moderate acute pyelonephritis	<ul style="list-style-type: none"> <li>• Ceftriaxone 1 g once a day</li> <li>• Cefepime 1 g once a day to twice daily</li> <li>• Aztreonam 1 g twice daily</li> </ul>
Severe acute pyelonephritis	<ul style="list-style-type: none"> <li>• Ticarcillin with clavulanic acid 3.1 g 4 times a day</li> <li>• Piperacillin with tazobactam 3.375 g 4 times a day</li> <li>• Meropenem 0.5 g 3 times a day</li> <li>• Ertapenem 1 g once a day</li> <li>• Doripenem 1 g 3 times a day</li> </ul>

screening for bacteriuria is done by urine analysis. According to the Infectious Disease Society of America (IDSA),<sup>9</sup> two consecutive voided urine samples with bacterial monoculture of  $\geq 10^5$  CFU/mL or a single catheterized urine sample with  $\geq 10^2$  CFU/mL is defined as bacteriuria. Repeated tests are recommended in women at high risk—those with diabetes, sickle cell anemia, immunological defects, urinary tract abnormalities, or history of recurring UTIs before pregnancy. Studies also suggest that women with no bacteria in the first trimester may still develop infection in the second or third trimester; hence, screening at each trimester is suggested. Since antibiotic resistance is rapidly evolving, treatment for infection should be based on microbial sensitivity testing.<sup>11</sup>

**Cystitis/urethritis.** Urinalysis showing cloudy appearance with  $10^2$ - $10^3$  CFU/mL is a diagnostic feature of this infection. Some other symptoms are dysuria, an increase in frequency and urgency of urination, and abdominal and suprapubic pain. Although treatment in this case is of longer duration, the principle is the same as with treatment of ABU: testing microbial susceptibility before

antibiotic prescription. Follow-up urine cultures at 1–2 weeks and then once a month are recommended. In patients with recurrent acute cystitis, prophylactic treatment is given to suppress microbial growth.<sup>12</sup>

**Acute pyelonephritis** is seen in second or third trimester pregnant women, occurring as a result of undiagnosed or improperly treated ABU. Old age and nephrolithiasis, as well as the other aforementioned risk factors, can increase the incidence of pyelonephritis. Symptoms include positive urine culture, fever  $>38^\circ\text{C}$ , lumbar pain, skeletal and joint pain, nausea and vomiting with or without dysuria, polyuria, and  $10^5$  CFU/mL of monobacterial population. Twenty percent of these women end up having septicemia—hence, parenteral antibiotics are recommended for the first 48 hours in all cases. The 2005 IDSA guidelines recommend hospitalization for at least 48 hours in all suspected cases of pyelonephritis with hydration, urine and blood cultures, ultrasound, and basic laboratory analysis.<sup>13</sup> Table 3 summarizes treatment options for various types of UTI in pregnant women.

## UTI in Children

UTI is more common in boys younger than 1 year, but after the first year more infections are seen in girls.<sup>14</sup> Most of these cases are asymptomatic but can result in severe illness like growth failure, severe GI manifestations, fever, irritability, lethargy, abnormal urination (oliguria, polyuria, malodorous urine), and jaundice. It is associated with high morbidity and mortality rates in newborns.

Several studies have shown a direct relation between untreated UTI in pregnant women and neonatal UTI,<sup>15</sup> which is the most common bacterial infection in children younger than 2 years. Diagnosis is important because of life-threatening sepsis in the newborn and potential risks of renal scarring in infants/school-aged children. Febrile UTI is the most common infection after throat and ear infection in preschool and school-aged children.

Developing guidelines of care management for UTI in children has been a challenging. First, there are not enough studies to support the toxicity or adverse effects of drugs (ethical issue). Second, diagnosis and treatment may be delayed as clinical presentation in infants is usually nonspecific. Third, reliable urine specimens for culture cannot be obtained without invasive methods (urethral catheterization or suprapubic aspiration [SPA]). Finally, children and adolescents with pyelonephritis double their risk of renal scarring when suffering from predisposing conditions like vesicoureteral reflux.<sup>16,17</sup>

**Case management of pediatric patients.** Studies have shown oral antibiotics to be as effective as IV antibiotics in most cases of simple pediatric cystitis. Hospitalization is required in critical cases such as patients with signs of renal obstruction, patients who are unable to tolerate oral fluids and medications, or when oxygen is required.<sup>18</sup> Care in hospital settings is also absolute for children or infants with sepsis, infants younger than 2



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TABLE 4

TREATMENT OPTIONS FOR VARIOUS UTI INFECTIONS IN CHILDREN AND INFANTS

Infection	Antibiotic/Dosage
Less than 2 months OR Any age but toxic/ unwell/unable to tolerate orally	<ul style="list-style-type: none"> <li>• Cefotaxime 150 mg/kg/day IV/IM divided every 6-8 h</li> <li>• Ceftriaxone 75 mg/kg/day IV/IM as a single dose or divided every 12 h (ceftriaxone should not be used in infants younger than 6week) or</li> <li>• Ampicillin 100 mg/kg/day IV/IM divided every 8 h plus gentamicin 3.5-5 mg/kg/dose IV every 24 h if patient younger than 7 days; otherwise gentamicin 5-7.5 mg/kg/dose IV every 24 h</li> <li>• Transition to oral antibiotic active after 24-48 h for total of 14-day course</li> </ul>
Less than 2 months with upper UTI/ pyelonephritis	<ul style="list-style-type: none"> <li>• Cephalosporin, trimethoprim (or co-trimoxazole) or co-amoxicillin-clavulanate oral for 10 days</li> </ul>
2 mo-2 y with cystitis	<ul style="list-style-type: none"> <li>• Nitrofurantoin 5-7 mg/kg by mouth divided every 6 h for 3-10 days (Should not be used in children with symptoms consistent with pyelonephritis as it is poorly concentrated in the bloodstream and has poor tissue penetration) or</li> <li>• TMP-SMZ 6-12 mg/kg/day by mouth divided every 12 h</li> </ul>
2 mo-2 y with pyelonephritis	<ul style="list-style-type: none"> <li>• Initial therapy with IV antibiotics for 3-4 days followed by oral therapy to complete a 10-14 day course is equivalent to 10-14 days of IV therapy</li> <li>• Initial oral therapy with cefixime or amoxicillin-clavulanate is equivalent to IV ceftriaxone for 3 days followed by oral therapy</li> <li>• IV gentamicin may be dosed daily, rather than 3 times a day, for children who require IV treatment or who are infected with multiresistant organisms</li> </ul>

months with presumed pyelonephritis, and for all patients older than 1 month. Short-course (3-day or 5-day) oral antibiotic therapy has been shown to be as effective as 10-day or 14-day courses for nonfebrile UTIs. For febrile UTIs, the minimum treatment duration should be 7 days and may extend to 10-14 days. Empiric antibiotics should be chosen for coverage of the most common uropathogens, namely *E coli* and *Enterococcus*, *Proteus*, and *Klebsiella* species. The possibility of antibiotic resistance must be considered when choosing empiric therapy, especially with ampicillin. Knowledge of the local antibiotic resistance helps in guiding antibiotic choice. Common choices for empiric oral treatment are either

second- or third-generation cephalosporin or amoxicillin/clavulanate, or TMP-SMZ. Amoxicillin has high resistance rates; therefore, in cases of pediatric pyelonephritis, initial treatment should include a cephalosporin, amoxicillin-clavulanic acid, TMP-SMZ, or an aminoglycoside.

There is rise in antibiotic resistance to commonly used agents such as fluoroquinolones and TMP-SMZ. In addition, there are known safety concerns with certain drugs like ciprofloxacin, a fluoroquinolone that is reported to cause arthropathy in weight-bearing joints in juvenile animals. Penicillin, cephalosporins, and sulfonamides are known to cause hypersensitivity reactions. Hence, the IDSA and European

Society of Microbiology and Infectious Disease suggest use of nitrofurantoin as the first agent. Comparable cure rates and a low rate of bacterial resistance have made nitrofurantoin a drug of choice especially in children. It has high efficacy for treating uncomplicated lower UTIs but has poor tissue penetration and low circulating levels; hence, it is not a drug of choice for treating upper UTIs, pyelonephritis, prostatitis, and intraabdominal abscess. It is an oral antibiotic taken with food (to improve bioavailability) and is also a drug of choice during pregnancy. Table 4 shows treatment options for UTI in children and infants.

Conclusion

According to the American Urological Association, 40% of nosocomial infections are UTIs. In 2008, the National Healthcare Safety Network found 13% of *E coli* and *Klebsiella*, 17% of *P aeruginosa*, and 74% of *Acinetobacter baumannii* from ICUs to be multidrug resistant. This is because of the ability of these bacteria to synthesize extended-spectrum beta-lactamases (ESBLs). Care management plays a major role in controlling the increasing morbidity and recurrence rates in UTI. In general, the treatment consists of hydration, and in cases with urinary tract obstruction, removal of the foreign body or catheter if feasible, and judicious use of antibiotics. Because most antibiotics are excreted in urine, their concentration is high enough to clear UTIs. However, with complicated infections such as pyelonephritis, tissue concentration of the drug should be taken into consideration. **CE I**

*This article was written based on the information from referenced articles only and no independent research or study was conducted for this publication.*

*Continues on page 32*



Approved for 2 hours ethics credit

CE II

# Ethical Dilemmas in Case Management

By Elizabeth A. Dailey, MBA, HCM, MSN, RN; Mareesa Hopkins, MSN, RN; David A. Zaworski, MSN, RN

## Introduction

Health and wellness cannot simply be defined as the absence of disease or disability. Patients anticipate a good quality of life as well as living a healthy life. With global concerns focusing on lifespan longevity, an increase in the number of patients with chronic conditions, and the availability and access to a variety of health care information sources, the need for ethical, quality health care is essential. Ethical issues occur with increasing frequency in the health care field and require consideration of many factors in determining the best actions to take to ensure positive outcomes.

Case managers are in a unique position to effect change and promote positive patient outcomes when ethical dilemmas are identified in the workplace. The increasingly complex role of the case manager in health care settings requires a thorough understanding of the process that involves collaboration in the coordination of care from needs assessment through an evaluation of the care provided. This article considers the background of ethical decision making in case management,

a look into the ethical dilemmas that surround case managers in today's society, and an analysis of the tools available to assist in identifying, clarifying, and resolving ethical issues that arise.

Case management has emerged over the last 30 years as a pivotal position that fosters the careful steering of health care funds while maintaining a consistent and primary focus on quality care and patient advocacy.<sup>1</sup> The function of case managers is reflected in their numerous roles, including that of coordinator, developer, implementer, monitor, and evaluator. Case managers are pivotal members of the interdisciplinary team and work tirelessly to ensure that the unique needs of the patient and family are met while employing significantly limited resources.<sup>2</sup>

The National Association of Social Workers (NASW) and the American Nurses Association (ANA) give rise to specific codes of ethical conduct reflective of the scope of practice and professional expectations of the nurse and social worker role. Similarly, the purpose of The Code of Professional Conduct for Case Managers<sup>3</sup> is to provide case managers with a framework for practice. Case managers are expected to adhere to the principles outlined in the code to provide safe, quality care. Because of the number of hats a case manager must wear, case managers are held to

The Code of Professional Conduct for Case Managers as well as the code specific to their discipline, including that of the Certification of Disability Management Specialists (CDMS; see Box 1 for the codes of several organizations).

According to Corvol and colleagues,<sup>4</sup> the four principles that provide the framework for ethical decision-making within the case manager role include beneficence (possessing a desire to do good), nonmaleficence (avoiding harm), justice (equal and fair treatment), and autonomy (respecting self-determination). The use of these principles in practice comes from a patient, or person-centered philosophy. Case managers begin to demonstrate a patient-centered viewpoint by communicating therapeutically with patients and their families in order to determine what matters most to them. The patient-centered philosophy promotes the reduction of barriers which may prevent patient from accessing services and receiving quality care.<sup>5</sup>

## Examples/Types

Ethical dilemmas can occur in a variety of settings, take on many forms, and may present significant challenges to the case manager. According to Corvol and colleagues,<sup>4</sup> ethical situations are most often one of three types: refusal of care, decisions related to the sharing

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**BOX 1**

**CODES OF ETHICS**

<b>CDMS</b>	<p>The fundamental spirit of caring and respect with which the Code is written is based upon five principles of ethical behavior. These include autonomy, beneficence, nonmaleficence, justice, and fidelity, as defined below:</p> <ul style="list-style-type: none"> <li>• <b>Autonomy:</b> To honor the right to make individual decisions.</li> <li>• <b>Beneficence:</b> To do good to others.  <b>Nonmaleficence:</b> To do no harm to others.</li> <li>• <b>Justice:</b> To act or treat justly or fairly.</li> <li>• <b>Fidelity:</b> To adhere to fact or detail.</li> </ul> <p>See the entire <a href="#">CDMS Code of Professional Conduct</a></p>
<b>NASW</b>	<p>The mission of the social work profession is rooted in a set of core values. These core values, embraced by social workers throughout the profession’s history, are the foundation of social work’s unique purpose and perspective:</p> <ul style="list-style-type: none"> <li>• Service</li> <li>• Social justice</li> <li>• Dignity and worth of the person</li> <li>• Importance of human relationships</li> <li>• Integrity</li> <li>• Competence</li> </ul> <p>See the entire <a href="#">NASW Code of Ethics</a></p>
<b>CCMC</b>	<p>Principles</p> <ul style="list-style-type: none"> <li>• Board-Certified Case Managers (CCMs) will place the public interest above their own at all times.</li> <li>• Board-Certified Case Managers (CCMs) will respect the rights and inherent dignity of all of their clients.</li> <li>• Board-Certified Case Managers (CCMs) will always maintain objectivity in their relationships with clients.</li> <li>• Board-Certified Case Managers (CCMs) will act with integrity and fidelity with clients and others.</li> <li>• Board-Certified Case Managers (CCMs) will maintain their competency at a level that ensures their clients will receive the highest quality of service.</li> <li>• Board-Certified Case Managers (CCMs) will honor the integrity of the CCM designation and adhere to the requirements for its use.</li> <li>• Board-Certified Case Managers (CCMs) will obey all laws and regulations.</li> <li>• Board-Certified Case Managers (CCMs) will help maintain the integrity of the Code, by responding to requests for public comments to review and revise the code, thus helping ensure its consistency with current practice.</li> <li>• Because case management exists in an environment that may look to it to solve or resolve various problems in the health care delivery and payor systems, case managers may often confront ethical dilemmas. Case managers must abide by the Code as well as by the professional code of ethics for their specific professional discipline for guidance and support in the resolution of these conflicts.</li> </ul> <p>See the entire <a href="#">CCMC Code of Professional Conduct</a></p>

and accumulating personal health information, and the function of the case manager as it relates to the distribution of resources.

Case managers caring for a patient who is refusing care, assistance, or help of any kind are attempting to create a balance between the ethical principles of autonomy and beneficence. Case managers have a fundamental duty to establish trust with their patients and advocate for their needs while also respecting their choices and decisions. The dilemma arises when an individual has been identified as needing help and is refusing this assistance. An example of this type of dilemma includes the patient with a worrisome health condition and persistent symptoms who refuses to be hospitalized.<sup>4</sup> Case managers who encounter these types of ethical situations must be prepared to provide substantial education and support to their patients, including in-depth discussion regarding the risks and benefits associated with each of their options.

While defending the patient’s decision is most often the appropriate choice, case managers must be prepared to intervene with the patient who is cognitively impaired to the point that the ability to make responsible judgements is compromised. Special consideration should be given to vulnerable populations including children, ethnic minorities, the elderly, and the uninsured. When confronted with acute situations where there is a concern for the preservation of life the case managers must act according to established ethical guidelines to help in preserving life while at the same time addressing the wishes of the patient and family if appropriate.

Case managers utilize a number of complex assessment instruments in order to collect information related





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## Health care workers endeavor to provide the best possible solutions for ethical dilemmas that occur in health care while prioritizing patients' interests and goals.

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to their patients. Many tools lead practitioners to ask questions of a financial, sexual, or religious manner in order to connect them with the resources most appropriate for their specific situation.<sup>4</sup> While collaborating with the interdisciplinary team and organizing the care of the patient, consideration should be given to the ethical principles of beneficence and non-maleficence. Working to help our patients and families experience the best possible outcomes while preventing from causing them any harm through our actions or omissions.

Case managers should work hard to ensure that each patient's information is protected and only shared with other health care providers who are directly involved in the care of that patient. Case managers are ethically accountable to each of their patients and must strive to respect each patient's privacy when sharing or collecting personal information. With the advent of electronic medical records (EMR) there is potential risk for dissemination of unintended information. The emphasis on confidentiality may overshadow the concerns for the availability and integrity of the information.

Case managers are frequently employed by organizations in which there are various regulatory and financial limitations related to the availability of resources.<sup>2</sup> Additionally, the resources that are accessible vary based on the financial constraints of each patient as well as the policies and procedures in place which direct how much care can be provided, how often, in which setting, and by what

professional. As case managers strive to provide quality care that is fair for all persons, the ethical principles of justice and beneficence should be considered.

### Methods/Tools

Health care workers endeavor to provide the best possible solutions for ethical dilemmas that occur in health care while prioritizing patients' interests and goals. It can be a challenge for providers to manage ethical decisions due to the unique needs of each patient. Consequently, the value of ethical decision-making should be appraised not only in terms of its outcome but also the process used to arrive at the decision.<sup>6</sup>

There are a number of decision-making tools that strive to simplify the process of making ethical decisions and work to clarify the source of moral perplexity. Moffat<sup>7</sup> describes the need for introspection regarding personal values and perceptions that can influence the ethical decision making process. Decision-making models help identify gaps in understanding and facilitate interdisciplinary communication with a patient-centered approach. Models that are consistently applied to ethical situations can assist in the application and analysis throughout the decision making process. Thompson and coauthors<sup>8</sup> developed the DECIDE Decision-Making Model. The acronym stands for define the problem, establish the criteria, consider the alternatives, identify the best alternative, develop and implement a plan of action, and evaluate the solution/outcome. Use

of this model will help case managers when making ethical decisions through the logical progression of the model.

### Implementation

Ethical decision making depends on the application of knowledge that is consistent and evidence based. Case managers come from diverse backgrounds in their professional training and previous work experience. This variation in educational background and experience requires a focus on workplace training that applies to the identification of ethical dilemmas, use of a framework or model to identify the values and principles involved, and the reasoning or justification for the decision.<sup>9</sup> The organizational mission, vision, and policies can also influence a case manager's ethical decision-making process and need to be considered as a part of any training program. Leadership and managers have the responsibility to develop and implement training regarding ethical decision making and be prepared to serve as an exemplar in practice.

Training protocols should address the basic tenets of ethical care including the care of the individual in a vulnerable condition, respect for individual autonomy, maintaining competency in practice, adherence to all laws, and consistency in the provision of care.<sup>1</sup> Organizational leaders should feel comfortable acting as role-models, coaches, and as a resource to case managers who struggle with ethical decisions in their practice.

An important initial step in managing an ethical dilemma is to identify the specific issue, as well as the level of the problem. Is this issue impactful only to the patient? Will the decision made reach an entire group or population? Case managers must be prepared to identify the ethical principles involved as well as how the dilemma originated. During this initial phase, case managers can address any information gaps that may be present. Case managers have a duty to ensure that the patient and family have all of the information necessary to make an informed and ethical decision. Case managers play a pivotal role in collaboration with the patient, family, and entire interdisciplinary team in determining the prevalent values and decisions.

Following the initial identification and assessment of the situation, case managers should formulate a possible course of action as well as a determination of the benefits and risks associated with each potential option. It is important to emphasize that case managers must avoid taking personal responsibility for system or organizational deficiencies and limitations. Each patient situation is very different and each outcome may vary greatly depending on multiple factors and decisions that are made throughout that patient's care.<sup>2</sup> A pertinent plan should be created in association with the patient, keeping in mind their unique perspective, values, and goals.

Once a specific course of action is selected and subsequently implemented, it is essential that case managers spend time reflecting upon the decisions that were made and reconcile those decisions with their own personal beliefs. Case managers are unable to make professional decisions based upon personal principles therefore increasing the

likelihood of personal anguish, burnout and moral distress. Moral distress can be described as a human reaction to ethical conflicts and limitations and can impact a case manager's ability to effectively perform essential job functions.<sup>7</sup>

Behavioral signs of moral distress and burnout may include low self-esteem, isolation, blaming, indifference, skepticism, and depression.<sup>7</sup> To mitigate the effects of moral distress, case managers should seek professional mentors, establish clear boundaries, and maintain appropriate self-care measures, including hygiene, diet, and exercise. Case managers who are unable to properly care for themselves are at risk for providing ineffective care to the vulnerable patients under their care.

### Conclusion

The evolving influence of technology, health care reform, and evidence-based practice make the role of the case manager essential to the interprofessional team. The functions of the case manager are vast, from that of change agent, to patient advocate and coordinator of services. It is important for the case manager to have an understanding of basic ethical principles and how these principles can be applied to their practice. The case manager must be prepared to identify ethical dilemmas, information gaps that may exist, and provide education and support to patients and their families in order to formulate an appropriate plan of care. The use of an established model such as the DECIDE model can provide the case manager with focus and direction in resolving ethical dilemmas in the workplace while limiting personal bias and opinion. **CE II**

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## exam I

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### Case Management of Gram-Negative Bacilli-Caused UTI in Women and Children

1. UTIs account for how much in health care expenditures?
  - a. \$2 billion
  - b. \$4 billion
  - c. \$6 billion
  - d. \$8 billion
2. What is the number one causative agent in UTIs?
  - a. *Klebsiella*
  - b. *E. coli*
  - c. *Proteus*
  - d. None of the above
3. Diagnosis of UTI based on clinical findings and the pathogen identified via urinalysis.
  - a. True
  - b. False
4. The antibiotic course and specific case management depends on the:
  - a. Site of infection
  - b. Type and degree of illness
  - c. Presence of other predisposing factors
  - d. All of the above
5. Appropriate case management can significantly decrease the occurrence of complicated infections in pregnant women, patients with urinary catheterizations, and/or women with anatomical obstructions, abdominal or pelvic mass, and stones.
  - a. True
  - b. False
6. The selected antibiotic should be effective for common uropathogens but should not expose patients to unwarranted risks.
  - a. True
  - b. False
7. What percentage of women develop a UTI during their lifetime?
  - a. 30%
  - b. 40%
  - c. 50%
  - d. 60%
8. An initial 500-mg dose of intravenous ciprofloxacin is recommended for treatment of acute pyelonephritis in women.
  - a. True
  - b. False
9. UTI is more common in boys younger than 1 year, but after the first year more infections are seen in girls.
  - a. True
  - b. False
10. According to the American Urological Association, what percentage of nosocomial infections are UTIs?
  - a. 20%
  - b. 30%
  - c. 35%
  - d. 40%

## exam II

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### Ethical Dilemmas in Case Management

1. What are the major concerns causing health care providers to focus on ethical issues?
  - a. Lifespan longevity
  - b. Increasing number of patients with chronic conditions
  - c. Availability and access to a variety of health care information sources
  - d. All of the above
2. The specific Codes of Ethical Conduct developed by professional associations and certifying bodies are meant to provide a framework for practice.
  - a. True
  - b. False
3. The framework for ethical decision making includes:
  - a. Beneficence
  - b. Non-maleficence
  - c. Justice
  - d. Autonomy
  - e. All of the above
4. What are the most common types of ethical situations?
  - a. Refusal of care
  - b. Decision related to sharing and accumulating personal health information
  - c. Function of the case manager as it relates to the distribution of resources
  - d. All of the above
5. Case managers who encounter ethical situations must be prepared to provide substantial education and support to their patient.
  - a. True
  - b. False
6. Special consideration need not be given to vulnerable populations when applying the tenets of ethical decision making.
  - a. True
  - b. False
7. When connecting patients with resources, the case manager may have to ask questions about:
  - a. Financial matters
  - b. Sexual beliefs
  - c. Religion
  - d. All of the above
8. Decision-making models help identify gaps in understanding and facilitate interdisciplinary communication with a patient-centered approach.
  - a. True
  - b. False
9. Ethical decision making depends on the application of knowledge that is consistent and evidenced based.
  - a. True
  - b. False
10. Case managers must recognize signs of moral distress in themselves when reconciling ethical dilemmas with their own beliefs. Signs of moral distress include:
  - a. Low self-esteem
  - b. Isolation
  - c. Blaming
  - d. All of the above

**exam I Case Management of Gram-Negative Bacilli–Caused UTI in Women and Children**

**Objectives:**

1. State the symptoms of UTI. \_\_\_\_\_
2. Describe current trends in treatment of gram-negative bacilli infections in women. \_\_\_\_\_
3. State three treatment options in the treatment of UTI. \_\_\_\_\_

Please indicate your answer to the exam questions on page 14 by filling in the letter:

1. \_\_\_\_\_ 2. \_\_\_\_\_ 3. \_\_\_\_\_ 4. \_\_\_\_\_ 5. \_\_\_\_\_ 6. \_\_\_\_\_ 7. \_\_\_\_\_ 8. \_\_\_\_\_ 9. \_\_\_\_\_ 10. \_\_\_\_\_

**exam II Ethical Dilemmas in Case Management**

**Objectives:**

1. State the four principles that provide the framework for ethical decision making. \_\_\_\_\_
2. Review two examples of ethical dilemmas in case management. \_\_\_\_\_
3. Describe three decision-making tools in resolving ethical dilemmas. \_\_\_\_\_

Please indicate your answer to the exam questions on page 14 by filling in the letter:

1. \_\_\_\_\_ 2. \_\_\_\_\_ 3. \_\_\_\_\_ 4. \_\_\_\_\_ 5. \_\_\_\_\_ 6. \_\_\_\_\_ 7. \_\_\_\_\_ 8. \_\_\_\_\_ 9. \_\_\_\_\_ 10. \_\_\_\_\_

**Continuing Education Program Evaluation** Please indicate your rating by circling the appropriate number using a scale of 1 (low) to 5 (high).

	exam I					exam II				
1. The objectives were met.	1	2	3	4	5	1	2	3	4	5
2. The article was clear and well organized.	1	2	3	4	5	1	2	3	4	5
3. The topic was both relevant and interesting to me.	1	2	3	4	5	1	2	3	4	5
4. The amount and depth of the material was adequate.	1	2	3	4	5	1	2	3	4	5
5. The quality and amount of the graphics were effective.	1	2	3	4	5	1	2	3	4	5
6. I would recommend this article.	1	2	3	4	5	1	2	3	4	5
7. This has been an effective way to present continuing education.	1	2	3	4	5	1	2	3	4	5
8. Additional comments:										

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# PharmaFacts for Case Managers



## New Approvals

### Zepatier™ (elbasvir and grazoprevir) tablets

#### Indications and Usage

Zepatier is a fixed-dose combination product containing elbasvir, a hepatitis C virus (HCV) NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor, and is indicated with or without ribavirin for treatment of chronic HCV genotypes 1 or 4 infection in adults.

#### Dosage and Administration

Testing prior to initiation:

- Genotype 1a: Testing for the presence of virus with NS5A resistance-associated polymorphisms is recommended.
- Obtain hepatic laboratory testing.
- Recommended dosage: One tablet taken orally once daily with or without food.

**TABLE 1**

**Dosage Regimens and Durations for Zepatier in Patients with Genotype 1 or 4 HCV with or without Cirrhosis**

Patient Population	Treatment	Duration
Genotype 1a: Treatment-naïve or PegIFN/RBV-experienced* without baseline NS5A polymorphisms†	Zepatier	12 weeks
Genotype 1a: Treatment-naïve or PegIFN/RBV-experienced* with baseline NS5A polymorphisms†	Zepatier + ribavirin	16 weeks
Genotype 1b: Treatment-naïve or PegIFN/RBV-experienced*	Zepatier	12 weeks
Genotype 1a or 1b: PegIFN/RBV/PI-experienced‡	Zepatier + ribavirin	12 weeks
Genotype 4: Treatment-naïve	Zepatier	12 weeks
Genotype 4: PegIFN/RBV-experienced*	Zepatier + ribavirin	16 weeks

\*Peginterferon alfa + ribavirin.

†Polymorphisms at amino acid positions 28, 30, 31, or 93.

‡Peginterferon alfa + ribavirin + HCV NS3/4A protease inhibitor.

- HCV/HIV-1 co-infection: Follow the dosage recommendations in Table 1.
- Renal Impairment, including hemodialysis: No dosage adjustment of Zepatier is recommended. Refer to ribavirin prescribing information for ribavirin dosing and dosage modifications.

#### Contraindications

- Zepatier is contraindicated in patients with moderate or severe hepatic impairment (Child-Pugh B or C) due to the expected significantly increased grazoprevir plasma concentration and the increased risk of alanine aminotransferase (ALT) elevations.
- Zepatier is contraindicated with organic anion transporting polypeptides 1B1/3 (OATP1B1/3) inhibitors, strong inducers of cytochrome P450 3A (CYP3A), and efavirenz.
- If Zepatier is administered with ribavirin, the contraindications to ribavirin also apply to this combination regimen. Refer to the ribavirin prescribing information for a list of contraindications for ribavirin.

#### Warnings and Precautions

- ALT elevations: Perform hepatic laboratory testing prior to therapy, at treatment week 8, and as clinically indicated. For patients receiving 16 weeks of therapy, perform additional hepatic laboratory testing at treatment week 12. For ALT elevations on Zepatier, follow recommendations in full prescribing information.
- Risk associated with ribavirin combination treatment: If Zepatier is administered with ribavirin, the warnings and precautions for ribavirin also apply.

#### Adverse Reactions

In subjects receiving Zepatier for 12 weeks, the most commonly reported adverse reactions of all intensity (greater than or equal to 5% in placebo-controlled trials) were fatigue, headache, and nausea. In subjects receiving Zepatier with ribavirin for 16 weeks, the most commonly reported adverse reactions of moderate or severe intensity (greater than or equal to 5%) were anemia and headache.

#### Drug Interactions

- Co-administration of Zepatier with moderate CYP3A inducers is not recommended as they may decrease the plasma concentration of Zepatier.

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- Co-administration of Zepatier with certain strong CYP3A inhibitors is not recommended as they may increase the plasma concentration of Zepatier.
- Consult the full prescribing information prior to and during treatment for potential drug interactions.

**Use in Specific Populations**

*Pregnancy*

No adequate human data are available to establish whether or not Zepatier poses a risk to pregnancy outcomes. In animal reproduction studies, no evidence of adverse developmental outcomes was observed with the components of Zepatier (elbasvir or grazoprevir) at exposures greater than those in humans at the recommended human dose (RHD). During organogenesis in the rat and rabbit, systemic exposures (AUC) were approximately 10 and 18 times (for elbasvir) and 117 and 41 times (for grazoprevir), respectively, the exposure in humans at the RHD. In rat pre/postnatal developmental studies, maternal systemic exposures (AUC) to elbasvir and grazoprevir were approximately 10 and 78 times, respectively, the exposure in humans at the RHD.

The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2%–4% and 15%–20%, respectively.

If Zepatier is administered with ribavirin, the combination regimen is contraindicated in pregnant women and in men whose female partners are pregnant. Refer to the ribavirin prescribing information for more information on use in pregnancy.

**Females and Males of Reproductive Potential**

If Zepatier is administered with ribavirin, the information for ribavirin with regard to pregnancy testing, contraception, and infertility also applies to this combination regimen. Refer to ribavirin prescribing information for additional information.

**Pediatric Use**

Safety and efficacy in pediatric patients have not been established in pediatric patients less than 18 years of age.

Clinical trials of Zepatier with or without ribavirin included 187 subjects aged 65 years and over. Higher elbasvir and grazoprevir plasma concentrations were observed in subjects aged 65 years and over. A higher rate of late ALT elevations was observed in subjects aged 65 years and over in clinical trials. However, no dosage adjustment of Zepatier is recommended in geriatric patients

**Gender**

Higher elbasvir and grazoprevir plasma concentrations were observed in females compared to males. Females experienced a higher rate of late ALT elevations in clinical trials. However, no dose adjustment of Zepatier is recommended based on gender.

**TABLE 2**

**Drugs that are Contraindicated with Zepatier**

Drug Class	Drug(s) within Class that are contraindicated	Clinical Comment*
Anticonvulsants	Phenytoin Carbamazepine	May lead to loss of virologic response to ZEPATIER due to significant decreases in elbasvir and grazoprevir plasma concentrations caused by strong CYP3A induction.
Antimycobacterials	Rifampin	May lead to loss of virologic response to ZEPATIER due to significant decreases in elbasvir and grazoprevir plasma concentrations caused by strong CYP3A induction.
Herbal Products	St. John's Wort ( <i>Hypericum perforatum</i> )	May lead to loss of virologic response to ZEPATIER due to significant decreases in elbasvir and grazoprevir plasma concentrations caused by strong CYP3A induction.
HIV Medications	Efavirenz†	May lead to loss of virologic response to ZEPATIER due to significant decreases in elbasvir and grazoprevir plasma concentrations caused by CYP3A induction.
HIV Medications	Atazanavir Darunavir Lopinavir Saquinavir Tipranavir	May increase the risk of ALT elevations due to a significant increase in grazoprevir plasma concentrations caused by OATP1B1/3 inhibition.
Immunosuppressants	Cyclosporine	May increase the risk of ALT elevations due to a significant increase in grazoprevir plasma concentrations caused by OATP1B1/3 inhibition.

\*This table is not a comprehensive list of all drugs that inhibit OATP1B1/3 or strongly induce CYP3A.

†Efavirenz is included as a strong CYP3A inducer in this table, since co-administration reduced grazoprevir exposure by ≥80%



## Race

Higher elbasvir and grazoprevir plasma concentrations were observed in Asians compared to Caucasians. Asians experienced a higher rate of late ALT elevations in clinical trial. However, no dose adjustment of Zepatier is recommended based on race/ethnicity.

## Renal Impairment

No dosage adjustment of Zepatier is recommended in patients with any degree of renal impairment including patients receiving hemodialysis. Administer Zepatier with or without ribavirin according to recommendations. Refer to the prescribing information for ribavirin tablets for renal dosage adjustment of ribavirin in patients with CrCl less than or equal to 50 mL/minute.

## Hepatic Impairment

No dosage adjustment of Zepatier is recommended in patients with mild hepatic impairment (Child-Pugh A). Zepatier is contraindicated in patients with moderate hepatic impairment (Child-Pugh B) due to the lack of clinical safety and efficacy experience in HCV-infected Child-Pugh B patients, patients with severe hepatic impairment (Child-Pugh C) due to a 12-fold increase in grazoprevir exposure in non-HCV infected Child-Pugh C subjects.

The safety and efficacy of Zepatier have not been established in patients awaiting liver transplant or in liver transplant recipients.

## Overview of Clinical Trials

The efficacy of Zepatier was assessed in 2 placebo-controlled trials and 4 uncontrolled Phase 2 and 3 clinical trials in 1401 subjects with genotype (GT) 1, 4, or 6 chronic hepatitis C virus infection with compensated liver disease (with or without cirrhosis). An overview of the 6 trials (n=1373) contributing to the assessment of efficacy in genotype 1 or 4 is provided. C-EDGE TN, C-EDGE COINFECTION, C-SCAPE, and C-EDGE TE also included subjects with genotype 6 HCV infection (n=28). Because Zepatier is not indicated for genotype 6 infection, results in patients with genotype 6 infection are not included in Clinical Studies.

Zepatier was administered once daily by mouth in these trials. For subjects who received ribavirin (RBV), the RBV dosage was weight-based (less than 66 kg = 800 mg per day, 66 to 80 kg = 1000 mg per day, 81 to 105 kg = 1200 mg per day, greater than 105 kg = 1400 mg per day) administered by mouth in two divided doses with food.

Sustained virologic response (SVR) was the primary endpoint in all trials and was defined as HCV RNA less than lower limit of quantification (LLOQ) at 12 weeks after the cessation of treatment (SVR12). Serum HCV RNA values were measured during these clinical trials using the COBAS AmpliPrep/COBAS Taqman HCV test (version 2.0) with an LLOQ of 15 HCV RNA IU per mL, with the exception of C-SCAPE where the assay had an LLOQ of 25 HCV RNA IU per mL.

## Clinical Trials in Treatment-Naïve Subjects with Genotype 1

### HCV (C-EDGE TN and C-EDGE COINFECTION)

The efficacy of Zepatier in treatment-naïve subjects with genotype 1 chronic hepatitis C virus infection with or without cirrhosis was demonstrated in the C-EDGE TN and C-EDGE COINFECTION trials.

C-EDGE TN was a randomized, double-blind, placebo-controlled trial in treatment-naïve subjects with genotype 1 or 4 infection with or without cirrhosis. Subjects were randomized in a 3:1 ratio to: Zepatier for 12 weeks (immediate treatment group) or placebo for 12 weeks followed by open-label treatment with Zepatier for 12 weeks (deferred treatment group). Among subjects with genotype 1 infection randomized to the immediate treatment group, the median age was 55 years (range: 20 to 78); 56% of the subjects were male; 61% were White; 20% were Black or African American; 8% were Hispanic or Latino; mean body mass index was 26 kg/m<sup>2</sup>; 72% had baseline HCV RNA levels greater than 800,000 IU per mL; 24% had cirrhosis; 67% had non-C/C IL28B alleles (CT or TT); and 55% had genotype 1a and 45% had genotype 1b chronic HCV infection.

C-EDGE COINFECTION was an open-label, single-arm trial in treatment-naïve HCV/HIV-1 co-infected subjects with genotype 1 or 4 infection with or without cirrhosis. Subjects received Zepatier for 12 weeks. Among subjects with genotype 1 infection, the median age was 50 years (range: 21 to 71); 85% of the subjects were male; 75% were White; 19% were Black or African American; 6% were Hispanic or Latino; mean body mass index was 25 kg per m<sup>2</sup>; 59% had baseline HCV RNA levels greater than 800,000 IU per mL; 16% had cirrhosis; 65% had non-C/C IL28B alleles (CT or TT); and 76% had genotype 1a, 23% had genotype 1b, and 1% had genotype 1-Other chronic HCV infection.

### Clinical Trials in Treatment-Experienced Subjects with Genotype 1 HCV

#### Treatment-Experienced Subjects who Failed Prior PegIFN with RBV Therapy (C-EDGE TE)

C-EDGE TE was a randomized, open-label comparative trial in subjects with genotype 1 or 4 infection, with or without cirrhosis, with or without HCV/HIV-1 co-infection, who had failed prior therapy with PegIFN + RBV therapy. Subjects were randomized in a 1:1:1:1 ratio to one of the following treatment groups: Zepatier for 12 weeks, Zepatier + RBV for 12 weeks, Zepatier for 16 weeks, or Zepatier + RBV for 16 weeks. Among subjects with genotype 1 infection, the median age was 57 years (range: 19 to 77); 64% of the subjects were male; 67% were White; 18% were Black or African American; 9% were Hispanic or Latino; mean body mass index was 28 kg/m<sup>2</sup>; 78% had baseline HCV RNA levels greater than 800,000 IU/mL; 34% had cirrhosis; 79% had non-C/C IL28B alleles (CT or TT); and 60% had genotype 1a, 39% had genotype 1b, and 1% had genotype 1-Other chronic HCV infection.

Treatment outcomes in genotype 1 subjects treated with Zepatier for 12 weeks or Zepatier with RBV for 16 weeks are



presented in below. Treatment outcomes with Zepatier with RBV for 12 weeks or without RBV for 16 weeks are not shown because these regimens are not recommended in PegIFN/RBV-experienced genotype 1 patients.

*Treatment-Experienced Subjects Who Failed Prior PegIFN + RBV + HCV Protease Inhibitor Therapy (C- SALVAGE)*

C-SALVAGE was an open-label single-arm trial in subjects with genotype 1 infection, with or without cirrhosis, who had failed prior treatment with boceprevir, simeprevir, or telaprevir in combination with pegIFN + RBV. Subjects received EBR 50 mg once daily + GZR 100 mg once daily + RBV for 12 weeks. Subjects had a median age of 55 years (range: 23 to 75); 58% of the subjects were male; 97% were White; 3% were Black or African American; 15% were Hispanic or Latino; mean body mass index was 28 kg/m<sup>2</sup>; 63% had baseline HCV RNA levels greater than 800,000 IU/mL; 43% had cirrhosis; and 97% had non-C/C IL28B alleles (CT or TT); 46% had baseline NS3 resistance-associated substitutions.

Overall SVR was achieved in 96% (76/79) of subjects receiving EBR + GZR + RBV for 12 weeks. Four percent (3/79) of subjects did not achieve SVR due to relapse. Treatment outcomes were consistent in genotype 1a and genotype 1b subjects, in subjects with different response to previous HCV therapy, and in subjects with or without cirrhosis. Treatment outcomes were generally consistent in subjects with or without NS3 resistance-associated substitutions at baseline, although limited data are available for subjects with specific NS3 resistance-associated substitutions.

**Clinical Trial in Subjects with Genotype 1 HCV and Severe Renal Impairment including Subjects on Hemodialysis (C-SURFER)**

C-SURFER was a randomized, double-blind, placebo-controlled trial in subjects with genotype 1 infection, with or without cirrhosis, with chronic kidney disease (CKD) Stage 4 (eGFR 15-29 mL/min/1.73 m<sup>2</sup>) or CKD Stage 5 (eGFR <15 mL/min/1.73 m<sup>2</sup>), including subjects on hemodialysis, who were treatment-naïve or who had failed prior therapy with IFN or PegIFN ± RBV therapy. Subjects were randomized in a 1:1 ratio to one of the following treatment groups: EBR 50 mg once daily + GZR 100 mg once daily for 12 weeks (immediate treatment group) or placebo for 12 weeks followed by open-label treatment with EBR + GZR for 12 weeks (deferred treatment group). In addition, 11 subjects received open-label EBR + GZR for 12 weeks (intensive pharmacokinetic [PK] group). Subjects randomized to the immediate treatment group and intensive PK group had a median age of 58 years (range: 31 to 76); 75% of the subjects were male; 50% were White; 45% were Black or African American; 11% were Hispanic or Latino; 57% had baseline HCV RNA levels greater than 800,000 IU/mL; 6% had cirrhosis; and 72% had non-C/C IL28B alleles (CT or TT).

**TABLE 3**

**C-SURFER: SVR12 in Subjects with Severe Renal Impairment including Subjects on Hemodialysis who were Treatment-Naïve or had Failed Prior IFN or PegIFN ± RBV, with or without Cirrhosis, with Genotype 1 HCV Treated with ZEPATIER for 12 Weeks**

Regimen	EBR + GZR 12 weeks (Immediate Treatment Group) N=122*
Overall SVR	94% (115/122)†
<b>Outcome for subjects without SVR</b>	
On-treatment Virologic Failure	0% (0/122)
Relapse	<1% (1/122)
Other‡	5% (6/122)
<b>SVR by Genotype</b>	
GT 1a	97% (61/63)
GT 1b§	92% (54/59)
<b>SVR by Cirrhosis status</b>	
No	95% (109/115)
Yes	86% (6/7)
<b>SVR by Prior HCV Treatment Status</b>	
Treatment-naïve	95% (96/101)
Treatment-experienced	90% (19/21)
<b>SVR by Dialysis Status</b>	
No	97% (29/30)
Yes	93% (86/92)
<b>SVR by Chronic Kidney Disease Stage</b>	
Stage 4	100% (22/22)
Stage 5	93% (93/100)
*Includes subjects (n=11) in the intensive PK group.	
†SVR was achieved in 99% (115/116) of subjects in the pre-specified primary analysis population, which excluded subjects not receiving at least one dose of study treatment and those with missing data due to death or early study discontinuation for reasons unrelated to treatment response.	
‡Other includes subjects who discontinued due to adverse event, lost to follow-up, or subject withdrawal.	
§Includes genotype 1 subtypes other than 1a or 1b.	

**Clinical Trials with Genotype 4 HCV**

The efficacy of Zepatier in subjects with genotype 4 chronic HCV

*Continues on page 32*



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*LitScan for Case Managers* reviews medical literature and reports abstracts that are of particular interest to case managers in an easy-to-read format. Each abstract includes information to locate the full-text article if there is an interest. This member benefit is designed to assist case managers in keeping current with clinical breakthroughs in a time-effective manner.

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***Clin Infect Dis.*** 2015 Nov 27. pii: theoncologist.2015-0162.  
[Epub *Clin Infect Dis.* 2016 Jan 29. pii: civ1224.  
[Epub ahead of print]

[CD4 cell count: declining value for antiretroviral therapy eligibility.](#)

**Ying R, Granich RM, Gupta S, Williams BG.**

Antiretroviral therapy (ART) policy for people living with human immunodeficiency virus (HIV) has historically been based on clinical indications, such as opportunistic infections and CD4 cell counts. Studies suggest that CD4 counts early in HIV infection do not predict relevant public health outcomes such as disease progression, mortality, and HIV transmission in people living with HIV. CD4 counts also vary widely within individuals and among populations, leading to imprecise measurements and arbitrary ART initiation. To capture the clinical and preventive benefits of treatment, the global HIV response now focuses on increasing HIV diagnosis and ART coverage. CD4 counts for ART initiation were necessary when medications were expensive and had severe side effects, and when the impact of early ART initiation was unclear. However, current evidence suggests that although CD4 counts may still play a role in guiding clinical care to start prophylaxis for opportunistic infections, CD4 counts should cease to be required for ART initiation.

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***MMWR Morb Mortal Wkly Rep.*** 2016;65(4):77-82. doi: 10.15585/mmwr.mm6504a2.

[Disparities in consistent retention in HIV care: 11 states and the District of Columbia, 2011-2013.](#)

**Dasgupta S, Oster AM, Li J, DPE, Hall HI.**

In 2013, 45% of new human immunodeficiency virus (HIV) infection diagnoses occurred in non-Hispanic blacks/African Americans (blacks) (1), who represent 12% of the US. **POPULATION:** Antiretroviral therapy (ART) improves clinical outcomes and reduces transmission of HIV, which causes acquired immunode-

fiency syndrome (AIDS) (2). Racial/ethnic disparities in HIV care limit access to ART, perpetuating disparities in survival and reduced HIV transmission. National HIV Surveillance System (NHSS) data are used to monitor progress toward reaching the National HIV/AIDS Strategy goals to improve care among persons living with HIV and to reduce HIV-related disparities. CDC used NHSS data to describe retention in HIV care over 3 years and describe differences by race/ethnicity. Among persons with HIV infection diagnosed in 2010 who were alive in December 2013, 38% of blacks with HIV infection were consistently retained in care during 2011-2013, compared with 50% of Hispanics/Latinos (Hispanics) and 49% of non-Hispanic whites (whites). Differences in consistent retention in care by race/ethnicity persisted when groups were stratified by sex or transmission category. Among blacks, 35% of males were consistently retained in care compared with 44% of females. Differences in HIV care retention by race/ethnicity were established during the first year after diagnosis. Efforts to establish early HIV care among blacks are needed to mitigate racial/ethnic disparities in HIV outcomes over time.

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***Clin Res Hepatol Gastroenterol.*** 2016 Jan 25. pii: S2210-7401(15)00294-6. doi: 10.1016/j.clinre.2015.12.003. [Epub ahead of print]

[Alterations in serum levels of fetuin A and selenoprotein P in chronic hepatitis C patients with concomitant type 2 diabetes: a case-control study.](#)

**Ali SA, Nassif WM, Abdelaziz DH.**

**BACKGROUND:** Insulin resistance (IR) and type 2 diabetes mellitus (T2DM) are serious extrahepatic manifestations of chronic hepatitis C virus (HCV) infection. However, the mechanism underlying the IR in chronic HCV is obscure. Hepatokines are group of liver-derived protein, which affect the glucose and lipid metabolism in several tissues. Fetuin A (also known as human 2-HS-glycoprotein) is one of the hepatokines, which was recognized as a natural inhibitor of the insulin receptor tyrosine kinase in liver and skeletal muscle. Additionally, selenoprotein P has emerged as an important hepatokine, which primarily acts as sele-

nium transporter and has been reported to be implicated in glucose homeostasis in human. **OBJECTIVE:** The aim of the current case-control study was to investigate the serum levels of both fetuin A and selenoprotein P in chronic hepatitis C patients with or without T2DM and to correlate their levels with other biochemical parameters of insulin resistance. **MAIN FINDINGS:** Our results showed that, serum fetuin A levels increased significantly in HCV patients compared with controls ( $P < 0.01$ ) and surplus increase was found in HCV with concomitant T2DM ( $P > 0.001$ ). However, selenoprotein P levels significantly elevated only in patients with both HCV and T2DM ( $P < 0.05$ ) compared with the healthy subjects. Both fetuin A and selenoprotein P were positively correlated with fasting blood glucose. Yet, only fetuin A was significantly correlated to the HOMA-IR ( $r = 0.28$ ;  $P = 0.03$ ). **CONCLUSIONS:** These results indicate crucial roles played by fetuin A and selenoprotein P in the IR caused by HCV and that both hepatokines may be targets for the development of therapies to treat or inhibit insulin resistance associated to HCV. However, further studies on large scale should be conducted to confirm our findings.

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*J Hepatol.* 2016 Jan 22. pii: S0168-8278(16)00014-3. doi: 10.1016/j.jhep.2016.01.009. [Epub ahead of print]

### [Increasing prevalence of cirrhosis among US adults aware or unaware of their chronic hepatitis C virus infection.](#)

**Udompap P, Mannalithara A, Heo N, Kim D, Ray Kim W.** **BACKGROUND AND AIMS:** Cirrhosis from hepatitis C virus (HCV) infection is a major cause of end-stage liver disease and hepatocellular carcinoma worldwide. We determine the prevalence of cirrhosis among HCV-infected American adults including those unaware of their infection. **METHODS:** Using the National Health and Nutrition Examination Survey (NHANES) data, we identified participants aged 20 years with detectable serum HCV RNA. The prevalence of advanced fibrosis and cirrhosis was determined for Eras 1 (1988-94), 2 (1999-2006) and 3 (2007-12) by using FIB-4  $> 3.25$  and APRI  $> 2.0$ , respectively. **RESULTS:** Out of 52,644 NHANES examinees, 49,429 were tested for HCV, of whom 725 met the inclusion criteria (positive HCV RNA with available data for FIB-4 and APRI). Based on APRI, 6.6% (95% confidence interval [CI]: 2.2-11.0) of HCV-infected adults in Era 1, 7.6% (95% CI: 3.4-11.8) in Era 2 and 17.0% (95% CI: 8.0-26.0) in Era 3 had cirrhosis. In the multivariable regression analysis, this era effect was attributable to increasing age (odds ratio [OR]: 1.04, 95% CI: 1.02-1.07), diabetes (OR: 2.33, 95% CI: 1.01-5.40) and obesity (OR: 2.96, 95% CI: 1.15-7.57).

Cirrhosis was as common among respondents who were unaware of their infection as those who were aware (both 11%). Results were identical when FIB-4 was used. **CONCLUSIONS:** Among HCV-infected American adults, the proportion with cirrhosis has increased rapidly. Cirrhosis prevalence remains high in individuals unaware of their HCV infection. These data highlight the urgency for HCV screening regardless of symptoms, systematic assessment for liver fibrosis in those with HCV infection and institution of antivirals to prevent advanced liver disease.

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*Am J Cardiol.* 2015 Dec 31. pii: S0002-9149(15)30077-1. doi: 10.1016/j.amjcard.2015.12.032. [Epub ahead of print]

### [Effect of early intervention with positive airway pressure therapy for sleep disordered breathing on six-month readmission rates in hospitalized patients with heart failure.](#)

**Sharma S, Mather P, Gupta A, et al.**

Rehospitalization for congestive heart failure (CHF) is high within 6 months of discharge. Sleep disordered breathing (SDB) is common and underdiagnosed condition in patients with CHF. We hypothesized that early recognition and treatment of SDB in hospitalized patients with CHF will reduce hospital readmissions and emergency room visits. Patients admitted for CHF underwent overnight polysomnography within 4 weeks of discharge. Patients diagnosed with SDB were provided therapy with positive airway pressure therapy. Patients were identified as having good compliance if the device use was for a minimum of 4 hours 70% of the time for a minimum of 4 weeks during the first 3 months of therapy. Hospital admissions for 6 months before therapy were compared with readmission within 6 months after therapy in patients with good and poor compliance. A total of 70 patients were diagnosed with SDB after discharge. Of the 70 patients, 37 (53%) were compliant with positive airway pressure therapy. Compliant patients were more likely to be older ( $64 \pm 12$  vs  $58 \pm 11$  years) and women (54% vs 33%) and less likely to be patient with diabetes (40% vs 67%) versus noncompliant patients. Although both groups experienced a decrease in total readmissions, compliant patients had a significant reduction (mean  $\pm$  SE:  $-1.5 \pm 0.2$  clinical events vs  $-0.2 \pm 0.3$ ;  $p < 0.0001$ ). In this single-center analysis, identification and treatment of SDB in admitted patients with CHF with SDB is associated with reduced readmissions over 6 months after discharge. Adherence to the treatment was associated with a greater reduction in clinical events.



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*Clin Cardiol.* 2016 Feb 3. doi: 10.1002/clc.22520.  
[Epub ahead of print]

### [Depression and multiple rehospitalizations in patients with heart failure.](#)

Freedland KE, Carney RM, Rich MW, Steinmeyer BC, Skala JA, Dávila-Román VG.

**BACKGROUND:** There have been few studies of the effect of depression on rehospitalization in patients with heart failure (HF), and even fewer on its role in multiple rehospitalizations. **HYPOTHESIS:** Depression is an independent risk factor for multiple readmissions in patients with HF. **METHODS:** A cohort of 662 patients with HF who were discharged alive after hospitalization were interviewed to evaluate symptoms of depression and were followed for 1 year. All-cause readmissions were documented by chart review. A marginal proportional rates model was used to model the effect of depression on the rate of rehospitalization with adjustment for known predictors of HF outcomes. **RESULTS:** Depression symptoms predicted multiple readmissions (adjusted hazard ratio [HR]: 1.08, 95% confidence interval [CI]: 1.03-1.13,  $P = 0.0008$ ). Compared with patients without depression, those who met the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria for major depression at index were at the highest risk for multiple rehospitalizations (HR: 1.51, 95% CI: 1.15-1.97,  $P = 0.003$ ). **CONCLUSIONS:** Depression is an independent risk factor for multiple all-cause readmissions in patients with HF.

*J Heart Lung Transplant.* 2015 May;34(5):685-92. doi: 10.1016/j.healun.2014.11.024. Epub 2014 Dec 8.

### [Factors associated with anti-human leukocyte antigen antibodies in patients supported with continuous-flow devices and effect on probability of transplant and post-transplant outcomes.](#)

Alba AC, Tinckam K, Foroutan F, et al.

**BACKGROUND:** One major disadvantage of ventricular assist device (VAD) therapy is the development of human-leukocyte antigen (HLA) antibodies. We aimed to identify factors associated with HLA antibodies during continuous flow (CF)-VAD support and assess the effect on transplant probability and outcomes. **METHODS:** We included 143 consecutive heart failure patients who received a CF-VAD as a bridge-to-transplant at 3 institutions. Factors associated with post-VAD peak panel reactive antibodies (PRA) among several measurements were identified using

multivariable linear regression. A parametric survival model was used to assess transplant waiting time and probability, risk of rejection, and a composite outcome of rejection, graft failure, and death. **RESULTS:** Thirty-six patients (25%) were female; mean age was  $47 \pm 13$  years. Eighty-one patients (57%) had a pre-VAD PRA of 0%, and 16 were highly sensitized (PRA > 80%). Age, female sex, and pre-VAD PRA were independently associated with post-VAD PRA. A 10-year increase in age was associated with a 5% decrease in post-VAD PRA ( $p = 0.03$ ). Post-VAD PRA was 19% higher in women vs men ( $p < 0.01$ ). A 10%-increase in pre-VAD PRA was associated with a 4.7% higher post-VAD PRA ( $p < 0.01$ ). During a mean follow-up of  $12 \pm 11$  months, 90 patients underwent cardiac transplantation. A 20% increase in post-VAD PRA was associated with 13% lower probability of transplant (hazard ratio, 0.87; 95% confidence interval, 0.76-0.99). A high PRA was not associated with adverse post-transplant outcomes. **CONCLUSIONS:** Younger age, female sex, and pre-VAD PRA were independent predictors of elevated PRA post-VAD. Higher PRA was significantly associated with lower transplant probability but not increased rejection, graft failure, or death after transplant.

*Chest.* 2016 Jan 21. pii: S0012-3692(16)00467-0. doi: 10.1016/j.chest.2015.12.039. [Epub ahead of print]

### [Age-related differences in the rate, timing, and diagnosis of 30-day readmissions in hospitalized adults with asthma exacerbation.](#)

Hasegawa K, Gibo K, Tsugawa Y, Shimada YJ, Camargo CA Jr. **BACKGROUND:** Reducing hospital readmissions has attracted attention from many stakeholders. However, the characteristics of 30-day readmissions after asthma-related hospital admissions in adults are not known. It is also unclear whether older adults are at higher risk of 30-day readmission. **OBJECTIVES:** To investigate the rate, timing, and principal diagnosis of 30-day readmissions in adults with asthma and to determine age-related differences. **METHODS:** Retrospective cohort study of adults hospitalized for asthma exacerbation using the population-based inpatient samples of 3 states (California, Florida, and Nebraska) from 2005 through 2011. Patients were categorized into 3 age groups: younger (18-39 years), middle-age (40-64 years) and older ( $\geq 65$  years) adults. Outcomes were 30-day all-cause readmission rate, timing, and principal diagnosis of readmission. **RESULTS:** Of 301,164 asthma-related admissions at risk for 30-day readmission, readmission rate was 14.5%. Compared to younger adults, older adults had significantly higher readmission rates (10.1% vs. 16.5%; OR, 2.15 [95% CI, 2.07-2.23];  $P < 0.001$ ). The higher rate attenuated with

adjustment (OR, 1.19 [95% CI, 1.13-1.26];  $P < 0.001$ ), indicating that most of the age-related difference is explained by sociodemographics and comorbidities. For all age groups, readmission rate was highest in the first week after discharge and declined thereafter. Overall, only 47.1% of readmissions were assigned respiratory diagnoses (asthma, COPD, pneumonia, and respiratory failure). Older adults were more likely to present with non-respiratory diagnoses (41.7% vs. 53.8%;  $P < 0.001$ ). CONCLUSIONS: After asthma-related admission, 14.5% had 30-day readmission with wide range of principal diagnoses. Compared to younger adults, older adults had higher 30-day readmission rates and proportions of non-respiratory diagnoses.

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*J Pediatr.* 2016 Jan 26. pii: S0022-3476(15)01656-X. doi: 10.1016/j.jpeds.2015.12.066. [Epub ahead of print]

### [Risk of asthma from cesarean delivery depends on membrane rupture.](#)

Sevelsted A, Stokholm J, Bisgaard H.

OBJECTIVE: To assess our prospective mother-child cohort and the national registry data to analyze the risk of asthma by delivery mode and whether cesarean delivery before or after membrane rupture affects this risk differently. STUDY DESIGN: The Copenhagen Prospective Studies on Asthma in Childhood 2000 is a high-risk birth cohort of 411 Danish children. Asthma was diagnosed prospectively by physicians at the research site, and associations with cesarean delivery were investigated using Cox proportional hazard models. From the Danish national prospective registry we included data from 1997-2010. Childhood asthma was defined from recurrent use of inhaled corticosteroids filled at pharmacies. Cesarean delivery was classified as either before or after rupture of membranes, and the risk of asthma was compared with vaginal delivery. Results were adjusted stepwise for age and calendar year, sex, birth weight, gestational age, multiple births, parity, and maternal factors (age, smoking/antibiotics during pregnancy, employment status, and asthma). RESULTS: In the Copenhagen Prospective Studies on Asthma in Childhood 2000 cohort, the adjusted hazard ratio for asthma was increased by cesarean delivery relative to vaginal birth 2.18 (1.27-3.73). Registry data replicated these findings. Cesarean delivery performed before rupture of membranes carried significantly higher risk of asthma, (incidence rate ratio to vaginal delivery 1.20 [1.16-1.23]) than cesarean delivery after rupture of membranes (incidence rate ratio to vaginal delivery 1.12 [1.09-1.16]). CONCLUSIONS: We confirmed cesarean delivery to be a risk factor for childhood asthma. This effect was more pronounced

for cesarean delivery performed before rupture of membranes.

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*Am J Kidney Dis.* 2015 Nov;66(5):837-45. doi: 10.1053/j.ajkd.2015.05.015. Epub 2015 Jul 7.

### [Functional status, time to transplantation, and survival benefit of kidney transplantation among wait-listed candidates.](#)

Reese PP, Shults J, Bloom RD, et al.

BACKGROUND: In the context of an aging end-stage renal disease population with multiple comorbid conditions, transplantation professionals face challenges in evaluating the global health of patients awaiting kidney transplantation. Functional status might be useful for identifying which patients will derive a survival benefit from transplantation versus dialysis. STUDY DESIGN: Retrospective cohort study of wait-listed patients using data for functional status from a national dialysis provider linked to United Network for Organ Sharing registry data. SETTING & PARTICIPANTS: Adult kidney transplantation candidates added to the waiting list between 2000 and 2006. PREDICTOR: Physical Functioning scale of the Medical Outcomes Study 36-Item Short Form Health Survey, analyzed as a time-varying covariate. OUTCOMES: Kidney transplantation; survival benefit of transplantation versus remaining wait-listed. MEASUREMENTS: We used multivariable Cox regression to assess the association between physical function with study outcomes. In survival benefit analyses, transplantation status was modeled as a time-varying covariate. RESULTS: The cohort comprised 19,242 kidney transplantation candidates (median age, 51 years; 36% black race) receiving maintenance dialysis. Candidates in the lowest baseline Physical Functioning score quartile were more likely to be inactivated (adjusted HR vs highest quartile, 1.30; 95% CI, 1.21-1.39) and less likely to undergo transplantation (adjusted HR vs highest quartile, 0.64; 95% CI, 0.61-0.68). After transplantation, worse Physical Functioning score was associated with shorter 3-year survival (84% vs 92% for the lowest vs highest function quartiles). However, compared to dialysis, transplantation was associated with a statistically significant survival benefit by 9 months for patients in every function quartile. LIMITATIONS: Functional status is self-reported. CONCLUSIONS: Even patients with low function appear to live longer with kidney transplantation versus dialysis. For wait-listed patients, global health measures such as functional status may be more useful in counseling patients about the probability of transplantation than in identifying who will derive a survival benefit from it. ■

## Models of Care for High-Need, High-Cost Patients: An Evidence Synthesis *continued from page 14*

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## PharmaFacts for Case Managers

*continued from page 26*

demonstrated in C-EDGE TN, C-EDGE COINFECTION, C-EDGE TE, and C-SCAPE. C-SCAPE was a randomized, open-label trial which included treatment-naïve subjects with genotype 4 infection without cirrhosis. Subjects were randomized in a 1:1 ratio to EBR 50 mg once daily + GZR 100 mg once daily for 12 weeks or EBR 50 mg once daily + GZR 100 mg once daily + RBV for 12 weeks. In these combined studies in subjects with genotype 4 infection, 64% were treatment-naïve; 66% of the subjects were male; 87% were White;

10% were Black or African American; 22% had cirrhosis; and 30% had HCV/HIV-1 co-infection.

In C-SCAPE, C-EDGE TN, and C-EDGE COINFECTION trials combined, a total of 66 genotype 4 treatment-naïve subjects received Zepatier or EBR + GZR for 12 weeks. In these combined trials, SVR12 among subjects treated with Zepatier or EBR + GZR for 12 weeks was 97% (64/66).

In C-EDGE TE, a total of 37 genotype 4 treatment-experienced subjects received a 12- or 16-week Zepatier with or without RBV regimen. SVR12 among randomized subjects treated with Zepatier + RBV for 16 weeks was 100% (8/8).

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## **Ethics and the Case Manager**

*continued from page 2*

certification and the Code of Ethics for their profession. The case manager must be knowledgeable about the principles and values of ethics including being aware of resources that are available to them after they have recognized an ethical dilemma. Resources may include Ethics Committees, courses in ethics, journal articles, and other published readings in ethics. Every organization should have a process for resolving ethical dilemmas.

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In this issue of *CareManagement*, we publish “Ethical Dilemmas in Case

Management” by Elizabeth A. Dailey, MNA, HCM, MSN, RN; Maressa Hopkins, MSN, RN; and David A. Zaworski, MSN, RN.

I invite you to share ethical dilemmas you encounter and how they were resolved. This is a wonderful opportunity for you to share with your colleagues first-hand information about ethical dilemmas you encounter on a regular basis. If you have an Ethics Committee or you organized one, tell us about it. I want to hear from you.

Gary S. Wolfe, RN, CCM  
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City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

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