

Virtual Mentor
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Unwarranted Variation in Health Care

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FROM THE EDITOR

Unwarranted Variations in Care: Searching for Sources and Solutions

The story behind this month's theme issue of *Virtual Mentor* begins in London in 1938, with a physician named Alison Glover. He was studying tonsillectomy rates among children in different school districts in England and Wales when he came across some startling results: the frequencies of tonsillectomies varied greatly from region to region, with rates in some areas up to eight times higher than others. Most importantly, Dr. Glover could find no statistically significant differences in health outcomes between any of the regions. Thus, it looked as though many children were undergoing unnecessary, invasive surgical procedures that provided no particular benefit to their health, and nothing in the data could explain why [1].

Glover published his findings in August of 1938, but discussion on this topic did not emerge in the United States until another physician, John Wennberg of The Dartmouth Institute for Health Policy and Clinical Practice (TDI), began analyzing Medicare data in the 1970s. His work showed striking geographic differences in health care delivery in the United States that could not be explained by increased rates of or predisposition to illness in the patient population. Wennberg called this difference "unwarranted variation" [2]. Since then, awareness of unwarranted variation in health care has increased dramatically within the medical community, and physicians, researchers, and policymakers are working to further understand this concept and what effect it has had on the American health care system.

According to Dr. Wennberg and his colleagues at TDI, there are three different categories of unwarranted variation in health care delivery: physicians' underutilization of evidence-based interventions, differences in preference-sensitive care, and supply-sensitive care [3]. The first type refers to the underutilization of certain medical practices by physicians in different areas. This type of variation is not attributed to a lack of resources but is instead associated with "the degree to which care is organized and coordinated" [3]. The second type of variation occurs in cases in which patients have a choice of effective treatments but, in actual practice, "medical opinion rather than patient preference tends to dominate the treatment choice" [4]. The third type, supply-sensitive care, refers to the finding that use of health care resources appears to correlate more strongly with their availability than with medical need. This type of unwarranted variation has the greatest potential to lead to significant increases in cost of health care delivery.

In this issue of *Virtual Mentor*, our authors look at the presence and ethics of unwarranted variation both at the individual physician level and in the United States medical system as a whole and discuss efforts to reduce it. The difference between

patient and physician preferences is at the center of the issue's first ethics case: a woman recently diagnosed with breast cancer must choose between undergoing a mastectomy or a lumpectomy, which have been shown to have equal survival rates in cases like hers. Heather MacDonald, MD, describes the medical and personal factors that affect such a decision and the role of the physician in helping the patient with that choice.

Another ethics case explores how physicians may react to data that suggest a correlation between their preferences and overutilization of services—in this instance, cesarean-section birthrates. Stephen J. Ralston, MD, MPH, emphasizes the obligation of physicians to analyze their own practice critically in order to improve the health care they provide. Hilda Bastian, one of the founding members of the Cochrane Collaborative, gives advice to young researchers on presenting important but potentially controversial evidence to a skeptical audience.

In the third ethics case, a medical student approaches the dean of his school after seeing two different—yet seemingly equally rational—approaches to screening patients for prostate cancer. Michael LeFevre, MD, MSPH, describes the complex and debated topic of prostate cancer screening and advises medical students and young physicians on how to approach the variation they will inevitably encounter in their medical training. Such differences in utilization can be legally significant: the locality rule, which has been used in deciding malpractice lawsuits, states that the regional customs and standards that a physician is exposed to should be taken into account in malpractice cases. Stuart P. Swadron, MD, Peter Milano, MD, and Anne M. Milano, JD, propose that the “locality” rule be reimagined as a “resource” rule in light of the influence that resource availability within a given institution at a given moment has on emergency physicians' practices. Richard Weinmeyer adds that the difficulty in standardizing informed consent practices from state to state can complicate legal determinations of malpractice.

Dr. Wennberg and his colleagues found that supply-sensitive variation is the largest contributor to regional differences in cost of health care. Leah A. Burke, MD, and Andrew M. Ryan, PhD, examine the relationship between cost and quality of health care delivery and the effect that unwarranted variation has had on both of those factors. Because of this relationship, tools and policy being developed to reduce unwarranted variation usually aim to reduce supply-sensitive care. William L. Schpero, MPH, discusses the creation and possible utilization of one of the policy-based efforts to reduce this variation: the Choose Wisely initiative. In another article, Michael Farias, MD, MS, MBA, and Rahul H. Rathod, MD, describe the Standardized Clinical Assessment and Management Plans (SCAMPs), a tool they developed that has been effective in reducing unwarranted deviations from care guidelines, optimizing resource use, and improving patient outcomes.

Because this “big data” has led to initiatives aimed at minimizing unwarranted variation, it is important that physicians entering the workforce be aware of this concept and mindful of how they let it affect their own day-to-day practice. Greg

Ogrinc, MD, MS, describes how the Geisel School of Medicine at Dartmouth, the home of Dr. Wennberg and TDI, has incorporated discussion of unwarranted variation and training in quality improvement into its curriculum. In his piece, Bill Davenhall, MA, describes the novel concept of “geomedicine,” urging physicians to start considering patients’ geographic histories in order to make fully informed decisions regarding their care.

Finally, in his op-ed, James Reschovsky, PhD, provides an alternative explanation for the differences found by Dr. Wennberg’s analysis of the Medicare data, countering TDI’s theory of unwarranted variation and reminding us that there is still a lot to learn and to understand about this burgeoning topic. It will be up to future physicians to determine where the differences in health care delivery originate, what areas of quality and patient care are affected, and how much of this variation is truly “unwarranted.”

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ETHICS CASE

The Importance of Quality of Life to Patient Decision Making in Breast Cancer Care Commentary by Heather Macdonald, MD

When Marsha was diagnosed with stage I breast cancer, her gynecologist referred her to Dr. Martin, a highly respected surgeon, to discuss removal of the mass. Dr. Martin recommended a mastectomy, explaining that he had long-term experience and success with the procedure, with very low complication rates and few cancer recurrences in his patients. Marsha was comforted by Dr. Martin's confidence and success rate, but left the appointment greatly concerned about undergoing such extensive surgery.

After some online research, Marsha found that, for women her age (38) diagnosed with early-stage breast cancers, a lumpectomy was an equally effective tumor-removal alternative to mastectomy. She read that, while the latter may provide more peace of mind by removing the entire breast, it was a more invasive procedure, often followed by reconstructive surgery and a significant recovery period. The lumpectomy would preserve most of the shape and sensation in her breast. And, as an avid runner who raced frequently and had an active lifestyle overall, Marsha considered the shorter recovery time and avoidance of reconstruction added benefits. Of course, her health and curing the cancer were her foremost concern, but, after careful consideration and many conversations with her family, Marsha decided to ask Dr. Martin to perform a lumpectomy instead of a mastectomy.

Marsha was surprised by Dr. Martin's reaction. Although studies had shown no statistically significant difference in survival rates in patients with stage I breast cancer who underwent lumpectomies versus mastectomies, Dr. Martin said that, based on his own training and experience, a mastectomy was a much better way of preventing recurrence. He said he did not want Marsha to have to face the possibility of a second surgery should the postoperative pathology report show positive lymph nodes or unclear margins. Dr. Martin urged Marsha to rethink her decision.

She left his office confused and overwhelmed. While her limited research had led her to believe that a lumpectomy was the better choice for her, she respected Dr. Martin's experienced clinical judgment and his concern for his patients' well-being. "When it comes to breast cancer in a woman your age," he told Marsha, "there is no such thing as being too cautious." Marsha would have to travel to a nearby city to find a surgeon to perform the lumpectomy if Dr. Martin refused. Since both forms of treatment had comparable outcomes, Marsha wondered whether she should put aside her own preferences and follow Dr. Martin's recommendation.

Commentary

The emotional minefield of a cancer diagnosis in a young woman can amplify conflict between a physician's recommendations and patient's wishes. Evidence-based medicine and adherence to ethical principles provide guidance for navigating these difficult situations.

Data on Treatment

First, consider the medical evidence. Women with early breast cancer have excellent survival rates. Studies starting in the early 1970s show equivalent 20-year survival rates for patients with breast cancer treated with mastectomy and those treated with lumpectomy, as long as clear margins are achieved and lumpectomy is followed by radiation therapy [1]. Recurrence rates are higher for patients who undergo lumpectomy (10 to 15 percent recurrence risk after lumpectomy and radiation therapy) versus mastectomy (2 to 5 percent recurrence risk) [1], but with close surveillance those recurrences can be caught and treated before they become life-ending diseases.

Patients who carry mutations in the BRCA genes may have more limited treatment options; their lifetime risk of recurrence in either the affected or unaffected breast is high enough that they benefit from double mastectomy [2]. Another group whose options may be limited comprises younger women, who tend to be diagnosed with later-stage disease because there is less routine screening of this population. More aggressive tumors, those that are hormone-receptor-negative or HER2-positive, more common in young women, lead some experts to recommend more drastic therapies for this group of patients, with the goal of protecting the many decades of life we hope this 38-year-old patient will have.

Further, recent advances in genomic profiling of tumors have increased our ability to understand the inherent indolence or aggressiveness of tumors, allowing oncologists to tailor treatment to the genetic profiles of breast cancers, using chemotherapy more selectively to combat the most threatening cancers while sparing patients with more indolent cancers from undergoing unnecessary and harsh treatments. For Marsha, the patient presented here, incorporating her BRCA mutation status, hormone receptor status (estrogen and progesterone), HER2 status, genomic profiling, and clinical stage, specifically involvement of lymph nodes, would allow a more personalized treatment approach.

Ethical Principles

Patient-physician relationships are guided by several ethical principles: nonmaleficence, beneficence, and respect for patient autonomy. First, physicians are charged with avoiding causing harm. Second, they are obligated to offer their best care to restore patients to health. Third, physicians must treat patients as independent persons capable of governing their own health and health care, presenting them with all the information necessary to make informed decisions. In the past several decades medical care has moved away from a paternalistic "doctor knows best" approach to one based on shared decision making. In this approach, the knowledge and expertise

of the physician is combined with the value system and understanding of the patient to create a consensus approach to treatment decisions.

In the case above, the physician is bringing his years of specialization and experience to offer the patient what he believes will maximize survival and minimize harm. He also has an obligation to present the relevant medical evidence in its entirety, explaining the benefits and risks of both mastectomy and breast conservation.

The patient contributes her values and desires for her therapy. Factors that may influence breast cancer patients' decision making include anxiety regarding disease recurrence, discomfort with mammograms and biopsies, concerns regarding body image and sexuality, length of treatment time and recovery, family experiences with breast cancer and treatment, and others. When faced with a choice of mastectomy or lumpectomy, some patients may have more anxiety about recurrence and therefore reject breast conservation in favor of removal of as much breast tissue as possible to reduce that risk. Another patient with a similar tumor may worry about feeling disfigured by a mastectomy and fear her self-confidence and intimate relationships would suffer, and therefore would prefer treatment that conserved her breast. Since evidence indicates that the two approaches are medically equivalent in terms of survival (although not equivalent with regard to recurrence), it is the patient's articulation of her values and concerns that informs the medical evidence presented by the physician. Together they come to a decision that is both medically sound and in keeping with the life the patient wants to lead. This shared decision making is most possible in an atmosphere of mutual respect in which both parties feel their contributions are heard and acknowledged. If a patient does not believe her wishes are being considered or feels her doctor is not listening to her concerns, she should find a doctor she trusts to communicate more openly with her.

If a physician who finds him- or herself in conflict with a patient, exploration of the patient's values, fears, and goals for treatment may allow the two of them to find common ground and reestablish trust. As she is unlikely to die in the near future of her disease, it is reasonable to discuss more than just cancer survival in her counseling and recommendations. Questions that can be useful to initiate this dialogue include:

- What is your goal in treating this cancer beyond being cancer-free?
- What do you fear about treating your cancer?
- What do you fear most about your disease after your treatment is completed?
- How do you picture your life in 5 years? How do you picture your appearance?
- What do you think you will look like after surgery?

Not every patient will be able to answer these questions immediately, but physicians who help patients articulate their goals and fears will gain critical insight into their values and expectations for therapy. Many patients will simply start with a desire to survive; if reassured they are likely to live at least 5 years, they will consider

recurrence, appearance, sexuality and intimacy, and other concerns that will inform their medical choices.

If a physician finds him- or herself in conflict with a patient who is not making a reasonable decision (refusing any medical intervention for breast cancer in lieu of herbal therapy, for example), the doctor is not obligated to provide therapy he or she believes to be useless or harmful. In other words, the principle of nonmaleficence must not be sacrificed in the name of patient autonomy. That would constitute a breakdown of the therapeutic relationship. If this occurs, the physician should refer the patient elsewhere for medical care.

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ETHICS CASE

Presenting Unwelcome Research Findings

Commentary by Steven J. Ralston, MD, MPH, and Hilda Bastian

Dr. Andreas nervously tapped her foot as she presented to her attentive specialty society audience. A practicing ob-gyn herself, Dr. Andreas was a doctoral student in health policy at an academic health center who, for the past several years, had been working on a study comparing vaginal births with c-sections in two neighboring towns. Now she was presenting the results of her soon-to-be-published work to the physicians whose patients had made up the study groups, and she was not sure how they would receive the implications of her findings.

“According to the data,” Dr. Andreas concluded, “there are no statistically significant medical, social, financial, or other demographic differences between the women in the two towns who were part of this study. Yet women in the first town were three times more likely to undergo c-sections when delivering their children than women in the second town, after age of the women, which pregnancy this was, whether or not a c-section had preceded this pregnancy, and the clinical course of pregnancy and fetal development were controlled for,” she says.

“But then what explains the difference?” asked an audience member.

“Well, that’s the fascinating part,” said Dr. Andreas excitedly. “The difference must lie not in the patient characteristics or clinical indications for the sections, but somewhere else—perhaps in patient preferences, perhaps in physician training and choices.”

“It sounds like you’re questioning our judgment,” a physician from the first town interjected. “Why would we willingly expose our patients to a more invasive and risky treatment? There must be a difference between the two patient populations.”

“Data analysis finds no significant correlation between the incidence of c-section and any clinical or demogr—”

“Well then your analysis must be wrong,” someone interrupted.

Dr. Andreas was convinced this data had value for clinical decision making, not to mention for health care costs and policy, but she was not sure of the most effective way to present it to the physicians whom it affected.

Commentary 1
by Steven J. Ralston, MD, MPH

This case raises a clear ethical issue: do individual physicians have a responsibility to monitor quality metrics and, if so, from where does that responsibility stem? It also raises a practical question: how to impart quality improvement data in a way that will lead to substantive and beneficial changes in patient care?

The ethical question is best understood, I think, through the lens of professionalism. What is it about medicine, the law, engineering, education, and other “professions” that distinguish them from other fields of employment? Certainly, any employee in any job can display professional and unprofessional behavior: human beings can act poorly in almost any setting. What distinguishes the fields we refer to as the professions, though, is a devotion to service and accountability [1].

Medicine as a profession entails a commitment to excellence in patient care that goes beyond our own self-interest in competing in the marketplace. Yes, we will be less competitive if we practice bad medicine, but our reason for practicing good medicine should be about doing what is right for our patients, not about protecting our market share. This is the core of beneficence: our actions should have as their goal the improvement of the patient’s health status. Furthermore, our ability to provide beneficent care is contingent upon our recognizing and understanding what care actually *is* in a patient’s best interests. Some of this requires delving into the particulars of our patients’ needs and desires, understanding them as full human beings. But beneficent care is also predicated on knowing what works and what doesn’t work: we must endeavor to practice evidence-based medicine whenever possible.

This includes being open to the evidence, even when we don’t like what we hear. The physicians in this case displayed a variety of reactions to the data being presented to them. Some were appropriately inquisitive: “But then what explains the difference?” This ethic of self-reflection and a desire to understand and expand our knowledge base is crucial to our profession’s commitment to excellent patient care. It is the defensive response of “It sounds like you’re questioning our judgment” that reflects a narrower, self-interested, more self-protecting attitude that does not serve the profession well. The whole purpose of quality improvement activities is to ensure that the care we provide is, indeed, the best possible and that the systems within which we are functioning are conducive to that. It is certainly an understandable human reaction to feel defensive in the face of such challenges—many of us have experienced this at any number of morbidity and mortality conferences when our patients have been discussed—but it is imperative that we rise above it with a modicum of humility and ask the tough questions: why did this happen and what can we do to avoid it in the future?

It is important, of course, to remember that the backdrop to this case is the rising rate of cesarean sections in the United States, which has increased from 21 percent in

1996 to 32 percent in 2007 [2]. Furthermore, US hospital data reveal extraordinary variation in cesarean section rates from 7 percent to 70 percent [3]. Obstetricians are under pressure from a variety of sources—insurance carriers, hospital administrations, peer review, threats of malpractice—that may affect their decision making regarding cesarean sections. This is a fascinating and problematic epidemiological phenomenon that is incompletely understood at present, but it is imperative that the profession take it seriously, attempt to tease apart the various factors that have led to this increase, and continue to question these reasons to find ways of addressing them.

So what is the best way to broach this topic with obstetricians or any other group of clinicians whose practice patterns seem to be outside of the desired norm? This is the practical question engendered by this case that, for cesarean section at least, has been addressed in the literature [4]. The evidence, I think, calls for a combination of approaches. First, an approach that looks at institutional systems will often be more fruitful than looking at individual doctor behavior. For example, addressing a labor unit policy of not allowing trials of labor after cesarean section (TOLAC or vaginal birth after cesarean, VBAC) will have a larger impact on cesarean section rates than addressing an individual practitioner's decision not to offer trials of labor in his or her practice. Other quality improvement techniques such as standardizing labor and delivery protocols are also effective.

Second, making it personal will often backfire. The approach of “Why does hospital A have a higher cesarean rate than Hospital B?” is likely to be more effective than “Why does Doctor A have a higher cesarean rate than Doctor B?” The latter will often be met with defensiveness and a digging in of heels. Within a hospital, it is probably more effective to publish anonymized cesarean section rates for each practitioner while giving the individual doctors their own rates so they can see how they compare with the department as a whole. That is not to say that there is no role for monitoring or correcting individual behavior; when a clinician's practice pattern falls outside of the standard of care, it is the responsibility of the department or institution to address and correct this.

Finally, the parties involved have to have some stake in the outcome and a reason to care beyond a lofty appeal to medical professionalism. Sadly, this may require sticks rather than carrots. The goal may be to reduce the cesarean section rate at your hospital because the perception—sometimes based on publicly available data—is that your rates are too high and that, to maintain your share of the market, these rates need to be lowered. Financial motivators are powerful: tying Medicaid reimbursements to elective induction rates was successful in Minnesota in reducing these inductions [5].

In summary, both individual practitioners and institutions need to be committed to providing excellent care to patients, and this will always require self-reflection and humility. An ongoing commitment to quality improvement is the first and most important step in reaching this goal.

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Commentary 2 by Hilda Bastian

We expect medical professionals to be empirically minded—their views shaped by evidence, not opinion. Clinical researchers are even supposed to be able to approach experimental work with what ethicists call “equipoise”: genuinely testing a “null hypothesis” without any bias.

But people rarely are totally open-minded or free of prior certainties. And being the bearer of bad tidings is never really smooth sailing. People tend to be critical of results they don’t want to believe—while glossing over the most blatant lack of rigor in studies that confirm their biases.

As Dr. Andreas found out, clinicians aren’t an exception to the tendency to see negative results as implied criticism. It’s best to go into any research or evaluative exercise with an eye to the worst-case scenario. Better to be overprepared and not need the precautions than to be ambushed as Dr. Andreas was.

Especially if you work in a controversial area, try to make sure you have colleagues the community trusts involved well before the end of the process. They will be invaluable if the going gets rough.

Walking into a specialty society presentation alone with soon-to-be-published unwelcome findings is like walking into a lion’s den. If you are in that situation, then you need to have prepared your talk and any materials you bring well. If it’s going to be published soon, those who are implicated in your findings may well feel betrayed and cornered. It’s better if they feel like their concerns can still have an influence.

Go carefully through the methodology, making sure those in the audience know the things you have in common with them, and try to put yourself in their shoes. They have a lot at stake—not as much as the patients in their care, but a lot. You may be excited about your findings but, if it's bad news to your listeners, speaking excitedly about your data isn't going to make them feel as though their reputations are in safe hands. Demonstrate your concern by picking your words carefully with their sensitivities in mind.

I've upset a lot of people with the results of some of my research. And I suspect that, even if you've done everything right, there is still going to be serious rough and tumble. It can take us time to understand and come to terms with our own unexpected findings, and those whom our findings affect more directly will certainly need time for that. Understanding that, and exercising as much patience as you can muster, can help.

Convincing everyone isn't generally a realistic goal when presenting findings others may not be happy to hear. Achievable goals for this kind of encounter may be to ensure some people really grasp the research, to gain at least one influential ally, and to keep communication channels open.

Hilda Bastian has been the editor of a clinical effectiveness resource, PubMed Health, at the National Institutes of Health since 2011. Her research interests have included the effects of communication on health care and systematic reviews of health care effectiveness. She has a blog called *Absolutely Maybe* at *Scientific American*.

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ETHICS CASE

Is More Screening Always Better?

Commentary by Michael LeFevre, MD, MSPH

Andrew, a fourth-year medical student, applied for a residency in family medicine. While on a rotation at his top-choice program, he noticed something interesting. During the family medicine rotation at his medical school, residents and attending physicians had recommended biopsy if a patient's prostate-specific antigen (PSA) levels were above 4 nanograms per milliliter (ng/mL). In the program that Andrew hoped to become part of, however, residents and attending physicians often recommended biopsies if the patient's PSA levels were above 2.5 ng/mL, a practice Andrew had not seen before.

When Andrew asked the resident about this, he was told that this lower PSA threshold for biopsy allowed doctors not only to catch more cases of prostate cancer but to catch those cancers earlier, when they were more treatable. This made sense to Andrew, and he wondered why the family medicine department at his medical school did not do the same.

He approached the chair of family medicine at his school, who told him there was not enough evidence that biopsies at lower thresholds actually improved patient outcomes and, in fact, they could lead to overuse of resources and overdiagnosis of prostate cancer.

Andrew was confused. Both approaches seemed reasonable to him, and, given his lack of experience and his respect for both institutions, he was unsure which was better. He decided to talk to the dean of curriculum at his medical school about his dilemma. After their discussion, the dean wondered how many of his students encountered similar variations in care on rotations at other hospitals and how those variations should be discussed in the medical school curriculum.

Commentary

Why did Andrew encounter different approaches to the PSA threshold for recommending biopsy? What should he learn from the experience? When he becomes a family medicine resident and takes care of his own panel of patients, what should he recommend? Finally, what, if anything, should Andrew's dean of curriculum do?

All medical care should seek to achieve one or more of three goals: to prevent future suffering, to relieve suffering, or to prolong life. Preventive services, by definition, are used to prevent future suffering or prolong life. Prostate cancer is a logical target

for a preventive service; much public discourse about prostate cancer prevention today focuses on screening. Cancer screening seeks to identify cancers in asymptomatic people with the hope of altering the natural history of those cancers destined to cause suffering without doing too much harm in the process.

What do we know about the relationship between PSA level and the presence of either low-grade or high-grade prostate cancer? The control group in the Prostate Cancer Prevention Trial (PCPT) [1], i.e., those not receiving finasteride, provided a unique opportunity to examine how common prostate cancer is in a population of men eligible for screening, as well as the relationship between PSA level and the presence of prostate cancer. During the study, prostate biopsies were offered to all men (in both the intervention and control groups) who had abnormal screening results, either an abnormal digital rectal exam or a PSA above 4.0 ng/ml. In addition, men who had not had a biopsy for cause were offered an end-of-study biopsy. Almost 25 percent of men in the control group had cancer diagnosed with a biopsy; 85 percent of those cancers were in the low-grade category. Of the men whose PSA was consistently below 4.0 ng/ml and who had end-of-study biopsies, 15.2 percent had prostate cancer. The PSA distributions were very similar for those whose end-of-study biopsy showed no cancer, low-grade cancer, and high-grade cancer. This study allows us to draw three important conclusions: (a) prostate cancer is very common; many more men have prostate cancer than will ever suffer from the disease, (b) there is no clear PSA threshold that provides an optimal sensitivity for high-grade cancer while minimizing both the false positive rate and detection of low-grade cancer, and (c) most cancers detected by screening are low-grade. The harder you look for prostate cancer, the more you will find. What this study could not tell us is whether looking hard for prostate cancer serves medicine's goals, either by preventing future suffering or prolonging life.

What do we know about the benefits of prostate cancer screening? The multicenter Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial [2] conducted in the US showed a non-statistically significant increase in prostate cancer mortality in the screening group, though the European Randomized Study of Screening for Prostate Cancer trial [3] showed a statistically significant absolute reduction of 0.10 prostate cancer deaths per 1,000 person-years after a median follow-up of 11 years. All-cause mortality was 19.1 percent in the screened group and 19.3 percent in the control group, a difference not statistically significant. Screening frequency and the threshold for referral for biopsy differed by screening location, but differences in outcomes between countries could not be clearly linked to screening protocol.

The small reduction in prostate cancer mortality in the European trial occurred in the context of a significant increase in the number of cancers diagnosed and treated in the screened group. Much of the morbidity resulting from prostate cancer is a consequence of the diagnosis and management of the disease, rather than the disease itself, and many screen-detected cancers would never become apparent—never cause suffering—in the lifetime of the patient without screening. Screening for prostate cancer may prevent future suffering or prolong life in a few men, but the detection

and treatment of indolent disease may actually harm more men than it helps. This overdiagnosis and overtreatment is the principal source of harm in PSA screening for prostate cancer. It was the judgment of the US Preventive Services Task Force (USPSTF) that the potential benefit of screening does not outweigh the harms [4].

Andrew's dilemma will be played out over and over about many forms of screening, diagnosis, and treatment as he progresses through his medical education and training. Several ethical questions arise in this situation. How good should the evidence of benefit and harm be before we offer or recommend a medical intervention to a patient? Are we obliged to offer services we hope, but don't know, will help? Should we focus primarily on benefit, or are harms of equal importance? Preventive services are offered to people who feel well; we are leveraging a real possibility of causing suffering in people who feel well against a possibility of avoiding future suffering or prolonging life. Should the evidence bar be higher for preventive services than for those that aim to relieve current suffering? If we do offer services about which evidence is unclear, what do we owe our patients to enable an informed decision?

The principles of beneficence and nonmaleficence often come into conflict. When faced with a risk of future suffering, "don't just stand there, do something" is often in direct conflict with "first, do no harm." All medical care has the potential to cause harms. A case can be made that benefits and harms must hold equal sway and that, particularly for preventive services, the evidence should be clear that across the population served we do more good than harm. If clear evidence favors action, then we act. Science must trump hope.

Should Andrew continue to pursue training at his top-choice program? A critical component of residency training should be learning how to think about clinical decisions, not just learning what to do. Good doctors who are recent residency graduates can easily become bad doctors in a decade if they are not continually questioning what they do and why they do it and assimilating new information into clinical care. Good clinical decisions incorporate the best science available, individual patient circumstances, and patient preferences. Faculty should be open to learners who challenge their thinking in the interest of learning. If Andrew's sense is that the faculty are not thinking critically about the care they provide, another program may prepare him better for the future.

How should Andrew's dean of curriculum respond? Medical students should graduate with an understanding of the significant variations in care that exist both across and within institutions. Students should be taught to use the variations as a stimulus to learn how decisions are being made, and to pursue for themselves the science that informs those decisions. One of our major responsibilities in medical education should be to promote intellectual curiosity and lifelong learning.

What should Andrew do about PSA screening when gets his own panel of patients? It is difficult to make the case that we have an ethical imperative to offer PSA screening, but the balance of benefit and harms does not preclude a physician

offering or a patient requesting the service. Patient autonomy and patient preferences and values must be respected, but a clear understanding of what the science tells us about the benefit and harms of PSA screening for prostate cancer should precede testing.

It's not "just a blood test"; a cascade of testing and treatment that is hard to stop begins with the PSA test. Prostate cancer is very common, but very few men actually benefit from early detection and treatment, and more will be harmed. A man who places a higher value on the possibility of avoiding a prostate cancer death than on the harms of overdiagnosis and overtreatment may make the autonomous decision to be screened. But we should not make it for him. It is fair to advise patients that different thresholds exist for further evaluation, but incremental benefit from the lower threshold remains to be demonstrated, and an increase in harms is almost certain.

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THE CODE SAYS

The AMA *Code of Medical Ethics*' Opinion on Pay for Performance

Opinion 8.056 - Physician Pay-for-Performance Programs

Physician pay-for-performance (PFP) compensation arrangements should be designed to improve health care quality and patient safety by linking remuneration to measures of individual, group, or organizational performance. To uphold their ethical obligations, physicians who are involved with PFP programs must take appropriate measures to promote patients' well-being.

(1) Physicians who are involved in the design or implementation of PFP programs should advocate for:

- (a) incentives that are intended to promote health care quality and patient safety, and are not primarily intended to contain costs;
- (b) program flexibility that allows physicians to accommodate the varying needs of individual patients;
- (c) adjustment of performance measures by risk and case-mix in order to avoid discouraging the treatment of high-risk individuals and populations;
- (d) processes to make practice guidelines and explanations of their intended purposes and the clinical findings upon which they are based available to participating physicians.

(2) Practicing physicians who participate in PFP programs while providing medical services to patients should:

- (a) maintain primary responsibility to their patients and provide competent medical care, regardless of financial incentives;
- (b) support access to care for all people and avoid selectively treating healthier patients for the purpose of bolstering their individual or group performance outcomes;
- (c) be aware of evidence-based practice guidelines and the findings upon which they are based;
- (d) always provide care that considers patients' individual needs and preferences, even if that care conflicts with applicable practice guidelines;
- (e) not participate in PFP programs that incorporate incentives that conflict with physicians' professional values or otherwise compromise physicians' abilities to advocate for the interests of individual patients.

Issued June 2006 based on the report "Physician Pay-for-Performance Programs," adopted November 2005.

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MEDICAL EDUCATION

Teaching Quality Improvement and Health Care Systems at Dartmouth's Geisel School of Medicine

Greg Ogrinc, MD, MS

The Geisel School of Medicine at Dartmouth has more than a dozen years' experience incorporating elements of quality improvement (QI) and systems into its curriculum. This began with introductory lectures in the late 1990s to create student awareness about health care quality and systems and has developed into an integrated, four-year curriculum that imparts a basic understanding of the health care system, interprofessional teamwork, health outcomes, and financing. As we engage in comprehensive curriculum redesign, these elements will be a core part of our new curriculum.

The Geisel School of Medicine admits about 85 students each year. The general curriculum focuses primarily on the scientific foundations of modern medicine in the first year, pathophysiology of disease in the second year, core clinical clerkships and electives in the third year, and advanced clinical training and required capstone courses in the fourth year. In 2006 and again in 2011, Geisel's medical education committee sought to increase coverage of these curriculum topics and experiential learning opportunities for second-year medical students. These changes have led to the current integrated four-year experience.

The first-year core curriculum includes the Fundamentals of Health Care Delivery Science seminar course. The discipline of health care delivery science (HCDS) combines evidence-based medicine and the study of health outcomes with leadership, teamwork, health care systems knowledge, and financing. The seminar series provides a broad foundation in health care delivery science in an interprofessional environment. Our teachers for these sessions come from expert faculty within the Dartmouth Center for Health Care Delivery Sciences, Geisel, the Dartmouth Institute of Health Policy and Clinical Practice, Tuck School of Business, Dartmouth-Hitchcock Medical Center, and the White River Junction VA Medical Center. Each class is a 75- to 90-minute large-group seminar session usually focused on a case study. The class meets about once a month between September and May. Students prepare for class by reading articles or short chapters or watching a video. Through student and faculty discussion, the class identifies health care system problems in the case and seeks resolutions for those problems. In the spring, each student writes an essay analyzing a case, using skills developed during the nine sessions.

In year two, the health care systems material is integrated into the Scientific Basis of Medicine organ-based pathophysiology courses. Students gain the knowledge and skills to describe the people, structures, and processes within a system as well as the principles of variation and measurement for QI and are introduced to analyzing data using statistical process control charting. They then apply their knowledge to local examples, such as regional variation in care for acute stroke, local performance gaps in the evidence-based practices for patients in the intensive care unit, and population health factors for vaccinations. In the cardiology course, for example, students explore the system-level interventions and measurement tools that are used to assess and improve door-to-balloon time for acute myocardial infarction. The QI and systems curriculum thus becomes a new endpoint to the study of pathophysiology from the cellular level to organs, organs to organ systems, organ systems to patient presentation and treatment, and from there to delivery system dysfunction and improvement. Importantly, the courses focus on outcomes at affiliated hospitals and efforts to close quality gaps at those hospitals.

Second-year students with a particular interest in QI and systems can also enroll in the quality improvement practicum. This elective pairs medical and nursing students and provides an opportunity to work on a QI project at a local site. In small-group sessions on campus, students start to develop skills such as writing an aim, evaluating processes, analyzing data, and recommending changes. The student teams then apply these skills in clinical settings with the assistance of a site coach. Over the years, student teams have increased routine urine screening for pregnant women, analyzed causes of delays in colonoscopy scheduling, and assessed the care of intravenous catheters on the oncology service. These student teams bring fresh eyes to the systems and processes at their sites.

In year three, Geisel students apply the foundational knowledge they gained in years one and two during core clinical rotations. For example, students who rotate on inpatient medicine at the White River Junction VA hospital, where QI is integrated into teams' routine work, have increased pneumococcal vaccination rates, deep venous thrombosis prophylaxis, and evidence-based smoking cessation interventions. While these opportunities are not present in every clerkship at every location, we have begun to integrate this work for our resident programs which makes the important connection for our medical students.

Year four brings all students back to campus for required capstone courses that deepen their knowledge of the health care system, QI, patient safety, and safe prescribing. Health, Society, and the Professional is a required interprofessional course for all medical students. There are two components to the course. In the first component, medical students spend four weeks in teams of about 10 with a QI coach analyzing a system of care delivery, reviewing outcomes data, and presenting recommendations to the site and their student and faculty colleagues. The second component of this course comprises weekly interprofessional sessions with nursing and physician assistant students. In small and large groups, the students discuss cases that focus on ethics, innovation in health care, finance, and policy. These sessions

provide an opportunity for all students from several professional schools to explore these important topics together before they enter practice together.

In the coming years, we are preparing for the next iteration of the Geisel curriculum. Our redesigned curriculum will include four required core courses for all students. Each spans four years and requires about 80 hours of curriculum time. The courses will provide a depth and breadth of knowledge and skills in critical appraisal of health care literature and evidence, design and improvement of systems, leadership in health care, and the contextual factors that impact the delivery of care for patients and populations.

We recognize that unprecedented progress in biomedical science and the tremendous pressures to contain the cost of care have transformed care delivery and the practice of medicine. This has placed greater urgency on translating research and evidence into practice and, at the same time, has fostered disparities in quality of and access to health care. It is no longer sufficient for physicians to be competent only in the biomedical and clinical sciences; they must understand the system of care in which they work, collaborate with all professionals on the health care team, and help improve the quality, safety, and value of care. From the bench to the bedside to the community and beyond, leaders are needed who can think critically, innovate creatively, and work collaboratively to realize high-quality evidence-based health care in the US and worldwide. We believe that Geisel is positioned to prepare students as leaders with the knowledge, skills, and experience necessary to address these challenges.

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JOURNAL DISCUSSION

A Resource-Based Locality Rule

Stuart P. Swadron, MD, Peter Milano, MD, and Anne M. Milano, JD, CPA

Lewis MK, Gohagan JK, Merenstein DJ. The locality rule and the physician's dilemma. *JAMA*. 2007;297:2633-2637.

Some physicians may find the semantics of the medico-legal world a bore. However, "The Locality Rule and the Physician's Dilemma," by Lewis and colleagues [1], really caught our attention. We consider the locality rule from the point of view of a practicing emergency physician (EP).

The locality rule, once widely applied in the United States and abroad, was designed to protect rural physicians from having to uphold the same standard of care as that provided in the academic health science centers and modern clinics of the city. Initially this was a matter of training, research, and resources; rural practitioners not only lacked the equipment of the urban centers but also did not benefit from the latest advances in science and practice that emanated from medical research conducted at urban center hospitals [2]. Most courts now hold, however, that this argument is not valid in an era of seamless electronic communication, national standards in medical training and lifelong education, and the flow of scientific information among medical institutions throughout the country [3].

Lewis et al. argue convincingly for the abolition of the rule, still in force in some states either by statute or case law. One of their strongest arguments is that the locality rule might actually promote substandard care by preventing practitioners from adopting newer or more evidence-based practices for fear of breaching a local "standard" that is actually inferior [1].

But completely eliminating the locality rule may not be the answer. Instead of defining "locality" as geography, the courts' traditional approach [4-6], we believe that the determination of the standard of care should be based on the resources available to the physicians in that area. This was the approach the court advocated in *Hall v. Hilbun*, redefining the standard of care as follows:

[G]iven the circumstances of each patient, each physician has a duty to use his or her knowledge and therewith treat through maximum reasonable medical recovery, each patient, with such reasonable diligence, skill, competence and prudence as are practiced by minimally competent physicians in the same specialty or general field of practice throughout the United States, *who have available to them*

the same general facilities, services, equipment and options (emphasis added) [7].

This view was reaffirmed in *Palmer v. Biloxi Regional Medical Center, Inc.* [8]. The Supreme Court of Mississippi upheld the trial court's decision to dismiss the plaintiff's charge of negligence against the medical center, partly because the plaintiff's medical "expert" had not familiarized himself with the facilities available to the defendant doctor or in the general area of the state. The court held that it is necessary and acceptable to consider the medical resources available in determining the standard of care required by the practitioner [9].

A resource-based approach, while broadly applicable, is especially appropriate for the practice of emergency medicine. Medical management decisions—often critically important ones—may hinge on the availability of resources at a given facility, in a given community, on a given day of the week and time of day. Even within a given community, a small hospital emergency department with minimal staffing and a limited specialist call panel may be just down the street from a major tertiary receiving center with specialists available in-house around the clock. Because of the considerable overlap in the scope of practice and actual practice of EPs and various medical and surgical specialists, EPs often perform procedures that medical and surgical specialists would perform in nonemergency circumstances.

One example is the variation in the performance of a resuscitative thoracotomy: a highly invasive and resource-intensive procedure that is sometimes performed on moribund victims of trauma at urban academic trauma centers. Despite a very low survival rate, the procedure nonetheless has some neurologically intact survivors [10]. EPs are trained in resuscitative thoracotomy but may decide not to apply the skill in practice because it doesn't make sense in their environments; without the immediate availability of an appropriately trained and prepared trauma team, patients are unlikely to survive beyond initial resuscitation. Thus, the availability of resources, especially human resources, is and should be intimately tied to medical decision making and therefore the standard of care.

A more commonly encountered example involves the drainage of abscesses in the emergency department. If an abscess is extremely deep and likely to involve vital structures, a decision may be made to defer drainage to a consultant surgeon, who is better prepared to deal with complications in the controlled setting of the operating room. However, things are not always that simple for EPs. A surgeon may not always be on hand. Even in hospitals with robust call panels, a consultant may not always be able to respond in a timely manner to an emergency if, for example, he or she is already in the operating room with another patient. In the event that an appropriate surgical specialist is not immediately available, the risk of complications may be outweighed by risk of delay in care. Ultimately, EPs are trained and willing to act in such circumstances, even if their experience with the procedure in question is less than the specialist's. Many patients who would benefit from care in settings with more resources by more specialized personnel receive emergency treatment by

EPs when this risk-benefit ratio passes a critical threshold. And that threshold varies with the resources available. So should the EP be held to a general “standard” or that of a similarly situated EP with similar resources?

A resources-oriented locality rule is implicit in the California requirement that testimony in the context of medical malpractice cases against EPs in that state be limited to other EPs, i.e., that it be specialty-specific [11]. EPs in other states do not enjoy this protection. In *Sami v. Varn* [12], for example, an obstetrician-gynecologist was qualified to give expert testimony on the standard of care for a pelvic examination performed by an EP. When resources and urgency are not taken into account, we risk holding EPs to an unrealistic standard.

Lewis et al. argue for the incorporation of evidence to the determination of the standard of care. While it is difficult to take issue with this approach, very few malpractice cases hinge solely on medical evidence, even when such evidence exists. The majority of modern medical practice remains unproven by modern scientific standards, and applying evidence to individual cases remains a matter of judgment. Thus, it continues to be necessary to rely on the expertise of practicing physicians to determine the standard in each individual case. Experts testify as to “the degree of care and skill that a physician or surgeon of the same medical specialty would use under similar circumstances” [13], not on a simple factual question.

We agree that the locality rule as originally designed is somewhat outdated. However, the underlying principle should still apply: each case should be viewed in its own context. A resources-based “locality rule,” if adopted nationwide, might protect clinicians from being held to an impractical standard of care that does not consider the totality of the circumstances under which they acted.

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STATE OF THE ART AND SCIENCE

Standardized Clinical Assessment and Management Plans: A Clinician-Led Approach to Unwarranted Practice Variation

Michael Farias, MD, MS, MBA, and Rahul H. Rathod, MD

A nine-year-old girl comes to your clinic with chest pain. Over the past four weeks she has been bothered by intermittent, fleeting pain in her chest that generally occurs at rest, but occurred last week when she was playing soccer. She is otherwise healthy. When you ask her where it hurts, she points to the center of her chest. Her physical exam is entirely normal. Her parents are especially worried because last month a local high school football player suffered a cardiac arrest during training camp.

One Complaint, Many Approaches

You consider potentially dangerous diagnoses like hypertrophic cardiomyopathy, an anomalous origin of a coronary artery, or a tachyarrhythmia, but you are confident that this child has only musculoskeletal pain. You obtain an ECG that is unremarkable and attempt to reassure her parents. However, their fears are not allayed and they seek another opinion. You later learn that the child underwent echocardiography and exercise stress testing and that the results of both studies were normal.

Why did the other doctor take such a markedly different approach? Was he or she justified in doing so? Did parental concern influence that physician's decision making, or perhaps did the monetary advantage of ordering additional testing play a role? Alternatively, had you been mistaken and was this child actually at greater risk than you had judged? Was the expensive additional testing indeed indicated?

These questions address many of the factors that underlie variation in care—lack of clear data to guide decision making, differences in clinician knowledge or experience, influence of patient preferences, and even perverse financial incentives. These factors, furthermore, are not limited to pediatric chest pain—they are universal throughout medical practice [1]. Some degree of practice variation is certainly justified: family histories, comorbidities, and special circumstances frequently necessitate individualized patient management. It is well documented, however, that there is considerable unnecessary variation in medical care. Although sometimes more care is sought by patients and their clinicians, more care does not necessarily equal better care, and this variation leads to increased costs without improved patient outcomes or satisfaction [2, 3].

A Challenging Problem to Fix

With health care costs continuously escalating, there is a pressing need to limit unwarranted practice variation. However, few efforts have met with considerable success. Pay-for-performance strategies promote care standardization and improvement, but can be limited in their efficacy because of inadequate metrics or insufficient incentives. At the other extreme, measures such as forcing guideline adherence or rationing care can significantly curb variation, but meet resistance from patients and clinicians alike for their restriction of clinical autonomy, limitation of individualized management, and potential ethical problems.

Recognizing the need to standardize practice in a manner that does not unduly restrict clinician autonomy or the ability to provide individualized care, our group hypothesized that a new kind of practice guideline was required. We created a novel decision-making tool, the Standardized Clinical Assessment and Management Plans (SCAMPs), with three goals in mind—to standardize care, optimize resource use, and improve patient outcomes [4].

What Is a SCAMP?

A SCAMP is a specialized care pathway for a particular condition designed by a multidisciplinary team of expert physicians, nurses, and biostatisticians to standardize the care of a diverse group of patients with a diagnosis of that condition. Each SCAMP comprises management recommendations alongside a systematic and targeted data collection process. One distinguishing feature of a SCAMP is its invitation and capture of knowledge-based diversions from its pathway, which not only permits but also learns from individualized patient management.

Analysis of collected patient data, outcomes, and management decisions provides valuable information on the efficacy of the SCAMP and helps to identify ways in which its algorithm can be progressively improved. In this way, every SCAMP encounter becomes a learning experience, and rapid-cycle improvement allows the SCAMP to provide state-of-the-art, relevant, and appropriate care recommendations. The 8-step SCAMP development process is summarized in Table 1.

Table 1. The SCAMP development process

1	Committee establishes a foundation for sound clinical practice through literature review, composes a background position paper, and, if necessary, conducts a focused retrospective study to analyze current practice.
2	Committee formulates plausible findings and statements that address known gaps in knowledge regarding the management of the disorder, which become the focus of targeted on-site data collection.
3	Committee builds expert consensus on the inclusion/exclusion criteria, assessment recommendations, and management algorithms (decision trees) for the SCAMP.
4	Committee develops data forms and information technology tools that provide management recommendations and collect targeted clinical information and reasons for diversions from the pathway.

5	Clinicians and/or support personnel (e.g., data coordinators) identify eligible patients for the SCAMP based on the previously defined inclusion/exclusion criteria. This can be done in real time or behind the scenes by the data coordinators.
6	Clinicians document targeted clinical data on paper or online data forms and record reasons for diversions from the pathways. Some necessary data that is already in the electronic medical record can be abstracted using information technology tools or by data coordinators.
7	Statisticians analyze SCAMP data and diversions from the pathway on a relatively frequent basis to assess the clinical and cost effectiveness of recommendations.
8	Committee periodically and iteratively revises the SCAMP based on this analysis and relevant updates from the medical literature.

In practice, the SCAMP can exist as a paper or electronic form that clinicians use during patient encounters to guide their decision making. If a clinician decides to diverge from the SCAMP recommendations, this decision and the rationale behind it are captured on the form.

The SCAMPs effort has made considerable progress since its inception in 2009, with more than 16,000 patients from 15 different institutions enrolled in 50 active SCAMPs. SCAMPs currently in use span the gamut of medical practice, from common outpatient concerns to advanced surgical procedures, in both pediatric and adult care. Many more SCAMPs are currently in development, and the list of institutions interested in joining the effort continues to grow.

Benefits of SCAMPs

The rapid spread of SCAMPs stems from the success of the tool in addressing several of the aforementioned challenges:

Standardizing patient care. Adherence to the recommendations of the first six SCAMPs (arterial switch operation, hypertrophic cardiomyopathy, aortic stenosis, aortic regurgitation, chest pain, and dilated aorta) exceeds 80 percent [5], which compares favorably to other guideline adherence rates, which range from 39 to 53 percent [6]. The much higher adherence rate suggests that physicians believe SCAMPs offer effective care standardization without significant curtailing of individualized patient management. We think physician comfort with SCAMPs is due in large part to its allowance of diversions from the pathway and iterative improvement of the recommendations to provide better patient care.

Optimizing resource use. The true optimization of resource use involves not only the elimination of unnecessary use but also the appropriate enhancement of necessary use, so that patients do not miss out on testing or treatments that are indicated. Underuse can occur for a range of reasons, from lack of clinician knowledge to poor insurance coverage or discriminatory provision of care (e.g., patients receive

suboptimal care because of age, race, or sex). SCAMPs can aid in the identification of over- and underutilization of necessary care.

As a guideline applicable to patients regardless of their demographics or economic status, SCAMPs have demonstrated both fair and real resource optimization. The implementation of a SCAMP on pediatric chest pain was effective in reducing unnecessary echocardiograms from 28 to 15 percent of visits and increasing necessary echocardiograms from 62 to 87 percent [7]. Overall, this resource-use optimization leads to real cost savings, with a 26 percent reduction in cost noted across 5 SCAMPs (chest pain, arterial switch operation, hypertrophic cardiomyopathy, aortic stenosis, aortic regurgitation) [5].

Improving patient care. The standardization of care and resource optimization achieved by SCAMPs has in no situation that we are aware of resulted in poorer patient outcomes. In fact, many SCAMPs show promise of significantly improving outcomes. As an example, a SCAMP on catheterization management for aortic stenosis in children increased the rate of cases with optimal results following balloon dilation from 34 to 52 percent and reduced inadequate results from 45 to 17 percent [8]. This improvement is predicted to markedly prolong event-free survival [9].

Implications

SCAMPs have achieved the above goals while obtaining acceptance from multiple stakeholders in the health care system, including clinicians, patients, hospitals, and insurance companies [5]. Because of this success and wide acceptance, SCAMPs offer a valuable paradigm for effectively reducing unwarranted practice variation in an evidence-based and equitable manner, with the added benefits of reducing costs and improving outcomes. Innovative tools like SCAMPs have the potential to positively impact a broad range of medical practice and should be considered by clinicians and health care leaders looking to ensure the delivery of safe, high-quality, and effective care.

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HEALTH LAW

Lack of Standardized Informed Consent Practices and Medical Malpractice

Richard Weinmeyer, JD, MPhil

The promise of efficient and appropriate health care has never seemed brighter. Telemedicine is providing needed access to medical services to patients in remote locations, research in genetics and genomics is teaching us more about human physiology and making personalized medicine possible, injuries and illnesses that were disabling or lethal in the not-too-distant past are now preventable and treatable. One might think that these advancements would contribute to a minimal standard of care for most medical conditions regardless of where a patient lives and seeks treatment. But, as the current research on variations in medical care demonstrates, such thoughts are false [1]. For example, a patient living in Baltimore, Maryland, is five times more likely to undergo a lower-extremity bypass for peripheral arterial disease of the leg than one living in Temple, Texas, while a patient with prostate cancer is three times more likely to be treated with a radical prostatectomy if he lives in Salt Lake City, Utah, than if he lives in San Francisco, California [2]. Whether it is the underuse of care, the overuse of care, or the inappropriate use of medical resources, national standards for health care are elusive.

Unwarranted variations in medicine not only have implications for physicians, patients, and payers but also have an impact on the law and the way courts and agencies regulate the conduct of physicians and health care institutions. When there is no consistent standard of care with which to assess the behavior of agents in health care, the law faces the formidable challenge of bringing about a fair and just result. This article looks at one particular topic in health law that is affected by variations in care: informed consent and medical malpractice. This is by no means the only legal matter that is tested by unpredictable practices in health care, but this example provides insight into how the law is attempting to adapt to fickle standards of care.

Measuring a Standard of Care

Variations in medical care can play a tremendous role in legal proceedings given that “the law attributes normative significance to the medical standard of care” [3]. Courts make determinations on whether or not a physician is liable for the injuries sustained by a patient during or following a medical intervention based, in part, on whether the physician deviated from the standard of care [4]. In order to ascertain exactly what the standard of care should be, courts rely heavily on the testimony of medical experts who possess the appropriate knowledge, education or training, skills, or experience to testify about the standard under scrutiny [4].

Two Standards for Informed Consent

The manner in which informed consent is achieved depends on the way the physician and the patient share information and how the patient ultimately makes her decision

to undergo or forgo a procedure. Just exactly how this deliberative process is undertaken can be the precise question before a jury in a medical malpractice case. In general, there are two kinds of informed consent in the United States: the physician-based standard and the patient-based standard [5]. Approximately half of the states in the country follow the physician-based standard [6], which is defined in reference to the actions of *other* physicians [7]. Within these jurisdictions, a physician “has a duty in the exercise of ordinary care to inform a patient of the dangers of, possible negative consequences of, and alternatives to a proposed medical treatment or procedure” [8] with the same “degree of skill and diligence exercised by a reasonably prudent practitioner in the same field of practice or specialty” in that same state [9]. The patient-based standard, on the other hand, which has been adopted in 23 states and the District of Columbia [10], requires a physician to disclose any material risk to the patient, meaning the physician believes a reasonable person in the patient’s position “would be likely to attach significance to the risk...in deciding whether or not to forego [sic] the proposed therapy” [11]. In order to support a claim of medical malpractice, a patient has to prove that (1) the physician failed to meet the applicable standard, (2) the patient would have decided not to undergo the procedure had the standard been met, and, (3) overall, the physician’s failure was the proximate cause of the patient’s injuries [12].

Is There Really a Single Standard?

When unwarranted variations in care plague medicine, determining whether the appropriate standard for informed consent has been met can prove problematic. While state legislatures and courts have adopted and applied a particular type of informed consent law, a single standard of care typically does not exist for most treatments, and researchers have demonstrated that standards vary substantially by region [13]. These variations are not random, but reveal differing patterns of practice: in some areas, physicians become specialized in certain treatments and then regularly recommend those treatments to patients suffering from particular conditions, while, in other areas, treatment decisions may be constrained by hospital or clinic management [14]. Furthermore, studies indicate that similar patients are not treated similarly; patient preferences and the supply of physicians fail to account for variations in care [15], and physician culture varies by location.

With respect to informed consent, the ambiguity around just what the standard of care is makes it difficult for courts to determine when a physician’s informed consent practices have fallen outside the range of reasonable options. As Feldman-Stewart and colleagues have found, physicians often do not reach a consensus on the quantity nor the content of information that should be disclosed to patients, and this holds true even among physicians living in the same geographic region and working in the same specialty [16]. Such a conclusion is problematic for states that abide by the physician-based standard. And, in terms of the patient-based standard, patients frequently disagree about what risks they consider to be “material” for a particular treatment option [17], and physicians tend to be quite poor at predicting patient preferences [18]. The legal theory behind informed consent laws, it seems, differs considerably from the reality of medical practice.

Attending to the Variability of Informed Consent

Because these variations in health care delivery standards make it difficult to assess conformity with informed consent laws, scholars have proposed solutions that would establish more appropriate legal standards. Perhaps the most persuasive of these proposals is that of King and Moulton, who argue that states should move towards a shared decision-making standard for informed consent because this framework incorporates evidence-based medicine and requires both the physician and the patient to share information and jointly participate in the decision-making process [19]. Under this type of system, the physician would “share with the patient all relevant risks and information on all treatment alternatives and the patient [would share] with the physician all relevant personal information that might make one treatment or side effect more or less tolerable than others” [20]. This model of informed consent, they suggest, would preserve patients’ individual autonomy by giving them greater access to the information they need in considering the options before them [19], while also improving physicians’ ability to advise their patients on treatment choices [21]. Despite the promise this legal revision would bring, King and Moulton acknowledge that an overhaul of informed consent law would require considerable resources and present implementation hurdles for both the US health care and legal systems; however, surmounting these obstacles may well be worth it for better protecting the decisions made by patients and physicians in the provision of care [22].

Conclusion

The study of variations in health care delivery reveals that a multitude of care options are offered to patients across the country, and this variety in care may not be compatible with existing legal standards. The ways in which informed consent is obtained in hospitals and clinics, for example, may no longer comport with what the law requires to shield physicians from liability. Solutions to this medicine-law mismatch surely exist in some melding of evidence-based medicine with legal theory, but the measured evolution of the law means that standardized informed consent may very well be an unattainable standard of care for many for the time being.

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POLICY FORUM

The Complex Relationship between Cost and Quality in US Health Care

Leah A. Burke, MD, and Andrew M. Ryan, PhD

Health care is extremely costly in the United States. Although the rate of growth in spending has attenuated in recent years [1], per capita spending on health care is estimated to be 50 to 200 percent greater in the United States than in other economically developed countries [2]. Despite leading the world in costs, however, the United States ranks twenty-sixth in the world for life expectancy [3] and ranks poorly on other indicators of quality [4].

Evidence of the low value of United States health care has led researchers to try to identify specific sources of wasteful spending. Many of these efforts have evaluated regional variation in spending patterns—particularly Medicare spending—within the United States. By finding that regional variation in spending is not generally correlated with patient outcomes [5, 6]—suggesting that some regions’ practices were not cost-effective—this literature captured the attention of policymakers and sparked public and private sector proposals to reduce unwarranted variation in treatment. Recent evidence suggests, however, that higher-intensity care may, in fact, improve patient outcomes, calling into question how much we stand to gain by reducing “waste” in health care spending. In this paper, we summarize what is known about the relationship between health care spending and quality of care and the current efforts to reduce unwarranted variation in care.

The Cloudy Relationship between Treatment Intensity and Quality

Much of the evidence that variation in health care treatment intensity (including the number or concentration of diagnostic tests, physician visits, hospitalizations, and procedures) is weakly related to quality comes from the Dartmouth Atlas of Health Care. In a landmark study, researchers from the Dartmouth Institute for Health Policy examined patients hospitalized between 1993 and 1995 for hip fracture, colorectal cancer, or acute myocardial infarction, as well as a representative sample of Medicare enrollees in their last 6 years of life, and determined each cohort member’s exposure to different levels of spending on end-of-life care [5]. The researchers documented significant variation in health care spending and quality across geographic regions in the United States for similar patients. Regions in the highest quintile of Medicare spending had 65 percent more medical specialists per capita but 26 percent fewer general and family practitioners. Medicare beneficiaries who lived in high-spending areas received approximately 60 percent more services than did those who lived in low-spending areas. Yet, this increased utilization was not explained by underlying illness rates and was not associated with any gain in life expectancy. On average, beneficiaries who lived in regions with higher Medicare

spending were not more likely to receive recommended treatment for routine health maintenance and for care related to myocardial infarction.

More recent evidence suggests, however, that higher-intensity care may, in fact, improve patient outcomes. A recent study evaluated the relationship between intensity of care and quality in New York State by exploiting the quasi-random assignment of patients to hospitals based on ambulance referral patterns. The researchers found that higher procedure intensity was associated with lower mortality one year after hospitalization [7]. Similarly, Silber and colleagues reported a relationship between greater care intensity and lower mortality in the 30 days after admission among Medicare beneficiaries who received general, orthopedic, and vascular surgery between 2000 and 2005 [8]. The decreased mortality was not due to fewer complications but rather to fewer deaths among those with complications. Outside of this 30-day window, however, Silber and colleagues found that patients from lower- and higher-intensity hospitals were no more likely to live or die in the following year and that patients return to the same “baseline hazard” of death after surviving that first month. Amber Barnato interpreted these results as meaning that “better hospital quality improves safety (e.g., survival conditional upon hospitalization), but it does not improve population health (e.g., longer life expectancy or slowed functional decline)” [9]. While the United States medical workforce has extensive specialty expertise in intensive medical treatments, the current health care system may fail to prioritize low-cost, low-intensity health care interventions (for example, vaccinations) that could dramatically improve overall public health.

Why Are Costs Not Strongly Related to Quality in the United States?

The Food and Drug Administration (FDA) in the United States approves a drug or device if it is shown to be safe and effective. For drugs, the FDA approval process relies mainly on the comparison of a single treatment to an extant treatment or placebo [10]. Standards are less stringent for medical devices: many are cleared for market under the “510(k)” provision, which requires only that a device be substantially equivalent to another device already on the market [11]. There is no requirement for new drugs or devices to be more effective or less costly than existing approved regimens. Payers, such as Medicare, have adopted these new technologies without considering cost effectiveness or comparative effectiveness. As a result, expensive new therapies are adopted without good evidence that they improve patient outcomes. A recent example comes from the approval of new cancer drugs, which can cost well over \$100,000 per year and are often expected to extend life for little more than a month [12].

Once approved, many treatments—while cost-effective in some cases [13]—are given to patients who have little to gain from them. For example, a study by Tu and colleagues showed that, despite similar survival outcomes, rates of coronary angiography, angioplasty, and bypass surgery following a heart attack were 5 to 10 times higher in the United States than in Canada [14].

Another reason why spending is not highly correlated with quality is that the price of the same service varies. Medicare pays physicians and hospitals using administrative prices that are adjusted based on a variety of factors—including geographic region, indirect medical education (which accounts for the cost of training residents and fellows at teaching hospitals), and the hospital’s “disproportionate share” (which reflects the burden of caring for indigent patients)—but vary little based on quality [15]. Variation in prices paid by private insurers is due largely to bargains struck with doctors [16, 17], rather than quality of care.

Efforts to Reduce Waste and Improve Value in Care

There are efforts under way to increase value in medical care by reducing unwarranted variation in medical services. The Choosing Wisely campaign [18] is an initiative of the American Board of Internal Medicine (ABIM) that encourages physicians, specialty societies, patients, and health care stakeholders to make decisions about the appropriateness of medical care based on a patient’s individual situation rather than automatically following guidelines. This initiative encourages avoidance of unnecessary tests and procedures that yield no benefit and could actually do harm. Commitment by national specialty societies to documenting such evidence-based recommendations should reduce regional variation. Nonetheless, researchers and physicians alike have struggled to identify specific instances in which treatments should be withheld. In a review of the literature, Korenstein and colleagues could identify only a handful of services that evidence strongly indicated were overused [19]. Reducing the use of these services nationwide would make a negligible impact on health care spending.

At the request of Congress, the Institute of Medicine (IOM) convened a committee to examine geographic variation in Medicare expenditures. The committee was asked whether Medicare should modify payments to adjust for the value of services delivered in a region by using a value index, which would account for both the health benefit obtained from delivered services and their cost. The committee found that, within any area, clinician behavior varied substantially, so that increasing reimbursement for all doctors in an area would unfairly reward those who performed poorly, and reducing reimbursement for all doctors in an area would unfairly penalize those who performed well [20, 21].

The Centers for Medicare and Medicaid Services have started to endorse value-based purchasing, bundled purchases, and accountable care organizations [22, 23]. Such practices encourage clinicians to deliver higher-quality care by tying reimbursements to quality metrics and cost reduction for an assigned population. It is unclear, however, whether the design of these programs provides sufficiently strong incentives for physicians [24] and hospitals [25] to improve quality and reduce costs.

Future Directions

Future efforts to reduce costs and promote quality will undoubtedly involve a multimodal approach. First, due to substantial differences in practice patterns that lead to varying degrees of health care quality within a region, we should strive to

tailor payments to decision-making entities (clinicians or health care organizations) based, in part, on measures of quality. Increased adoption of value-based purchasing practices and the creation of accountable care organizations, which tie reimbursements to quality metrics, are examples of this. Second, the Centers for Medicare and Medicaid Services should collaborate with private insurers so that new payment models can be evaluated by both. There is some encouraging movement in this direction [26].

Third, it is crucial not only to fund comparative effectiveness research, but to use its findings to develop national guidelines and insurance coverage decisions with a focus on value [27]. The highest-quality medical care is that which yields the greatest benefit to patients at the lowest possible cost. However, there is currently a high degree of uncertainty about whether certain treatments are beneficial, how alternative treatments compare to one another, and which treatments are the most cost-effective. Fourth, we must expand private-payer price transparency and reference pricing [28], which together have the potential to reduce variations in prices and reduce costs overall.

Fifth, the medical community needs to conduct research and develop standards for measuring and monitoring overutilization of services in order to best utilize our current health care resources. Lastly, there needs to be a continued commitment by physicians, patients, and health care stakeholders to reduce regional variation and waste of health care resources, to provide care according to proven best practices, and to perform only those tests and procedures that will meaningfully alter clinical management.

A reduction of aggressive health care that is not cost-effective is a national priority. However, we must also ensure that cost-cutting does not compromise health care quality and patient outcomes. Given the evidence that high intensity care can improve patient outcomes, policymakers should use the scalpel, rather than the hacksaw, to reduce unwarranted variation in care.

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POLICY FORUM

Limiting Low-Value Care by “Choosing Wisely”

William L. Schpero, MPH

The Dartmouth Atlas of Health Care has long documented widespread variations in use of effective care. In its 2003 landmark study on the quality of health care in the United States, the RAND Corporation found that just over half of Americans received recommended preventive care, acute care, and care for chronic conditions [1].

Needed attention is now being paid to use of ineffective—or low-value—care, a form of overtreatment. While definitions vary, “low-value care” most often refers to medical services, including tests and procedures, that should not be performed given their potential for harm or the existence of comparably effective and often less expensive alternatives. Spending on overtreatment amounted to between \$158 and \$226 billion in 2011 and is estimated to be one of the biggest contributors to waste in the US health care system, second only to administrative complexity [2]. Reducing the use of low-value care is particularly appealing given the opportunity it represents to both lower costs and increase quality. Before low-value care can be reduced, however, it must be identified and described.

In 2008, the National Quality Forum convened 28 national health care organizations, including advocates for physicians, consumers, and businesses, to form the National Priorities Partnership, which was charged with developing a strategy to achieve a “high-performing, high-value healthcare system” [3]. The National Priorities Partnership identified the following nine broad areas of wasteful or inappropriate care: (1) inappropriate medication use, (2) unnecessary laboratory tests, (3) unwarranted maternity care interventions, (4) unwarranted diagnostic procedures, (5) inappropriate nonpalliative services at the end of life, (6) unwarranted surgical procedures, (7) unnecessary consultations, (8) preventable emergency department visits and hospitalizations, and (9) potentially harmful preventive services with no benefits [3].

In 2009, the American Board of Internal Medicine (ABIM) Foundation gave a grant to the National Physicians Alliance to develop lists to help primary physicians “be good stewards of resources” [4]. Howard Brody, envisioning a more substantial role for physicians in identifying opportunities to reduce low-value care, proposed in the *New England Journal of Medicine* in 2010 that all specialty societies generate “top five” lists that “would consist of five diagnostic tests or treatments that are very commonly ordered by members of that specialty, that are among the most expensive services provided, and that have been shown by the currently available evidence not

to provide any meaningful benefit to at least some major categories of patients for whom they are commonly ordered” [5].

Brody’s proposal laid the groundwork for the ABIM Foundation’s Choosing Wisely campaign, which was announced in March 2011. Nine specialty societies released the first Choosing Wisely lists in April 2012 [6], and, as of December 2013, 44 societies had contributed to the campaign [7]. The ABIM Foundation frames the Choosing Wisely lists as an opportunity to “spur conversation about what is appropriate and necessary treatment” [7]. Several efforts are under way to disseminate the lists to both physicians and patients; notably, the ABIM Foundation has partnered with a number of consumer groups, including AARP and *Consumer Reports*. The ABIM Foundation is explicit in stipulating that the Choosing Wisely guidelines “should not be used to establish coverage decisions or exclusions” [7].

The Choosing Wisely campaign is now perhaps the highest-profile effort to identify opportunities to reduce use of low-value care in the United States. In exploring the practical utility of the Choosing Wisely campaign—and its ethical implications—it is necessary to further examine how the Choosing Wisely lists were developed, what they include, and how they may be used.

How Were the Choosing Wisely Lists Developed?

Each specialty society’s Choosing Wisely list includes a short description, with references, of how the items on the list were identified. Most societies relied on a workgroup or committee composed of a diverse array of clinical and administrative stakeholders who reviewed relevant evidence in the literature and made recommendations to the society’s executive committee. All societies also included reference to their respective disclosure and conflict of interest policies.

The societies differed, however, in the following: (1) the criteria used to identify items (e.g., clinical evidence of efficacy and harm, cost, potential for improvement, potential for overuse, potential for misuse, potential for harm, prevalence of utilization), and (2) whether the society consulted additional experts, its broader membership, or other societies to refine items.

Publicly available documentation on the campaign suggests that the methodologies varied particularly with respect to involvement of experts on evidence evaluation, the use of external review, and the involvement of nonphysicians, including patient representatives. Though the Guideline Panel Review working group indicates that lacking any of these elements is a “red flag” in clinical guideline generation [8], holding the Choosing Wisely campaign to such standards may be too stringent; the ABIM Foundation frames the campaign’s lists as opportunities for conversation, rather than explicit guidelines for clinical practice.

What Do the Choosing Wisely Lists Include?

Choosing Wisely lists are populated principally by recommendations on imaging and cardiac-related testing, although recommendations on procedures, medication usage,

and laboratory testing are also common. The tests and procedures included in the campaign are notable for significant variation in how commonly they are used, their cost, and the extent to which they directly affect the revenue streams of the specialty society that submitted them (rather than the revenue streams of a different specialty). While several societies include high-yield items that are both commonly used and relatively expensive, not all do. The inclusion of low-cost, uncommon tests and procedures may limit the efficacy of the campaign in reducing unnecessary resource use.

How May the Choosing Wisely Lists Be Used?

The Choosing Wisely campaign is intended primarily to create educational opportunities for physicians and patients. The campaign's recommendations also have obvious relevance to performance measurement for quality improvement. Payers are likely to consider the recommendations when developing coverage parameters, quality-contingent payment systems, and value-based benefits. Yet, given their clinical nuance, not all of the recommendations can be readily measured using claims data, which suggests at least some of them are best operationalized solely at the physician practice level for quality improvement and will have little utility for payers [9].

The Choosing Wisely campaign, as a physician-led initiative, represents an important step in identifying and reducing waste in health care while avoiding the “rationing” label that has been put on other efforts led by nonphysician stakeholders [10]. Although there is considerable variation in the methodologies used to develop the lists included in the campaign, and not all of the list items are likely to significantly reduce utilization of low-value care, it is a good starting point from which to begin a conversation about unnecessary care and policy interventions to curtail it.

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MEDICINE AND SOCIETY

Place: The Seventh Vital Sign

Bill Davenhall, MA

Now well into my sixth decade of visiting doctors, my role as an informed and engaged patient continues to evolve. In my first two decades I had little to say directly to my doctors; my mother did all the talking. The information that was exchanged then is all but history and probably of little value or use to the doctors I visit now, with one exception: facts about where I have actually lived for the last six decades. Geomedicine is about this missing information, and I believe it's important that we learn how to access and use all the relevant information we have available to us. This is why I believe it has value to every physician—and to their health-seeking patients as well.

Geomedicine is a modern reconstruction of a very old, very simple idea. In fact, Hippocrates had this concept in mind more than two millennia ago, instructing physicians on how they could come to understand the origins of their patients' illnesses. Hippocrates implored his students to be observant about the quality of the air, water, and food that a patient was exposed to. He also believed it was important to distinguish between patients who lived high on the hills and those who lived low in the valley, breathing bad vapors. And he was keen to know if and how patients carried out personal hygiene from bathing to coughing and spitting. The implication was that people's environments had a great deal to do with what made them sick or would help them get well. In our own time, Ethan Berke has articulated the role of place in a person's health and health behaviors, calling it "a vital sign" [1], and the field of environmental medicine is considering the ways in which health is affected by such factors [2].

In practice, however, physicians have no ready way of sorting out the critical toxic elements of local environments from all the other situational, genetic, and more obvious clinical signs and symptoms. In many ways, a patient's historical environmental context has been all but eliminated from the record-keeping and diagnosis process of modern-day medicine. I know this because not a single physician in the last six decades has asked me to describe all the places I have lived. I have never seen that question asked on any of my patient information questionnaires.

Today people move about with relative ease, changing their local environments many times. In the US, the average person moves about 11 times in a lifetime—and some people, like me, move many more times than that. I have moved 16 times in 6 decades, and each of these moves has significantly altered elements of my

environment, such as population density, exposure to pollutants, and the sources and quality of my drinking water and food choices, and each has exposed me to the well-documented hazards of living in the “wrong” places. And, while there appears to be a great deal of similarity between places, the things that would likely harm me the most are neither visible nor obvious.

Let’s say a reproductive-fertility physician trained at a Southern California medical school and doing a residency at the Mayo Clinic Hospital in Scottsdale, Arizona, sees a patient born in Buffalo, New York, with idiopathic symptoms. Would it be of any value in the early stages of the diagnosis if the physician knew that the patient in question drank tap water for a decade from the aquifer that drained Love Canal back in the 1970s?

The chance that a recently trained physician would know this fact or have access to an information system that alerted him or her to relevant factors about patients’ current and past addresses is small. This is startling, to say the least—that a physician could be diagnosing a patient who resided near one of America’s most infamous toxic waste sites, with known and proven negative health impacts, and that this potentially valuable piece of information would not pop up in the diagnostic tools he or she was using.

The promise of geomedicine is to eliminate this type of disconnect by bringing this silent and hidden data to the forefront.

To help health-seeking patients and physicians harness the power of geomedicine, we at Esri have created My Place History, a mobile app that lets users discover their likely exposure to toxic chemicals based on where they have lived in the United States [3]. To use the app, users enter as many of their former addresses as they can remember and run a report to learn if any chemicals reported to the United States Environmental Protection Agency (EPA) show up within three miles of any of those places. This type of data—Toxics Release Inventory or TRI—has been collected annually by the EPA for about 26 years [4], and the My Place History app makes it easily available for the first time.

From my perspective, a digital record of place history and environmental context is the latest medical “invention,” providing yet another piece of clinically relevant information that will not just help physicians in real time but possibly inform the entire health care ecosystem. From the moment I complete My Place History, the people who are charged with my care have a leg up—seeing things from possible diagnoses to the availability of healing resources near where I live—that is significant to diagnosis and treatment.

Take a few minutes to think about where you have lived since 1987. Download the app and explore your place history, and think how this kind of information could inform your own medical records as well as those of your patients. The next step is to consider, as those in environmental medicine are doing, about what other types of

contextual information about your patients might be useful: the quality of the air they breathe; the quality of the water they drink; and their proximity to fresh food, parks, exercise trails, swimming pools, pharmacies, and other healing resources that support compliance and recovery.

Geomedicine is not a destination, but a first step in a journey of integrating vast amounts of relevant geographical information into patient care in an efficient and smart way. Making it a useful element in the evolving electronic records that support our personal health and wellness will be the greatest challenge.

As always, I would appreciate a second opinion.

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OP-ED

Does Location Determine Medical Practice Patterns?

James Reschovsky, PhD

It is said that the three most important factors in real estate are location, location, and location. There is a large body of research that suggests the same applies to health care spending. The Dartmouth Atlas of Healthcare, first published in 1996 by John Wennberg and colleagues, has shown wide geographic variation—as much as a 250 percent difference between one place and another—in fee-for-service Medicare spending [1]. The group’s basic narrative is that, after adjusting for area differences in Medicare payment levels and patient health, very wide geographical disparities in costs remain. Moreover, adjusted area spending is not positively correlated with better health outcomes, and in some instances it may be negatively correlated. As a result, the unexplained variation in costs across geographic regions represents differences in how cost-efficiently health care is provided. Finally, since area costs tend to be higher in areas with greater numbers of physicians and hospital beds, the major culprit according to the atlas is too many “supply-sensitive” services (as opposed to effective or preference-sensitive services) provided in high-spending areas. Supply-sensitive services, including some physician visits, diagnostic tests, hospitalizations, and admissions to intensive care, are those whose appropriate use and frequency are not well established by clinical research. Implicitly, these are services of marginal or no value to the patient for which physicians are able to “induce” additional demand [2, 3].

To be sure, the Dartmouth Atlas and associated researchers have done a great service in highlighting these variations and in using the variations to make the case that our health care system is very inefficient. There are few US health services researchers who would disagree that our health care system is rife with inefficiency. The US pays about 50 percent more than other developed nations for the same or poorer health outcomes. Nor would most argue that physicians never respond to economic incentives or induce demand for their services. However, I would argue that although there are clearly variations in clinical practice across areas—some of which reflect relative degrees of system efficiency—the degree of variation and the importance of geography in general are overstated by the Dartmouth group and parts of their basic narrative rest on simple associations that may not stand up under closer scrutiny.

All agree that there are many factors that influence Medicare spending. Some are “warranted,” while others, most clearly fraud and abuse, are not. Among two of the most important warranted reasons are payment variation and population health [4]. First, the traditional fee-for-service Medicare system reimburses different amounts for the same service in different areas of the country. For the most part, these

adjustments are for local input prices (e.g., local wage levels), although they also reflect a complex web of other payment policies.

Second, it is widely accepted that disease burdens vary considerably across regions, as a result of differing demographic characteristics, rates of smoking and obesity, and so on. The Dartmouth research has by and large used inadequate methods to adjust for area differences in payment and population health. In work with Jack Hadley and Patrick Romano, we find that careful control for Medicare price variations accounts for over 20 percent of geographic spending variation, and that—after controlling for payment variations—population health accounts for at least 75 to 85 percent of the remaining variation. We also found that the approach used by Dartmouth researchers to adjust for area variations in patient health actually adjusts very little because it rests on the faulty assumption that patients in different regions are equally sick in their last months of life [5].

Absent much better clinical data, there is no perfect way to adjust for patient health, and we researchers will continue to argue over the best methods. Despite the uncertainty about how much geographic variation remains after adjusting for payments and health, it is not appropriate to attribute the remaining geographic variations in spending to “unwarranted” variations in the efficiency of health care delivery, as Dartmouth researchers have often done. The unexplained variations could also be attributable to patient preferences for care, state policies affecting health care professionals, further variations in patient health that current case-mix methods don’t account for, and other factors [4].

The assertion that high-spending areas have no better health outcomes than low-spending ones is based on observational studies that fail to account for the fact that sick people typically use more medical care and have worse health outcomes than healthy people [6]. In other words, correlation has been confused with causality. More sophisticated studies that have addressed this problem of reverse causality find that spending more on Medicare patients improves health outcomes. Similarly, inadequate adjustment for patient health likely confounds the positive correlation found between area costs and clinician supply [7-9]. There is more demand for medical care where people are sicker.

Particularly in earlier years, it was often stated by Dartmouth researchers that, if only the high cost areas could emulate the way that health care is delivered in low-cost areas, the Medicare program could realize 30 percent or more in savings [2, 3], a number still often cited [10]. Yet, there is no clear path to turning a high-cost area into a low-cost one. In a recent study, colleagues and I found that the mix of services varies considerably both among both high-cost sites and among low-cost ones. This suggests that local health care systems find their own ways to provide medical care, with no simple way available for higher-cost sites to emulate lower cost ones. Two of the services that disproportionately contributed to variations between high- and low-cost sites were durable medical equipment and home health, services that have been rife with fraud and abuse in many areas—undoubtedly a cause of health system

inefficiency [11]. Indeed, increased efforts to cut down on Medicare fraud in recent years have led to sharp declines in spending in communities such as Miami, Florida, and McAllen, Texas, which have received much attention as high-cost bastions.

In other recent work, we looked at geographic variations in the treatment of specific conditions. We found, similar to results of a study by the Medicare Payment Advisory Commission (MedPAC) [12], that areas tended to be high-cost in the treatment of some conditions and low-cost in the treatment of other conditions [13]. Although local practice patterns and perhaps even the supply of relevant physician specialists were associated with the costs of treating specific conditions, it was the prevalence of those conditions and the number of comorbidities among those who were treated for them that were most strongly associated with total per-beneficiary costs across areas [13].

All this is to say that, although location matters, variations in medical practice are far more complex than the simple narrative popularly attributed to the Dartmouth Atlas. This point was emphasized in a recent report on geographic variations by the Institute of Medicine [14]. Apart from noting that geographic cost variations differ considerably by payer (Medicare, Medicaid, and private), they found that within the hospital referral regions typically used by the Dartmouth Atlas project there is often as much cost variation within regions as between them.

Where I think most health services researchers, including those associated with the Dartmouth Atlas group, can agree is that the best approach to increasing the efficiency with which we deliver health care in this country, and coincidentally reducing geographic variations, is to better define and communicate best clinical practices, encourage physicians to enter integrated systems of care—larger multispecialty organizations that provide greater care coordination and management—and reform the payment system to promote better outcomes and greater value rather than fees for service, which rewards provision of more services. To their credit, some Dartmouth researchers have been leaders in advocating for new delivery and payment models—such as accountable care organizations (ACOs)—that are currently being tested by public and private payers.

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