TO THE EDITOR: Katz and colleagues (1) present a provocative and appealing model to address the challenge of attracting committed and trained physicians into nursing home care. The barriers to such practice are already assumed. In a 2006 report, Katz and Karuza (2) noted that only 1 in 5 physicians who were identified as primary care physicians reported any involvement in nursing home care, and that those who were involved averaged only about 2 hours per week. Furthermore, the 2005 survey of the American Medical Directors Association (AMDA) (3), the national association of approximately 4000 nursing home medical directors, found that 18% of member respondents had reduced their attending physician hours in the preceding 3 years and that 7% had stopped working as an attending physician in nursing homes entirely (3). Although assumptions abound as to why physicians do not seek to provide care in nursing homes, Katz and colleagues make clear that nursing home care differs from other health care settings. The individual patients are often the same ones whom primary care physicians saw in their office the week before, or even discharged from the hospital the day before, but the domain of the nursing home is complex and highly regulated. It is a team-based dynamic that many physicians have little experience or comfort with. It requires knowledge of the regulatory world, the skills of functional assessment and rehabilitation, and the ability to integrate patient and family goals into care plans that may extend into years, rather than the few days typical of the short-term hospital setting. In addition, the nursing home population is not homogeneous by age, goals of treatment, or functional limitations. The nursing home is an ideal setting to apply clinical skills in the care of complex patients in the context of person-centered values over an extended time frame. But without the knowledge, vocabulary, and training required in any unique specialty or system of care delivery, the challenge for most physicians is simply daunting.

So would specialty recognition, defined time requirements for on-site service, and “closed” medical staffs help physicians meet these challenges? Although such a concept has considerable appeal and potential, not only do other substantial barriers continue to deter physicians from practicing in nursing homes, but Katz and colleagues’ recommendations create some new challenges as well. The first issue is liability risk. Kapp (4) noted in his 2008 issue brief to the California HealthCare Foundation that liability risk, although not the sole reason physicians avoid nursing home care, is often mentioned as a negative factor. Whereas specialty status might afford some theoretical protection to lawsuits, the incentives for including attending physicians in such litigation are often entirely separate from their level of training or experience. Attracting substantial numbers of physicians who would identify themselves as nursing home specialists will require both tort reform and demonstration that the real and perceived risks are balanced and manageable (and are insurable by liability carriers).

Another barrier to advanced training requirements and closed staff models are often the nursing home leaders (owners, executive officers, and administrators) themselves. In communities with competitive markets and excess available nursing home beds, the performance measure for success is “a head in the bed.” Thus, a “good” physician is one that provides a volume of admissions and allows the nursing home to primarily manage the care. Although we all recognize the short-term thinking of such logic and know that well-trained, committed physicians will far better support the success of the nursing home over time (both financially and in regulatory compliance), it is often difficult to get the nursing home to end a relationship with a physician who provides poor quality of care but can be counted on for frequent admissions.

Finally, Katz and colleagues compare the advantages of the growing prevalence of the hospitalist model to the described nursing home specialist model. Although much good has come from the hospitalist trend, all is not perfect. The challenges of transitions of care are multiplied. Advance care planning is often a lower priority than reducing the length of stay and moving the patient to the next level of care as quickly as possible. Families and patients bemoan the loss of physician continuity and remember when “my doctor used to see me here.” Specialty designation will do little to resolve the challenges of fragmented care, and the stated specific time requirements may be a disincentive to those few primary care physicians who are still willing to follow their own patient into postacute and custodial long-term care settings.

The challenges to attract physicians to the specialty nursing home care, with its unique settings and specific required skills, are substantial. Yet it is unacceptable and unsustainable to continue viewing nursing home care as separate from the professional standards, peer review, and specialty expertise found in “regular” medical care. Not only will the status quo further drive the workforce crisis, but the quality of care delivered to these vulnerable patients will suffer. Although full implementation of the elements defined by Katz and colleagues will take decades to resolve and implement, the value to the development of a core curriculum and some level of professional recognition of advanced training in nursing home practice will immediately benefit those who work in the nursing home environment and to those who have yet to join.

Cheryl L. Phillips, MD, CMD
On Lok Lifeways
San Francisco, CA 94109

Potential Financial Conflicts of Interest: None disclosed.

References
1. Katz PR, Karuza J, Intrator O, Mor V. Nursing home physician specialists: a response to the workforce crisis in long-term care. Ann Intern Med. 2009;150:411-3. [PMID: 19293074]
2. Katz PR, Karuza J. The nursing home physician workforce. J Am Med Dir Assoc. 2006;7:394-7; discussion 397-8. [PMID: 16843242]
3. Lett JE 2nd. Professional liability in long-term care: the pressure mounts [Letter]. J Am Med Dir Assoc. 2005;6:426-8. [PMID: 16286073]
4. Kapp M. Is There a Doctor in the House? Physician Liability Fears and Quality of Care in Nursing Homes. Oakland, CA: California HealthCare Foundation; 2008.

TO THE EDITOR: Although Katz and colleagues’ suggestion (1) is well intentioned, mentioning skilled-nursing facility (SNF) practice a specialty might impede entry of practitioners into long-term care, which could be a big tactical error. I witness fine practitioners start to attend residents of SNFs, then become quite attached to this practice setting. They ask questions, become informed, and then do an ex-
TO THE EDITOR: We read with interest the article by Katz and colleagues (1). The nursing home in the United States and other countries has a heterogeneous population of short-stay and long-stay residents. Short-stay residents include persons who come for rehabilitation after a hospital admission, for respite stays, and for palliative or end-of-life care. Long-stay residents include persons with cognitive, physical, or a combination of impairments that require extensive assistance with activities of daily living. Providing excellent care to these persons requires extensive knowledge not only of chronic disease management, acute disease management, and geriatric syndromes, but also of the capabilities of the health care system, its regulations, and the advantages of the interdisciplinary care team. In this setting, physicians need to be adept at quality improvement, transitions of care, dementia diagnosis, the appropriate use of medications, and dementia behavioral management.

New models of care are emerging. In North Carolina, we have 2 thriving long-term care specialty practices. In addition, we have many physicians who spend 20% or more of their professional time caring for nursing home patients. Also, we have an active state chapter of the AMDA, and 62 physicians have completed the requirements to become certified medical directors through a process provided by AMDA. We believe that excellent care means being in the nursing home on a predictable schedule so that members of the interdisciplinary care team can discuss relevant issues, family meetings can be scheduled, and routine care can be provided and discussed with nurses and other care providers.

Physicians are the practitioners best trained to manage the care of nursing home patients. This care may be provided in collaboration with nurse practitioners and physician assistants, but it should not be abdicated to nonphysician providers without physician involvement. There are excellent and experienced nurse practitioners and physician assistants who are providing similar, and in some cases better, care than what is currently provided by physicians. However, the complexity of the clinical cases; the frequency of care transitions to the hospital, home, and other intermediate settings; the expectations of patients and their families; and the leadership needed to ensure quality health care in the nursing home require that physicians remain in a role of providing and managing care for individual patients in the nursing home.

We are strongly in favor of creating a nursing home specialty that would highlight the degree of involvement in nursing home care, recognize the unique competencies of these physicians, and require a medical staff model that fosters the specialty and improves the quality of care provided to individuals in need. We are not in favor of hindering physicians who only spend a small percentage of their professional time in nursing homes. Moving toward creating a nursing home specialty should be done in such a way that would not restrict young physicians or experienced physicians from participating in nursing home care, even at less than 20% of their time, especially if this will eventually lead to a greater time commitment or will fulfill a need in a rural setting. Because physicians-in-training receive little exposure to this care setting, it continues to be important for physicians at all experience levels to try out this practice setting, hopefully with the availability of appropriate mentors.

Heidi K. White, MD, MHS
Guendolen Bahr, MD, MHS
Duke University School of Medicine
Durham, NC 27701

Jose Gonzalez, MD
Extended Care Physicians
Asheville, NC 28802

On behalf of the North Carolina Medical Directors Association

Marie-Luz Villa, MD
University of Washington School of Medicine
Seattle, WA 98104

Potential Financial Conflicts of Interest: None disclosed.

References
1. Katz PR, Karuza J, Intrator O, Mor V. Nursing home physician specialists: a response to the workforce crisis in long-term care. Ann Intern Med. 2009;150:411-3. [PMID: 19293074]
2. American Academy of Home Care Physicians. Independence at Home Act Introduced! Accessed at www.aahcp.org/iahpr.pdf on 5 August 2009.

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Heidi K. White, MD, MHS
Guendolen Bahr, MD, MHS
Duke University School of Medicine
Durham, NC 27701

Jose Gonzalez, MD
Extended Care Physicians
Asheville, NC 28802

On behalf of the North Carolina Medical Directors Association

Marie-Luz Villa, MD
University of Washington School of Medicine
Seattle, WA 98104

Potential Financial Conflicts of Interest: None disclosed.

References
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Reference
1. Katz PR, Karuza J, Intrator O, Mor V. Nursing home physician specialists: a response to the workforce crisis in long-term care. Ann Intern Med. 2009;150:411-3. [PMID: 19293074]

TO THE EDITOR: The suggestion by Katz and colleagues (1) to create a nursing home medical specialty to ameliorate the serious shortage of physicians in long-term care is creative and bold. It is a natural outgrowth of the field of geriatric medicine and is an appropriate response to the modest manpower progress (2) experienced thus far in the field of geriatric medicine. In addition to this new specialty idea, Katz and colleagues disagree with the Institute of Medicine’s recommendation (3) to expand the role and supply of mid-level providers, such as nurse practitioners, in the nursing home as a response to the need not met by physicians. This acceptance of a “2-level” health system—nurse practitioners as primary care for frail elderly patients in nursing homes and physicians as primary care for most everyone else—needs to be openly discussed for its clinical and ethical implications.

In 1968, when the American Board of Internal Medicine approved the first U.S. residency fellowship in geriatric medicine (created by Dr. Libow), the primary site of the geriatrics training program was indeed the nursing home (4, 5). Geriatric medicine was defined in the residency fellowship as focusing on the multiple “sites and phases” of illness and of health that physicians and the health establishment did not usually embrace. Today, millions of subacutely ill older persons are admitted every year to nursing homes directly from hospitals. Most have complex illnesses, recover, and return home, although many others remain for lifelong care. Many astute clinicians, their teams, and enlightened medical directors are needed in the nursing home. Yet too few physicians select careers in geriatrics, and too many fellowship positions remain unfilled (2).

The shortage of physicians in nursing homes can be explained in part by the modest financial rewards; by the emotional difficulties, which for some outweigh the positives; and by the understandable need to deny one’s own ultimate aging, frailty, and mortality.

The development of a nursing home specialty, together with the vigorous struggle within geriatric medicine to keep the field alive and move geriatric knowledge, approaches, and skills into the hands of all clinicians, will probably improve the relationship and balance between physicians and their nursing homes. Our nursing home patients remain hopeful of receiving the care they expect and deserve from their “doctor.”

Leslie S. Libow, MD
Mount Sinai School of Medicine
New York, NY 10029

Gisele Wolf-Klein, MD

Potential Financial Conflicts of Interest: None disclosed.

References
1. Katz PR, Karuza J, Intrator O, Mor V. Nursing home physician specialists: a response to the workforce crisis in long-term care. Ann Intern Med. 2009;150:411-3. [PMID: 19293074]
2. Butler RN. Thoughts on the development of geriatrics [Editorial]. J Am Geriatr Soc. 2007;55:2086-7. [PMID: 18081676]
3. Institute of Medicine. Retooling for an Aging America: Building the Health Care Workforce. Washington, DC: National Academies Pr; 2008.
4. Libow LS. A fellowship in geriatric medicine. J Am Geriatr Soc. 1972;20:580-4. [PMID: 4639422]
5. Libow LS. A geriatric medical residency program. A four-year experience. Ann Intern Med. 1976;85:641-7. [PMID: 984619]

TO THE EDITOR: As a partly retired, board-certified internist and geriatrician who has spent most of the past dozen years caring for patients in the nursing home setting, I was very interested to read the recent article by Katz and colleagues (1). More than 80% of my “evaluation and management” encounters in a typical month are for patients in nursing homes, including subacute care, long-term care, or hospice. I wish to offer some comments.

First, do we really need another specialty type of certification, with more examinations, more requirements, more paperwork, and more fees and its own small bureaucracy to administer things? Would this form of “certification” become another barrier to retaining those physicians who already see nursing home patients and to getting more physicians involved?

Second, I did not know that we were involved in a less-than-legitimate medical practice setting. Those of us who see nursing home patients come to that type of practice from different levels of experience and different types of credentials, but we share a commitment to caring for this very deserving and complex group of patients. Nursing home patients are often no longer “connected” to their previous primary care physicians and are frequently sent from the hospital to our care with incomplete information. Much important history can easily be lost in the series of hand-offs from the community physician to the hospitalists and housestaff to the providers at the nursing home, who will often be caring for these patients for the rest of their lives.

It is true, though, that those of us who care for patients in the nursing home often feel, not that we are not legitimate, but that [to quote Rodney Dangerfield] we “get no respect.” I think the best cure for this is telephone communication—I feel better taking over the care of a patient when I have heard directly from the hospitalist or housestaff team with their report on the patient and what needs to be done. The discharge paperwork or electronic summary can often be ambiguous or contain conflicting statements.

It is also true that nursing home providers need to pick up the telephone and do their detective work, calling up the patients’ family members and previous community physicians, as well as the hospital team. This may take extra time in the beginning, but will prevent mistakes down the line.

Finally, I have had the rewarding privilege to provide bedside teaching to residents and geriatric fellows, as well as physician assistant and nurse practitioner students in the nursing home setting. Whether rounding with the nursing home practitioner for just a few days or for a month or longer, this should be an important part of every new practitioner’s training. The number of elderly patients confined to nursing facilities (1.6 million and growing) will surely challenge us all.

I am grateful to read an article about physicians who do what I and my colleagues do. Nonetheless, we and our practice settings are “legitimate” in every sense of the word, and creating a new certification program may be an appealing idea in some respects, but it does
not directly address the greatest need that nursing home practitioners have: improved communication with our peers in the hospital and community settings.

William B. Freedberg, MD, PhD  
Tufts University, Baystate Medical Center  
Springfield, MA 01199

Potential Financial Conflicts of Interest: None disclosed.

Reference  
1. Katz PR, Karuza J, Intrator O, Mor V. Nursing home physician specialists: a response to the workforce crisis in long-term care. Ann Intern Med. 2009;150:411-3. [PMID: 19293074]

IN RESPONSE: Although the authors of these letters seem to agree about the need for physicians with the knowledge and skill set unique to nursing home care, they each describe several challenges, including the complex organizational, quality improvement, team management, and regulatory interface that is required.

Dr. Phillips suggests, specialty status can be an effective first step in evoking credibility and attracting physicians to the field. Phillips and Dr. Villa note that the industry must take a central role in defining the priorities for medical practice. A first step is establishing quality metrics, such as preventing rehospitalization and assuring seamless care transitions. As Dr. Phillips suggests, full system reform will take decades to implement. Still, these new metrics can be used to reward high performers, whether through a pay-for-performance mechanism or through avoidance of survey citations.

We agree with Dr. White and colleagues’ contention that physicians are the practitioners best trained to manage the care of nursing home residents. Rather than resorting to alternative care models that rely predominantly on nurse practitioners or physician assistants, the focus should be on physician recruitment, retention, and performance. As Drs. Libow and Wolf-Klein point out, a 2-tiered approach to caring for frail elderly persons must be vigorously debated. Although nurse practitioners can provide quality care, the benefits of collaborative models of care that include physicians remains largely unexplored (1).

Populating the physician nursing home workforce will require that trainees have contact with high-quality teachers. We agree with Drs. Libow and Wolf-Klein, Dr. Villa, Dr. White and colleagues, and Dr. Freedberg that nursing home physicians who demonstrate commitment and competence are ideal role models. Currently, internal medicine residents often graduate without ever stepping into a nursing home. The fact that many of these residents become hospitalists, a specialty in which knowledge of the continuum of care is critical, cries out for reforms from the Accreditation Council for Graduate Medical Education.

Dr. Freedberg is right that nursing home physicians get no respect. This underpins our rationale in calling for the creation of a nursing home specialty. Instead of fearing a “silo mentality,” as Dr. Phillips suggests, specialty status can be an effective first step in evoking credibility and attracting physicians to the field.

Defining the prerequisites for a nursing home specialist remains a challenge. Dr. White and colleagues aptly point out the risk for excluding physicians who spend only a small percentage of their time in nursing home practice. We chose 20% as the minimum threshold because of evidence from settings other than long-term care that demonstrates a relationship among competency, patient volume, and experience (2, 3).

Paul R. Katz, MD  
Jurgis Karuza, PhD  
University of Rochester School of Medicine and Dentistry  
Rochester, NY 14620

Potential Financial Conflicts of Interest: None disclosed.

References  
1. Caprio T. Physician practice in the nursing home: Collaboration with nurse practitioners and physician assistants. Ann Long Term Care. 2006;14:17-24.  
2. Birkmeyer JD, Stukel TA, Siewers AE, Goodney PP, Wennberg DE, Lucas FL. Surgeon volume and operative mortality in the United States. N Engl J Med. 2003;349:2117-27. [PMID: 14645640]  
3. Halm EA, Lee C, Chassin MR. Is volume related to outcome in health care? A systematic review and methodologic critique of the literature. Ann Intern Med. 2002;137:511-20. [PMID: 12230353]

Vitamin K to Correct Overanticoagulation

TO THE EDITOR: In their recent study on managing supratherapeutic warfarin administration with or without vitamin K, Crowther and colleagues (1) use flawed methodology to arrive at what may be an apocryphal conclusion, which is that vitamin K therapy has no role in managing patients with high international normalized ratios (INRs).

The study uses a commercially unavailable vitamin K preparation. The pharmacokinetics and effectiveness of this preparation have not been clinically validated.

Confronted with overanticoagulation, clinicians explore recent relevant events; exclude patient dosing errors; consider vitamin K; and most important, modify doses of warfarin. Crowther and colleagues attempt to control for dose adjustment by simply blinding us to it. We are given no specific parameters used by practitioners in the trial with regard to warfarin dosing. We are thus asked to accept the conclusions of a trial whose methodology has an element of nihilism.

Crowther and colleagues agree that patients who received vitamin K in this trial had more-rapid corrections in INR than those who received placebo. Because the warfarin regimen was left to clinician judgment and was not followed after patient enrollment in the study, we wonder if clinicians chose less warfarin dose reduction when the INR showed more rapid correction in the group treated with vitamin K. This could easily account for the overall similarity in major bleeding events between the 2 study groups (which the study is underpowered to determine).

Among patients with INRs between 4.5 and 6.0 during the first 7 days of the trial, 12 in the vitamin K group and 22 in the placebo group experienced bleeding. For patients with INRs of 6.1 or greater, the lack of a major difference in bleeding events between the groups represents the severity of their anticoagulation. In such patients, 1.25 mg may be too low a corrective dose of vitamin K. Because the INR for patients receiving warfarin does not budge
until vitamin K–dependent factors in the tissue factor pathway decrease to at least 15% of normal values, an INR of 6.0 represents profound anticoagulation.

Groopman and Hartzband (2) recently wrote about the importance of blending deliberative and intuitive decision making for good patient care. We note this in the overall context of about one seventh of patients in both the vitamin K and the placebo groups having at least 1 bleeding complication—an event rate that seems high. Because of the lack of association of vitamin K administration with thrombotic events, we view low-dose vitamin K as an appropriate treatment strategy for certain overanticoagulated patients.

Mark W. Swaim, MD, PhD
Regional Hospital of Jackson
Jackson, TN 38305

B. Gail Macik

Potential Financial Conflicts of Interest: None disclosed.

References
1. Crowther MA, Ageno W, Garcia D, Wang L, Wint DM, Clark NP, et al. Oral vitamin K versus placebo to correct excessive anticoagulation in patients receiving warfarin: a randomized trial. Ann Intern Med. 2009;150:293-300. [PMID: 19258557] 2. Groopman J, Hartzband P. Meld intuition with deliberation to sidestep diagnostic trap. ACP Internist. 2009;29:5.

TO THE EDITOR: We read with interest the study by Crowther and colleagues (1). On the one hand, we appreciated the attempt to create some order in the management of patients who have received excessive anticoagulation, but on the other hand, we are concerned because the authors’ conclusions suggest that changing the treatment policy used in many thrombosis centers in Italy is needed. Since the publication of our first work in the field (2), we usually give oral vitamin K to patients without bleeding events whose INR is greater than 5.0. In a recent retrospective study (3), we reported 1043 events of overanticoagulation (INR, 5.0 to 10.0) occurring over 10 years that were treated with oral vitamin K, 2 mg. This approach was associated with a very low incidence of bleeding: Only 1 major bleeding event (secondary to intervention) occurred during 30 days of follow-up (0.1% [95% CI, <0.01% to 0.60%]). Our protocol differs from that used by Crowther and colleagues in that we based the vitamin K dose on slightly different levels of overanticoagulation, used a different pharmaceutical form of the administered drug (in solution), and administered the drug promptly at the time of INR determination. Despite treatment, 10% of the patients were still overanticoagulated the next day. Our results make us hesitant to create some order in the management of patients who have received excessive anticoagulation, but on the other hand, we are concerned because the authors’ conclusions suggest that changing the treatment policy used in many thrombosis centers in Italy is needed. Since the publication of our first work in the field (2), we usually give oral vitamin K to patients without bleeding events whose INR is greater than 5.0. In a recent retrospective study (3), we reported 1043 events of overanticoagulation (INR, 5.0 to 10.0) occurring over 10 years that were treated with oral vitamin K, 2 mg. This approach was associated with a very low incidence of bleeding: Only 1 major bleeding event (secondary to intervention) occurred during 30 days of follow-up (0.1% [95% CI, <0.01% to 0.60%]). Our protocol differs from that used by Crowther and colleagues in that we based the vitamin K dose on slightly different levels of overanticoagulation, used a different pharmaceutical form of the administered drug (in solution), and administered the drug promptly at the time of INR determination. Despite treatment, 10% of the patients were still overanticoagulated the next day. Our results make us hesitant to change our policy according to Crowther and colleagues’ conclusions. Data from the concurrent trial being conducted by Crowther and colleagues (1) evaluating the efficacy of low-dose oral vitamin K to reverse over-anticoagulation in patients presenting with an international normalised ratio above 10.0 [Letter]. Thromb Haemost. 2009;101:410-1. [PMID: 19190831]

4. Denas G, Cucchini U, Iliceto S, Pengo V. An oral vitamin K protocol to reverse over-anticoagulation in patients receiving warfarin. First, Crowther and colleagues should be commended for carrying out such an important and well-designed study in an area that has received little attention. Despite warfarin accounting for one of the highest annual rates of adverse drug event–related deaths in the United States, the management of excessive anticoagulation in a clinical practice setting has received little study. Although Crowther and colleagues could not demonstrate a reduction in bleeding events with oral vitamin K, several important considerations should be mentioned. First, Crowther and colleagues do not discuss the duration of warfarin therapy before the elevated INR was found. This may be important, because the annualized bleeding rate is 2-fold higher in the first month of warfarin therapy (2), and as such, outcomes may be different during the early period of warfarin management. Second, Crowther and colleagues did not mention other potentially important clinical variables that may increase risk for bleeding in the setting of excessive anticoagulation, such as concomitant antiplatelet agents or presence of a structural site prone to bleeding (such as recent surgery) (3). Finally, it is important to recognize that this was mostly a study of vitamin K in patients with a modestly elevated INR: 67% of patients had an INR less than 6.0. Because the overall study was underpowered to detect benefits of low-dose vitamin K in reducing major bleeding events, this could be an even greater issue for patients with an INR greater than 6.0.

With these caveats in mind, the conclusions and recommendations of the 2008 American College of Chest Physicians’ evidence-based guidelines for the management of patients with an INR in the range of 5 to 9 are still prudent. Specifically, practitioners have a choice of either omitting 1 to 2 doses of warfarin or administering low-dose oral vitamin K, especially if bleeding risk is increased (4).

Vittorio Pengo, MD
Gentian Denas, MD
Seena Padayattil Jose, MD
Padua University Hospital
35122 Padua, Italy

Potential Financial Conflicts of Interest: None disclosed.

References
1. Crowther MA, Ageno W, Garcia D, Wang L, Wint DM, Clark NP, et al. Oral vitamin K versus placebo to correct excessive anticoagulation in patients receiving warfarin: a randomized trial. Ann Intern Med. 2009;150:293-300. [PMID: 19258557] 2. Pengo V, Banzato A, Gardelli E, Zasso A, Biasiolo A. Reversal of excessive effect of regular anticoagulation: low oral dose of phytonadione (vitamin K1) compared with warfarin discontinuation. Blood Coagul Fibrinolysis. 1993;4:739-41. [PMID: 8292723] 3. Denas G, Marzot F, Offelli P, Stendardo A, Cucuzza U, Russo R, et al. Effectiveness and safety of a management protocol to correct over-anticoagulation with oral vitamin K: a retrospective study of 1,043 cases. J Thromb Thrombolysis. 2009;27:340-7. [PMID: 18338109] 4. Denas G, Cucuzza U, Iliceto S, Pengo V. An oral vitamin K protocol to reverse over-anticoagulation in patients receiving warfarin. First, Crowther and colleagues should be commended for carrying out such an important and well-designed study in an area that has received little attention. Despite warfarin accounting for one of the highest annual rates of adverse drug event–related deaths in the United States, the management of excessive anticoagulation in a clinical practice setting has received little study. Although Crowther and colleagues could not demonstrate a reduction in bleeding events with oral vitamin K, several important considerations should be mentioned. First, Crowther and colleagues do not discuss the duration of warfarin therapy before the elevated INR was found. This may be important, because the annualized bleeding rate is 2-fold higher in the first month of warfarin therapy (2), and as such, outcomes may be different during the early period of warfarin management. Second, Crowther and colleagues did not mention other potentially important clinical variables that may increase risk for bleeding in the setting of excessive anticoagulation, such as concomitant antiplatelet agents or presence of a structural site prone to bleeding (such as recent surgery) (3). Finally, it is important to recognize that this was mostly a study of vitamin K in patients with a modestly elevated INR: 67% of patients had an INR less than 6.0. Because the overall study was underpowered to detect benefits of low-dose vitamin K in reducing major bleeding events, this could be an even greater issue for patients with an INR greater than 6.0.

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Letters

Only with additional high-quality studies will we be able to identify subsets of patients who benefit most from the administration of vitamin K in the setting of excessive anticoagulation while receiving warfarin therapy.

Robert C. Pendleton, MD
Sara Vazquez, PharmD, BCPS, CACP
University of Utah
Salt Lake City, UT 84108

Potential Financial Conflicts of Interest: None disclosed.

References
1. Crowther MA, Ageno W, Garcia D, Wang L, Witt DM, Clark NP, et al. Oral vitamin K versus placebo to correct excessive anticoagulation in patients receiving warfarin: a randomized trial. Ann Intern Med. 2009;150:293-300. [PMID: 19258557]
2. Hylek EM, Chang YC, Skates SJ, Hughes RA, Singer DE. Prospective study of the outcomes of ambulatory patients with excessive warfarin anticoagulation. Arch Intern Med. 2000;160:1612-7. [PMID: 10847254]
3. Ansell J, Hinch J, Hylek E, Jacobson A, Crowther M, Palareti G; American College of Chest Physicians. Pharmacology and management of the vitamin K antagonists: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition). Chest. 2008;133:160S-198S. [PMID: 18574265]

TO THE EDITOR: Crowther and colleagues (1) raise an important management question regarding a common clinical problem: What do we do with patients who are not bleeding but who have prolonged INR between 4.5 and 10.0 while taking warfarin?

Although the study showed administering oral vitamin K, 1.25 mg, to be statistically significantly more effective in decreasing INR to the therapeutic range than just withholding 1 dose of warfarin, the conclusion was that “[l]ow-dose oral vitamin K did not reduce bleeding in warfarin recipients with INRs of 4.5 to 10.0.” Thirty-four patients (10.1%) in the placebo group versus 136 patients (41.6%) in the vitamin K group had an INR between 2.0 and 3.0 (P < 0.001) (1). So why the contradictory results?

First, participants from at least 2 centers did not receive the study medication close to the time of initial INR determination, because the INR tests were done outside the clinical centers in which the patients were treated and because of the need to get consent from the patients by telephone and to ship the study medication to the enrolled patients. Because INR testing is very dynamic and delays of up to 24 hours could substantially change those results, the patients’ real INR could have been over- or underestimated at the time the study medication was received, which could be a reason for the negative result of the study.

In addition, although we agree with Crowther and colleagues about the importance of longer follow-up (1 month and 3 months), early bleeding risk is the most relevant issue because most of the oral vitamin K effect occurs within 24 hours. Consequently, the maximal potential benefit of oral vitamin K is expected in the first few days after the patient receives vitamin K for excessive prolongation of INR secondary to warfarin therapy.

In another study (2) of 105 patients with INRs greater than 6.0, 5 major bleeding events occurred; 2 were delayed and occurred on days 12 and 14. “Both [patients] had symptoms referable to bleeding the week before hospital admission,” and both had prolonged INR values on hospitalization of 3.1 and 3.3 despite the interval.

Crowther and colleagues should provide the timing of all bleeding events with accompanied INRs after randomization. If bleeding occurred in a patient in whom the INR did not end up within the therapeutic range, many explanations besides lack of efficacy are possible (for example, nonadherence or inadequate dose). Until more data are obtained and a more substantiated conclusion can be reached, I recommend following the American College of Chest Physicians guidelines in the management of this clinical problem (3).

Ayad Jindeel, MD
Harbor-UCLA Medical Center
Torrance, CA 90509

Potential Financial Conflicts of Interest: None disclosed.

References
1. Crowther MA, Ageno W, Garcia D, Wang L, Witt DM, Clark NP, et al. Oral vitamin K versus placebo to correct excessive anticoagulation in patients receiving warfarin: a randomized trial. Ann Intern Med. 2009;150:293-300. [PMID: 19258557]
2. Hylek EM, Chang YC, Skates SJ, Hughes RA, Singer DE. Prospective study of the outcomes of ambulatory patients with excessive warfarin anticoagulation. Arch Intern Med. 2000;160:1612-7. [PMID: 10847254]
3. Ansell J, Hinch J, Hylek E, Jacobson A, Crowther M, Palareti G; American College of Chest Physicians. Pharmacology and management of the vitamin K antagonists: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition). Chest. 2008;133:160S-198S. [PMID: 18574265]

TO THE EDITOR: The article by Crowther and colleagues (1) carries a slightly misleading title. Their study addresses only patients with an INR between 4.5 and 10.0 who are not bleeding. Because all patients with bleeding events were self-excluded from their study, Crowther and colleagues cannot comment on the efficacy of low-dose vitamin K to treat bleeding complications in any given patient with prolonged INR.

It is also hard to conceive that the effect of low-dose vitamin K might persist as long as 90 days. Several dietary constituents have substantial amounts of vitamin K (for example, one-half cup each of Brussels sprouts, broccoli, and cauliflower contain 460, 248, and 150 µg of vitamin K, respectively). This amount should be sufficient to override any effect of a single dose of low-dose vitamin K.

According to Crowther and colleagues’ data, the day-7 bleeding events show a trend toward improvement in the vitamin K group. Could a higher dose of vitamin K, such as 2.5 mg, be effective in improving the outcome?

P. Dileep Kumar, MD
Port Huron Hospital
Port Huron, MI 48060

Potential Financial Conflicts of Interest: None disclosed.

Reference
1. Crowther MA, Ageno W, Garcia D, Wang L, Witt DM, Clark NP, et al. Oral vitamin K versus placebo to correct excessive anticoagulation in patients receiving
IN RESPONSE: Our study found that low-dose oral vitamin K does not reduce bleeding in asymptomatic patients who present with INR values between 4.5 and 10.0. Thus, one should not recommend vitamin K to patients similar to those we enrolled if the intent is to reduce bleeding.

The INR decreased more rapidly in patients who received vitamin K, consistent with the pattern we have observed in previous studies. This INR decrease confirms that the formulation used in our study was effective (1). Similarly, we decided only after extensive discussion that we would not mandate how warfarin was given after study drug administration. We agree with Drs. Swaim and Macik that patients whose INR decreased quickly (whether they received vitamin K or placebo) probably had less-dramatic reductions of warfarin dose. Such warfarin dose adjustment is not only appropriate but also reflects routine clinical practice. Thus, our study represents the best estimate of the efficacy (or lack thereof) of vitamin K in the “real world.”

We acknowledge that INR (and the coagulant potential of the blood) could change between the time of measurement and the administration of study drug several hours later. However, this delay had no effect on the observation that the rate of major hemorrhage at 7 days among the patients who received placebo was low—a finding consistent with other studies (2, 3). Furthermore, it reflects how vitamin K is given in the real world, where most patients have INR measured in a community laboratory, are found to have an elevated INR, and are called to make arrangements for vitamin K administration hours later.

Larger doses of vitamin K may have produced larger INR corrections and thus may have reduced bleeding; however, overcorrection of the INR with an attendant risk for thrombosis would then be a consideration. Our choice of dose was based on our previous articles and on the fact that the 1.25-mg dose was one quarter of a standard-sized vitamin K tablet available in the United States. However, we cannot rule out the possibility that larger doses (or other formulations) of vitamin K might have reduced bleeding or increased thrombosis.

We welcome Dr. Pengo and colleagues’ comments, because he and his research group have done much of the seminal work in this area (4). However, the observational data he presents in his letter lack a comparator group; therefore, conclusions about relative efficacy cannot be drawn.

Mark A. Crowther, MD, MSc
McMaster University
Hamilton, Ontario L8N 4A6, Canada

David Garcia, MD
University of New Mexico
Albuquerque, NM 87131

Potential Financial Conflicts of Interest: Consultancies: M.A. Crowther (Anton Pharmaceuticals).

References
1. Crowther MA, Julian J, McCary D, Douketis J, Kovacs M, Biagori L, et al. Treatment of warfarin-associated coagulopathy with oral vitamin K: a randomised controlled trial. Lancet. 2000;356:1551-3. [PMID: 11075768]
2. Witt DM, Humphries TL. A retrospective evaluation of the management of excessive anticoagulation in an established clinical pharmacy anticoagulation service compared to traditional care. J Thromb Thrombolysis. 2003;15:113-8. [PMID: 14618079]
3. Garcia DA, Regan S, Crowther M, Hylek EM. The risk of hemorrhage among patients with warfarin-associated coagulopathy. J Am Coll Cardiol. 2006;47:804-8. [PMID: 16487849]
4. Pengo V, Banzato A, Garelli E, Zasso A, Biasiolo A. Reversal of excessive effect of regular anticoagulation: low oral dose of phytonadione (vitamin K1) compared with warfarin discontinuation. Blood Coagul Fibrinolysis. 1993;4:739-41. [PMID: 8292723]

Correction: Error in Name of Study Group Member
In Simonneau and colleagues’ article on combination therapy of sildenafil and epoprostenol for pulmonary arterial hypertension (1), the name of a member/investigator of the PACES (Pulmonary Arterial Hypertension Combination Study of Epoprostenol and Sildenafil) Study Group was incorrect. Mardi Gomberg should be Mardi Gomberg-Maitland.

Reference
1. Simonneau G, Rubin LJ, Galie N, Barst RJ, Fleming TR, Frost AE, et al; PACES Study Group. Addition of sildenafil to long-term intravenous epoprostenol therapy in patients with pulmonary arterial hypertension: a randomized trial. Ann Intern Med. 2008;149:521-30. [PMID: 18936500]