National Health Information Network Cost and Structure

TO THE EDITOR: We agree with Kaushal and associates’ (1) conclusion that the cost of building a national health information network is underestimated, but we believe that the separation of costs into functionality and interoperability may hinder readers from recognizing that the latter is critical in achieving the former. Interoperability is an essential and foundational component of all the functions (results viewing, electronic health record [EHR] systems, computerized physician order entry, claims submission, eligibility verification, patient communication, electronic prescriptions) that are described.

Furthermore, we believe that interoperability standards are best broken down into technical and semantic components (such as mapping from a local terminology to a standard terminology) because these require different skill sets to implement. The cost of the latter is the component most often underestimated. By recognizing that functional requirements depend on interoperability standards, the United States will be able to focus on building the necessary foundation. Good standards take time to build. Just as 3 women cannot pool their resources to deliver 1 baby in 3 months, there are constraints on the rate at which a standard can be developed, regardless of expenditures. Good standards do exist today (such as SNOMED’s Clinical Terms [2] and Health Level 7’s Version 3, including the Health Level 7 Clinical Document Architecture [3]), as do large-scale successful implementations (4).

A focus on foundational components, along with a push for adoption of these components, will move the United States toward a national health information network with a higher likelihood of success and a reduced probability of wasting resources.

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Potential Financial Conflicts of Interest: None disclosed.

References

TO THE EDITOR: As Congress considers financial incentives to speed the adoption of health information technology, it must pay attention to the findings and conclusions of the study by Kaushal and colleagues (1). Their most striking observation was the estimated $48 billion annual operating costs that will be required to maintain a national health information network. These ongoing costs and the lack of financial return on investment to providers are perhaps the greatest barriers to attracting small physician practices into the information technology age. As Basch (2) correctly points out, it is this “misalignment of incentives” that translates into vast savings for payers and leaves small physician practices holding the bag.

Sensing the need for federal intervention, Kaushal and colleagues suggest various policy options to encourage the widespread adoption of a national network. They single out legislation by Senators Frist and Clinton and Representatives Murphy and Kennedy as a remedy. Unfortunately, these bills will do little to attract those small physician practices that are trying to justify the business case for adopting EHR systems into their practices. The American College of Physicians has worked closely with congressional leaders to develop incentives aimed at small physician practices by proposing that the Medicare physician payment system use an add-on code for office visits and other evaluation and management services when using an EHR system. Senators Stabenow and Snowe and Representatives McHugh and Gonzalez have introduced similarly bipartisan bills that would do just that (3, 4). By recognizing the substantial financial savings that are likely to result from a reduction in medical errors and duplicative tests, policymakers should strategically target ongoing incentives toward small physician practices to help offset the daily operating costs of an EHR system. This return on investment will be well worth it.

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Potential Financial Conflicts of Interest: None disclosed.

References

TO THE EDITOR: I was dismayed by the superficiality that underpinned much of the article by Kaushal and colleagues (1). The wholesale adoption of the Santa Barbara County Data Exchange (SBCDE) as a working model for the nation because it could provide good cost data seems something like a drunk looking for his keys not near where he dropped them but instead beneath the streetlight because that is where light is.

By using the SBCDE as a template, the authors reasoned that “Each data supplier requires a dedicated server to store aggregated data for exchange.” With that server come several associated expenses that include, but are not limited to, staff and equipment to perform routine data backups, staff or contracted services to keep the server software updated, and the need to create secure physical conditions
TO THE EDITOR: Kaushal and colleagues (1), Baron and colleagues (2), and Basch (3) accurately outline the challenges we must overcome to accomplish the inevitable conversion from paper charts to a computerized health information system. However, an important factor regarding physician adoption of EHR has been overlooked by these papers and is absent from the national debate.

Virtually all electronic medical records programs make use of templates to facilitate rapid clinical record keeping and accurate coding with Current Procedure Terminology. The secret to effective use of EHR software lies in the ability to download relevant clinical templates over which the encounter documentation is layered. Such templates need to be created by physicians, not by computer programmers. They must meet the high standards of the physician-user who rightly expects them to facilitate accuracy, speed, competence, and compliance. In addition, the templates must be natural to use in the clinical setting. After all, the encounter is the major interface—not only between physician and patient but also between physician and machine. If the templates are inadequate, the experience will be frustrating and physician adoption of the EHR will suffer.

We have written computerized templates for multiple specialties on several different EHR platforms. We have helped dozens of physicians to integrate EHR into their practices. A common pattern has been observed: For EMR to succeed, the templates must conform to the physicians, not the other way around.

We agree that the grand vision of an integrated electronic national health information system will require a massive effort and investment as outlined by the authors. These steps are taking place on the large stage of government and corporate policy. But the ultimate success of EHR will rely on the degree of functionality delivered to an individual physician during a single, private patient encounter.

There is a great need for an association of physicians who are committed to the development and dissemination of clinical templates for EHR systems. Without the support of physicians who are willing to invest time in template development, the tremendous potential of EHR will remain unfulfilled.

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References
IN RESPONSE: Each letter in response to our article raises interesting and thoughtful points. Drs. Dolin and Wiesenthal raise concerns that we separated functionality from interoperability costs, whereas Dr. Kretz raises concerns that we applied the SBCDE as a national model of interoperability. We agree that functionality and interoperability go hand in hand, and we did not mean to imply that one could be implemented without the other. However, to model costs, it was conceptually and methodologically easier to approach each set of costs separately. The nation as a whole has not reached consensus about how to approach interoperability. The SBCDE system is one of the most successful early examples of broad clinical data exchange and we were able to access costs for it, making it a reasonable choice. This is, however, only one of the possible architectures that can be used.

We agree with Dr. Kretz that it may not be the best approach because the data exchanged were not coded, thereby limiting benefits (1).

Dr. Kretz further states that VISTA should be given significant consideration when developing a model for a national network. Although VISTA has provided tremendous benefits to its population (2), we do not believe that its interoperability approach will be the most useful outside this closed system. Dr. Kretz questioned our assertion that an important financial barrier to wider adoption of health information technology is that benefits accrue to parties other than those who bear the costs. From the policy perspective, who receives the benefits versus who must pay is critical; this issue was addressed by several recent studies (1, 3). It is not simply a question of whether the party bearing the costs accrues benefits greater than the costs. We must also consider the period over which costs and benefits are dispersed and the matter of equitable distribution of costs to those who benefit financially. This is particularly essential for small physician practices, as highlighted by Mr. Doherty. We agree that financial savings from health information technology will be substantial (1, 4).

Finally, we completely agree with Drs. Rothkopf and Jackson about the importance of appropriate user interfaces. For successful implementation of health information technology, we must address cultural issues, speed of the system, appropriate training, technical support, and seamless connectivity (5). All these factors must be addressed to realize the dream of widespread, interconnected information technology and the attendant benefits in safety, quality, and efficiency. The recent experience of tremendous health data problems for Hurricane Katrina victims highlights the urgency of implementing an effective network in the United States.

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Potential Financial Conflicts of Interest: None disclosed.

References

Prevention of Exacerbations of Chronic Obstructive Pulmonary Disease with Tiotropium

TO THE EDITOR: The decision of Niewoehner and colleagues (1) to compare tiotropium with placebo instead of with ipratropium for prevention of exacerbations of chronic obstructive pulmonary disease (COPD) is problematic for several reasons. The authors state they designed the study “to reflect community practice.” However, community practice includes the use of anticholinergic bronchodilators to manage COPD, evidenced by the fact that 80% of study participants received this therapy at baseline. Therefore, the comparison group (placebo) was actually receiving less care than is standard in accepted community practice. It is difficult to determine the significance of the study findings when an appropriate comparator (ipratropium) was not used.

Furthermore, studies of ipratropium therapy have demonstrated a 32% decrease in COPD exacerbations in patients who had FEV1 measurements (approximately 1 liter) that were similar to those in the study by Niewoehner and colleagues (2). These studies were all published long before patients were recruited for the present study. This raises the real possibility that patients in the placebo group could have been harmed as a result of participating in the clinical trial. We ask that the authors provide a table that compares mean COPD health care events (as detailed in their Table 1) for the placebo group at baseline and during the study period, excluding data from those patients who withdrew from the study before reaching study conclusion or a clinical end point.

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Potential Financial Conflicts of Interest: None disclosed.

References
TO THE EDITOR: Niewoehner and colleagues’ report (1) is concerning because it does not satisfy either of the 2 basic moral considerations that govern the ethics of clinical trial design (2).

The first consideration dictates that the research must strive to answer clinically important questions by using scientifically valid methods. Inhaled ipratropium can be considered a standard of care for patients with moderate to severe COPD; as evidence, this treatment had been prescribed for most patients in the tiotropium trial and most were actively taking ipratropium at the time they enrolled in the trial. As such, the trial does not answer the questions of importance to clinicians: Is tiotropium more effective than ipratropium? Because tiotropium is more convenient for patients than ipratropium, is tiotropium as effective as ipratropium? How does tiotropium compare in a cost-effectiveness analysis? Although a standard-of-care control is not necessarily required for a trial to be considered ethical, it is often needed to ensure that the trial results have clinical utility (2).

The second moral consideration governing the design of clinical trials dictates that research participants must be protected from exploitation or harm. In the tiotropium trial, 80% of the patients were instructed to stop using ipratropium; the safety of discontinuing ipratropium therapy in this patient population is unknown. The use of a standard-of-care control group would have allowed the researchers to ensure the safety of patients in the other groups (2).

The trial design does not allow us to feel comfortable that either group of participants in the trial was adequately protected from harm, let alone had better outcomes than patients who receive “usual care.” It is possible that prescribers who change their practice on the basis of this trial’s results may actually be harming patients.

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Potential Financial Conflicts of Interest: None disclosed.

References

IN RESPONSE: The authors of both letters express concerns related to the discontinuation of ipratropium therapy in many participants. They view ipratropium as a standard of care in the community and therefore conclude that withdrawing the drug makes the trial both clinically irrelevant and unethical. We will briefly review the scientific basis for their claims.

Two large trials compared the bronchodilator effects of ipratropium, albuterol, and both drugs used in combination (1, 2). Both trials clearly demonstrated that ipratropium is an effective bronchodilator in COPD, but albuterol produces almost identical responses. Combined treatment produces better bronchodilation than either drug alone, but the additive effect is small and is not associated with overall differences in symptom scores among the 3 treatment groups. These results indicate that albuterol and ipratropium can be used interchangeably for short-term control of symptoms, a conclusion in full accord with current expert recommendations (3). The clinical utility of combined therapy for this purpose remains unproven (4). In addition, there is very good evidence that regular use of ipratropium does not affect long-term changes in lung function (5).

Drs. Good and Longo make the additional claim that ipratropium reduces exacerbation rates by 32% when used with a short-acting β-agonist. The basis for this assertion is a meta-analysis of 3 trials (6), with the overall conclusion generally being drawn from the 2 previously cited studies (1, 2). Exacerbation rates in those 2 trials were inferred from changes in prednisone use, which was reduced when ipratropium was added to albuterol. However, prednisone use was only 1 of numerous other secondary efficacy and safety variables that showed no treatment effects. Claims based on secondary or post hoc analysis must be recognized for their limitations because they often prove to be incorrect when appropriate prospective testing is performed. Furthermore, authors of another review identified 4 trials that involved more than 1000 patients and showed no significant advantage of ipratropium over placebo for reducing exacerbations (relative risk, 0.95 [95% CI, 0.78 to 1.16]) (7).

Drs. Good and Longo asked us to provide a table comparing health care events for COPD before the study with the same events during the trial to determine whether stopping ipratropium therapy had adverse effects in the placebo group. These data are to be found in Table 1 (baseline characteristics) and 3 (secondary outcomes) of our article. We obtained retrospective information from patient self-report and prospective information from monthly interviews and medical records. We expressed frequencies in both tables in common units of mean events per patient-year. Some comparisons were not possible (for example, courses of antibiotics vs. days of antibiotics). We can compare COPD hospitalization rates by summing the 2 categories for hospitalization in Table 1 with the single category in Table 3. The resulting 915 patients in the placebo group reported a mean rate of 0.24 COPD hospitalization per patient-year in the previous year; we identified a mean rate of 0.25 hospitalization per patient-year during the 6 months of the trial. We can similarly compare the sum of urgent physician visits and emergency department visits in Table 1 (mean, 0.59 per patient-year) with the umbrella term of unscheduled visits in Table 3 (mean, 0.49 per patient-year). These comparisons are deeply flawed for obvious reasons, but we can fairly conclude that they raise no red flags. For the reasons previously detailed, we strongly refute the suggestions that we conducted an irrelevant or unethical trial, either willfully or through ignorance. Our decision to allow albuterol as the sole rescue therapy is fully consistent with the scientific evidence. Our study highlights the importance of conducting prospective clinical trials with predefined primary end points and thereby provides definitive evidence of the effect of tiotropium on COPD exacerbations.

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Potential Financial Conflicts of Interest: Employment: S. Kesten
Letters

Exorcising Ghosts and Unwelcome Guests

TO THE EDITOR: We applaud the editors of Annals for their effort to increase awareness regarding ghostwriting (1). Drs. Laine and Mulrow cite our editorial (2), but a slight correction is needed; they imply that the GATE principles were proposed by the European Medical Writers Association. Actually, we initially proposed these guidelines ourselves in our editorial (2). However, we were influenced by the association’s statements and by our own experience when we formulated these guidelines.

There is increasing concern about ghostwriters because it is difficult to prove their existence. Therefore, whenever help from professional writers is necessary, it is imperative that the GATE principles are maintained. Maybe a uniform policy should be implemented by journals (in our editorial, we proposed a formula of acknowledgment statements to achieve maximum transparency). One key issue not addressed by Laine and Mulrow is the possibility of regulating professional writers. In other words, writers would need to be registered and evaluated to maintain minimum standards (2).

The earliest article on ghostwriting that we identified through a search of PubMed was published in 1934 (3). It is about time that we sort out this issue. Professional writers, if they have to be used, should have a legitimate role in assisting (not replacing) experts to provide a quality document while maintaining high ethical standards. However, the experts should always play a key role and have the final say on content. Hidden ghosts, unwelcome guests, and hired experts do not have any place in the medical literature.

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Potential Financial Conflicts of Interest: None disclosed.

References

TO THE EDITOR: I was pleased to read Drs. Laine and Mulrow’s editorial about ghosts and guests, which I thought steered a very sensible course through a difficult topic (1). I feel that 1 minor point of clarification is required, however. The GATE principles referred to in the editorial were not described by the European Medical Writers Association but were described in an editorial (2) that accompanied the association’s guidelines. Readers of Annals may also be interested in the original guidelines (3), which were not cited by Drs. Laine and Mulrow in their editorial.

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Potential Financial Conflicts of Interest: Dr. Jacobs is a former president of the European Medical Writers Association and is a coauthor of the association’s guidelines on the role of medical writers in developing peer-reviewed publications.

References

CLINICAL OBSERVATIONS

Inhaled Treprostinil for Treatment of Chronic Pulmonary Arterial Hypertension

TO THE EDITOR: Background: Treprostinil is a stable prostacyclin analogue that is approved for the treatment of pulmonary arterial hypertension when administered by continuous subcutaneous infusion (1). Inhalation of the stable prostacyclin analogue iloprost has

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None disclosed.

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None disclosed.
proven clinical efficacy in patients with pulmonary hypertension in a randomized, controlled trial (2).

Objective: To characterize the effects of inhaled treprostinil with special regard to safety, tolerability, and efficacy in patients with severe pulmonary arterial hypertension.

Methods and Findings: Three patients with severe pulmonary hypertension underwent catheterization of the right heart and femoral artery for evaluation of pulmonary and systemic hemodynamics. The protocol consisted of assessment of baseline values; administration of nitric oxide at a concentration of 20 parts per million; and administration of a single 15-µg dose of treprostinil, inhaled in 3 breaths through a modified OptiNeb ultrasonic inhalation device (Nebu-Tec, Elsenfeld, Germany). All 3 patients had severe pulmonary hypertension; mean pulmonary vascular resistance (± SE) was 1355 ± 286 dyne/s per cm². Inhalation of nitric oxide resulted in a mean reduction (± SE) in pulmonary vascular resistance of 26% ± 22.8%. Inhalation of treprostinil substantially reduced pulmonary vascular resistance (mean maximum change [± SE], −45.2% ± 17.5%) for a sustained period (duration of effect, >180 min). Pulmonary selectivity of the approach was reflected by a substantially reduced ratio of pulmonary vascular resistance to systemic vascular resistance; the mean area under the curve (± SE) was 30% ± 11% for pulmonary resistance and 16% ± 3% for systemic resistance. One patient had a favorable vasodilator response (shown in the Figure) and was therefore given high-dose calcium-channel blocker therapy.

The other 2 patients were offered long-term inhaled treprostinil therapy (on a compassionate treatment basis), consisting of 4 daily 15-µg doses. Over the first 3 months of treprostinil therapy, the functional status of both patients improved dramatically (New York Heart Association class improved from IV to III and from III to II, respectively; 6-minute walking distance increased from 0 to 143 m and from 310 to 486 m, respectively). No side effects were observed.

Conclusion: In this preliminary report, single applications of inhaled treprostinil induced highly pulmonary selective and sustained vasodilation. The drug was clinically effective, safe, and well tolerated when 15 µg was inhaled in 3 breaths 4 times daily. The current results warrant controlled studies to investigate this approach in a larger group of patients.

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Potential Financial Conflicts of Interest: Consultancies: H.A. Ghofrani (LungRX), W. Seeger (LungRX), H. Olschewski (LungRX); Honoraria: H.A. Ghofrani (LungRX); Grants received: W. Seeger (LungRX).

References

Neurocysticercosis in Kansas

TO THE EDITOR: Background: In the United States, neurocysticercosis is a disease that is most often identified in persons of Hispanic ethnicity. Cases of the disease have been reported from large urban areas (1); however, no studies have evaluated neurocysticercosis in rural areas.

Figure. Acute hemodynamic response of a patient with idiopathic pulmonary arterial hypertension to the inhalation of nitric oxide (20 parts per million) and 15 µg of treprostinil.
Objective: To describe neurocysticercosis in Kansas from April 1986 to April 2001.

Methods and Findings: We reviewed all charts of patients with a discharge diagnosis of cysticercosis between April 1986 and April 2001 at all 3 hospitals and both infectious disease specialty practices in Wichita, Kansas. All participating institutions used the International Classification of Diseases, Ninth Revision (ICD-9) for billing and coding. In addition, we surveyed the 3 community hospitals serving the counties with the largest Hispanic populations by letter and subsequent telephone call. None of the surveyed institutions reported any cases of cysticercosis or neurocysticercosis during the study period. To categorize data by county, we matched ZIP codes that were recorded in the medical record as part of the patient's primary residence with the associated county by using information publicly available from the U.S. Postal Service. Hispanic population data were collected from the U.S. Census Bureau. We delineated 2 periods to evaluate trends in cases of the disease and fluctuations in the Hispanic population as determined by the census data. The first study period ranged from April 1986 to April 1994; the second period ranged from May 1994 to April 2001.

We identified 42 cases of neurocysticercosis between April 1986 and April 2001; 39 of these diagnoses were made in Kansas residents. Of all patients, 30 (71%) presented with seizure activity and 40 (95%) were of Hispanic ethnicity who report neurologic symptoms. In both periods, most patients were of Hispanic ethnicity. In both periods, most patients were of Hispanic ethnicity. Our data corroborate previously reported data from urban areas (1) and allow us to reasonably conclude that the prevalence of neurocysticercosis would probably increase as the Hispanic population increases in a region.

A recent study by the Centers for Disease Control and Prevention demonstrated that although neurocysticercosis is widely distributed throughout the United States, the prevalence is highly variable and the disease is more common among Hispanic immigrants and in the southwestern United States (3). We believe this is an important observation because of increasing Hispanic populations in rural areas, regions in which a diagnosis of neurocysticercosis is not often considered. Like other states, Kansas has experienced a significant growth in Hispanic population over the past decade (4); however, 9% of Kansas counties account for 75% of the state’s Hispanic population. Furthermore, only 4% of the state’s counties have populations greater than 100,000 persons. We strongly encourage physicians, particularly in rural settings, to examine their practices for changes in immigrant populations. We also emphasize the need to actively search for evidence of neurocysticercosis in persons of Hispanic ethnicity who report neurologic symptoms.

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* 1990 U.S. Census population data.
† 2000 U.S. Census population data.

Potential Financial Conflicts of Interest: None disclosed.
References


Correction

Correction: Advanced Lipoprotein Testing in Young Adults
In Tzou and Stein’s (1) letter regarding advanced lipoprotein testing in young adults, Dr. Stein’s affiliation was reported incorrectly. Dr. Stein has provided consulting services to LipoScience, Inc., but he has never been an employee of the company.

Reference