

Virtual Mentor

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From the editor

Ethics in oncology: modern concerns for an age-old disease

Cancer has been plaguing patients since it was first described in ancient Egyptian writings over 3,500 years ago. Although physicians have been treating this disease since antiquity, it remains a major cause of death and suffering throughout the world. In fact, it was the second most common cause of death in the United States in 2004, accounting for over 23 percent of all mortality [1]. This infamously deadly disease is considered so destructive that the American Heritage Dictionary defines it not only as a malignancy, but also as “a pernicious, spreading evil.”

Despite the vast number of deaths attributed to cancer each year, the mortality rate from this disease is steadily declining [2]. As dedicated researchers and clinicians work to understand the complex biology of cancer, novel approaches to prevention, diagnosis and treatment are being developed. As a result, the subdisciplines in oncology have become some of the most specialized and technologically advanced medical fields, and most cancer patients are now experiencing measurably better outcomes than they would have only a few decades ago.

The battle against cancer is being waged not only in the research laboratory, but also on the public health and policy level. Policy interventions are an essential component of oncology because, even though researchers have created precise tools to sabotage the intricate molecular machinery that drives this disease, much of the cancer mortality in this country could be avoided by far simpler means. For example, public health policy aimed at reducing tobacco use would go far toward preventing many of the 150,000 cancer-related deaths in the U.S. that are attributed to smoking each year [3].

In addition to smoking, the risk of dying from certain cancers is affected by factors such as race, income and level of insurance coverage [4-6]. As the technology of cancer treatment has advanced, some groups of patients have undeniably been left behind. Although these disparities in cancer survival may be among the most alarming and egregious injustices in modern medicine, they are also remediable. Some policy advocates are also helping to fight this disease by striving to provide all patients access to effective cancer prevention and treatment.

These varied approaches to combating cancer demonstrate the complexity and breadth of oncology. Cancer care is at once an age-old practice and an ever-evolving field that encompasses a broad array of disciplines within clinical medicine, research,

public health and health policy. Accordingly, an exploration of the ethics of oncology must include a wide range of distinct but interrelated topics, many of which are specific to this field.

One aspect of oncology that distinguishes it from the management of less severe illnesses is the realization among patients and physicians that cancer is often a fatal disease. Because the clinical encounter with a cancer patient may be permeated by this specter of mortality, cancer treatment often gives rise to some of the most compelling and fundamentally difficult dilemmas in medical ethics.

Ethical challenges also arise due to the development of experimental therapies that must go through clinical trials. Although such trials are necessary to improve treatment, individual patients—as potential subjects—may not share the goals of the research, a discord that can generate distinct ethical conflicts.

New technologies that result from this research, such as genetic testing and high-priced new therapies, present their own new sets of ethics questions. What advantages and disadvantages are associated with knowing that one is at increased risk for an illness, for example, and how does one set a fair price for a life-saving drug?

Outside the clinic, the roles that society and public policy play in cancer prevention and treatment are also the subject of much analysis and debate. For example, during the same month that this issue of *Virtual Mentor* is published, Washington will join many other U.S. cities in banning smoking in bars, restaurants and other public places. The often-contested responsibility of our government to protect us from cancer will surely be at the forefront as smokers are forced outdoors in the nation's capital.

In this issue of *Virtual Mentor*, experts examine many of these ethical uncertainties that inhere in the practice of oncology. I hope their thoughtful analyses provide helpful guidance for medical students and physicians who must navigate the intricacies of cancer care. The discussions in this issue may also benefit those who, through research and health policy, are ensuring that we continue to advance in the battle against this devastating disease.

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Clinical case

Testing minors for breast cancer

Commentary by Anne-Marie Laberge, MD, MPH, and Wylie Burke, MD, PhD

Rebecca Freeman is a lawyer and mother of two daughters. During her morning shower one day, she was surprised to feel a small, hard mass in her left breast. After having a mammogram, she underwent a core biopsy and was diagnosed with a 2-centimeter invasive ductal carcinoma.

Because Mrs. Freeman is only 34, her physician thought that she might have a genetic mutation that would greatly increase her chance of developing breast cancer. Mrs. Freeman asked to be tested and was in fact found to express a BRCA1 mutation.

Mrs. Freeman's surgeon, Dr. Hanes, advised that her breast tumor be removed by a lumpectomy. But after learning her BRCA1 status, Mrs. Freeman had become anxious about developing another breast cancer, and elected to undergo bilateral mastectomies. At her first postoperative visit, she seemed noticeably relieved.

"I just couldn't live with the fear of finding another breast lump some day," Mrs. Freeman told Dr. Hanes. "And I've been thinking that I don't want my daughters to live in fear and uncertainty either. I'm going to have them screened for BRCA mutations, too."

"Your daughters are 8 and 10 years old, is that right?" Dr. Hanes asked. "Even if they have the mutation, they wouldn't be at risk for cancer for many years."

"I know," she said, "I just want them to be prepared."

"Well maybe you should at least wait until they are a bit older and can decide for themselves if they want to be screened," Dr. Hanes countered.

"No," Mrs. Freeman answered, "I've made up my mind, and if our insurance won't cover it, I will pay myself to have them tested. They'll be better off knowing their breast cancer status now."

Commentary

Rebecca Freeman, diagnosed with a BRCA1 mutation and a personal history of early-onset breast cancer, is determined to have her two minor daughters (8 and 10

years of age) undergo genetic testing to discover whether either has inherited the mutation. Mrs. Freeman refuses her physician's suggestion to wait until her daughters reach adulthood and can decide on their own whether or not to be tested.

Predictive genetic testing of children for adult-onset diseases like hereditary breast cancer raises two main ethical issues [1]. The first is whether the putative benefits of predictive testing outweigh the risks, and the second is whether parents' requests for this type of testing on their child's behalf should be honored by the physician.

Do the benefits outweigh the risks of testing?

Predictive testing can sometimes provide medical benefit. Identification of an individual who has a high risk of future disease might lead to disease prevention or diligent screening for early detection and treatment [1]. Several interventions are available to reduce the risk for cancer in women with a BRCA1 mutation. These include early initiation of mammography, breast MRI screening, and prophylactic mastectomy and oophorectomy [2, 3]. Although these measures are imperfect and not always acceptable, they do provide a means to reduce the cancer risks facing women with BRCA1 mutations [2-6]. Current practice standards recommend that these women start screening in early adulthood (25-35 years) [7]. As a result, no interventions would be recommended to Mrs. Freeman's daughters at this time, even if either tested positive. If no medical benefit is available to Mrs. Freeman's daughters before adulthood, what would be the benefit of knowing their mutation status now?

Benefits of testing are not all related to health. Psychosocial benefits must also be considered. Knowing their genetic status would reduce the Freeman girls' uncertainty about their risk of breast cancer and allow them and their family to make informed choices for the future, including plans for health care, education, career and reproduction [1].

Psychosocial harms are also possible. A daughter who inherited the mutation might worry about her future health [8]. The mother might develop feelings of guilt or anxiety about her daughter's future. Knowledge of an adverse test result could change the parents' expectations of the child's future in a negative way [1, 9, 10]. In response to an adverse test result, parents might think of the child as "sick and damaged" or might perceive her as vulnerable and become overly protective of her [1]. Relationships between siblings can also be affected, especially if one has the BRCA1 mutation and the other does not. Predictive testing during childhood might have a lasting impact on the girl's developing self-identity, in either positive or negative ways; integration of her risk status into her developing identity could lead to a loss of self-esteem, or, alternatively, to a sense of empowerment [1, 11]. Identification of a deleterious mutation might have negative consequences for the child's future in terms of insurance or employment discrimination [1, 9, 11].

After considering these potential risks and benefits, most experts have concluded that predictive testing of children for adult-onset diseases is not appropriate unless

specific medical interventions are recommended prior to adulthood or the request is voluntary and comes from a competent and informed adolescent [1]. The determination to delay testing until adulthood is based on the speculative nature of the psychological benefits and harms.

Should parents' requests for predictive testing for their children be honored?

This question addresses the right of minors to self-determination. The case of Mrs. Freeman demonstrates the tension between the parents' right to make medical decisions for their children and the children's opportunity to exercise their own decision making in the future.

In general, parents have the authority to make decisions about their children's health care, unless those decisions are obviously harmful [1, 12, 13]. Because parents are primarily responsible for their children's well-being and know them better than anyone else does, they are permitted to decide what's best for them [1, 12, 14]. Yet, physicians have obligations to both parents and children [15]. Parents may have their own interests in mind when requesting genetic testing or may be seeking reassurance from a negative test result, so the physician must ensure that parents have considered the consequences of both negative and positive results for the child as well as for the rest of the family [12].

Although parental consent is required to perform testing, the child's assent should be sought as early as age 7, according to the American Academy of Pediatrics (AAP) [15]. Physicians and parents must respect the child's right to dissent [15].

The argument for preserving a minor's right to decide for himself or herself whether or not to undergo testing, i.e., the right to choose in the future "not to know," is supported by the observation that only a fraction of adults at risk for late-onset genetic disease decide to undergo predictive testing [12, 14]. Some have argued that letting parents request predictive testing for their children does not reduce the child's future autonomy, because knowledge of one's status provides an opportunity to prepare and adapt for the future [14, 16].

Predictive testing can be allowed before adulthood when mature adolescents seek it out [11, 17, 18]. In such cases, the American Society for Human Genetics (ASHG) and the American College of Medical Genetics (ACMG) recommend assessing the child's competence, obtaining her assent or consent, and ensuring that her decision is voluntary [1]. If the adolescent demonstrates "mature decision-making capacities," the physician should respect her autonomy to decide to undergo testing [17, 18].

Deferring testing until late adolescence or adulthood makes it easier for the physician to communicate the test results and their implications for the future to the individual being tested. A young child may not understand the implications of the test results, and it is often unclear who has the responsibility of disclosing the results to this child years later when she is old enough to understand them.

Conclusion

Predictive testing of children involves both potential harms and potential benefits and restricts the child's present and future autonomy in favor of the parents' present autonomy. Professional organizations, such as the ACMG, the ASHG, the AAP, the American Society of Clinical Oncology and the American Medical Association do not recommend testing minors for adult-onset genetic conditions, even in high-risk families, unless there are proven medical benefits to childhood testing [1, 15, 18-21]. Although physicians should respect the decision of competent adolescents and their families, they have no obligation to provide a service that is not in the best interest of the child. Nevertheless, the concerns of the parents deserve serious consideration and emotional support [22].

In this case, it would be appropriate to refuse genetic testing of Mrs. Freeman's children, on the grounds that they are unlikely to derive benefit from testing at this early age but would benefit from having the opportunity to participate in the decision-making process when they are old enough to do so. Family relationships and well-being should be taken into account when making this decision, however [22]; Dr. Hanes should assure Mrs. Freeman that deferring testing will not compromise her daughters' health. He should also offer her the opportunity to discuss her concerns further, and recognize the fact that she is motivated by the desire to protect her children.

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Related article

[Genetic testing of children](#)

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Clinical case

Medical student in the middle

Commentary by Peter Angelos, MD, PhD

“This next woman, Ms. West...” Dr. Young said, sighing, his voice trailing off. “...well, it’s a sad situation.” Dr. Young paused outside the room with Bill, a third-year medical student.

“I treated her for stage III cervical cancer two years ago, and I’ve been following her ever since. Her treatment went very well. We thought we had gotten rid of her cancer, but her latest bone scan revealed a few areas in her thoracic spine that are highly suspicious for metastases. It doesn’t look good. I asked her to come in so we can discuss the latest scan.

“The thing is,” Dr. Young continued, “she lives alone and doesn’t seem to have many friends or much social support. You’ll see in her chart that she has suffered from major depression ever since her cancer diagnosis. So we have to be careful not to upset her too much with this development. I’m afraid her depression could affect her chances for survival.”

Dr. Young entered the room and Bill followed close behind. Ms. West sat slumped in a chair in the corner, looking much older than her 42 years.

“It must be really bad news if you asked me to come down here in person,” she said, without lifting her gaze from the floor. “Am I going to die?”

“C’mon, don’t talk like that,” Dr. Young replied trying to sound encouraging. “I asked you to come in because I’m a bit concerned about your latest scan results. I’ll need to run a few more tests, and most likely you’ll have to be treated again. But we have some effective treatment options, and we’re going to take good care of you here, just like we did two years ago. My student Bill is going to examine you, if that’s okay, and I’ll be back to chat in a couple of minutes.” Dr. Young smiled warmly and stepped out of the room, leaving Bill and Ms. West alone.

“Wow,” she said, finally glancing up towards Bill. “I thought I was really in for some bad news, but it looks like I’m going to be OK after all, right?”

Commentary

In this case Dr. Young needs to communicate bad news to Ms. West. He is concerned that her previous depression will worsen with this news and that the depression will have a negative impact on her chances for survival. This situation will test the relationship between Dr. Young and Ms. West, since Dr. Young must communicate the test findings clearly and honestly while assuring Ms. West of continuity of care and presenting her with the options available for treatment. In the middle of the established relationship between Dr. Young and Ms. West, is Bill, the third-year medical student who is placed in a difficult position. Bill has been left alone with Ms. West minutes after she has heard that Dr. Young is “a bit concerned about...latest scan results.” She has not yet been told what those findings were or what they mean. When Ms. West asks if she is going to be all right, Bill is faced with a tough question—one that would challenge even an experienced physician. As a medical student, Bill has greater cause for distress than Dr. Young. Dr. Young has to think about how the interaction will affect his relationship with Ms. West; Bill must figure out how to be honest with Ms. West while explaining things the way he believes Dr. Young would want him to.

Communication between patients and physicians

Let us consider the principles that should guide the communication between patient and physician and then those that should guide the patient-student interaction. The exchange between a physician and a patient should be honest and complete. The disclosure of bad news should be part of an ongoing dialogue rather than just a single interaction. When communicating bad news to patients, physicians should strive to acknowledge the inherent uncertainties of any medical prognostication, as well as the fear and uncertainty that the patient is experiencing. The doctor should emphasize what options are available both immediately and down the road for the patient and should affirm that he or she will stick with the patient throughout the illness and the treatment. These are reassurances that only the physician—and not a student—can give. In the present case, Dr. Young initiated this important component of communicating bad news when he stated, “we have some effective treatment options for you, and we’re going to take good care of you...” In relaying these messages, physicians should never lie to a patient in an attempt to protect his or her “hope.” Certainly no doctor should be so paternalistic as to believe that he or she fully understands what will give a patient a sense of hope.

Communication between patients and students

If we now consider what principles should guide the patient and student discussion, we readily see that the same principles apply. The student should acknowledge more uncertainty, however, since he or she will almost always know less about the implications of the bad news than the attending physician does. One additional guideline traditionally observed between students and faculty is that the student should not be the first to deliver bad news to a patient. Why does this seem to be so widely accepted? Doctors and patients both understand that how information is transmitted is important, and the way in which patients first hear bad news can have an impact on how they react to it.

The case at hand

After such good initial communication between Dr. Young and Ms. West, Dr. Young abruptly left the room, placing Bill in a situation where he was being pressured to be the first to disclose the test findings and prognosis to Ms. West. This role is one that Bill is understandably anxious to avoid.

What could Dr. Young have done to spare Bill this awkward encounter? First, he could have discussed the recent results more fully with Ms. West before leaving Bill to complete the physical examination. This would have allowed her to hear all of the information and to ask questions of Dr. Young and later of Bill. Such an approach would help ensure that Ms. West received the benefit of a physician's knowledge, so that the student would not be asked the toughest questions.

Another possible approach that would free Bill from pressure to lie to, or at least be vague with, Ms. West would be for Dr. Young to withhold information from *Bill* until after he has given Ms. West the news. This would save Bill from having to wonder what the patient should be told. What Bill does not know, he cannot tell, so there is no deception in not sharing information with Ms. West.

Given the situation as described in the case, however, what is Bill to do? First, he should be honest; he has been told little about the test results and what implications they might have. It is often best for the student to simply repeat what the physician has already said to the patient. In the current case, Dr. Young has said that further treatment is most likely necessary and that there are some effective treatment options. A key role for Bill in his interaction with Ms. West is to reinforce these statements.

Perhaps the most helpful thing that Bill can do during his limited interaction with Ms. West is make clear that he is on her side. An alliance with a patient is one relationship that students can readily encourage. Bill can foster this partnership by being open with Ms. West and pointing out that both of them have less knowledge about her recent scan results and its implications than Dr. Young. If Ms. West asks Bill a question that he cannot answer, such as, "It looks like I'm going to be OK, right?" Bill should assert that it is a critical question but that he really doesn't know enough to answer. Suggesting that the question be asked of Dr. Young puts Bill and Ms. West together on a fact-finding quest. Students can often help patients to understand what questions need to be asked even when they themselves do not have the answers. They can also help patients clarify which concerns to bring up in future discussions with the physician. In this role, Bill could work to develop a stronger relationship with Ms. West while not giving medical information he is not fully prepared to provide.

This case illustrates how the relationships that develop between medical students and patients are similar but distinct from those between patients and physicians. It is valuable for physicians and students to be cognizant of the challenges of the patient-

student relationship so that students can acquire the skills they need to be more comfortable in the relationship and, most importantly, even helpful to patients.

Peter Angelos, MD, PhD, is professor of surgery, chief of endocrine surgery and associate director of the MacLean Center for Clinical Medical Ethics, all at the University of Chicago.

Related article

[Student role in discussion of diagnosis with patients](#), December 2003

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Clinical case

Helping patients decide whether to participate in clinical trials

Commentary by Martin L. Smith, STD, and Eric D. Kodish, MD

“I’ve been feeling miserable lately, and I haven’t been able to eat much at all,” Mr. Brooks said, wincing as he shifted on the exam table.

“Well, end-stage colon cancer is a pretty nasty disease,” Dr. Winston, his primary care physician of 15 years, replied softly. “And I understand from your chart that the masses in your liver and lungs haven’t gotten any smaller since your last round of chemo.”

“That’s right. And the last drug we tried was the only standard option left, which might be a good thing, since I’m getting pretty tired of all of the awful side effects. My oncologist, Dr. Lin, really wants me to try one more drug, and I think I’m going to do it. I guess he’s in charge of this study. He told me it’s called a phase 1 trial. He said this drug has worked really well in mice and that it might work well for me too.”

“Hmmm, well I don’t know much about experimental cancer treatments, but phase 1 studies are very new and often have more benefit for future patients than for study participants,” Dr. Winston cautioned.

“Honestly doc, I hate to sound selfish, but at this point I’m not really thinking about helping other people. I just want to feel better, and Dr. Lin said that this is my best shot. Joining the study sounds like a good idea, right?”

Commentary

How should Dr. Winston respond to his ailing patient, Mr. Brooks? This patient is asking a seemingly simple but actually a very challenging question: “Joining the study sounds like a good idea, right?” The inexorable natural history of advanced colon cancer, the fundamental human need for hope, and the complexity of finding the right balance between honesty and optimism in the patient-doctor relationship all make this situation difficult for both Mr. Brooks and for Dr. Winston. The ethical differences between the goals of scientific research and the goals of patient care provide the keys to understanding this case.

Scientific research

On the scientific research side, Mr. Brooks has been invited (and perhaps even encouraged by Dr. Lin) to enroll in a phase 1 research trial. Traditionally, phase 1

protocols have the identification of toxicity and tolerability parameters as their primary objectives. Such trials typically investigate pharmaceutical agents that are being administered to human research subjects for the first time with the aim of establishing “maximum tolerable dose,” often with little or no therapeutic benefit expected for research participants. The stereotypical profile of phase 1 protocols is that they are high risk for study subjects without likely benefit. But recent meta-analyses of phase 1 clinical oncology trials may be telling a different story. The level of risk experienced by cancer patients taking part in phase 1 trials may be trending downward, due in part to the targeted and less-toxic nature of newer cancer drugs and to increased attention to the safety of clinical research [1]. Further, some phase 1 oncology studies have demonstrated that participants’ quality of life improved as a result of their research experience compared with the alternative of receiving only supportive care [2]. Finally and importantly, enrolling in phase 1 studies should not necessarily preclude the possibility of a patient’s receiving symptom management or palliative care simultaneously [3].

Potential conflicts of goals

In the thin description of this case, there is little information about Dr. Lin, the oncologist, or the study that is being considered. Dr. Lin is probably the principal investigator of the clinical trial, and he may be encouraging, if not trying to persuade, Mr. Brooks to enroll. Dr. Lin may have more than one motivation for doing so: he may want to *both* help this patient *and* advance scientific knowledge. Some may consider having multiple motives a conflict of interest [4], but we do not. There are many circumstances in which individuals have more than one motivation for any particular action. As Mr. Brooks’ oncologist, Dr. Lin has an ethical duty to promote his patient’s best interests. As a researcher, he has an interest in promoting scientific advancement (and perhaps his career) by enrolling research subjects and overseeing the study. These two roles and sets of goals are not necessarily in conflict—depending on what is known already about the study drug, the possibility of benefit for Mr. Brooks and the moral integrity of Dr. Lin. More often than not, these two goals live in an ethically acceptable co-existence and tension [5, 6].

Mr. Brooks’ goals seem fairly evident. He does not seem to be in denial about the seriousness of his illness, but like many patients with advanced cancer he remains hopeful that modern medicine can still help him. In general, his goals seem to include a better quality of life through symptom management. He recounts that he has been feeling miserable and weary and unable to eat, all probably due to the progress of his colon cancer and the side effects of medications. In his own words, “I just want to feel better.” His goals at this time do not include helping future cancer patients.

Dr. Winston, in preparing to advise Mr. Brooks as his primary care physician, may have at least two sets of goals, one related to his patient and the other related to Dr. Lin. If Dr. Winston operates out of an “enhanced autonomy” model of the patient-physician relationship [7], he will be aiming to engage Mr. Brooks in a conversation that leads to an exchange of information and ideas, a clarification of Mr. Brooks’

values and goals, and a sharing of power and influence that serves Mr. Brooks' best interests. Regarding Dr. Lin, Dr. Winston may want to appear at least collegial by refraining from any frank expression of disagreement with Dr. Lin's recommendation, if indeed he has some hesitancy or disagreement with Dr. Lin's promotion of the phase 1 study.

Within the context of the above-noted actual and possibly conflicting goals, and that of an "enhanced autonomy" partnership and relationship with Mr. Brooks, how should Dr. Winston respond to his patient's assertion and question, "Joining the study sounds like a good idea, right?"

Answering the question

Dr. Winston should begin with assisting Mr. Brooks' understanding of the general processes of human research and the meaning of the different phases of research trials (i.e., phase 1, phase 2, etc.). Helpful resources would include the *Journal of the American Medical Association* Patient Pages titled, "Cancer Clinical Trials" [8], and "Participating in Medical Research Studies" [9]. A potentially relevant note from the "Cancer Trials" page, depending on Mr. Brooks' financial situation, is that, "Health insurance may not cover all the costs associated with participating in a clinical trial" [8]. Further, Dr. Winston should explain the role of palliative care and symptom management and encourage Mr. Brooks to ask Dr. Lin whether participants in the phase 1 study can use palliative care simultaneously. The *Journal of the American Medical Association* Patient Page on "Palliative Care" [10] may be helpful for this part of the conversation.

Dr. Winston should encourage Mr. Brooks to be a full and assertive participant in the informed consent process related to the phase 1 study, including asking any and all questions related to the study. Mr. Brooks should be counseled to read the informed consent form carefully, with special attention to the sections on information about the research and its risks and discomforts. For example, it would be relevant to Mr. Brooks' daily routine if he will need to travel to an academic center and spend a few hours each day over many days to receive an infusion of the experimental agent. Also, with the goal of making Mr. Brooks a better-informed potential research subject, it may be possible to find out if he would be among the very first patients to receive the phase 1 drug and whether he could talk to someone who has already participated in or completed the research study.

In the end, the decision to enroll in the phase 1 study must belong to Mr. Brooks, as he weighs a complex set of projected burdens, benefits and trade-offs. Nevertheless, Dr. Winston has an ethical responsibility to advise, counsel and inform his patient to the best of his ability. One of Dr. Winston's goals, as he answers his patient's question, is to help him avoid therapeutic misconception (conflating research with clinical care) and therapeutic mis-estimation (underestimating risk, overestimating benefit or both), while not interfering with Mr. Brooks' therapeutic optimism (hoping for the best personal outcome) [11]. Dr. Winston should not attempt to erode the trust that Mr. Brooks seems to have in Dr. Lin. The proper balance between

honesty and optimism in this case requires that Dr. Winston confront his dilemma and answer the simple question with a clear answer [12]. We believe that his answer should be: “It sounds like a good idea to me, and I hope it does help you. If it doesn’t, at least you will be helping others in the future.”

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Medical education

Teaching smoking cessation in U.S. medical schools: a long way to go

by Alan C. Geller, MPH, RN, and Catherine A. Powers, EdD, LSW

Cigarette smoking remains the leading cause of preventable morbidity and mortality in the United States [1]. Despite numerous educational campaigns and public knowledge of the devastating health effects, 45 million Americans—21 percent—continue to smoke [2]. More encouragingly, a large body of evidence supports the effectiveness of physician interventions [3]; in fact, smoking cessation is strongly recommended by the U.S. Preventive Services Task Force [4]. Past research had shown that physicians ineffectively counseled their patients to quit smoking, but recent studies have found that more physicians are getting better at practicing at least the first three of the “5A’s”—ask, advise and assess—though they continue to fall short on two—assisting and arranging follow-up [5]. Training physicians in smoking cessation techniques is essential to achieving the cancer control goals of the U.S. Department of Health and Human Services’ Healthy People 2010. Medical students, if skillfully trained in counseling adults, families and children, can be vital players in the effort to combat this great public health problem.

Two sentinel reports documented “missed opportunities” and inattention to tobacco dependence curricula in U.S. medical schools. Ferry et al. found in 1999 that 31 percent of schools averaged less than one hour of instruction per year in tobacco cessation [6], and Spangler et al. observed both instruction gaps and teaching methods that resulted in only short-term retention of intervention skills by students [7].

In response to the documented inadequacy of smoking cessation interventions, a subcommittee of the Interagency Committee on Smoking and Health published a National Action Plan for Tobacco Cessation that included a recommendation for investing “...in training and education by FY 2005 to ensure that all clinicians in the United States have the knowledge, skills and support systems necessary to help their patients quit tobacco use” [8]. The action plan specifically recommended that the U.S. Department of Health and Human Services “...convene a diverse group of experts to ensure that competency in tobacco dependence interventions is a core graduation requirement for all new physicians and other key health care professionals” [8].

New information

The National Cancer Institute funded a consortium of 12 U.S. medical schools

known as PACE: Prevention and Cessation Education in Medical Schools to develop, test and integrate tobacco curricula throughout the four years of medical school. In 2004, site investigators at each of the 12 schools conducted comprehensive assessments of their behavioral science and tobacco curricula. In contrast to the findings of Ferry and Spangler and their colleagues, many first-year and second-year courses contained tobacco information, and most clerkships, notably family medicine and internal medicine, provided skills and approaches that future physicians could use with patients who smoke [9]. Overall, PACE schools reported that 36 percent of medical school courses included information on tobacco and averaged about 10 hours of tobacco-related teaching over the four years [9]. One can only speculate that the momentous national anti-tobacco groundswell fueled by tobacco taxes, the national media campaign and partial reimbursements for tobacco counseling spilled into the once-resistant medical school curriculum. PACE researchers also developed competencies for graduating medical students [10].

Recent analysis of more than 1,600 second-year and fourth-year student responses from the PACE schools mirror many of the findings in a national curricular assessment [9]. Nearly half of the fourth-year students in the national sample reported receiving more than one teaching session on tobacco cessation via case-based discussion, a simulated patient encounter or a clinical skills course; nevertheless, more than 80 percent of fourth-year students felt that there was not enough cessation information in their courses [11]. Students whose intended career was primary care had self-reported skill levels similar to those choosing a specialty, and students who had never smoked had skill levels similar to those who had smoked for at least three years. Students reported receiving instruction for assisting patients with smoking cessation in family medicine (80 percent) and internal medicine (70 percent) clerkships but far less so during clerkships in pediatrics (54 percent), ob/gyn (41 percent) and surgery (16 percent). Not surprisingly, curriculum assessments of surgery, pediatric and ob/gyn clerkships found the student's reporting to be largely accurate [9].

Like the physician data cited earlier, student rates were high when it came to asking patients about (94 percent), advising patients (82 percent) and making assessments of patient smoking habits (75 percent). But opportunities to assist with a cessation plan (30 percent) and to arrange follow-up (21 percent) were noticeably lower. In many routine settings, the chance to practice cessation-assisting techniques was still low. Only a minority of students had ever provided a hospitalized patient who wanted to quit smoking with a referral, and most students had not seen reminders such as chart stickers, checklists or new vital sign measures that include smoking status to prompt them to motivate patients not to smoke [11].

Some next steps

Curricula must be reformed in at least two connected ways. First, students and academic leaders should work together to weave a new tobacco curriculum into existing courses and modules, as has been done for substance abuse or behavioral counseling and interviewing techniques. The explosion of new scientific information

coupled with the breadth of professional responsibility creates constant demands and challenges to the already-packed medical school schedule. An underlying assumption of this approach is that tobacco control objectives can best be achieved if they are integrated with and complementary to learning objectives in the core curriculum. Training in smoking cessation and prevention counseling encompasses skills that are important to all aspects of care, such as: (1) communicating effectively; (2) obtaining full patient histories; (3) counseling in behavior change and motivational techniques; (4) advising patients of treatment options; (5) negotiating and sharing decision making; (6) educating patients and families; (7) working as part of a health care team; and (8) identifying factors that place individuals at risk for disease.

Second, it is equally, if not more, important that education for physicians and physicians-in-training attack longstanding attitudes and misconceptions. Our study of students at the PACE schools found that fourth-year students had more negative attitudes about their ability to impact patient smoking behaviors than second-year students [11]. Consequently, the benefits of tobacco cessation counseling should be intertwined into all core curricula. Training for physicians and medical students should center on the following motivational points:

Many patients are quitting. For the first time ever, the proportion of U.S. adults who have successfully quit smoking surpasses the proportion of those who continue to smoke—more than 46 million quitters compared to 45 million current smokers [12].

Clinical interventions can be remarkably successful. Only three to five percent of smokers can quit on their own, but guideline-driven interventions can boost cessation rates to 15 percent to 25 percent, translating into millions of new ex-smokers each year.

Patients expect their physicians to counsel them about smoking. Eighty percent of smokers report that they want to quit and more than 70 percent of smokers see a physician each year [13].

Tobacco dependence is a chronic condition that often requires repeated interventions. Tobacco dependence requires perseverance on the part of the physician, student and patient alike. Nonjudgmental persuasiveness coupled with full utilization of the 5A schema can accelerate patient interest in treatments for smoking cessation and subsequent successful quitting strategies.

Medical students and medical student organizations can effect change. These groups have the power to create their own tidal wave for tobacco counseling. In clerkships such as ob/gyn, where patients are in desperate need of encouragement and motivation to prevent an all-too-common relapse, 16,000 U.S. medical students intervening with at least one

obstetric and one gynecologic patient could have profound impact on the lives of not only the patients but the families as well. In response to the scarcity of curriculum in ob/gyn and pediatric settings, PACE investigators have developed new modules for tobacco education in these clerkships. Likewise, the adults in 25 percent of U.S. households who continue to smoke in front of their children could benefit greatly from student counseling and guidance.

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Journal discussion

Connecting inadequate health insurance to poorer cancer treatment outcomes

by Allison Grady

McDavid K, Tucker TC, Sloggett A, Coleman MP. Cancer survival in Kentucky and health insurance coverage. *Arch Intern Med.* 2003;163:2135-2145.

The high cost of cancer treatment is well known. Also well known is the fact that the costs increase—while the likelihood for treatment success decreases—as the disease progresses. It has been hypothesized that individuals with adequate health insurance—usually defined as employer-provided—have a greater chance of being diagnosed with cancer at an earlier stage because they have more ready access to preventive services and screening tests and have a lighter financial burden when seeking treatment [1].

In 2003 Kathleen McDavid and colleagues published research in the *Annals of Internal Medicine* that had studied whether type of health insurance played a significant role in a patient's chances for survival after cancer diagnosis. The article, "Cancer Survival in Kentucky and Health Insurance Coverage," used the Kentucky Cancer Registry (KCR) as a data source [2]. This study, while similar to others [3], distinguishes itself because "most cancer survival studies did not use individual level health insurance data collected by the cancer registry, control for treatment, or examine as many sites" [4].

The study

Kentucky requires that all health care facilities and doctors "report new cancer cases to the KCR within four months of diagnosis" [4]. The KCR works collaboratively with the death clearance registry (that matches KCR files with the state death records) to locate

cancer patients who have not been identified and registered through the health care system, and it allows the registry to update vital status information on those who have been registered. Vital status is also updated by regular contact with reporting hospitals, private pathology laboratories, freestanding treatment facilities and physician offices [4].

McDavid and colleagues collected information on patients between the ages of 18 and 99 who had diagnoses of female breast, prostate, colorectal or lung cancer.

Subjects of this inquiry had been diagnosed between 1995 and 1998 and followed for at least one year. Patients were then classified by the type of cancer they had, the stage at diagnosis (local, regional, distant, unknown/unstaged), the first-course treatment—that is, treatment received during the initial four months following diagnosis—and type of insurance that the patient had at the time of diagnosis. Insurance status was classified into one of seven categories: private, Medicare plus a supplemental insurance, Medicare only, other federal source (e.g., Veteran’s Administration), Medicaid/welfare, uninsured (this included self-pay and charity care) and unknown [4].

McDavid and colleagues’ findings were characterized by health insurance, cancer site, relative survival by age and sex, crude and relative survival by type of insurance, and relative risk of death within three years by type of cancer [5]. The study found that the age group most represented for each cancer site was 65-74 years, but breast cancer had similar incidence numbers for patients aged 45-54 and 55-65 [6]. Breast cancer and prostate cancers were the most likely to be found while the disease was still local, whereas only 20.8 percent of lung cancer and 34.8 percent of colorectal cancer were found that early. In the study, the Medicare-plus-supplement was the most frequently cited type of insurance for all cancers studied except for breast cancer where private insurance ranked highest. This is probably because of the large proportion of participants in the 65-74-year-old age range who are Medicare eligible and the high number of breast cancer patients who were under 65 and not Medicare eligible [6]. An interesting demographic statistic was noted by McDavid and colleagues who found that even though only 6.5 percent of all study participants were African American, they accounted for 11.6 percent of members in the “other federally funded” insurance category and 10.3 percent of the Medicaid/welfare insurance group [6].

The role of insurance was particularly revealing when comparing disease stage at the time of diagnosis. Of those diagnosed with distant, advanced stage cancer, 31.4 percent were uninsured and 31.2 percent were on Medicaid. Type of insurance seemed to be most influential for patients with breast, prostate and colorectal cancer. McDavid writes, “patients with Medicare had a 32% higher risk [of death] than those privately insured, while those with Medicaid/welfare had a 56% higher risk and those with unknown coverage a 66% greater risk of death” [7]. For breast cancer, the privately insured were the most likely to survive three years while “women insured by Medicaid/welfare were at 66% higher risk of death than women who were privately insured” [7]. Prostate cancer figures also bore out the important role that insurance plays. McDavid et al. observe, “Men in the Medicaid/welfare and unknown insurance groups had elevated risks of death within 3 years of diagnosis compared with men privately insured” [7].

Overall McDavid and colleagues found that “colorectal, prostate, and breast cancer had similar patterns of survival by insurance category. Patients insured privately or by Medicare, Medicare plus supplement, or other federally funded [sources] had relatively better survival compared with patients in the other insurance categories”

[8]. For those with lung cancer, private insurance was even more significant. The relative one-year survival rate for a patient with private insurance was 49.7 percent but there was less than a 40 percent one-year survival rate for those in every other insurance category except Medicaid [9].

Discussion

McDavid and colleagues have presented compelling evidence to affirm that private insurance coverage is associated with optimal outcomes but that any form of insurance is better than no insurance. This conclusion is supported by the success rates of privately insured women with breast cancer whose 3-year survival was 90.6 percent compared to 57.5 percent for those with unknown insurance [8]. It is worth noting, however, that of those in the unknown insurance type category, nearly three-fourths of participants did not receive treatment [8]. The findings also seem to suggest that screenings and preventive services are lacking for those who are uninsured or insured by Medicaid, based on the fact that the percentage of those diagnosed at late stages of disease was nearly 14 points higher among those with Medicaid or no insurance than among the privately insured [6].

Regrettably this research did not control for socioeconomic status but relied on type of insurance as a proxy for income level. This may not accurately capture the socioeconomic picture, given the hyperspecific qualifying criteria for many of these programs and the rising cost of private health insurance that has forced many with middle-class incomes to forgo coverage. Further, as in similar studies, the racial breakdown was simply black or white, thus limiting the scope of the study. It might be worthwhile to compare survival rates and diagnosis patterns based on finer ethnic distinctions, given the known disparities in health care among members of various ethnic groups. Although the authors of this study used a wide range of insurance types, the “unknown” category still presents a challenge because, while this group almost always fares the worst of the seven, it cannot be determined what effect this population’s insurance status data would have on the study’s findings.

Finally, an obvious limitation of the study is its non-transferability. All of the data collected was specific to one state— Kentucky—and some of its demographics, including the percentage of the uninsured (3 percent) and the socioeconomic status of the state (Kentucky is the sixth poorest state in the U.S.), set it apart from much of the country [10]. Further, few states keep records as detailed and up-to-date as the KCR does. The amount of time, money and staff needed to create either a similar nationwide registry or one for each individual state would be high and perhaps, impractical.

Overall the Kentucky study is valuable because it demonstrates a long-held, but largely anecdotal, notion that lack of adequate insurance results in worse outcomes for patients.

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Clinical pearl

Development of the human papillomavirus vaccine and guidelines for its use

by Amy L. Jonson, MD

Background

Cervical cancer is an international problem. Worldwide, more than 500,000 women are diagnosed with cervical cancer each year. By the end of 2006, 10,000 new cases will be diagnosed and nearly 4,000 women will die of cervical cancer in the United States alone.

Epidemiologic studies published in 1999 determined that 99.7 percent of cervical carcinomas expressed DNA from the human papillomavirus (HPV) [1]. HPV is a circular double-stranded DNA virus that infects both cutaneous and mucosal epithelia. More than 100 HPV genotypes have been identified and categorized as either high-risk or low-risk relative to their association with the development of anogenital carcinoma. Human papillomavirus is the most common sexually transmitted disease in the United States; over the span of a lifetime, women and men have an 80-percent chance of being infected. The high-risk subtypes, HPV-16 and HPV-18, are believed to account for 70 percent of all cervical cancers, 50 to 60 percent of moderate to severe dysplasia (CIN II-III) and 25 percent of mild dysplasia (CIN I). Subtypes HPV-6 and HPV-11 are low-risk and account for 90 percent of genital warts (*condyloma acuminata*) and 10 percent of mild dysplasia.

Introduction of the Pap test in 1928 resulted in a dramatic reduction in the incidence of cervical cancer in the U.S. Despite the effectiveness of this screening modality, however, the incidence of cervical cancer has reached a plateau and is no longer declining. The newest approach in cervical cancer prevention is not a new screening technique but the prevention of the HPV infection through a vaccine. The primary public health goals of the HPV vaccine are to reduce the incidence of HPV-related dysplasia (CIN I, II and III) and cervical cancer.

Vaccine development

The HPV vaccine is composed of self-assembled virus-like particles (VLPs) that form when a specific HPV protein is produced by microbial organisms through a fermentation process. These VLPs closely resemble native HPV particles and act as the antigen that evokes the production of HPV-neutralizing antibodies in the human body. The vaccine does not contain DNA and is therefore considered to be noninfectious. Nor does the vaccine contain RNA, mercury, antibiotics or egg products.

To date, there are two primary vaccines developed against the human papillomavirus. Gardasil, developed by Merck, is the only current Food and Drug Administration (FDA)-approved vaccine [2]. It is a quadrivalent recombinant vaccine that spurs production of antibodies against HPV subtypes 6, 11, 16 and 18. The efficacy of Gardasil was established in four placebo-controlled, double-blind, randomized phase 2 and 3 clinical trials [2-4]. A bivalent vaccine known as Cervarix designed to be effective against HPV-16 and HPV-18 has been produced by GlaxoSmithKline and is awaiting FDA approval.

Administration

The federal Advisory Committee on Immunization Practices (ACIP), the American College of Obstetricians and Gynecologists (ACOG), and the Society of Gynecologic Oncologists (SGO) have all issued formal recommendations favoring vaccination against HPV [5, 6]. The vaccine should be offered to all women aged 9-26 years. Vaccination requires three separate intramuscular injections given on day 1, month 2 and month 6. The vaccine is most effective when administered prior to the onset of sexual activity, but should also be given to women who have a history of abnormal Pap test results, cervical dysplasia, genital warts or positive test results for high-risk HPV. It is believed that these women can benefit from protection against subtypes other than those by which they have been previously infected. Although the vaccine's efficacy has not yet been formally established in immunocompromised patients, both ACOG and SGO state that this population should not be excluded from receiving the vaccine and that it should be offered to immunocompromised women in the 9-26 age range.

The HPV vaccine has been categorized by the FDA as category B in its pregnancy risk classification, meaning that there is not enough information about it to determine whether it poses a risk to the fetus. Until more is known, the vaccine should not be administered to women who know they are pregnant. If a dose is given during pregnancy, the remaining dose(s) should not be administered until after delivery. Vaccination during lactation, however, is considered safe and appropriate.

Post-vaccination surveillance

It is imperative that clinicians educate patients about the HPV vaccine. The vaccine is not intended as a treatment for pre-existing HPV infection or HPV-related disease. Neither of the currently developed vaccines protects against all subtypes of the virus. It is estimated that 30 percent of cervical cancers are due to infections with other, non-HPV-16 or HPV-18 high-risk subtypes. Furthermore, vaccination does not negate the need for screening. The current consensus guidelines recommend initiating screening within 3 years of first sexual intercourse or by age 21. Women under 30 should have Pap tests every 1-2 years, and women 30 years or older should have the test every 2-3 years as long as there is no cytologic abnormality and high-risk HPV is not identified. The guidelines should be followed regardless of the woman's vaccination status.

The future of the HPV vaccine

Vaccination against the human papillomavirus is an exciting advancement in the war against cancer. This achievement deserves great respect, but it should be approached with thoughtful acknowledgment of the many questions still unanswered [5, 7]. One of the larger unknowns is the length of time that the HPV vaccine provides protection against the target subtypes. It may or may not be necessary to administer booster doses of the vaccine throughout a woman's lifetime. The regional and global impact of the vaccine has yet to be determined. The true efficacy of the vaccine is going to be limited by barriers such as cost, access and compliance—the same factors that have impeded the success of cervical cancer screening. Other challenges that remain include determining the utility of the vaccine in immunocompromised patients and its efficacy in men or in women over the age of 26.

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Health law

Experimental breast cancer treatments and health insurance coverage

by Lee Black, LLM

The only way that most people can afford medical treatment today is through health insurance. Aside from basic preventive care, and except for very wealthy people, the expense of care for major illnesses requires a third party to step in. Health insurance provides the benefit of paying for medical services that most people could otherwise not afford, but there are risks in assuming that having health insurance is the answer to all medical expenses.

Insurance contracts are complex documents, and most people do not read or fully understand them before signing away certain rights and remedies that may later be necessary to avoid either crippling debt or the inability to obtain proper care. When employers provide insurance coverage, the employee often does not automatically receive a copy of the health plan, within which there are usually exclusions of coverage. For example, many plans do not cover treatment for pre-existing illnesses and experimental or investigational treatments. Exclusions for experimental treatments are especially troublesome. The insured person, confident that all illnesses will be covered, may discover only after diagnosis that, while his or her illness is covered, all treatments for that illness are not.

Beginning in the 1990s breast cancer treatment, specifically high dose chemotherapy (HDC), peripheral stem cell rescue (PSCR) and autologous bone marrow transplant (ABMT), became a legal battleground for the fight over how and when the experimental or investigational exclusion clause could be applied. The problem usually arises when an insurer is asked to pre-authorize treatment and denies the request. The dispute ends up in court after the insured patient unsuccessfully appeals the decision to the insurance company, believing that the company was erroneous in its determination that the recommended treatment was experimental. Because of the expected devastating outcome if the patient does not obtain treatment and potentially unsatisfactory alternatives if insurance does not cover the sought-after therapy, these cases bring much emotion to the courtroom.

Insurance provisions for experimental treatment

The variety among insurance contract provisions relating to coverage of experimental treatments is astounding. They range from very sparse language which offers little insight into what an insurer considers experimental to very detailed provisions. In general, the less detailed the language, the better the outcome for the

patient who challenges a denial. This formula, however, is by no means foolproof. In some instances, even a definition of experimental that seems to allow for flexibility can be viewed by a court as sufficiently precise to preclude a challenge by the patient.

The following examples of contract language describing coverage for experimental treatment come from legal cases where the denial of coverage for breast cancer treatment was challenged.

1. “‘Experimental’ means those procedures and/or treatments which are not generally accepted by the medical community...” [1].
2. “[C]harges for treatment or service that (are) determined by the Plan Administrator to be experimental, investigational, unnecessary, and/or inappropriate for the condition, even if prescribed and/or ordered by a Doctor’ are excluded from coverage” [2].
3. “...Services...are Medically Necessary if they are...commonly and usually noted throughout the medical field as proper to treat the diagnosed condition, disease, Injury, or Illness...” [3].
4. “A drug, device or medical treatment or procedure is Experimental...if Reliable Evidence shows that the drug, device or medical treatment or procedure is the subject of ongoing Phase I, II, or III clinical trials or under study to determine its maximum tolerated dose, its toxicity, its safety, its efficacy, or its efficacy as compared with the standard means of treatment or diagnosis...” [4].

The last example above is most specific as to what is considered experimental; the second and third are more vague and do not provide a definition of “experimental” that would aid an insured patient in determining what is covered. Herein lies the difficulty for HDC, PSCR and ABMT: especially in the 1990s, these medical procedures were given inconsistent treatment by judicial circuits.

In most cases, the terms of the insurance contract played a larger role in judicial decision making than medical opinion, a fact that had considerable consequence because parties generally interpret contracts in ways that are consistent with their own best interests. For insurance companies, best interests meant denial of a claim (although a poorly reasoned denial could more easily lead to liability). Patients, on the other hand, have an interest in treatment, so experimental procedures were quickly interpreted as “accepted by the medical community” as soon as they had received a few endorsements.

Experimental procedures in the courts

A wealth of cases examined experimental exclusion clauses in insurance contracts. The variety of bases for denial make it nearly impossible to apply one or even a few court decisions to the whole category. The cases discussed here have a few things in common: a patient and his or her physician believed that the proposed treatment was the best option for the patient, and the insurance company denied coverage on the

grounds that the treatment was experimental and therefore excluded or that other language in the contract exempted the treatment from coverage.

In *Lewis v. Trustmark Insurance Company*, the contract contained the least ambiguous definition of “experimental” in that it explicitly included clinical trials and studies as bases for exclusion. There was sufficient evidence to demonstrate that the proposed treatment fell into this definition, since numerous trials and studies were being performed on its safety and efficacy at the time [5]. With these facts before it, the court determined that the insurer was justified in denying coverage for HDC/PSCR.

At the opposite end of the ambiguity spectrum is *Reed v. Wal-Mart*. In this case the patient was diagnosed with stage II disease with cancer cells found in six lymph nodes. The insurer denied coverage, claiming it only covered HDC, PSCR or ABMT when 10 or more lymph nodes tested positive for malignancy; hence, the patient’s diagnosis meant the proposed treatment was experimental. The court found that the medical literature at the time, as well as the expert testimony at trial, did not establish sufficient justification for differentiating between six nodes and 10. Additionally, the experimental exception contract was deemed ambiguous, and unclear contract language is considered to be the fault of the drafter, in this case, the insurer. Strangely, some of the insurer’s expert witnesses testified that “experimental” had not been defined by the insurer, and these witnesses defined the term differently from each other. With the medical information available and the ambiguity in contract provisions, the court found for and granted judgment to the patient.

A final case with an unpredictable outcome is *Healthcare America Plans v. Bossemeyer*. The health plan language at issue in this case revolved around the ambiguous phrase “not generally accepted by the medical community” [6]. Both parties to the lawsuit submitted expert opinions, testimony and medical literature to support their respective arguments. Although the court upheld the insurer’s decision that the treatment was experimental, the evidence presented showed that there was significant opinion in medicine that the procedure, HDC/PSCR, was generally accepted. The fact that there were still trials to determine efficacy, especially between the proposed and other treatments, did not change the judgment of many physicians that the “experimental” option was the best available.

The court decided that because the contract gave the plan administrator the authority to use discretion over what was considered experimental, the phrase “not generally accepted by the medical community” was unambiguous. Even if the language was itself vague, the plan administrator’s discretionary authority meant that the contract did not meet the “arbitrary and capricious,” standard generally required for decisions in the patient’s favor. Since the administrator made decisions based on some information that the procedure was still experimental, the administrator was deemed justified in denying coverage.

Conclusion

Physicians can find it difficult to determine what is considered “experimental” and to plan patient care around the insurance uncertainties that they and their patients face. Clearly, there may be differences of opinion on what treatments are generally accepted and necessary, and insurance contracts have not always addressed or defined exclusions well enough to meet legal standards. Yet, even when courts find that health insurance contracts are sufficiently well-defined, patients and physicians still may not know what is covered and what is not.

Promising treatments that are still being investigated may be particularly helpful to certain patients. As the examples of high dose chemotherapy, autologous bone marrow transplant and peripheral stem cell recovery show, treatments that many physicians believe are appropriate, safe and efficacious may not meet the requirements of insurance contracts. Although these contracts may not intend to cheat patients out of necessary care, they are often perceived to do just that. Physicians should fight for what they believe is best for their patients. But it will not be easy. Once an insurer judges a treatment to be in the experimental, investigative or study stage, physicians will have an uphill battle. One thing that has not changed in the years since most of these court cases were decided is that the fundamental interests of physicians and insurers are at odds as often as not.

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Policy forum

Setting fair prices for life-saving drugs

by Bruce A. Chabner, MD, and Thomas G. Roberts Jr., MD, MSocSci

Cancer drugs are big business. Worldwide sales are projected to reach \$25 billion in 2006 and to increase to almost \$50 billion by 2010 [1]. This represents a startling growth in a segment of the drug industry once shunned by major pharmaceutical manufacturers as too high-risk and unprofitable. While a few drug companies, notably Bristol-Myers Squibb (BMS) and Pharmatalia, made significant profits on cancer drugs between 1970 and 1990 when the first effective combination therapies came into common practice, the turning point in this industrial segment occurred in 1992 with the approval of Bristol-Myers Squibb's paclitaxel, which became a multibillion-dollar-per-year product by 1998.

To understand our current concerns with cancer drug costs and their potential effect on medical care financing and access, one needs to be familiar with the paclitaxel experience. The story of paclitaxel's discovery and commercial development reflects both the lack of interest that industry had in cancer drugs at that time and the sudden emergence of drug cost as a social justice issue.

In 1964 Monroe Wall and associates, working at the Research Triangle Institute under a National Cancer Institute (NCI) contract, isolated the active compound in paclitaxel from the bark of the common yew tree [2]. Its tortuous development, complicated by difficulties in material procurement, compound purification and formulation, delayed its entry into clinical trials until 1983, and its efficacy in treating ovarian cancer was not demonstrated until 1987 [3]. Because of the need to procure large amounts of plant material for its isolation and the tendency of the necessary solvent (Cremophor EL) to cause hypersensitivity reactions, there was little commercial interest in the compound. When NCI announced an open competition for clinical development of the compound in 1990, only four companies responded. Two of the applicants were small firms, unprepared for the task of drug production and clinical development. A third was a foreign company that already held rights to a competitor compound in the same class. BMS was the only major U.S. company to apply for the development rights and won the contract in 1991. Shortly thereafter, the drug's effectiveness against breast cancer became apparent, and it emerged as a blockbuster.

Congressional involvement

Pricing of the drug immediately became a concern for the U.S. Congress [4].

Because it had been discovered and developed under government contracts with the NCI, members of Congress scrutinized the price set by BMS. The NCI had urged BMS to set a price consistent with that of competitive compounds in the field of ovarian cancer. NCI directors believed that the production costs, limited range of uses and novelty of the compound justified a cost per treatment of approximately \$2,000, and the BMS price was consistent with this target price. NCI also wanted to assure that patients could get the drug regardless of their insurance status, a concern to which BMS responded by setting up a program of free distribution to indigent patients. But members of Congress castigated BMS at open hearings, pointing out the government's key role in the drug's discovery and deploring the profit BMS was making. An unstated, but recurring theme in these hearings was the plight of cancer patients who had no choice but to pay or seek insurer reimbursement for this uniquely effective medication. Even though the drug was shown to confer a survival advantage in multiple forms of cancer, most notably breast and ovarian, some countries, including those in the United Kingdom, refused to grant approval based on a cost-benefit analysis. Parenthetically, the U.K. National Health Service continues to deny use of other expensive new drugs, such as bortezomib, on the same basis.

During this tumultuous period of paclitaxel marketing, when the U.S. Congress and the public first directly confronted the pharmaceutical industry over the cost of life-saving cancer drugs, it became apparent that the public had no other option but to pay the price. Federally mandated price controls were openly discussed at Senate hearings, but rejected as impractical (what is a fair price?) and potentially fatal to the rapidly growing biotechnology industry. No one—neither physicians nor the patients in need—could place an appropriate dollar value on the worth of one year of human life [5].

Challenges for pricing drugs in the 21st century

The paclitaxel experience set the stage for the dilemma of cancer drug pricing that is now playing out on a much larger scale. Since the mid-1990s the biotechnology industry has made major contributions to cancer treatment with targeted therapies—agents that have specific molecular targets and which, alone, are not toxic to cells at standard doses. (Traditional chemotherapy agents are cytotoxins that cause cell death at standard doses.) Targeted therapies include monoclonal antibodies such as bevacizumab (Avastin) and trastuzumab (Herceptin) from Genentech; selective small molecule tyrosine kinase inhibitors such as erlotinib (Tarceva) from OSI pharmaceuticals/Genentech Inc.; and multi-targeted kinase inhibitors such as sorafenib (Nexavar; Onyx Pharmaceuticals/Bayer AG) and sunitinib (Sutent; Pfizer Inc.). The antibodies have achieved annual sales in excess of \$1 billion each, and their potential for further expansion seems unlimited (figure 1).

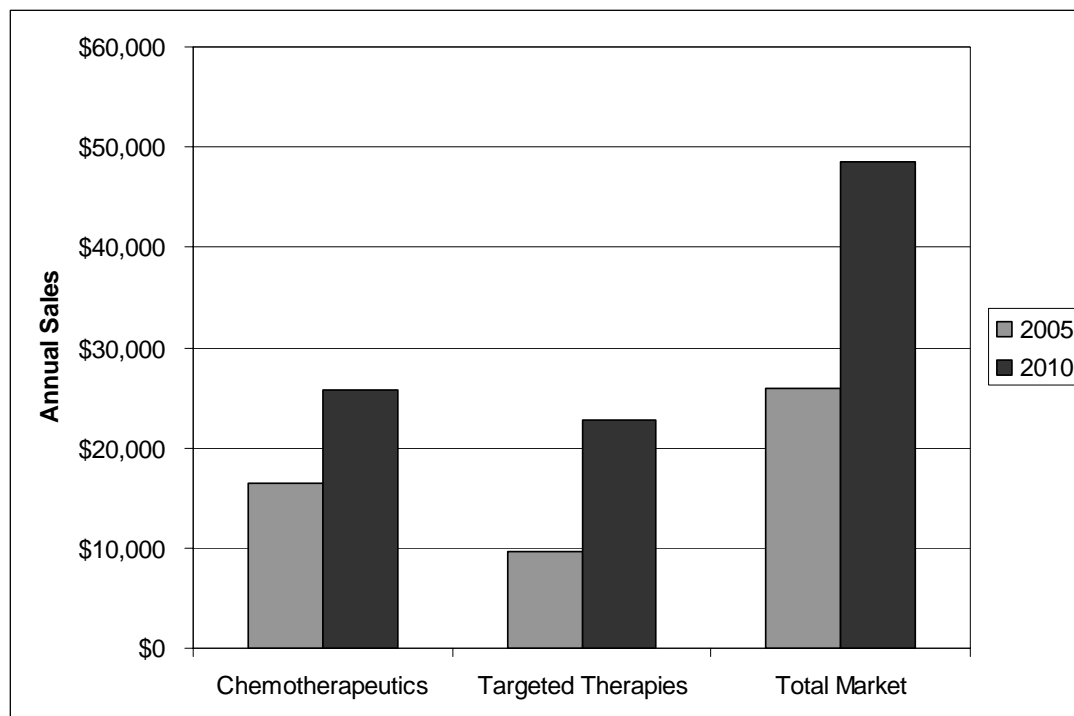


Figure 1. Estimated Worldwide Market for Oncology Drugs by Class (in millions) in 2005 and 2010 (Data are from S.G. Cowen and Company; Reference 1).

The cost of these medications ranges from approximately \$3,000 per treatment cycle for the small molecules to \$7,000-\$10,000 per treatment cycle for the antibodies [6]. One antibody in particular, cetuximab (Erbix; Imclone Systems Inc/BMS), an EGFR (epidermal growth factor receptor) inhibitor indicated for treatment of colorectal and head and neck cancer, has attracted significant publicity because of its high cost and low response rates. While each of the companies has established mechanisms that provide assistance for uninsured or indigent patients, the high cost of these new medications has attracted considerable attention in the medical and lay press [7]. How can it be justified?

The risk-reward ratio for companies engaged in cancer drug discovery and development remains unfavorable. The cost begins with a major investment in basic research, often heavily supplemented by NCI and other grants, followed by extensive preclinical evaluations and clinical trials involving hundreds of patients and many years of effort. If one takes into account the expenses associated with failed drugs, the industry spends approximately \$1 billion for each compound that reaches the market [8]. Obviously, for the individual successful compound and its company, the cost is significantly less, but there is no doubt that this is not an industry for the faint-hearted or for those with shallow pockets. No more than 7 percent of cancer compounds that enter clinical trials end up reaching the market.

While several hundred biotech companies are now engaged in cancer drug discovery and development, the number of new drugs approved each year remains in the single digits, and most companies ultimately fail to earn a profit. Certain classes of

promising compounds, such as vaccines and cell cycle inhibitors, in which multiple companies have invested hugely, have not yet produced a single approved drug. Recent public and congressional concerns about the need for post-marketing surveillance to ensure safety would further increase the cost of drug development.

Pretrial systems for predicting clinical success, based on mouse models of human disease or human tumor cell lines, have largely failed. When breakthrough drugs such as imatinib (Gleevec; Novartis AG) for chronic myelogenous leukemia do succeed, their period of uniqueness is often brief, as competitors quickly produce new and perhaps better drugs, such as dasatinib (Sprycel; BMS), for the same target illness [9]. And, finally, the period of patent protection, typically 20 years from the time of patent filing, is too brief, considering the time—10 years on average—spent in development and the fact that the pharmaceutical industry must reinvest up to 30 percent of its profits in new drug research.

Forces that may reduce the cost of cancer drugs

While talk of price controls continues in Congress, other factors are likely to mitigate pricing. The first is competition. A new antibody, panitumumab (Vectibix; Amgen Inc.), an effective EGFR inhibitor, has entered the market in competition with cetuximab (Erbix) and costs less. A number of small molecules are in the late stage of development and are being groomed to compete with the most expensive drugs, namely the monoclonal antibodies. There are differences between the antibodies and their small molecule competitors (e.g., site of action, target access, pharmacokinetics, etc.), so a lot of comparative development remains to be done. Nonetheless, the small compounds, traditionally priced below the antibodies, will, if approved, most likely drive down the cost of cancer care. Orally administered small molecules have the additional attractive feature of not requiring a hospital visit and thus obviate the cost of intravenous infusion, a major economic benefit for the health care system. As prescription drugs, however, they are not always covered completely by the insurance of those who need them; that is, they can fall into Medicare's proverbial "donut hole" of noncoverage.

A second force for reducing the cost of care will be improvements in patient selection for therapy. With few exceptions, cancer drugs are presently used in settings in which only a fraction of patients will benefit. Cetuximab, which is among the most costly antibodies, produces responses in 10-15 percent of patients with chemotherapy-resistant colorectal cancer. It may benefit a larger subset of patients when given in combination with irinotecan, but there is no test currently available to identify the responsive subset of patients.

Through the use of molecular diagnostics (biomarkers), it may be possible to improve the response rates and eliminate the needless expense of "shotgun" therapy. Examples of successful patient selection include the use of imatinib in chronic myelogenous leukemia (CML), in which all patients have tumors with translocations involving the same gene. Further, CML patients who develop resistance to imatinib harbor further mutations, most of which are sensitive to dasatinib [9]. Molecular

analysis clearly has a role in creating a treatment plan for these resistant patients. The experience with EGFR inhibitors such as erlotinib and gefitinib has yielded a strong correlation between receptor mutations and responsiveness, a relationship that could lead to up-front or adjuvant use of these drugs in selected patients [10].

The NCI and Food and Drug Administration (FDA) have jointly endorsed the development of biomarkers for drug selection in cancer and have outlined an ambitious research effort. At the same time, however, the FDA is tightening its oversight of “home brew” diagnostic tests, asking for stronger prospective validation of assays. In the past, reimbursement for these tests was determined by the regional Medicare carrier and by individual insurers. Depending on the standard to which these tests will be held, the development of molecular diagnostics for cancer could encounter significant regulatory delays in the future.

Finally, the government possesses a strong weapon in bargaining for lower prices of cancer drugs. It is a major purchaser of pharmaceuticals through the Veterans Administration system and sets reimbursement rates for medical procedures and services in the Medicare program. Congress is threatening to become more involved in issues of drug pricing, using its bully pulpit—congressional hearings—to expose excessive profits. Through legislative action, it could ask for a cost-benefit analysis as part of Medicare reimbursement policy and could extend patent life as a reward for corporate programs that expand free access to drugs, ensuring that all patients will benefit from the federally funded research that underlies virtually all of these new discoveries.

In conclusion, the high cost of cancer drugs tests corporate responsiveness to public needs, while challenging scientific innovation and the potential of the competitive marketplace to control prices. The federal government will surely exercise indirect influence over pricing through its ability to expose the issue in congressional hearings and through the multiple points of intersection of the executive branch and industry. Meanwhile scientific progress is driving the cost of cancer care ever upward. This progress is saving lives, but there have to be limits. At this point, no one has a clear idea what these limits might be.

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Policy forum

Is it ethical to send patients to low-volume hospitals for cancer surgery?

by Timothy M. Pawlik, MD, MPH, and Kenneth K. Tanabe, MD

Over the last decade, multiple studies have concluded that cancer patients may have better outcomes if their surgery is performed in high-volume rather than low-volume hospitals [1-6]. These findings have generated great interest in volume-outcome studies, not only in the medical literature but in the lay press. Specifically, patients frequently seek practical medical advice about how they should interpret volume-related data and whether they should seek care in high-volume centers. Appealing to hospital-based volume data, physicians sometimes think they have an ethical obligation to refer cancer patients to high-volume centers. In discerning whether such an obligation exists, one must understand both the hospital volume data and the related ethical issues.

Understanding volume data

Volume-outcome relationships constitute one measure by which an institution may be judged, but statistics generated by aggregating data from numerous centers are not informative about a specific institution. Outcomes measured for specific institutions are superior in value and appropriateness of application. Thus if a low-volume center demonstrates excellent outcomes, these data clearly trump simple volume data pertaining to the center. A large caseload is not necessarily indicative of optimal treatments or outcomes [7]; individual high-volume centers may have worse outcomes because they treat higher risk cases and, if they are teaching hospitals, more indigent patients. Small-volume hospitals may still provide excellent care and achieve excellent outcomes [8].

Most volume-related data are not surgeon-specific. This is a critical shortcoming, since the predicted outcomes for some procedures (e.g., hernia repair) are highly surgeon-dependent while predicted outcomes for others (e.g., renal transplantation) are highly hospital-dependent. Furthermore, most current data include outcome information only on patients who underwent surgery. Judgment, clinical expertise, experience and wisdom go into deciding which patients should and should not have surgery; this critical aspect of clinical decision making is not captured in surgery-based volume-outcome studies. Finally, the majority of volume-outcome data with the notable exception of cardiac surgery is not risk-adjusted, so volume-related data may reflect a select patient population—rather than true improved quality—at high volume centers.

Volume-related studies also have inherent statistical problems that can result in misleading conclusions and overly strong suggestions of association. For example, the standard deviation applicable to a single center's outcome data is dependent on its patient volume. Hence, the predicted outcome of a single low-volume center based on its own data will be associated with a greater standard deviation (e.g., variability) than that of a single higher-volume center. This higher standard deviation is often misinterpreted as “less certainty” or “more unpredictable”—terms with negative connotations.

A second statistical problem involves the potential clustering of patients within physician practices [9]. In other words, a few unusually outstanding physicians might achieve higher-than-mode-predicted outcomes that exaggerate the estimated difference in performance between “typical” high-volume and low-volume hospitals [9].

Ethical considerations

Information on volume and outcome specifically following cancer surgery are derived from large administrative data sets designed to answer policy questions—not provide individual patient recommendations. In fact, it is estimated that the average gain from being treated at a high-volume versus low-volume hospital is actually quite small for the individual patient; rather, most volume-related benefits are realized at the population level [5]. Therefore, the ethical duty of physicians to refer a *specific* patient to a high-volume center for fear of a worse outcome at a low-volume center cannot be directly derived from the data. When a physician is balancing benefits and burdens, the relative improvement in outcome at a high-volume center must be weighed against the additional burdens of having to obtain care in that facility.

The term “outcome” should be carefully scrutinized and defined by the physician and, more importantly, by the patient. One person may decide that surviving the surgery is the most important outcome on which to base a decision, while another may reasonably conclude that cancer-free survival is most important. Others may consider results of satisfaction surveys or long-standing relationships with community medical personnel in their decision making.

Every individual will bring a different set of values to bear on the decision and will weigh pieces of data differently. The calculus of benefit versus burden therefore needs to be interpreted within the context of a specific clinical situation. We know, for example, that the benefits of high-volume centers are more pronounced with some operations (hepatectomy, pancreatectomy and esophagectomy) [1, 5, 6] and less clear in others (pneumonectomy, gastrectomy or ovarian cancer resection) [3, 5]. When discussing therapeutic options, it is appropriate to highlight the relative benefits of a higher-volume center for certain operations only. This may assist the patient in judging, on balance, the best decision in light of other personal considerations.

At times, the definition of a high-volume center is prohibitively restrictive, leaving most hospitals categorized as low volume. In one study, only 10 to 12 centers in the entire nation were defined as high volume for pancreatic or liver surgery [6]. In contrast, more than 1,000 centers were categorized as low volume. Such definitions of high-volume centers can be logistically untenable and ethically problematic. Most patients do not have the resources (personal, travel or financial) to be treated in one of 10 or 15 high-volume centers in the entire country.

It would not be feasible, even if it were desirable, to refer all patients to high-volume institutions. The centralization of all cancer patients and resources in a handful of hospitals does not serve to improve quality of care for the entire population, nor does it help improve the outcomes at low-volume hospitals. A downward spiral of fewer and fewer cases at low-volume centers would ostensibly result in worse care for the few patients who, by choice or lack of choice, are treated at these institutions. Further, surgeons at low-volume hospitals would lose proficiency in related procedures. Rather than automatically referring all cancer patients to high-volume centers, physicians have an opportunity to focus on more than just volume and outcome data. We must strive to identify the specific elements of patient care in large-volume hospitals that lead to better outcome and then implement these elements in lower-volume centers.

Conclusion

The ability to predict outcomes is limited to statements of probabilities. In contrast, the ethical responsibility of the physician is more contextual and grounded in the process of informed consent. Physicians should provide patients with knowledge—including the interpretation of aggregate volume-outcome and institution-specific data—that will help them make educated, well-informed decisions. Physicians should be able to discuss relative volume and outcome data that pertain to local, regional and national centers.

Ultimately referrals and recommendations should be based less on volume data and more on the physician's familiarity with a particular institution and confidence that it will deliver the best possible care for the specific patient. It is then the patient's responsibility to integrate these data with his or her own values, priorities, fears, anxieties and philosophy of life in reaching a decision about where to be treated. For example, it may not be unreasonable for a patient to select a doctor he knows and likes over another he dislikes, even if the latter doctor has a better outcomes record. This tradeoff is a balance that the physician needs to discuss with each patient to ensure that he or she understands how care may be affected. Physicians perform their ethical duty when they fully disclose all of the foreseeable risks, benefits and alternatives to proposed treatments so that whatever patients finally consent to or reject, their decision is truly informed. Finally, physicians should take the lead in measuring and providing relevant outcome data for their own practices.

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Policy forum

Inequality of care and cancer survival

by Victor R. Grann, MD, MPH

Although great strides have been made in the screening, prevention and treatment of cancer, the benefits are only available to those who have ready access to health care. According to recent Surveillance, Epidemiology and End Results (SEER) data, one-third of patients with breast and colon cancer are cured following screening, early detection and adjuvant therapy [1, 2]. Disparities in cancer care are still well recognized between those with ready access to care and low-income individuals who present with advanced disease at the time of diagnosis and do not share in the advantages of recent medical achievements. Survival rates among low-income individuals with cancer and other life-threatening illnesses offer revealing insight into the role that insurance plays in patient outcomes.

Medicaid

Almost all of the people with either no health coverage or inadequate health coverage are poor [3]. Over half have incomes that fall below 200 percent of government-designated poverty level, and one-quarter of these have incomes that are actually below poverty level. The uninsured, many of whom are still healthy, are less likely to be working full time and are unable to afford insurance. But the uninsured is a constantly changing group. By definition, its numbers represent individuals who lacked insurance for 12 consecutive months [3]. This figure may miss close to 50 percent of individuals who have coverage for as little as one month each year. Many Medicaid recipients go on and off of this insurance and may be classified as *underinsured* [4].

Medicaid covers close to 13 percent of the U.S. population but less than 50 percent of those who have no alternative access to insurance. To qualify for Medicaid, patients must meet a combination of income level and population group criteria. Eligible population groups are children, the parents of dependent children, pregnant women, the disabled and the elderly. Childless adults who are not disabled and seniors with low incomes rarely qualify. Eligibility differs by state and, under certain circumstances, is directly proportional to how many dependent children are living at home [3].

The uninsured

Minorities are overly represented among the uninsured; African Americans constitute close to 20 percent; Hispanics, 30 percent. Many of the uninsured have

jobs that are seasonal or unsteady—in agriculture or construction—or simply do not offer health care coverage. Jobs that do offer insurance may require a buy-in premium that is too high for their income [3].

The *underinsured*

Even workers with more secure jobs, like municipal employees in New York City or the self-employed with low incomes, do not have adequate health insurance. Medicaid recipients may fall into this category too. The underinsured are frequently shut out of preventive care and recommended screening and may fail to seek out health services before they develop advanced or incurable disease [5-7]. In a recent study Bradley and colleagues used the Michigan tumor registry to show that subjects enrolled in Medicaid at least one month before being diagnosed with breast, colorectal or lung cancer had double the survival rates of those enrolling in Medicaid in the same month as diagnosis or afterward [6]. Their hypothesis was that subjects who enrolled in Medicaid after diagnosis were more likely to have advanced stage disease and may only have been eligible to enroll because of their diagnosis [6].

Recent research

In another recent study, ambulatory follow-up appointments after emergency room (ER) care were shown to depend heavily on the type of insurance coverage the patient had. Sixty-three percent of callers with insurance coverage received clinic appointments within one week of their ER visit compared with 34.2 percent of those with Medicaid. Among those with no insurance who offered to pay \$20 at the time of the visit and the balance later, 25.1 percent were scheduled within one week of the ER visit. Note that even among the insured, one-third of patients were not granted timely outpatient appointments [7].

Over the past decade, studies have begun to call attention to the needs of the uninsured and underserved. As noted earlier some uninsured patients become enrolled in Medicaid only as the result of a hospitalization or a late-stage diagnosis. A 2003 study found that among the patients in Kentucky's Cancer Registry (KCR) database, 31 percent of Medicaid and uninsured patients first presented with stage IV cancer, compared to 17 percent of those with private insurance and 22 percent of those with Medicare [5]. A look at the impact on survival of privately insured compared to uninsured prostate cancer patients showed that 98 percent and 83 percent respectively survived for 3 years; for breast cancer it was 91 percent, and 78 percent; for colorectal cancer, 71 percent and 53 percent; and for lung cancer, 23 percent and 13 percent. Another report showed that the adjusted risk of death four to seven years after diagnosis among breast cancer patients was 49 percent higher for the uninsured and 40 percent higher for Medicaid patients than for privately insured patients [8].

In a study using the Behavioral Risk Factor Surveillance System, more than 100,000 adults were compared for rates of preventive service use, including screening for cancer, cardiovascular disease and diabetes [9]. Nearly half of uninsured adults with annual incomes below \$15,000 had not seen a physician when needed during the

prior year due to the cost of care. Hypertensive screening was three to four times less likely to occur among the uninsured. Similar findings were present for recommended cancer screening such as mammography. Even breast biopsies appeared to be performed less frequently among those on Medicaid and the uninsured [10]. These patterns lead to advanced stage diagnoses, more intensive treatments and reduced chances for cure. Ultimately, higher health care costs accrue.

The future of health care

The U.S. stands alone among developed countries in not providing insurance to all its citizens [11]. Lack of insurance and limitations on its use have resulted in use of hospital emergency rooms for primary care and increased medical costs. The plight of the uninsured and underinsured affects those with adequate insurance, who now face higher deductibles that limit access to preventive services and ongoing essential care. The per capita cost of health care in this country is the highest among any in the industrialized world, yet the outcomes overall are no better [12].

Major improvements are also needed to enhance quality of care; technological advancements such as informatics add to productivity and encourage physicians to follow evidence-based guidelines. Primary care doctors in the U.S. and Canada lag far behind those in Australia, the Netherlands, New Zealand and the United Kingdom in the use of electronic medical records, clinical test reporting and medication accounting systems [11]. System-wide information technology is capable of tracking patients and preventing treatment errors. With the savings from these initiatives, we should be able to move more aggressively in the direction of universal health care.

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Medicine and society

The ethics of requiring employees to quit smoking

by Howard Brody, MD, PhD, and E. Bernadette McKinney, JD

In early 2005 a Michigan firm, Weyco Inc., made national news by firing several employees who smoked. The company had given employees advance warning about the new policy and provided a free smoking cessation program. A number of employees successfully quit smoking; those who did not were fired. The company justified the firings based on the cost of health insurance for employees at risk for smoking-related illnesses.

In this article, we investigate the ethical issues such a policy raises by examining a spectrum of possible employer actions. We assume from the start that employers can, and should, create a smoke-free workplace so that nonsmokers do not face additional health risk. But the employer's right to regulate an employee's health-related behavior outside of working hours remains in question.

Consider three companies.

- Company A provides a fully voluntary smoking cessation program and other health-promotion programs at the worksite during lunch as an employee benefit.
- Company B provides a free smoking cessation program and imposes a health insurance surcharge on employees who smoke. The surcharge is eliminated upon successful smoking cessation.
- Company C provides a smoking cessation program and fires employees who fail to quit by a given date.

We argue that the behavior becomes harder to justify as one moves down the list.

Assessing the burdens

Company A demonstrates the exemplary policy. The workplace seems an excellent and often underutilized site for health promotion, although efficacy data are not striking [1]. Company A will benefit eventually as more of its employees quit smoking and become healthier in other ways. The benefit to the company does not detract from the policy's real benefits to the workers; it promotes health, is voluntary and intrudes minimally into their private lives. We believe that, absent an emergency, voluntary and less-intrusive approaches to a public health problem ought to be tried before mandatory and more intrusive methods are resorted to.

Company B's policy is more intrusive and burdensome for employees. It bases its justification purely on cost, explaining that it is simply passing along the extra cost of insurance to the employee. It is of some interest that smoker protection laws, which have been passed in 30 states and the District of Columbia, prohibit the employer from discriminating against smokers for tobacco use during nonworking hours yet permit the insurance surcharge that Company B imposes.

Our major ethical concerns lie with Company C. First, note the possibility of a slippery slope. After firing employees who did not give up smoking, Weyco Inc. decided to charge an additional \$1,000 per year to employees whose *spouses* tested positive for nicotine in monthly tests [2]. It is unclear whether or not the surcharge applied only to spouses who were covered by the employee's health insurance. Considerable research has shown that those who attend church regularly are healthier than those who do not [3]. Would we permit an employer to demand church attendance as a condition of employment? These examples demonstrate that the mere fact that a certain employee behavior has implications for the employer's insurance costs does not automatically grant the employer the right to regulate that behavior.

Company C's policies have important implications for the personal physicians of its employees. How will compliance with company policy be monitored? Company C is within its legal rights to require that its employees submit to urine screens for smoking markers, for example, as a condition of continued employment. So long as employees sign a release, the physicians are not violating confidentiality if they transmit the test results to the company. Yet the physicians are nonetheless being conscripted to help police the company's workforce. The implications for patient-physician trust could be serious.

Several legal challenges to Company C's approach could be considered. Smoking occurs more commonly among the members of some minority groups; American Indians and African American men, for example, have a higher incidence of health problems related to smoking [4]. Patients with chronic mental illnesses are also at higher risk for smoking [5]. Therefore, Company C's policy could be viewed as unjustly discriminatory.

Company C's policy regarding workers who smoke could be challenged under Title VII of the Civil Rights Act of 1964 or the Americans with Disabilities Act [6] assuming that they are otherwise able to function well in the workplace. If it can be shown that there are genetic factors that make some individuals more prone to addiction to nicotine, then the case could be made that Company C's policy punishes some employees for factors beyond their voluntary control [7]. Genetic or not, nicotine addiction is difficult to overcome. The overall success rate of smoking cessation programs, even among those who are highly motivated to quit, is sufficiently low to call into question the assumption that lurks behind Company C's policy—smokers can readily quit if only they choose to do so. For instance, one review reported “quit rates” at 6 months for various intervention strategies ranging between 2 percent and 35 percent, with relapse being extremely common [8].

Conclusion

Even if Company C were able to ward off legal challenges, we find its approach ethically objectionable. The company failed to try voluntary, less intrusive means before resorting to more draconian policies. The same logic that is used to justify this smoking cessation measure could be applied to other measures that would seriously violate employees' and others' basic rights. And the ripple effects of the policy, such as the impact on the employees' relationships with their physicians, create further cause for concern.

It is not enough, however, merely to object to the specific policy used by Company C. Recall the logic chain that was used to justify the company's behavior. At one end of the chain, the cost of health care coverage for smokers is higher than that for nonsmokers, a fact that has important implications for the company's bottom line. At the other end of the chain is the American public policy choice to tie the provision of insurance for the majority of working adults to their worksite and employer. If we find the fire-the-smokers policy objectionable, we must at least raise the ethical question of whether this tight link between place of employment and health insurance status is a serious part of the problem. If so, it provides us with yet another reason to demand major reform in how the U.S. provides and pays for health care.

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Op-ed

Challenging teenagers' right to refuse treatment

by Art L. Caplan, PhD

The case of Starchild Abraham Cherrix

What should a physician do when a young teenager refuses life-saving medical care? And how should society react if the teenager insists on not undergoing such care? The case of 16-year-old Starchild Abraham Cherrix, who refused the highly efficacious treatment his doctor recommended for his life-threatening Hodgkin's disease, raised these questions and triggered a national debate about how to answer them [1]. The case illustrates the types of moral considerations that must be weighed in reaching a decision about how to manage an older child who refuses crucial medical treatment.

The boy at the center of the national controversy that erupted in the summer of 2006 goes by the name of Abraham. At the time he lived with his parents and four younger brothers and sisters in rural Chincoteague, Virginia. He is a tall and articulate young man who gives the impression of being older than his 16 years. Abraham was diagnosed with Hodgkin's disease in 2005, and doctors at the Children's Hospital of the King's Daughters in Norfolk, Virginia, recommended chemotherapy. The treatment left him bald, feverish, nauseated and so weak he could not walk [2]. Two months later the cancer came back. His doctors said Abraham needed to go through another round of chemotherapy supplemented with radiation. Statistics showed that the success rate in curing this form of cancer was 90 percent after three rounds of chemotherapy [3]. But having been through the rigors of chemo once, Abraham declined further treatment. Instead, the teen and his parents stated they wanted to pursue an alternative treatment method that they learned of on the Internet. What they wished to try is known as the Hoxsey treatment.

The Hoxsey treatment is a decades-old American folk remedy based on an observation made by Harry Hoxsey in 1920. Hoxsey noted that a tumor on a horse disappeared after the horse had grazed in a field with a distinctive set of plants. Believing that ingestion of some of the vegetation in the field had caused the tumor to go into remission, Hoxsey attempted to determine what wild plants the horse had eaten in order to prepare an elixir for use in humans [4].

The Hoxsey treatment, mixing various plant and root extracts, was condemned in the United States by the Food and Drug Administration (FDA) in 1956 [5]. It is still available, however, in a clinic in Tijuana, Mexico, run by a nurse who once worked

with Hoxsey. Information about the botanical formula—which has evolved over the years—is available on the Internet, as are advertisements for the clinic [6].

Despite FDA disapproval of the treatment and the proven efficacy of additional chemotherapy, Abraham's family chose to pursue the Hoxsey treatment in Mexico. When they returned home, Abraham's dad stewed up the brew that served as Abraham's sole form of treatment. It consisted of cascara (*Rhamnus purshiana*), potassium iodide, poke root (*Phytolacca americana*), burdock root (*Arctium lappa*), barberry root (*Berberis vulgaris*), buckthorn bark (*Rhamnus frangula*), Stillingia root (*Stillingia sylvatica*) and prickly ash bark (*Zanthoxylum americanum*). Abraham was given this potion four times a day while his parents offered up prayers.

Intervention by Virginia authorities

In May 2006 physicians who had been treating Abraham became aware of the family's decision to pursue a therapy judged to be quackery by the FDA and the American Medical Association (AMA) and reported the family to the Department of Social Services in Accomack County, Virginia. Social Services representatives determined that Abraham was not receiving appropriate life-saving care.

The family was taken to Accomack Juvenile and Domestic Relations Court in July 2006 where the parents were charged with medical neglect. The domestic court judge ruled that the parents should relinquish custody of their child, so the state could see to it that Abraham submitted to the recommended cycle of higher dosage chemotherapy and radiation by late July.

On July 25, 2006, minutes before the order was to take effect, the family obtained a stay from the Circuit Court of Accomack County. The parents regained full custody of their son, and Abraham continued with the Hoxsey treatment. The appeals court set a date to hear the case against the parents.

On August 16, 2006, Accomack Circuit Court Judge Glen Tyler cleared Abraham's parents of all charges of medical neglect. He announced that a settlement had been reached between the family and the Virginia Department of Social Services. Abraham would be allowed to pursue the Hoxsey treatment so long as he was monitored by a board-certified oncologist in Mississippi experienced in alternative cancer treatment. The court stated it would keep an eye on Abraham to make sure that his treatment was reasonable [7].

Principles governing forced treatment of adolescent children

Assessing teenagers' right to refuse medical treatment poses special challenges to both medical ethics and social policy. American law does not recognize teenagers as adults until they reach 18 years of age. Teenagers under this age may not consume alcoholic beverages, vote, hold federal office or serve in the military. They are also subject to age-specific curfews set by local governments. On the other hand, those in their upper teens but not yet 18 can drive, work, obtain contraceptives, marry in

some states and, under certain legal circumstances, be held accountable as adults for their actions [8].

Although teenagers are not adults, their ability to make decisions about their medical care as they grow older is widely acknowledged by experts in pediatrics and child development. Older teenagers are recognized as capable of a high degree of self-determination [9]. Still society has an interest in trying to insure that life-saving medical care is provided to children. How—using ethical standards and guidelines—ought the conflict between the emerging autonomy of a teenager and the need to insure access to life-saving care be resolved?

A number of factors must be weighed in cases like that of Starchild Abraham Cherrix. First, what is creating the need for medical intervention? Life-threatening disease and the likelihood of severe disability must exist if the state is to justify interference with parental decision making and family privacy.

Second, how efficacious is the standard medical intervention? The more uncertain the efficacy of treatment, the more novel or untested it is, the more difficult it becomes to override parental refusals or refusals by older teenagers.

Third, how invasive, risky and painful is the standard treatment? Risk must be weighed when offering any treatment to a patient. Patients and their families have the right to weigh the burden of treatment when considering its desirability. A blood transfusion does not carry the level of risk and burden that a third liver transplant or the removal of stomach and bowel with nutrition forever provided through total parenteral nutrition (TPN) does.

Fourth, what, if any, alternative course of care do the teenager and parent propose to follow? Sometimes in the face of uncertainty watchful waiting can be a reasonable response—even if it is not the optimal mode of care from a medical point of view. In other cases what is proposed as treatment—prayer or unproven or disproven alternative remedies—is not.

Fifth, consideration must be given to the impact of forcing medical care on the stability and integrity of the family. If a teenager is likely to be completely noncompliant with therapy, to flee or to be rejected by his family, then the case for coercing medical care is weakened. If there are reasons to suspect undue pressure from family members to follow nonstandard care, the case for coerced treatment is correspondingly strengthened. The impact of treatment on family life must be weighed in the equation of what truly is in a teenager's best interest.

The case for the Virginia courts to leave Abraham and his parents alone seemed to many to be very strong. He had been through a round of treatment which did not work and left him sick. Abraham's parents, who obviously loved him, agreed with him and supported him in his decision to pursue alternative medicine.

So should physicians have reported the family for medical neglect? And should the Department of Social Services of Accomack County, Virginia, having examined the facts of the situation, gone to court? In light of the key moral factors governing this case, I think the answer should, despite Abraham's self-assurance and his family's support, be "yes" to both questions.

Abraham, for all his apparent sophistication and thoughtfulness, is still a teenager living at home under the strong influence of his parents and their values. It is not clear that he will choose to pursue the lifestyle, philosophy or stance toward medicine that his parents exhibit when he reaches adulthood. As he broadens his experience of the world and attains greater independence he may or may not reject traditional medicine.

Further, the disease Abraham has is serious and life-threatening. The success rate associated with three rounds of chemotherapy possibly supplemented with radiation is high—near 90 percent. These facts make it imperative that his failure—or any teenager's failure—to follow such a proven medical treatment be reported by physicians, nurses and hospital administrators to child welfare authorities.

True, the young man went through a round of treatment and hated it, but the course of care the family and Abraham chose to pursue is known to be non-efficacious. The Hoxsey treatment is not standardized in any way, and there is no evidence whatsoever that it has succeeded in curing any type of cancer. These facts justify reporting the failure to utilize standard medical care to social service officials in this and similar cases.

That said, can one really force a 16-year-old to take a miserable treatment that he does not want? The answer is "probably." And the way to turn "probably" to "yes" is to find a doctor who has a good rapport with the boy and his family and is open to working with them and allowing them to pursue their ideas about healing in conjunction with the standard medical treatment for cancer [10].

Keep in mind that there would not have been any resolution if the state had not stepped in and demanded that Abraham and his parents go to court. Abraham would have been left to pursue a quack form of medicine on his own without the oversight of a medical expert. By intervening, social services and the Virginia courts forced an accommodation that respects the family's values but also insures that standard, proven medical care will continue to be offered even if it is not accepted. In addition, Abraham and his family will be kept under the supervision of a physician and the court.

Some say the best thing to do when it comes to teenagers who refuse standard medical care is to leave them and their families alone. But respecting autonomy does not mean that a decision cannot be challenged. Autonomy is perfectly compatible with demanding a justification before legal authorities when a minor refuses

recommended life-saving medical treatment. Sometimes a bit of a push from government officials and courts can help doctors do the right thing for a teen.

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Medical humanities

Surviving (and thriving with) cancer

An interview with Brian Ciccotelli

Brian Ciccotelli was a typical high school senior. He was on the soccer team and a part-time manager of the volleyball team; he went out with friends and had a girlfriend. But his life took a turn when he was diagnosed with early-stage Hodgkin's disease on December 23, 1998. Brian was treated at Yale-New Haven Hospital with a combination of chemotherapy and radiation that lasted for more than six months. Despite his illness, he was able to graduate from Jonathan Law High School in Milford, Connecticut, with the rest of his class in June 1999 and go on a religious mission to California in early 2000. Brian has been in remission for seven years and has shown no signs of relapse.

Recognizing that his is an exceptional story—few indeed recall their experiences with cancer in such a positive light—*Virtual Mentor* sat down with Brian in December 2006 to find out more about his life as a young cancer patient and now as a cancer survivor. Brian kept a journal throughout his time in the cancer clinic and shared some of his stories and views with us.

Q. How did keeping a cancer journal affect your treatment?

A. It didn't. The journal was really just a daily record of what I was doing. I never wrote any deep feelings or secrets in the book. I never vented. I wasn't worried about my disease; I never feared I would die. The book was a way to remember all the things I was able to do with cancer as my excuse. I kept track of how many days I missed school (81) and yet still graduated on time. I also wrote about all the great people I met in the cancer clinic, including doctors, nurses, other kids and the clowns. It wasn't a journal to keep track of eating habits, exercise, pills or anything else to do with my health. Those things periodically made it into the journal, but it was always in passing. For example, "The doctor told me I'm not allowed to eat anything with preservatives, but when I got out of the hospital, I was craving a 99-cent double cheeseburger, so I shot over to McDonald's and got one. With fries. And if he thinks I'm giving up Hawaiian Punch, he can think again." My blatant disregard for doctors' orders was well documented.

I didn't try to hide that I wasn't obeying the doctors. They would reprimand me, saying, "You have to do this-and-this or your health isn't going to improve," or, "It's going to affect your treatment." In the beginning, I listened to almost everything. After the first time they gave me chemo and none of the bad side effects they predicted came about, I only halfway paid attention to them. I figured, even if

something bad happened because I ate a box of Oreos, it wouldn't be as bad as what was supposed to be happening. Cancer interrupted my life; I tried hard not to let it interrupt my lifestyle. I decided to eat and drink and do what I wanted to and accept the consequences. Luckily, the consequences were minimal.

My mother and my grandmother were somewhat supportive of my decision not to follow the doctors' orders. They made sure that I knew the doctor said I couldn't do certain things, but I told them that I didn't care. At first they worried, but when I had no adverse reactions they were cool with it. They said, "It's your health, your body; if you wanna do it, then you do it."

Q. What was the cancer clinic like?

A. I was older than most of the other kids on the floor because I had just turned 18, but the doctor decided that I should be with them. And it's a good thing; when all my treatments were done and I was in another part of the country and went for follow-ups every six months, I had to be with the adults. And when you walk into the adult ward it feels like you're walking into death. The adults have known so many people who have died from cancer and the atmosphere there is like, "I'm just waiting to die now." But the kids were so alive. The hospital tries to make the children's cancer clinic as much fun as possible. And it makes sense. Since attitude is such a large part of recovery, they try to make your treatments as enjoyable as possible. I had so much fun there. I brought my guitar once; we watched movies; we played games; I met *lots* of people. It was always fun to meet the new kids, scared as can be on their first day, and see the transformation as they began to meet and talk and laugh with others who had the same disease. By the end of the four-hour treatment, they knew everyone in the room and they were having a good time. I wrote about those experiences and kids in the journal, and I love re-reading those stories.

The sad thing is that all of the friends I kept in touch with—all of the people I was friends with—have died. Friends who were so full of life and so much fun to talk to. All of my memories were of the times we were together, when we were having fun. I never had any memories of them suffering at all. So when they died, it was like they were in a car accident. I didn't see it coming at all. Every one of them relapsed; there was a complication or they couldn't get a bone marrow transplant in time; none of them survived. And because we were all in such high spirits when we were at the clinic, I didn't see it coming. I just figured all of us would survive. When they didn't, I took it hard.

Q. Were you ever scared during the course of your illness?

A. No. Not at any point in my treatment, from the day my friend Tiffany told me I should get the lumps on my shoulder checked to the last day of radiation therapy, was I ever scared. I figured the side effects were inevitable so I just accepted it. I took the attitude that I'd deal with them when they came, but they never did. All of the doctors told me, "This is what's going to happen," and I figured, that was what was going to happen. The doctors, usually four or five of them, told me *everything* to expect. Before I had my biopsy, after my biopsy and before the results, they told me

all of the possibilities. “It *could* be an infection and this is what we do if it’s an infection; it *could* be Hodgkin’s and this is what we do if it’s Hodgkin’s. This is how long it will take and this is what you will have to go through.” And because they went over every single option so clearly before I was diagnosed, when I was going into treatment I knew *exactly* what I was getting into. I was extremely happy that the doctors had told me so much because I knew all of the bad things to expect and I was mentally ready for them. I firmly believed that everything happened for a reason, and I knew that whatever I had to go through, I would learn from it, grow and be a better person because of it. But when none of the side effects happened, it made me feel that much more lucky and that much more blessed. Because everyday I was feeling fine, I knew that I should be throwing up; I should be fatigued; I should be having night sweats; I should be losing weight and losing my hair. Because I knew what *should* have happened, I was able to appreciate my health so much more.

Q. What made the experience more manageable?

A. Nothing I did made my treatment or recovery more manageable. That fell squarely on my grandmother’s shoulders. I owe my miracle health story to her. She kept me alive and well. If anything, I only hindered my recovery through constant consumption of junk food and doing my best to ignore any part of the doctors’ advice that I didn’t particularly like. My grandmother’s ability to keep me healthy astounds me to this day. She learned about chemotherapy and all of the destruction it was supposed to do to my system (in addition to clearing out the cancer). She also gave me vitamins, other pills (about 25 a day) and food from the health store. I told my doctors that I was taking stuff that my grandma had gotten, but it was never anything that they explicitly recommended. Sometimes the doctors disagreed with what I was taking, but after a while they were okay with everything, especially when they saw that I, a cancer patient, was healthier than they were during flu season. I had to laugh when they came in sniffing and I was clear as a bell. They jokingly asked if my grandma could fix up something for them to take, too.

Anything I needed to do or any treatments I needed my mom *always* came with me. As far as socializing goes, after the first week my friends saw that I wasn’t sickly and they would all come over and hang out. Nobody seemed to avoid me—they were all supportive. The only reaction I didn’t like was when I first got diagnosed and had to go around telling people that I had cancer. I was just kind of *informing* them—I wasn’t telling people I was going to die—which is how a lot of people took it. I knew I was going to be fine; it never occurred to me that I might die from this. Since I was diagnosed on December 23rd, I ended up *killing* two Christmas parties, which I hated doing, because I try to be the life of the party. I didn’t really like the sympathy either—unless it was giving me free stuff.

Q. Did you have a favorite doctor? Did you develop a relationship with any of the doctors or nurses?

A. Six years later I remember two people. First and foremost is Rachel, the doctor who took care of me the most. Being my doctor she wanted to make me feel better, but she made me feel loved. She was so happy to see me every week, and she always

wanted to hear what I'd been up to. She knew everything. She knew about all of the junk food I ate, the basketball incident—when I came in with a new wound less than an inch away from my porto-cath because I had run into a stray piece of rebar—and the snowboarding escapades. She never told the other doctors (at least as far as I knew). She just made me promise to be more careful next time. She felt like a mom; she cared about me but she was still a friend that I could share secrets with.

The second person I remember is the nurse from recovery. I had surgery three times while I had cancer, and after each one they put me in a room to recover, and the same nurse would come and check up on me and bring me water. I remember her because she was so cute. After my first surgery, I was wearing an Old Navy shirt with a dog on it, and a few weeks later after my next operation, she brought me a little green stuffed dog. Of all the people that must go through there every day, somehow she remembered me and brought me something. That made me so happy, as cheesy as it sounds. I felt so special, and I've never forgotten her.

Q. What was the rest of your life like at that time? Did your family treat you differently?

A. Even though I wasn't in school, I was in the play and in the fashion show. I still went to track practice. The doctors were supportive of me running track as long as I didn't overdo it. Of course, I overdid it; I ran long distance after all. The only person who had a problem with me running track was the principal, because she said if I was healthy enough to run track I was healthy enough to go to school ... and I couldn't really get out of that one. But just before I went back to school in May I got a freak cold and the nurse told me to go home and finish my treatments. So I was able to stay out of school.

As far as my family, when I was diagnosed they were a little scared and worried, but they tried not to show it because they wanted to be supportive. Once they saw how well I was reacting to the treatment they were completely normal. Really, in my family it seemed like nothing out of the ordinary. It was never, "We have to do this because this could be Brian's last time." And I certainly didn't need any more attention.

Q. To what degree is your life shaped by the fact you survived cancer? How much do you think about the experience? How has it changed your world view?

A. My general outlook on life has always been optimistic, and I try to make the most out of every opportunity that comes my way. Having *had* Hodgkin's has allowed me to help other people deal with cancer in their lives. As far as being a "cancer survivor," most new people I meet are not aware that I had it. Telling people I had cancer usually evokes sympathy, and I don't deserve that at all. I got to make a wish through the Make-A-Wish Foundation and get treated like royalty—an all-expenses-paid trip to Orlando, no lines at Disney World, Universal Studios, or Sea World, free food at Hard Rock Cafe and any other place you can think of, and general celebrity status at any place I walked into. I was able to sail around Boston Harbor for four days, and explore uninhabited islands (Island of Hope, a weeklong escape for young

cancer survivors), and I got to skip class half my senior year, do less than half the work, still play with my friends and graduate on time. Most people think I'm joking when I say I had cancer, because I say it so easily, and I end up showing my battle wounds (the scars on my shoulder and chest from the surgeries).

As far as cancer reshaping my life or my thoughts, that hasn't really happened. I never gave cancer the respect it deserved. I treated cancer like a cold; I figured it would just go away on its own. I never, not for a moment, even considered the possibility that I might die. I was shocked when they told me I could make a wish: "I thought Make-A-Wish Foundation was only for kids that were dying." "Well, Brian, you did have cancer." "Yeah, but I wasn't *dying*," was my reply. Subconsciously, perhaps, cancer solidified my idea that life is short. I take advantage of every opportunity I come upon, and I try to make the most of each day. No matter what happens to me, I firmly believe that something good comes out of everything.

I have had a lot of experiences that have shaped me into who I am today. I backpacked around Europe, I served a two-year mission for my church, I spent a month in Cambodia and I just spent six months in Mexico. I include cancer as one of the great experiences of my life that afforded me many other new opportunities. I think about it often, only because I have daily reminders. Cancer is so widespread that it has affected almost everyone I know in one way or another, and I am able to encourage and give hope to many people who are so afraid.

My world view hasn't really changed. I've never been one for politics, but if there's a scientist out there who finds a cure for all cancer, I'll vote for him.

Q. Have you changed your goals or aspirations since your diagnosis and survival?

A. After I was in remission, someone told me about a list of goals they had made for their life. So I decided to make a list of "Things To Do before I Die." The list is four pages long, and I constantly add to it. It includes everything from "walk on the Great Wall of China" to "write a book somebody will actually read" to "learn conversational Italian." On average, I check off about three or four goals per year. This year I've checked off "go see the Mayan temples in Mexico" and "get scuba-certified." I want to visit all seven continents and every major city in the world. I'm happy to come to Chicago; this is another check on the list.

Q. Has your respect for cancer increased given the death of your grandmother (2000) and mother (2006) from cancer?

A. When I left Connecticut, my grandmother was completely healthy. I learned through letters that she was sick and had cancer and then that she had passed away. I wasn't there for any of it; I wasn't there to go through it with her. She wasn't in any pain; she was just tired and in bed all of the time. She didn't go through chemotherapy because the cancer was too far along.

My mom's experience was entirely different. The whole time I was talking to her—even up until the day before I flew home from Mexico to be with her—she kept saying, “Don't worry, don't come home, I'm going to be fine.” And because she kept saying that she was fine, I just backed her up on that and told her, “You're handling it like a champion.” She had to go through a *lot* more than me, and she had a lot of pain and suffering, but she handled it incredibly well. All of the doctors and family members in Connecticut were amazed. She had the same attitude I had. The doctors told her what was going to happen just like they did for me—and all of the nasty side effects actually happened for her—but she just accepted it, and said, “I'm going to take all of the treatments; I'm going to do what they tell me to do; I'm going to be done with it and get on with my life.” And the whole time, this is what she was telling me too. She would say, “It hurts, but it's just for a short time, and then it will all be over, and we'll just get on with life.”

Even though they both died from their cancer, my outlook on cancer hasn't changed. When I got diagnosed, I knew people who had died from the disease. I've just seen *more* people die from cancer. I've always known that cancer *can* kill you, but for me, that just wasn't a consideration. If I get it again in the future, I'm going to treat it the same way I did the first time.

Q. What is your prognosis, seven years later?

A. The doctors told me that once I finished radiation, I would be “in remission,” which would mean that they thought they got it all. If it hadn't come back after five years of being in remission, I would be cured, and the chances of me getting cancer again would be about the same as everybody else's. They gave me certain guidelines to follow during the five-year interim to decrease my chances of getting it again, but of course I didn't follow them. As far as I was concerned that cancer was gone long ago. I honestly felt like they had gotten rid of it all in the first four treatments of chemo, and the rest was just precautionary.

If by some random chance, I do get cancer again, I'll just go through chemo and be done with it. I'm sure I'll meet some more great people and have some more great experiences.

One week after the doctor told me to stay out of the sun (saying I had a higher risk of skin cancer, which runs in the family), I was at Six Flags all day without a shirt on. My mom called her sister asking, “Why doesn't he wear a shirt? Why doesn't he listen to the doctors?” My aunt replied, “Because he's not worried about getting cancer. He's back to normal.”

My five-year anniversary was just a good excuse to have a party.

Q. Looking back, is there anything you would change?

A. I would not change a single part of my experience.

This interview was conducted by Allison Grady, Virtual Mentor editor.

Brian Ciccotelli is participating in an internship as the manager of a retail store in Aruba. Prior to that he was studying business management at Brigham Young University in Provo, Utah. He has traveled extensively in Europe, Southeast Asia and the United States. His future plans include becoming a professional photographer and authoring travel books.

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Suggested readings and resources

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