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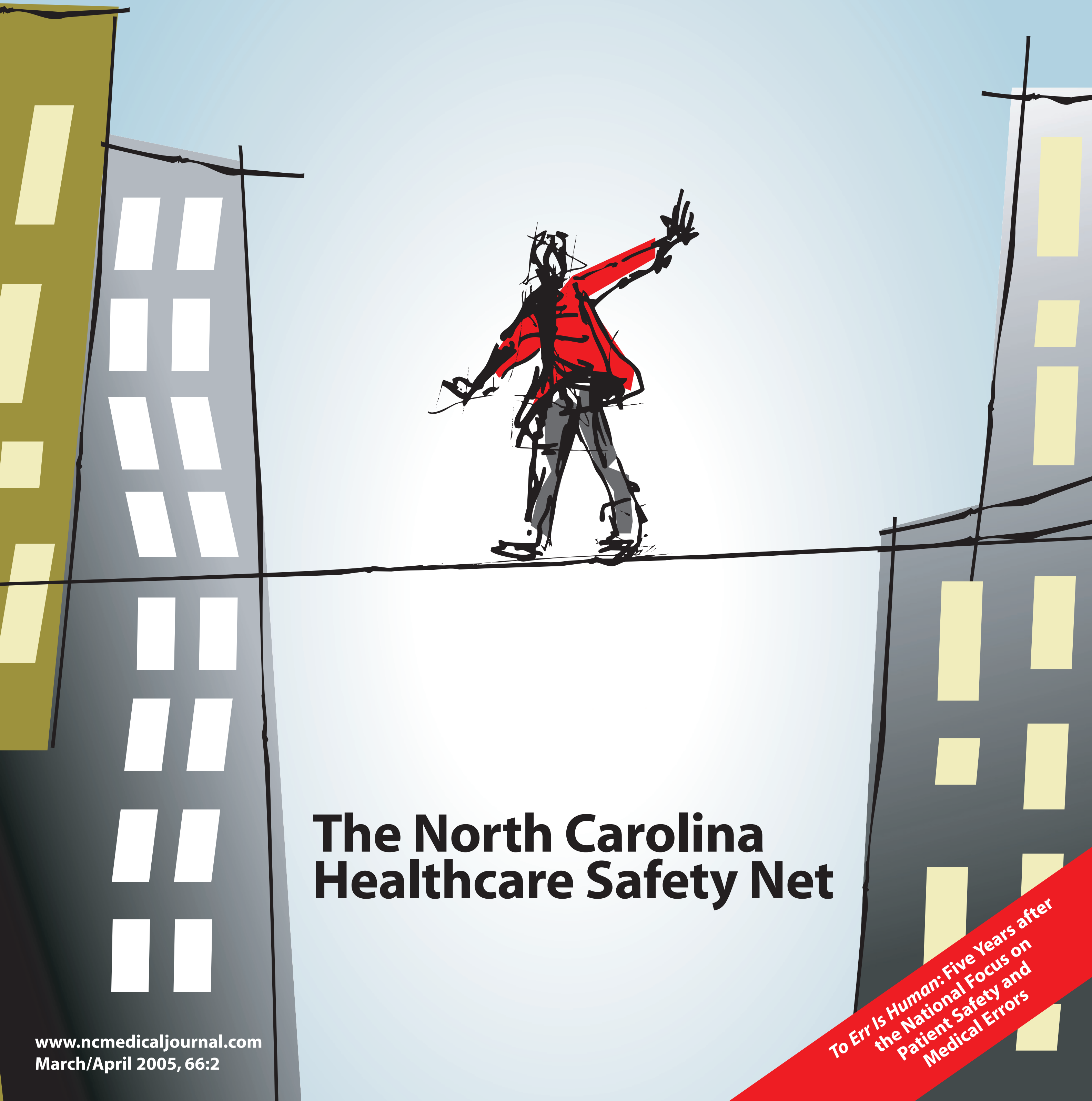

The North Carolina Healthcare Safety Net

To Err Is Human: Five Years after the National Focus on Patient Safety and Medical Errors

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MEDICAL JOURNAL

Founded by the North Carolina Medical Society in 1849
Published by The North Carolina Institute of Medicine (ISSN 0029-2559)

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Members of these organizations receive the Journal free of charge. Additional major funding support comes from **The Duke Endowment**.

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March April 2005, Volume 66, Number 2 **Published by the North Carolina Institute of Medicine**

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MEDICAL JOURNAL

This paper is derived from the author's keynote presentation to the "Patient Safety Symposium" sponsored by the North Carolina Foundation for Nursing Excellence. January 20-21, 2005

Patient Safety:
Rejecting the Status Quo

Arthur A. Levin, MPH

A little over five years ago, the National Academy of Science's Institute of Medicine (IOM) released its groundbreaking report on medical errors *To Err Is Human*.[1] The report, a product of more than a year's work by the Committee on the Quality of Health Care in America—on which I had the privilege to serve—was a startling indictment of the unsafe state of hospital care prevalent in the United States.

As this report was released there was an enormous media response, especially to the body count of patients that the IOM attributed to safety lapses (44,000 to 98,000 deaths in America's hospitals each year). The range of estimated fatalities meant that medical error was the fourth or eighth leading cause of death in the United States, and even more alarmingly, many of these deaths were said to be preventable.

Reaction to the IOM's *To Err Is Human*

To Err Is Human caused a firestorm of reaction, some of which was highly critical of specific conclusions or recommendations made by the committee. While few denied that there were safety problems, many took issue with either the IOM's assessment of the dimension of the problem or to its specific recommendations—especially those that proposed mandated changes in the ways that hospitals and health professionals went about providing care and how they were held accountable for the safety of patients.

There was, in general, an expression of gratitude for the IOM's leadership in bringing the problem to the forefront of national consciousness, and while many went back to business as usual, many other providers, professionals, and policy makers rolled up their sleeves to try to do something about the safety problem.

President Clinton pulled together an interagency task force to tackle safety within the federal healthcare system. Congress, heeding one of the IOM's principal recommendations, budgeted an extra $50 million to the Agency for Health Care Research and Quality (AHRQ) to be used to improve patient safety throughout the healthcare system.

That same year, a group of large employers formed the Leapfrog Group to discuss how they could work collectively to influence healthcare quality and affordability. The group promised (and threatened) to use their combined financial leverage to drive the system toward improved safety and better quality outcomes.

Hospitals began to plan for computerized physician-order entry systems (CPOE), bar coding, and the use of clinical pharmacists on rounds to reduce medication errors. Operative sites were to be marked for identification (or, was it the "non-operative" site that was to be marked?), and operating room "time-outs" were instituted to ensure that the right patient was getting the right operation for the right site. Three decades or more of plans for converting from paper to electronic medical records, digitizing films and test results, and other ways of sharing critical patient information in real time were dusted off. Joint Commission on Accreditation of Healthcare Organizations (JCAHO) quickly developed accreditation standards that focused on patient safety, and the American Medical Association (AMA) founded the National Patient Safety Foundation. Legislatures in more than a dozen states began considering legislation aimed at attacking the patient safety crisis.

So, from early 2000, it appeared, at least to some observers, that patient safety was an issue whose time had come, and that perhaps the IOM's challenge to healthcare providers and professionals—to work toward a 50% reduction in medical errors by the end of 2004—was a real possibility.

Quagmire

But, there were some divisions that had begun to erode any unified sense of purpose and almost immediately began to slow forward motion. For example, there was a lot of push-back on the estimates of 44,000-98,000 patient deaths each year that the IOM said were linked to medical errors in hospitals. These estimates, which were based on two different studies by Harvard researchers,[2,3] were being challenged as vastly overblown. Critics agreed that there was a patient safety problem,

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but it was far less lethal than *To Err Is Human* claimed. And, they argued, "error" was a subjective, imprecise event that defied simple definition (i.e., many deaths attributed to error were more likely due to other factors outside of the control of providers and professionals). Thus, a protracted debate ensued about the lethality of medical errors in hospitals and, of course, some provider and professional associations (perhaps embarrassed by the sorry state of patient safety) seized on these critiques to argue that patients were not nearly as much in harm's way as the IOM report claimed, and that they (providers and professionals) had the situation well in hand.

I would have hoped that the numbers distraction would have evaporated more quickly, but it did not. As recently as last year the medical society of my home state, New York, characterized the IOM estimate as having been "discredited" by critics such as Troy Brennan, MD, JD, MPH, a physician, health services researcher, and lawyer from Harvard who is also, paradoxically, a co-author of both of the large studies of hospital patient errors that the IOM relied upon in its report. Brennan, however, while preaching caution, still believes the human toll of medical error is substantial:

> "Whenever you extrapolate from relatively small samples, you have concerns about the statistical precision of the estimates… although we don't know exactly how many people die from medical errors, there is no doubt it's at least 50,000 per year in hospitals and many additional outpatients."[4]

Focusing on Systems and Assuring Professional Compentency

One very key IOM recommendation disappeared from the radar screen almost instantly. It was a recommendation for establishing state-based, mandatory reporting systems for medical errors that caused serious patient harm. Even more contentious was the committee's belief that some of the information collected by states should be publicly disclosable. The IOM committee actually had the temerity to suggest that the healthcare system should be held publicly accountable for its safety performance.

In my mind this was not a radical suggestion. After all, industrial plants post the days without an employee work-related accident in plain view—why shouldn't hospitals and doctors? I debated two successive presidents of the AMA over this issue, and, arguably, their position against mandated reporting of serious harm and any public disclosure of that harm, has for the most part carried the day.

A good part of the IOM's message was that, even more important than individual behavior, there is a lack of effective systems to prevent the epidemic of medical mistakes. The very title of the report, *To Err Is Human*, was, after all, recognition that human error is almost inevitable, especially in complex, constantly evolving environments like healthcare. And so, the essential task, the IOM concluded, is to build systems that are sensitive enough to recognize the conditions that are antecedent to error and that are adept at preventing patient harm from actually occurring. This "de-individualized" approach was seen as transformational—a turning away from a tradition of blame and shame and mostly punitive approaches to error prevention that had so clearly failed in the past. Needless to say this move from a focus on individual provider or professional responsibility to a "systems approach" was *welcomed* by the "players" in hospital care—perhaps *embraced* would be a better description. For the most part, I agree that a systems approach has great merit (the recommendations of an IOM committee are the result of a consensus process), but I worry about the wisdom of a too enthusiastic rush to dismiss the importance of a professional's competency in the patient safety equation.

Ironically, it was the "it's the system approach" permeating the IOM report that may have helped doom the recommendation that there be mandatory reporting of serious error accompanied by some public disclosure. That theme was fodder for critics of an error-reporting mandate to characterize it as antithetical to a non-punitive, systems-based approach to safety improvement. This partly explains why that essential IOM recommendation dropped off the table. Another reason for the disappearance of reporting mandates from ensuing discussion was that many who wanted meaningful improvement in safety and quality to move forward rapidly worried that such efforts would fail to gain traction if there was a fractious break with providers and professionals over a requirement to report harm.

The airline industry's approach to error became the role model for the patient safety movement. Of course, the fact that pilots happen to be the first to hit the ground when serious errors are committed in the cockpit, does not detract from the industry's seriousness of purpose in its safety efforts. Nor that serious harm to pilots and crew, their passengers, and their aircraft is always announced in a very public manner. It is also well-established public policy to invest almost unlimited resources in a painstaking forensic analysis of the causes of any flight failure that is performed by an independent, highly skilled agency. And the lessons learned from the root cause analysis often are used to mandate airline safety improvements. This is not at all analogous to how attempts to understand what went wrong play out in a highly secretive, mutually protective healthcare system, a system that is comfortable with having mistakes remain ambiguous in origin and that historically lacks a culture of safety. The airline analogy also fails to consider that, unlike healthcare professionals (who are more often than not licensed in perpetuity), cockpit crew licensees are tested for competency routinely throughout their careers and in addition, are required to prove competency as they take any different responsibilities, either as to aircraft or crew position.

In healthcare, except for the hit-or-miss, often misdirected employee firing, loss or reduction of credential or privileges, monetary fine, lawsuit or action against a license, there is really no program in place that demands understanding and accountability for unsafe practices.

I did then, and still, take issue with two reasons often used to bolster the benefits of voluntarism and anonymity in reporting: that it produces more and better quality reporting. I think there is little or no evidence to support these claims and, in fact, we seem to have some evidence quite to the contrary. For example, New York State's hospital incident reporting system, known as NYPORTS, which was cited as an example of mandated reporting by the IOM, receives many times more reports of events that meet a sentinel event definition than the total number reported to JCAHO by hospitals across the country. And, the Food and Drug Administration's (FDA) MedWatch system for collecting adverse drug reactions (ADRs) is estimated to receive only from one-to-ten percent of the number of ADRs that actually occur. Even though the FDA has no interest in or any authority to punish those professionals or organizations that report an ADR, there is still vast under-reporting.

Providers have less of a problem with the other half of the IOM reporting recommendation—one that called for a national *voluntary* system of *anonymous* reports of so-called near misses that occur in hospitals. The model for this system has usually been the NASA-run "incident" reporting system used in the airline industry. That system collects anonymous narrative reports of "incidents," which, in airline talk, are "near misses." The reports are reviewed by retired pilots and controllers to spot important lessons to be learned; and these, in turn, are published so as to improve performance.

But, to-date no such voluntary system exists. Bills purportedly addressing this omission passed in both the houses of Congress last session, but failed to reach a conference to settle differences between them. These bills miss the mark and would mainly serve only to protect hospital patient errors, even those causing serious harm, from any outside discovery. The proposals, rather than build on existing organizations such as the federally funded Quality Improvement Organizations (QIOs), would create a new type of entity, Patient Safety Organizations (PSO), to collect, protect and analyze the safety information that hospitals voluntarily submit. The bills set no data standards, no criteria for judging the success of the PSOs in improving patient safety, allow hospitals to opt out of reporting safety data, and add yet even more expense to a healthcare system steadily marching toward 1.8 trillion dollars in annual costs.

Another key IOM recommendation, one that addressed new responsibilities for licensing and credentialing agencies and organizations in assuring professional competency and knowledge of patient safety practices, went almost unnoticed. But, the concept of periodic, routine competency assessment is gaining traction, especially among medical specialty societies.

This encouraging development can inform the work of other health professions and those providers that credential or privilege professionals. It would seem logical to assume that routine assessment of professional competency could have a substantial positive impact on patient safety and healthcare quality. And by making it routine, it becomes a *systems approach*, not a punitive one.

Why am I spending so much time on the past when what's really important is to understand where we are today? An appreciation of the history of professional and provider reactions to the IOM errors report (what was accepted and what was not) helps us understand how we arrived where we are today.

The Situation Today

Three years after the IOM report was published, author and journalist Michael Millenson had this to say in the March/April 2003 issue of *Health Affairs*:

"…the silence within much of the healthcare community about the true dimensions of the crisis caused by poor quality has changed only modestly over time. Many continue to avert their eyes."[5] Millenson, author of *Demanding Medical Excellence; Doctors and Accountability in the Information Age* went on to say:

"There is a world of difference between calling for a revolution and actually leading one. (And, yes, the latter is far riskier to one's professional well-being.) That difference is why the quality improvement movement, it pains me to say, remains essentially a sideshow for most providers and most of the public."[5]

Millenson's words ring as true today as they did in 2003. There is a profoundly disappointing lack of urgency and unified sense of national purpose to support immediate, forceful steps to significantly reduce and eventually eliminate preventable patient harm.

Consider this: if medical errors kill approximately 50,000 patients each year in hospitals alone, then as many as 250,000 patients may have died since the IOM report was published—a greater toll of human lives than that of the recent tragic December 20, 2004 tsunami. One essential difference, however, is that lethal patient error is not a natural disaster for which we have had little or no warning and no way to prevent.

According to a Kaiser Family Foundation poll released in November 2004, four in ten people surveyed believe the quality of care has gotten worse in the last five years.[6] One in three report that they, or a family member, have experienced a medical error at some point in their lives, and for one in five Americans, the error had "serious health consequences" such as death (8%), long-term disability (11%), or severe pain (16%).[6] Remember the immediate, visceral provider and professional opposition to IOM's recommendation of mandatory, publicly reported error tracking systems? Perhaps not surprisingly, nine out of ten of those surveyed said that reporting of serious medical errors should be required, and two out of three wanted this information to be public.

Patient Body Counts Move Public Policy

Patient "body counts" make providers and professionals uncomfortable, but they are necessary to move public policy in the right direction and to have it stay the course. Talking about preventable death puts a face on what is otherwise a "wonkish" debate and is a necessary element in convincing policy makers and the public that improvements in patient safety are critically needed.

Remember the $50-60 million dollars that Congress was providing to AHRQ for patient safety? Without commenting on whether it was money well spent or the miserliness of allocating only $50 million for safety in a 1.5 trillion dollar healthcare economy, the fact is that the money now competes with other needs [e.g., health information technology initiatives (IT)]. The shift of AHRQ funding from "safety" to "IT" tells me that without a body count to vividly remind us of the magnitude of havoc created by unsafe healthcare; adequate, sustained support for improvement is unlikely.

Upon discovering the lack of attention paid to the considerable human costs of preventable harm that occurs in our healthcare system, Millenson describes himself as at first stunned, then depressed, and finally outraged. That outrage is the appropriate response to the lack of progress toward saving lives evident at the five year anniversary of *To Err Is Human*.

The fall 2004 issue of *Health Affairs* published an article by Robert Wachter,[7] which was commissioned by the Commonwealth Fund for a quality improvement colloquium and marked the fifth anniversary of *To Err Is Human* in November 2004. Dr. Watcher's assessment is that the healthcare system deserves only a "C+" over-all grade for the progress it has stimulated in addressing patient safety. That's not great news, considering the costs of not getting an "A." As if a C+ grade is not bad enough, this report card's grading is highly subjective. The reality is—a reality confirmed by all those attending the November quality colloquium—that we do not have an effective safety data collection system to track medical errors (beyond internal systems in place in many hospitals) and; therefore, cannot say whether things are better, the same, or worse than five years ago. How is this state of affairs acceptable when tens of thousands of lives are at stake, and how did it happen? Remember that the IOM recommendation about tracking medical errors causing serious harm was abandoned not very long after it was made.

For the record, it has not been abandoned everywhere. Some states have subsequently legislated reporting and public disclosure. Minnesota, for example, has just published a report on hospital errors that is the result of a law passed in 2003.[8] Because we have no baseline medical error rate and no way to count errors across systems, we cannot measure the progress made overall in meeting the IOM's error reduction challenge.

In *his* answer to the question "Are we making progress?" Wachter writes: "after hearing of yet another sentinel event in their institutions, every patient safety leader I know laments how little headway we've made in the last five years." He goes on to say "… signs of progress are unmistakable." He illustrates this assessment by telling us that when he asked 400 hospitalists (i.e., physicians who spend the bulk of their practice caring for inpatients) for their views about progress in improving patient safety, 45% of them said things were better than five years ago, 38% said they were the same, and 17% said things had gotten worse.[6] Wachter admits this is only anecdotal evidence, but, inexplicably, he finds it "instructive and reassuring." My problem is two fold: (1) it is not credible evidence because we do not have a valid tracking system; and (2) even anecdotally, more than half of those asked said there has been no progress.

These anecdotal responses of the hospitalists are alarmingly *instructive* and certainly not reassuring. Consider the apparent disconnect of the majority of the hospitalists' somewhat-rosy view that things were better, or at least no worse, with the considerably more pessimistic view of the public surveyed by the Kaiser Family Foundation—that the system is no safer or less safe than five years ago.

Bob Wachter is certainly one of the best in the patient safety and quality improvement movement, but he, like most healthcare professionals, is probably troubled by the truth—that tens of thousands of patients continue to die because healthcare, and all its constituent parts and players, have not applied forceful enough pressure to stop the bleeding caused by safety lapses.

That said, it would be unfair not to point out the hard work that is being done by many around the country to make patients safer every day and the great successes in improving safety that have been achieved through dedicated hard work in individual hospitals, clinics, delivery systems, and other settings. That's the "good news." Patient safety does not have to be an intractable or inevitable problem in healthcare. Providers and professionals do care, and they are able to substantially reduce patient harm if and when they put their shoulders to it. On the other hand, the fact that the healthcare field often knows what to do, what will work (either gleaned from first-hand experience or the lessons provided by others) and still it isn't done consistently or at all (think: hand washing) adds to the frustration of those who believe patient safety has not been made the national priority it should be.

The failure of the healthcare system and policy makers to squarely address the crisis in patient safety and, thus, to allow tens of thousands of preventable deaths each year should be viewed as morally unacceptable public policy. It must be a violation of the ethical standards of every healing profession to be knowingly involved in the delivery of substandard, dangerous care. This should not imply that healthcare workers, as individuals, make conscious decisions to harm patients. Rather, the point is that considerable threat to patient well-being occurs in everyday practice, and these dangers are well known to all the players.

The timidity with which we (those who make public policy or, like myself, try to influence it) have approached providers and professionals alike, to beg, cajole, and entice a meaningful, unwavering devotion to fixing our patient safety crisis must change. Keeping patients safe can no longer be just one more request made of a healthcare provider or professional to improve care. It must become the pass/fail condition of continuing to practice and to serve patients.

A Positive Step

I would be remiss if I did not end on a more positive note. It is my opportunity to issue you a challenge to make things better—to provide a "how to do better" along with my outrage about what has not happened five years after *To Err Is Human*. So, I would like to call to your attention to a courageous and critically important initiative just begun by Dr. Donald Berwick and the Institute for Healthcare Improvement (IHI) —the campaign to save 100,000 lives.

I call it "courageous" because, for the first time, someone of great influence in the safety and quality movement is willing to mention the body count, albeit in a positive framework of prospectively saving lives. I call the campaign critically important because, if successful, it could actually save tens of thousands of lives in a relatively short period of time, and wouldn't that be a wonderful turn of events? It's also important because, by joining, healthcare providers and professionals admit both ownership of the tragic error problem and the ownership of working toward hopeful solutions.

The campaign aims to enlist at least 1,500 hospitals across the United States to commit to six key evidence-based, safety and quality improvements that have the potential to save 100,000 lives over the next 18 months—and beyond. These key improvements are:

(1) *Rapid response teams* (RRTs). These are teams that can respond, assess, and take action quickly at the first sign of a patient's decline. RRTs were pioneered in Australia, and studies have reported they can reduce hospital mortality rates by 27%.

(2) *Prevention of central line-associated bloodstream infections*. While not rocket science, this safety intervention can be almost 100% effective. The bundle consists of five steps; hand hygiene, barrier precautions, proper skin antisepsis, proper site care, and no routine replacement. All five, the "bundle," must be delivered to be optimally effective.

(3) *Prevention of surgical site infections*. Again, there is emphasis on the use of well-understood processes of good care, which include the appropriate selection, timing, and duration of antimicrobial prophylaxis; glucose control; proper surgical site hair removal technique; and other basic prevention strategies. These strategies can cut surgical site infections in half.

(4) *Prevention of adverse drug events*. Implementation of proven safety measures (e.g., standardizing and implementing core medication processes in high-risk areas) and learning from many successful examples of what works from innovating hospitals around the country prove it is possible to reduce fatal adverse drug events and even to eliminate them.

(5) *Improved care for acute myocardial infarction (AMI) patients*. The so-called AMI "bundle" of five specific interventions: beta blockers at admission, aspirin at admission, an ACE inhibitor, reperfusion, and beta-blockers at discharge has been shown to reduce AMI mortality by 40%.

(6) *Prevention of ventilator-associated pneumonia* (VAP). The ventilator "bundle:" elevation of the patient's head by 30 degrees, peptic ulcer prophylaxis, deep venous thrombosis (DVT) prophylaxis, "sedation vacations," and strict hand-washing can eliminate cases of VAP altogether.

I think this initiative is worth your careful consideration as a very public way to show that your organization or your profession: (1) recognizes that there has been and will continue to be a significant loss of life as long as healthcare is not safe care; (2) recognizes that much has been learned about how to do things safer and better and these procedures have been tested in settings not unlike your own; (3) makes a public commitment to refocusing current work on patient safety in ways that will demonstrably and almost immediately begin to save lives; and (4) willingly agrees to having progress tracked and fed back to your organization or profession for comparative purposes (although at this point not publicly disclosed).

Berwick concluded his announcement of the 100,000 lives campaign in December 2004 with these words:

"…the patients whose lives we save can never be known, and though they are unknown, we will know that mothers and fathers are at graduations and weddings they would have missed, and that grandchildren will know grandparents they might never have known, and holidays will be taken, and work completed, and books read, and symphonies heard and gardens tended, that without our work, would have never have been….the point is, lets get started…"

I hope that Berwick's words help to inspire you to make patient safety the priority that those who come to you for care deserve. As we remarked in *To Err Is Human*: "The status quo is no longer acceptable and cannot be tolerated any longer." **NCMJ**

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Improving Diabetes Care among Low-Income North Carolinians:

Project IDEAL

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Abstract

Objectives: *Many barriers exist in implementing evidence-based guidelines for diabetes care, particularly for low-income patients. To address this, the North Carolina Project IDEAL (Improving Diabetes Education, Access to Care, and Living) Diabetes Initiative was created.*

Study Design/Setting: *Fourteen programs representing different types of agencies and intervention strategies across the state participated in the initiative.*

Data Collection: *Separate random samples of medical charts of participating patients were reviewed at baseline (n=429) and three-year follow-up (n=656) to assess changes in six process (assessment of hemoglobin A1c, cholesterol, blood pressure, and urinary protein; conduction of foot and retina examination) and three outcome (glycemia, blood pressure, and lipid control) measures. Four national guidelines (DQIP, HEDIS, NCEP and ADA) were used as benchmarks.*

Results: *Large increases were observed for some measures (hemoglobin A1c control and testing, LDL-cholesterol testing), while modest increases were observed for others (dilated eye exam, blood pressure testing, and control).*

Conclusions/Relevance: *Project IDEAL was successful in improving access to high-quality diabetes care for low-income patients. Additional effort is needed to address specific areas of concern, particularly retinopathy screening.*

Key Words: *Quality of care, DQIP, HEDIS, NCEP, low-socioeconomic status.*

Introduction

As with the rest of the nation, diabetes mellitus is a tremendous public health burden in North Carolina. Over 500,000 North Carolinians have diabetes, and about one-third of them have not been diagnosed. Diabetes is the seventh leading cause of death in the state and accounts for about 14% of all hospitalizations at a cost of about $1.5 billion.[1] Persons with diabetes in North Carolina have an 80% greater rate of death from stroke, more than twice the rate of death from coronary heart disease, and three times the rate of death from hypertensive heart disease, compared to those without diabetes.[2] North Carolina ranks in the top 25% of all states in diabetes mortality. The burden of diabetes in North Carolina is highest or higher, whichever is true, among the state's sizeable population of older adults, ethnic minorities, and persons of lower-socioeconomic status.

Evidence clearly suggests that the implementation of evidence-based guidelines for treatment of persons with diabetes can greatly reduce the risk of chronic complications associated with diabetes,[3,4] and these guidelines are readily available. However, across a number of different patient populations, there is low adherence to these guidelines, generally as a result of patient- and

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provider-oriented barriers.[5] Patients may have limited time or transportation to visit their doctor, while providers may be constrained by time or by challenges in communicating prevention strategies to patients. Thus, there is a need to implement unique and creative approaches to address these barriers to reduce the burden of diabetes.

This report describes a unique community-based initiative implemented in North Carolina designed to improve the quality of care and quality of life of many of the state's vulnerable diabetes population. Included in this report are results that describe improvements in the quality of care provided to patients of programs participating in the initiative.

Methods

The Project IDEAL Diabetes Initiative

Beginning in May 1999, The Kate B. Reynolds Charitable Trust funded 14 programs across North Carolina under the Project IDEAL (Improving Diabetes Education, Access to care and Living) Diabetes Initiative that proposed to enhance the delivery of healthcare services to and the quality of life of underserved North Carolinians with or at risk for diabetes mellitus. Organizations that received funding included public and private, non-profit, healthcare organizations that served populations with a substantial burden of diabetes and had evidence of collaboration among community organizations as well as demonstrated sustainability and local commitment. The range of funds provided to the programs during the three years was $160,000-$275,000.

The Kate B. Reynolds Charitable Trust contracted with the Wake Forest University School of Medicine (WFUSM) Department of Public Health Sciences to develop, administer, and evaluate the initiative. An advisory committee consisting of representatives of state, federal, and private public healthcare agencies was convened by the management team at WFUSM to provide guidance in the development of the request for proposals, to review proposals received, and to provide technical assistance and continuing education to participating programs.

Each of the 14 programs developed their own unique interventions based on the needs of their community to reach their target populations. Examples of such interventions included: establishing new diabetes education and care programs in existing but underutilized physical facilities; using mobile healthcare units; creating "health depots" (off-site stations where screenings were performed and health information was distributed) in rural communities; staffing satellite sites in community pharmacies, physicians' offices, and other locales; and sending visiting healthcare professionals (e.g., diabetes educators and nurse practitioners) to low-income residential facilities. These interventions are described in more detail elsewhere.[6]

Data Collection

To measure change in quality of care, a baseline and post-intervention chart review was conducted. Since we were unable to conduct an evaluation with separate control and intervention sites, each of the programs served as their own controls, and data are presented in aggregate for the pre- and post-intervention time period. Each participating program identified their patients with diabetes from a list of patients either at their program site or at a collaborating clinic site. Patients were identified on the basis of having at least one diagnosis of diabetes in calendar year 1998 for baseline and calendar year 2001 for follow-up. Eligibility for the follow-up was based on patients who had participated in the interventions at each site. Program-specific and aggregate baseline reports were provided to each of the programs. Aggregate data for the baseline results have been published elsewhere.[7] Cases were eligible for project inclusion if they met the following criteria:

- One face-to-face encounter with a diagnosis of diabetes at baseline or follow-up, and
- Over the age of 18 as of December 31, 1998 for baseline and December 31, 2001 for follow-up.

The lists of eligible patients was provided to Wake Forest University School of Medicine staff. For programs with 60 or fewer patients, all patients were included in the evaluation. For programs with more than 60 patients, a random sample of 60 patients was selected from that site. The random sample was created using a random number generator in SAS Statistical Software Program (Cary, NC). Three of the 14 programs did not participate in the baseline evaluation, and two of the 14 did not participate in the follow-up evaluation. Data for the baseline and post-intervention are presented in aggregate.

Demographic information for project cases was gathered from patient records and imported into an electronic data collection tool developed in collaboration with the Medical Review of North Carolina (MRNC), which is the Centers for Medicare and Medicaid Services (CMS)-designated Quality Improvement Organization (QIO) for North Carolina. The tool was developed to capture information on patient characteristics and care processes from primary care medical records. Specially trained nurses and health information management personnel employed by MRNC entered data into the tool. Reliability was conducted using intra-reader assessment of a 10% sample of charts with excellent results.

Quality Indicators

Project IDEAL quality indicators were based on the national Diabetes Quality Improvement Project (DQIP)[8] and on Health Plan and Employer Data Information Set (HEDIS)[9] diabetes-related measures. The DQIP indicators represented a common set of comprehensive, evidence-based measures supported at the time of program initiation by the American Diabetes Association (ADA), the Foundation for Accountability (FACCT), the National Committee on Quality Assurance (NCQA), and the Health Care Financing Administration (HCFA). For this project, six process measures [testing for hemoglobin A1c, low-density lipoprotein (LDL)-cholesterol, nephropathy, retinopathy, hypertension, and neuropathy] and three outcome

Table 1.
Summary of Quality Indicators for Project IDEAL Evaluation

Indicator	Description	Considerations
Glycemia Assessment	At least one measurement of HbA1c during study period.	
Glycemia Control	HbA1c <9.5% on most recent test or level of control unknown.	Persons with no HbA1c test during study period were considered to not be in good control.
Lipid Assessment	At least one measurement of lipids during study period.	
Lipid Control	LDL-C <130 mg/dL on most recent test or level.	Persons with no lipid assessment in the study period were considered to not be in good control.
Nephropathy Assessment	At least one screening for diabetic nephropathy during study period via urinalysis or microalbuminuria testing (latter only if indicated).	A positive test for macroalbuminuria was considered acceptable, but a negative test for macroalbuminuria required testing for microalbuminuria. Patients with a documented history of nephropathy per medical record review were excluded from the eligible cases for this measure (the denominator).
Diabetic Retinopathy Assessment	Receiving a dilated eye exam performed by an ophthalmologist or optometrist, or having a 30-degree fundus photography read by an optometrist or ophthalmologist during study period.	Cases meeting the criteria for biennial eye exams (having any two of the following: not taking insulin; HbA1c <8.0%; no evidence of retinopathy on previous year's eye exam) were excluded from calculation of the annual eye exam rate.
Blood Pressure Assessment	At least one measurement of blood pressure during study period.	
Blood Pressure Control	Systolic blood pressure less than 140 mmHg and a diastolic blood pressure less than 90 mmHg.	Persons with no measurement of blood pressure during the study period were assumed to not have good control.
Foot Examination	Having a visual foot inspection, a pedal pulse assessment, and a sensory examination during study period.	

measures [control of: hemoglobin A1c (HbA1c), LDL-cholesterol, and blood pressure] were reported. The quality indicators chosen for this project are consistent with DQIP and HEDIS 1999 diabetes related measures with the addition of blood pressure and foot examination measures. These measures, along with the criteria for documenting compliance for each measure, are described in table 1.

Statistical Analyses

All statistical analyses were performed using the SAS Statistical software program (Version 8.0, Cary, NC). Bivariate chi-square tests were performed to determine statistical significance in the proportion of patients meeting each of the quality of care indicators. In addition, the adjusted proportions at each time period were derived by fitting a random effects logistic regression model, which took into account clinic cluster correlation and controlled for age, sex, race/ethnicity, and insurance status. The results were obtained by using the SAS macro GLIMMIX, extracting Wolfinger/O'Conell's pseudo-likelihood estimates, estimating the expected adjusted means at baseline and follow-up, and transforming back to the sample proportions.[10] The 95% confidence intervals of the differences in adjusted proportions were found by bootstrapping using the SAS macro BOOT and selecting the default 200 sub-samples. The normal approximation was used to find the upper and lower bound of the confidence intervals.[11] Additionally, the bootstrapping procedure allowed for the estimated differences in proportions to be corrected for bias. Ordinary adjusted logistic regression was also performed. As the results were similar and the variance estimates from the mixed logistic regression analyses are preferred, only the latter results are presented here.

Results

Table 2 provides demographic and medical history information for baseline and follow-up samples for the aggregate data. The racial/ethnic distribution was significantly different at follow-up compared to baseline (p=0.04), with a larger proportion in the follow-up group of whites and those classified as "other." The follow-up sample was also significantly older (p<0.001) than the baseline sample, which is reflected in the greater proportion of patients at follow-up on Medicare. Patients at follow-up were also less likely to be on insulin therapy (p=0.02).

Quality of care indicators for baseline and follow-up are described in Table 3. All indicators increased from baseline to follow-up. Testing of HbA1c significantly increased from 52.7% at baseline to 72.0% at follow-up (unadjusted difference: +19.3%; adjusted difference: +39.3%, 95% Confidence Interval [CI], 31.7-47.0%). This is a modest estimate of HbA1c testing, since this indicator refers to at least one test per year. HbA1c control increased from 39.6% at baseline to 64.9% at follow-up (unadjusted difference: +25.3%, adjusted difference: +37.5%, 95% CI, 30.6-44.4%). Since persons without an HbA1c measure were considered not in control, we only examined those with at least one HbA1c measurement. If missing values for HbA1c were ignored, control increased from 74.7% at baseline to 89.2% at follow-up. Using more intensive thresholds,[3] control to less than 8% increased from 26.0% to 55.0%, and control to less than 7.0% increased from 13.6% to 36.3%.

Measurement of lipids increased from 44.5% at baseline to 56.7% at follow-up (unadjusted difference: +12.2%, adjusted

Table 2.
Patient Descriptors for Baseline and Follow-up Samples

	Baseline (1998) (n = 429)	Follow-up (2001) (n = 656)	χ^2 P-value
Race/Ethnicity			
African-American	43.8%	35.8%	0.04
White	46.9%	52.4%	
Hispanic	1.6%	1.2%	
Other	7.7%	10.5%	
Gender			
Male	31.9%	34.0%	0.48
Female	68.1%	66.0%	
Age			
< 45	26.3%	13.4%	<0.001
45 – 64	49.4%	50.1%	
65 +	24.2%	36.3%	
Median Age (Years)	53	59	<0.001§
Medical History			
Insulin Use	29.6%	23.1%	0.02
Current Smoker	21.9%	13.1%	<0.001
History of CAD*	19.1%	14.8%	0.06
History of Hypertension	63.6%	62.8%	0.78
History of Nephropathy	6.3%	7.6%	0.40
History of Neuropathy	6.3%	6.9%	0.71
History of Peripheral Vascular Disease	3.7%	4.1%	0.75
History of Non-Traumatic LEA**	0.9%	0.2%	0.12§§
Insurance Status			
Medicaid, Medicare, HMO	25.4	39.6	>.001
Other	66.0	33.8	
Not Indicated	8.6	26.4	

*CAD denotes Coronary Artery Disease
**LEA denotes Lower Extremity Amputation
§ Test of Medians
§§ Fischer Exact Test used due to low frequencies

Table 3.
Percentage of Patients Meeting Quality Indicators at Baseline and Follow-up

Quality Indicator	Baseline	Follow-up	Absolute Difference	Adjusted Difference (95% Confidence Interval)
Hemoglobin (HbA1c) Test	52.7%	72.0%	+19.3%	39.3 (31.7-47.0)
HbA1c Control	39.6%	64.9%	+25.3%	37.5 (30.6-44.4)
Lipid Assessment	44.5%	56.7%	+12.2%	19.7 (13.0-26.3)
LDL Cholesterol (LDL-C) Test	23.6%	41.8%	+18.2%	21.6 (1.5-41.7)
Nephropathy Assessment	8.0%	25.4%	+17.4%	17.0 (10.1-24.0)
Dilated Eye Exam	6.3%	7.3%	+1.0%	4.3 (1.2-7.5)
Blood Pressure Testing	77.9%	82.8%	+4.9%	19.5 (9.7-29.3)
Blood Pressure Control	37.1%	43.6%	+6.5%	7.0 (0-14.1)
Complete Foot Exam	3.3%	21.2%	+17.9%	13.2 (6.7-19.6)

difference: +19.7%, 95% CI, 13.0-26.3%). While 23.6% of the baseline sample had LDL-C within accepted levels at baseline, that indicator increased to 41.8% at follow-up. Control of LDL-C below 100 mg/dL, consistent with Adult Treatment Panel (ATP) III guidelines,[12] increased from 9.1% to 24.4%.

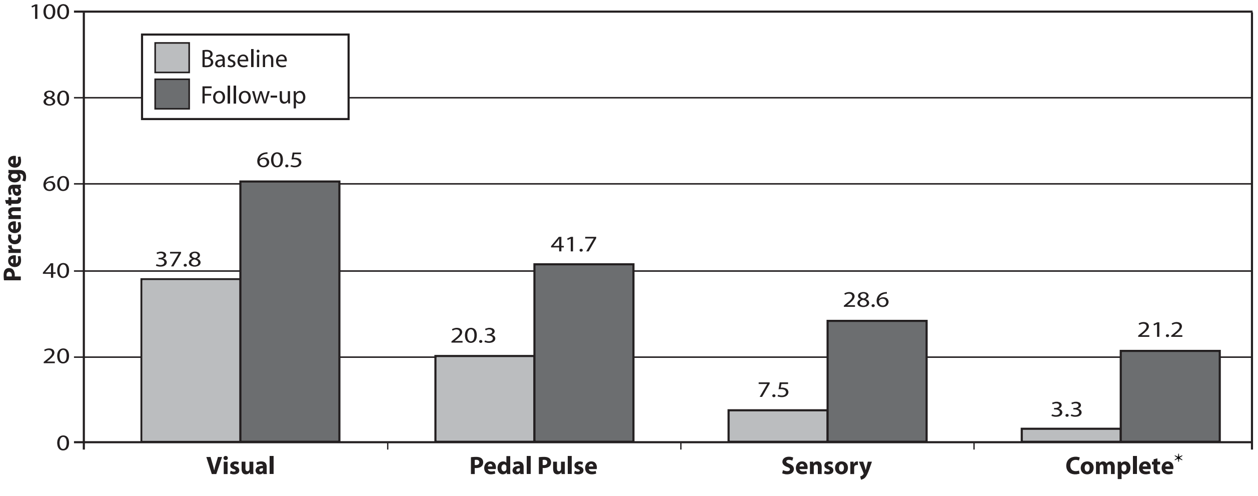
Two of the most problematic indicators identified at baseline were nephropathy and retinopathy assessment. Nephropathy assessment increased dramatically, from only 8.0% of the aggregate baseline sample to 25.4% of the follow-up sample (unadjusted difference: +17.4%; adjusted difference: +17.0%, 95% CI, 10.1-24.1%). The percentage of documented dilated eye exams only increased from 6.3% to 7.3% (unadjusted difference: +1.0%; adjusted difference: 4.3%, 95% CI, 1.2-7.5%); however, the percentage of patients receiving a recommendation for an eye examination nearly quadrupled, from 4.9% at baseline to 19.0% at follow-up (data not shown).

The vast majority of patients received a blood pressure measurement during both study periods. Blood pressure control (defined as systolic blood pressure less than 140 mmHg and diastolic blood pressure less than 90 mmHg) increased from 37.1% at baseline to 43.6% at follow-up, although this difference was not statistically significant. Using the more recent JNC VI high blood pressure recommendations[13] (systolic blood pressure less than 130 mmHg and diastolic blood pressure less than 85 mmHg), the percentage of patients with good control increased from 22.8% to 27.9%.

Foot examinations were another area of concern in the study population. Complete foot exam (having a visual, pedal pulse, and sensory exam) increased from only 3.3% at baseline to 21.2% at follow-up (unadjusted difference: 17.9%; adjusted difference: 13.2%, 95% CI, 6.7-19.6%). All three types of foot exams increased from baseline to follow-up (see figure 1). The most common examination was a visual inspection (37.8% at baseline, 60.5% at follow-up), followed by an assessment of pedal pulses (20.3% at baseline, 41.7% at follow-up).

Further examination of the control measures revealed that

Figure 1.
Distribution of Various Types of Foot Examinations among Project IDEAL Participants, Baseline and Follow-up



* Complete means having all three assessments within the study period.

few patients met all the criteria for adequate control (data not shown). Using the more stringent criteria (HbA1c less than 7%, systolic blood pressure less than 135 mmHg, and LDL-cholesterol less than 100), only 1% of patients met all of those criteria at baseline, and 5% met those criteria at follow-up. Using more conservative criteria (HbA1c less than 8%, systolic blood pressure less than 140 mmHg, and LDL-cholesterol less than 130 mg/dl), 3% met those criteria at baseline and 14% met those criteria at follow-up.

Discussion

This study showed modest to significant increases in the quality of care provided to low-income patients with diabetes among participants in a statewide diabetes initiative. This is important because the dramatic increase in the prevalence of diabetes in recent years translates to tremendous increases in future healthcare costs related to treatment of diabetes and its complications.[14] Reducing the complications of diabetes requires a strong, concerted effort from both the healthcare provider team and the individual with diabetes. While implementation of diabetes clinical guidelines, which are readily available to primary and specialty care providers, has been proven to be effective in reducing the risks associated with diabetes,[3,4] many barriers exist. Racial and ethnic differences in access to and use of healthcare services occur and disproportionately affect the underserved. Low health literacy prevents many patients from making full use of the latest treatments and up-to-date clinical information on their illness. Additionally, provider barriers such as limited clinic time with patients, inability to manage multiple guidelines, and negative perceptions of patients influence healthcare providers' implementation of diabetes care guidelines.[15]

General awareness regarding health-related issues and the benefits of accessing healthcare services could be improved through culturally appropriate community-based outreach and education programs.[16,17] However, each community will face a unique set of barriers, which precludes a one-size-fits-all solution. Healthcare delivery customized by local health leaders, but based on proven guidelines (the method demonstrated in Project IDEAL), may be necessary to achieve maximal benefits for racially diverse and medically underserved populations.

A number of studies have shown that adherence to clinical guidelines is poor for patients with diabetes, and this pattern appears to be consistent across a variety of populations. A sample of these studies is reviewed briefly here. Using the claims from Medicare beneficiaries in 1997-1999, Arday and colleagues[18] observed that only 67.8% of patients with diabetes received an annual HbA1c test, 68.3% received eye exams, and 56.8% received a lipid profile. In an assessment of quality of care among patients at 55 mid-western federally-funded community health centers, Chin and colleagues[19] found that 70% had at least one measurement of HbA1c, 26% had a dilated eye examination, and 51% had received some type of foot care. Using HMO data in California, Peters and colleagues,[20] found that 44% of patients with diabetes had received at least one HbA1c test, 48% had received a test of urinary proteins, and only 6% had received at least one foot examination. Consistent with these data, we also found low levels of adherence to diabetes care guidelines[7] in the baseline sample of low-income, largely ethnic minority patients selected for this project.

Our study has a number of limitations that must be taken into consideration. First, this study did not have a true control group, so the outcomes could have been attributed to factors other than the intervention, such as possible increased awareness of diabetes care in the community and in the healthcare arena, implementation of other local diabetes initiatives, and availability of additional healthcare resources. Also, since all sites participated in the intervention and, thus, were not blinded to treatment group as in a randomized placebo-controlled trial, there is the possibility that outcome measures were more aggressively pursued and recorded to enhance the results of the program initiative. However, this is somewhat unlikely given that systematic improvements were not shown in this study and that these data come from chart review and not from self-report by providers. In most cases, individuals coding data into the medical chart were not directly associated with the study.

The programs participating in Project IDEAL developed and implemented their own unique interventions with financial support from The Kate B. Reynolds Charitable Trust and technical support and evaluation from the Wake Forest University School of Medicine. Many opportunities for improvement were identified in the baseline data from 1998. Follow-up aggregate data revealed significant improvement for most quality indicators that supports the overall program intent: to deliver appropriate diabetes care and services to underserved North Carolinians. However, given the rather conservative assessment of quality care in this report, there is still much room for improvement. Also, the lack of an observed improvement in assessment of diabetic retinopathy indicates that this might be an area for future targeted interventions.

Conclusions

This study has a number of limitations which affect the generalizability of these results. First, there is insufficient data to test the impact of program-specific interventions. Second, the results reflect short-term changes in quality of care measures, which may not be sustained for extended periods of time. Third, these data were limited to medical chart reviews in primary care facilities, which may not adequately reflect the level of care being administered. Nonetheless, these results support the contention that programs that customize the delivery of healthcare to fit the unique needs of the community, such as demonstrated in Project IDEAL, can be successful in improving the quality of care that patients, particularly those of low-income communities, receive in primary care settings. Mechanisms for dissemination and maintenance of these approaches are needed to broaden the impact of diabetes control efforts in the population. **NCMJ**

Acknowledgements

The Project IDEAL Diabetes Initiative was supported by The Kate B. Reynolds Charitable Trust, Winston-Salem, North Carolina.

The authors wish to acknowledge the following: Dawn Doss, Assistant Project Manager, for superior work in assisting project management and program coordinators; the Project IDEAL clinic staff for their hard work toward reducing the burden of diabetes in North Carolina; the staff at the Medical Review of North Carolina and the North Carolina Baptist Hospital Health-on-Call staff, for their assistance in collection of evaluation data; and, the Advisory Committee for their role in the development and technical assistance and resources provided for this initiative:

Project IDEAL Advisory Committee (Dr. Joseph Konen, Chair): Hugh Young, Howard Campbell, Paul Dunn, North Carolina Diabetes Advisory Council; Betty Lamb, Centers for Disease Control and Prevention; Markita Moore, North Carolina Primary Health Care Association; Kathy Johnson, North Carolina Office of Rural Health; Clark Luikart, North Carolina Area Health Education Association; Bob Weiser, Director, and Kelly Goonan, Senior Project Management Medical Review of North Carolina.

Editor's note: These affiliations were current during the committee member's time of service.

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Accommodating a New Medical Profession:
The History of Physician Assistant Regulatory Legislation in North Carolina

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In 1967, the first graduates of the Duke University Physician Assistant Program received their certificates and began their practice. The Duke program was the first in the country to train this new professional group.[1] There was no legal framework in place for their practice, other than a ruling from the Attorney General of North Carolina that performance of delegated, physician-supervised activities by a physician assistant did not contravene the licensure laws of the state.[2,3] Other institutions were beginning programs of their own, some using the Duke model, and others a very different structure. National interest in this new manpower innovation was high, as was interest in the new profession by prospective students.[4]

Recognizing their obligation as the innovators and pioneers in physician assistant education, the parent department of the program at Duke University Medical Center, the Department of Community Health Sciences undertook the process of studying the unique problems of regulation of this new professional group and designing model legislation to implement this regulation.[1,2,5]

The process by which this model legislation was designed was unique, as was the regulatory framework which resulted. Following the development of the model, it was framed as a legislative act and considered by the North Carolina General Assembly the following year. It was passed with no major opposition.[6] This framework has served the state, the medical profession, and the physician assistant profession well for over three decades and has been the model for similar legislation in a number of other states.[7]

The purpose of this paper is to describe the process, some of the options that were considered, and some of the factors that led to a new and very unique basis for regulation of physician assistants. At the same time, it will highlight some of the characteristics of the process by which the proposed regulatory system was studied and developed. In retrospect, these appear to have heavily contributed to the favorable reception of the new regulatory process by the medical community within the state. The authors feel that recognizing these characteristics, and duplicating them, can be very useful to those with the responsibility for designing new licensure and regulatory statutes for medical occupations that may evolve in the future.

The Environment and Early Preparation

The Duke Physician Assistant Program arose from the awareness that many areas of the state, especially rural areas, were suffering from a growing shortage of physicians. The first class began in 1965, with a curriculum that resembled a shortened medical school curriculum: 12 months of pre-clinical sciences and 15 months of clinical instruction taught by medical school faculty. Interest in the program was immediate. Other medical institutions began programs of their own, some using the Duke model, and others a very different design, such as the Medex Program at the University of Washington. Entrepreneurial interest was also evident, with for-profit programs offering a certificate after only a few weeks of training. The need for standards for educational and clinical preparation of physician assistants was seen as an urgent priority, as was a framework for licensure and regulation.[5,7]

The Duke Physician Assistant Program was conceived and begun by Dr. Eugene A. Stead, then the Chair of the Department of Medicine.[8] He retired from this position in 1966, just after Duke University formed a new department—the Department of Community Health Sciences (later Community and Family Medicine)—with the first author of this paper as its chairman. The new Physician Assistant Program fit more easily into the mission and interests of this new department, and it was transferred to the new department late in 1966, before the graduation of the first class of students. This department initiated a number of studies of the new profession and also began to explore other required steps for its inclusion as a recognized component of the medical community. In addition to the looming problem of licensure and regulation, there was

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the need for accreditation of educational programs and a process for testing the educational preparation of graduating students. Drs. Estes, Stead, and D. Robert Howard, Director of the Physician Assistant Program, became the planning group for these activities, with the Department of Community Health Sciences as the organizational seat of the activity.[1,9] This paper will only consider those activities related to licensure/regulation.

The federal government recognized the need for uniform standards for the profession, and early in 1969 the Department of Health, Education, and Welfare awarded a contract to the Duke Department of Community Health Sciences to develop model legislation for the regulation of physician assistants. One of the first steps in carrying out the contract was to select a project operating officer, Martha Ballenger, JD, who immediately began to review published information about licensure of medical personnel. Her findings became the basis for a *white paper*, which was used for project planning and as background information for participants in the series of conferences that followed.[2]

This white paper pointed out that the responsibility for physician and other medical occupational licensure is a state prerogative, and there are differences from state to state. Legislation for physician licensure arose in the late 19th and early 20th century to control the rampant quackery and poor medical education characteristic of that time. These licensure acts were framed in very broad and general terms, permitting physicians to carry out any act or task taught in medical school, with no restrictions. As new health professions evolved and gained acceptance, their members were granted more circumscribed licenses, enabling them to perform only those specific functions for which they were qualified by training and experience.

The paper also pointed out that the process of awarding independent licensure for a new professional group was often hotly contested by those professional groups whose professional territory was being invaded. The result was an array of professional groups within healthcare (each with a sharply defined set of authorized functions) with frequent scope-of-practice conflicts as they sought to expand their functions.

Five options were identified for discussion and debate, each with advantages and disadvantages. The "status quo" option was a continuation of the existing policy. Physicians would delegate functions to their assistant, and custom and useage would validate the process over time. This option was seen as leaving both the employing physician and the assistant vulnerable to legal action for improper delegation. Independent licensure of physician assistants was the second option. Difficulty in precisely defining the duties to be permitted was seen as a major problem with this option. The third option was to license the physician or institution that wished to utilize a physician assistant. This was seen as a new function of the Medical Board. The fourth option was create a new statute authorizing general delegation by physicians. Four states were found to have some features of legislation authorizing general delegation within their medical practice acts. Lack of protection for the public was an identified problem with this approach. The fifth and last option was to create a Committee on Health Manpower Innovations, which would report to the medical board. The Committee would evaluate and pass judgment on new types of health workers, based on the need and the ability of the applicant individual or institution to support and supervise the innovation. The need for representation by all health professions on the new Committee was recognized, but at the same time, it was predicted that each of the representatives would tend to be protective of their own turf.

No judgment was offered on the relative merits of each of these options, since this was to be the subject of open discussion and debate in the series of conferences planned for the future. The purpose of presenting options was to encourage consideration of possibilities beyond those in use at the time and to present the unique challenges of the task ahead. Chief among these was the need for flexibility while meeting the responsibility to protect the patient and the public interest.

Drafting the North Carolina Statute for Licensure and Regulation of New Medical Professionals

The next step in the process was to hold a conference on licensure/regulation of new medical professions, with physician assistants as the principal focus.[10] Representation was sought from all groups seen as having a significant interface with the new professional group. The invited participants included:

- Nationally recognized experts on licensure of health personnel, identified from their contribution to the literature on this subject;
- Representatives from medicine, nursing, and hospital administration in North Carolina, including both practicing members of these professions and members of their legal staff;
- Members of the North Carolina legislature, the North Carolina Institute of Government, and the regulatory boards governing medicine and nursing;
- Educational representatives from Duke University School of Medicine and the Physician Assistant Program;
- Members of the newly graduated classes of Physician Assistants and their employing physicians; and
- A representative of the United States Department of Health, Education, and Welfare.

The first conference was held in Durham, North Carolina, on October 26 and 27, 1969. The previously listed options were presented and discussed during the first day. It was the consensus of those present that the best approach would include a combination of several options, most closely resembling option four—a statute authorizing general delegation of functions to an assistant. For the protection of the public, it was felt that this delegatory authority should be restricted to assistants functioning under credentials and constraints reviewed and approved by the North Carolina Board of Medical Examiners. Following the conference, a group of legal consultants met to prepare a first draft of a model statute, which was circulated to all those who attended, with a request for added comments and suggested revisions. Following a rewrite incorporating several of these suggestions, the revised version was again circulated to all who had attended.

A second conference was held in Durham, North Carolina on March 1, 1970, to discuss the product of these revisions, and to discuss in detail a modification proposed by one of the legal consultants. After lengthy discussion, the "October Proposal" was endorsed by the group, and became the proposal forwarded to those responsible for framing new legislation. It was enacted into law, essentially as proposed, in the 1971 session of the North Carolina General Assembly.[6]

At the time of the previously mentioned actions, the North Carolina General Statutes, Section 90, paragraph 18, after prescribing penalties for the unlicensed practice of medicine, read:

> "Any person shall be regarded as practicing medicine or surgery within the meaning of this article who shall diagnose or attempt to diagnose, treat or attempt to treat, operate or attempt to operate on, or prescribe for or administer to, or profess to treat any human ailment, physical or mental, or any physical injury to or deformity of another person: Provided, that the following cases shall not come within the definition above recited."

This was followed by a series of permitted exceptions, including the use of home remedies within the family, the practice of dentistry by a licensed dentist, the practice of pharmacy by a licensed pharmacist, etc. The proposal was exception (14) to this definition of the practice of medicine. It read as follows:

> "(14) Any act, task or function performed at the direction and under the supervision of a physician licensed by the Board of Medical Examiners, by a person approved by the Board as one qualified to function as a physician assistant when the said act, task, or function is performed in accordance with rules and regulations promulgated by the Board."

This proposal established a two-stage method of control. Before the physician assistant could have the benefit of the protection afforded by the statute, he or she must have gained the approval of the Board, through graduation from a recognized educational program. Once approved, the assistant might subsequently demonstrate incompetence or unwillingness to perform within the limits set by the physician, or the physician might be shown to be using his assistant in an inappropriate manner. Thus, there was an implicit power of the Board to deny or revoke approval at a later time. The final clause of the exception requires the Board to promulgate rules as needed.

The model legislation had several attractive features. It avoided specificity in definition of functions allowed by assistants. The functions permitted are, in effect, any functions delegated by the physician. It placed the promulgation of rules in the hands of the Board of Medical Examiners, not the General Assembly, thereby making changes possible without the formal action of an elected body.

Since its adoption in 1971, the afore mentioned approach has had the desired effect of permitting and supporting the function of physician assistants, while safeguarding the safety of the public. It has required very minimal alteration over time, and most changes have been accomplished through changes in the rules and regulations rather than the statute.[12,13] After its enactment, a similar approach was used to permit the medical acts of nurse practitioners. Recognizing that the nurse practitioner is already acting under another licensing authority, the North Carolina Board of Nursing, the legislation added nurse practitioners to the list of exceptions to the unauthorized practice of medicine. Legislation also established a joint committee of both boards to promulgate rules and regulations for nurse practitioners, specifying that both boards must approve these rules.

Still more recently, the same model has been used to permit the function of clinical pharmacist practitioners, who are now permitted to prescribe and manage illness under rules established by a committee with membership from both boards.

The model legislation proposed in 1969-1970 thus proved its merit through its adoption in North Carolina and many other states, and it has proved a very workable and flexible in action. It has also been used as a model for other professional groups that have joined physician assistants in performing medical acts. Physician assistants now work in every medical specialty, and their functions have been accommodated as new tasks have been developed and implemented, in ways that could not have been predicted when the legislation was developed.

The Process of Development of Model Legislation

The development of the model legislation for physician assistants was a very intense process with much debate and exchange of opinion. Yet, at the end, the resulting legislation passed the North Carolina General Assembly with very little dissent. This result has caused the authors to examine the process by which it developed in more detail, and to speculate cause and effect. Several characteristics of the process of development are identified as important in achieving the successful outcome. These are presented and discussed in the following section, with the hope that they will be useful to others who wish to achieve accommodation of a new professional group into the health professions.

The following characteristics are identified as important to the outcome:

- All professional groups identified as being impacted by the new professional group, physician assistant, were represented in the group invited to develop the model legislation;
- Identified national experts, from outside the medical profession, were invited to participate and contribute to the development of ideas;
- The process emphasized, at all stages, that a major objective for the model legislation was protection of the public and the individual patient, not preservation of professional turf;
- The process permitted all participants to review prior work;

submit their own new ideas, and revise old ideas through several iterations of the developing model; and

- The process produced near unanimous agreement on the details of the model before it was sent forward.

It was obvious that the new physician assistant would interact with every other major medical professional group: nurses, hospital administrators, pharmacists, etc. For this reason, an effort was made to include each of these groups in the conference and subsequent discussions. This proved very useful in allaying anxiety and suspicions and in informing all about the provisions of the model legislation.

Physician support was an essential requirement. It was fortuitous that the president of the North Carolina Medical Society was a family practitioner from a rural area, who had seen the need for the new profession firsthand. He was also a very perceptive and innovative individual who had a very warm relationship with many members of the North Carolina General Assembly. This individual, Edgar Beddingfield, MD, had served for many years as the head of the Legislative Committee of the Medical Society of the State of North Carolina (later the North Carolina Medical Society). He was also very active as a delegate and elected officer in the American Medical Association and was very helpful later in establishing a mechanism for accreditation of physician assistant education programs through that organization.

Nursing was represented by Dr. Eloise Lewis, a senior stateswoman in this profession, and the dean of a highly respected School of Nursing. The legal counsel to the North Carolina Nurses Association was also included.

The regulatory boards for both medicine and nursing were also included, with both members and legal counsel from each. This inclusion insured that the point of view of each of these boards was expressed and understood by the other, and the usual suspicions of ill intent, based on fragmentary or distorted information, were avoided.

The inclusion of national experts on licensure of medical personnel had several important effects. Their writings were known from the preliminary research, but their presence as a part of the discussion and deliberation broadened the approach. Their presence also provided an assurance to all participants that all major issues had been considered and that the work of the committee was important. They were also tenacious defenders of the public protection requirements of the model legislation, and their presence lent authority and validity to the product developed.

The emphasis on protection of the public was unifying in many ways. Each professional group could understand that this was not an attempt to restrict or diminish other professional groups, but to serve all interests as, together, we serve our patients.

The last two points can be considered together. Every participant was invited to comment, criticize, revise, object, and contribute to the development of the model. When differences were discovered, these were discussed in detail, and a consensus obtained. When the process was finished, all felt that they had contributed and felt ownership of the product. The group included legislators who were very effective in answering questions from fellow legislators during the debates and at avoiding conflict as the North Carolina General Assembly proceeded toward passage of the measure.

Summary

The first physician assistant program in the United States was at Duke University Medical Center. This program served as a model for other institutions to begin similar educational programs, and the profession has quickly become a major source of medical services throughout the country. Less well-known is the role of Duke University and North Carolina in the development of a unique regulatory system, which also became a national model. This system has been effective in protecting the public and the patient, and has had the flexibility to adapt to changing medical practice and changing standards. The process by which this regulatory system was developed was unique, and its unique characteristics are felt to have been a significant factor in its success. Duplication of these characteristics is recommended for those who wish to incorporate new medical occupations into the larger medical community. **NCMJ**

Acknowledgements

The authors would like to gratefully acknowledge the interest and advice of Dr. Eugene A. Stead, the founder of the Physician Assistant Program at Duke University Medical Center, in the preparation of this manuscript. Dr. Stead was a critical participant in the studies and conferences cited, and he has remained an active contributor to the development and evolution of the profession over the intervening years. His friendly but persistent requests for a written record of the development of regulatory legislation led the authors, long his friends and admirers, to honor his wishes.

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POLICY FORUM
The North Carolina Healthcare Safety Net

> *"Lack of health insurance coverage decreases worker productivity; negatively affects the health of children and, thus, their ability to learn; and has unfavorable financial implications for those healthcare providers who provide care to the uninsured."*

COMMENTARIES

INTRODUCTION

Policy Forum:
The North Carolina Healthcare Safety Net

For more than three years, as we have published 20 issues of the *North Carolina Medical Journal*, there have been multiple occasions when we thought the word "crisis" was an appropriate moniker for a situation of urgent importance to the health of North Carolinians or the future of the healthcare services upon which we all depend. Certainly the growing number of North Carolinians without health insurance is an alarming trend. But, when one considers the fragility of the healthcare services available to serve the needs of this rapidly increasing component of our population—now nearly one-fifth of all North Carolinians—here is yet another occasion when the word "crisis" seems appropriate.

The recent analysis of a blue ribbon Task Force on the North Carolina Healthcare Safety Net convened by the North Carolina Institute of Medicine (NC IOM) directs our attention to a set of issues many healthcare providers (individual private practice professionals, hospitals, clinics, and public health departments) have known all too well in recent years. The burden of providing free and uncompensated care to larger and larger numbers of the uninsured (for types of services that range from the everyday concerns of the "worried well" to extensive and expensive specialty care from physicians and intensive hospital services) is putting enormous pressure on providers who are legally responsible for serving all who ask for help or on volunteers who give their time and professional expertise to those unable to pay for the care they receive.

The NC IOM Task Force was ably co-chaired by Carmen Hooker Odom, MPR, Secretary of the North Carolina Department of Health and Human Services, and Sherwood Smith, Jr., JD, Chair Emeritus of Carolina Power & Light (now Progress Energy). Staff leadership was provided by Pam Silberman, JD, DrPH, Vice President of the NC IOM. Dr. Silberman and the two co-chairs, along with other colleagues at the NC IOM, have offered a detailed Issue Brief summarizing the major dimensions of the healthcare safety net problem in our state. Other members of the NC IOM Task Force were invited to discuss particular pieces of this puzzle in a series of commentaries that follow the Issue Brief.

The Task Force acknowledged that one of the most important steps that could be taken to address the problems of the uninsured would be to assure insurance coverage for greater numbers of those without such coverage. There are many strategies by which this could be done, but until healthcare insurance is universal, the uninsured will remain a health policy issue of concern.

The commentaries in this issue of the Journal give a clearer picture of those at risk by not having insurance, the complexities of state and federal regulations that govern the organization and delivery of personal healthcare services to the uninsured, the voluntary outreach of local physicians and other healthcare professionals in service to the uninsured, and the efforts of private pharmaceutical companies to make needed medicines available to those unable to afford them. In addition, the commentaries explain the tremendous burden our hospitals and local public health departments carry, as providers of last resort, through their emergency departments and clinics, respectively. The commentaries also highlight the school-based efforts in providing needed primary and preventive health services to children and adolescents with no other source of care and the way in which North Carolina's Department of

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Health and Human Services has led the nation in the development of rural health centers to serve communities who were without access to needed primary healthcare services.

We also felt like it was important to include a recent (March 9, 2005) letter from Governor Easley to the United States Senators and Representatives of North Carolina. The letter explains how reducing the federal Medicaid match to states would affect North Carolina's healthcare safety net, and, in turn, its medically vulnerable citizens.

Serving the healthcare needs of the uninsured is a demanding job, involving thousands of healthcare professionals, hospitals, health departments, and clinics (many of whom are linked in operative networks to maximize their effectiveness and to lessen the burden on one or a few providers in each community). We hope that this issue of the Journal illustrates the enormity of the problems we face in this area. We also hope it provides some recognition for the citizenship and high-level professionalism of so many individual and institutional providers who have joined together to care for the uninsured. To all of these, we tip our hats and express our heartfelt thanks. It is hoped that in the not to distant future, the numbers of uninsured will be reduced, and some of the problems addressed in this issue of the Journal will be less of a concern than they are at the moment.

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The North Carolina Healthcare Safety Net, 2005:
Fragments of a Lifeline Serving the Uninsured

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In 2003, nearly 20% (1.4 million) of North Carolinians under age 65 lacked health insurance coverage.[1] Since the year 2000, more than 300,000 people have lost their health insurance—a 31% increase in the uninsured. With nearly one in five people living without insurance, North Carolina is, without a doubt, in the midst of a major healthcare crisis, and as healthcare costs continue to rise, there is little chance of an immediate respite.

Coping with the large, and still growing, number of uninsured is a national problem, but North Carolina has been harder hit than many states. As a result of recent trade relocation and downsizing, North Carolina lost a large number of manufacturing, textile, and technical jobs, which left thousands of people unemployed and uninsured. The downturn in the economy, together with the rising cost of health insurance, is making it more difficult for people to afford healthcare or healthcare insurance.

Most of the uninsured in North Carolina (62%) have annual incomes less than 200% of the federal poverty guidelines (FPG)—less than $18,620 for an individual and $47,140 for a family of four in 2004.[2] This makes it challenging for the uninsured to pay for needed healthcare. Even people who have insurance sometimes have difficulty paying for needed healthcare, but it is typically harder for the uninsured. The uninsured are less likely to have a regular source of care and are more likely to delay or forgo needed care than people with insurance coverage. The uninsured in North Carolina were far more likely than those with insurance to report that they have no person whom they consider to be their personal doctor or regular healthcare provider in 2003 (50.7% compared to 12.4%, respectively).[3] Approximately 15% of North Carolinians reported that there was a time in the last 12 months when they needed to see a physician, but could not due to cost; however, the uninsured were more likely to report this problem (41.2%) than those with insurance coverage (9.5%). Further, when the uninsured do seek care, they are generally sicker than the insured population and, as a consequence, experience poorer health outcomes.

> *"As a result of recent trade relocation and downsizing, North Carolina lost a large number of manufacturing, textile, and technical jobs, which left thousands of people unemployed and uninsured."*

What Is the Healthcare Safety Net?

The lack of health insurance coverage obviously affects the uninsured person and his or her family, but it also has a broader societal impact. Lack of health insurance coverage decreases

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worker productivity; negatively affects the health of children and, thus, their ability to learn; and has unfavorable financial implications for those healthcare providers who provide care to the uninsured. The state and federal funding sources available to meet the healthcare needs of the uninsured are not keeping pace with the growing needs. The increased numbers of uninsured and inability to raise revenues from third party payers or other sources is creating significant financial strain for many safety net institutions. Without these institutions, the capacity to provide healthcare services for the uninsured and other underserved groups would be seriously undermined.

Safety net providers are those who deliver a significant amount of healthcare to the uninsured, Medicaid, or other vulnerable populations, and offer services to patients regardless of their ability to pay. They typically provide healthcare services at no charge, on a sliding-fee scale, or help make services financially affordable in some other way.

Who Are the North Carolina Safety Net Organizations?

In North Carolina, the safety net consists of federally qualified health centers (e.g., community and migrant health centers), state-funded rural health centers, local health departments, free clinics, Project Access or Healthy Community Access Programs, school-based or school-linked health centers, hospitals, and other organizations that have a central goal of providing care to patients regardless of their ability to pay (see sidebar). Many private providers provide services to the uninsured, albeit not always on a sliding-fee scale.

While some safety net resources exist in most communities, they are not always sufficient to meet the many healthcare needs of the uninsured. Some communities have multiple safety net organizations, but the system of care is fragmented. Others have a basic capacity to provide primary care services, but cannot meet the need for specialty consults or referrals, prescription medications, or more complex care. Still other communities lack even the capacity to meet the basic primary care needs of the uninsured.

The Healthcare Safety Net Task Force

In December 2003, The Kate B. Reynolds Charitable Trust funded the North Carolina Institute of Medicine to establish a Healthcare Safety Net Task Force that would examine the adequacy of the existing safety net structure. The Honorable Carmen Hooker Odom, MA, Secretary for the North Carolina Department of Health and Human Services, and Sherwood Smith Jr., JD, Chair Emeritus of Carolina Power & Light (now Progress Energy), chaired the 48-member Task Force, which included representatives of safety net organizations and provider associations, state and local elected officials and agency staff, non-profits, and advocacy organizations. The Task Force met once a month for nearly one year (March 2004-January 2005).

The goal of the Task Force was to develop a plan to better coordinate and integrate existing safety net institutions, identify

Components of the North Carolina Healthcare Safety Net

Federally Qualified Health Centers (FQHCs)

There are 23 FQHCs in North Carolina with a total of 76 delivery sites, serving more than 272,000 patients in 56 counties. FQHCs, often referred to as community or migrant health centers, provide comprehensive primary healthcare services as well as health education, preventive care, chronic disease management, oral and behavioral health services, all on a sliding-fee schedule. These centers have seen a 32% increase in the number of uninsured patients served in the past five years, serving more than 122,000 uninsured patients in 2003.

State-Funded Rural Health Centers (RHCs)

The North Carolina Office of Research, Demonstrations, and Rural Health Development in the North Carolina Department of Health and Human Services helped to establish 83 rural health centers throughout the state, with 32 of these receiving on-going support from the state. In return for the ongoing operational funds, these centers must agree to provide care to low-income uninsured individuals on a sliding-fee scale. These state-funded centers served 21,252 uninsured low-income patients in 2003.

Local Public Health Departments

There are currently 85 local health departments covering all 100 counties, with 79 of these covering single counties and six serving multi-county districts. These agencies provided clinical and preventive health services to 641,601 patients in 2003, of whom 260,603 were uninsured.

Free Clinics

These are non-profit organizations serving low-income uninsured populations by drawing on local healthcare resources and lay/professional volunteers. There are currently 60 free clinics or pharmacies in North Carolina, serving 48 communities. Most of these clinics are open one or two evenings per week and serve those needing care on a first-come, first-served basis. Free clinics served 69,320 low-income patients in 2003 (with 59,840 offered primary care services and 9,480 served in specialized clinics providing only pharmaceutical or behavioral health services).

Project Access or Healthy Communities Access Programs (HCAPs)

These are local community initiated efforts to fill gaps in the array of healthcare services available to meet the needs of the uninsured. Typically, these initiatives help link the services of traditional safety net providers to healthcare services offered by private practitioners and hospitals in the community. The Project Access model has been implemented in nine North Carolina communities in the following counties: Buncombe, Watauga-Avery, Mecklenburg, Cabarrus, Mitchell-Yancey, Guilford, Pitt, Vance-Warren, and Wake.

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communities with inadequate systems to care for the uninsured and underinsured, ascertain possible funding sources (nationally and locally) that can be used to expand care to the uninsured, and ultimately to expand and strengthen the capacity of healthcare providers and safety net institutions to care for underserved populations. This article provides an overview of the Task Force's findings and principal recommendations.

Are Safety Net Services Available throughout the State?

On the surface, it appears that North Carolina has a wide array of safety net organizations, located throughout the state (see map 1). However, few communities have sufficient safety net resources to meet the healthcare needs of all of the uninsured. The Task Force collected data on the number of uninsured residents receiving care in existing safety net institutions and compared this to the estimated numbers of uninsured in each county. Using these data (the percentage of uninsured with no identified source of primary care), the Task Force determined that only 25% of all the uninsured across the state receive primary care services from safety net organizations. This combined with other studies showing that the uninsured are less likely to have a regular healthcare provider and more likely to report access barriers, suggests that the healthcare safety net is not sufficient to meet the needs of the uninsured.

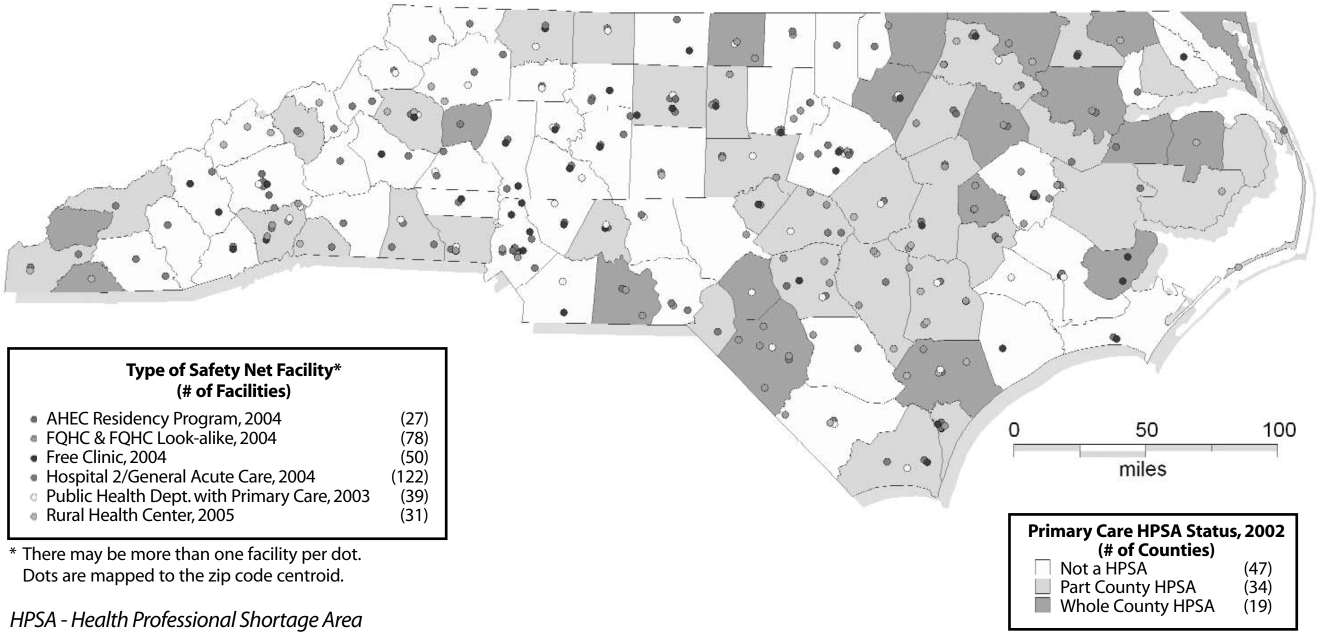
The percentage of uninsured served by the safety net varies widely across the state. Some counties appear to have enough safety net providers to meet the primary care needs all of their uninsured, while others appear to have none. The Task Force identified 28 counties with the least safety net capacity. Thirteen of these counties also had lower than average primary care provider-to-population ratios, suggesting that it would be difficult for the private providers to meet the primary care needs of the uninsured in these counties: Brunswick, Columbus, Davidson, Edgecombe, Franklin, Granville, McDowell, Onslow, Randolph, Rockingham, Stanly, Vance, and Wilkes. Further, access to pharmaceuticals, specialty care, behavioral health, and dental services is still a problem in many communities, including those that have adequate primary care capacity.

A few communities have been able to develop integrated systems of care to address a broader range of healthcare services needed by the uninsured. However, this is the exception rather than the rule. Most communities have fragmented systems of care for the uninsured. This is due, in part, to the difficulties in sharing patient information across providers, turf issues, and/or the need to compete for paying patients to help cover the costs of caring for the uninsured.

The Uninsured and Access to Prescription Medications

Prescription drugs are a critical component of healthcare. More than 40% of all Americans take at least one prescription drug, and 17% take three.[4] There has been a lot of public and

Map 1.
Safety Net Providers—North Carolina 2003-2005



* There may be more than one facility per dot.
Dots are mapped to the zip code centroid.

HPSA - Health Professional Shortage Area

Produced by: NC Rural Health Research Program, Cecil G. Sheps Center for Health Services Research, UNC-CH.

Sources: NC Association of Free Clinics, 2004; NC Division of Facilities Services, 2004; NC Community Health Center Association, 2004; North Carolina AHEC, 2004; Office of Research, Demonstrations and Rural Health Development, 2005; NC Institute of Medicine, 2005; NC Division of Public Health, NC Division of Medical Assistance, 2003; Area Resource File, 2003.

media attention focused on the ability of Medicare recipients to pay for needed medications, but this same problem plagues the uninsured. A 2003 Kaiser health insurance survey found that 37% of the uninsured said that they did not fill a prescription because of costs, compared to 13% of people with insurance coverage.[5]

The pharmaceutical companies have tried to address this problem by offering free or reduced-charge medications through their Patient Assistance Programs (PAPs). Nationwide, 75 pharmaceutical companies offered approximately 1,200 different medications in 2003. More than 270,000 North Carolinians accessed medications through these programs.[6] Yet, it is not always easy to obtain needed medications. Each manufacturer determines which drugs will be offered through their program and sets specific eligibility requirements. The application process can be laborious. It is often difficult for private physicians' offices as well as some smaller safety net programs to take advantage of these free medications, because of the programs' complexity. The North Carolina Foundation for Advanced Health Programs, Inc., with funding from The Duke Endowment, has developed software to assist providers and advocates in accessing appropriate PAP programs. Further, the North Carolina Health and Wellness Trust Fund has provided funding to community groups to help them develop medication assistance programs. These programs help individuals apply for free or reduced-cost medications and provide drug management to patients.

Many safety net providers also help their patients obtain needed medications, either by accessing PAPs or by offering free or reduced charge medications in-house. Despite these resources, ensuring that the uninsured obtain needed medications is still a problem. In many communities, providers are willing to volunteer to treat the uninsured, but are reluctant to do so if there is no assurance that the uninsured will be able to obtain the prescribed medications.

Collaboration and Integration

Few counties have the ability to meet the healthcare needs of all of the uninsured, regardless of how many or how few safety net organizations they have. However, there are some counties that have had more success. These counties have been able to work together to maximize their resources and to identify partners who can help in meeting the unmet healthcare needs of the uninsured.

There are various levels of collaboration and integration that have occurred throughout the state, ranging from periodic meetings of safety net organizations, community planning efforts and joint projects, to more elaborate inter-organizational agreements. In some counties, the hospital has collaborated with non-profit organizations to create primary care clinics for the uninsured. In other counties, local health departments have been successful in working collaboratively with FQHCs to expand care to the uninsured. Other counties have been able to develop more comprehensive systems of care, combining the efforts of traditional safety net providers with private providers

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School-Based or School-Linked Health Centers
Because school-age children, especially adolescents, are not always able to access comprehensive and coordinated systems of healthcare, some schools have established school-based or school-linked health centers to provide comprehensive primary care and mental health services to students. Currently, there are 27 comprehensive centers operating in middle and high schools in the state and another 12 centers that provide primary care services delivered by nurse practitioners or physician assistants. In addition to these health centers, many schools have hired nurses that can provide more limited health services to children.

Private Physicians
Physicians in private practice are a major source of care to the uninsured; many of whom provide services for reduced fees or at no charge. A national survey of households in 2001 revealed that nearly two-thirds of the uninsured reported a private practice physician as their regular source of care, and half of these respondents reported having received services in a physician's office. There has not been a North Carolina study to document the extent to which physicians in this state provide charity care, but most would agree that this is an important component of the healthcare safety net.

Area Health Education Centers (AHECs)
As part of its mission to meet the educational needs of the state's healthcare workforce, the AHECs in North Carolina support five residency programs in family medicine, three in rural family medicine, four in internal medicine, four in obstetrics/gynecology, three in pediatrics, and three in surgery. In 2003-2004, these programs provided services to 35,427 uninsured patients.

Hospitals
Almost all (110 of 113) general acute community hospitals in North Carolina operate emergency departments, which serve as an important safety net provider of last resort, regardless of ability to pay. In 2003, the uninsured represented 10% of outpatient visits, and of those, 22% (672,799 patients) were uninsured patients making emergency room visits.

Prescription Drug Programs
The largest source of free medications for the uninsured is the Patient Assistance Programs (PAPs) offered by private pharmaceutical companies. These programs vary a great deal from one company to another in terms of medications offered, eligibility requirements, and application processes. In addition, a few communities in North Carolina have seen the development of locally-organized pharmacy assistance programs to help low-income uninsured patients obtain needed medications. These programs fill a vital gap in the overall healthcare safety net, but at present levels of funding and availability, they are not able to meet all of the medication needs of the uninsured.

of care. For example, Project Access and Healthy Communities Access Programs (HCAP) help link the services of traditional safety net providers to healthcare services offered by private providers in the community. Generally, communities that have been able to develop integrated delivery systems for the uninsured have been more successful in meeting the healthcare needs of these populations.

Although many counties have been successful in establishing collaborative arrangements across safety net organizations, others have had more difficulty. Because there is little funding available to pay directly for services to the uninsured, safety net organizations often cross-subsidize the care they provide by using revenues from other paying patients. As a result, safety net providers in some counties compete for Medicaid or North Carolina Health Choice patients or other paying patients. Further, funding sources that are limited to certain types of safety net organizations sometimes create ill-will among other organizations that also provide care to the uninsured, but have no source of funding. In addition, there are other barriers—both real and perceived—that make it difficult to collaborate. For example, state medical confidentiality laws are perceived as obstacles to sharing patient information among providers who serve the same patients at different locations.

Financing Options

Many safety net organizations receive some financing from a variety of sources, including Medicaid, Medicare, private third-party insurance, out-of-pocket payments, and charitable donations. The source and proportion of funding from different sources varies across institutions and types of organizations.

By far, Medicaid is the largest funding source for those who would otherwise be uninsured. In North Carolina, the federal, state, and county governments expended approximately $8.5 billion in SFY 2004 to cover 1.5 million low-income individuals during the year; most of these people would have been uninsured but for the Medicaid program.[7] Medicaid is also a major revenue source for many safety net organizations, including hospitals, FQHCs, rural health clinics, health departments, non-profit health clinics, school-based health centers, and other private providers who care for the uninsured. North Carolina Health Choice, the State Children's Health Insurance Program, is another major revenue stream for some safety net providers. The federal and state governments paid approximately $188 million to cover close to 175,000 previously uninsured children through North Carolina Health Choice in SFY 2004.[8]

In addition to funding for Medicaid and North Carolina Health Choice (which pays for services provided to people insured through these programs), there are limited funds available to support care for the uninsured through safety net organizations. For example, the federal government provides some funding to support operational costs for FQHCs, and the state provides limited funds to help pay for care to the uninsured through state-funded rural health centers. In addition, the North Carolina General Assembly appropriated $7 million in non-recurring funds last year (2004) to help support and expand the services available to the uninsured and medically indigent through certain safety net organizations, including FQHCs, FQHC look-alikes, public health clinics, and state-funded rural health centers. At the time this article was being written, it was still uncertain whether these funds would be continued in the 2005 budget. Some new federal funds are available to increase the number of people who can be served by federally qualified health centers through the President's Initiative for Health Center Growth; however, funding under this initiative is competitive, and North Carolina health centers have only been awarded approximately 3% of new funds over the last three years. The federal, state, and/or county governments also provide funds that offset some of the costs of providing specific services to the uninsured (e.g., child and maternal health services or services provided to people with HIV/AIDS).

While limited funding is available to help subsidize care to the uninsured, it is not sufficient to cover all of the costs, and is not well-targeted to those safety net organizations that provide the largest share of care to the uninsured. Certain safety net organizations provide a disproportionate share of care to uninsured patients, and as a result, these organizations collect a smaller share of their revenues from paying patients. This makes it harder for these institutions to pay for the care provided to the uninsured. The proportion of uninsured patients seen by different safety net providers varies across organizations:

- On average, 47.6% of the North Carolina FQHC users in 2003 were uninsured, but this varied from more than 65% in five centers, to less than 30% in seven centers.
- On average, 21% of patients in state-funded rural health centers were uninsured. This varies from more than 30% of patients who were uninsured in four state-funded rural health centers, to less than 10% of patients who were uninsured in two centers.
- The percentage of total hospital discharges attributable to the uninsured varied from a high of more than 10% in nine hospitals to a low of less than 2% in 14 hospitals; and the percentage of hospital discharges attributable to both Medicaid and the uninsured varied from a high of more than 35% in nine hospitals to a low of less than 10% in 10 hospitals.

The increased numbers of uninsured and inability to raise revenues from third party payers or other sources is creating significant financial strains for many of these organizations.

Recommendations

The Task Force formulated a set of 28 recommendations that could help strengthen and expand the capacity of healthcare safety net providers to address the healthcare needs of the growing numbers of uninsured in the state. These recommendations are fully described in the formal report issued by the North Carolina Institute of Medicine,[9] but they are generally described here.

The recommendations offered by the Task Force address four principal sets of issues facing the healthcare safety net organizations in our state. These are: (1) the need to ensure that the uninsured have health insurance coverage; (2) expanding the capacity of the healthcare safety net to meet the needs of the uninsured; (3) developing systems to better integrate existing safety net services in local communities; and (4) increasing funding to support the work of safety net providers. Brief explanations of each of these four sets of issues are offered below.

The need for additional insurance coverage for the uninsured. The primary barrier that the uninsured face in obtaining needed health services is lack of insurance coverage. Not only does lack of coverage affect the ability of individuals to access needed services, but it also affects a person's health status. To address this issue, the Task Force recommended that the North Carolina General Assembly take steps to make health insurance coverage more affordable and to expand health insurance coverage to more individuals and families who are currently uninsured. Until the uninsured have coverage, the Task Force recognized the importance of supporting and expanding existing safety net capacity to be able to meet more of the vital healthcare needs of the uninsured. In a very real sense, the healthcare *safety net* is just that, a stop-gap set of programs and voluntary efforts to minimize the effects of lack of healthcare insurance coverage for a growing segment of our population. The problems caused by lack of adequate health insurance coverage cannot be solved until most or all of those now uninsured, for all or part of a year, are included in some form of insurance to meet their healthcare needs.

The need for increased safety net capacity to address the healthcare needs of the uninsured. Because there is not unlimited funding or resources to support new or expanded safety net services across the state, the Task Force attempted to identify those communities or counties with the greatest unmet needs. The Task Force was able to collect data from some safety net providers about the number of uninsured people who received primary care services in the prior year, but these data were not uniformly available across types of safety net organizations. Data are not currently available from private practitioners, or from hospital emergency departments or outpatient clinics. Further, there are few sources of data to identify the capacity of communities to address the behavioral health, dental health, specialty, and medication needs of the uninsured. The Task Force recognized the importance of collecting these data, in order to target new resources to the communities most in need and to monitor the capacity of the safety net to address the healthcare needs of the uninsured over time. Therefore, the Task Force recommended that the North Carolina Department of Health and Human Services take the lead in monitoring services provided by public and private safety net providers across the state. In addition, the Task Force recommended that the Department, along with other safety net organizations, help develop a planning package and provide technical assistance to communities interested in expanding their safety net capacity.

The Task Force also recognized that there are barriers in existing laws that discourage some private practitioners from volunteering their time to serve the uninsured. Some private providers have expressed concern that they may be subject to a lawsuit for a bad health outcome if they provide services to the uninsured. Although North Carolina already has a Good Samaritan statute that provides protection against monetary liability, it does not currently shelter providers from the cost (either financially or emotionally) of having to defend a lawsuit. The Task Force identified a need to make the act of volunteering to serve the uninsured less of a burden, and recommended that the North Carolina Free Clinic Association work with the North Carolina Medical Society and other safety net providers to explore other ways of reducing the barrier that potential malpractice claims create to encouraging private practitioners from volunteering to serve the uninsured.

The Task Force was also concerned with assuring access to needed medications by those who are served by various safety net providers. A recommended therapeutic regimen is meaningless without the ability to follow through with access to prescribed medications. While there are some resources available to provide needed medications through the pharmaceutical companies' Patient Assistance Programs (PAPs) or through local safety net organizations, the current resources are insufficient to ensure that the uninsured can obtain necessary medications. There is also a federal program that allows certain safety net organizations to negotiate for highly discounted medication prices (called the 340B program). However, federal law restricts the 340B drug discount program to certain safety net organizations, including FQHCs, public health, and some hospitals. The deeply discounted prices are not available to free clinics, state-funded rural health centers, or other non-profit safety net organizations. Thus, the Task Force made a series of recommendations aimed at expanding the availability of low-cost or free medications to the uninsured. First, the Task Force recommended that existing programs to help low-income uninsured individuals access free or reduced-cost medications through the PAPs be expanded and that the pharmaceutical companies streamline and simplify the PAP application process. The Task Force also recommended that Congress expand the 340B drug discount program to include more safety net organizations. In addition, the Task Force recommended that state philanthropic organizations provide funding to help the North Carolina Department of Health and Human Services establish a bulk purchasing program that would help negotiate volume discounts from pharmaceutical companies for safety net organizations around the state.

Strengthening safety net integration and collaboration efforts. The patchwork of services, programs, and organizations serving the uninsured is being stretched in a number of directions as the demand for care among the uninsured has increased. Few communities in our state have been able to meet all the needs of the uninsured, regardless of how many providers of such care there are. The Task Force identified the need for increased levels of collaboration and, in some cases, the potential for the integration of services and organizations, in order to more effectively meet the needs of those served by safety net providers.

In communities with few or no safety net providers, these issues do not arise. But, in communities where multiple organizations are serving, often with overlapping efforts, the same uninsured populations, the need for collaboration is more evident. The Task Force therefore recommended a number of efforts to encourage collaboration among safety net providers and ways to encourage the involvement of professional and business organizations in these community-wide efforts.

The Task Force recognized the need to create an ongoing state-level Safety Net Advisory Council (SNAC) that can continue the work of the Task Force and encourage state-level and local safety net collaborations and integration efforts. The SNAC would be charged with collecting and disseminating "best practices" and models for service organization and delivery. Additionally, the SNAC should work with North Carolina foundations to help convene a best practices summit that would help local communities identify ways to build and strengthen their capacity to meet the healthcare needs of the growing uninsured population and reduce barriers to interagency collaboration and integration.

The Task Force also heard that existing state confidentiality laws have created barriers to sharing patient information across safety net providers—even when providing services to the same patients. The Task Force recommended that the General Assembly enact laws to clarify state confidentiality laws to ensure that safety net providers are allowed to share identifiable health information with each other when providing care to the same patients.

Increased funding to support and expand the existing safety net system. The Task Force identified four strategies that could help provide financial support for care to the uninsured: (1) ensuring that North Carolina receives its fair share of federal funding for safety-net programs, including funding from the President's Initiative for Health Center Growth and Expansion; (2) expanding state funds to support safety net organizations; (3) enhancing Medicaid reimbursement for safety net organizations, to help ensure that Medicaid reimbursement is at least sufficient to cover the costs of treating these patients; and (4) ensuring that individuals who are eligible for Medicaid enroll in the program, in order to make more limited state, local, or federal funds available to serve uninsured individuals who cannot qualify for Medicaid.

Although the Task Force spent considerable time trying to identify new sources of funding, the Task Force's highest recommendation was to maintain the state's major safety net funding source: Medicaid. As noted earlier, North Carolina has 1.4 million people who are uninsured; 62% of them have incomes below 200% of the federal poverty guidelines. The numbers of uninsured would be much larger without the existence of Medicaid and the North Carolina Health Choice programs. There is currently some discussion at the federal level about turning Medicaid into a block-grant program. This could be devastating to the state, safety net providers, and to low-income citizens of the state who rely on Medicaid to cover their healthcare needs. (See the open letter from Governor Easley on page 120-121) In addition, Task Force members felt strongly that the state was not getting its fair share of existing federal funds through the State Children's Health Insurance Program (North Carolina Health Choice), the President's Initiative for Health Center Growth (which funds FQHC health center expansion), Ryan White CARE funds for people with HIV/AIDS, or the Special AIDS Drug Assistance Program. Therefore, the Task Force recommended that the North Carolina Department of Health and Human Services and other safety net organizations work with the North Carolina Congressional delegation to: (1) oppose efforts to limit the availability of federal Medicaid funds and (2) ensure that the state receive its fair share of other funds available to underwrite health services for the uninsured.

Although new federal funds are available to expand the availability of healthcare services through FQHCs, there are barriers that prevent local health departments from applying for these funds. One such barrier is the state-required composition of local health department boards. Federal laws mandate that the governance structures of FQHCs be predominantly composed of the safety net organizations healthcare consumers; however, state law prescribes that local health departments boards be composed primarily of healthcare or other professionals. Thus, even though the populations served by health departments and FQHCs are the same, or very similar, local health departments are ineligible for this federal support. The Task Force recommended that the General Assembly give county commissioners the authority to change the local health department board composition in order to make these agencies eligible for federal funding.

The Task Force also recommended continued and expanded state funding for safety net organizations. Last year, the North Carolina General Assembly appropriated $7 million in one-time funds to expand the availability of healthcare services to the uninsured through new or existing safety net organizations: $5 million to FQHCs and $2 million for state-funded rural health centers and/or local health departments. The Task Force supported the General Assembly's efforts and recommended that this funding be expanded to $11 million on a recurring basis: $6 million for FQHCs and $5 million for state-funded rural health centers, local health departments, or other nonprofit safety net organizations with a mission of serving the uninsured.

Another need that has surfaced in many policy discussions in recent years is the need for additional school health nurses. The Task Force was aware of the important role these nurses play in meeting the primary healthcare needs of children and adolescents in our public schools. For many children, and especially for adolescents, school nurses are the only healthcare professionals they see, yet North Carolina has a shortage of such personnel. The recommended ratio of school nurses to students is 1:750; the statewide ratio in North Carolina is 1:1,918. Last year (2004), the General Assembly appropriated funds to enable the hiring of an additional 145 nurses to work in the public schools (with 65 of these positions time-limited). Even with this additional funding, there is still a need for 973 nurses to meet these recommended ratios. The Task Force recommended an additional appropriation to accomplish this goal.

The Task Force also recommended that the North Carolina Department of Health and Human Services explore options to enhance Medicaid reimbursement to safety net organizations that serve a higher than average proportion of uninsured patients and that the state ensure that local health departments—like other publicly-funded health providers—receive cost-based reimbursement for the clinical services they provide. Any new funding provided to FQHCs, FQHC look-alikes, rural health centers, hospitals, and/or health departments should be targeted toward serving the uninsured.

The Task Force suggested ways to capture savings that the state is currently realizing through implementation of the Community Care of North Carolina program (CCNC), a system that provides case management and disease management services to improve the health of Medicaid recipients with chronic or complex health problems. At the present time, local CCNC networks cannot retain any funds that are saved as a result of improved care management for these Medicaid recipients. In contrast, managed care companies that offer contract services to low-income populations are able to retain realized savings. The Task Force recommended that the Division of Medical Assistance explore the possibility of creating a system of "shared savings" with regional CCNC networks. The shared savings system would enable the networks to use their savings to support the provision of services to the uninsured.

Finally, the Task Force made a series of recommendations to ensure that uninsured individuals who are currently eligible for Medicaid are enrolled in the program. Ensuring Medicaid coverage for those who are eligible would help target the limited state funds for safety net providers toward uninsured individuals who cannot receive coverage elsewhere. National data suggest that only 72% of eligible children and 51% of eligible non-elderly adults enroll in Medicaid.[10] Many eligible individuals do not know they are eligible for coverage or are discouraged because of the stigma attached to applying for public programs. Others are discouraged because the application process is difficult to complete. The state has made significant progress in simplifying the Medicaid and North Carolina Health Choice application process for children, but the state has not yet incorporated these simplifications into the adult Medicaid application process. To address this problem, the Task Force recommended that the state streamline and simplify the Medicaid program for adults, by creating simplified application forms, extending the length of time for recertification, and exploring the possibility of eliminating the resource test for families with children (just as the state has already done for families that apply on behalf of their children only). The Task Force also recommended that the state modify Medicaid policies to make it easier for individuals with high medical expenses to qualify for Medicaid.

Summary

North Carolina is in the midst of a quiet, but growing healthcare crisis. The number of uninsured residents is rising at an alarming rate—and a faster rate than in most other states. Almost one of every five (20%) non-elderly North Carolinians have no health insurance, which means a sizeable portion of our population has unmet healthcare needs. As healthcare costs continue to increase, North Carolina is likely to continue seeing increased numbers of uninsured. Until we can dramatically reduce the volume of the uninsured, there will be a continuing and growing need for governmental, private sector, and voluntary healthcare providers to serve this population.

In this issue of the Journal, we have attempted to draw attention to the volume and variety of services, programs, and organizations involved in meeting this important healthcare need among our state's most vulnerable populations. The organizations involved in rendering these services, and the private physicians and other healthcare professionals who give of their time and talents to meet these needs, are stretched to their limits in most communities. The Task Force has recommended several concrete steps that would shore up safety net organizations' and individual providers' capacity/ability to meet these needs. Some of these steps will require rather straightforward changes in regulations and laws governing the provision of healthcare services. Others will require appropriation of funds to augment the public, private, and voluntary support now given through these safety net provider organizations in support of their efforts to serve the uninsured.

While some effort needs to be made to bring these issues to the attention of the state's Congressional delegation in Washington, DC, many of these problems should not have to wait for federal action. The needs are great, and the demands for service are increasing among those organizations and professionals who have assumed these responsibilities in counties and communities across our state. For those with healthcare insurance, these problems and their administrative complexities may seem of remote interest and concern. But, for the people who depend on the safety net services, these problems can mean the difference between health, work, and opportunity, or between disease, disability, or death. There is a genuine collective benefit to meeting the healthcare needs of the uninsured, for the health and wellbeing of a fifth of our state's population affects the health of all of us. Depending on a stop-gap, safety net to maintain the health of such a large segment of our population is a societal risk we all must confront. Failure of any part of the healthcare safety net could be detrimental to the stability of the larger healthcare system on which we all depend. **NCMJ**

Acknowledgements

This work would not have been possible without generous support from The Kate B. Reynolds Charitable Trust and the volunteer efforts of the Task Force and Steering Committee Members included below:

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University of North Carolina (UNC) School of Medicine; Gillian K. Baker, MHA, Director, Appalachian Healthcare Project; Andrea Bazan-Manson, MSW, MPH, Executive Director, El Pueblo, Inc.; James D. Bernstein, MHA, President, NC Foundation for Advanced Health Programs, Inc.; George F. Bond, Jr., MPH, Health Director, Buncombe County Health Department; Sonya J. Bruton, MPA, Executive Director, NC Community Health Center Association (NCCHCA); Moses Carey, JD, MPH, County Commissioner, Orange County, Executive Director (Retired), Piedmont Health Systems; Mike Cinoman, MD, Director, Pediatric Critical Care-WakeMed, Executive Director, WakeMed Faculty Physicians, Executive Director, Wake AHEC; Lawrence M. Cutchin, MD, President & CEO, Health Care Savings, Inc.; Richard L. Daugherty, Vice President (Retired), IBM; Leah M. Devlin, DDS, MPH, State Health Director, Division Director, Division of Public Health, NC DHHS; L. Allen Dobson, MD, President & CEO, Cabarrus Family Medicine and Director of Graduate Medical Education, Northeast Medical Center; Brian Ellerby, MSPH, CMPE, Executive Director, Guilford Child Health, Inc., Guilford Adult Health, Inc.; Margaret P. Elliott, MPA, Executive Director, Crisis Control Ministry, Inc.; Bobby England, MD, Representative, NC General Assembly; John H. Estes, Healthcare Consultant, Office of Research, Demonstrations and Rural Health Development (ORDRHD), NC DHHS; Robert J. Fitzgerald, Director, Division of Facility Services, NC DHHS; Olivia Fleming, MA, Clinic Director, Open Door Clinic, Urban Ministries of Wake County; Gary Fuquay, Former Director, Division of Medical Assistance, NC DHHS; Rick Gilstrap, President, Halifax Regional Medical Center; John Graeter, Executive Director, Hot Springs Health Program; Robert G. Greer, Chairman, New Hanover County Commissioners; Paul B. Harrison, MPH, Executive Director, Wake County Medical Society; Fletcher Hartsell, Senator, NC General Assembly; J. Andrew Hartsfield IV, JD, Vice President, Public Policy and Advocacy, GlaxoSmithKline; M. Anita P. Holmes, JD, MPH, Executive Director, Center for Health and Healing, General Baptist State Convention of NC; Thomas G. Irons, MD, Professor of Pediatrics, Associate Vice Chancellor, Brody School of Medicine, East Carolina University; Johanna S. Irving, DDS, MPH, Dental Health Director, Wake County Human Services; Howard Lee, Chair, NC State Board of Education; Alan T. McKenzie, CEO, Buncombe County Medical Society; G. Earl Marett, MSW, Director, Johnston County Department of Social Services; John O. McNairy, President, Harvey Enterprises and Affiliates; John Mills, CAE, Executive Director, NC Association of Free Clinics, Richard H. Parks, Chief Executive Officer, Cape Fear Valley Health System; Burnie Patterson, Rural Health Group (Retired); William A. Pully, JD, President, NC Hospital Association; William R. Purcell, MD, Senator, NC General Assembly; Wanda L. Sandelé, MPH, Health Director, Craven County Health Department; Adam G. Searing, JD, Project Director, NC Health Access Coalition; Shirley Faison Sims, Wayne County Board of Education, Wayne Initiative for School Health; Stephen T. Smith, JD, Program Associate, NC Council of Churches; John Sullivan, Senior Vice President, Regional Facilities, Carolinas Healthcare System; and J. Douglas Yarbrough, MBA, President & CEO, Duplin General Hospital, Inc.

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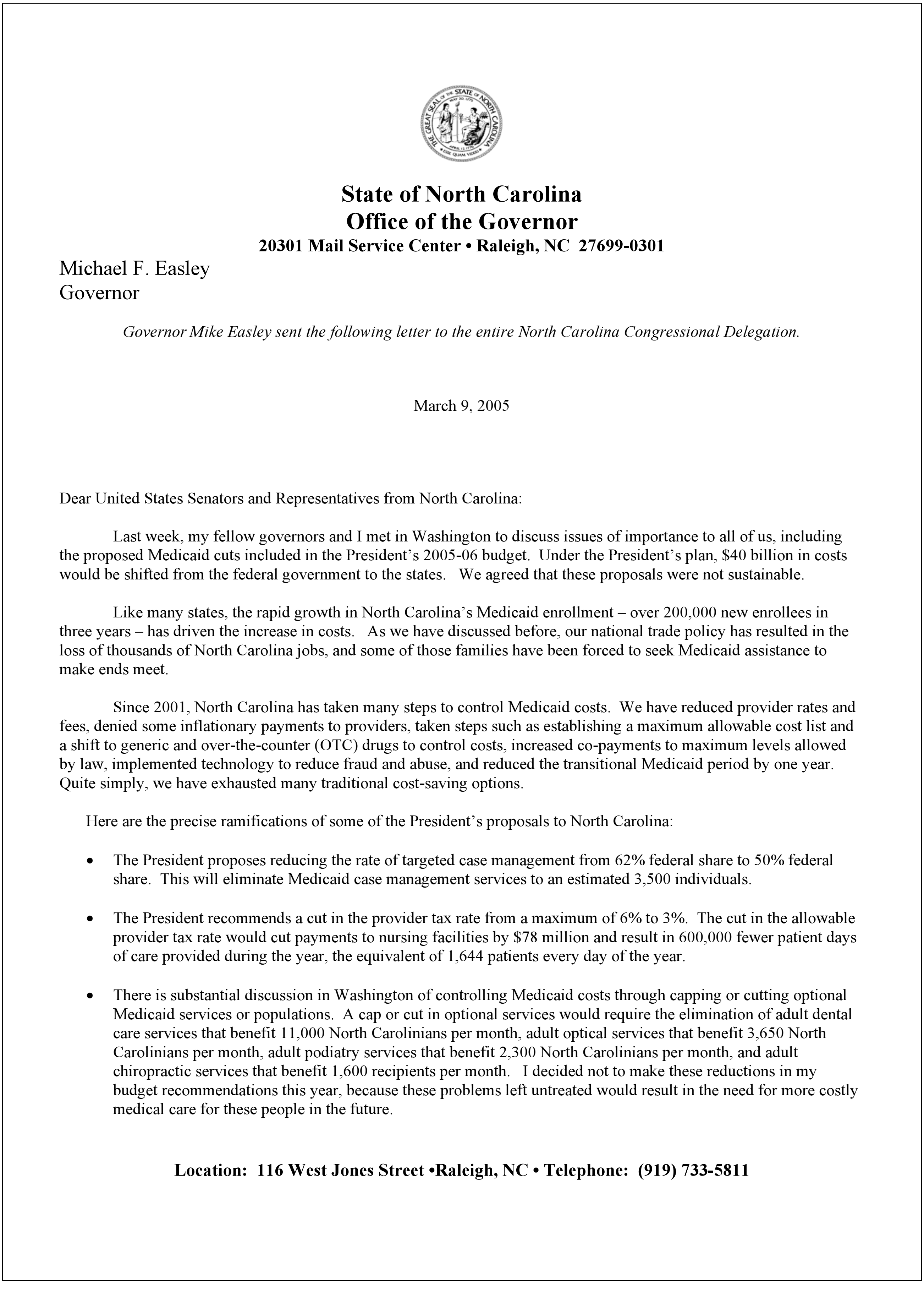


State of North Carolina
Office of the Governor
20301 Mail Service Center • Raleigh, NC 27699-0301
Michael F. Easley
Governor

Governor Mike Easley sent the following letter to the entire North Carolina Congressional Delegation.

March 9, 2005

Dear United States Senators and Representatives from North Carolina:

Last week, my fellow governors and I met in Washington to discuss issues of importance to all of us, including the proposed Medicaid cuts included in the President's 2005-06 budget. Under the President's plan, $40 billion in costs would be shifted from the federal government to the states. We agreed that these proposals were not sustainable.

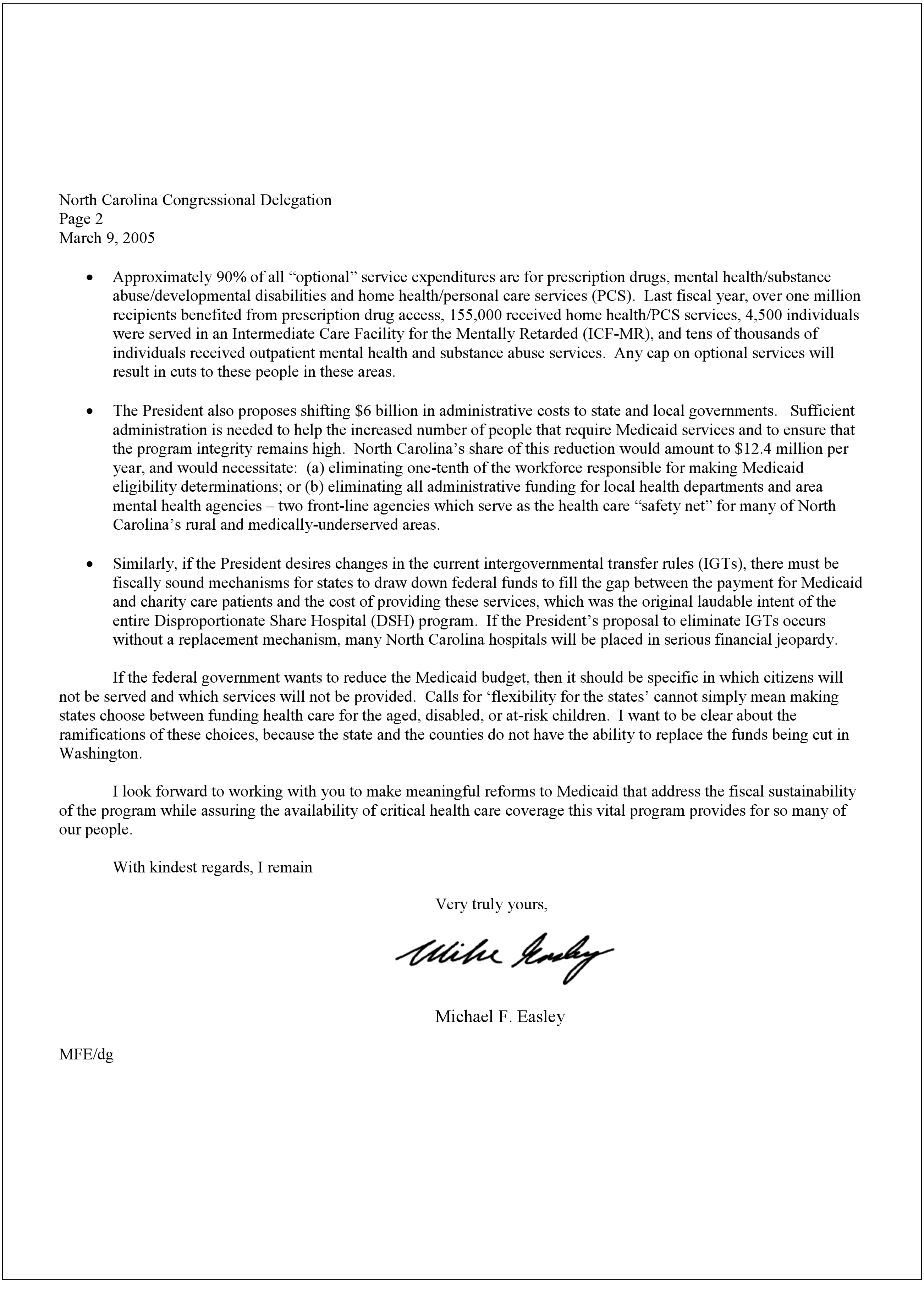
Like many states, the rapid growth in North Carolina's Medicaid enrollment – over 200,000 new enrollees in three years – has driven the increase in costs. As we have discussed before, our national trade policy has resulted in the loss of thousands of North Carolina jobs, and some of those families have been forced to seek Medicaid assistance to make ends meet.

Since 2001, North Carolina has taken many steps to control Medicaid costs. We have reduced provider rates and fees, denied some inflationary payments to providers, taken steps such as establishing a maximum allowable cost list and a shift to generic and over-the-counter (OTC) drugs to control costs, increased co-payments to maximum levels allowed by law, implemented technology to reduce fraud and abuse, and reduced the transitional Medicaid period by one year. Quite simply, we have exhausted many traditional cost-saving options.

Here are the precise ramifications of some of the President's proposals to North Carolina:

- The President proposes reducing the rate of targeted case management from 62% federal share to 50% federal share. This will eliminate Medicaid case management services to an estimated 3,500 individuals.
- The President recommends a cut in the provider tax rate from a maximum of 6% to 3%. The cut in the allowable provider tax rate would cut payments to nursing facilities by $78 million and result in 600,000 fewer patient days of care provided during the year, the equivalent of 1,644 patients every day of the year.
- There is substantial discussion in Washington of controlling Medicaid costs through capping or cutting optional Medicaid services or populations. A cap or cut in optional services would require the elimination of adult dental care services that benefit 11,000 North Carolinians per month, adult optical services that benefit 3,650 North Carolinians per month, adult podiatry services that benefit 2,300 North Carolinians per month, and adult chiropractic services that benefit 1,600 recipients per month. I decided not to make these reductions in my budget recommendations this year, because these problems left untreated would result in the need for more costly medical care for these people in the future.

Location: 116 West Jones Street •Raleigh, NC • Telephone: (919) 733-5811



North Carolina Congressional Delegation
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- Approximately 90% of all "optional" service expenditures are for prescription drugs, mental health/substance abuse/developmental disabilities and home health/personal care services (PCS). Last fiscal year, over one million recipients benefited from prescription drug access, 155,000 received home health/PCS services, 4,500 individuals were served in an Intermediate Care Facility for the Mentally Retarded (ICF-MR), and tens of thousands of individuals received outpatient mental health and substance abuse services. Any cap on optional services will result in cuts to these people in these areas.

- The President also proposes shifting $6 billion in administrative costs to state and local governments. Sufficient administration is needed to help the increased number of people that require Medicaid services and to ensure that the program integrity remains high. North Carolina's share of this reduction would amount to $12.4 million per year, and would necessitate: (a) eliminating one-tenth of the workforce responsible for making Medicaid eligibility determinations; or (b) eliminating all administrative funding for local health departments and area mental health agencies – two front-line agencies which serve as the health care "safety net" for many of North Carolina's rural and medically-underserved areas.

- Similarly, if the President desires changes in the current intergovernmental transfer rules (IGTs), there must be fiscally sound mechanisms for states to draw down federal funds to fill the gap between the payment for Medicaid and charity care patients and the cost of providing these services, which was the original laudable intent of the entire Disproportionate Share Hospital (DSH) program. If the President's proposal to eliminate IGTs occurs without a replacement mechanism, many North Carolina hospitals will be placed in serious financial jeopardy.

If the federal government wants to reduce the Medicaid budget, then it should be specific in which citizens will not be served and which services will not be provided. Calls for 'flexibility for the states' cannot simply mean making states choose between funding health care for the aged, disabled, or at-risk children. I want to be clear about the ramifications of these choices, because the state and the counties do not have the ability to replace the funds being cut in Washington.

I look forward to working with you to make meaningful reforms to Medicaid that address the fiscal sustainability of the program while assuring the availability of critical health care coverage this vital program provides for so many of our people.

With kindest regards, I remain

Very truly yours,

Mike Easley

Michael F. Easley

MFE/dg

Federally Qualified Health Centers:
Providing Healthcare to North Carolina's Communities in Medical Need

Sonya J. Bruton, MPA

> *"I wouldn't trade Lincoln doctors for nothing. Whatever illnesses I have, they deal with it right away. If I have to see a specialist, they try and send me to one. They don't take chances. They always deal with my heart to make sure that it's in good condition; because, everything starts from the heart."*
>
> *Sixty-four years ago, Thelma Woods was born at Lincoln Hospital—now Lincoln Community Health Center—in Durham, North Carolina. She grew up receiving care at the Center, and when she returned from New York after 30 years, it once again became her medical home. Ms. Woods discovered during a pre-employment physical that she had a blood pressure reading of 200/200. She sought care at Lincoln the next morning and learned that she had hypertension, high cholesterol, and diabetes. For three years, the medical staff helped Ms. Woods manage those conditions, and on January 18, 1993, they navigated her through a successful open-heart surgery. Today she serves as a member of the Board of Directors, and Lincoln provides medical care to Ms. Woods, her children, and grandchildren. "I think Lincoln has some of the best doctors around," she said. "I know without them caring for my health, I wouldn't be here today."*

Lincoln Community Health Center is one of 23 federally qualified health centers operating in North Carolina. Federally qualified health centers (FQHCs) were created 40 years ago to respond to the reality that the poor have fewer options in the healthcare marketplace and are often shut out entirely from private medical practices. The statute authorizing the award of federal grants to health centers can be found under section 330 of the Public Health Service Act and includes a family of broad and specific health options: (1) Community Health Centers (CHCs), (2) Migrant Health Centers, (3) Public Housing Primary Care, and (4) Healthy Schools, Healthy Communities.

FQHC Defined

FQHC-designated community health centers are community-located and -operated clinics that receive federal support to care for residents living in the targeted area surrounding the center. The geographic scope may extend to zip codes or counties in an attempt to provide access to care for those in need. In order to receive federal assistance, the specified community must have a medical need. The need could be for more physicians, for more places willing to accept Medicaid/Medicare, or for a place that will care for community members who have no healthcare coverage. The care offered to these residents must include primary care services, health education, preventive care, chronic disease management, oral health, and behavioral health services. They also have to make sure that language, cultural, or economic factors neither impact a patient's ability to schedule or complete a visit nor stop them from receiving all of the follow-up services that may be needed to recover from an illness. This may mean making sure that medication or specialty services are secured. Federally-funded community health centers offer the following menu of primary care and enabling services to all patients either at the office or through a pre-arranged referral:

"FQHC-designated community health centers are community-located and -operated clinics that receive federal support to care for residents living in the targeted area surrounding the center."

- Preventive dental services;
- Immunizations;
- Primary medical care;
- Immunizations;

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- Diagnostic laboratory services;
- Preventive services including prenatal, perinatal, and well-child services (such as eye, ear, and dental screenings for children);
- Cancer and other disease screenings;
- Screening for elevated blood lead levels;
- Diagnosis and treatment of communicable diseases;
- Family planning services;
- Preventive dental services;
- Emergency medical and dental service;
- Pharmacy services;
- Substance abuse and mental health services;
- Enabling services including outreach, transportation, interpreters, and case management services; and
- Services to help the health center's patients gain financial support for health and social services.

When referrals are made, health centers must coordinate and oversee the care provided to their patients, and access to care must be available through an after-hours call system or clinic hours that extend beyond the normal 9:00 am-5:00 pm work schedule.

Nationally, the community health center program was created in 1965 as part of President Lyndon Johnson's "Great Society" and "War on Poverty" initiatives. The movement came to North Carolina in March of 1970 with the creation of the Orange-Chatham Comprehensive Health Center in Chapel Hill, North Carolina. This center was followed by Lincoln Community Health Center in June of that same year.

Today there are 23 federal grantees, receiving section 330 funds, operating 76 delivery sites in North Carolina. These primary care facilities serve 56 counties and nearly 300,000 patients. In addition, there are three community-based primary care providers that are in compliance with Section 330 program requirements, but do not receive federal grant support. Instead, these centers, known as federally qualified health center look-alikes, receive:

- Drug pricing discounts;
- Special Medicaid reimbursement rates;
- Onsite Medicaid eligibility workers;
- Waived Medicare deductibles;
- Ability to waive co-payments of patients <200% of FPG;
- Medical providers through the National Health Service Corps; and
- No-cost vaccines for children.

Nevertheless, the proportion of residents without a usual source of care is much higher than the national average in North Carolina. At least one-in-five residents has no regular provider of care.[1] As a result, the push to develop more FQHCs throughout North Carolina continues. Research indicates that more health centers would significantly diminish the Hispanic/white and black/white primary care visit disparity.[2] One study recently found that a 10% increase in the number of health centers per 10,000 population would lead to a 6% increase in the probability of visiting a physician.[3] In general, expanding health center capacity reduces unmet need and increases the percent of the uninsured with a regular source of care.

Governance Structure

One of the foundations of the FQHC program is the mandate that governance of the health center organization involve a Board of Directors made up predominately of the people who use the health center's services (consumers/users). A consumer member should have used the health center services within the last two years and consider the health center his or her medical home. Health center expectations indicate that a user should be an individual who considers the health center his or her medical home for the purposes of receiving primary and preventive care.[4] For example, if upon becoming ill with the flu, an individual makes an appointment at the health center for diagnosis and treatment, the person would be considered a user of the health center's services. Conversely, if an individual uses the health center annually for a blood pressure check, but uses the services of a private physician in the community when he or she becomes sick, the individual would not be considered a health center user for the purposes of satisfying the requirement, because he or she is not using the health center as the principal source of primary healthcare. The section 330 implementing regulations state, "a majority of board members shall be individuals who are or will be served by the center and who, as a group, represent the individuals who are or will be served by the center and who, as a group, represent the individuals being or to be served in terms of demographic factors, such as race, ethnicity, sex."

From the inception of the health center program, Congress indicated that health centers should be governed predominately by the people who would care most about, and have the greatest interest in and commitment to, the scope of services offered by the health center, the health center's location and accessibility, the hours that services would be available, the programmatic priorities that the health center would pursue, etc.—the patients themselves.

Financial Stability

This year, the federal Community Health Center program celebrates its 40th anniversary. Also celebrating 40 years of service is the Medicaid program. In 1977, Dr. Karen Davis, President of the Commonwealth Fund, said, "the two programs were specifically designed to work in tandem with one another to make access to quality healthcare available to millions of Americans who previously had, at best, extremely limited access to needed care and who, as a result, experienced the worst health status among all Americans."

At 40, the FQHC program is thriving and growing under President George W. Bush's campaign to double the number of communities and people served by the end of 2006; while the Medicaid program is facing escalating costs that threaten its ability to offer coverage through the existing formula.

The weakened position of Medicaid, combined with an increasing number of uninsured, increasing healthcare costs, and downsizing of worker health benefits threaten the financial position of Community Health Centers. Approximately 25% of North Carolina health center patients are Medicaid beneficiaries, resulting in nearly 43% of North Carolina FQHC total revenues. FQHCs are left to wonder how they will continue to deliver high quality primary care to their vulnerable patients in the face of a disproportionate funding-to-need ratio environment. During this fiscal year (2005), federal grant dollars to North Carolina health centers decreased by nearly 1% across the board. Reductions to North Carolina Medicaid funding could result in increased cost sharing, forcing health centers to subsidize Medicaid using the already dwindling federal grant dollars intended for the uninsured. **NCMJ**

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COMMENTARY

North Carolina State Government and the Healthcare Safety Net:

Building the Nation's Most Extensive Network of Rural Health Centers

Torlen L. Wade, MSPH, and Andrea D. Radford, MHA

Since its inception in 1973, the North Carolina Office of Research, Demonstrations, and Rural Health Development has worked to transform government into a catalyst for improving access to quality and cost-effective healthcare services for underserved residents of North Carolina. Under the leadership of its founding director, James D. Bernstein, the Office adopted a state/local partnership approach and made community investment the cornerstone of its improvement strategy. Bernstein focused on five key philosophies that have remained the guiding principles of the Office's partnership initiatives over the last 30 plus years:

- Ownership is vested with community participants;
- Roles and responsibilities of all participants, both community and governmental, are clearly defined;
- In-depth technical assistance is provided on a continuous basis;
- Accountability is clear and measured; and
- Meeting patient and community needs remains the focus of all activities.

Jim Bernstein believed strongly that if improvement in care or service was the goal, then those who were responsible for making it happen must have ownership of the improvement process. State government could not merely issue edicts or dangle money; it had to engage in meaningful partnerships, be prepared to make long-term investments in communities and nurture the leadership needed to deliver the desired improvements.

Community Involvement

The Office began to apply these principles in its initial rural health development work. When the Office was founded in 1973 as the Office of Rural Health Services, it was charged by the North Carolina General Assembly with assisting North Carolina's rural areas in tackling a critical shortage of primary healthcare services in their communities. As large numbers of aging general practitioners retired in the early 1970s, they were not being replaced by younger physicians. The prospects for North Carolina's isolated rural communities to attract replacements were dim. The programs to train the new specialty of family practice physicians were just getting underway, and the competition for the few physicians available was intense. Meeting the growing rural healthcare crisis required new strategies and new infrastructure.

To help rural communities address these challenges, the Office promoted two important structural changes to North Carolina's healthcare delivery system. The first structural change was the development and use of community nonprofit boards, comprised of local residents, as the owners and operators of their community's healthcare program. To support this level of

> *"State government could not merely issue edicts or dangle money; it had to engage in meaningful partnerships, be prepared to make long-term investments in communities and nurture the leadership needed to deliver the desired improvements."*

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community involvement, the Office designed and developed a comprehensive set of support services that helped make community ownership and direction a reality. By building a cadre of specialized technical expertise, the Office was able to assist interested communities in establishing nonprofit corporations, organizing fund raising campaigns, designing and building facilities, recruiting and hiring staffs, and overseeing medical operations. The combination of community leadership and the comprehensive technical assistance delivered by the Office was a highly effective approach in making medical care available to their residents for many rural communities. What was viewed as a radical development in the early 1970s is an integral component of North Carolina's medical landscape today. More than 80 community-owned rural health centers developed with Office of Rural Health assistance now serve approximately 350,000 North Carolinians across the state.

Using Physician Extenders

The second structural change that was a centerpiece of the Office's initial efforts to increase access to healthcare in rural communities was the reliance on non-physician primary care providers—family nurse practitioners and physician assistants—to provide needed medical services. Major changes in medical practice and reimbursement rules and regulations were initiated to enable these non-physician primary care providers to practice in medical offices geographically removed from a supervising physician. Family nurse practitioners and physician assistants became, and still are, important providers at many rural health centers.

Key Programs Serving the Medically Vulnerable

The principles from which the Office of Rural Health developed over 30 years ago in addressing access to care in rural communities across the state are now used to guide the Office and its partners in bringing about improvement in other healthcare areas that target the underserved and medically vulnerable, including:

- *Community Care of North Carolina*. Managing the care of Medicaid recipients through community health networks that are organized and operated by local physicians, hospitals, health departments, and departments of social services. The 15 Community Care networks, serving more than 600,000 Medicaid recipients, are putting in place the management systems needed to achieve long-term improvement in the quality, cost, and health outcomes of recipient care;
- *Medical Assistance Plan (MAP)*. Providing direct funding for primary care services to indigent patients served by nonprofit providers in high-need counties;
- *Prescription assistance*. Improving providers' ability to access free and low-cost medications for their low-income patients; and
- *Farmworker healthcare*. Targeting the unique healthcare needs of seasonal and migrant farmworkers across the state by building up local delivery systems in high-impact areas.

Future Planning

As the Office of Research, Demonstrations, and Rural Health Development moves into the 21st century, it looks to build on the legacy of community ownership and collaboration established as guiding principles in the early days of the Office. Establishing and sustaining successful safety net providers still requires the active participation of the community to be served and coordination with existing healthcare providers. Challenges seen in the early days of the Office, key physicians retiring with no one to replace them, and medical students choosing specialty practice over primary care, are re-emerging and call for creative solutions that require communities, providers, and government agencies to work together. The needs of North Carolina's uninsured and medically vulnerable citizens are greater than current resources. Collaboration among both communities and healthcare providers is critical to avoid duplication of effort, to develop programs that are sustainable over time, and to use limited resources wisely. While common problems plague the safety net as a whole, each community has its own unique set of circumstances and offers its own unique set of resources to tap into. The time-tested philosophy of community-driven healthcare avoids a one-size fits all solution and seeks to work with a community to maximize the impact and effectiveness of existing resources and to assist them in designing workable approaches to healthcare needs. This philosophy of community-driven healthcare is one of the key factors that allowed North Carolina to build and sustain the nation's most extensive network of rural health clinics. **NCMJ** combination of paid staff and volunteers—physicians, nurses, pharmacists, laboratory personnel, and support personnel. They share other common characteristics:

- *Free care*. There is little to no charge for services or prescriptions.
- *Target population*. The target population includes people who have low-incomes and are uninsured (i.e., have no health insurance, no Medicare, no Medicaid, no Veterans Benefits). Low-income determinations are made by the individual clinic and range from 100-200% of federal poverty guidelines.
- *Core values*. Delivery of high-quality, compassionate care based on a belief that lack of income should not prevent access to healthcare. Free clinics place strong emphasis on providing non-judgmental, compassionate care while respecting the dignity and self-worth of every patient.
- *Volunteer driven*. The majority of services are provided by volunteers, who receive no compensation for their services.

Volunteerism is the major difference between free clinics and other safety net providers. Services are provided by individuals who are at the free clinic because they want to be. Volunteers consistently say that they receive more than they give in their encounters with patients. Physicians, with no managed care constraints or productivity requirements are able to practice medicine as they see fit. It reminds many of them of the practice setting that lured them into medicine in the first place. A collegial atmosphere exists in free clinics, with frequent communication and interchange about patients among nurses, physicians, and pharmacists. This atmosphere, with leading professional provider volunteers, results in the delivery of high-quality medicine to free clinic patients.

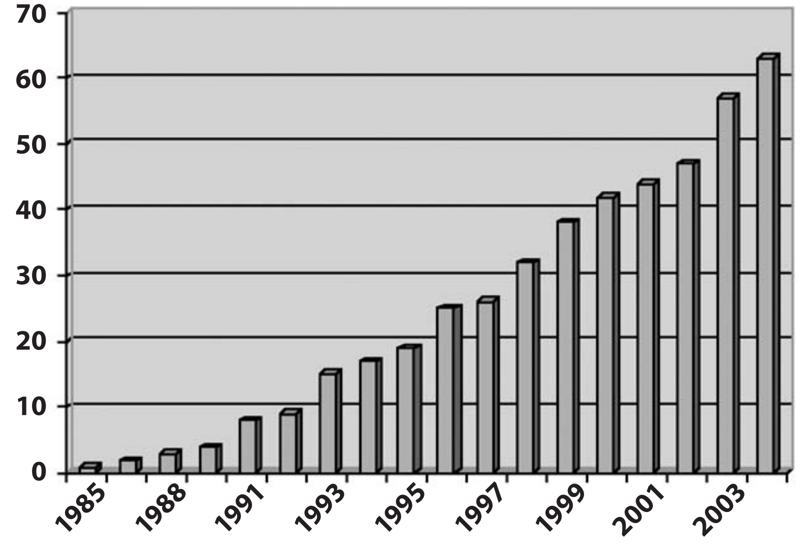
Development of Free Clinics in North Carolina

In the 1970s, concerned physicians began free clinics in the Winston-Salem area. Those clinics operated from area churches, but were not able to sustain operations and closed in the late 1970s.

In 1985, Dr. Don Lucey and other community physicians developed a free clinic, the Open Door Clinic, at the Urban Ministries in Raleigh after recognizing that lack of health and resulting poor health status were causes of unemployment and increased the potential of homelessness. Urban Ministries Open Door Clinic is one of over 60 free clinics serving uninsured North Carolinians at the present time (see figure 1).

> *"It's places like this that renew your faith in humanity."*

Figure 1.
Growth of Free Clinics in North Carolina



North Carolina leads the nation in the number of free clinics with 53 medical clinics, approximately 25 with state-licensed pharmacies (10 with stand-alone pharmacies or pharmacy programs). In 2003, North Carolina's free clinics served more than 69,000 patients, dispensed 450,000 prescriptions, and provided $50 million in healthcare services.

Free Clinic Services

North Carolina's free clinic services vary by community, depending on needs and resources of the individual communities. Services may include the following:

- Medical—acute episodic medical treatment; management of chronic diseases,
- Dental,
- Pharmacy,
- Laboratory and other diagnostic tests,
- Physical therapy,
- Podiatry,
- Behavioral health,
- Medical specialty services—including ophthalmology, orthopedics, cardiology, and dermatology among others, and
- Social work.

Even though services are provided at no charge, most free clinic patients receive the full-range of services needed for their medical condition. Patients receive medical care, laboratory services, referrals for other diagnostic or therapeutic services, health education, prescription medications, and specialty care. If a needed specialist is not available on-site, most free clinics have arrangements for community physician specialists to see patients in their offices.

Free Clinics in North Carolina:
A Network of Compassion, Volunteerism, and Quality Care for Those without Healthcare Options

Olivia Fleming, MA, and John Mills, CAE

Ida and her husband Jim both worked full-time. Ida's job did not provide health insurance, but Jim paid extra so his insurance policy would cover both of them. Jim developed multiple sclerosis, which progressed rapidly causing Jim to lose his job. Despite their limited financial resources, they were able to continue his insurance through COBRA. Unfortunately, they did not have the resources to continue hers. Ida was faced with managing her hypertension without insurance. She turned to Urban Ministries Open Door Clinic (ODC) in Raleigh for treatment and medication. A routine screening mammogram revealed a lump in Ida's breast. Uninsured and frightened, she turned again to the ODC. ODC coordinated care and, within a month, Ida had a mastectomy and had begun a chemotherapy regimen. One year later, Ida is cancer-free and has found a new job with healthcare benefits, leaving the ODC with an opening for another person in need without other healthcare options.

Nancy, a young woman in her late 20's, came to ODC because she didn't feel well. Diagnosis: diabetes mellitus. Her hemoglobin A1c was 15, and other clinical measures were similarly high. Nancy entered ODC's specialized diabetes management program, the Diabetes Care and Risk Reduction Program. By meeting regularly with a certified diabetes educator; making significant changes in her eating and exercise habits; and receiving medications, a glucometer, and test strips at no charge, Nancy has brought her hemoglobin A1c to 5.2 and other clinical measures are in line. She is able to move toward her goal of getting pregnant, something that six months ago was not advisable due to her health status.

Approximately 1.4 million North Carolinians are uninsured, and that number is larger when statistics include individuals who lack health insurance at a given point during the year. It is a common misconception that low-income individuals are eligible for Medicaid coverage. To be eligible, one must fit into a few limited categories, such as being pregnant, being under 18 years of age or younger, age 65 and older, or before being disabled. There are also maximum resource and income levels allowable for each category. Simply being poor does not qualify one for governmental healthcare. Free clinics are a community response to the crisis facing these uncovered individuals. The clinics are by no means a comprehensive solution, but they represent a compassionate, economical, and proven source of healthcare. More than 50% of free clinic patients are employed, many working more than one job to make ends meet. However, they work for low wages and for employers who do not offer affordable healthcare insurance. It is in this environment that concerned individuals began to seek ways to improve access to healthcare in their communities.

> *"More than 50% of free clinic patients are employed, many working more than one job to make ends meet."*

What is a Free Clinic?

Free clinics rely on community collaboration and the spirit of compassion that leads persons to volunteer their services to assist their less fortunate neighbors. Free clinics in North Carolina reflect the needs and resources of their individual communities. There is no template, yet there are similarities. They are non-profit organizations, directed by concerned community leaders. Typically, the clinics provide services through a

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Patients are emotionally invested and touched by the concerned and high-quality care they receive in these free clinics. As one Urban Ministries Open Door Clinic patient recently stated, “It’s places like this that renew your faith in humanity.”

Financials and Free Clinics

Free Clinics receive no federal or state funding. Because they receive no revenue from their patients, free clinics must turn to their communities for support. They are funded with cash and in-kind donations from a variety of sources including:

- Individual contributors,
- Churches,
- Businesses,
- Hospitals,
- United Way, and
- Foundations.

In 2004, free clinics raised over $13 million from private funding sources. Because they use volunteer providers and secure donated supplies, medication, and ancillary services, free clinics were able to leverage these gifts into over $50 million in healthcare services to their patients.

In 2004, the Blue Cross and Blue Shield of North Carolina Foundation announced a five-year, $10 million grant to the North Carolina Association of Free Clinics for the support of existing free clinics and the creation of new clinics in underserved areas.

Challenges Facing Free Clinics

North Carolina’s free clinics face multiple challenges as they continue to offer compassionate healthcare services to those without other options, including:

- *Meeting changing demographics*. Providing culturally appropriate services to diverse racial/ethnic populations is challenging. Access to interpreters in rural areas of the state is increasingly difficult.
- *Volunteer recruitment and retention*. Free clinics’ dependence on volunteers for service delivery requires them to continually recruit and retain licensed volunteer providers.
- *Finances*. Sustaining funding to operate the clinics once they have been operating for several years is challenging. Start-up grants are generally available, but they are short-term funding solutions.
- *Infrastructure issues*. Lack of funding to support staff is an issue. Most clinics operate with small staffs who must recruit, retain and support volunteers, and develop and maintain systems to ensure high-quality care delivery.
- *Liability concerns of volunteers*. While there is no history of a malpractice suit brought against a North Carolina free clinic, the specter of liability is prominent in the minds of most volunteer providers. Clinics must find an affordable solution for offering liability protection for providers.

Free clinics do not profess to be the answer to the crisis of access to healthcare for North Carolina’s uninsured, but they are a continuing stop-gap measure until there is a more comprehensive funding stream for indigent medical care. As Don Lucey, MD, states, “In 1985, when we started Open Door Clinic, we thought we’d be around for only a couple of years, until the country dealt with this problem of access to healthcare. Twenty years later, we’re still waiting.” **NCMJ**

COMMENTARY

Local Physicians Caring for Their Communities:
An Innovative Model to Meeting the Needs of the Uninsured

Gillian K. Baker, MHA, Alan T. McKenzie, and Paul B. Harrison, MPH

"Thank you for saving my feet, and my life." Those words warm the heart of the physicians who care for Joe.

About a year ago, Joe was not feeling well. He felt something was wrong, but he knew he did not have the money to go to the doctor, so he tried not to worry about it. However, as his health began to deteriorate, a friend told him about how physicians in his county will take care of him, even if he cannot pay. A local project coordinates healthcare for folks like Joe, who do not have insurance and cannot afford to go to the doctor.

Joe was very excited about the possibility of being able to get the much-needed healthcare and applied for the project. Joe met the criteria and was accepted into the project and assigned to a primary care provider. On Joe's initial visit to the doctor it was discovered that he has diabetes. Through the project, Joe is able to get the medical care, tests, medications, and supplies he needs to get and keep his diabetes under control. In addition, it was discovered that the disease has caused sores on Joe's feet that, which without the care of a specialist, could result in Joe's feet needing to be amputated. Through Joe's visit to a specialist, his feet have gotten better, and he has been able to avoid an amputation.

In your county a project like this might be called Project Access, or Appalachian Healthcare Project, or maybe Community Care Plan, but it is all the same—physicians donating their time and talents to do what they do best—helping those who are sick.

There are now many counties throughout North Carolina that have volunteer physician care projects, and the number of them continues to grow in North Carolina and throughout the country. For example, Charlotte/Mecklenburg County began officially serving patients through its Physicians Reach Out initiative in late 2004. But, it all began in Asheville, in 1994, when a grant from the Robert Wood Johnson Foundation started Project Access. The premise of these projects is that local physicians participate in a volunteer medical service program designed to meet the medical needs of residents who have no health insurance and have incomes typically below 150% to 200% of the poverty guidelines. Hospitals also donate care to patients enrolled in such projects. The projects coordinate donated inpatient and outpatient services and pay for limited outpatient medication requirements.

In Buncombe County, the Buncombe County Medical Society administers the first Project Access program, which serves as a model for replications throughout the state. Private physicians can participate in one of two ways in Buncombe County: (1) They can commit to serve patients at one of the safety net clinics, and/or (2) They can agree to see a certain number of patients in their office per year. Eighty percent of the physicians in private practice have agreed to participate in the program. Primary care providers agree to see 10 uninsured

> *"The premise of these projects is that local physicians participate in a volunteer medical service program designed to meet the medical needs of residents who have no health insurance, and incomes typically below 150% to 200% of the poverty guidelines."*

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low-income patients, and specialists agree to see 20 patients per year. Local hospitals donate all lab tests and inpatient and outpatient services. Patients who visit a specialist (or a primary care doctor) in their private office can obtain their medications through a county-funded medication assistance program.

In an effort to document the care being delivered by the project, the County Medical Society processes standard insurance claims forms voluntarily submitted by physicians, hospitals, and pharmacies to document which services were provided and the value (i.e., the usual cost) of the services. Patients referred by private physicians have their eligibility determined through the Medical Society. The average program enrollment period is approximately six months, but this varies based on the patient's needs and length of time that he or she is uninsured.

These projects help address problems associated with donated care including: physicians concern that they would be inundated with requests; patient eligibility, differentiating which patients could afford to pay; and concern that uninsured patients would be able to obtain needed medications or diagnostic services. In addition, the project office eases some of these concerns by verifying patient need and distributing patient referrals equitably among many different providers. This helps spread the burden/risk of caring for the uninsured. In addition, reminder phone calls are made to reduce no-shows and help ensure that patients can obtain specialty and ancillary services and needed medications.

Today people with incomes below the allowed Federal Poverty Level have access to comprehensive care through a network of primary care clinics and private physicians seeing patients in their practices and in the hospital. There is a system of specialty care referral, free pharmacy, and other services. Doctors are routinely donating their time and talent to provide treatment for diabetes and hypertension and perform procedures like heart surgery, knee surgery, and even brain surgery. All of this is done in their private practices and at local hospitals without regard to a patient's ability to pay.

Physician Leadership Role

Project Access initiatives are dependent on physician leadership and the identification of local physician champions. Physician leadership develops and executes all aspects of physician recruitment in an organized volunteer care program. The message of the physician champion is straightforward: the indigent population needs to have better care, and the only way it will be delivered is if the medical community contributes to this care in a way that does not unfairly tax any individual provider. All segments of the healthcare delivery system need to participate, and there needs to be organization, documentation, and controls to ensure the system is treating those in need (both economically and medically) as efficiently and effectively as possible. With a commitment from a significant portion of the medical community, the process can move forward.

Physicians are recruited to participate in the project. By the point of project implementation, 35% to 100% of the physicians in each of the counties where the project is active have joined the effort. Primary care physicians agree to accept 10-12 patients as their responsibility. Specialty physicians agree to accept 20-24 patients per year from the program. Local medical societies, hospitals, health departments, county governments, departments of social services, and area pharmacies have participated in these initiatives to varying degrees based on program location.

Why Physicians Participate

Physicians report great satisfaction from the personal rewards they receive as a result of the service they are providing to the community. They note that the image of their medical community has been enhanced through the positive publicity that the program brings to the profession as a whole, as well as individual participants. This increased awareness of the significant contributions physicians make to the safety net has, in turn, led to increased credibility and political and social influence in their community and at the state and national levels.

There is renewed camaraderie and pride in the medical profession and commitment to the general welfare of their communities. These physicians have discovered that by working together in their communities they can make a difference. They have improved the health of their communities and their profession.

Clearly, physician leadership at the local level produces dramatic results: enhanced healthcare delivery, improved health of communities, and a renewal of the only inexhaustible resource of the healthcare delivery system—the compassion of its caregivers.

Measuring Outcomes

Access to Continuum of Care Increases

In Buncombe County during 2004, of the 210,000 total population, there were approximately 38,000 uninsured. Of the uninsured, approximately 65% (or 25,000 residents) had incomes below 200% of the federal poverty guidelines. Amazingly, over 24,000 of these estimated 25,000 low-income uninsured patients were seen at least once in a safety net clinic or in a private primary care physician's office during that calendar year. Of these, 2,800 were referred for specialty care, hospital services, and/or medications beyond the scope of services available in these free clinics and community clinics. Ninety-three percent of all county residents now report having a medical care home.

Health Status of Uninsured Improves and Charity Costs Decrease

Community-wide health assessments conducted in Buncombe County found that the uninsured were more likely to report being in good or excellent health than the insured. The uninsured were also less likely to report using the emergency room than the insured. Of the patients served through Project Access, 25% reported improved productivity on the job, and 17% reported reduced absenteeism. Per patient charity care costs decreased, perhaps related to improved health status and increased access to primary and preventive care services fostered through the collaboration of private doctors, hospitals, safety net clinics, and area pharmacies. Area hospitals have documented an average of $3 million annually in avoided charity care costs.

History of Replication

In late 1998 Buncombe County Medical Society was selected from nearly 1,700 applicants to receive the prestigious Ford Foundation Innovations in American Government Award. With that award came a commitment by the Medical Society to help others replicate its system of care. As a result of the experience gained by the Buncombe County Medical Society, it has now developed a sophisticated approach to helping communities adopt and adapt the Project Access model to their unique circumstances; and thereby, dramatically expand access to care in their communities by better organizing existing resources. Using Project Access as a model, many North Carolina counties have operational systems, including Avery, Watauga, Mitchell, Yancey, Wake, Mecklenburg, Pitt, Cabarrus, Guilford, Forsyth, Caldwell, Vance and Warren Counties, while others have secured necessary funding and are in the process of organizing their systems. Nationally, there are project access systems operating in dozens of communities, such as Wichita, Kansas; Spokane, Washington; Austin, Texas; and Marquette, Michigan. A more comprehensive listing with links to program web sites may be accessed at www.apanonline.org.

Project Access can be replicated in both rural and urban settings such as these projects in Wake and Watauga-Avery Counties.

Appalachian Healthcare Project: A Rural Model

While the Project Access model is easier to establish in communities with large provider bases and existing safety net providers, Project Access models have been established in less resource-rich environments as well. The first rural Project Access program, the Appalachian Healthcare Project, serves Watauga and Avery Counties. Watauga County has a population of 42,857 people with 25 primary care providers and 60 specialists. Avery County has a population of 17,610 with 17 primary care providers and two specialists.

In the spring of 2000, the only place for low-income uninsured patients to receive care was the hospital emergency department. There were no safety net organizations or free clinics providing comprehensive primary care. The Appalachian Healthcare Project was made possible by the commitment of the medical communities in these two counties. Each provider pledged to see anywhere from 12 to 24 patients per year. In addition, the local hospitals offered inpatient, outpatient, and diagnostic services to Appalachian Healthcare Project patients. The commitment of the medical community allows the patient load to be distributed equitably among the physicians. Since the project was implemented in April 2001, approximately 600 people have been served. On average, there are about 200 active patients at any time. In 2004, the medical community provided nearly $2 million in medical care and medications to Appalachian Healthcare Project patients.

Wake County Project Access: An Urban Model

Urban volunteer service programs, like Project Access, are dependent on community stakeholders working collaboratively for the "common good." In this instance, the presence of six physician champions during the 12-month planning period persuaded leaders of the three hospital corporations and 450 physicians to sign on as participating providers.

The program has allowed the medical community to document the volume of donated care for patients who would not likely be able to pay for services. For this reason, hospital-based physicians and hospital corporations could only gain by their participation in Project Access, which has been strongly supported by local private practice physicians.

The project works collaboratively with an array of primary care safety net clinics, the health department clinics, hospital emergency departments, and private practice physicians. Since its inception in late 2000, Project Access of Wake County has enrolled 5,030 patients and has generated $20 million in donated care provided by physicians and hospitals. Operating expenses, including the cost of outpatient medications, account for $1 million, which yields a ratio of cost-to-donated care equal to $1:$20.

Current Needs for State Policy Development and Funding

Nationally, over 70% of physicians report providing charity care to the uninsured, yet this remains an often-overlooked component of our state's safety net services to the uninsured. In the absence of more thoughtful policies at the state level, the "specialty care" gap between primary care safety net services and hospital-based services will continue to widen, and many more patients will "fall through the cracks."

While scant state or federal policy has been developed to support continued private physician practice-based charity care, communities are stepping forward and producing dramatic gains in access, improved health, and reduced costs in serving the uninsured. These communities are investing in:

- Creating accountable safety net systems that improve the health of the uninsured and demonstrate significant returns on investment through reduced community costs and improved business productivity from healthier workforces.
- Building and sustaining physician-led administrative support that better organizes and celebrates physician charity care.
- Strategic planning that creates a healthcare safety net providing the full continuum of needed services.
- Systems that assure that uninsured patients receive the medications prescribed by physicians.
- Outcomes measurement systems that document the return on community investment.

State and federal policies are needed to help communities with these needed investments. In addition, the North Carolina Institute of Medicine North Carolina Healthcare Safety Net Task Force Report[1] calls for careful analysis of the

North Carolina's Good Samaritan legislation to assure that it provides appropriate liability protection for doctors donating their care to the uninsured, in particular to assure that this protection extends to cover doctors who are seeing patients for free in their private practices. Current legislation provides protection for patients who are referred by community clinics, but the protective legislation does not clearly extend its coverage to doctors who are participating in organized systems of charity care and seeing patients (for free) in their practices who may not have been referred by a clinic.

Conclusion

While our healthcare finance system cannot be based on charity, care donated by private physicians is a vitally important, yet vastly undervalued, component of our state's healthcare delivery system. Clearly charity care exists and will exist for the foreseeable future. Strategic investment in better organizing and integrating this care has been demonstrated to produce significant return on investment and public policy should be pursued to deliver this care effectively. **NCMJ**

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The Hospital Emergency Department:
An Anchor for the Community's Healthcare Safety Net

Jeffrey S. Spade, CHE

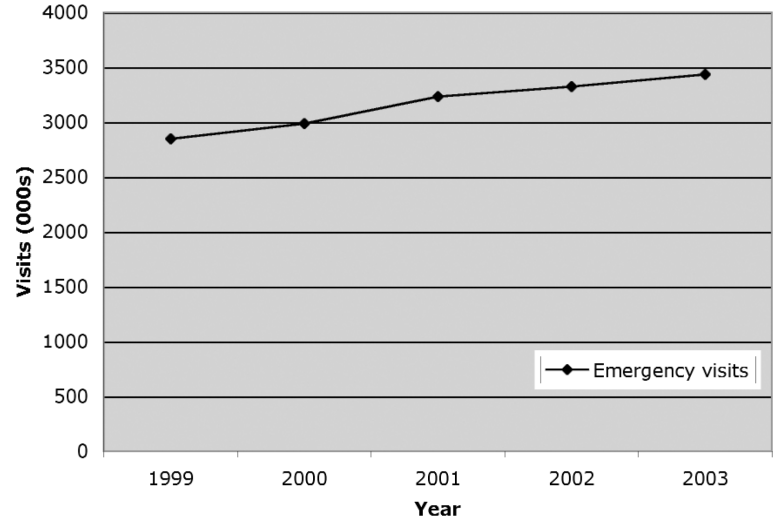
North Carolina's community hospitals have a long respected tradition of undergirding the health and welfare of citizens and communities across the state, wealthy or poor, urban or rural, healthy or frail. One hundred thirteen (113) community hospitals provide needed healthcare services for North Carolina's 100 counties, ensuring local community access for both basic healthcare requirements and more complex interventions and therapies. North Carolina's community hospitals are also a prime anchor of the safety net that protects the state's most vulnerable citizens: the elderly, those with chronic disease, the poor, the disadvantaged, and the uninsured. Without a local hospital, many North Carolina communities would struggle to maintain even the most basic health services.

The North Carolina Healthcare Safety Net Task Force Report[1] by the North Carolina Institute of Medicine effectively describes the increasing burden of the uninsured and the poor, while documenting the "frayed edges" and the "worn patches" that shore up the state's healthcare safety net. While hospitals represent the virtual anchors of the safety net, hospital emergency departments are the ever-present backbone of the safety net's architecture. Emergency departments are often the first line of defense against community epidemics, like influenza and respiratory diseases, a provider of hope and life for citizens faced with debilitating disease or life-threatening injury, and a provider of last resort when no other avenues for healthcare seem available.

North Carolina Emergency Departments Carry a Huge Burden

In 2003, North Carolina hospitals provided emergency services to 3,433,432 patients, an increase of 21% percent over five years (see figure 1). North Carolina's rate of increase exceeds the national growth in emergency visits, which increased 11.6% over the same five-year period.[2] In a national survey completed in 2002 by the Centers for Disease Control, abdominal pain, chest pain, and fever were the most commonly recorded principal reasons for an emergency visit, accounting for one-fifth of all emergency visits. The most frequently reported diagnoses were contusions, acute upper respiratory infections, open wounds, and abdominal pain. Diagnostic/screening services, procedures, and medications were provided at 86.8%, 43.2%, and 75.8% of emergency visits, respectively. Additionally, 12% of emergency visits result in hospital admission; and more than one-third of patients admitted to the hospital are first treated in the emergency department.[3]

Figure 1.
North Carolina Hospital Emergency Visits, 21% Increase in Visits Since 1999



In North Carolina in 2004, 21% of the emergency visits were attributed to patients without health insurance; 22% of

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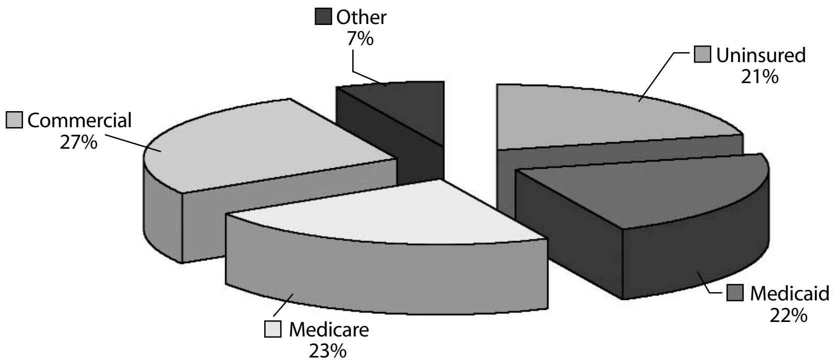
Figure 2.
North Carolina Hospital Emergency Visits by Payment Type in 2004



Total Emergency Visits for North Carolina Hospitals in 2003 = 3,433,432

emergency visits were by those with Medicaid; and 27% of the emergency visits in 2004 were covered by commercial insurance (see figure 2). The rate of uninsurance (21%) in North Carolina's emergency departments is greater than the national rate (16%). Furthermore, North Carolina's hospitals experience higher use of emergency services by the poor and elderly (Medicare and Medicaid) and lower rates of commercial coverage than the average emergency department nationally. Fifty-six percent (56%) of North Carolina's emergency visits occur in urban hospitals and 44% in rural hospitals. North Carolina's large hospitals, those with 200 licensed beds or more, accounted for 64% of emergency department admissions in 2004. North Carolina's largest hospitals, those hospitals with 400 or more licensed beds, serve the greatest proportions of uninsured and poor emergency care patients (23% uninsured and 26% Medicaid, respectively, 49% combined). For the average North Carolina hospital, the uninsured and poor account for 43% of the emergency admissions.[4]

The Multiple Roles of Hospital Emergency Departments

In the National Hospital Ambulatory Medical Care Survey by the Centers for Disease Control (CDC), the authors state, "the primary role of the hospital emergency department is the treatment of seriously ill and injured patients. However, the emergency department provides a significant amount of unscheduled urgent care, often because there is inadequate capacity for this care in other parts of the healthcare system. The emergency department also serves as referral site for other providers to evaluate and stabilize patients."[5]

A May 2004 study published by the CDC examined the characteristics of emergency departments serving high proportions of safety net patients. Interestingly, the study defined a "high-burden safety net emergency department" as having greater than 40% combined services to Medicaid and uninsured emergency patients. Given that the average North Carolina hospital emergency department treats 43% uninsured and Medicaid patients combined, many North Carolina emergency departments would readily meet the CDC definition as serving a high burden of safety net patients.

Furthermore, the CDC study found that emergency departments serving high proportions of poor and uninsured patients have a greater proportion of visits made by children and minority residents; have higher percentages of non-urgent and 'urgent, but primary care-treatable' cases; and higher percentages of cases that left the emergency department without being treated. Of note, the CDC study found that the percentages of 'emergent conditions that were avoidable with preventive care' were not significantly different between hospital emergency departments with varying (high versus low) proportions of the uninsured and poor. In addition, hospital emergency departments with higher proportions of uninsured patients had lower percentages of emergency cases that were 'avoidable with primary care' in comparison to hospitals with high proportions of Medicaid visits to the emergency department.[6]

Comparable data describing the use, characteristics, and demographics of emergency departments and patients in North Carolina are lacking. Therefore the appropriateness of emergency department admissions and the reasons for seeking emergency care by vulnerable populations, such as the poor and the chronically ill, are not well documented.

However, recent developments will improve the understanding of emergency care in North Carolina. A new partnership between the North Carolina Division of Public Health (NCDPH) and the North Carolina Hospital Association (NCHA), with support from two nationally prominent information technology companies, Solucient and MercuryMD, organized and developed the North Carolina Hospital Emergency Surveillance System (NCHESS). The main purpose of the NCHESS partnership is to capture near real-time emergency care data to quickly assess and manage public health or population health emergencies.

Biodisaster preparedness is the reason NCHESS was developed. Because of this unique and successful partnership, North Carolina is the first state in the country to develop and implement this advanced biopreparedness warning system. An important and valuable by-product of the NCHESS development will be the collection and analysis of emergency department diagnoses, trends, demographics, and outcomes. In the near future, NCHESS will help the state's healthcare systems and providers understand the usage trends in emergency services and, in turn, be able to design interventions and healthcare access models to improve community health. NCHESS will greatly contribute to the understanding of the adequacy of the healthcare safety net in North Carolina.

Emergency Department Care: Often Inappropriate and Expensive When No Alternatives Exist

While specific North Carolina data are unavailable, national studies routinely conclude that providing care for non-emergent or primary care-treatable conditions in emergency settings is expensive, sometimes inappropriate, and often inefficient. The federal Agency for Healthcare Research and Quality (AHRQ) recently published a study examining the health and economic costs of the lack of preventable primary care for diabetes patients. The study estimates nearly $2.5 billion in savings annually if patients received more appropriate primary care for diabetes complications.[7] Community Care of North Carolina networks across the state have documented reductions in emergency department usage by patients with chronic diseases, namely asthma and diabetes, when the local and regional primary care systems collaborate to improve and support chronic disease management in the community setting.

A national study by the Center for Health System Change concludes that uninsured citizens rely on emergency departments for one-fourth (25%) of their ambulatory care visits, compared to 8% for the privately insured population.[8] The authors posit that the greater reliance by the uninsured on emergency departments for primary care is likely due to a decline in access to office-based providers. The same study indicates, however, that contrary to popular wisdom, uninsured patients are not driving the increased use of hospital emergency departments. Instead, privately insured patients and Medicare beneficiaries accounted for two-thirds of the overall increase in emergency department visits, nationally, between 1996 and 2001.[8]

The Center for Health System Change suggests that capacity constraints experienced by office-based providers, combined with a loosening of managed care restrictions, may contribute to the increase in non-urgent emergency visits, a trend apparent in all payer segments. The Center's 2003 Issue Brief states, "other research shows that more patients are having difficulty making appointments with their doctors, and more people have long waits for appointments. For their part, more physicians report having inadequate time to spend with their patients and are increasingly closing their practices to some new patients, despite spending more time in direct patient care activities. With extended hours and no appointment necessary, emergency departments increasingly may be viewed by many patients as more convenient sources of primary care than their regular physicians. For uninsured patients, emergency departments are one of the few remaining primary care options."[8]

A 2005 report by the National Association of Community Health Centers tracks the federal government's plan to place federally-funded community health centers serving the poor and uninsured into every poor county in the United States. The report identifies 47 poor counties in North Carolina, divided into 20 counties with a community health center (CHC) and 27 North Carolina counties without a CHC.[9] With the rising numbers of uninsured and poor in North Carolina, the ability of the public system of care (health departments, CHCs, indigent care clinics, rural health clinics and centers, free clinics, etc.) to accommodate the increasing indigent care burden is certainly being stretched.

Hospital emergency departments are increasingly the last remaining reliable and routinely available source of primary healthcare in many North Carolina communities. If the uninsured visit rate of 21% is applied to the emergency visits tabulated for North Carolina in 2003 (3.43 million emergency visits), then North Carolina hospitals experienced more than 721,000 uninsured emergency visits in 2003. Adding in Medicaid, hospital emergency departments provided care for nearly 1.5 million uninsured or poor North Carolina residents in 2003.

> *"Emergency departments are often the first line of defense against community epidemics..., a provider of hope and life for citizens faced with debilitating disease or life-threatening injury, and a provider of last resort when no other avenues for healthcare seem available."*

The Emergency Medical Treatment and Active Labor Act (EMTALA) of 1986 has had a profound effect on hospital emergency departments. EMTALA requires emergency departments to screen and stabilize all patients that present to the emergency department regardless of ability to pay. The federal government does not guarantee such expansive access to any other segment of the healthcare system. Thus, emergency departments are often viewed as the ultimate safety net providers, ensuring a minimum level of care and services regardless of the patient's disease category, background, ethnicity, immigration status, or insurance class. While EMTALA is viewed as an unfunded federal mandate and presents enormous compliance issues for the hospitals, the concept of the hospital emergency department as a guaranteed source of immediate healthcare is important and vital to sustaining and improving community health.

Challenges Faced by North Carolina Hospitals' Emergency Departments

It is comforting to know that North Carolina's hospitals and emergency departments are a solid anchor and backbone for the state's healthcare safety net. However, regardless of the strength and commitment of community hospitals to emergency care, hospitals face many difficulties in maintaining this important aspect of the safety net anchor. Among the issues that impact hospital emergency departments are reasonable and adequate financing, increasing volumes of uninsured patients, access to capital for expansion and technology enhancements, adequate physician coverage for unassigned and uninsured patients, the unstable nature of mental health reform in the state, the rapid influx of immigrants and foreign-born citizens requiring care, and the rising cost of malpractice insurance premiums. Several of these issues are worthy of further examination.

> *"...the concept of the hospital emergency department as a guaranteed source of immediate healthcare is important and vital to sustaining and improving community health."*

Financing the Care of the Uninsured. Operating and maintaining a modern, fully equipped, adequately staffed and appropriately sized emergency department is an expensive proposition. Yet, emergency care is such a basic and essential aspect of community health networks that almost every community hospital in North Carolina offers emergency care. The primary financing mechanism for emergency departments is insurance coverage for health services. For the average North Carolina hospital, one in five patients (21%) is uninsured, with very little or no resources to pay for their care. Another 45% of emergency care is provided to Medicare and Medicaid patients. Obviously, maintaining adequate levels of reimbursement, especially from the government payers, Medicare and Medicaid, is essential if hospital emergency departments are to remain viable and accessible. Cutting hospital payments in Medicare and Medicaid, especially at a time when the numbers of uninsured residents are rising, will definitely impact the quality and availability of essential, yet expensive hospital services such as emergency departments. In the federal 2006 fiscal budget, Medicaid expenditures are under attack, threatening the ability of the state of North Carolina to adequately fund its Medicaid program. The retraction or reduction of Medicaid funding by the federal government cannot be allowed. This one factor alone, inadequate Medicaid funding, is a major threat to North Carolina's healthcare safety net.

Malpractice Insurance Costs. The rapid rise of malpractice insurance premiums also hampers the emergency department safety net. Some North Carolina hospitals and physicians have experienced malpractice premiums increases of 300% or more over the past few years. The malpractice cost increases are so dramatic and expensive that some physicians can no longer afford to cover certain services, such as labor and delivery, or even general surgery. Also emergency department back-up coverage is often considered a high-risk, high-liability service, which can influence the cost and/or availability of malpractice insurance, driving physicians to curtail or drop emergency department coverage from their privileges. Losing community physicians from the coverage panel for the hospital emergency department is a serious problem. Having fewer physicians available for emergency patients, especially those patients who present at the hospital without a regular physician, means that hospital emergency departments may be unable to provide care for some very basic, yet essential, healthcare services. Solving or at least abating the malpractice crisis in North Carolina will give some respite to hospitals and health providers that struggle daily to maintain adequate emergency care coverage.

Growth of the Numbers of Uninsured. The expanding ranks of the uninsured in North Carolina cannot be ignored either. The loss of manufacturing, tobacco, and textile jobs in North Carolina will continue to push the number of uninsured residents into record territory (almost 20% of residents under age 65 in 2004). Uninsured residents frequently do not have a regular source of primary healthcare. Thus, uninsured residents may seek primary care in hospital emergency departments, often too late, after a treatable condition has progressed into a true emergency. If the rate of increase of the uninsured continues at the current pace, then hospital emergency departments may be one of the few remaining care settings available for uninsured patients. A hospital emergency department with 30% or more of its care provided to uninsured patients and 20% or more emergency care being provided to Medicaid patients is at serious risk for financial failure.

Mental Health Reform. Mental health reform is a vastly important issue for hospital emergency departments. The state of North Carolina is currently undergoing major reforms to the mental health system. As a result, the mental health system in North Carolina is very fragile; not enough providers, too few community-based services, inadequate reimbursement, uneven insurance coverage, and an increasing demand for service. The rate of uninsurance is 70% higher for mental health visits to the emergency department than the average emergency visit. If mental health reforms, such as the development of community service alternatives and mental health reimbursements, are not adequate or incomplete, then hospital emergency departments will be overwhelmed with patients requiring care for mental health conditions. In fact, many hospital emergency departments across the state already report significant increases in patients requiring mental health service with few options for community referral.

The Need for Expanded Primary Care Options. Besides preserving and protecting Medicaid funding, one major solution is recommended to help maintain the hospital emergency department's strength and viability as a safety net anchor: the commitment to create and maintain multiple and additional community access points for primary care service for the uninsured, the poor, and the vulnerable. Community health centers, rural health clinics and centers, public health departments, free clinics, mental health centers, and community physician practices must be developed and supported in close collaboration with the local care networks, especially in the neediest communities and counties. If additional primary care access points for the uninsured are not developed and funded, then hospital emergency departments will become increasingly crowded, suffer from inadequate staffing and less advanced equipment and technology, and require more financial subsidies. **NCMJ**

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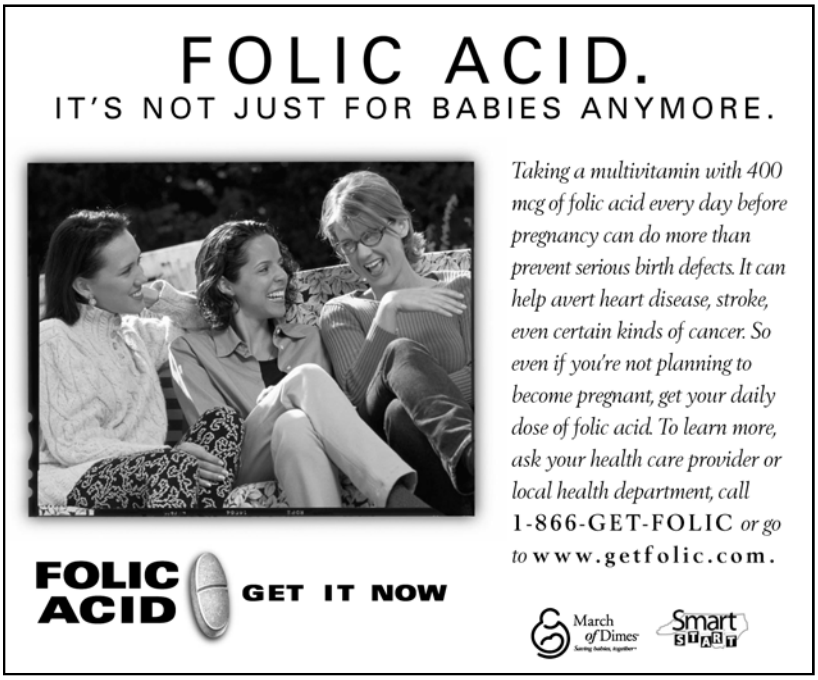

COMMENTARY

Our Healthcare System Is Failing

J. Douglas Yarbrough, MBA

What do we think when we hear about someone who has no health insurance coverage? Our first thought is that they may not get the care they need. Then we wonder if they could lose their savings and/or incur massive debts if they or someone in their family has a catastrophic illness. This should concern us, but this is not the whole picture. In reality, providing medical care for the uninsured is an even greater problem for our healthcare delivery system. In fact, it is crippling our system; and if left unresolved, it will destroy our system. Nationally, there are approximately 44 million people without medical coverage. Another 38 million have inadequate coverage. That means approximately 28% of the United States population is without adequate healthcare coverage.[1]

With some exception, uninsured people pay very little of the cost of providing their healthcare at the hospital level. For years, we in the hospital industry have referred to the uninsured as "self-pay." For financial purposes, we classify our patient receivables as Medicare, Medicaid, other government, commercial, or self-pay. We informally refer to self-pay as "no-pay." That is because we collect a very small percentage of what we charge the uninsured. Many of them are classified as charity care, and a large portion of their care is written off. Some uninsured patients have the ability to pay, but decide not to, and their balances become bad debts. Some fall into a monthly payment category where they make very small monthly payments (without interest). How do hospitals deal with the cost of the uninsured? Like any business, we pass it on to the paying customers. It becomes a piece of overhead. Call it what you want, but it is a part of the total cost, and somebody has to pay for it.

"How do hospitals deal with the cost of the uninsured? Like any business, we pass it on to the paying customers."

From a financial perspective, accounting for healthcare is much like accounting for any other type of service. We must have enough revenue to cover our costs. If we cannot make a profit, we cannot replace worn out plant and equipment or invest in the latest technologies. However, there is one difference unique to the healthcare field. That is the enormous amount of free care and under-paid care we deliver. We must charge each patient more to recover the unreimbursed cost of care provided to the uninsured and "government payers." As a result, hospitals write off 40-50% of what they charge.

Hospitals Are Underpaid by Medicaid and Medicare

Let me explain why government payers present another unique problem for healthcare providers. Earlier I referred to the classification of patients as Medicare, Medicaid, other government, commercial, or self-pay. In North Carolina, hospitals are not receiving enough payments from government payers to cover the cost of treating government-pay patients. Medicare payments to hospitals are not based on what hospitals charge, and, in most cases, do not cover the true cost of providing the care. Imagine owning a business where your customers walk in, take your product or service, and then tell you what they are willing to pay. Why can Medicare do this? Medicare covers half of the patients that come to our hospitals. Medicare is the number one payer by far; they can virtually enforce any payment system they choose, and hospitals have no choice but to accept. Historically, the Medicare program has grown much more than government estimates, and they had to come up with payment systems that allow them to meet their budget. For the first 18 years of Medicare's existence, the program paid hospitals for the "cost" of the care provided. However, since 1983, the payments have been slowly declining in relationship to the actual cost of providing care, and now hospitals are receiving less in payments than the actual cost of the care. How do hospitals recover this shortfall? Simple: they pass it on to other payers.

Unfortunately, Medicaid, the second largest payer for many

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hospitals, has been doing the same thing as Medicare. They are paying less to hospitals than the cost of providing care to Medicaid patients. Hospitals are burdened with yet another class of payer that does not cover the cost of care provided. What do hospitals do to cover that short fall? Obviously, the same remedy is to pass that on to other payers. Unfortunately, the only payers remaining are commercial insurance carriers. Insurance companies have historically paid hospital bills based on billed charges rather than a government imposed payment scheme.

Insurance Companies Demand Deep Discounts

In recent years the number of commercially insured patients has dwindled. With factories closing and workers attracted to jobs with little or no insurance coverage, the problem is exacerbated. Employers have reached the boiling point with health insurance costs, and they are beginning to increase employee deductibles and coinsurance, passing the cost on to their employees. The insurance companies are tired of paying the shortfall for all the other payer classes. Consequently, insurance companies are beginning to negotiate deep discounts and alternative payment systems. This creates a great dilemma for hospitals. There is no one left to absorb the cost of the uninsured.

Hospitals Are Left with Few Acceptable Business Options

Many hospitals in North Carolina have run out of ways to recoup the cost of providing free care, and they are now losing money on their bottom lines. Where does the money come from to fund those losses? Like any business, losses come out of surplus—surplus that should be used to replace worn out plant and equipment and purchase new technologies. Hospitals operate in a high-tech, labor-intensive environment, and they cannot survive without the latest technologies. When a hospital uses its surplus to fund loses from operations, sooner or later, they have either to cut services drastically or close. Unfortunately, we have some hospitals in North Carolina that are now in that situation. We also have many hospitals that are currently losing money and will be in that situation if nothing is done to break the cycle.

How do we break the cycle? If hospitals were like other businesses, they would simply discontinue unprofitable services, add profitable lines, lay off employees, and certainly stop giving away their services. As we all know, none of these solutions will work for hospitals, particularly the not-for-profit community hospitals. We are not here simply to make a profit. The services we provide are essential to the community. Our mission is to improve the health of our community, regardless of patients' ability to pay, regardless of how profitable or unprofitable the service is. We are the last place for many patients to go. We are their "safety net." Our emergency rooms are full, and we will continue to take care of them as long as we can. Unfortunately, under the current system, our days are numbered.

Suggestions for Change

So, what are we going to do? I will share a few of my suggestions. First, we, meaning all of us, providers of care, insurance companies, Medicare, Medicaid, etc., must quit playing the blame game. We are in this fix because we have spent the last four decades blaming each other for these problems. Our problems will continue until we all come together and take equal responsibility for fixing them. Hospitals and healthcare providers should not be the fall guys in the system. The enormous burden of the uninsured must be borne by all of us.

Second, we need meaningful reform on the legal side of healthcare. Regardless of who is right or wrong about tort reform, the legal climate is terrible. At one time in this country, many of our physicians came from physician families. Now, physicians are encouraging their kids to go into other fields. The fear of malpractice suits, complicated billing and payment systems, and government regulation is discouraging new physicians from going into private practice. In order to have enough physicians in rural areas, hospitals are forced to contract with physicians as employees or guarantee them a fixed income. This further depletes hospital resources and puts them at financial risk.

A very large hidden cost in our system is the increasing volume of unnecessary diagnostic testing. Fear of being sued is the number one reason why physicians order so many tests. The number of MRIs, CT scans, x-rays, etc. are growing each year, simply because physicians are afraid not to order them. One lawsuit can destroy a physician's livelihood. Most physicians feel trapped in a system where sensible, conservative medicine can no longer be practiced. Defensive medicine is costing us a fortune.

Last, we must educate our communities. Not only do we all need education on healthier lifestyles and preventive medicine, but also we must learn to make wise choices about our care. We must also learn to form reasonable expectations about our healthcare system. Everyday, I am amazed at the level of dedication exhibited by our healthcare workers. They are compassionate and caring. They work around the clock to be here whenever we need them. But, medicine is not an exact science, and people are not perfect. We need to take the profiteering out of our legal system. **NCMJ**

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Public Health Departments:
The Under-funded Provider of Last Resort

George F. Bond, Jr., MPH, and Wanda L. Sandelé, MPH

To understand a healthcare safety net, perhaps we should begin by reflecting back on our days as children at the circus watching that daring young girl on the flying trapeze and her strong "catcher," both poised 50 feet above the floor. The only thing standing between them and certain death is that thin rope safety net just above the floor. With that image in mind, three basic characteristics of a safety net stand out. First, it is *effective* in avoiding certain death, it must work! Second, it should offer *complete* coverage. A net, covering 90% of the arena is useless to those who fall on the 10% not covered. Third, the *net must always be there*. Do you recall when the ringmaster called for the removal of the net for the last five minutes of the act just to heighten tension and excitement in the audience? When the poles holding up the net were removed, it fell to the ground and *there effectively was no safety net!*

Let us now turn our thoughts from the circus to an examination of the healthcare safety net in North Carolina. When most healthcare professionals define the healthcare safety net, they include payment sources such as Medicaid and Health Choice; they include rural health centers and free clinics; and they almost certainly will include federally qualified health centers (FQHCs) and FQHC look-alikes. Rarely is the local health department mentioned in these definitions, even though the evidence clearly shows them to be an integral part of the net and indeed the "provider of last resort" in many North Carolina counties.

Effective?

Traditional safety net providers would like to be 100% effective in providing care for the uninsured and underinsured. Sadly, however, they are seriously under-funded by state and federal sources to respond to that need. Their funders, and indeed their own balance sheets, tell them that they need to be self-sufficient. Thus, when times get tough, co-pays, deductibles, and lab fees go up by necessity, and sometimes patients without a payment source are turned away. Last year, local health departments provided more than $11 million in un-reimbursed prenatal care alone to low-income clients who could not pay for their healthcare. When community health centers have to turn away patients because of mounting operational deficits, those patients go to the *local health department*.

> *"Public health is known as the 'silent miracle' because the process of preventing epidemics, assuring food safety, and providing clean water is invisible and, all too often, taken for granted."*

Complete Coverage?

Community health centers are located all over North Carolina, but coverage is still incomplete. In western North Carolina, for example, there are community health centers in Hot Springs, Asheville, and Hendersonville; but beyond that line, there is not a single community health center in any of our eight western-most counties. Those eight counties tend to be poor, they have high unemployment rates, and they meet virtually any definition of medical need. Probably because of

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their sparsely populated nature these counties have not been attractive sites for new community health centers. However, every single one of those eight counties has a *local health department*! Local health departments last year provided an estimated *$40 million of uncompensated care*!

The Net Is Always There?

Across North Carolina, community health centers have grown up as independent, freestanding organizations with consumer boards. While independence has advantages, it leaves community health centers financially vulnerable because they are not connected to a "deep pocket" such as a county government, a hospital, or a university. Thus, when the local economy stumbles, cash flow constricts, and there are only limited reserves from which to draw. Either fees have to go up, or costs have to come down. Either way, access for the low-income patients is threatened. Our rapidly increasing Hispanic population faces financial challenges as well as language barriers to health access. Health departments are required by the Civil Rights Act to serve this challenged population. There is a local health department within a 30-minute drive of every resident in every county in North Carolina.

We should all be proud of our fine system of community health centers working tirelessly in our state delivering quality healthcare. However, we cannot say in good faith that those traditional safety net providers alone form an impervious healthcare safety net. In fact, there are large holes in that net, both in terms of eligibility and geography. There is, however, a system already in place with buildings that deliver healthcare in every single county in North Carolina. There is at least a minimal level of healthcare staffing on the payroll of a "deep pocket" that either already provides, or has the potential to provide, primary care to the uninsured and underinsured in every county. There is already access to at least some basic level of clinical service in all 100 counties from Hanging Dog in the west to Hatteras on the coast. That system is our 85 *local health departments*. We believe that the current value and future potential of health departments as safety net providers have largely been overlooked.

Public health is known as the "silent miracle" because the process of preventing epidemics, assuring food safety, and providing clean water is invisible and, all too often, taken for granted. Public health is the "provider of last resort." The term suggests that the local health department somehow miraculously picks up the loose ends when the private sector either finds certain services or segments of the population unprofitable or inconvenient. "Provider of last resort" also suggests that the care is of lesser quality and only a temporary, desperate measure that must suffice until something better comes along. The truth is that thousands of citizens receive high-quality clinical service from their local health departments, perhaps because they have an overdue balance at their private provider, or since no other provider accepts Medicaid, or maybe because of their transportation and language challenges. We in public health are honored to be able to fill some of today's gaping holes in the safety net.

Because we are required to complete a Community Health Assessment every four years, health departments learn about access problems through our data gathering and analysis. A health department that chooses to embrace the function of "provider of last resort" unfortunately positions itself to operate continuously in a crisis mode, especially when the economic climate or the personality of the healthcare community changes. Most health departments do not have large primary care programs, but maintaining even a small clinical program assures capacity and allows for rapid expansion to greater volume when circumstances dictate. Such was the case in one eastern North Carolina county where the only two obstetrical practices merged and decided that they could not see pregnant women covered by Medicaid. Overnight, the prenatal workload at the health department more than tripled. This could not have been accomplished on such short notice if the program did not already exist. Since expansion is always easier than absolute creation, local health departments struggling to serve the low-income population have more than once questioned why a brand new community health center gets approved, funded, and built right down the street when the dollars could better be spent shoring up their existing program.

The explanation for this apparent lack of collaboration lies both in federal regulations and in state law. The system of FQHCs, begun in the 1960's to extend primary care access, did not allow North Carolina health departments to fulfill that vital community role, even though a number were already major providers of such services in their communities. By federal regulation, an FQHC must have a board with a majority of consumers. Standing in direct opposition, North Carolina statutes do not currently permit a board of health, which governs the health department, to exist in that form. That artificial barrier to FQHC status needs to be removed. We are pleased that the North Carolina Healthcare Safety Net Task Force Report[1] contains a recommendation for the removal of the legal barrier that prevents health departments from becoming FQHCs.

Adequate Funding

The real problem with the safety net lies not at the feet of the providers. The problem is that *no one has adequately funded care* for the uninsured at the federal, state, or local levels. It matters not whether the organizational structure is run by a consumer-dominated board, a hospital board of trustees, or a board of health—somebody has to be willing to "foot the bill" for those who cannot pay. Even though the public health department directors are prone to complain about other members of the safety net who are not seeing their "fair share" of the indigent, in reality, the only way any of us are able to see the uninsured is through a combination of donations or local appropriations and the very skillfully orchestrated practice of cost-shifting. Even though health department staff are government employees, they still must be paid, they still have to buy medical supplies, and there must be phones and heat in the building. County Commissioners in some counties have chosen to support their local health departments in the provision of medical service to the uninsured. That does not render medical care at the health department free; it just means that someone has accepted a responsibility to pay for care not covered by insurance. All we really need in this state to complete our safety net and make it impervious—stretching from the mountains to the shore—is funding for the uninsured. We already have a voucher system available to some providers to pay for the uninsured. If that program could be expanded significantly, if federal dollars can be attracted to support new FQHCs, and if statutory barriers to FQHC status for local health departments could be removed, then North Carolina, as a state, with all the safety net providers working together as a system, can and will address the needs of those who currently are denied routine access to our healthcare system.

In a nation that long ago walked on the moon and currently supports over 125 heart transplant centers, surely we can muster the political will to solve the problems with our safety net. Health departments can play a significant role in the implementation of that solution. President Bush has proposed a dramatic increase in the numbers of community health centers across the nation. Federal dollars of this magnitude have not been available for many, many years. We must aggressively act on this historic funding opportunity. We must also pledge to work together to develop a reliable funding stream to cover uninsured patients.

Forty years ago, President John F. Kennedy challenged the nation to put men on the moon by the end of the decade. We need that same kind of bold political leadership in North Carolina to answer the problems of the uninsured. The uninsured cannot solve the dilemma of access to care for all North Carolinians. They do not speak for themselves with a loud political voice. In fact, they may not speak at all, or they could speak in a foreign tongue. However, we can and we must speak for them! **NCMJ**

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COMMENTARY

Pharmaceutical Companies Meet the Needs of the Poor and Uninsured:

An Important Element in the Healthcare Safety Net

J. Andrew Hartsfield IV, JD

> *"I am writing to say that I really appreciate the help you gave me in getting my medications. . . You may not realize how life-saving you are. . . I can never thank you all enough for helping me when I so desperately needed it."*
>
> — Excerpt from patient letter to GlaxoSmithKline

Our government spends hundreds of billions of dollars on healthcare entitlement programs every year, the largest programs being the federal Medicare program for senior citizens and the disabled; the federal/state Medicaid program for low-income patients; and the State Children's Health Insurance Program for children, up to age 19, who are not already insured. Despite the scope of these programs, there are many low-income people who do not qualify for any of them. These people depend on the complex and vast array of sometimes confusing public and private programs that make up the healthcare safety net.

As part of their commitment to improving access to medicines, pharmaceutical companies play an important and essential role in helping low-income, uninsured, and other vulnerable populations get the medicines they need as part of this safety net.

At GlaxoSmithKline, we do not want a lack of insurance coverage or financial means to put a patient at risk by causing them to either not fill a prescription or to fill it through unsafe channels. Thus we—like most other major pharmaceutical companies—offer programs designed to ensure that vulnerable populations get the prescription drugs they need.

> *"As part of their commitment to improving access to medicines, pharmaceutical companies play an important and essential role in helping low-income, uninsured, and other vulnerable populations get the medicines they need as part of this safety net."*

Pharmaceutical Industry Patient Assistant Programs

More than six million patients across America received more than 22 million free or discounted medications with a wholesale value topping $4.17 billion from pharmaceutical companies last year.[1] Expanded outreach efforts continue to increase use of these programs.

The industry also launched an innovative program that serves as a clearinghouse for the more than 275 public and private prescription assistance programs available. Augmenting these efforts, the industry's trade association, PhRMA, launched a new web site, www.pparx.org, making it much easier to learn about the many different public and private programs available and to identify ones that can help patients on an individual basis. These efforts are designed to increase awareness of and enrollment in existing programs.

As part of these efforts, GlaxoSmithKline's patient assistance programs, Bridges to Access and Commitment to Access™, provided over $372 million worth of prescription medicines to eligible low-income, uninsured patients in the United States

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during 2004. In North Carolina alone, more than 25,900 patients received medicines worth nearly $20 million from GlaxoSmithKline.[2] Importantly, GlaxoSmithKline's programs also provide a bridge for patients, offering coverage under the program during the time a patient applies to other programs, such as the AIDS Drug Assistance Program, where waiting lists and delays can often mean a long wait for the patient.

The success of GlaxoSmithKline's and the industry's programs are rooted in the local support of community health groups, physicians, and many others. Working together, these partnerships reach out to vulnerable individuals, conduct training sessions on enrollment, and spread the word that help exists for people who need it.

Discount Card Programs

Pharmaceutical company patient assistance programs are one important part of the safety net, but there is also help for patients who don't qualify for these programs due to income. Many pharmaceutical companies also offer free discount card programs through which qualified individuals can receive significant discounts on their medicines. A few programs are highlighted below.

Orange Card^{SM}

GlaxoSmithKline introduced the Orange Card^{SM} in 2001. It was the first such manufacturer discount card offering significant savings for low-income senior citizens. More than 175,000 seniors, including 13,000 North Carolina seniors, have an Orange Card^{SM}. Through the Orange Card^{SM}, qualifying seniors can get their GlaxoSmithKline medicines at a savings of about 20-40% off the usual price paid. To qualify, Medicare beneficiaries must have no public or private prescription drug insurance and have an income under $30,000 for a single person or under $40,000 for a couple.[*]

Together Rx Card™

Soon after the launch of the Orange Card^{SM}, seven pharmaceutical companies created the Together Rx™ free prescription drug savings program. Together Rx™ is a discount card through which the participating manufacturers offer savings of approximately 20-40% off their brand-name medicines. Patients can save on more than 155 FDA-approved medicines, and some pharmacies offer savings on generics as well. Medicare enrollees who have no other prescription drug coverage and earn less than $28,000 ($38,000 for couples) are eligible.[†]

Resources for Drug Assistance

America's pharmaceutical companies want patients to be able to get the best and safest medicines available. For low-income patients there are a number of resources and programs available to help. Here are some web sites that provide information on programs and eligibility requirements:

HelpingPatients.org
www.helpingpatients.org

GSK Orange Card^{SM}
www.OrangeCard.com

Together Rx Card™
www.Together Rx.com

Together Rx Access Card™
www.TogetherRxAccess.com

Bridges to Access™
Bridgestoaccess.gsk.com

Commitment to Access™
commitmenttoaccess.gsk.com

Medicare
www.medicare.gov

Nearly 1.5 million seniors, including more than 75,000 North Carolina seniors, have a Together Rx™ card, and to-date seniors have saved over $700 million on their medicines.

Both the GlaxoSmithKline Orange Card^{SM} and the Together Rx™ card will be available until the Medicare prescription benefit takes effect in 2006.

Together Rx Access Card™

The Orange Card^{SM} and the Together Rx™ card programs provide savings for low-income Medicare beneficiaries. Yet, there are millions of Americans who lack health insurance that don't qualify for Medicare. In January, GlaxoSmithKline and nine other major pharmaceutical companies introduced an innovative program to fill that gap and help many of those uninsured. The Together Rx Access Card™ helps Americans without prescription drug coverage better afford their medications by providing them with meaningful savings on many brand-name and generic products—at local pharmacies.

To be eligible, individuals must not be eligible for Medicare, have no prescription drug coverage (public or private), and

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[*] Income limits may be different in Alaska and Hawaii; GlaxoSmithKline (GSK) expects Orange Card^{SM} participants to realize out-of-pocket savings ranging from 20-40% of the price individuals without drug coverage would usually pay their pharmacies for GSK medicines. Actual savings will vary depending on a pharmacy's customary pricing for a specific GSK medicine. GSK offers Orange Card^{SM} participants direct savings on their outpatient GSK prescription medicines equal to 25% of our wholesale list price. See application for important details and limitations.

[†] This program is for Medicare enrollees who have an annual income that is less than $28,000/singles ($38,000/couples) and do not have prescription drug coverage (public or private); this range of savings reflects the savings presently offered. Savings may vary depending on a pharmacy's customary pricing for a specific medicine and the savings offered by the participating company that makes it. (Participating companies independently set the level of savings offered and drugs included in the program. Those decisions are subject to change.) Income limits may be different in Alaska and Hawaii.

have a household income equal to or less than $30,000 for a single person, $40,000 for a family of two, or $50,000 for a family of three.[‡] Participants can expect to save about 25-40%—and sometimes more—off the usual pharmacy price paid on these prescription products. More than 275 FDA-approved prescription products, as well as a wide range of generics, from 10 major pharmaceutical companies are included in the program, including dozens of medicines used to treat diabetes, hypertension, high cholesterol, cancer, allergies, asthma, arthritis, and depression, which are among the most common conditions affecting Americans. Together Rx Access™ could benefit approximately 80% of the 45 million Americans—including more than eight million children—who are uninsured and don't have prescription drug coverage.

Ninety-eight percent of pharmacies nationwide will accept the Together Rx Access™ Card. The goal of the Together Rx Access Card™ is to help the millions of Americans without prescription drug coverage gain access to the prescription products they need and to help them take care of what's most important—their health. Since January, Together Rx Access™ has enrolled more than 300 uninsured North Carolinians.

Medicare Prescription Drug Benefit

One of the most important recent efforts to increase access to healthcare was the enactment by Congress of a Medicare prescription drug benefit. Enrollment for the Medicare prescription drug benefit begins in November 2005, and it is an important change in the nation's healthcare safety net. Beginning in 2006, Medicare beneficiaries will have access to a benefit that will cover outpatient prescription drugs. The benefit will be administered by private prescription drug plans, and seniors will have a choice of which plans to join. The new program is especially beneficial to low-income patients. They will get full coverage with minimal copays and will not have to pay premiums or deductibles. Every low-income senior citizen should take advantage of the new Medicare prescription drug benefit. Also, seniors with high prescription drug costs can benefit from the catastrophic coverage offered under the new benefit.

Until the prescription drug benefit goes into effect, there are Medicare prescription drug discount cards available. These cards offer discounts on prescription drugs and can charge a premium. But again, for low-income seniors, these cards are a great deal. Qualifying low-income seniors can get a card with up to $600 already available for them to use toward the purchase of prescription drugs.

Conclusion

Lack of access to even basic medication and healthcare facilities is a situation nobody should experience. GlaxoSmithKline recognizes the importance of our nation's healthcare safety net and is committed to playing a role in helping people avoid this crisis. No single organization can produce a solution; we will continue to work with other stakeholders to improve the health of our nation and improve our healthcare system. **NCMJ**

[‡] Savings may vary depending on the pharmacy's customary pricing for each product and savings offered by the participating company that makes it. Participating companies independently set the level of savings offered and the products included in the program. Those decisions are subject to change. Income limits may be different in Alaska and Hawaii.

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COMMENTARY

Free Prescriptions? Yes, There Is a Way!

Margaret P. Elliott, MPA

There may not be such a thing as a free lunch, but you can get your prescription medication free if you qualify. Just ask the Martin family. I'll never forget their story. This couple's niece called from Ohio to our free pharmacy to see if anyone could help her aunt and uncle whom she discovered were paying $700 per month for their prescription medications. To make matters worse, she learned that they were paying for them by charging the cost of their medications on a credit card. In debt, reaching beyond their ability to ever pay it back, the Martins turned to Crisis Control Ministry in Winston-Salem, which houses North Carolina's first state-licensed free pharmacy.

In one hour's time, after an interview to determine the couple's financial situation, the Martins were enrolled as certified clients of our pharmacy, and able to have their $700 worth of prescriptions filled for free! In addition, our pharmacy was spared the cost of their medications, thanks to the drug assistance programs offered by the pharmaceutical companies who manufactured the couple's medications. By completing applications that verified their inability to pay, our staff helped steer this couple through the guidelines of programs that vary depending on the company. Their medications were mailed to a local physician and dispensed to the couple at our free pharmacy.

Just six years ago this scenario was very different. Every day the free pharmacy staff faced very real challenges to meeting the needs of the individuals who visited us and could not afford their life-sustaining prescription medications. Even though we purchased medications, some were just too expensive to buy. If we happened to have received some sample donations from local physicians, we called it providential and were grateful to have the donation to dispense. Unfortunately, that didn't happen every day. We had to ask some patients to call back later to see if we received the medications. We had to tell others that we just didn't have their medication, and we couldn't afford to buy them, even at a discount wholesale price.

In 2000, the annual budget for Crisis Control Ministry's free pharmacy in Winston-Salem was $400,000. Four years later, we operated on less than half that budget, with costs offset by donated drugs. In 2003-2004, we dispensed nearly 34,000 prescriptions, 21% more prescriptions than in 2000—medications valued at over $2.1 million on a $197,000 budget thanks to pharmaceutical donations from local nursing homes and our participation in helping patients enroll in pharmaceutical companys' Patient Assistance Programs (PAPs). In 2004, our free pharmacy received $423,000 worth of drugs from drug manufacturers—drugs that we earlier had purchased or simply could not afford to provide.

Many people are no longer able to afford their medications due to the rising cost of prescription drugs. These individuals may be eligible for the patient assistance programs and discounts offered by pharmaceutical companies, but these programs are complicated. They are all different, and it is not always easy to get the information you need to use them.

> *"One of the most important roles we play as advocates and human service providers is educating and helping our neighbors in need to access the services that are available to them."*

Pharmaceutical manufacturers have designed programs to serve the most financially needy patients, those who lack health insurance or financial resources, and those who have exhausted all other options to cover needed medications. Though these programs are very beneficial, locating information and navigating through the complex application process is sometimes an overwhelming task.

The majority of brand name as well as generic medications are available through PAPs. Although eligibility requirements vary according to manufacturer, there are requirements that typically must be met:[1]

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- *United States Residency.* Depending on the program, some companies simply require that patients be permanent residents of the United States. Others require that they reside in the United States legally and others require United States citizenship.
- *No prescription coverage.* The patient must not be covered or eligible for coverage under any public or private insurance that covers prescriptions.
- *Low income.* Each company has its own eligibility standards regarding income. Most will not provide assistance to patients with monthly incomes that exceed 200% of the federal poverty guidelines.
- *Chronic medical conditions.* Patients who require on-going medication to treat chronic medical conditions are typically the only patients who will qualify for assistance. Since the application process may take several weeks, these programs are usually not appropriate for acute medication needs.

Benefits of Patient Assistance Programs

There are many benefits of PAPs to patients, healthcare providers, communities, and drug manufacturers. Patients are provided access to much needed, sometimes life-sustaining, prescription medications for free or at a reduced cost. This enables the patient to use his or her remaining financial resources to provide for other basic life needs, such as food and shelter. The patient experiences less emotional stress and, with the provided medication, has improved health.

Healthcare providers benefit because the patient stays compliant with a recommended course of treatment. There are fewer trips to the emergency room and fewer admissions into nursing homes. Sample medications can be used for other purposes.

The community benefits by supporting safety net providers who help provide access to the PAPs. Resources saved can be directed toward other needs in the community.

Drug manufacturers, who are not required to offer these programs, benefit with PAPs by providing an opportunity to contribute to improved patient outcomes. PAPs also allow companies a marketing opportunity, help with public relations efforts, and offer potential tax deduction.

Details of Patient Assistance Programs[1]

Individual Programs. The complexity of accessing free medications through PAPs is revealed in the challenges one faces while completing the applications. The eligibility criteria, system of medication delivery (either to the patient, the physician, or accessed through a voucher to use at a retail pharmacy), and application forms are different for each program. Safety net providers, such as free clinics or social workers, assisting patients with the process must learn the criteria of each company's program.

Access to forms. Most forms are available on the pharmaceutical company's website or through specialized software that accesses the forms. Some forms must be requested each time a patient is identified. Waiting to receive a form in the mail only delays the application process.

Citizenship/Residency requirements. Many programs require patients to be legal residents or United States citizens to be eligible for PAPs. This serves as a barrier in communities that seek to serve undocumented residents or those who are not yet citizens.

Frequent changes. The application process, the medications covered, and the eligibility criteria can change quite often; therefore, it is imperative that healthcare providers keep up with them in order to complete the patient enrollment forms correctly.

Long waiting times. It is not unusual for a patient to wait four to six weeks to receive medication ordered through a PAP. During these waiting periods, healthcare providers and safety net providers must seek other ways to access medications to provide for the immediate needs of the patient.

Reapplication required. Many programs provide only a 90-day supply of medication and require the patient to reapply for the next supply. This requires a tremendous amount of organization and reminder cues to ensure continuity of care for enrolled patients.

Detailed documentation. Supporting documentation necessary to qualify for patient assistance programs sometimes includes pay stubs, tax returns, or a letter from the Medicaid office verifying that the patient was denied enrollment in that program.

Conclusion

Though the process of acquiring free medications from pharmaceutical providers is tedious and time consuming, the cost savings to safety net providers is worth the effort. One of the most important roles we play as advocates and human service providers is educating and helping our neighbors in need to access the services that are available to them. The safety net providers in our state are aptly described as being part of a patchwork system of responders who attempt to meet the needs of individuals and families who lack financial resources and are part of the growing number of uninsured. I recently was invited to meet with the presidents of two local hospitals. One of them had never even heard of patient assistance programs offered by pharmaceutical manufacturers. I was not so surprised. I am the first to say that the patchwork of services such as those provided at free clinics and free pharmacies across the state are not the long-term solution for the uninsured population. In the meantime, until the political process allows for affordable health insurance for all of our residents, we safety net providers become experts at pooling our resources and at figuring out ways to serve the economically poor families whose healthcare needs would otherwise be unmet. **NCMJ**

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COMMENTARY

Integrating Multiple Service Providers in Service to the Poor and Uninsured:

The Critical Conditions for Effective Collaboration

Thomas G. Irons, MD

Roberta Burgess, a HealthAssist Nurse Case Manager, was made aware through community contacts that Mary M. was in trouble. An employed but uninsured 49-year old woman who lived alone in a mobile home, she had become morbidly obese and was about to lose her job. She was woefully under-medicated and rapidly progressing toward disability and irreversible cardiovascular disease. Roberta made a home visit, finding Mary barely able to rise from of her chair or walk without assistance. With the help of Lynn Howard, a project social worker, she found Mary a walker and, with her, embarked on a journey of recovery. First it was necessary to control her diabetes, hypertension, and hyperlipidemia. Regina Coyle, a nurse practitioner, saw her in a series of clinic visits, prescribed appropriate medications, and placed Mary on a carefully limited exercise and weight-loss program. Meanwhile, HealthAssist team members were making contacts with several community and state agencies. The progress toward recovery was slow but continuous, and in 2004 Mary had successful gastric bypass surgery, funded by the North Carolina Division of Vocational Rehabilitation Services. As of this writing, she is employed full-time and soon will require no HealthAssist services. Roberta said recently, "She came by to see me and I hardly recognized her. She looked wonderful!"*

*HealthAssist is the original program component of the Eastern Carolina Community Health Consortium (ECCHC).

> *"In no case has complete integration been approached, but many have achieved broad-based, genuine collaboration among diverse entities."*

For a long time now, I have, on a few moonless nights every year, fished a flounder net in the lower Pamlico River. Because of its large and flexible 5 1/4 inch mesh, it spares most other fish, and the flounder's physiology allows him to rest on the bottom until I remove him. Around mid-July and extending into mid-September, blue crabs become a serious problem. The ones I usually catch are free-swimming as "doublers," meaning they are occupied with the business of reproduction. They get themselves all wrapped up, and I often must break a strand to get them out. One broken monofilament strand doubles the size of the hole formed by the mesh, and pretty soon, as we say Down East, I've got "holes you could walk through." One might say, stretching the metaphor a bit, that the fisherman's success depends on the "connectedness" of his net. Once it gets really "holey," he'll still catch a few flounders, but most will escape. The healthcare safety net is disturbingly similar. At best it is a fragile, "patchwork array," with certain relatively consistent components, the compromise of any one of which can create a major service gap. A brief look at those components might be helpful.

The Components of the Healthcare Safety Net

Most communities of medium-to-large size have at least one free clinic and even some small rural areas have found ways to provide limited, part-time free health services. In addition to primary care services, these entities often provide medication support, ranging from sample distribution to helping clients access drug company programs and/or purchasing and distributing limited

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medications. In some cases, pharmaceutical assistance is provided, but there is no direct healthcare. Public health departments, in addition to their traditional prevention-focused programs, provide a range of primary care services ranging from minimal to comprehensive, the outstanding example of the latter being in Buncombe County. These exceptional programs notwithstanding, few public health departments can provide medication support outside that required for management of sexually transmitted diseases, pregnancy prevention, and tuberculosis. The community health centers often referred to in this report as federally qualified health centers (FQHCs) are the most economically viable model for comprehensive indigent health services, and some across the state have done so with remarkable effectiveness. Greene County Health Care, headquartered in the tiny rural community of Snow Hill, recorded encounters with over 18,000 people last year. They offer comprehensive primary care including prenatal services, dental care, and an award-winning Latino outreach program. Still, despite the so-called "President's Initiative," new center applications are highly competitive, and regulations prohibit establishing centers in many areas. Private physicians carry a share of this burden as well, depending upon variables such as work-load of insured patients, the availability of volunteer "off time," and the availability of Project Access-like programs that allow them to provide donated services within an organized structure. Public hospitals, of course, bear a huge "charity care" burden. There are many other community organizations and agencies, both public and volunteer, providing human services that are essential to improving the health of low-income people.

> *"Early on, we agreed on a simple sentence that captures the essence of this element: 'We will do what is right, we will do it well, and we will do it together.'"*

How Likely Is Collaboration or Integration to Occur?

Across the board, these services are rarely integrated, though notable exceptions exist. Among them, Community Care of North Carolina (CCNC) has had the greatest impact. Thanks in large part to the visionary leadership of Allen Dobson, MD, President of Community Care of Cabarrus County, and James D. Bernstein, founding Director of the state's rural health program, CCNC has managed to contain Medicaid cost increases, while significantly improving health outcomes and provider and patient satisfaction. Using a nurse case management strategy and depending upon volunteer physician leadership, it has helped communities across the state coordinate services to Medicaid recipients. There are a number of local examples, often operating in coordination with CCNC. Many have been temporarily funded under the United States Health Resources and Services Administration Healthy Communities Access Program (HCAP). These include, but certainly are not limited to, the Eastern Carolina Community Health Consortium (ECCHC), headquartered in Greenville, the above-mentioned Buncombe County coalition, and a similar one operating in Cabarrus County. In no case has complete integration been approached, but many have achieved broad-based, genuine collaboration among diverse entities.

The Essential Elements of Community-Level Collaboration

As I have traveled around the state to advise others engaged in this work, I have spent many hours reflecting on the elements of successful programs. The following five components are, I believe, the essential ones:

- *The Right Kind of Leadership.* Organizational self-interest ("turf") and mutual mistrust are the absolute enemies of collaboration. Public service and charitable entities are far from immune to these and cannot easily set them aside. One who leads these coalitions must be generally well-known, absolutely trustworthy, and have the maturity to put aside personal biases and respond in a non-reactionary way to negative or confrontational situations. Often these are physician leaders, like Allen Dobson in Cabarrus, Lindsey De Guehery in Wilson, and many others.

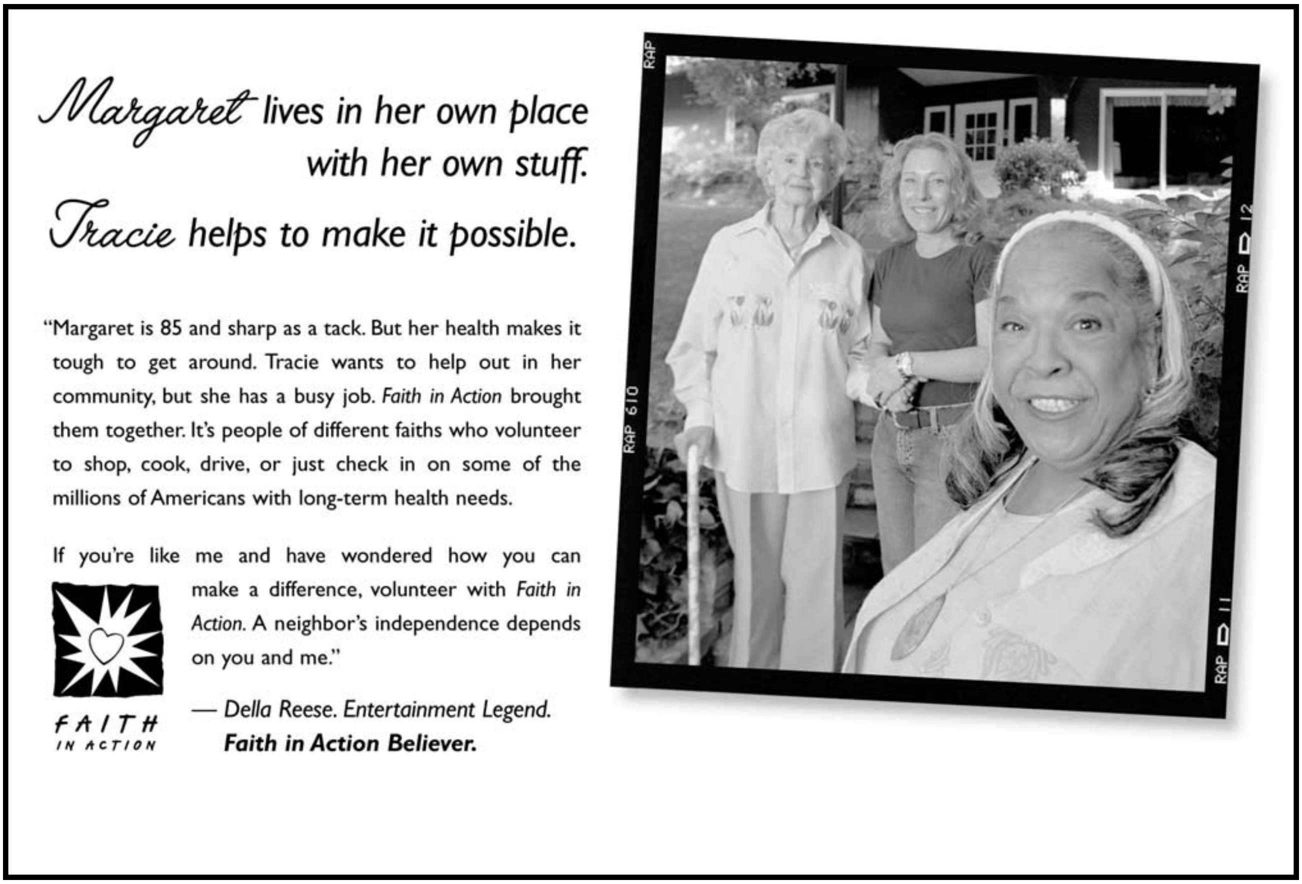
- *A Clear, Simple, and Continually Reinforced Value.* Collaborators must agree upon a common value that can be easily articulated. In the eastern North Carolina group, we agreed that all are committed to improving the health status of poor and low-income people, *period*. When conflict has arisen or our spirits have lagged, we have stopped and asked, "What are we here for?" reinforcing this core value. Early on, we agreed on a simple sentence that captures the essence of this element: "We will do what is right, we will do it well, and we will do it together."

- *A Source of Funding.* Many would list this component first. I do not for two reasons. First, acquiring funding before genuine collaboration has been achieved is a sure prescription for failure. All of us who are engaged in this work can cite numerous examples. Secondly, it is not only possible to build a coalition of committed partners with little or no outside funding, it is essential. If the entities involved are not committed to each other and the coalition's core value, the program will fail whatever its financial condition. On the other hand, programs that can demonstrate in a grant application or site visit that genuine collaboration is present are far more likely to be funded.

- *Inclusiveness.* No community is likely to be successful in bringing all stakeholders to the collaborative table. Still, coalitions should make it their goal to do so. In building the ECCHC, we faced numerous threats. Perhaps the most serious one was the historically strained relationship between the components of the University Medical Center and Greene County Health Care (GCHC). Program leaders recognized early on that GCHC could bring extraordinary strength to the coalition, and GCHC leaders, likewise, saw the need for healthy partnership. Solving this problem required clear communication about issues of disagreement and demonstrated commitment from both parties to rebuilding trust. This was slow and difficult work, but its success was assured from the beginning by the mutual commitment of leaders from both entities to effective collaboration. Much of this work was done in a highly productive series of private meetings between the GCHC Executive Director, Doug Smith, MBA, and this author. In another example, these same entities are cooperating in the construction of a 15,000 square foot community health center in northern Pitt County, with GCHC agreeing to operate the center as an expansion site. This expansion could compromise an important program operated by the Pitt County Health Department, its prenatal care clinic. Because the Pitt County Health Director, Dr. John Morrow, is an active coalition leader, discussions among the appropriate parties were held early on and the potential conflict averted.

- *Flexibility.* Finally, successful coalitions, like my flounder net, must have sufficient flexibility to stretch as much as possible without tearing. Sudden changes in political priorities, funding streams, population need, etc., are inevitable. Such flexibility requires a constant reinforcement of the mission and an underlying spirit of optimism, a belief that doing what is right will ultimately be both successful and rewarding.

My own observation, as one coalition leader, is that I am responsible for upholding this spirit among our partners, and to work continually to praise and thank those who do the day-to-day work. When I find myself discouraged, I remember our vision, and say to myself, often aloud, "We will do what is right, we will do it well, and we will do it together." **NCMJ**



Rising Student Health Needs Require a School Safety Net

Leah M. Devlin, DDS, MPH, and Marilyn K. Asay, RN, MS

The fourth grader was lethargic and gray. Thin to begin with, he had lost six pounds in the past four to six weeks. After two days of very reduced alertness in class, the school guidance counselor and the boy's teacher contacted the school nurse. The nurse, newly hired by the school district as its first-ever nurse, reviewed the boy's symptoms and called his mother for permission to check his blood sugar. The nurse then contacted a local pharmacist who donated blood sugar testing supplies that same day. With a blood sugar of 578 mg/dl, the nurse urged the mother to seek immediate medical attention for her son. The boy was hospitalized and diagnosed with Type I Diabetes. In collaboration with the boy's physician, mother, and teacher, the nurse subsequently began preparing for the boy's return to school by developing a care plan and training the teacher, principal, and counselor in monitoring the student's self-care. The teacher reports that thanks to the school nurse, who identified this child's diabetes and managed his successful reentry into school, this student is "back to his normal self, has more energy, and is learning better."

A freshman came into his high school's health center for a sick visit. While there, the staff asked him to complete a health risk questionnaire in order to get more information about his risk-taking behaviors and conditions. The multi-disciplinary team at the center (which includes a nurse practitioner, nurse, mental health professional, nutritionist, and health educator) treated the young man for high blood pressure, rosacea, and acne and provided mental health and weight management counseling. He was enrolled in the North Carolina Health Choice Program (North Carolina's State Children's Health Insurance Program) and received glasses from the Lens Crafters Gift of Sight Program. By integrating and delivering his medical and mental health services at the school-based health center, this student was able to miss very little school while receiving multiple services, and his mother missed very little work. He is now a senior with a brighter future ahead of him.

At a metropolitan high school, the school nurse splits her attention between two boys. A 16-year-old football player has fallen and may have re-injured a broken ankle. A 15-year-old freshman, taking medication for both bipolar disorder and attention deficit hyperactivity disorder, is feeling light-headed. The nurse examines the students, calls the parents, and assists in coordinating primary care and specialty providers. Across town in another school, with no school-based nurse, the health needs of students are addressed as best as possible by teachers, secretaries, and administrators.

> ***"...each of North Carolina's school nurses [are] responsible on average for approximately 1,900 students, ...rather than the nationally recommended 1:750..."***

These true stories are but three examples of the variety of health concerns that students bring with them to school each day. These health problems impact their ability to be successful in school and require that the school healthcare safety net be strengthened. The needs of students have also changed dramatically in the past ten years, creating increased demands for appropriate care while at school. For example, the North Carolina Annual School Health Services Report for Public Schools for 2003-2004 reported that:

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- Over 161,000 (12%) students suffer from chronic illnesses or special healthcare needs (diabetes, asthma, seizure disorders, etc.).
- More than 14,000 students needed one or more invasive procedures performed during the school day (nebulizer treatments, tube feedings, urinary catheterizations, tracheostomy care, blood glucose monitoring, and the management of insulin pumps, etc.).
- At least 7% of students received medications at school, including controlled substances.

In addition to the growing numbers of children with complex health problems that often require intensive management at school, the prevalence of risk-taking behaviors continues to be elevated. These include substance abuse, homicide, suicide, child abuse and neglect, and developmental problems such as Attention Deficit Hyperactivity Disorder (ADHD). Mental health issues such as anxiety, depression, school refusal, anger, and eating disorders are increasing and are affecting attendance, school performance, and student well being. Prevention programs have become a greater focus in schools, as the obesity epidemic is affecting children and adolescents at earlier ages. One in four North Carolina teens and one in five children ages five to 11 years of age are now overweight. The ability to learn at school is directly related to the status of a student's health. "Students who are hungry, sick, troubled, or depressed cannot function in the classroom, no matter how good the school,"[1] according to the Carnegie Council on Adolescent Development. Students who drop out of school experience more health problems, delayed employment, and poverty. Data from the United States Bureau of the Census underscore that high school dropouts have the lowest expected lifetime earnings compared with workers at all other levels of educational attainment. It is well documented that people in poverty are less likely to have access to healthcare and less likely to engage in healthy lifestyles. The Council of Chief State School Officers and the Association of State and Territorial Health Officials have jointly noted this interdependency between health and education by suggesting that "healthy kids make better students and better students make healthy communities."[2]

> *"The absence of a strong safety net of nurses in North Carolina's schools represents one of our most critical missed opportunities to help children be successful."*

The School Nurse as a Safety Net "First Responder"

When nurses are present in the school, parents often rely on them as first responders for early identification, referral, and follow-up for their children's primary care needs. Often the school nurse is the first person a parent seeks out in order to make a decision about the need for health services. "Go see the school nurse, and if she thinks you are sick enough to go to the doctor, tell her to call me." With each of North Carolina's school nurses responsible on average for approximately 1,900 students (often scattered over a minimum of three to four schools), rather than the nationally recommended 1:750, it is very difficult to provide the level of safe care needed and to assist families in locating and using local healthcare resources. Teachers and other school staff are asked to assume more and more health related responsibilities, and school nurses are expected to provide training and on-going supervision for these individuals.

The North Carolina General Assembly, understanding the school nurse's role in the development of healthy students who are more likely to achieve academic success, appropriated money for the School Nurse Funding Initiative (SNFI) to the Division of Public Health in 2004. The Initiative included an annual state appropriation of $4 million to fund 80 permanent positions and approval of Maternal and Child Health Bureau funds of $3,250,000 annually for 65 time-limited (two-year) positions. Governor Easley has called for 165 additional nurses in the budget over the next two years. Many of these nurses will work in Child and Family Support Teams to further link children at-risk to community services

School Health Centers: A Second Safety Net for Some Schools

With regard to comprehensive services for adolescents, the safety net in most communities is thin. While access to comprehensive services has improved for some adolescents in the state, most service delivery remains fragmented and categorical, with treatment for illness, sports physicals, mental health services, or counseling for nutrition concerns all being provided at different locations. School-based and school-linked health centers located on or easily accessible to school campuses have brought comprehensive, "one-stop-shopping" opportunities to adolescents and a focus on emerging health problems. The obesity epidemic, for example, is receiving increased attention in these centers as evidenced by the requirement for state-funded health centers to include a body mass index (BMI) performance measure.

With parental permission, students can receive help in these health centers for a variety of medical and psychosocial needs. Currently, there are 27 comprehensive centers operating in middle and high schools in the state and another 12 centers that provide primary care services delivered by nurse practitioners or physician assistants.

Health Is Academic

With high school graduation rates falling in North Carolina from 64% in 1990 to 60% today, it is essential that every student has access to healthcare and the opportunity to develop healthy behaviors so they can learn and graduate. The absence of a strong safety net of nurses in North Carolina's schools represents one of our most critical missed opportunities to help children be successful. Closing the health disparity for children is a critical strategy to close the achievement gap. We must ask ourselves, "Have we done all that we can to make certain that children and teens are ready and able to learn supported by healthy families?" North Carolina is now answering this question under the leadership of the Governor, the General Assembly, the State Board of Education, local schools, and health departments with their respective boards. The State Board of Education is also requiring all districts to create School Health Advisory Councils bringing parents, healthcare providers, and community organizations to the school health table as well. This momentum is critical, for it will take all of us working together to strengthen the school health safety net and thereby our children's chances for success in school. **NCMJ**

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COMMENTARY

AHEC Teaching Clinics in Service to the Uninsured

Thomas J. Bacon, DrPH

One of the primary reasons for establishing the North Carolina Area Health Education Centers (AHEC) Program in the early 1970s was to create a statewide infrastructure to expand the training of primary care physicians in the state. With support from the North Carolina General Assembly, AHEC today supports eight residency programs in family medicine, four in internal medicine, four in obstetrics and gynecology, three in pediatrics, and three in surgery. These programs employ 260 full-time faculty and 285 residents, which is nearly 15% of the total number of residents in training in the state.

These AHEC residency programs, in close partnership with their community teaching hospitals, provide a significant amount of safety net care throughout North Carolina. As with teaching programs across the country, the clinics operated by these residencies and teaching hospitals take all patients, regardless of ability to pay. In addition, the teaching services serve as the means to admit patients to hospitals that come through the emergency room and have no regular physician. Frequently, these patients do not have insurance coverage.

> *"...AHEC residencies work closely with other safety net providers to create better systems of care."*

During 2003-2004, AHEC teaching services provided more than 450,000 outpatient visits and more than 184,000 inpatient visits of care. Nearly 100,000 of these outpatient visits were for uninsured patients, and more than 36,000 of the inpatient visits were for uninsured patients. AHEC clinics also have high numbers of Medicaid and Medicare patients, and the reimbursement rates of both public programs have not kept up with the rising costs of care.

Beyond their own clinics, AHEC residencies work closely with other safety net providers to create better systems of care. Most work closely with health departments to improve the safety net, including rotating residents to health department clinics, coordinating and in some cases integrating health department and AHEC clinic services, and seeking grants to establish new models of care. In some AHECs, such as Wilmington, faculty lead outreach clinics in surrounding rural counties to expand access for the uninsured. In Fayetteville, the AHEC hosts the regional child abuse clinic, and supports HIV/AIDs and other outreach clinics in nearby rural counties. AHEC faculty have taken the lead in developing new community-wide safety net programs, such as the role Mountain AHEC faculty played in establishing Project Access in Asheville.

The workforce development role of AHEC residencies is also critical to maintaining and strengthening the safety net services in the state. AHEC residencies were initially established to expand statewide capacity to train physicians to meet the physician workforce needs of underserved communities. Data from the past 25 years indicate that the AHEC residencies are effectively fulfilling that mission. Over 1,500 residents have graduated from AHEC primary care residencies, and two-thirds of them have remained in North Carolina to practice. In addition, graduates of AHEC residencies are more likely to settle in rural and other underserved communities than graduates of residencies at a university medical center.

As with other safety net providers, AHEC and hospital-based clinics face a number of financial challenges. The number of uninsured patients seeking care continues to grow as employer-based health insurance becomes more expensive and less available. State appropriations for AHEC and other related programs have declined over the last four years, and federal grant support via the Bureau of Health Professions has also declined. At the same time, costs for malpractice premiums, new technology, and recruiting and retaining faculty have all increased.

In spite of the challenges, the AHEC Program remains committed to maintaining and strengthening its statewide network of primary care residencies. As the population of North Carolina continues to grow at a rate faster than the national average, it may be necessary to further expand the number of residency positions to assure that the physician supply for the state remains adequate to meet the growing needs of our population. **NCMJ**

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COMMENTARY

Who is at Risk of Losing Safety Net Healthcare?

Adam G. Searing, JD, MPH

Ms. McDaugherty, a 30-year-old widow with two children, works as a waitress. Her job pays enough to put her income slightly above eligibility for the North Carolina Medicaid program ($11,425 annually), but offers no health insurance coverage. Her earnings of roughly $1,000 a month are quickly used to pay for rent and utilities for an efficiency apartment ($700), food ($150), and public transportation ($100).

Just as she was starting to get on her feet economically, less than a year after she lost her husband, Ms. McDaugherty found a lump in her breast. Tests performed at a community clinic found that she had a malignant tumor that had already spread to her lymph nodes.

Since her income is slightly above the federal poverty level, she can only qualify for Medicaid as an "optional benefitiary" because she has been diagnosed with breast cancer. Because of Medicaid, Ms. McDaugherty was able to see a specialist who advised her that she needed a lumpectomy, followed by chemotherapy and radiation treatment. The Medicaid program currently covers all of Ms. McDaugherty's cancer treatments, including medications for the side effects of chemotherapy, which help her continue working part-time.

As an "optional beneficiary," she would be one of the first to completely lose health coverage as a result of federal or state budget cuts to Medicaid, since her income is slightly above poverty level. Even if coverage is continued, North Carolina could select a narrow list of services that would be covered for people like her. For example, the state might limit the drugs that help control the side effects of her cancer drugs and allow her to work.[i]

Strengthening the Safety Net, Covering the Uninsured, Controlling Health Costs

Three years ago I wrote an article for the *North Carolina Medical Journal* entitled "The Uninsured and Medicaid."[1] I surveyed the Medicaid program and the situation of the uninsured, noted the drivers of rising costs, the necessity of denying healthcare to people currently covered by Medicaid to achieve truly substantial cost savings called for by proposed state budget cuts, and the need for new revenue to sustain the program in a time of economic downturn so that even more people would not join the ranks of the uninsured.

To borrow an apt example from a noted health policy researcher,[2] Bill Murray in the movie "Groundhog Day" and I have much in common as I address this issue again for the Journal. Medicaid costs continue to increase along with general healthcare costs and as we ask the program to absorb more people who have lost insurance. Substantial budget cuts are proposed by the federal government that could only be covered by denying Medicaid coverage to tens of thousands of North Carolinians.[3] Once again, we need to find new revenue in order to address growing health costs and the growing numbers of the uninsured. Finally, there are no detailed plans for reform under consideration by political leaders in North Carolina.

Although the problems are the same today as they were in 2002, they could be much worse. Unlike many states, North Carolina chose to enact incremental tax increases over the last three years so we could maintain state health, education, and other vital services for our residents. While there have been some cuts, we have avoided the examples of states as diverse as Oregon, Texas, and Mississippi, where hundreds of thousands of vulnerable seniors and children have joined the ranks of the uninsured after being cut from Medicaid coverage.

Still, the picture in North Carolina is grim. New reports show that from 2000 to 2003, over 457,000 North Carolinians

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[i] This example is based on a real person and was developed by FamiliesUSA and the North Carolina Health Access Coalition. See "The Bush Administration's Proposed Structural Changes to Medicaid: Hurting Real North Carolinians," www.familiesusa.org.

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have lost health insurance due to rising health costs and the economic downturn—one of the highest rates in the country.[4,5] Over 300,000 people have joined the ranks of the uninsured since 2000, and we have added over 230,000 people to Medicaid. Premiums for employer-based plans in North Carolina have risen by 43.4% between 2000 and 2003.[4] A family health insurance plan in North Carolina now costs about $9,000 per year.[5] There are now 1.5 million people on Medicaid in North Carolina and 1.4 million people without health insurance.

When people talk about health reform, they often imagine a magic bullet that will decrease health costs, extend coverage, and not cost any more than we spend right now. Over the last 70 years, no magic bullet has appeared, although many have been proposed. The current crop includes medical malpractice changes, health savings accounts, a single payer health system, and electronic medical records. While each of these ideas probably has some positive aspects, none of them is either politically feasible or will really have any appreciable effect on the underlying problems our health system faces.[7,8,9,10] To really address the growing numbers of the uninsured, our overstrained safety net, and rising health costs, reform in North Carolina must take a different path.

Successfully strengthening the safety net in North Carolina means three mountains must be climbed. First, our tax system must be reformed so it collects (consistently from year-to-year) the revenue necessary to fund the public health safety net services we already have. Second, we must collect more revenue through the tax system to cover people now currently uninsured and make health insurance more affordable for those who are already insured—both reforms the public says it wants. Third, we need to develop a plan for reform that businesses, advocates for the uninsured, policymakers, and other stakeholders can support.

Reforming the Tax System to Fairly Meet the Health Needs of North Carolinians

Health and related human service programs account for approximately 25% of North Carolina's state budget spending. The majority of this spending is on safety net programs like Medicaid, Health Choice, and other health and child development programs.[11] All but about 5% of other state government spending goes for education, justice, and public safety programs. That nearly 95% of state spending is for these public services should not be surprising. Education, healthcare, and justice services all enjoy broad popular support among North Carolinians. For example, a recent survey of North Carolina voters shows that 87% support Medicaid to fund healthcare for low-income people in the state.[12]

North Carolina's tax system has not kept pace with the public's interest in funding these key state services. This is not an argument that more revenue needs to be generated from taxes, just that the current laws on the books mean that the tax burden is distributed unfairly and cannot respond to our growing state population. Our tax system is antiquated and so full of loopholes that it does not fund state needs over time and is easily affected by economic downturns. An example of this is the sales tax that extends to most products while not covering services people increasingly buy instead of products. The person who used to pay sales tax on the purchase of a lawn mower now pays no sales tax on the purchase of a lawn mowing service. Because of problems like this, "families earning less than $15,000 in North Carolina pay the greatest share of their income [10.9%] in state and local taxes while the top 1% of income-earners pay the lowest share of their income [6.3%] in taxes."[13]

> *"...our tax system must be reformed so it collects (consistently from year-to-year) the revenue necessary to fund the public health safety net services we already have."*

Another example of why we need tax reform is the shift of the tax burden away from corporations to individuals.[14] As revenues from corporate taxes decline, the state must look to individuals to make up the difference, often with inequitable results. A major Fortune 500 company in North Carolina, BB&T, had basically no state income tax liability (0.1%) from 2001-2003 despite making $4.6 billion in profits.[15] Without reform of our tax system, we will not have the money to fund current state safety net programs that have broad public support, like Medicaid and Health Choice, much less enough money to make improvements in the future.

Generating Revenue to Strengthen and Expand the Safety Net

A reformed tax system would better keep up with the growth of state safety net programs and services now available. However, any expansion to address the problems facing the safety net or to extend coverage to the growing uninsured population will need new revenue.

Recently a group of farmers came to demonstrate at the General Assembly in Raleigh with two demands: (1) keep and increase tax breaks for farmers, and (2) make health insurance more affordable.[16] This call highlighted one of the main obstacles to strengthening the safety net and addressing the problem of the uninsured—people want the government to do something to make healthcare more affordable and accessible, but they believe they pay too much for government services already and want lower taxes. These two goals are simply not compatible.

Strengthening North Carolina's Medicaid and other safety net programs to insure parents of already covered children would begin to reduce North Carolina's uninsured rate. This costs money. Ideas like establishing a statewide reinsurance pool for employees in small businesses with extremely high health bills could reduce small business health premiums significantly. This costs money. Allowing medically uninsurable North Carolinians to buy into state health plans would reduce the numbers of uninsured. This costs money.

Any one of these reforms is achievable within the context of North Carolina's $15 billion budget, but at least some new revenue will have to be generated to meet these needs and the public's other priorities in education and public safety. The bottom line is that for significant health reforms to have a chance, people who want health reforms must also advocate for a tax system that will generate enough revenue to fund reforms.

Steps to Strengthen the Safety Net and Expand Health Insurance Coverage

Developing a plan to strengthen the safety net and extend affordable health coverage is the easy part, once enough revenue has been raised to achieve real reforms. Proposals abound, but funding them is always the critical component. The following proposals would each individually slash the number of people without health insurance. Enacting all of them would elevate North Carolina to the status of a national leader in reducing the costs of health insurance for business and individuals, while extending coverage to the uninsured.

- Expand Medicaid and North Carolina Health Choice (children's health insurance) to offer affordable coverage to low-income parents of children currently covered if a family's income is under 200% of federal poverty guidelines ($31,340 annual income for a family of three).
- Direct more funding to safety net health centers like community health centers, rural health centers, and public health clinics to enable them to expand and provide services to the growing number of people either uninsured or covered by Medicaid.
- Allow childless adults, children, and parents to buy into the state employees' health insurance plan if their income is below 300% of federal poverty guidelines ($47,010 annual income for a family of three). Charge premiums on a sliding-fee scale with families and individuals who have higher incomes paying the full cost of coverage.
- Establish a state high-risk insurance pool that would subsidize coverage for people who, because of a health condition, cannot find affordable coverage anywhere else.
- Start a state reinsurance pool for small and mid-size businesses that would take over paying for the health costs of any employee whose medical bills exceeded $50,000. By removing the risk of paying for catastrophic care, employer health premiums would drop, and coverage would become more affordable.

Treading water is simply not acceptable. As costs mount in tandem with calls to cut Medicaid, North Carolina's major health safety net program; as employers find they can no longer afford coverage for employees; and as the numbers of uninsured grow, we cannot simply stand by. Federal action is unlikely, and North Carolina must begin to address the problem of affordable health coverage and the uninsured on its own. Without action by the federal government, it is unlikely that North Carolina will be able to completely strengthen the healthcare safety net and extend health coverage to 100% of people without health insurance. However, indifference in Washington is no excuse for North Carolina not beginning to address these serious problems with its own innovative solutions. **NCMJ**

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Take Note

Book Review:

Scientific Publications by Walter Kempner, MD: Volume II. Radical Dietary Treatment of Vascular and Metabolic Disorders. Edited by Barbara Newborg, MD. Gravity Press, Durham, NC, 2004. 557 pages.

For this reviewer, this volume is a trip back to 50 years ago, when Dr. Kempner was the most renowned clinician at Duke University Medical Center. He is best known as the originator of the rice diet, and the first to demonstrate that severe hypertension and glomerulonephritis could be successfully treated by its application and that malignant hypertension, a common, largely fatal diagnosis of that time, could be treated and reversed.

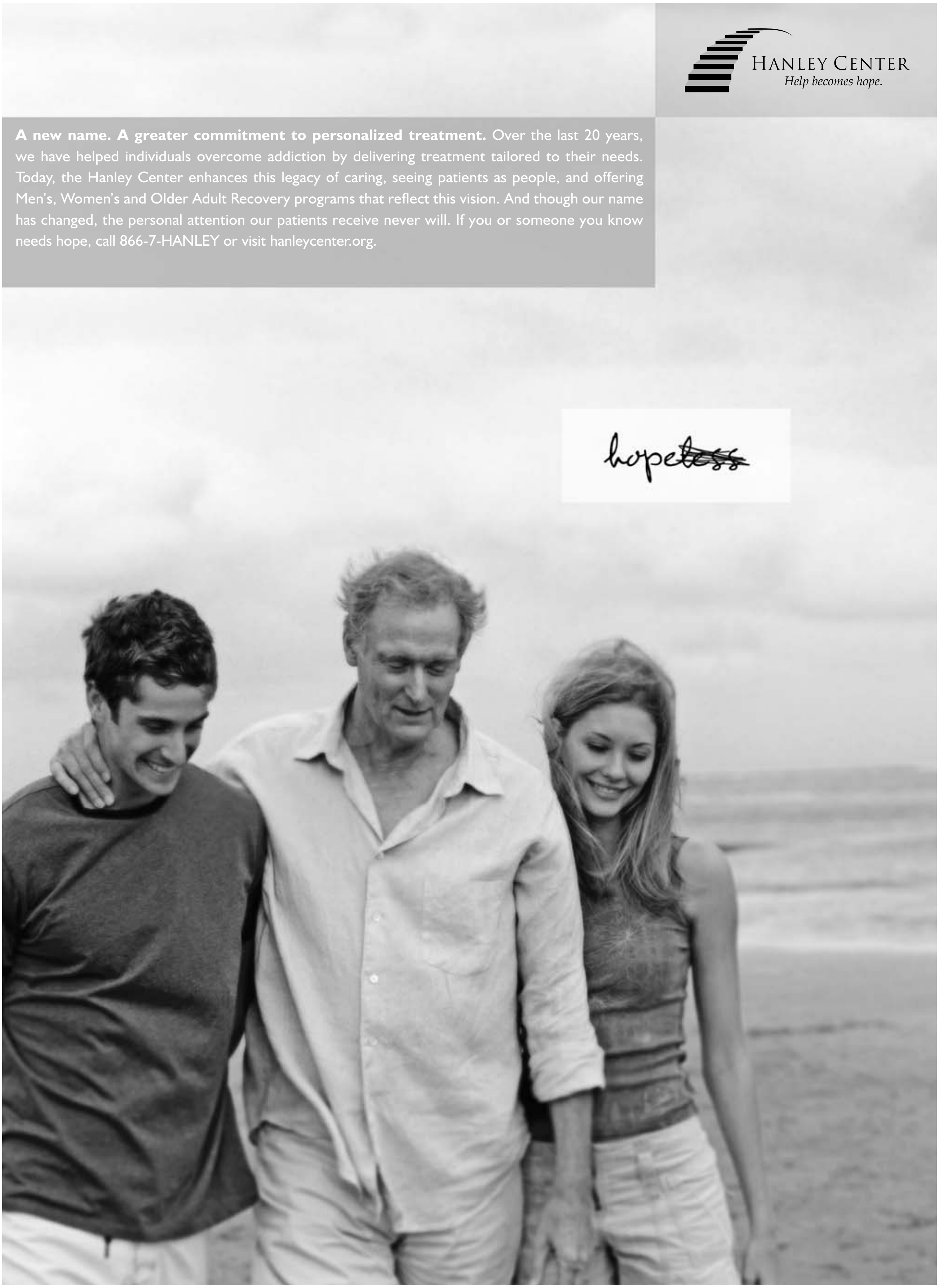
The book is not a biography, nor is it a discussion of his radical dietary therapy. It is a collection of his scientific papers, plus those of other closely associated team members at Duke. It is of special interest to readers of this Journal and North Carolina physicians, because most of the earlier Kempner papers were published in the *North Carolina Medical Journal* in the early 1940's. The volume also includes papers about Kempner by physicians who knew and worked alongside him, such as Morton Bogdonoff, Jay Skyler, and Eugene Stead, all of whom contributed to a symposium in Kempner's honor in the *Archives of Internal Medicine* in 1974 on the occasion of his retirement from the Duke faculty.

These papers are remarkable in many ways and worth reading. They reflect the limited knowledge base of that time relating to hypertension and kidney disease, and they also reflect the meticulous and detailed data collection and recording that are a part of Kempner's legacy. There are extraordinary before and after pictures of ocular fundi showing the resolution of papilledema and chest films showing reversal of cardiomegaly. These are so dramatic that they caused some well-known physicians of the time to doubt their validity. They also demonstrate the effective use of flow sheets in patient care, long before these became popularized as part of the problem-oriented record.

It is regrettable that these papers cannot portray the personality and power of this remarkable man. He began his career as a bench scientist, working in the laboratory of the famous Otto Warburg in Germany, and continued his studies of cellular physiology in his early years at Duke. He became a clinician again during World War II, when many of the Duke faculty departed to join the Duke hospital unit in England. His early successes with the rice diet were published and noted, but his earliest presentations were not well received. Such success in the treatment of diseases previously considered incurable was too good to be believed! His patients—most of whom came to him after receiving a death sentence from their physicians at home, and most of whom returned home much improved, and even "cured"—were his staunch supporters and returned to his care over and over again, bringing their friends and making him a wealthy man. Many at Duke were jealous of his success, and it is said that the recruitment of Eugene A. Stead, Jr., MD, to Duke in 1946 was favored by those who thought that Stead would force him out. Instead, Stead recognized the importance of his work and adopted his techniques for his own patients, which is documented in Stead's comments in this volume. Stead defended and supported Kempner, and he, in turn, provided Stead, in his earliest years at Duke, with the financial means to develop his department into a world leader.

Kempner's diet was a combination of severe sodium, fat, and protein restriction, which was found to benefit a number of significant morbid conditions: hypertension, kidney disease, vascular disease, diabetes, obesity, etc. The development of diuretics, potent antihypertensive drugs, and cholesterol reducing agents, plus the difficulty of remaining on this difficult and different diet, made the rice diet less important and even outmoded in the opinion of some, but he was never convinced that any of these "advances" were more beneficial to the patient than his diet. Clearly, much of his success reflects the strength of conviction and a personality that helped motivate his patients to remain on the diet. This complex and remarkable man deserves full credit as the first physician to offer a ray of hope to those with several previously irreversible illnesses, to which the papers in this compilation give convincing documentary evidence.

— E. Harvey Estes, Jr., MD
Professor Emeritus
Department of Community and Family Medicine
Duke University Medical Center


hope~~less~~

North Carolina Voluntary State Registry of Advance Healthcare Directives

In 2001, the North Carolina General Assembly passed legislation authorizing the NC Secretary of State to create a voluntary on-line registry of advance healthcare directives for the benefit of the citizens of the state and their healthcare providers under circumstances where immediate access to such directives would be needed. Citizens wishing to register their notarized directives may place three types of healthcare directives and an organ donor card on the Internet web site maintained by the Office of the Secretary of State at the following Internet location:

http://www.secretary.state.nc.us/ahcdr/

Those wishing to take advantage of this service by filing their information by mail may get information to facilitate their registration by calling 1-919-807-2000. Forms are provided for:

- Health Care Power of Attorney
- Declaration of Desire for Natural Death (Living Will)
- Advance Instruction for Mental Health Treatment
- Organ Donor Card

"Sallie" and others just like her provide 80% of all long-term care

One of every 5 adults in NC is caring for someone age 60 or older.

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Refer patients and caregivers to local resources

- North Carolina's Family Caregiver Support Program can provide help for caregivers of persons 60 or older.
- To locate local resources through your Area Agency of Aging visit
  http://www.dhhs.state.nc.us/aging/fcaregr/fcjobs.htm
  http://www.fullcirclecare.org and
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Running the Numbers

A Periodic Feature to Inform North Carolina Healthcare Professionals
About Current Topics in Health Statistics

From the State Center for Health Statistics, North Carolina Department of Health and Human Services
www.schs.state.nc.us/SCHS

Uninsured and Underinsured Adults in North Carolina

The United States spends more per capita on healthcare than any other industrialized nation. It is also the only industrialized nation that provides no universal healthcare for its citizens. Therefore, there must be a "safety net" of healthcare providers who cover the uninsured and underinsured. The United States spends billions of dollars treating the uninsured once their health problems become too severe to be ignored. The uninsured receive less preventive care, are diagnosed with more advanced disease, and receive less therapeutic care once diagnosed than the insured. In North Carolina, preventive services for the uninsured are most often provided by local public health departments and community and migrant health centers.

The North Carolina Behavioral Risk Factor Surveillance System (BRFSS) is a random telephone survey of persons ages 18 and older. Each year, a question is asked about whether the respondent has health insurance. In 2004, several questions were included to address the issue of underinsurance. Following are selected BRFSS data on the uninsured and underinsured, weighted to reflect the entire adult population of the state.

- 17% of North Carolina adults had no health insurance.
- Among persons ages 18-24, those with less than a high school education, and those with household income less than $25,000, approximately 30% had no health insurance.
- 65% of Hispanic adults had no health insurance—35% of English-speaking Hispanics and 75% of Spanish-speaking Hispanics.
- 41% of uninsured adults reported that there was a time in the last 12 months when they needed to see a doctor, but could not due to the cost, compared to 10% of adults with health insurance.
- 35% of uninsured diabetics reported that there were times in the past 12 months when they were unable to obtain testing supplies and diabetes medicines due to the cost, compared to 9% of diabetics with health insurance.
- 51% of uninsured adults reported that they have no personal doctor or healthcare provider, compared to 12% of adults with health insurance.
- Among the BRFSS respondents who did have health insurance, 17% reported that they had to give up some living expenses in the last year to pay healthcare costs.
- Among those with health insurance, 18% reported that they took a tax deduction for healthcare expenses on their federal tax return, 16% said that someone in their household had problems paying medical bills, and 13% said that their household had been contacted by a collection agency about owing money for medical bills.
- Among those with health insurance, 20% said that their total out-of-pocket healthcare expenses (including health insurance premiums) were more than $5,000 during the past year, including 5% who said they spent more than $10,000.

Contributed by Paul A. Buescher, PhD
State Center for Health Statistics, North Carolina Division of Public Health

Readers' Forum

New Directions in End-of-Life and Palliative Care

The following was previously published in the Raleigh News & Observer, March 27, 2005 and is reprinted here with permission.

Reaching for reassurance at the end of life

CHAPEL HILL—"What would you do?" I've been asked this question hundreds of times since I started medical school in 1983. I was asked it as a medical student, as a surgical resident, as a trauma surgeon, a critical care specialist, and as the director of an ICU in a rural North Carolina hospital. I've been asked it about a variety of issues, but most commonly I've been asked it by families who were making end-of-life decisions about their loved ones.

Should they put a feeding tube in their grandmother, now too demented to eat? Should they donate the organs of their brain-dead son? And what about their father and his massive stroke—should they disconnect him from the ventilator?

"What would you do?"

For years, this question made me nervous. It was a relic of the old days, before I came along, when doctors had all the answers, when we simply went ahead and did what we thought was right without much input from patients and their families. I didn't train in the era of paternalism. I trained in the era of patient autonomy, so when families asked, "What would you do," I thought that they were asking me what they should do, as if there were some kind of objectively right answer, separate from the wishes of the people for whom they were speaking.

For years, I sidestepped this question. I told families that I didn't know what I would do in their situation. I said you never knew what you would do until you were the one that was having to do it. In fact, however, this was often a lie. Generally, I knew what I would have done: I wouldn't have put in the feeding tube, I would have donated the organs, I would have turned off the ventilator.

But for years I didn't tell people that. I didn't want them to do what I wanted them to do. I wanted them to do what the patient would have wanted. I thought that injecting my own opinion would make them think more about me and less about the patient, that the possibility of doing something their doctor disagreed with would only make their decision more difficult.

Over time, though, I began to notice something. I wasn't the only person hearing "What would you do?" Families asked nurses too, and they asked the nursing assistants whose job it was to bathe the patients, change their sheets, empty their catheters, turn them side to side to prevent them from developing pressure sores. When I moved to rural North Carolina, the family meetings at which we discussed all this expanded to include "church family" and the patients' ministers. They faced the question too: "What would you do, Reverend?"

After a while, I began to realize that the families weren't actually asking what they should do. In fact, most of them already had an idea about what they should do. Most of them felt they should withdraw life support, because the majority of my families knew that somewhere along the line, the patient had told his brother or his wife or his daughter or his mother something about not wanting to be kept alive by tubes and machines.

And so I came to understand that the families weren't asking what they should do. Instead they were asking us all for permission to actually do it—permission to withdraw life support and allow the patient to die. They weren't asking for legal permission—they knew it was legal. But they were asking for true social sanction. They wanted to know that other families did this, that people from the church wouldn't think of them as murderers, that their neighbors wouldn't fault them when the word got out.

Families were also asking for reassurance that the patient wouldn't suffer. They needed to believe that if they elected to withdraw support, we could continue to comfort patients and alleviate their suffering as they moved toward death.

Families asked nurses and nursing assistants as often as they asked me, because they knew the nursing staff well. They had seen the nurses rub lotion on the patient's dry feet. They had seen the aide comb out the patient's matted hair. They had watched techs readjust tape and bandages and tubes and IV lines so they didn't tug and tear at the patient's fragile skin. Family members, watching this, were touched by the staff who cared the most for their family member. When they asked staff members what they would do, they chose the ones that they trusted most. They chose ones that they knew would never have done anything that would have increased the suffering of the patient.

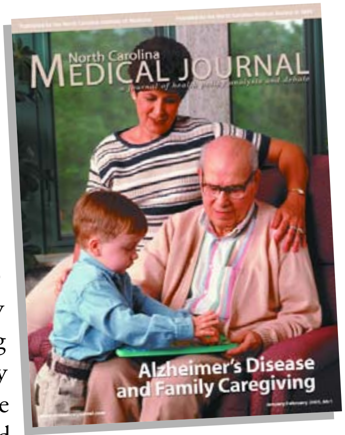
I am dismayed that the president and Congress, particularly the physician members of Congress, have elected to intervene in the Terri Schiavo case. The physicians above all should understand the delicate, carefully wrought relations of trust that are an essential part of patient care and decision-making, especially at the end of life. The name-calling and grandstanding that have accompanied this case will only make it more difficult for families in the future to make end-of-life decisions.

Just as sadly, I think, they will cause families who have already had to make these painful decisions to question themselves and the decisions for which they so plaintively begged reassurance.

Elizabeth Dreesen, MD, is a fellow of the American College of Surgeons and a specialist in surgical care. Formerly the Medical Director of the Critical Care Unit of the Lincolnton Medical Center and in private practice, she is now on sabbatical in Chapel Hill. She can be reached at 919-967-3529.

Alzheimer's Disease and Family Caregivers

To the Editor



Your January/February 2005 issue (66:1) of the *North Carolina Medical Journal* is truly overwhelming because of: the staggering numbers of us who will have one day, by current projections, Alzheimer's Disease; the depiction of the incredible amount of sad work involved in care giving; the financial burdens families must bear; the description of the pathos/grieving associated with being around these patients; and because of the paucity of policy options available to North Carolina or the United States.

Sixteen million people afflicted with dementia by 2050 will clearly require a carefully planned/well-funded system of organized, standardized care. Such a system can only be achieved by the design/construction of a very large number of Alzheimer domiciliaries patterned after the concept of tuberculosis in sanitaria as built in the late 1800s-early 1900s. Patchwork of respite options, as in the table from Karisa Derence's commentary will not suffice and almost certainly would not prevent bankruptcies within families, churches, or governmental agencies. Of course building a multitude of structures for patient's with TB had the notions of "healthy" food/air contributing positively to the treatment of and the need for isolation to prevent contagion as a powerful force to get the policymakers to act.

For Alzheimer's dementia, the impeti are the logistics of financing such care, defining the care to be provided, and the recruitment of an adequate sized army of caregivers. Remember, some of the requirements of these 16 to 50 million folk will be: housing; feeding; protection from cold/heat; prevention of injury to self/others while permitting maximum freedom to pace, wander, or babble early on in the disease; preserving some activities of daily living for as long as possible; cleanliness; and dignity; however society chooses to define it by then. Such requirements extrapolate into the need for unique interiors/furnishings for this kind of housing. Then, there are the matters of: choking/feeding for many who can't chew or swallow or have lost the ability to use knife/fork/spoon; air handling of odors, washability of repeatedly soiled every day items (beds, bedding, chairs, walls, floors, etc.), and an endless supply of diapers, diaper changers/diaper disposals to mention just a few. Finally, in the last trimester of the illness our hosts and their staff will have to make hard decisions about how/whether to treat malnutrition, dehydration, skin breakdown, urinary tract infections with resistant organisms, pneumonia, sepsis; exacerbations of the other chronic medical conditions that were on the problem list before the onset of dementia or developed during the dementia; and the occasional intercurrent acute surgical event.

No matter how such "hotels" are financed, whether at the state or federal level, there will still be a need for volunteerism beyond any exhibited in this country to-date. As an aside, we must not limit such volunteerism by requiring bureaucratic certification in feeding, bathing, dressing, or walking with these cognitive invalids. Indeed, perhaps we will need a form of universal subscription (say between the junior and senior years of high school) to swell the ranks of caregivers.

There are, of course, many objections to this proposal, such as: how much dare we spend on a structured solution lest we siphon funds away from the promise of a cure by research or from the cost of a truly effective chronic treatment; the unfair requirement in some less populated states that visitors might have to travel for a day to visit a relative or loved one; and the logistical problem of who will and how to decide about eligibility for admission. Perhaps a happy long-term concern will be what to do with all that new construction once the disease joins the list of easily preventable or successfully treatable disorders. If we're optimistic, then we should plan on multipurpose structures and consider geography accordingly.

Be assured that despite the anticipated letters and outcry by social scientists, politicians, clergy, and ethicists to what appears to be a calloused practical solution to a challenge of staggering proportions, there will be millions of relatives clamoring to get a loved one admitted when the institution is as conceptualized in my mind and as it could/should be.

"If we build them, they shall come!"

Harold R. Silberman, MD, FACP
Professor Emeritus
Duke University Medical Center
Durham, NC

The North Carolina Institute of Medicine

Since January 2002, Publisher of The *North Carolina Medical Journal*

In 1983 the North Carolina General Assembly chartered the North Carolina Institute of Medicine as an independent, nonprofit organization to serve as a non-political source of analysis and advice on issues of relevance to the health of North Carolina's population. The Institute is a convenor of persons and organizations with health-relevant expertise, a provider of carefully conducted studies of complex and often controversial health and healthcare issues, and a source of advice regarding available options for problem solution. The principal mode of addressing such issues is through the convening of task forces consisting of some of the state's leading professionals, policy makers and interest group representatives to undertake detailed analyses of the various dimensions of such issues and to identify a range of possible options for addressing them.

Members of the North Carolina Institute of Medicine are appointed for five-year terms by the Governor, and each task force convened by the Institute typically includes at least one-third of its membership from among the appointed members. Topics to be addressed through task force efforts are chosen following requests from the Governor, the General Assembly or agencies of state government. In some cases, topics are selected on the basis of requests from a number of stakeholder organizations across the state where this type of analytical process is considered to have potential value.

The North Carolina Institute of Medicine assumed the role of publisher of the *North Carolina Medical Journal* in January 2002 through an agreement with the North Carolina Medical Society, which founded the Journal in 1845. The Institute views the *North Carolina Medical Journal* as an extension of its mission. The Journal provides a forum for stakeholders, healthcare professionals, and policy makers and shapers to study and discuss the most salient health policy issues facing our state. Like many states, North Carolina is grappling with issues such as an increasing number of uninsured, the unmet health needs of the growing Latino population, a critical shortage of nursing personnel, the health risks of tobacco and obesity, rising prescription drugs costs, mental health system reform, the increasing societal burden of chronic illness care, the threat of bioterrorism and the necessity of assuring adequate public health preparedness—all in the midst of an economic downturn. Each of these issues presents unique challenges to healthcare providers and state policy makers. Yet, a fully implemented task force to consider each of these sets of issues is not feasible. The Journal makes it possible to present an organized and balanced overview of some of these issues, six times per year, and allows interested persons the opportunity to engage in the ongoing discussion of these issues throughout the year. The Institute hopes that our readers of the *Journal* will, in this way, become involved in the continuing debate about the most promising avenues for assuring the highest standards of health and healthcare for all North Carolinians.

health policy
North Carolina Institute of Medicine

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John W. Williams, Jr., MD, MHS
Scientific Editor, *North Carolina Medical Journal*

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While medical researchers in North Carolina have many journals to which they can submit their manuscripts, we want them to consider keeping their work here at home. To be more specific, we invite the authors of our state to submit their papers to the *North Carolina Medical Journal*.

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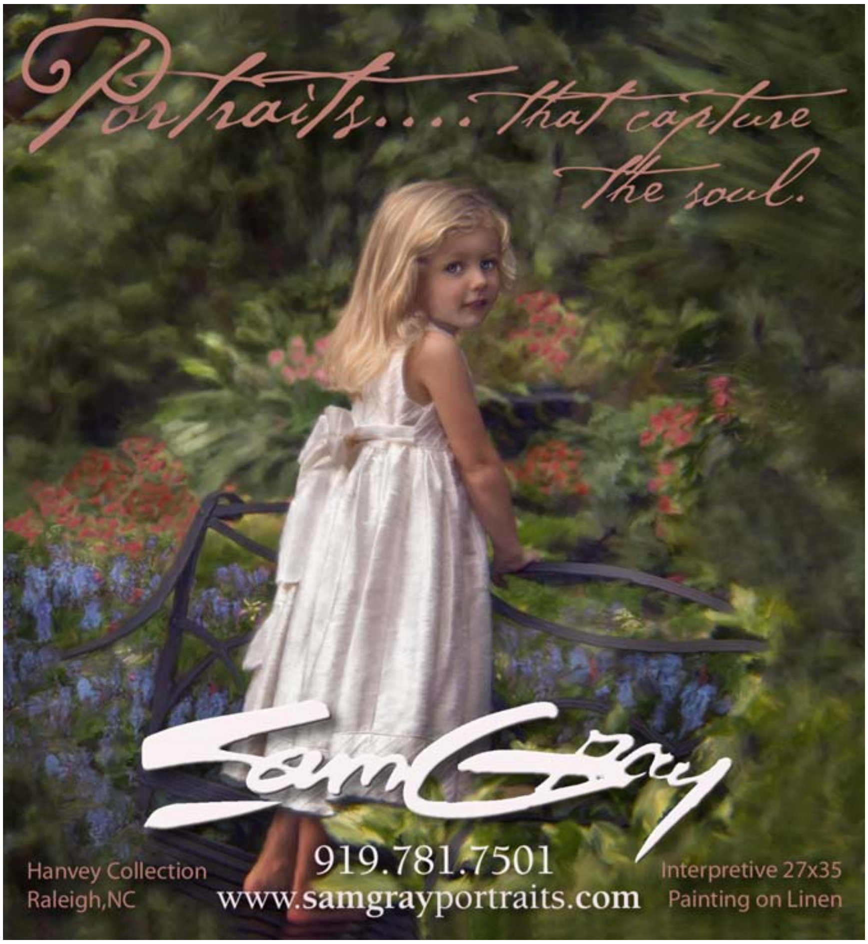
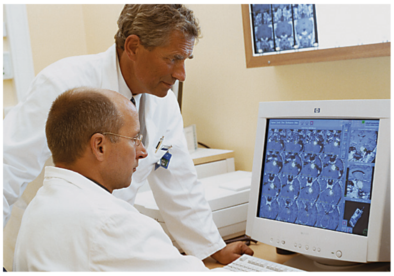


A partnership that's working for eastern North Carolina



Better tools mean better care

Cooperation and vision are bringing leading-edge technology to help patients in eastern North Carolina who are diagnosed with brain lesions. Pitt County Memorial Hospital has received state approval to buy and install a Leksell Gamma Knife, one of medicine's newest and most powerful tools for the treatment of brain tumors and other neurological conditions. The Leksell Gamma Knife is the most recent addition to the hospital's growing armamentarium of leading-edge diagnostic and treatment technology.

The project, which is expected to be operational in the fall of this year, is the result of careful collaboration and planning involving the hospital, the Leo W. Jenkins Cancer Center, the Brody School of Medicine Department of Radiation Oncology and private physician practices including Eastern Neurosurgical and Spine Associates, Eastern Radiologists and Carolina Radiation Medicine.

The Brody School of Medicine, University Health Systems and private physicians are working together to make things happen—in the community, in the region and in the state.

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