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Awareness of the Bicycle Helmet Law in North Carolina

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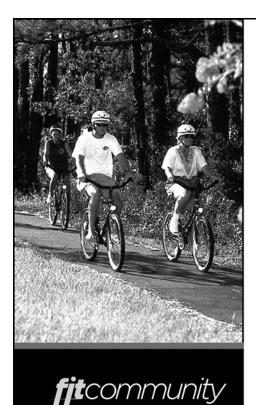
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Founded by the North Carolina Medical Society in 1849 Published by The North Carolina Institute of Medicine and The Duke Endowment (ISSN 0029-2559)

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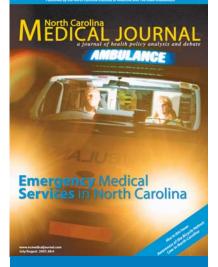
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Co-Sponsors of the Journal are: The Carolinas Center for Medical Excellence, formerly Medical Review of North Carolina / North Carolina Association of Pharmacists / North Carolina Dental Society / North Carolina Health Care Facilities Association / North Carolina Hospital Association North Carolina Medical Society

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

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July/August 2007, Volume 68, Number 4

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Tarheel Footprints in Health Care

Recognizing unusual and often unsung contributions of individual citizens who have made health care for North Carolinians more accessible and of higher quality



Stanley Wardrip

Stanley Wardrip is what many would consider a model emergency medical services (EMS) professional. Mr. Wardrip started his EMS career at the age of 15 with the Jacksonville Volunteer Rescue in Jacksonville, North Carolina. During his tenure at Jacksonville Rescue, he and his fellow rescuers received recognition for their superior service and performance delivering EMS care. Throughout high school, Mr. Wardrip worked in EMS and in 1987 he won the North Carolina Governors Award for Youth Rescuer of the Year. Mr. Wardrip went on to graduate at the top of his paramedic class and graduated with an Associate Degree in Emergency Medical Science from Catawba Valley Community College.

Mr. Wardrip has worked for New Hanover EMS for 17 years. He is a senior paramedic, public relations coordinator, and field training officer. As a member of the New Hanover County Board of Health and the New Hanover County Public Health and Safety Committee, Mr. Wadrip has worked hard to help promote the health and safety of New Hanover's citizens. He has a strong appreciation for the role EMS plays in community health which is why he also started a Boy Scout Explorer Post for New Hanover Regional Medical Center EMS to help encourage younger people to get involved in EMS. His community-based efforts have been well-received and have positively impacted eastern North Carolina.

As an advocate for EMS, Mr. Wardrip identified a gap in representation for eastern North Carolina EMS professionals at the state and national level. To address this gap, he helped start the Eastern Carolina EMS Association, a professional organization of individuals within eastern North Carolina who are engaged in EMS and who wish to make an impact upon the health and welfare of the public and also promote, represent, and provide guidance for the practice of prehospital care. This association is open and free to all emergency responders in eastern North Carolina. The association offers first aid instruction and CPR classes to the public at a low or no cost. Other safety topics promoted by the association include child bike and gun safety.

Currently, Mr. Wardrip works for Pender EMS as a paramedic and member of the North Carolina State Medical Assistance Team. Friends feel he is one of the top paramedics in the state due to his great patient care and his kind heart. He always finds time for his family and friends, something that is very difficult to do in EMS.

Besides being a tireless advocate for EMS and community health and being family man, Mr. Wardrip works with Medical Missions to help others in times of need. In 2007 he plans to work with Wrightsboro United Methodist Church Medical Mission to provide medical assessment and treatments to those who cannot afford medical care in St. Anne's Bay, Jamaica. The *North Carolina Medical Journal* would like to recognize Stanley G. Wardrip Jr. as a model EMS professional and offer appreciation to EMS professionals across the state who offer their time and talent to help improve prehospital care in North Carolina.

Contributions from Doug Strickland, NREMT-I

Readers' Forum

To the Editor:

In the March/April 2007 issue of the *North Carolina Medical Journal*, Roche et al wrote about the importance of screening for intimate partner violence (IPV) after a study of 321 adult female patients were surveyed in an urban medical center in North Carolina. Respondent characteristics of the women screened are offered in the article.

I agree wholeheartedly with the authors' assertion that IPV is a very common and serious problem that is perhaps underinvestigated by health care providers. Teaching medical students and residents how to appropriately screen their

patients in the outpatient and inpatient settings as well as the emergency department is essential. However, as much as a history of IPV is frequently not obtained by health care practitioners, more often than not a sexual orientation history is not obtained either. I commend the authors of this study for using the inclusive and nonjudgmental term "partner" repeatedly in their article. However, in the authors' survey they address their patients' marital status. Because same-sex marriage is legal in very few places, they therefore do not specifically address IPV in same-sex relationships. Data shows that IPV in lesbian couples occurs at a frequency similar to that in heterosexual couples. In a 2005 study published by the Centers for Disease Control and Prevention (CDC), 11% of women aged 15 to 44 reported having been in same-sex relationships—not an insignificant



number. Perhaps a number of the 43.9% of patients claiming to be "single" in this study include some of these patients.

One may ask why obtaining a sexual orientation history is important. Studies show that victims of IPV by a same-sex partner find it more difficult than their heterosexual counterparts to seek help for their problem. This seems to be largely out of fear of homophobia by the organizations offering assistance or fear of being "outed" if they seek help. Perhaps if they are asked about who their partner is in a way that is supportive and nonjudgmental (ie, not "are you married or single?"), they will feel safer in divulging the violent situation they are trapped in. Instead of asking "Are you married," simply ask "Are you in a relationship?

With whom?" Those questions are simple to ask, even for the provider not completely comfortable with addressing specific questions about sexual orientation.

I urge the authors of this study and interested readers of this journal to see the CDC-sponsored National Violence Against Women Prevention Research Center website on this particular topic (http://www.vawprevention.org/lesbianrx/factsheet.shtml). Several references are offered on the website for further information. With careful screening for IPV by caring and nonjudgmental health care providers, we can hopefully better address the needs of all patients trapped in destructive relationships.

John E. Snyder, MS, MD

Editor's note: In the May/June 2007 issue of the *Journal*, the article *Issue Brief: Weathering the Practitioner Workforce Shortage* inadvertently omitted reference to the central role the Kate B. Reynolds Charitable Trust (KBR) played in the formation, funding, and deliberation of the task force. The original impetus for the task force grew out of a meeting convened by KBR that focused on trends in provider supply. In addition, KBR provided the funding for the task force, and shared its experience in this area through task force participation. The Kate B. Reynolds Charitable Trust has a long history of grant making to improve access to practitioners in rural and underserved areas. The editor and authors apologize for the oversight in failing to reference the important role that KBR played in the task force's work. This oversight is corrected in an online version of the article available at: http://www.ncmedicaljournal.com/may-jun-07/toc0607.shtml.

Awareness of the Bicycle Helmet Law in North Carolina

Kelly A. Carter, MD; Kori L. Brewer, PhD; Herbert G. Garrison, MD, MPH

Abstract

Background: One in 3 bicyclists killed in North Carolina is under the age of 16. Since enactment of a mandatory bicycle helmet law for children in 2001, there has been no observed increase in helmet use in North Carolina. The goal of this study was to assess perceptions of helmet effectiveness and the level of awareness of the North Carolina bicycle helmet law.

Methods: A written survey was distributed to parents, physicians, teachers, and emergency medical services (EMS) personnel throughout Pitt County, North Carolina, to ask their knowledge of the bicycle helmet law, the frequency of their helmet use, their perceptions of the effectiveness of helmets, their opinions of who should be providing education about bicycle helmets, and their knowledge of proper bicycle helmet use.

Results: The survey response rate was 72% (n= 413). Seventy-five percent of teachers and EMS personnel, 69% of parents, and 58% of physicians were aware of the North Carolina helmet law. Nineteen percent of parents responded that their children wore helmets "always," 21% answered "often," and 18% answered "never." The effectiveness of helmets in preventing head injuries was underestimated by many respondents with 49% estimating 50%-75% effectiveness.

Limitations: This survey was distributed only in Pitt County and does not reflect helmet awareness for the state as a whole.

Conclusions: The majority of parents, teachers, physicians, and EMS personnel in Pitt County, North Carolina, are aware of the mandatory bicycle helmet law for children. Enforcement of and education about the bicycle helmet law should be increased.

he North Carolina Division of Transportation reports that a bicyclist is injured or killed in the state every 6 hours, with one in 3 bicyclists killed in North Carolina being under the age of 16.¹ Among bicycle injuries, one-third of emergency department visits, two-thirds of hospital admissions, and three-fourths of deaths are due to head injuries.² Bicycle helmets have been shown to reduce the incidence of head injury by 85% and the risk of traumatic brain injury by 88%.³ Because head injuries from bicycle crashes are such a significant problem, 20 states have implemented statewide mandatory helmet laws and another 16 states have counties with helmet use laws.⁴ In October of 2001 North Carolina passed a law requiring all children younger than 16 years of age to wear a helmet while riding a bicycle. This law holds the parent or legal guardian responsible for the child's helmet use with a penalty of a civil fine of \$10.5

A 2002 study⁶ conducted by the University of North Carolina Highway Research Center concluded that the mandatory helmet law had little impact on the use of helmets by children under the age of 16. The study observed helmet use in the same randomly picked cities in 3 regions of the state in 1999 and 2002. They found that on-street helmet use by children under the age of 16 increased from 12% to 16% (reported Law Effect, p =0.5627), and one-fifth of helmets observed in 2002 were misused. Weighted estimates of total helmet use (including adults) found that the coastal region of North Carolina, which includes Pitt County, had the lowest observed helmet use and no observed increase in overall helmet use after the law was implemented (9.5% pre-law, 9.2% post-law, with a state average of 17.8% and 24.3% respectively). In support of these findings, a database from the North Carolina Department of Transportation⁷ on bicycle-car crashes also found no reported

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Kori L. Brewer, PhD, is an associate professor and associate chief of the Division of Research at the Department of Emergency Medicine of the Brody School of Medicine at East Carolina University.

Herbert G. Garrison, MD, MPH, is a professor of Emergency Medicine at the Department of Emergency Medicine of the Brody School of Medicine at East Carolina University and director of the Eastern Carolina Injury Prevention Program at the University Health Systems of Eastern Carolina.

increase in helmet use in children under the age of 16 after the law was implemented. In the 4 years prior to the law, 42 of 1303 (2.3%) children involved in bicycle-car crashes wore helmets; in the 4 years following implementation of the law only 22 of 849 (1.3%) children were documented to be wearing helmets.

The purpose of this study was to determine if the ineffectiveness of the mandatory helmet law is due to a lack of awareness of this law or a lack of knowledge of the utility of helmets in preventing head injury. We assessed these factors by surveying parents, teachers, physicians, and prehospital emergency medical services (EMS) personnel in Pitt County, North Carolina, a geographically distinct area that included communities with bicycle helmet ordinances in place before the statewide law. Ultimately, our goal was to define areas of focus that will improve bicycle helmet use among children.

Methods

All protocols were reviewed and approved by the University Medical Center Institutional Review Board. The study was conducted in Pitt County, North Carolina. Pitt County is mostly rural with a year 2000 population of 138 690. It is located in the eastern region of the state and is comprised of approximately 650 square miles.

A written survey was distributed to the following groups: a convenience sampling of Pitt County public school district parents of school-aged children (n=150); a convenience sampling of Pitt County public school district teachers from elementary to high school, both rural and urban (n=210); pediatricians, emergency physicians, and family physicians (n=88); and EMS personnel (n=124). We used the following strategies to recruit

envelopes; and (4) all Pitt County EMS personnel were given surveys to be mailed in when completed. These groups were chosen since they are most likely to interact with children on a daily basis or to see the results of a bicycle crash when it occurs. The survey was distributed between October and December of 2006. All surveys included in the study were returned by January 2007.

The survey included questions about: (1) the presence of a mandatory helmet law for children; (2) helmet use among respondents and use among the children of the parent group; (3) perception of helmet effectiveness in preventing head injuries; (4) perceptions of who should be providing education about proper helmet use and laws (more than one answer was allowed for this question); and (5) familiarity with the proper use and fit of helmets. (See Table 1.)

Responses were recorded in a database and response percentages were calculated. Differences in response rates between groups (eg, teachers vs. parents) were analyzed using chi-square analysis with p<0.01 indicating statistical significance. The use of p<0.01 to indicate significance is a more stringent criterion than p<0.05 and helps adjust for the necessary multiple testing. The relationship between helmet use and knowledge of the helmet law and perceived effectiveness of helmet use was assessed using logistic regression. Helmet use and perceived effectiveness were each used as the dependent variable and assessed using simple logistic regression (LR) to produce a coefficient of determination (r-squared calculated using STATVIEW by SAS, Inc). The adjusted r-squared was calculated based on the following equation: Adjusted $r^2 = 1-(1-r^2) ((n-1)/n-k-1))$ where n = # of observations and k = # of independent variables.

survey participants: (1) to obtain a survey of parents, Parent Teacher Associations (PTAs) in Pitt County were contacted and surveys were given to interested PTA leaders which were then distributed to parents and collected by the PTA leaders for return; (2) principals from Pitt County public elementary, middle, and high schools were contacted and those interested in the project distributed surveys to teachers their and returned them by mail; (3) all pediatricians, emergency physicians, and family physicians in the Pitt County Medical Society were mailed surveys with response

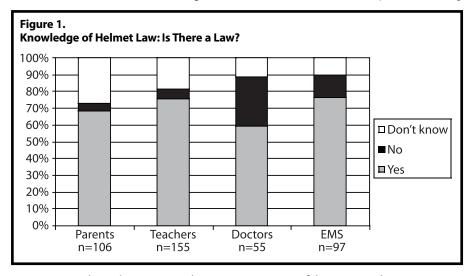
Is there a North Carolina	a law requiring bicyo	le helmet use in chi	ldren younger thar	16 years old?
Yes	No	Don't know		
If not, should there be a	law?			
Yes	No	Don't know	_	
How often does your ch	ild (age 5-15) wear a	a bicycle helmet? *		
Always	Often	Sometimes	Rarely	Never
How often do you wear	a bicycle helmet?			
Always	Often	Sometimes	Rarely	Never
What percentage (%) of	head injuries due to	o bicycle accidents o	an be prevented by	y wearing a helmet
0%-25%	25%-50%	50%-75%	75%-100%	
Who do you think is res	ponsible for providii	ng education about	bicycle helmets?	
EMS Personnel		Doctors	Teacher	Internet
Parents	Police Officers	Other:		
Who do you think parer	nts expect to provide	e education about b	icycle helmets to c	hildren? **
EMS Personnel		Doctors	Teachers	Internet
Parents	Police Officers	Other:		
How would you rate you	ur understanding of	proper helmet fit a	nd helmet use?	
Very good	Good	Okay		
I don't know any	thing about helmet	S		

Results

The overall response rate for this survey was 72.2%. One hundred six of 150 parents (71%), 155 of 210 teachers (74%; 61/88 elementary school, 16/22 middle school, 78/100 high school), 55 of 88 physicians (63%; 14/27 emergency physicians, 16/20 family physicians, 25/41 pediatricians), and 97 of 124 (78%) EMS personnel returned surveys.

Awareness of the Helmet Law

Four years after the implementation of the bicycle helmet law, 69% of parents, 75% of teachers, 58% of physicians, and 75% of EMS personnel surveyed were aware of the law. (See Figure 1; p=0.06). Of those who answered "no" or "don't know," most (91/115 or 79%) thought there should be a law.



Among teachers, elementary teachers were most aware of the law (80%) followed by middle school teachers (75%) and high school teachers (72%). These differences were not statistically significant (p=0.049). Knowledge of the law was not associated with physician specialty (p=0.098). However, pediatricians had the highest awareness of the law (68%); only 57% of emergency physicians and 47% of family physicians were aware of the law.

Helmet Use

When asked how frequently their children wore their bicycle helmets, 18% of parents with children ages 5 to 15 responded "never" with 5% adding that their children do not ride bicycles. Nineteen percent of parents stated their children "always" wear a helmet. Among the respondents themselves, 21% reported "always" wearing their helmet when riding a bicycle. Physicians were statistically more likely to report "always" wearing a helmet (46%) compared to all other groups (12% of EMS personnel, 11% of teachers, and 8% of parents; p<0.001). Parents (65%), teachers (65%), and EMS providers (57%) most often reported "never" wearing a bicycle helmet.

There was no relationship between helmet use and knowledge of the law (adjusted $r^2 = 0.020$), perceived effectiveness of helmets (adjusted $r^2 = 0.008$), or knowledge of proper helmet fit (adjusted $r^2 = 0.050$).

Knowledge of Proper Helmet Use

The respondents' understanding of proper helmet use and fit was reported by them to be "okay" for the majority in all groups. Ten percent of parents, 20% of teachers, 7% of physicians, and 8% of EMS personnel answered that they "don't know anything about helmets." Sixty-four percent of those responding that they "don't know anything about helmets" answered "no" (17%) or "don't know" (47%) when asked about the existence of the helmet law.

Perceived Effectiveness of Helmet Use

All groups underestimated the effectiveness of helmet use in preventing injuries with the majority of teachers (53%), physicians (64%), and EMS personnel (57%) perceiving that 50%-75% of head injuries could be prevented by a helmet. Thirteen percent

of all responders answered that less than 50% of head injuries could be prevented. The perceived effectiveness of the helmet was independent of their knowledge of the law (adjusted r^2 = 0.17). Forty-nine percent of those who knew there was a law and 51% of those who stated there was not a law thought that helmets prevented 50%-75% of head injuries.

Education

A majority (80%) of respondents indicated that the burden of educating children about bicycle helmets should fall on parents, a finding that was consistent across all groups of

respondents. Fewer expected that teachers (60%), physicians (46%), law enforcement officers (34%), and EMS personnel (22%) should provide education.

When asked "Who do you think parents expect to provide education about bicycle helmets to children?" only 18% of teachers, 26% of physicians, and 26% of EMS personnel responded "parents." The majority of respondents (61%) responded that parents expected teachers to provide education on bicycle helmets.

Discussion

This study demonstrates that while there is general awareness of the North Carolina bicycle helmet law, there is a lack of knowledge about helmet effectiveness and proper fit and a limited use of helmets by those with frequent contact with children. Based on the responses from parents, a substantial portion of children do not wear helmets while riding bicycles despite their family's awareness of the law.

Mandatory helmet use legislation in Canada and New York has been shown to increase helmet use among children by observing helmet use among those admitted to the hospital for bicycle crashes.^{8,9} An international systematic review of published observational studies relating to mandatory helmet use legislation also showed an increase in helmet use; however, it did not control for time since law enactment, enforcement, or education about the law.¹⁰ In contrast, the observational study performed in North Carolina 6 months after the passage of its helmet law failed to show an increase in helmet use among children younger than 16.⁶ There were no educational programs associated with the North Carolina bicycle helmet law prior to this study. This provides an opportunity for improvement because research has shown that helmet use in communities where bicycle helmet legislation is combined with educational programs is greater than in communities without these programs.^{11,12}

The results of our study suggest that education is necessary among parents, teachers, physicians, and EMS personnel in North Carolina in order to improve the number of children wearing helmets and decrease the number of bicycle-related head and brain injuries. The survey results suggest that most people expect parents to be the main educators of children about bicycle helmets. Reaching parents could provide the greatest impact. The survey participants are potential role models for children. Only 21% reported "always" wearing a bicycle helmet, suggesting that an educational campaign should also be extended to adult use.

This education should also include instructions on proper fit of the bicycle helmet. Of the 21% of improperly used bicycle helmets observed among children aged 5-15 in the 2002 North Carolina study,⁶ the most frequent misuse (40%) was due to the helmet being tipped back, exposing the forehead. The next most frequent (31%) mistake was a helmet that was too large or a chin strap that was loose. (See Figure 2 for details of proper helmet use.)

Many methods to educate about helmets as well as increase the use of helmets among children have been studied including free helmet giveaways,^{13,14} requiring the purchase of a helmet with a bike,¹⁵ police enforcement of legislation,¹⁶ physician involvement in behavior change counseling and education,¹⁷ and community programs.¹⁸ A 2005 Cochrane Review of nonlegislative interventions aimed at increasing helmet use among children found that the most effective method is a community-based education program along with free helmet distribution with some evidence supporting interventions in the school setting.¹⁹

Bicycle helmet use and legislation is comparable to seat belt use and legislation. North Carolina was the pilot state for enforcing seat belt use. In 1985 the North Carolina General Assembly passed a law requiring all front-seat passengers to wear seat belts. An initial rise in seat belt use followed, but by 1993 the seat belt use returned to near prelaw levels at 65%.²⁰ The *Click It or Ticket* campaign started in October of 1993 with a month of public education and high-visibility enforcement. Seat belt use rose to 80%, but by May 1994, just 7 months later, it had dropped to 73%. A return of enforcement and education in July of 1994 brought seat belt use back to 81%.^{21,22} According to the National Highway Traffic Safety Administration (NHTSA), seat belt use in North Carolina was reported to be 86.7% in 2005.²³ This shows that coupling education and law enforcement increased seat belt use in North Carolina. A similar strategy may increase bicycle helmet use among children.

Limitations

The data from this study was collected by survey which introduces nonresponder bias. It is possible that those recipients of the survey not interested in or educated about helmet use may have been less inclined to complete and return the survey, creating a bias towards awareness of the law or helmet use.

The question about knowledge of the law may have been misinterpreted. The survey asked about the state law (enacted 2001) when there also was a citywide law in place in Greenville, North Carolina (roughly half of the population of Pitt County) since 1998 requiring bicycle helmets in children under the age of 16. This could create a bias towards knowledge of the law. Also, for the question asking how frequently helmets were worn, an option was not given stating "do not ride a bike." This response was written in on some surveys, and it is possible respondents answered "no" to this question when in reality they do not ride a bike. Furthermore, frequency of and reason for bicycle use was not addressed, and this may also impact helmet use. Respondents who frequently use their bicycle for exercise could be more likely to wear a helmet than those who infrequently ride their bicycle. Some responders did not answer all questions on the survey; however, this was limited to the follow-up item to the question asking about the need for a law. This question was "If not, should there be a law?" Results were reported only on the respondents who answered "no" to the initial question, all of whom answered the follow-up question.

Further limitations provide areas for continued research. This study did not include an observational component and therefore only shows the opinions of the respondents, not actual helmet use. The survey was distributed only in Pitt County, North Carolina, and does not reflect helmet awareness for the state as a whole. A state-wide observational study should be repeated.

Conclusion

Helmets have been shown to be effective in reducing head and brain injuries among children which is the basis for the mandatory helmet law for children in North Carolina. A majority of surveyed parents, teachers, physicians, and EMS personnel in North Carolina were aware of the helmet law, yet they underestimated the effectiveness of helmets and felt uncomfortable with their level of understanding about proper helmet use and fit. Education aimed at parents and teachers may improve the overall understanding of helmets. However, awareness is not enough. Enforcement of and education about the helmet law is necessary to improve helmet use among children. **NCMJ**

Table 2. Proper Bicycle Helmet Fit ²⁴			
Step 1: Size	With the helmet sitting flat on top of your head, make sure it doesn't rock side to side. Sizing pads come with new helmets; use the pads to securely fit the helmet to your head.		
Step 2: Position	The helmet should sit level on your head and low on your forehead —one or two finger-widths above your eyebrow.		
Step 3: Buckles	Center the left buckle under the chin by shortening and lengthening the straps.		
Step 4: Side strap	Adjust the slider on both straps to form a "V" shape under, and slightly in front of, your ears.		
Step 5: Chin strap	Buckle your chin strap. Tighten the strap until it is snug, so that no more than one or two fingers fit under the strap.		
Step 6: Final fitting	 A. Does your helmet fit right? Open your mouth widebig yawn! The helmet should pull down on the head. If not, refer back to step 5 and tighten the chin strap. B. Does your helmet rock back more than two fingers above the eyebrows? If so, unbuckle, shorten the front strap by moving the slider forward. Buckle, retighten the chin strap, and test again. C. Does your helmet rock forward into your eyes? If so, unbuckle, tighten the back strap by moving the slider back toward the ear. Buckle, retighten the chin strap, and test again. 		

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Medical Journal

POLICY FORUM Emergency Medical Services in North Carolina

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The Future of Emergency Medical Services Communications Systems: Time for a Change Kevin K. McGinnis, MPS, EMT-P

INTRODUCTION

Policy Forum: The North Carolina System of Emergency Medical Services

Running on adrenaline and altruistic motives, nearly a million first responders, emergency medical technicians (EMTs), and paramedics across the US perform life-saving procedures every day. They do this under stressful and dangerous work conditions, for very little pay, and with little recognition. Funding and support for maintaining readiness is limited. Reimbursement for services rendered is often below actual costs. Low patient volumes, limited billing capacity, high turnover, and reliance on volunteers force many rural-based emergency medical services (EMS) systems, including some in North Carolina, to close or convert to a different type of EMS model.

Current research and policy reviews indicate that we possess very little knowledge and understanding of EMS; how it works today, how it is supported, how the personnel are trained and educated, what professional issues emergency responders face, and what operational and political obstacles prevent timely and high quality EMS care.

The public's visibility of the current status of EMS was raised recently by the Institute of Medicine of the National Academies (IOM) report on the status of EMS. The report pointed to inefficiencies, workforce problems, and other systems-level challenges. The overarching recommendation from the IOM was for the establishment of a permanent federal lead agency within the US Department of Health and Human Services dedicated to EMS. This issue of the *North Carolina Medical Journal* follows the IOM's footsteps by focusing attention to the challenges and needs of North Carolina's EMS system.

Lifelong EMS professionals in North Carolina feel the state has been on the forefront of the EMS evolution. Many national and internationally recognized EMS leaders live in North Carolina and have contributed to this issue of the Journal. Groundbreaking ideas and advances in EMS research and education are incubated and cultivated in North Carolina institutions of higher learning. State officials are tackling the most pressing challenges—recruitment and retention—by describing the extent of the problem and offering alternative solutions.

All of health care delivery is under scrutiny as we seek ways to provide the best possible care at a reasonable cost. However, we often don't look at this problem in a fully systematic way—largely because we do not have a uniform system of care. A uniform health care system would link and coordinate its many parts, including the emergency services components that have immediate and important roles to play in keeping our citizens healthy and bringing them quickly to definitive care.

This issue of the Journal seeks to highlight this part of the system by describing its origins and development and outlining the future organization and operation of EMS. There are decisions to be made at the local and state levels regarding how we can keep this important part of health care delivery functioning effectively for the citizens of North Carolina and the nation.

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Overview of Emergency Medical Services in North Carolina

William K. Atkinson II, PhD, MPH, MPA

he emergency department is an integral part of our nation's , health care safety net. Emergency medical services (EMS) are the integral thread in the safety net.¹ The position EMS care has in health care is significant and the services it provides are unique. There are more than 18 000 EMS systems in the United States² and approximately 800 separate service units operate in North Carolina. Coordinated at the county level, giving North Carolina 100 local "systems," North Carolina EMS systems incorporate local rescue squads and hospital, public health, and public safety personnel.³ In many rural areas of the US, there may be a single volunteer rescue squad that serves as the only form of health care for miles.⁴ Spread across almost every community in the US, there are nearly one million paramedics, emergency medical technicians (EMTs), and emergency first responders.⁵ An estimated 33 000 EMTs and paramedics are currently certified in North Carolina and most are volunteers.⁶

In most communities, EMS care is available to anyone, for any reason, at any time. On average, individuals use EMS care

twice in their lifetimes.⁴ The likelihood of using EMS care increases as an individual ages.⁷⁸ In some communities, demographic and socioeconomic factors associated with EMS utilization include lower income (poverty), minority race, female gender, and Medicaid or health maintenance organization insurance coverage.⁹⁻¹⁵

It is unclear exactly how frequently EMS care is accessed on a national scale. A recent Institute of Medicine of the National Academies report estimated 16 million EMS transports to emergency departments (EDs) in 2002.¹⁶ Other publications cite much higher frequencies with as many as 28

million EMS encounters.¹⁷ Thousands of other EMS encounters involve interfacility transports or transports to clinics, physicians' offices, or other institutions. North Carolina citizens use EMS over 1 million times each year.¹⁸

Emergency medical service systems are well known for their ability to handle cardiac emergencies and traffic-related trauma, but much of the medical care EMS provides is nonemergent in nature.^{14,19-22} Research shows that an overwhelming number of visits to the ED are nonemergent²³ and, in fact, are unnecessary,^{19,24,25} and use life-saving and expensive health care services needed by others.

A Call to Action

There are things in life and in health care that move along at yesterday's pace for seemingly no good reason. Many aspects of today's system of EMS care vary little from what was seen in the 1970s. In the 1950s and 1960s in North Carolina and across the nation, ambulance services provided little more than "scoop and run" transport.²⁶ Untrained personnel in hearse-type vehicles sped to an emergency scene, "scooped" up the patient with no regard to injury, illness, or care and raced—sometimes with both the driver and an attendant (if present) riding in the cab—to an ill-equipped and poorly staffed emergency room. Such was the case in almost every community across this nation.

"Before the 1960s, ambulance transportation was often provided by volunteer rescue squads or through local funeral homes."

> Before the 1960s, ambulance transportation was often provided by volunteer rescue squads or through local funeral homes. It was the norm and something that was accepted. Funeral home ambulances were solely for convenient, horizontal transportation. As of 1959, local governments were also authorized to help finance rescue squad operations.³¹ At that time, North Carolina's volunteer emergency squads were structured and

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funded in a haphazard way. These volunteer squads were mostly dependent on local donations to fund their activities. Rescue squads were sometimes formed through local fire departments, police departments, or civil defense units. Regardless of affiliation, the availability and quality of rescue and ambulance services across North Carolina was generally questionable. North Carolina wasn't alone; emergency services across the country were much the same.

Physicians and other health care providers insisted we could do better. In 1965, the National Academy of Sciences (NAS) published a report entitled *Accidental Death and Disability: the Neglected Diseases of Modern Society*.²⁷ The report forced public officials to take concrete steps to establish standards for ambulance design and construction, EMS equipment and supplies, and training programs and protocols for personnel. The NAS, drawing on lessons learned in the military in Korea and Vietnam, reported 52 million accidental injuries in the US, with 107 000 deaths. Of those who survived their injuries, more than 10 million were temporarily disabled and another 400 000 permanently disabled, all at a cost of \$18 billion. The report described accidents as the "neglected epidemic of modern society" and "the nation's most important environmental health problem."

The report stimulated the passage of the National Highway Safety Act of 1966, which called on the US Department of Transportation (DOT) to develop minimum standards of care for accident victims. It also gave the federal DOT the right to withhold 10% of its highway design, construction, and operation funds to states that did not comply. This risk equated to millions of dollars annually for each state and, as intended, quickly drew the attention of state governments.

Between the DOT and the National Highway Traffic Safety Administration (NHTSA), model EMS systems were developed. The appropriations for each agency included more than \$48 million for national training standards for emergency medical training. This structure provided for multiple levels of training to include emergency medical technician-basic (EMT-Basic), EMT-Intermediates, and EMT-Paramedics.²⁸

On November 16, 1973, Congress approved the Emergency Medical Services Systems Act of 1973 (PL 93-154)^{29,30} which funded and authorized the US Department of Health, Education and Welfare to help develop EMS programs throughout the country. Funding allocated \$30 million for the fiscal year ending June 30, 1974, \$60 million through June 30, 1975, and \$70 million through June 30, 1976. The act identified 15 "key elements" of an EMS system including manpower, training, communications, transportation, facilities, critical care units, mutual aid, consumer participation, accessibility to care, transfer of patients, standard record keeping, consumer information and education, review and evaluation, disaster linkage, and use of public safety agencies. Because PL 93-154 called for the development of a comprehensive system with a minimum of 15 complex components, an EMS system built around the federal model actually became many different innovations rolled into one umbrella known as EMS.

North Carolina as a Leader in EMS Innovation

North Carolina was one of the first states in the nation to address EMS development through state government involvement and on a statewide basis. National and state-level legislation led the way in the formation of modern EMS programs across the country. But while many states approved EMS development on an element-by-element basis, North Carolina approached EMS from a comprehensive system development perspective. Considerable federal and state resources were applied to system development and talent was drawn from both in-state and out-ofstate to support the overall program and its implementation.

North Carolina adopted the federal 15-element model and actively pursued implementation of EMS across the state. The central theme and intent of the EMS Systems Act was to develop systems of emergency medical care that would significantly decrease death and disability rates. However, implementation is often far more complicated than planning. In North Carolina's case, some volunteer emergency squads were just as ready to block federal intervention then as other types of North Carolina volunteers were ready to block Union troops in the American Civil War. Federal ambulance and training standards, even though they were to be administered through state government, were viewed by many local rescue volunteers as an intrusion on their rights, values, and way of life. This set the stage for another battle. This time it was state regulators, armed with federal standards and an innovative concept called emergency medical services, squaring off with community volunteers from across the state.

Due to many factors, by August 1966, 56 counties in North Carolina were threatened with the loss of ambulance service. Some municipalities stepped up to the plate to offer services that were lost, and some commercial providers began operation, but those services were normally of poor quality and limited financial means. Some commercial providers were allocated subsidies from local governments, but even with that, most still failed. By 1967, the lack of a sound approach to ambulance service was more visible than ever before. Many public and private interest groups, along with a growing list of medical professionals, began to focus on the statewide ambulance issue. Funeral directors began to withdraw from the delivery of the service, in part driven by the cost of labor due to newly introduced federal labor standards. The North Carolina General Assembly responded by passing the Ambulance Act of 1967. The act placed the legal responsibility for ambulance availability on county governments as an extension of public health.

In North Carolina, the Ambulance Act of 1967 represented the first major step for ambulance legislation in the state. More states across the country were taking advantage of federal dollars for technical assistance and funding in support of ambulance improvements and model projects. With money from the US Department of Transportation, the Jacksonville, Florida, fire department began efforts to reduce traffic related deaths by implementing a citywide EMS system.³² Overnight, the city government became involved in ambulance service. All of the community funeral homes and commercial ambulance services quit providing the service during a strike. In 1968, a similar situation occurred in North Carolina's Guilford County. The county had to step in and assume immediate responsibility for ambulance service when the only local, private service went on strike. Incidents like these were not isolated and occurred in numerous locations across the nation and throughout North Carolina.

State government, with limited funding, began to oversee North Carolina's ambulance and rescue services. For the first time in the state's history, minimum training standards, very minimum by today's rules, were established. Ambulance "attendants" were required to complete a 24-hour course in standard first aid through the American Red Cross or other training source. The North Carolina Board of Health also established equipment standards for all ambulances, based on recommendations from the American College of Surgeons' Committee on Trauma. Even with the minimal requirements, some rescue squads still refused to participate because they were wary of government intervention and they resisted change.

The North Carolina Board of Health was designated to inspect ambulances, but again, the quality of this oversight process was poor. Staff was assigned to monitor a system that truly didn't exist. F. O'Neil Jones, a freshman senator from the 24th district (Anson County), learned of the problems from Dr. Bill McKennon, a friend and physician, who said that something needed to be done. Armed with McKennon's advice and help from David Warren at UNC-Chapel Hill's Institute of Government, Jones created a research commission to examine statewide issues in emergency care and transportation. The results of the commission were outlined in the 1972 report *Emergency Medical Services in North Carolina: Transportation, Communication and Personnel.* The report stated:

North Carolina has approximately 400 organizations with 927 vehicles and 6,300 persons providing ambulance and/or rescue services. About one half of these providers is volunteer agencies and one-fourth is funeral home operators. Though volunteer and funeral home units represent almost 75 percent of the providers, they respond to only 43 percent of the calls. Governmental and commercial responders, who constitute less than 20 percent of the providers, respond to 52 percent of the calls. Other providers, such as hospitals, respond to the remaining calls.... It is estimated that only 202 service units meet the minimum requirements. (RTI, 1972:3)³³ ... The presumption is that people are dying needlessly at the hands of ambulance attendants who are so medically under skilled that they do not know how to deal effectively with many common medical emergencies.

Jones' work and the report of the commission resulted in the North Carolina EMS Act of 1973 and the creation of the North Carolina Office of Emergency Medical Services (NC OEMS) in the North Carolina Department of Human Resources. Subsequently, North Carolina was one of the first states in the country to begin a statewide effort to establish an EMS system in every community. This lead agency, under the secretary of the North Carolina Department of Human Resources, established broad powers and responsibilities to create, maintain, and oversee prehospital EMS operations and hospital-based trauma and helicopter ambulance services in the state. David Warren was appointed as acting chief of NC OEMS with instructions to get the office organized and do a national search for the best person to become permanent chief. That led to the hiring of a man who many emergency service professionals across the globe now describe as an emergency medical services pioneer—James (Jim) O. Page.

Jim Page, an attorney and a Los Angeles County fire battalion chief, was a leader of one of the first agencies in the nation to train paramedics and provide advanced prehospital care. Page, at the time, was also technical advisor to the NBC hit show "Emergency!" This program and Page's leadership brought him to North Carolina to lead the new agency after he came to the state for a speaking engagement and was enticed to apply for the newly created chief's position. He assumed the role as chief of North Carolina OEMS on December 19, 1973.

Page and the talented OEMS team he developed found it straightforward to upgrade vehicles and equipment through federal funding and new national standards in ambulance design and construction. Funds were also available to assist with the initial development of local and statewide EMS communications systems and air ambulance services. Likewise, the designation of hospital trauma centers was also a duty assigned to NC OEMS.

Implementing training standards and working with the hundreds of emergency service providers across the state proved to be another challenge—one that would eventually cost Page his job. The task of training and certifying basic EMTs was monumental. Urban areas rapidly accepted and adopted the new training standards while eastern and western parts of the state resisted implementation. Specifically, major pockets of opposition quickly built within the volunteer squads in and around Wayne County in the east and Gaston County in the west. The resistance was "organized, highly vocal, media intensive and politically active."³⁴

Rescue squads and funeral homes saw the training as an extra burden that was too much to ask of their members or employees. Page's support for training and education set him up as a political lightning rod. A number of state senators were complaining to the secretary of the Department of Human Resources that their local rescue squads were angry and putting significant political pressure on them about Page and NC OEMS.

Another looming problem and one that hints at reasons why some squads resisted initial training was illiteracy. For the first time, ambulance personnel would be required to attend formal training, read an EMT textbook, and pass written and practical exams. At the time, illiteracy was a problem plaguing squads from the mountains to the coast. Political pressure mounted to extend the basic EMT certification deadline, which Page was willing to do, and allow for oral examination for EMT candidates, which he was not. Giving in to "voter pressure," Page was asked to resign by the secretary, but he refused to do so. Page was then terminated. He was at the helm less than two years.

Page was replaced with Colonel Charles A. Speed, former commander of the North Carolina Highway Patrol. Speed was a highly principled man who also refused to compromise on the training standards. Although the road remained rocky for some time, the statewide training program moved forward; by 1977 all 100 counties had adopted basic EMT training, and by 1984 the number of certified EMTs had climbed to more than 50 000.

Following Colonel Speed's retirement, strong leadership continued to be a characteristic of NC OEMS. Under each chief, including the current chief, Drexdal Pratt, the implementation of all 15 key elements and many more add-on components and policy advances of the state's EMS system have continued to take place.

EMS Today

Today no one debates the merits of a 9-1-1 system, skills certification for paramedics, or the need for understood "levels" of care whether those be in the hospital-based trauma program or the neonatal intensive care unit. As September 11, 2001 taught us, the ability to communicate is essential in order to protect lives. When terrible things happen, people turn to their hospitals for help. As the recent tragic events at Virginia Tech also showed us, a level III trauma center handled more than 20 wounded students, many of them in critical condition, with skills and processes that make us all proud.

Are all of our hospitals in North Carolina and all of our first responders ready to handle such a terrible event? What should be the level of care we expect of any hospital in our state that has an emergency department? Many of our state's original emergency services physicians, nurses, physician assistants, and paramedics have or are approaching retirement. How will we replace their skills and expertise?

These are important questions the state's hospitals, physicians, policy makers, and their partners in emergency medical services are considering and debating. Once again, it will be surprising if North Carolina does not lead the way in finding solutions.

Essential Components of EMS: A Status Report

Over time, EMS systems in North Carolina and in the nation have evolved into sophisticated and mobile medical care units with highly trained medical professionals. In this special issue, local, state, and national experts and leaders in EMS provide detailed discussions and commentaries on the essential components of EMS.

Recruitment and retention of EMS personnel at all levels is perhaps the most visible challenge for EMS systems in North Carolina and nationally.³⁵ The EMS industry is in a struggle at the moment with advancing the profession while sustaining the existing workforce to meet rising public need and demand. Dr. Daniel Patterson comments on the nature of the manpower challenge for our state and the nation. Although research is limited, many states, local leaders, and colleagues in foreign nations are experimenting with a variety of approaches to ensure every citizen has access to the emergency care they need. We in North Carolina should monitor these trends and adopt emerging and innovative approaches to sustaining the EMS workforce.

In most locales, EMS professionals are first trained at the basic level of certification to deliver essential life saving care. With additional training, professionals are certified as intermediate technicians, paramedics, or critical care professionals. The bulk of the nation's and North Carolina's EMS professionals are trained in the community college system. Studies of EMS professionals show that many would prefer a degree over certification only.³⁶ In several commentaries, national and state leaders in EMS education and training discuss the role of community colleges, universities, and national registration organizations in the training of EMS professionals.

EMS communications include the transmission of information between EMS professionals, members of public safety (ie, police), and others. Cell phones and text messaging are increasingly being used to facilitate EMS communications. Much consideration has been given to gaps in communications due mostly to the communications challenges experienced during September 11, 2001 and during recent natural disasters. Communications experts Carl Van Cott of North Carolina and Kevin McGinnis of the National Association of State EMS Officials outline EMS communications in North Carolina, the challenges we face, and what is on the horizon in terms of new communications technologies and how they can help prevent miscommunication.

Data are the foundation for research that advances knowledge and even a profession. While we know that our nation's emergency departments receive over 100 million visits annually, we have no true sense of how many EMS responses and transports are made in America. Nor do we know very much about the details of EMS utilization or how best to go about reducing unnecessary use and improving the quality and safety of care for those who need EMS assistance. Sporadic record keeping in EMS is partly to blame. A lack of data has in many respects stalled the advancement of EMS as a service to our citizens. Work performed right here in North Carolina with support from a variety of federal agencies has helped to construct a national EMS information system, NEMSIS. Dr. Greg Mears of the University of North Carolina at Chapel Hill describes NEMSIS and what it can do for the state of North Carolina and EMS nationally.

EMS has evolved such that it works in concert with public safety and health care while standing on the outside looking in. EMS is a very fragmented system where it is difficult to make the vertical and horizontal connections between EMS and many of its partners in public safety or health care. Poor integration impacts patient transportation and transfer (by air or ground) to different facilities such as critical care units. It also impacts how one EMS system communicates and works with other EMS systems. Several commentaries included in this issue touch on these components from a variety of vantage points.

Emergency medical service was founded under the umbrella of traffic safety. Over time, various federal and state agencies have assumed responsibility for some or all aspects of providing EMS care. Identifying who or what agency is responsible for EMS can be difficult. Bob Bailey, a former chief of the NC OEMS, describes federal EMS legislation and what the legislation is intended to do. Drexdal Pratt, the current chief of the North Carolina Office of EMS, describes North Carolina's EMS legislation.

Financing EMS services is a very complex and often contentious issue. Many EMS systems receive some support from federal, state, and local governments. This funding usually represents a very small component of total system revenues or capital. In many instances, EMS systems must bill for services rendered which means transportation. If an EMS system responds to a scene and the patient is not transported, most systems are not reimbursed for the costs incurred. Todd Hatley, a former North Carolina local EMS training officer and EMS quality consultant, describes the EMS financing system, financial challenges, and experiences.

When one compares the amount of published research on topics specific to EMS to the amount published on non-EMS topics or in other disciplines, one word comes to mind: paucity.³⁷ Some our nation's most recognized leaders in EMS research are located right here in North Carolina. Two leaders, Dr. Herb Garrison of East Carolina University and Dr. Jane Brice of the University of North Carolina at Chapel Hill, discuss research and evaluation in EMS, focusing their attention on gaps in EMS research and where we need to be in terms of advancing the profession.

A survey of some Eastern North Carolina residents found that many have very little idea what their local EMS system provides in terms of medical care.³⁸ This lack of understanding also extends to many medical professionals. EMS professionals are designated agents of a physician.³⁹ In other words, EMTs and paramedics provide medical care under the license of a physician. With supervision and guidance, EMS professionals administer medications and perform many cognitively complex medical procedures outside of the hospital setting. Added to the list of 15 essential components of an EMS system after the 1973 legislation was written, medical oversight is an extremely important element of EMS care and delivery.⁴⁰ Local EMS systems, their chiefs, and their personnel must overcome many challenges in order to access and receive the medical oversight they need to perform their duties. Rural areas are known to have limited access to adequate medical oversight.⁴¹ The National Association of EMS Physicians (NAEMSP) and others have published a list of duties all physicians engaging in medical oversight activities must provide a local EMS system.^{42,43} Dr. Brent Myers, the medical director for Wake County EMS and WakeMed's Emergency Services Institute, comments on medical oversight in North Carolina and in the nation.

Providing a very in-depth look into one of the most controversial medical procedures performed in the prehospital setting is Dr. Henry Wang of the University of Pittsburgh. Endotracheal Intubation (ETI) is the insertion of a plastic tube into the mouth and throat of a patient in order to establish or maintain an open airway. For many reasons, performance of this procedure by EMTs has attracted a great deal of scrutiny from the medical community. Dr. Wang comments on the origins of ETI, outlines some of the controversies, and speculates on the future of ETI in EMS.

Threats of terrorism and natural disasters are prominent on the minds of most citizens and policymakers. Regardless of the type of event, EMS must be prepared for mass casualties. Drs. Roy Alson and Jane Brice are intimately involved in EMS preparedness activities and planning. They comment on preparedness in North Carolina.

Conclusion

At some point in time, virtually every North Carolinian and every American will require the assistance of EMS. One Congressionally supported report published in the late 1980s anticipated that every American could anticipate a minimum of two EMS encounters in his/her lifetime.⁴ The importance of our state and nation's EMS system should not be understated. When EMS is needed, we expect them to get there as fast and safely as possible. It is only at that point in our own history that we can truly appreciate the significance of our local EMS system, the training EMTs and paramedics go through, and the challenges they encounter while tending to our emergency needs.

Unfortunately, while we may all voice our appreciation for EMS in our community, the state's system of prehospital care, and that of the nation, is in jeopardy. In the recently released Rural and Frontier EMS Agenda for the Future,⁴⁴ the authors noted that the infrastructure upon which EMS was built is crumbling. More recently, our nation's emergency care system received an overall grade of C- in the first ever National Report Card on the State of Emergency Medicine.45 Overcrowding, poor access to emergency care, and liability issues were identified as prominent factors. The nation's leading independent health policy body, the Institute of Medicine of the National Academies, released three scathing reports on the state of emergency departments, EMS, and pediatric emergency care in 2006. The reports focused on the lack of federal leadership in the development of EMS systems as the most critical of factors in the delivery of EMS care today.¹⁶

Throughout its 50-year history, North Carolina's modern EMS system has played a prominent role in the evolution of EMS health care nationally. While there are many obstacles and many challenges, as the reader will learn in the pages that follow, North Carolina EMS authorities are well positioned to lead efforts in innovation and improvement. With recognition from state policymakers that EMS is a vital component of health care, public safety, and public health, our state's EMS system can continue to improve and serve as the EMS model for the nation. **NCMJ**

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Emergency Medical Services Legislation in North Carolina

Drexdal Pratt

North Carolina's history of emergency medical services (EMS) legislation dates back to 1967. The study commission and subsequent legislation in the state was a result of the federal National Highway Safety Act of 1966. This federal act created the National Highway Safety Administration and directed each state to develop a regional EMS system. The North Carolina Governors Highway Safety Program was charged with assisting in the funding of such a program in our state. Soon after the enactment of this act the US Department of Transportation released national standards for the design and equipment of ambulances and training for ambulance attendants.

In 1967 the North Carolina General Assembly passed the Ambulance Services Act under Chapter 130, Article 26, Regulation of Ambulance Services. This act placed the regulatory responsibilities of EMS under the North Carolina State Board of Health and provided the board authority for adopting standards for equipment, inspection of medical equipment, and supplies

required for ambulances. In addition, the law required that ambulances have permits and the board adopted regulations setting forth the qualifications required for certification of ambulance attendants.

The 1967 law also created an Advisory Committee on Ambulance Service to assist the North Carolina State Board of Health in developing standards for use in Article 26. The advisory committee consisted of 9 members and representative of the North Carolina Funeral Directors Association Inc., Funeral Directors and Morticians Association of North Inc., North Carolina Carolina Ambulance Association Inc., North Carolina Medical Society, North Carolina Hospital Association, American Red Cross, North Carolina State Association of Rescue Squads Inc., North Carolina Association of County Commissioners, and North Carolina League of Municipalities.¹ This advisory committee still exists today and has expanded in membership to represent the many EMS stakeholders. The committee's name has changed to the North Carolina EMS Advisory Council, and it continues to offer a valuable service to the state and the citizens of North Carolina.

In 1971 Senator F. O'Neil Jones sponsored Senate Resolution 827 authorizing a Legislative Research Commission "to study and investigate the problem of emergency care in North Carolina and to plan and develop an adequate system of providing comprehensive emergency medical care throughout the state with sufficient resources to save human lives and diminish the immeasurable emotional burden and vast economic losses of avoidable disability."² The Commission was instructed to report its findings and recommendations to the 1973 session of the General Assembly. Senator Jones chaired the commission and provided its report and recommendations to the General Assembly in January 1973.

"North Carolina's history of EMS legislation dates back to 1967. The study commission and subsequent legislation in the state was a result of the federal National Highway Safety Act of 1966. This federal act created the National Highway Safety Administration and directed each state to develop a regional EMS system."

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One of the recommendations of the commission was the establishment of the Office of Emergency Medical Services within the Department of Human Resources (now Health and Human Services). In addition, the agency should be adequately funded and empowered to coordinate and control all state EMS programs and have the ability to pursue federal and private funding and make allocations to both governmental and private local EMS systems. There were several other recommendations to increase the minimum standards for EMS training and to change the name of the Advisory Committee to the EMS Advisory Council and increase its membership to better reflect all of the state's EMS stakeholders.

As a result of the study commission's work, the Office of Emergency Medical Services was established in 1973 and placed in the Division of Facility Services. Funding was appropriated to the agency to improve training, transportation, hospital emergency rooms, and communications consistent with the 15 federally recognized components of an EMS system. Chapter 224 of the law consolidated the rule-making authority over ambulances and personnel in the Medical Care Commission. In Chapter 1121 the law authorized training emergency medical technicians to perform advanced first aid and limited medical procedures under the rules and regulations of the Board of Medical Examiners.

Over the next 20 years some minor changes were made to the EMS statutes and many administrative rule changes were made. In 1976 the North Carolina Medical Care Commission published a document entitled "Rules & Regulations Governing Ambulance Services," thus creating the state's basic life support rules. Also in 1976 the North Carolina Medical Board adopted rules to allow advanced skills for EMTs under the certification of Mobile Intensive Care Technicians.

In 1993 G.S. 131E-162 was passed and required the department to develop a Statewide Trauma System and, in 1995, G.S. 131E-155.1 was enacted to require the licensing of EMS providers. This legislation served EMS in our state well for many years and established a solid foundation to build on for the future.

North Carolinas EMS Legislation Rewritten in 2001

In 1999 the NC Office of Emergency Medical Services embraced the National Highway Traffic and Safety Administration's plan entitled *Emergency Medical Services, Agenda for the Future.* The agenda listed 14 attributes of an EMS system much like the previous 15 components but revised to meet the needs of a more expanded and developed profession. Realizing that EMS continues to be a local community based system, the new vision brings clarity and places emphasis on the fact that EMS is truly a port of entry to the overall health care system. Integration of health services are needed with such partners as public health, social services, community agencies, and academic institutions as part of the new vision.³ The new attributes address areas such as EMS research, system finance, prevention, information systems, evaluation, and others requiring additional statutory authority for implementation and funding. Those of us that have worked in the EMS system since its inception realized that North Carolina needed to rewrite its laws and rules governing EMS to fully embrace and implement the agenda.

Therefore, in 1999 we began the process to educate EMS stakeholders on the National EMS Agenda for the Future and rewrite the existing EMS laws. With help and support from the secretary of the Department of Health and Human Services, the director of the Division of Facility Services, the North Carolina EMS Advisory Council, 18 EMS stakeholder groups, and the dedicated staff of the Office of Emergency Medical Services, Representative Thomas Wright, New Hanover County, agreed to introduce House Bill 452, An Act to Revise and Update the EMS Act of 1973, and House Bill 453, Regulation of Emergency Medical Services, two of the most comprehensive EMS system bills in the country. The bills were passed in the 2001 session of the General Assembly and became law on January 1, 2002. The North Carolina Medical Care Commission adopted temporary rules to coincide with the legislation's enactment.

The new legislation required many changes to the structure of EMS in the state. Since most EMS providers in the state had progressed using the previous enabling legislation to provide advanced life support, it was apparent that EMS rule making needed to reside under the authority of one entity, either the NC Medical Care Commission or the NC Medical Board. After much discussion with the stakeholders it was decided to move all rule-making authority under the authority of the NC Medical Care Commission. The NC Medical Board retained statutory authority in G.S. 143-514 for defining the scope of practice for all levels of EMS personnel.⁴

The law now defines emergency medical services in G.S. 131E-155 (6) as: "services rendered by emergency medical personnel in responding to improve the health and wellness of the community and to address the individual's need for emergency medical care within the scope of practice defined by the North Carolina Medical Board in accordance with G.S. 143-514 in order to prevent loss of life or further aggravation of physiological illness or injury." The law also defines the Statewide Emergency Medical System in G.S. 143-507 (b).

Another major change in the law clearly places the responsibility of ensuring that every citizen has access to EMS to the Board of County Commissioners for each county. The new law establishes local EMS systems with no more than one system per county. New rules require that all counties submit a comprehensive EMS system plan to the Office of EMS and that all EMS providers licensed to operate in the county function as part of the county's EMS system. These requirements help standardize and coordinate the EMS care provided by the more than 850 EMS agencies operating in the state.⁵

New rules enacted by the NC Medical Care Commission

enable counties to advance their systems to earn the designation of "Model System."^a Model System designation far exceeds the minimum system requirements, is voluntary, and allows counties less regulatory oversight by the state. Less regulatory oversight includes self inspection of vehicles with appropriate documentation and more flexibility in all areas of their program management. In order to obtain the designation, counties must provide documentation that all system components of medical oversight, peer review, continuing education, and emergency medical dispatch are met and ensure the same high level of care is being provided to its citizens 24 hours, 365 days per year. The OEMS reviews the documentation then verifies through an on-site visit with the county before awarding the designation. The designation is awarded for a six-year period. Currently there are 12 counties in North Carolina that have obtained this designation.

Although air medical services were included in the previous rules, the new rules changed the terminology to include Specialty Care Air and Specialty Care Ground to address the interfacility patient transport. The term specialty care also assists EMS systems with reimbursement issues because this is a recognized term for Medicare and Medicaid. The law also provides liability protection for local and regional peer review meetings and requires electronic patient records to be submitted to the department on a daily basis. The data provides valuable information to assist the counties and state in assessing needs and looking at statewide patient outcomes for prehospital care.

The law also expanded membership on the EMS Advisory Council to be more representative of today's EMS system and created a 7-member EMS disciplinary committee that reviews all EMS personnel disciplinary cases and provides recommendations to the Office of EMS for possible action.

Throughout North Carolina EMS history the General Assembly, the Department of Health and Human Services, and the Division of Facility Services have supported efforts to improve the state's EMS system and have been proactive in passing legislation and rules to meet the needs of an ever expanding North Carolina EMS system. **NCMJ**

a The requirements for Model System designation can be found in the North Carolina Administrative Code 10A NCAC 13P .0202.

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Federal Policy Leading the Way in Emergency Medical Services

Bob W. Bailey, MA

The most influential piece of federal legislation during my 30-year tenure with the North Carolina Office of Emergency Medical Services (NC OEMS), the last 15 as the state Emergency Medical Services (EMS) director, was creation of the EMS program at the National Highway Traffic Safety Administration (NHTSA). Since then, federal EMS legislation, programs, and agencies have profoundly impacted the evolution of EMS throughout our nation and my personal career in North Carolina.

Federal EMS legislation permitted NHTSA to 1) assist states and local communities with the purchase of ambulances; 2) fund for automobile extrication courses; 3) provide national-level guidance and support to evolving EMS systems; and 4) standardize emergency medical technician (EMT) training across the nation. The NHTSA also made the term EMT a household word and created a universally recognized symbol for EMS, the blue "Star of Life."

The 1973 National EMS Systems Act helped shaped state legislation including that of North Carolina. The NHTSA state EMS assessments and reassessments program, a program supporting expert team evaluations of state EMS systems, continues to help guide the development of state EMS systems. NHTSA publications, such as the *EMS Agenda for the Future* and its various spin-off documents including the *EMS Education Agenda for the Future*. A Systems Approach, the EMS Research Agenda for the Future, and others, encouraged the nation to adopt a collaborative, consensus-based, and forward-thinking approach to EMS issues.

The passage of the Emergency Medical Services Systems (EMSS) Act of 1973 brought positive changes to EMS. Health care provided in the hospital could now be extended into the community¹ and mechanisms were now available for funding the development of regional EMS systems.² The EMSS Act brought much needed recognition to emergency medicine as a field of medicine.³ It also placed substantial obligations on hospitals which compelled them to provide new funding for emergency

and trauma facilities including adding laboratory, imaging, and other services as resources for emergency departments.⁴

Under the EMSS Act of 1973, requirements for medical direction were nonnegotiable, which in turn stimulated the involvement of prominent physicians in EMS. Hospitals, specialty care centers, and rehabilitation facilities became recognized as essential components of an effective EMS system. The EMSS program and the North Carolina 1973 EMS legislation fundamentally changed the North Carolina EMS system for the better. Unfortunately, the federal program was discontinued in the early 1980s when the funding was incorporated into the Preventive Health and Health Services Block Grant program.

"The EMSS Act brought much needed recognition to emergency medicine as a field of medicine."

Since 1984, the Emergency Medical Services for Children (EMS-C) program at the Health Resources and Services Administration (HRSA) within the Department of Health and Human Services (HHS) has provided national leadership in the improvement of emergency medical care for children in both prehospital and hospital environments. The program helps ensure that each state EMS office has someone dedicated to the emergency medical care needs of children, has utilized special projects or "targeted issues grants" to develop pediatric products and tools, and has promoted research in pediatric care. Although the EMS-C program is primarily intended to improve EMS care for children, HRSA recognizes that emergency medical

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care for children cannot be built on the foundation of a crumbling EMS system. As a result, the program also plays a prominent role in promoting comprehensive EMS system development overall. Through this and other programs, HHS coordinates extensively with all federal agencies involved with EMS.

In 1990, the Trauma Care Systems Planning and Development Act, which focused on improving emergency care of the seriously injured patient, became law. The resulting federal trauma program was located at HRSA. Some of the program successes include creating a Model Trauma Systems Plan for states to use as a template to develop inclusive trauma systems, providing limited grant funding for states to develop trauma systems, and stimulating national interest in and attention to trauma systems. As a state EMS director, we used federal highway safety funds through the NC Highway Safety Office and later the federal Trauma Program grants to convene trauma system stakeholders, develop a trauma system for North Carolina, and initiate a state trauma registry. Ultimately, this resulted in comprehensive state trauma system legislation. Although program authorization and funding for the federal program has lapsed several times, this program has demonstrated strong leadership and the wise allocation of limited federal resources to further the development of trauma systems. The program has again been reauthorized, but not yet funded.

Several years ago Drew Dawson, the Montana State EMS director for 20 years became the head of NHTSA's EMS program. Under Drew's leadership I've seen an unprecedented level of federal activity in relation to EMS. With its long-standing history of providing support to EMS, the NHTSA EMS Division was elevated to the Office of Emergency Medical Services (OEMS) with a mission to "reduce death and disability by providing national leadership and coordination of comprehensive, evidence-based emergency medical services and 9-1-1 systems."

Although working with other federal agencies has long been daily business for NHTSA, the importance of federal agency collaboration on EMS was further emphasized by Congress in the creation of the Federal Interagency Committee on Emergency Medical Services (FICEMS). Created by the secretaries of the departments of Transportation, Health and Human Services, and Homeland Security, FICEMS comprises high-level representatives from a variety of federal departments and is charged with identifying the nation's EMS needs, coordinating EMS support among federal agencies, and reporting to Congress. The National Highway Traffic Safety Administration is responsible for providing staff and administrative support to FICEMS. With the advent of FICEMS comes the opportunity to further enhance and institutionalize the already excellent cooperation among those federal agencies with an EMS mission.

To provide a formal mechanism for nonfederal input to NHTSA'S EMS activities, the Department of Transportation created a National EMS Advisory Council (NEMSAC). This 26-member advisory council membership reflects the national diversity of EMS including volunteers, fire-based EMS providers, trauma surgeons, emergency physicians, nurses, and private EMS services. The combination of FICEMS and NEMSAC will help to formalize and improve the long-term federal support of EMS.

Other promising developments in federal EMS support are also occurring. For example, the creation of the Office of Health Affairs at the Department of Homeland Security (DHS) provides a DHS-specific focal point for all things medical-including EMS. The Pandemic and All-Hazards Preparedness Act (2006) assigns additional responsibilities for EMS preparedness to the Assistant Secretary for Preparedness and Response at HHS. In addition, Congress recently established a National 9-1-1 Office. Jointly operated by NHTSA and the National Telecommunications and Information Administration at the Department of Commerce, the office is physically located at the NHTSA Office of Emergency Medical Services. Its mission is to provide leadership and coordination of comprehensive and technologically enhanced 9-1-1 services. Another important example of federal collaboration efforts to assist states includes the collaboration among NHTSA, EMS-C, the Department of Homeland Security, and the Division of Injury Response in the National Center for Injury Prevention and Control at the Centers for Disease Control and Prevention (CDC) to develop information related to world-wide bombings, surge capacity issues for hospitals, and revision of the American College of Surgeons Committee on Trauma Field Triage Decision Scheme.

The synergism of several federal agencies working collaboratively to enhance EMS clearly exceeds that generated by any single agency. Collaboration and cooperation, not silo building, continue to be the mantra of federal agencies involved in EMS. Federal EMS programs have had an enormous impact on the development of state EMS systems throughout the country including North Carolina. **NCMJ**

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Recalling the Birth of Emergency Medical Services in North Carolina

George Johnson Jr., MD, April 6, 1926–May 15, 2007

n 1972 a legislative committee was formed to study emergency medical services in North Carolina with Senator O'Neil Jones as chairman. The committee included doctors, legislators, and everyday citizens who were concerned with emergency medical services (EMS) in the state.

At that time, most of the people needing emergency care were transported by hearse. There were many problems with this system of emergency transportation. We had a hearse arrive

at an emergency room with no patient in the back they'd either driven off without them or lost the person on the way. In another instance, a woman gave birth and the hearse attendants never took her underpants off. The baby died.

The members of the legislative committee wanted to improve emergency care across the state; we felt emergency services should be as good in Chinquapin as they were in Raleigh. Martin Hines from the Department of Public Health was very interested in emergency medical services "We helped set up a trauma center classification system that worked well with the American College of Surgeons system. That led to the creation of a trauma system database that we still use to track cases through the system."

and helped us in many ways. There was interest in a centralized system based in Raleigh, but we recognized that a one-man show would not work. We engaged a group in Tennessee, and they suggested dividing the state into several trauma center areas—regionalization of services was a big trend at the time. The Regional Medical Program was in full-swing, and we were on the verge of setting up the North Carolina Area Health Education Centers (AHEC) program. We didn't think a regionalized trauma system would work for emergency services because of the proximity of the medical centers at Duke University, the University of North Carolina at Chapel Hill, and Wake Forest University. We did think that we ought to upgrade the whole system, and we pushed for a new office to

> coordinate training and organization. We helped set up a trauma center classification system that worked well with the American College of Surgeons system. That led to the creation of a trauma system database that we still use to track cases through the system.

> Legislation was passed in the North Carolina General Assembly that created an Office of Emergency Medical Services (OEMS) within the Department of Human Resources. Jim Page from Los Angeles, who was a paramedic

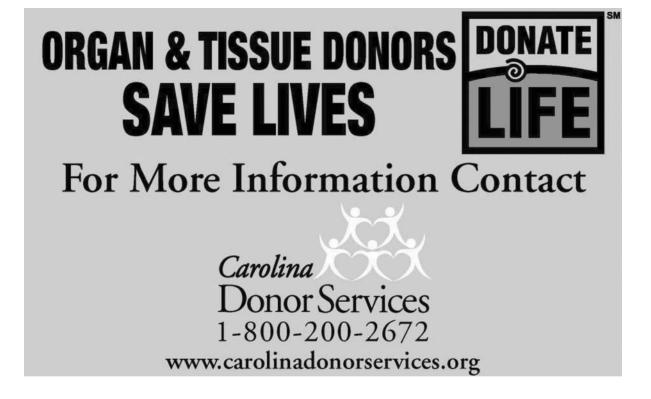
and wrote a television program about EMS, was the first chief of the OEMS. An advisory committee was formed to advise the OEMS. It was emphasized that this was an advisory committee and had no authority. The members were emergency department personnel, members of the North Carolina College of Surgeons

George Johnson Jr., MD, widely regarded as the father of modern EMS systems in North Carolina, passed away in May of 2007 shortly after contributing his recollections of the development of EMS in North Carolina. Johnson was a distinguished, nationally prominent surgeon serving on the faculty of the University of North Carolina at Chapel Hill School of Medicine and on the staff of UNC Hospitals from 1959 until shortly before his death. In recognition of his seminal contributions to emergency care in the state, the North Carolina Office of Emergency Medical Services established the George Johnson Award for Emergency Medical Services for individuals who have made significant impact on EMS in the state.

Trauma Committee, and other personnel interested in emergency medical care. These members were included to contribute based on their expertise in emergency medicine.

Although there have been several efforts to move OEMS out of the Department of Human Resources (DHR), thankfully this could not be done. We felt emergency personnel ought to be linked closely to health, and we advised that they stay in DHR. The OEMS worked with rescue squads, EMS training programs, pediatricians, hospital personnel, physicians involved in emergency medical care, and the NC Board of Medical Examiners. Standards were set up in order to deliver emergency medical care that was uniform throughout the state.

All this worked well enough, but there were bumps along the way. Several areas wanted exemptions to the statewide rules because they thought they already had superior emergency care; this was not allowed. The firemen and rescue squads were in a different department of the state and had their own training. It was difficult to get them to abide by the standards of the OEMS, but eventually they came on board. The OEMS was able to make great use of the community colleges to train personnel; this was a great success and it continues today. **NCMJ**



Research and Evaluation in Out-of-Hospital Emergency Medical Services

Herbert G. Garrison, MD, MPH; Jane H. Brice, MD, MPH

When people dial 9-1-1 to request assistance for a medical emergency, they expect the responding paramedics and emergency medical technicians (EMTs) to provide safe, competent, and effective care. Competent practice in medicine and health care should be based on evidence that is substantiated by research. Such is far from the case for out-of-hospital emergency medical services (EMS), whose practitioners commonly utilize protocols and interventions that have limited substantiation from research. Instead, much of the EMS care delivered is based on expert opinion and consensus or has been taken directly from the hospital to the street with no investigation.

The gaps in EMS knowledge and the structural barriers to

filling those gaps have been well-documented.¹⁻³ Investigators in North Carolina have a good track record in EMS research and are working toward filling those gaps. Research in EMS in North Carolina will be even better once investigators access a new statewide population-based data system that the state Office of EMS has implemented. There are, however, many more steps to take to allow EMS research to fill the gaps in knowledge.

Gaps in Knowledge

The gaps in EMS knowledge were made clear by a recent systematic review of the medical literature. Smith et al⁴ identified 400 out-of-hospital trials with steady increases in trials through the late 1990s. Nearly two-thirds (63%) of the 400 reports of trials concerned resuscitation and cardiac care. While resuscitation research has improved outcomes from cardiac arrest and demonstrated the benefit of different specialties collaborating on one disease entity, similar progress is lacking on other fronts. As the authors point out: "The principal finding of this study is the contrast between the wide scope of the out-ofhospital field (resuscitation, airway diseases, injury, out-ofhospital medical treatments, etc) and the lack of high-quality evidence on which to guide practice. Although taking nothing away from the quality of research in this area, cardiac arrest and acute resuscitative attempts account for only 2% of all ambulance responses.... Therefore, the majority of interventions used in the out-of-hospital environment are not based on strong evidence...."⁴

There are many other EMS interventions that require study. The National EMS Research Strategic Plan³ assembled and prioritized an exhaustive list of core topics for which there is a

"Competent practice in medicine and health care should be based on evidence that is substantiated by research. ... Instead, much of the EMS care delivered is based on expert opinion and consensus or has been taken directly from the hospital to the street with no investigation."

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need for investigation. Questions in need of research answers include: What are the most effective and safe EMS airway management strategies? Which EMS treatments, including destination decisions, are effective for acute cardiac ischemia? Does out-of-hospital therapeutic hypothermia mitigate brain injury? Which patients, if any, require spinal immobilization? What are the attributes of professional competency in EMS? Is air medical transport cost-effective? What is the impact of emergency department overcrowding on the delivery of EMS care?

Some questions have significant implications for North Carolina. For example, what is the right mixture of staffing an ambulance: one paramedic and one EMT, two paramedics, or two EMTs with backup from a paramedic-staffed quick response vehicle? This question is unimportant when resources are plentiful. However, resources for EMS are shrinking, volunteers are fewer, and paramedics are in short supply.⁵

Are the gaps in knowledge important? The answer is an unequivocal yes. While a call to 9-1-1 will likely produce an ambulance and a ride to the hospital, there is no guarantee the care will be consistent from one EMS system to another. A recent study comparing systems across the nation found that out-of-hospital care for trauma patients varied substantially.⁶ As Delbridge and March⁷ pointed out in their commentary on this study, "Rather than indicating areas of poor quality, variation in out-of-hospital care for trauma patients may indicate a collective uncertainty about the effectiveness of some interventions."

Structural Barriers

The National EMS Research Agenda¹ highlighted 5 impediments to high quality EMS research: (1) a paucity of highly skilled researchers; (2) inadequate funding; (3) failure of EMS professionals to understand the importance of conducting EMS research and translating the findings into clinical practice; (4) a lack of integrated information systems that provide for meaningful linkage with patient outcomes; and (5) logistical problems in obtaining informed consent.

Removing these barriers takes on a special urgency when one considers the impact they may be having on EMS research productivity. Since 2000 there has been a precipitous drop in the number of published EMS research trials.⁴ It is unclear why this decrease in studies has occurred. But the implication is very clear: the structural barriers to EMS research are effective.

North Carolina's Role in Filling the Gaps

The good news is that researchers in North Carolina are doing their part to bridge the gaps in EMS knowledge despite the barriers. The record of EMS contributions from North Carolina is too long to list here. As examples, investigators in our state are producing new knowledge on the effectiveness of out-of-hospital electrocardiograms,⁸ the role of EMS in public access defibrillation,⁹ the duty of EMS in reporting domestic violence,¹⁰ and the out-of-hospital care of stroke patients.¹¹ But much work remains.

Next Steps

What should we do here in North Carolina to facilitate research and evaluation of EMS interventions and to assure that the care provided on the streets and in the homes of our state is evidence-based? First, we should and do congratulate the emergency medicine programs on the work already accomplished and encourage them to keep EMS research as a priority in their departments. The academic departments of emergency medicine in this state have an obligation to lead the efforts to evaluate the evidence, conduct high quality EMS research, and make recommendations on what paramedics and EMTs should and should not be doing in the field. To this end, they should foster collaborative partnerships with other specialties that can be leveraged for external funding. In addition, they should seek EMS fellows with passion and energy and facilitate their learning and investigations. Emergency medical services research will take off when investigators with passion have the partnerships and resources in place to advance knowledge.

Second, these departments should work closely with their respective institutional review boards (IRBs) to jointly explore the problem of obtaining consent on EMS patients who are minimally to nonresponsive and who have no relatives at hand. Mutual understanding of the issues implicit in out-of-hospital informed consent will lead to stronger research protocols. The more EMS researchers interact with the IRB on the problem, the easier it will be to gain approval of out-of-hospital clinical research on unresponsive patients.

Third, while North Carolina has a good system for approving new therapies and practices, the system could benefit from a few modifications. In the current process, proposed additions are vetted by the state EMS medical director and the Office of EMS (OEMS). The medical director then makes a recommendation to the NC EMS Advisory Council. The members of that group will approve the recommendation, which then goes to the NC Medical Board. This system works well but could be improved with two modifications: (1) the state medical director should have the discretion of commissioning outside systematic reviews of proposed interventions, especially for those therapies that are controversial or are being pushed by a special interest group; and (2) the NC OEMS should develop a system for periodic examination of current approved therapies and practices to determine what should be eliminated due to a lack of support from research.

North Carolina is very fortunate to have a progressive Office of EMS. Because of its progressiveness, North Carolina now has a statewide, state-of-the-art population-based data system to which data are submitted by all EMS agencies in North Carolina.¹² Once this data is linked to outcomes, investigators will be able to study—on a broad scale—very important questions about the effectiveness of EMS interventions. This is one of the most important developments in EMS research and evaluation for our state in a long time.

Expectations

North Carolinians expect and receive a prompt response from EMS when they call 9-1-1. They have an equal expectation that EMS care will be the best possible and will be based

on evidence from credible research. North Carolina provides leadership for so many other fields and we should likewise be leaders in EMS research and help break down the barriers and advance EMS knowledge. The people of our state should expect nothing less. NCMJ

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Emergency Medical Services Education: Past, Present, and Future

Gregg S. Margolis, PhD, NREMT-P

As medical technology expanded and became increasingly specialized in the 1960s a need emerged for a cadre of health care workers with specific skills and knowledge. In 1966, Congress passed the Allied Health Personnel Training Act (P.L. 89-751) which paved the way for a virtual explosion in the variety and types of occupations collectively referred to as "allied health professions." Most established and newly forming allied health professions developed specialized educational program accreditation models that paralleled those of nursing and

medical schools. The American Medical Association Council on Medical Education collaborated with professional associations to establish educational standards and guidelines for many health sciences education programs in this era.¹

As a result, the educational infrastructure of most allied health programs followed a health care or medical model. Most allied health professions built educational systems by providing funding for pilot programs in established institutes of higher learning, developing faculty, and investing in national educational program accreditation and credentialing systems. Emergency medical services (EMS) education developed down a very different path which by all accounts has played a significant role in the way in which the EMS professional has been integrated into the larger health care workforce and system.

Also in 1966, the National Academies of Science National Research Council published the landmark paper *Accidental Death and Disability: The Neglected Disease of Modern Society*, which provided considerable funding for the development of EMS throughout the nation.² It reported that "there are no generally accepted standards for the competence or training of ambulance attendants" and recommended that "there is a need for delineation of a standard course of instruction [for ambulance personnel]." It was from this recommendation that the practice of developing nationally standardized education for EMS personnel began and continues today.

In contrast to the model followed in most other emerging allied health professions, EMS began what would become a reliance on a centralized curriculum model. In 1969, the Highway Safety Bureau (now the National Highway Traffic

"An EMT in one state may not have the same (or even similar) education, training, or scope of practice as in another state. This variation causes confusion among the public and colleagues in other disciplines as well as making professional mobility and recognition challenging."

> Safety Administration, NHTSA) contracted with Dunlap and Associates to develop a curriculum to standardize ambulance attendant education. In 1971, the Emergency Medical Technician-Ambulance (EMT-A) National Standard Curriculum (NSC) was released and included specific learning objectives, highly detailed lesson plans, and hours of instruction.³ This document established a precedent, and to a large extent,

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an expectation from the EMS educational community for federally developed, highly detailed course support materials.

The EMT-A NSC was a highly efficient method of stimulating the creation of EMT training programs nationwide. Especially in an area where few EMTs existed and in a time when many courses were taught by nurses or physicians, the NSC proved to be a useful way of providing consistent training to a new occupational group. In part due to the success of the EMT-A NSC, NHTSA contracted with Dr. Nancy Caroline, then with the University of Pittsburgh, to develop the first EMT-Paramedic National Standard Curriculum in 1977.

Throughout the late 1970s and 1980s, the NHTSA EMS curricula became the defacto standards for EMS education and were referenced in many state laws and administrative rules. The NSC had an impact beyond education and in many states became the basis for the scope of practice for EMS personnel. All levels of the NSC were revised in 1984 by the National Council of State EMS Training Coordinators and again in the mid-1990s under contract with the Center for Emergency Medicine in Pittsburgh, PA. The 1990s revisions became particularly contentious because the NSC revision process was the only major national forum for discussing EMS education and scope of practice issues. While the EMS community began to ask the question "Is there a better way?" another major EMS initiative was beginning to take shape.

In the mid-1990s NHTSA began a bold project to set a path for the future of EMS. The *EMS Agenda for the Future* proposed a vision for EMS beyond that of an emergency response system. Specifically, it proposed that EMS assume a larger public health role.⁴ To support this goal, the agenda recommended a number of changes to the EMS educational infrastructure, including an expansion of accreditation, affiliation of higher level EMS education with academic institutions, and replacing the NSC with "core content."

NHTSA convened a work group to deliberate on ways to improve EMS education. The EMS Education Agenda for the Future; A Systems Approach proposed an improved system intended to prepare the next generation of EMS professionals. Drawing on the strengths of the existing system that relied heavily on federally developed curricula and those of other professions, a system was proposed that provides for efficiency, consistency, and coordination. The EMS Education Agenda for the Future proposed the replacement of the National Standard Curricula with 3 documents (National EMS Core Content, National EMS Scope of Practice Model, and National EMS Education Standards) and the further support of National EMS Certification and Educational Program Accreditation. The authors believe this approach blended the advantages of the experiences of both EMS and allied health education.

The EMS Education Standards, under development in 2007, are intended to replace the need for highly detailed, nationally standardized curricula. The standards are being written in such a way as to encourage instructional creativity and educational innovation while clearly conveying what must be included in EMS educational programs. The creation of the *National EMS Scope of Practice Model* (released in 2006) as a separate document facilitates the decoupling of education and scope of practice issues and should facilitate educational change initiatives.

The format of education standards, modeled after accreditation standards and guidelines, is admittedly broader and subject to more interpretation than detailed curricula or lesson plans. For this reason, the success of the EMS education standards will rely on the entire EMS educational system. When supported by national accreditation and certification, there will be considerable guidance as to what must be taught in each level of EMS education, with the flexibility of how to teach it left up to individual programs and instructors, where it should be.

In 2006, the Institute of Medicine of the National Academies (IOM) released the report *Emergency Medical Services at the Crossroads* which recommended that states strengthen the EMS workforce by adopting common EMS certification levels, accepting national certification for state licensure, and requiring national accreditation of paramedic education programs.⁵ For EMS to evolve, these educational initiatives should receive support.

Four Recommendations

Adopting Nationally Consistent Levels of Practice and Nomenclature

There is considerable state to state variation in the titles and scope of practice of EMS personnel; thus, the training and education of EMS personnel varies from state to state. A recent study conducted by the National Council of State EMS Training Coordinators identified at least 39 unique levels of EMS provider (many with slightly different titles) in a survey of 29 states. An EMT in one state may not have the same (or even similar) education, training, or scope of practice as in another state. This variation causes confusion among the public and colleagues in other disciplines as well as making professional mobility and recognition challenging. The lack of consistency creates inefficiencies because educational support materials and services (eg, accreditation and certification) may not be aligned with an individual state's requirements.

Require National Certification for State Licensure

The primary purpose of licensure and certification must be to protect the public against subcompetent providers.⁶ Most mature health care professions have a single national standard for the measurement and verification of entry level competence. Unfortunately, no such system exists in EMS. The National Registry of EMTs is utilized by 45 states as part of the credentialing process for each level of EMS personnel. Fourteen states and the District of Columbia use a state level credential for at least one level of EMS personnel.⁷ These systems vary in credibility, validity, and content. For EMS to mature as a discipline, a single national definition of competence at each provider level must exist and be adhered to by all states.

The EMS Name Game

The credentialing and titling of emergency medical personnel is currently a confusing picture for individuals not intimately familiar with emergency medical services (EMS). First, it is essential to realize that each state has the responsibility and authority to create EMS licensure/certification levels. While many other levels exist, the National Highway Traffic Safety Administration has developed curricula for 5 levels of EMS personnel: First Responder, Emergency Medical Technician (EMT)-Basic, EMT-Intermediate (1985 edition), EMT-Intermediate (1999 edition), and EMT-Paramedic. Most states have adopted some of these levels (with minor changes in scope of practice), and many states have created additional levels to address local needs.

National level	Approximate number of training hours	Number nationally certified ¹	General role	Examples of skills and knowledge
First Responder	40-60 hours	13 510	Intended to serve as the initial responder generally arriving before other EMS resources.	Cardiopulmonary resuscitation (CPR), oral airways, bleeding control, ventilation.
EMT-Basic	110-140 hours	198 200	Intended to represent the minimum training necessary to serve as an ambulance team member.	Basic airway management, bag valve mask ventilation, automated external defibrillator (AED) use, spinal immobilization, splinting, extrication.
EMT-Intermediate 85	60-120 hours ²	12 701	An EMT-Basic with a few selected advanced skills.	Dual lumen airways, intravenous access and fluid administration.
EMT-Intermediate 99	200-400 hours ²	2527	Intended to provide core advanced resuscitation skills, especially in rural settings.	Endotracheal intubation, basic electrocardiogram (EKG) recognition, cardiac arrest resuscitation medications.
EMT-Paramedic	800-1200 hours²	61 121	Represents the highest level of EMS credential and intended to provide advanced assessment and treatment of a broad range of emergency conditions.	Needle cricothyrtomy, needle thoracentesis, advanced EKG recognition, emergency medications and pain relief.

The recently released National EMS Scope of Practice Model proposes 4 levels of credentialing for EMS personnel: Emergency Medical Responder, Emergency Medical Technician (EMT), Advanced Emergency Medical Technician (AEMT), and Paramedic. It is expected that many states will be transitioning to these levels over the next few years.

1 As of Jan 2007. Note, no reliable data exists on the number of state licensed/certified EMS personnel, but it may be 2 to 3 times the number of those nationally certified.

2 In addition to EMT-Basic, which is generally a prerequisite.

Link National Certification Eligibility to Graduation from an Accredited Institution

The primary purpose of the accreditation of educational programs is to protect students and potential students from enrolling in an educational programs plays a small role in EMS compared to most other allied health professions. The Committee on Accreditation for the EMS Professions (CoAEMSP) currently accredits 220 paramedic programs—probably representing one-half to one-third of the paramedic programs nationally. While accreditation is technically a voluntary process, most professions limit eligibility of entering the credentialing process to graduates from accredited programs. Without requiring a single national educational program accreditation program accreditation process, it will be effectively impossible to implement national EMS educational change initiatives.

Increase the Role of Higher Education in EMS

One educational issue not recommended by the IOM but that deserves support is to increase the role of higher education in EMS. Formal post secondary educational institutes play a comparatively small role in EMS education. While many community college, technical schools, and universities sponsor EMS educational programs, a large percentage of EMS education remains agency or hospital based. A significant portion of EMS education still occurs in an academy setting or is sponsored by small proprietary training companies. While some of this training is excellent, it offers the student little in terms of formal recognition of EMS education toward the achievement of larger academic or degree goals.

The EMS community should recognize the associate degree as the appropriate academic preparation for paramedic level education. Emergency Medical Technician-Basic education should be sponsored by academic institutions that have the resources, student/faculty support services, and stability necessary to assure quality education. All EMS-related courses should offer college level credit.

Currently, 14 institutions offer bachelor's degrees in EMS.⁸ Unfortunately, there is no consensus as to the role that these degrees play in EMS career progression and there is little consistency in the curricula. While these programs should be supported, they must be encouraged to develop a vision for the role of bachelor's (and master's) level education in EMS.

Conclusion

Occupational groups that have successfully transformed themselves have typically done so through improvement of their educational systems. Education is the catalyst for change, growth, and evolution of groups of people. The history and sociology of professions are filled with examples (many in health care) of workers who had a desire for an expanded role that offered greater service to the community. The EMS professions are at such a crossroads and will be able to realize the vision of the *EMS Agenda for the Future* only through bold leadership and support of educational change initiatives. **NCMJ**

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Responding to the Educational Needs of Our Emergency Medical Services Responders

William Lineback, BS, EMT-P

A lmost 30 years ago, community colleges across North Carolina began providing instruction to members of fledgling emergency medical service (EMS) agencies—known then as "rescue squads." The role that North Carolina community colleges currently play in educating future emergency medical technicians is a direct result of the federal 1973 EMS Systems Act.

Presently, 58 North Carolina community colleges serve several roles in the delivery of medical education to current and future EMS personnel. In 2005-2006 there were 32 777 individuals

enrolled in one or more EMS courses at North Carolina community colleges. In addition to preparing students with no prior medical background to become EMS personnel, community colleges provide credentialed EMS personnel with ongoing continuing education. Because community colleges throughout the state are readily accessible to the majority of North Carolina's EMS and firefighting personnel, these institutions provide much of the education necessary for these first responding professionals to remain proficient and knowledgeable of medical developments. This accessibility

also serves the public well by making first aid, CPR, and safety and prevention instruction readily available at a reasonable cost. By consolidating state and county resources, community colleges also can provide access to EMS educational equipment that is beyond the budgetary reach of many smaller EMS agencies or systems. Paramedics must have access to intraosseous drills, 12-lead electrocardiogram (EKG) monitors, simulation manikins, ventilators, continual positive airway pressure devices, and other expensive equipment to become proficient. North Carolina community colleges are uniquely poised to provide access to these and other necessary pieces of equipment.

Our state's community colleges also are playing a role in

meeting the medical care needs of our communities across the state. With the ranks of senior citizens swelling with the influx of the baby boomers, the demand for health care workers in all fields, especially EMS, will increase for the foreseeable future. This presents several challenges to our state's community colleges that must be solved. Our colleges must be able to locate qualified and knowledgeable EMS faculty. This is difficult to do when community college faculty salaries are often lower than those found at EMS agencies, which are already shorthanded and forced to compete with colleges for the limited number of

"In addition to preparing students with no prior medical background to become EMS personnel, community colleges provide credentialed EMS personnel with ongoing continuing education."

> experienced EMS professionals. Also, colleges must attract more students into their EMS and health care programs. This is challenging because average starting EMS salaries in the state are low. Last, but certainly not least, community colleges must be better funded. Too many colleges are forced to squeeze by with outdated equipment, facilities in need of major repair, and inadequate staffing. Funding is a critical issue to meeting these challenges.

> Emergency medical service education underwent a significant change in 2004 when modifications to the North Carolina Administrative Code were enacted. Section 10A-NCAC-13P allowed community colleges and other educational institutions

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that were providing EMS education to assume more control of their programs. These approved institutions were charged with serving as the gatekeepers for those choosing to enter the EMS workforce.

Additional changes lie ahead for education in EMS, especially in the community college setting. The National Highway Transportation Safety Administration's *EMS Education Agenda for the Future: A Systems Approach* details 5 major national education system components to be developed and implemented in the not-too-distant future: core content, scope of practice, education standards, program accreditation, and certification. While physicians will govern core content and regulatory bodies govern scope of practice, North Carolina community college EMS faculty members will have input into developing and updating education standards and community colleges will apply for EMS program accreditation.

Community colleges will also play a part in shifting EMS workforce demographics to become more representative of the communities the EMS agencies and the colleges serve. Community colleges must work to target underrepresented populations in EMS—African American, Hispanic, female and assist their members to enter and succeed in the completion of EMS programs.

Our community colleges must look to partnering with other agencies to develop new programs and new venues for increasing the health care workforce. Those community colleges offering 2-year Associate in Applied Science EMS degree programs will need to partner with 4-year colleges and universities to offer seamless bridging to health care-related bachelor of science degree programs in EMS, nursing, premedicine, and other health care fields. Within their own programs, community colleges will need to develop bridging programs for health care workers to move from one discipline to another: registered nurse to EMT, paramedic to respiratory therapist, and so forth.

As EMS evolves and the paramedic scope of practice increases

in complexity, access to EMS associate degree programs will become a necessity for potential students so that they can master the patient care procedures to be added. Currently in North Carolina, paramedics may perform intraosseous infusions, read and interpret 12- and 18-lead EKGs, perform needle cricothyrotomies, intubate (oral and nasal intubation), perform rapid sequence induction, and perform needle thoracotomies. Five to 10 years from now, especially as community needs for health care workers drive paramedics from the ambulance into the public health arena, the number and complexity of allowed procedures will likely grow.

One challenge currently being addressed by our community colleges is the increasing need for distance education offerings. Even though EMS has a strong hands-on component, much of the cognitive and affective instruction could be conducted through various nontraditional methods including Internet web-based instruction. Several community colleges in the state have developed "hybrid" courses in which the students meet in a traditional lab setting for skill instruction and evaluation while they attend the didactic portion of the course online. For courses without a psychomotor component, some colleges are offering them entirely online.

North Carolina community colleges are also adapting to meet the scheduling needs of the medical community. They are designing and providing programs with flexible scheduling to accommodate those students with rotating shift work schedules —"flip-flop" scheduling—allowing students to attend classes on changing days of the week. Several colleges are developing or offering specialized academies to EMS agencies so that newly hired personnel with limited EMS education can rapidly be taught and immediately begin to contribute to the workforce. Our North Carolina community colleges play an important part in the maintenance and growth of our state's EMS workforce and look to provide even greater contributions in the coming years. **NCMJ**

Baccalaureate Emergency Medical Services Education in North Carolina: History, Challenges, and Opportunities

Michael Hubble, PhD

E mergency medical services (EMS) is a critical component of the public health response system, treating and transporting 25 to 30 million patients per year.¹ The number of patients treated by EMS is expected to continue to increase, and for some of these patients, their prehospital treatment will have a dramatic impact on their clinical outcomes. Consequently, a well-educated and competent prehospital workforce is an essential component of community health.

Prior to 1976 all paramedics received nondegree "certificates" as opposed to degrees to verify their training. Today these

as opposed to degrees to verify their training certificate programs exist alongside associate in applied science (AAS) and bachelor of science (BS) degree programs. For some, this raises questions about the necessity of simultaneously offering both degreed and nondegreed paramedic programs. Unfortunately, there is a paucity of research about the influence of educational preparation on patient outcomes.

However, some evidence suggests that education improves the delivery of EMS health care. One study noted that paramedics who held degrees, although not EMS degrees specifically, were better able to calculate drug dosages than nondegree paramedics.² There is also evidence that students who attend an accredited program are more likely to pass the National Registry of EMT-Paramedic exam,³ and by extension, are better prepared for roles as field clinicians. This same study also found pass rates to be higher for those holding an AAS degree and baccalaureate

degree. A separate investigation found a link between pass rates and the instructor's educational level. The first-time pass rate was 62.7% for students taught by an instructor with an associate degree, 69.4% for bachelor's degree, 72.7% for master's degree, and 78.5% for doctoral degree, which suggests the need for baccalaureate and/or graduate-prepared educators.⁴ Moreover, Brown et al found that although the EMS administrators rated both degree and nondegree paramedics equally, 46% preferred hiring AAS degree paramedics over nondegree paramedics, and 40% reported promotion preference for degree paramedics.⁵

In addition to the perceived clinical advantages of EMS degrees, degree programs also prepare the future generation of EMS leaders including researchers, administrators, and educators. The *EMS Education Agenda for the Future* (EMSEAF) recommends that all EMS programs attain national accreditation. At the baccalaureate level it will be particularly

"Western Carolina University supports the paramedic programs within the North Carolina Community College System and recognizes the need for seamless articulation of students from the community college programs."

> important to expand opportunities for degrees for EMS educational program directors because that credential is crucial for the community colleges to be able to meet the Committee on Accreditation of Educational Programs for the Emergency Medical Services Professions (CoAEMSP) accreditation requirements.

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The Role of Western Carolina University in EMS Education

College level paramedic education in North Carolina began in 1976 when Western Carolina University (WCU) established the Emergency Medical Care (EMC) program as the nation's first baccalaureate program for EMS. Concurrently, Guilford Technical Community College established North Carolina's first paramedic program leading to an AAS degree. Since then, 13 additional community college degree programs have been established in North Carolina. Accredited in 1988, WCU's EMC program remains the only baccalaureate program in North Carolina and one of only 12 similar programs in the US.

As a baccalaureate program, the EMC program has a unique dual educational role: to educate paramedic practitioners and future EMS leaders. Broadly defined, future EMS leaders include EMS administrators, educators, advanced practice clinicians, and researchers. To achieve these goals, the curriculum requires two years of general education and preprofessional coursework followed by two years of the paramedic core curriculum and area of concentration. Unique to baccalaureate degrees, the general education component develops skills in writing, thinking, and analyzing. These, along with two semesters of chemistry and two semesters of anatomy and physiology, serve as the foundation for the paramedic curriculum. The junior and senior years constitute the professional course sequence and in addition to the core paramedic curriculum, require 17 semester hours in one of two areas of concentration: science or health services management. The science concentration is essentially premedicine and includes upper level courses in biology, chemistry, and physics. The management concentration prepares graduates to assume management roles and incorporates courses in personnel administration, marketing, accounting, finance, and health policy. Both concentrations require a course in research methods and biostatistics because of the increasing role of research in EMS.

Building upon the preprofessional courses in chemistry and biology, the paramedic curriculum promotes clinical reasoning as opposed to rote memorization of signs, symptoms, and treatment algorithms. In addition to addressing state and national paramedic learning objectives, the curriculum is heavily influenced by evidence-based medicine and Bayesian clinical decision making. Furthermore, in an effort to facilitate integration into the overall health care system, students are introduced to epidemiology, injury and illness prevention, and occupational health. The curriculum is also buttressed by an extensive clinical program that includes rotations through coronary intensive care unit (ICU), neurotrauma ICU, neonatal ICU, pediatrics and pediatric ICU, labor and delivery, operating room, cardiac catheterization lab, psychiatry, and dialysis rotations, in addition to emergency department, helicopter, and ambulance rotations. Because paramedics are increasingly choosing to practice in nontraditional venues such as urgent care clinics and emergency departments, broad-based clinical experiences are crucial for well-rounded clinicians.

Challenges and Opportunities

The National Standard Curriculum (NSC) describes the knowledge base for EMS in the United States.⁶ The curriculum proved useful during the formative years of EMS, however, the NSC is being replaced by a new approach to EMS education as outlined in the *EMS Education Agenda for the Future*.⁷ Once implemented, the EMSEAF recommendations will define the EMS general body of knowledge, delineate the technical skills within an EMS scope of practice, provide education standards for instructors and educational programs, and define procedures for national certification of paramedics and accreditation of educational programs. The EMSEAF is EMS education's guidebook for advancing the profession.

North Carolina has many opportunities to advance EMS education. Likewise, there are many challenges to delivering educational opportunities for current and future North Carolina paramedics. Due to changing demographics in the US, the demand for paramedics is expected to climb. The National Bureau of Labor Statistics estimates that between 2004 and 2014 an additional 21 000 paramedics will be needed to meet demand.⁸ This will be a serious challenge because North Carolina and the nation as a whole are currently experiencing a paramedic shortage.

Like most community college programs, WCU responded to the paramedic shortage by expanding enrollment capacity for initial paramedic training. In addition, WCU has been supportive of increasing access to baccalaureate and master degree programs using distance learning venues. It has allocated faculty and technical support to expand online access at both levels over the past 7 years. However, a stronger collaborative approach to recruitment and education is needed. A successful network should include the public school system, local EMS systems, community colleges, and WCU to consistently recruit students and deliver efficient, effective, and coordinated educational services at the associate and baccalaureate levels.

Articulation

Western Carolina University supports the paramedic programs within the North Carolina Community College System and recognizes the need for seamless articulation of students from the community college programs. To facilitate this transition, WCU has established articulation agreements with all North Carolina associate degree EMS programs. These agreements are particularly important for the distance learning program which is offered only to practicing paramedics who hold AAS degrees. The distance learning technologies enable paramedics across the state to access the program without displacing them from the communities in which the serve.

Student Support

Many students come to a university setting unprepared for the rigor of university-level academic work. While our distance learners are older and bridging from an associate degree, they face some of the same challenges as our traditional college-aged students. Many must strengthen writing, math, and science skills. To address these needs, WCU has a writing and math tutoring center that is available to all resident students and has been extended to distance learning students through distributed learning technologies.

Increasing tuition costs, coupled with limited scholarships and shrinking financial aid for students in general, have negatively impacted both student recruitment and retention. From 2001 to 2005, the cost of attending a public university in North Carolina increased 33%, and a year in school now consumes 25% of the average North Carolinian's household income.⁹ To put this increase in perspective, the urban consumer price index rose only 18% during the same period. A dedicated scholarship for students interested in EMS would help attract students into the profession and make the EMS educational programs more affordable. Furthermore, graduation rates would be improved if students were not obligated to work while in school to pay for tuition and other financial obligations.

Clinical Support

The cornerstone to any paramedic training program is its clinical rotations. Unfortunately, EMS programs at WCU and the community colleges must compete for clinical space with nursing and other allied health programs. While EMS agencies recognize the recruiting benefit of entering into clinical agreements with paramedic educational programs, most hospitals have a less clearly-defined benefit.

Clinical rotations are guided by the National Standard Curriculum which recommends a minimum number of patient contacts and skills for paramedic students, but these recommendations are not based upon empirical evidence. Furthermore, in a recent analysis of paramedic graduates across the US, only 6% completed all of the clinical experiences recommended by the current National Standard Curriculum and less than half of the graduates completed the required geriatric, trauma, psychiatric, obstetric, and pediatric patient assessments.¹⁰ Complicating matters, more recent research indicates that the NSC recommendations may underestimate the true number of repetitions necessary to attain clinical competence. Wang et al reported that up to 25 intubations were necessary to attain competence, despite the recommendation of 5 by the NSC.¹¹ Many EMS education programs encounter difficulty gaining access to the operating room to perform intubations.¹² To ensure the clinical competence of paramedics, it is imperative that hospitals and the physician community recognize the importance of their participation in clinical rotations for paramedic programs.

Research Support

The National EMS Research Agenda (NEMSRA), published in 2002, noted the lack of scientific evidence in support of most prehospital interventions.¹ The NEMSRA specifically noted the lack of cost-effectiveness and outcome studies. This widely disseminated report recommended, among other things, that educational programs include an introduction to the research process as part of the paramedic curriculum. It also recommended that academic institutions develop programs to train EMS researchers and to establish organizational partnerships that promote collaboration between academia and EMS agencies to advance the EMS scientific body of knowledge.

Recognizing the research opportunities afforded by its unique location in a university setting, WCU's EMC program is committed to promoting research in EMS. A research methods and biostatistics course is a required component of the undergraduate curriculum. At the most basic level, this course promotes an appreciation for the scientific method and the use of scientific evidence in clinical medicine as well as EMS administration. The course also prepares students for designing and implementing their own studies.

In an effort to increase the number of EMS researchers as recommended by the NEMSRA, the EMC program is launching a graduate program in the fall of 2008. The graduate program will offer tracks in EMS administration and EMS education. In addition to courses specific to each track, the curriculum requires substantial course work in research methods, epidemiology, quantitative methods, and biostatistics. This degree program will be entirely online in an effort to make it widely available to practicing EMS professionals.

To facilitate the research process for faculty and graduate students, the EMC program developed the Consortium for the Advancement of Research in EMS (CARE). The CARE consortium is composed of 15 EMS systems and 15 EMS education programs, and its goal is to facilitate EMS research by forming a partnership between academic settings, community college EMS programs, and EMS agencies. Launched in 2007, the CARE consortium will focus on the research priorities described in the NEMSRA Implementation Plan including clinical outcomes assessment, cost-effectiveness analyses, professional competence, and EMS systems.¹³

Although these research efforts are designed to advance the body of knowledge specific to EMS, they cannot occur in a vacuum. The investment of faculty time must be valued by academic institutions, and EMS agencies must also be willing to commit staff time and resources. Furthermore, an adequate funding stream for EMS research must be identified, which will likely include public and private funding.¹

Conclusion

Although many challenges lie ahead, Western Carolina University is committed to taking the necessary steps to address the paramedic shortage, meet EMS research needs, and offer undergraduate and graduate level education for the future leaders of the paramedic profession. However, these efforts will be successful only to the extent that effective partnerships can be established and maintained with the EMS community, the North Carolina Community College System, hospitals, and the medical community at large. **NCMJ**

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Medical Journal

Management and Financing of Emergency Medical Services

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ike other organizations, emergency medical services (EMS) systems have revenues and expenses. The unpredictability of calls and the oftentimes inefficient nature of EMS operations make EMS management and financing difficult. Annually, EMS costs patients, insurers, and the federal government billions of dollars.¹ In fiscal year 2002, Medicare spent \$3 billion on ambulance transportation.¹ The insufficiency of reimbursement for the total cost associated with 24 hour, 7 days per week coverage is the subject of constant debate and discussion among EMS managers. Recent modifications to the reimbursement formula used by the Centers for Medicare and Medicaid Services (CMS) has both benefited and disadvantaged many of the more than 18 000 EMS systems in America;²⁻⁴ reducing the gap between costs and revenues for some while increasing that gap for other EMS systems. The purpose of this commentary is to describe the major components of EMS financing and management and to discuss the current and ongoing challenges in EMS financing.

Revenues to an EMS system include subsidies from local governments, income from special event support, and reimbursement for transportation of patients. Fifty-five percent of revenues for an average EMS system come from Medicare, 15% from Medicaid, 5% from private payment, and 25% from the commercially insured.⁵ Personnel and benefits are the largest fixed expenses for the average EMS system.⁶

Revenues and expenses are not completely uniform across systems. For volunteer-staffed EMS organizations in very rural areas, processing bills for transportation is either not possible or an unattractive practice that would take away from the volunteer nature of the organization. Thus, most revenues for such organizations come from donations and support from local governments. In addition, submitting a bill to Medicare or Medicaid does not guarantee payment. In 2000, the average collection rate for bills submitted by North Carolina EMS systems was 25%.⁷

The average cost for an ambulance transport is \$415, but ranges from \$99 to \$1218. Average costs in very rural areas are significantly higher than costs in urban areas, \$538 and \$409, respectively.⁸ Ten years ago, the estimated average charge for transport to the emergency department approached \$400.⁹ It is unclear what the true average charge for an EMS transport actually is today. In some communities, a ride to the hospital or

"Fifty-five percent of revenues for an average EMS system come from Medicare, 15% from Medicaid, 5% from private payment, and 25% from the commercially insured."

elsewhere can be as high as \$700.¹⁰ For a trip in a helicopter, the cost can reach thousands of dollars.^{11,12} A combination of factors result in high transport costs including the need to cross subsidize transport for the indigent and uninsured and the cost of 24 hours a day readiness. Extremely high rates of turnover among personnel also contribute to inefficient budgetary practices.

The medical necessity of EMS transportation is used by CMS to determine whether or not a patient's transportation

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will be paid. For some systems, convincing the intermediaries that an ambulance transport was medically necessary is a daily and ongoing battle. Submitting multiple claims for the same ambulance transport is not uncommon. In fiscal year 2002, the Health and Human Services Office of Inspector General (OIG) determined that 25% or \$402 million dollars in ambulance transports did not meet the government's criteria for medical necessity.¹ For emergency ambulance transports, CMS defines medical necessity as a medical condition that manifests itself with acute symptoms of such severity that the absence of immediate medical attention would jeopardize the patient's health.¹ For nonemergent transportation, a ride in an ambulance is medically necessary when the patient is bed-confined and/or his/her condition is such that other methods of transportation are contraindicated.¹ The OIG report identifies transports to dialysis centers as a significant source of unnecessary transports.

Financial Obstacles

Due to the rapid increase in expenditures and difficulties in administrating benefits, the federal government in the Balanced Budget Act of 1997 called for ambulance reimbursement to be placed on a fee schedule.² The act proposed an implementation date of January 1, 2000. Due to the quick action and concerns of numerous EMS administrator groups throughout the United States, CMS agreed to enter into a negotiated rule making process that ultimately led to a proposed fee schedule implementation date of April 1, 2002 and a final implementation date of January 1, 2006.

While EMS administrators were able to buy some time before implementation, the final rule is now in place and the financial effects are being felt by EMS providers throughout the nation. The final rule led to the establishment of a national base rate of \$171 for the transport of a patient to a medical facility. This \$171 rate is supplemented by adjustment factors that modify reimbursement based patient severity, region of the country, and a special adjustment for the super rural regions. However, it still falls short of covering the actual cost of transport for most EMS providers.⁴

The national base rate of \$171 dollars was chosen largely on the direct cost of providing care and transporting a patient (personnel cost, equipment cost, supply cost) and failed to incorporate the significant indirect cost associated with readiness to respond to a request for service. Factoring in the total cost of providing the temporal and geographical demand coverage necessary to respond in a timely manner to medical and surgical emergencies increases per transport estimates to as much as \$300 to \$400. This gap between the established national rate and the total estimated cost per transport is creating a critical financial situation for many EMS providers. Some in the EMS community have even begun litigation against the government.¹³

Compensating for this fiscal gap between the Medicare and Medicaid reimbursement is critical when one considers that this reimbursement accounts for as much as 64% of most EMS providers' patient mix. Since it is mandated that EMS providers accept this reimbursement by assignment it means that increasing rates does little to increase revenue. This leaves EMS providers with the options of either increasing their local tax subsidy or decreasing operation costs. Due to widespread fiscal pressures that are being exerted on most local municipal agencies, EMS providers are meeting enormous resistance when requesting increases to local taxes to cover the cost of providing EMS. This only leaves the second option, which is to increase operational efficiency in an attempt to decrease overall operational cost.

One of the first steps many EMS providers need to take in deciding how they will compensate for decreased revenues is to spend some time developing a clear understanding of the purpose and role of their service within a given community. Many providers find themselves involved in functions other than providing emergency care. These services include things such as technical rescue, support for hazard material incidence, and other uncompensated services. In some communities, the EMS provider may be the only provider of these services, but in other communities EMS providers duplicate services more appropriately provided by other public service agencies. The decision to provide these supplemental services should be based on the needs of the community and its willingness to financially support these added services. It is important that EMS providers remember their first priority is to provide emergency medical care and transportation of patients.

The second highest leverage area of improvement that could be undertaken by many EMS providers is in the area of resource deployment. In the mid-1980s, the EMS industry was introduced to the concept of System Status Management (SSM).¹⁴ System Status Management is a methodology used to determine the number of ambulances needed for each hour of the day, each day of the week and where these ambulances should be placed in order to respond in a timely manner to a request for emergency assistance. While the knowledge of deploying EMS resources has expanded from the use of SSM to the existence of sophisticated computer simulation models that can predict geographical grid level coverage capability, only the most sophisticated EMS systems in the nation have even adopted the use of SSM. The use of these methods could not only decrease operation costs for most EMS providers, they could also improve their ability to respond in a timely manner to the aid of sick and injured patients.

While the two issues mentioned above are important for EMS providers to address, there are many other areas in which current EMS operations could be improved and the financial viability of EMS sustained. These include things such as the implementation of more efficient and less costly education and training methods, the improved management of supply and equipment inventories, and improvements to EMS billing processes. Addressing these issues can improve EMS care of the sick and injured. However, even after implementing these ideas, the sustainability of EMS financing and management will likely continue to be a challenge for many years to come. **NCMJ**

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Service Integration and Workforce Trends in Emergency Medical Services

P. Daniel Patterson, PhD, MPH, EMT-B; Michael Yonas, DrPH, MPH

To commemorate the report credited with the development of modern emergency medical services (EMS), the Institute of Medicine of the National Academies (IOM) examined the current status and future of emergency care in America. *Emergency Medical Services at the Crossroads* reports the IOM's findings and provides an informative view of our nation's EMS or prehospital emergency care system.¹ The report is part of a

trend in exploring and dissecting the American system of emergency care, identifying problem areas, and making recommendations for improvement. The IOM highlights many system-wide deficiencies that inhibit EMS from accomplishing its primary mission of responding to emergencies whenever and wherever. Based on these findings, the IOM labeled the US "ill-prepared" and referred to the current EMS situation as nothing less than a "crisis."¹

For some time, efforts have been underway to resolve many of the EMS challenges identified in the IOM's analysis. These include promoting integration of EMS with other health care services and addressing challenges associated with maintaining a skilled and experienced workforce. More recently, health care pioneers have invested time and energy into expanding the health care role and responsibilities of EMS personnel to include more preventive and primary care tasks.²⁻⁶ As potential momentum for the formation of future policy and research in North Carolina, these trends deserve some attention.

Integration of the EMS System

The provision of basic EMS care involves overcoming many organizational obstacles on a day-to-day basis. One such obstacle is the organizational clash between police, fire, and EMS—the 3 components of the public safety triad. While these 3 are often seen working together at the scene of an accident or emergency situation, substantial differences in roles and responsibilities have created conflict and inhibited integration.⁷⁻⁹ Specifically, there appears to be a lack of mutual professional respect for the vital roles filled by EMS, hospital staff, and public safety staff. Integration among these professionals and organizations is stalled or significantly hindered by institutional and/or cultural barriers.

"Improved integration of EMS services with those provided by public safety, public health, and all other health care services has been touted as a solution to access and EMS infrastructure problems."

Integration refers to the formation of a seamless communications network among all parties and agencies involved in the care of an individual's emergent or chronic health needs. Improved integration of EMS services with those provided by public safety, public health, and all other health care services has been touted as a solution to access and EMS infrastructure problems.^{10,11} The Medicare Rural Hospital Flexibility Program (Flex) is perhaps the most visible integration improvement effort for EMS. This program was created as part of the Balanced Budget Act of 1997 to strengthen and improve rural health care

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infrastructure primarily by converting small rural hospitals to critical access hospitals (CAHs). A CAH is a hospital that qualifies for special reimbursement and federal funding that reduces the likelihood of the hospital closing. The Flex program endeavors to integrate EMS into Flex-related rural health care networks. Since its inception, the program has supported numerous service integration activities led by local and state authorities. Some examples include partnerships between EMS systems in different areas of a state, support for the development of state prehospital databases and information systems, and creation of EMS partnerships with many of the 1286 designated critical access hospitals.

However, the investment in integrated EMS service structures has not been universally adopted. One evaluation finds that many states have chosen to focus on bolstering education systems, addressing human resource challenges, or providing local services small grants for purchasing equipment.¹² Integration initiatives are inhibited by uncertainty among all parties over EMS's role in health care networks, EMS fears over losing autonomy, preoccupation with day-to-day challenges, and a general misunderstanding of what integration is and what it means.¹³ Despite these obstacles, interest and support for the integration of EMS is high, meaning that federal and state initiatives will likely continue to promote integration as a national EMS priority.

Addressing Workforce Challenges

Improved integration may curb poor recruitment and retention of EMS professionals which are, by all accounts the most widely reported problems for EMS systems.¹⁴⁻²³ National EMS organizations rank recruitment and retention first in a long list of challenges for rural EMS systems.^{24,25} Exploration of new EMS staffing models was recently posited by the IOM as a possible remedy to workforce problems.¹ The National Highway Traffic and Safety Administration (NHTSA) Office of EMS, the federal Office of Rural Health Policy, and the National Rural Health Association are also actively examining these issues in order to improve knowledge around the EMS workforce.

There is very little certainty over the true size of the nation's EMS workforce. Estimates range from a few hundred thousand based on documentation from the US Department of Labor²⁶ to as many as 1 million (including all possible first responders) which is based on a survey of states conducted by an EMS consulting firm.²⁷ NHTSA is leading national efforts to improve and expand what we know by funding the Longitudinal Emergency Medical Technician Attributes and Demographics Study¹ and the Emergency Medical Services Workforce for the 21st Century project.

The current body of EMS workforce research does not adequately document the critical elements associated with turnover of EMS personnel, whether paid or volunteer, leaving many questions about the nature of the workforce problem unanswered. Factors like burnout, stress, and dissatisfaction with certain aspects of the occupation have been identified in several studies as influential or potentially influential in turnover.²⁸⁻³⁰ Few studies have explored why individuals enter the profession. Among those studies exploring entry, excitement and altruism have been identified as two important attractants.^{29,31} The influence of these factors may differ across rural and urban areas. Rural community EMS systems are staffed primarily by volunteers³² who may enter and leave the profession for reasons that differ from paid professionals. Research is needed to identify what differences may exist between volunteer and paid personnel. With funding from the federal Office of Rural Health Policy, investigators at the Cecil G. Sheps Center for Health Services Research at the University of North Carolina are exploring some of these issues.

In North Carolina, recruitment and retention are visible challenges for EMS and they receive substantial attention from the media and state EMS officials. In Wake, Cabarrus, Duplin, and other North Carolina counties EMS officials are facing critical human resource challenges including poor recruitment and high turnover.^{18,21,33} In some North Carolina communities, fewer ambulances are put on the road due to inadequate staffing.¹⁸ Reports suggest that EMS professionals in these areas leave for better pay in other systems or in other professions like nursing. In rural areas, low pay is a major factor detracting paid personnel,³³ whereas availability of time appears to be the primary detractor for volunteers.¹⁵ The NC Association of EMS Administrators, in partnership with the NC Office of EMS, is surveying EMS officials, credentialed professionals, and students in an effort to increase the state's understanding of workforce challenges and help in the design of materials for increasing recruitment and retention.

Expanded Role for EMS Professionals

Career advancement is potentially an important factor in recruitment and retention of EMS professionals.^{29,34,35} Other than assuming greater clinical responsibility through additional EMS-specific certifications, the EMS professional career is quite limited.³⁶ By placing EMS professionals inside the hospital and in primary health care clinic settings, as has been accomplished in many communities,^{4,37,38} officials have expanded career possibilities while at the same time improving linkages between EMS and health care, which promotes integration. Nationally and internationally there is growing support for expanding the role and scope of EMS professionals.^{2,37} The International Roundtable on Community Paramedicine (IRCP), for example, promotes expanded roles for EMS professionals and defines this new health care provider and model-the community paramedicine model-as "a model of care whereby paramedics apply their training and skills in 'nontraditional' communitybased environments outside the usual emergency response/ transport model."3

For many reasons, growth of community paramedicine programs in the US is possible and is potentially beneficial to EMS and communities. Community leaders are increasingly looking to midlevel and other health care professionals to fill voids in primary, dental, and mental health care services in rural and frontier areas where access is limited.³⁹ Emergency

medical services professionals are traditionally paid less than nurses and other professionals also serving expanded roles, and thus community paramedicine models are potentially cheaper to administer and have the potential to reach more citizens with fewer resources. Emergency medical services systems and professionals have historically been community-based, are visible and recognizable, and are respected and trusted by the public. Existing federal programs like the National Institutes of Health (NIH) Roadmap Initiative can be used to test and evaluate the clinical and cost effectiveness of community paramedicine.⁴ Growth of community paramedicine lies, in large part, with the recognition from researchers, community leaders, and policy makers that EMS systems and professionals are highly skilled medical professionals with an established rapport with the community.

Next Steps for Addressing Integration and Workforce Issues

Monitoring national EMS trends is important for continued growth and improvement of EMS in North Carolina. Integration of EMS is a national priority receiving support from federal initiatives and national associations sensitive to EMS issues. Many obstacles to integration exist. Improved integration, however, can be achieved through expanding the role and responsibilities of EMS professionals, which may also have a positive impact on reducing personnel turnover. Where possible, the state and local EMS leadership in North Carolina should partner with state health care leaders and academic researchers to promote testing and evaluation of diverse models of integration. Local and state officials and industry leaders must take the initiative.

Historically, EMS in the state of North Carolina has been led by innovators and out-of-the-box thinkers. Recent efforts by state EMS leaders to explore workforce problems represent forward thinking and a step in the right direction towards improving workforce conditions. Next steps should include a planned approach involving local EMS systems, community leaders, state and federal EMS leadership, and academic researchers. The NC Center for Nursing (NCCN) is a good example for North Carolina EMS. The NCCN is a statesupported agency that provides ongoing analyses of the state's nursing workforce. A perfect storm of factors including the nursing shortage of the late 1980s led to the creation of the NCCN. While workforce challenges have plagued EMS for more than 20 years, that perfect storm has never effectively materialized for EMS. Twenty years of waiting has proven ineffective. Local and state officials must act and be proactive to address ongoing challenges before the true negative effects of inadequate staffing are revealed.

North Carolina is fortunate to have an exceptional pool of academic researchers and research institutions. Unfortunately, few researchers have been successful or have recognized the NIH Roadmap Initiative as an opportunity for improving EMS clinical procedures and service structure knowledge. Few have recognized community paramedicine as an emerging model of EMS care offering a variety of research opportunities. As a research approach, community-based participatory research offers a unique model for EMS researchers to explore integration, workforce, and other EMS systems and clinical care issues. North Carolina EMS researchers and practitioners should explore community-based participatory research as a vehicle for expanding EMS research. It is increasingly being recognized as a particularly well-suited approach to research involving partnerships with community members and community based health care organizations like EMS.⁴⁰

It is important to have some sense of national EMS priorities and trends by which we can compare North Carolina's EMS development in relation to the rest of the country. Like many states, North Carolina is in the middle of an EMS workforce "challenge," but it is responding by first assessing the size and nature of the problem. Supporting integration and research into expanded roles for EMS professionals could help North Carolina leverage limited federal funding that could be key to improving the state's EMS system. **NCMJ**

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Emergency Medical Services Information Systems

Greg Mears, MD

E mergency medical services (EMS) are often defined as the intersection between public safety, public health, and health care. From a public safety and public health perspective, EMS is the safety net for those who become suddenly ill or incapacitated. This community-level responsibility requires EMS to anticipate events, provide services, and care for patients individually or through the management and coordination of multiple patients. Due to this anticipatory role, EMS must function from a preparedness model.

A preparedness model requires that the EMS component of health care be delivered to the patient as opposed to the patient

presenting on their own. Because many EMS events such as cardiac arrest and major traumatic injuries are time dependent, EMS must provide this service and care through an organized mesh of ambulances, personnel, and resources configured to assure a timely response to every event within the EMS service area. No other component of the

health care industry is required to function in their day-to-day operations from this preparedness-based, "go to the patient" model. From an operational and clinical perspective, EMS is the most complex and data dependent component of the US health care system. Unfortunately, EMS is also the most underdeveloped component of the health care industry from a personnel, data, financial, educational, or resource perspective. Information systems are critical for effective EMS system implementation because each EMS event requires knowledgeable personnel, appropriate equipment, and other required resources within an optimal EMS response time to the correct location.

The Importance of EMS Data

In the United States, there are over 25 million EMS events each year requiring patient care or transport. North Carolina's 8.6 million people call 9-1-1 and receive EMS services over 1 million times each year. These services range from life-threatening emergencies to medical transports between hospitals and other health care facilities.

At the local EMS system level, EMS data are critical to determining where and how to allocate EMS resources to assure that the correct equipment and personnel are provided for each event in a timely fashion. Data that describe patterns of use can direct the allocation of resources, vehicles, personnel, and supplies. Information systems provide the EMS medical record, documenting the clinical care provided as well as supporting the administrative demands of the system. This documentation

"From an operational and clinical perspective, EMS is the most complex and data dependent component of the US health care system."

also gives guidance to the content of EMS personnel's initial and continuing education. Information systems provide the framework for ongoing quality management and performance improvement initiatives and data systems feed into the billing and reimbursement systems required to operationally sustain local EMS systems.

At the state level, EMS data are required to determine how to coordinate regional and statewide systems of care such as trauma, acute cardiac, and stroke. Data drive the development of operational and clinical protocols, initial education, continuing education, and medical direction needs. Technical assistance, funding, and advocacy can and should be driven by issues and needs identified and justified through a state EMS data system.

At the national level, a national EMS database is critical to define EMS needs and to support EMS as an industry and a key component of the health care system. Emergency medical service data systems can help shape national educational standards by

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identifying the needs of patients. A data system can help prioritize federal EMS funding and support decisions by the Centers for Medicare & Medicaid Services (CMS) for reimbursement levels for Medicare and Medicaid patients. A comprehensive data system can also be used for basic and policy focused research.

Linkage of EMS data to other databases at the local, state, or national level is also needed. Through the linkage of data systems, insight can be obtained beyond what each individual data source can provide. EMS data systems should be linked with vehicular crash and other injury surveillance data to provide insight into improving the safety of roadways, vehicles, and trauma systems. Linkage of EMS data to hospital data can provide insight into the service delivery, personnel performance, and clinical care provided to each EMS patient. Linkage of EMS data to trauma, stroke, injury, and medical examiner data systems can provide information on how to target, design, and implement injury prevention and public education programs.

What is NEMSIS?

In 1999 the US Department of Health and Human Services (US DHHS) through the Health Resources Services Administration (HRSA) Emergency Medical Services for Children Program (EMSC) funded a feasibility study to determine if an organized EMS data initiative could be developed to support the EMS industry as the International Classification of Diseases (ICD-9) and Health Level 7 (HL7) standards have informed the rest of the health care industry. This feasibility study led to the formal funding of the National EMS Information System Project (NEMSIS) through the US Department of Transportation (US DOT) National Highway Traffic Safety Administration (NHTSA) Office of Emergency Medical Services. The NEMSIS Project has 4 primary goals and objectives:

- (1) Establish a standardized national EMS dataset which would be used to document the EMS service delivery, personnel performance, and care for every EMS event in the nation.
- (2) Establish an electronic EMS documentation system in every local EMS system to support service delivery and clinical care operations.
- (3) Establish a state EMS database in every state where a portion of the data collected by each local EMS system could be aggregated to support state EMS regulatory and disaster management functions.
- (4) Establish a national EMS database where a portion of the data maintained by each state's EMS database could be aggregated to support federal EMS program, educational, fiscal, and advocacy needs.

Currently, the NHTSA Uniform PreHospital Dataset (Version 2.2.1) is used. This national standard has been adopted

by 49 of the 50 US states. At the time of this publication New York had not adopted this EMS data standard. A total of 37 states have operational state data systems in place today. Every state has a goal, pending resources and funding, to establish a state EMS data system. In 2007, 4 states (North Carolina, Minnesota, Mississippi, and New Hampshire) are providing data to the national EMS database. Current NEMSIS Project funding and deliverables provide for a staggered implementation of the national EMS database with the addition of 10 new states per year until all states are participating.

North Carolina's EMS Data System

The North Carolina PreHospital Medical Information System (PreMIS) was developed in 2002 and currently maintains data on all EMS events in North Carolina. The data collected from the one million plus EMS events per year are used as a resource to guide local EMS systems across the state in their daily operations. Data from PreMIS are protected by North Carolina statute and are only accessible by the North Carolina Office of EMS and each local EMS System. Funding for PreMIS was initially provided through the Governor's Highway Safety Initiative. Currently, PreMIS is funded through a combination of state and federal funds associated with domestic preparedness.

Data from PreMIS are used daily in North Carolina's Bioterrorism Surveillance Program as well as in local EMS quality management and performance improvement initiatives. The Duke Endowment currently supports EMS through the EMS Performance Improvement Toolkit Project. The EMS Toolkits are detailed reports that cover a specific EMS topic. Each EMS toolkit evaluates the 100 North Carolina EMS Systems and provides custom recommendations to improve EMS service delivery, personnel performance, or clinical care. The web-based EMS toolkits have been developed to assist EMS systems with optimizing EMS system response times, thus improving EMS cardiac arrest, trauma, pediatric, and stroke care. The EMS Toolkit Project is a partnership with the NC OEMS and The Duke Endowment. Future EMS Toolkit funding will be used to assist individual EMS systems in addressing the specific problems identified by each local toolkit.

Summary

The future of EMS and the US health care system is dependent on interactive, real-time data systems that can be used to design, develop, implement, evaluate, and maintain quality evidence-based systems of care. North Carolina is a national and international leader in EMS given its support of the PreMIS System, the EMS Toolkit Project, EMS Bioterrorism Surveillance, and participation in the National EMS Database. **NCMJ**

Medical Oversight for Emergency Medical Services: Defining Success

Brent Myers, MD, MPH, FACEP

The provision of emergency medical services (EMS) is a practice of medicine. Although it has been present in various forms since the days of Napoleon, the currently utilized EMS system in the United States began in 1966 with the publication of the EMS "White Paper" from the Institute of Medicine of the National Academies (IOM) and the passage of the Highway Safety Act.^{1,2} Over the past 4 decades, the public and members of the medical community have come to rely upon the prompt, professional response of the EMS system, summoning ambulances over one million times per year in North Carolina alone.³ Indeed, the EMS practice of medicine is one of the largest in every community because all citizens are potential patients. On an annual basis, between 7% and 9% of the population become actual patients and summon EMS via 9-1-1.

Unfortunately, these have not been 4 decades of clinical progress in EMS. There are shining examples of clinical success, but we often fail to dedicate sufficient resources to the prehospital medical effort. As the recent IOM report confirms, the federal government has not provided sufficient funding in the areas of research or disaster preparedness, with EMS receiving less than 5% of the preparedness funding since the attacks of September 11, 2001.⁴ The medical community remains uncertain of exactly how to incorporate EMS physicians, for while the number of EMS fellowships continues to grow, the American Board of

Medical Specialties has yet to incorporate the subspecialty of EMS into the formal board structure. Finally, the IOM report calls for a new federal agency to oversee EMS, indicating that EMS neither belongs exclusively in the National Highway and Traffic and Safety Administration (the current federal oversight agency for EMS) nor exclusively in the

"From system design to treatment protocols to hospital destination directives, modern EMS systems require active involvement of EMS physicians to ensure clinical excellence in prehospital emergency care."

areas of public health or homeland security.⁴ From the local to the federal level, EMS is truly at the crossroads, and leadership from physicians and the broader medical community is now urgently needed to guide us through this transition.

What is an EMS Physician?

The EMS physician divides clinical activities into two spheres: the traditional, direct care activities in the emergency department and the less traditional, indirect patient care that is delegated to EMS providers in the community. In the latter role, the EMS physician is responsible for all medical components of the prehospital encounter, including dispatch algorithms for the 9-1-1 center, development and revision of patient care protocols, education for all providers, and remediation of providers when necessary. Gone are the days when the EMS physician could create protocols once every few years and meet with paramedics only when they violated these protocols. The practice of EMS medicine is truly a partnership between receiving hospitals, public health, emergency medical dispatchers, basic life support first responders, and, in most communities, advanced life support providers. This partnership requires intensive and frequent interaction with the EMS physician in order for it to function in the patient's best interest. For maximum patient benefit,

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these interactions should occur both in the formal settings of the classroom, boardroom, and conference room as well as in the informal settings of the 9-1-1 center and the houses and highways where EMS providers operate. The appropriate balance of administrative activity and in-the-street observation directly influences patient outcomes, particularly in the area of cardiac arrest.⁵

Rather than simply performing the "sign and go" tasks related to infrequent protocol revision and remediation, the modern EMS physician will be actively involved in the initial and continuing education of all participants in the medical practice. This includes reviewing protocols for the dispatch center, ensuring first responders have access to the latest medical information, and interacting with advanced life support providers on a regular basis.

The need for physician leadership is most urgent as we begin to address this simple question: Are we providing quality clinical care for our EMS patients? The overall clinical care provided by EMS involves two components: the treatments provided by EMS providers and the decisions reached about patient disposition. In regards to the former, a surprising majority of the treatments and interventions provided by EMS are supported only by anecdotal evidence and deference to historical precedent. Medical antishock trousers (MAST) and high dose epinephrine for cardiac arrest are familiar examples of established treatments that did not survive the test of scientific scrutiny. More recently, the "established treatments" of endotracheal intubation (with or without rapid sequence induction) and ventilations during cardiopulmonary resuscitation (CPR) have been called into question. Finally, with the advent of automated external defibrillators (AEDs) and thus defibrillation by basic life support first responders, the relative importance of paramedic response time is being reexamined in a scientific manner.

Decisions regarding patient disposition also directly impact the quality of care rendered by EMS, not only in the urban environments but in the suburban and rural settings as well. In the urban setting, there is compelling evidence suggesting patients with ST-segment elevation myocardial infarction be diverted to a hospital capable of percutaneous coronary intervention (PCI).^{17,18} In the rural setting, investigators with the Reperfusion of Acute Myocardial Infarction in Carolina Emergency Departments (RACE) initiative and others are working to ensure prompt treatment for this patient population either by primary lytic therapy or early activation of the air ambulance for transfer to PCI.¹⁹

Finally, the EMS physician has the responsibility for caring for patients who suffer cardiac arrest in the out-of-hospital setting, both from sudden cardiac death and from a variety of other medical and traumatic etiologies. Mandating hospital transport for all of these patients not only consumes limited emergency department resources for futile cases, it may also impede resuscitation for those cases which are not futile. We now know that interruptions in cardiac compressions as brief as 20 seconds may decrease the probability of successful resuscitation in a meaningful way, and the movement of a patient from the location of the arrest to the ambulance will inevitably create many such pauses. In the optimal setting, the EMS system is responsible for the resuscitation of cardiac arrest, and the emergency departments and hospitals are responsible for postresuscitation care. Obviously, the EMS physician must be actively involved in all components of the EMS system for such a system to function appropriately.

The EMS system, led by the EMS physician, has the opportunity to improve the outcomes for individual patients as well as to enhance the health of the community as a whole. From system design to treatment protocols to hospital destination directives, modern EMS systems require active involvement of EMS physicians to ensure clinical excellence in prehospital emergency care.

The Challenges Ahead

The EMS physicians of 2007 face many challenges. First, we must provide leadership in the area of workforce stability and career development for our prehospital providers. No matter how involved in our medical practice we become, it is for naught in the absence of a qualified and willing workforce. As the demand for all allied health workers exceeds supply, paramedics become attractive candidates to educational institutions training nurses and respiratory therapists as well as to hospitals and medical clinics seeking highly qualified technicians to operate in the cardiac catherization lab, emergency department, or other settings. In nearly all of these situations, scheduled work in a climate-controlled environment is offered for a higher salary than EMS currently offers. Paramedics may most accurately be viewed as members of the allied health community and, as such, reimbursement must be reexamined. EMS physicians must be allies for our prehospital providers and seek to improve reimbursement for the important work they do.

The EMS physician must actively participate in defining quality in EMS. In just one example of unintended consequences, it may appear logical to support improved response times for EMS. It will surprise some to know, however, that there is no evidence in the medical literature indicating an association between advanced life support response times and survival.¹⁴⁻¹⁶ Moreover, there is a clear association between response time of a BLS defibrillator and survival from cardiac arrest, but this is often not measured or reported.²¹ Finally, it appears that the annual experience of a paramedic may be at least as important as the response time. In each community, cardiac arrests occur with a predictable annual incidence of about 1 per 10 000 population. As one adds more paramedics to a system with a stable population, the individual paramedic encounters fewer patients in cardiac arrest each year. Preliminary studies indicate improved survivability from cardiac arrest in areas with fewer paramedics, raising the hypothesis that rapid response of a basic provider with an AED followed by a delayed response of a well-experienced paramedic may be superior to rapid response of a relatively less experienced paramedic.^{22,23} This is not surprising, as the same has been demonstrated for invasive cardiologists and other medical specialists: there is a minimum number of high acuity encounters required on a regular basis in

order to maintain clinical excellence.²⁴⁻²⁶ This, combined with the known short supply of paramedics mentioned above, may eventually place the EMS physician in the seemingly unusual position of calling for fewer paramedics while ensuring the paramedics that are in the field receive the best training, equipment, and reimbursement possible.

This is not to say the historical duties of the EMS physician may be neglected. Protocol revision and assurance of protocol compliance remain the cornerstones of excellent EMS practice. For today's EMS physician, however, these revisions must occur frequently because evidence regarding treatment and transport decisions is emerging more rapidly than at any time in the 4-decade history of EMS. Just in the past 12 months, evidence from North Carolina researchers indicates noninvasive positive pressure ventilation (NIPPV) may become the standard of care for prehospital treatment of pulmonary edema and potentially other forms of respiratory distress.²⁷ National and international manuscripts have challenged our current methods of CPR and defibrillation with indications that continuous compressions can markedly increase the proportion of patients with neurologically intact survival from cardiac arrest.^{9,20,28} The timely revision of EMS protocols is now required to ensure optimal patient outcomes.

Assurance of protocol compliance may be adequately performed with chart review but is only optimally performed after observation in the field. Response with EMS personnel to assess both the quality of the care provided as well as the quality of the medical protocols is necessary for excellence in medical oversight.

Finally, the EMS physician is called upon to perform duties not directly related to routine, individual patient encounters. The events of September 11, 2001 and Hurricane Katrina reminded us that disaster preparedness is not an optional activity. Fortunately, in North Carolina we have several resources including Med-1 at Carolinas Medical Center in Charlotte, the Special Operations Response Team in Winston-Salem, and the State Medical Assistance Teams to assist local resources in any such response. Issues surrounding public health response to infectious disease as well as injury prevention and public safety are also issues for the EMS physician.

Where Do We Go From Here?

Although the challenges are great, the dedication of resources to address them is perhaps the most significant it has been in our 4-decade history. The clarity of the recent IOM report, the multi-center NIH supported Resuscitation Outcomes Consortium (ROC), and the outstanding initiatives emerging from the EMS Performance Center in North Carolina are just a few examples of this dedication. Funding remains a challenge, but as our treatments become more evidence-based, a more cogent argument for dollars becomes available to us. In Hubble's paper for example, we learn that the need for an intubation in the emergency department is avoided for every 6 pulmonary edema patients treated with prehospital NIPPV. The health care dollars saved by the avoidance of a single intensive care unit admission could pay for many NIPPV units in the prehospital setting. As our evidence becomes more robust, the appropriateness of increased funding will hopefully become self-evident.

In conclusion, despite all of the challenges we face, the career of the EMS physician is satisfying and rewarding. When I began my fellowship in EMS, someone with years of experience in the field stated that the duties were 80% political and 20% clinical. They actually were wrong—they are 90% political and 10% clinical on the best days. Yet, despite all of this, the opportunity to care for those cannot otherwise care for themselves is afforded every day. We impact those who have been down on their luck for years as well as those from all walks of life who experience an unexpected illness or injury—and we can help them each in unique ways. At the end of the day, via this dedicated practice, I am able to recall why I entered the medical field in the first place: to help my fellow man. **NCMJ**

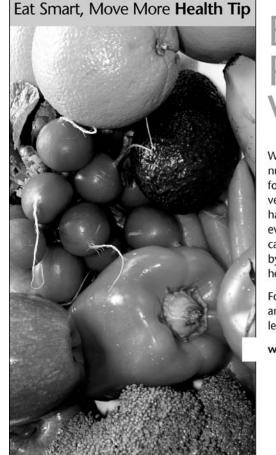
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Paramedic Endotracheal Intubation

Henry E. Wang, MD, MS

Prehospital practitioners perform a range of critical life saving interventions such as delivery of cardiopulmonary resuscitation chest compressions, rescue defibrillation shocks, administration of intravenous fluids and drugs, and establishment of a patient airway. The equipment used in these interventions require special modifications to enable their portability and delivery in the field setting. For example, while inhospital cardiac arrest equipment is often stored in large mobile "crash carts,"

such devices would be impractical for prehospital use. Instead, paramedics use portable "jump bags" filled with medications as well as a lighter portable defibrillator/cardiac monitor.

One of the most important recent scientific findings is that medical procedures executed in the field setting may not perform equivalently to the same interventions carried out in the hospital. Thus, simply imitating inhospital practices may not necessarily improve outcomes. In some cases these prehospital interventions may lead to worsened outcomes.

Paramedic Endotracheal Intubation

An excellent example of the challenges surrounding prehospital medical interventions is

endotracheal intubation (ETI). Airway management is the process of establishing an open passage between the mouth and the lungs in order to deliver life-saving oxygen. Critically ill individuals such as those suffering from cardiac arrest or major trauma are often unconscious and cannot maintain an open airway on their own. Therefore, airway management is a fundamental priority in the care of the critically ill. Without an adequate supply of oxygen, vital organs (in particular, the brain) begin to die. Airway management may encompass a spectrum of basic methods (eg, mouth-to-mouth or bag-valve-mask ventilation) or more advanced techniques (eg, endotracheal intubation).^{1,2}

Endotracheal intubation (ETI) is the most prominent and invasive form of airway management. A plastic breathing tube is inserted through the mouth, between the vocal cords, and into the trachea (windpipe). Endotracheal intubation provides a direct, patent conduit to the lungs to facilitate optimal and controlled delivery of oxygen.² The endotracheal tube also has an inflatable cuff designed to prevent the aspiration of stomach contents into the lungs. Endotracheal intubation is the standard method for airway management in the hospital setting including the operating room, emergency department, and intensive care unit.

"One of the most important recent scientific findings is that medical procedures executed in the field setting may not perform equivalently to the same interventions carried out in the hospital."

The History of Paramedic Endotracheal Intubation

Paramedics in the United States first performed field ETI over 20 years ago during an era of intense efforts to improve the out-ofhospital care of patients suffering from sudden cardiac arrest.³ Experts viewed delivery of oxygen as a fundamental component of cardiac arrest care, and most viewed ETI as the best way to deliver oxygen to the lungs in comatose individuals. Endotracheal intubation was widely performed on cardiac arrest patients in the hospital, and thus it seemed reasonable to train paramedics to act similarly on out-of-hospital patients. Prior to this time paramedics used older methods of airway management such as bag-valve-mask ventilation and the esophageal-obturator airway, neither of which was seen as adequate in this clinical context.⁴

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The first scientific reports of paramedic ETI originated from San Diego, Columbus (Ohio), Boston, and Pittsburgh.⁵⁻⁸ These groups of paramedics received intense preparation encompassing classroom and mannequin training as well as practice in the operating room on live patients. Anesthesiologists, viewed as the masters of ETI and airway management, played active training and mentoring roles in the pilot efforts. These studies garnered significant scientific attention and spurred efforts to generalize paramedic ETI throughout the United States.

Today, ETI is a standard of paramedic care. In Pennsylvania alone, paramedics perform ETI on over 11 000 out-of-hospital patients annually.⁹ Clinicians view ETI as one of the interventions that distinguishes paramedic care.¹⁰

Controversies Surrounding Paramedic Endotracheal Intubation

Is Paramedic ETI Life-Saving?

The intention of a resuscitation intervention is to improve patient survival or other health outcomes. Since its inception, most have assumed that paramedic ETI is beneficial: ETI provides a direct protected conduit to the lungs—how could it possibly be harmful? However, many recent studies suggest that paramedic ETI may in fact not improve survival or other outcomes. In some cases, the intervention may even worsen outcomes.

Multiple studies have examined the connection between paramedic ETI and patient outcomes.¹¹⁻¹⁸ The recurrent finding among these studies is that paramedic ETI does not improve survival and, in some cases, may actually increase mortality. These studies also have not identified any neurological benefit from the procedure. For example, Gausche et al performed a prospective pseudo-randomized controlled trial alternating ETI with bag-valve-mask ventilation of critically ill children; the authors found no difference in survival or neurological outcome.¹⁴ Davis et al evaluated out-of-hospital head injured patients intubated with the assistance of succinylcholine, a neuromuscular blocking agent.¹² The use of these drugs causes temporary paralysis of the patient to facilitate ETI and is normally reserved for physician use in the hospital.² Compared with historical matched controls that did not receive ETI, the experimental ETI group exhibited a higher adjusted odds of death.

We analyzed over 4000 head injured patients treated by paramedics in Pennsylvania over a 4-year period.¹⁶ We found that those intubated by paramedics had a 4 times higher adjusted odds of death than those intubated in the receiving hospital emergency department.

ETI Adverse Events and Errors

Some have attributed worsened outcomes to adverse events and errors occurring during out-of-hospital ETI. Clinically, this is plausible since ETI is an inherently difficult process requiring the coordination of numerous cognitive and manual steps. In addition, paramedics face other latent challenges when performing ETI such as the uncontrolled chaotic nature of the field environment. For example, it is not unusual for a paramedic to provide airway management on a patient entrapped in the wreckage of a motor vehicle collision. Given these many factors, the occurrence of adverse events is not only possible but probable.

The most serious adverse event associated with ETI is inadvertent placement of the breathing tube in the esophagus. If not recognized and corrected, this error results in oxygen delivery to the stomach instead of the lungs. Katz and Falk presented the most prominent report of ETI adverse events, finding the endotracheal tube misplaced in 25 of 108 patients intubated by paramedics; in two-thirds of these cases, the tube was in the esophagus.¹⁹ Other studies using similar methods found lower_but not negligible—rates of tube misplacement.^{20,21}

Recent efforts have highlighted previously undefined ETI errors. Endotracheal intubation ideally should occur rapidly so that there is minimal disturbance to the patient's oxygen level or heart rate. Dunford et al examined a subset of 54 patients receiving succinylcholine-assisted paramedic ETI.²² The authors found that patient oxygen saturation and/or heart rate decreased significantly during ETI in over half of the patients. Of greater concern, the paramedics considered 84% of these ETI cases to be "easy." Thus, even when equipped with state-of-the-art monitoring equipment, paramedics were not aware of these adverse events.

When individual events are aggregated, the resulting ETI error rates may be higher than expected. We collected data on over 1900 ETI performed by paramedics across Pennsylvania, focusing on reports of three error events: (1) ETI tube misplacement or dislodgement; (2) multiple ETI attempts; and (3) failed ETI efforts.²³ We found that one or more of these errors occurred in 1 in 4.5 patients receiving ETI efforts.

ETI Training and Practice

Given the complexity of ETI, one would expect that paramedics receive substantial training and practice in the procedure. However, current ETI training standards and practices may not afford adequate baseline or maintenance experience.

For example, whereas resident physicians in emergency medicine and anesthesiology must perform 35-50 ETI prior to graduation, paramedic students are required to perform only 5 ETI.^{24,25} Examining a series of 7500 ETI performed by 800 paramedic students, we found that paramedic students perform a median of only 7 ETI (IQR: 4-12) during their training.²⁶ We also found that paramedics students required at least 15 to 20 ETI encounters to achieve adequate baseline proficiency. Emergency medicine residents typically spend 160 hours in the operating room learning ETI under the tutelage of anesthesiologists. However, in a survey of paramedic training program directors, we found that most paramedic students spend only 16 to 32 hours in the operating room learning ETI.²⁷

Paramedic clinical ETI experience also falls below expected levels. Using Pennsylvania statewide data for 2003, we found that paramedics perform a median of only one ETI annually.⁹ While the minimum annual number of procedures is not defined, the best air medical programs require that paramedics perform at least 12 ETI annually.²⁸

While some agencies provide additional training and experience

using mannequins or human simulators, the effectiveness of these training modalities remains unproven. Mannequins and human simulators do not accurately recreate the feel of live human flesh nor the heterogeneity in airway anatomy between different persons.²⁹ Studies linking mannequin and simulator training to paramedic ETI performance have significant limitations.^{30,31}

Is Change Possible?

We now recognize that efficacy demonstrated in small controlled settings may not necessarily translate to widespread success when replicated on a large scale. In the case of ETI, the original demonstrations of the technique involved relatively small teams of paramedics receiving intense training and monitoring.^{5,6,8,30} Few considered that many EMS agencies nationally would not have the resources necessary to ensure the same degrees of success. Today, our current systems of EMS care and education lack the resources to ensure success on a national scale. There are, in fact, potential system level solutions. For example, one approach might involve substituting ETI with simpler alternate airway devices such as the Combitube or King LT airway.^{1,32,33} These newer devices are relatively easy to insert, work well in a variety of different clinical scenarios, are easier to master than ETI, and may not depend on live human practice for adequate training. In order to adhere to the most recent Advanced Cardiac Life Support guidelines, several individual paramedic agencies nationally have switched from ETI to alternate airway devices.³⁴

Facilitating change in ETI, however, comes accompanied by other challenges. One such challenge would be the workplace culture of EMS. Endotracheal intubation is a defining procedure of paramedic care.¹⁰ Taking ETI away from paramedics would be like taking scalpels away from surgeons—this proposition would likely face significant resistance. The optimal method for facilitating change in the face of these many challenges remains unknown. **NCMJ**

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Emergency Preparedness in North Carolina: Leading the Way

Jane H. Brice, MD, MPH; Roy L. Alson, MD, PhD

North Carolina is situated in an ideal climatic location to be at risk for natural disaster. Hurricanes, ice and snow storms, and tornadoes all strike the state with fair regularity. As such, the emergency responders in North Carolina have had to develop and hone their preparedness skills and maintain a state of readiness. They do not have the luxury to let down their guard. Man-made disasters such as recently experienced in the chemical fire in Apex or the pharmaceutical plant explosion in Kinston also test the preparedness of our responders on the front lines.

Changes in the environment in which we live require constant surveillance and assessment of threats in the community. Recent experiences with SARS in Canada and the isolated case in Chapel Hill dramatically illustrate the effect of new pathogens on communities. As we watch the progression of avian flu in the world, EMS must be ever vigilant as both they and the emergency department are likely to be the first to report the spread of disease in their environments.

In addition, the practice of medicine has evolved in the last few years. Hospitals have fewer available beds due to downsizing, nursing shortages, and minimizing the financial margin. Medicine has begun to emphasis home care. Patients are discharged from the hospital sooner and sicker. There is a smaller margin of error for these patients. More patients are maintained at home on ventilators, home oxygen, and in bed-bound states. When disaster strikes, these patients are most at risk. Finally, our emergency departments are overcrowded with admitted patients awaiting an available and clean bed, making surge capacity slim.

The last 10 years have taught several major lessons to EMS, hospitals, and the medical community at large. First and foremost, we have recognized that hospitals do not provide medical care in a vacuum. Hospital disaster plans used to focus solely on the hospital and were primarily mass casualty plans. We now see hospitals, the medical community, EMS, fire departments, and law enforcement working together with public health and emergency management to develop comprehensive community-wide plans. Lines of communication and coordination are being established before events. As mandated by the Joint Commission on the Accreditation of Healthcare Organizations, hospitals have embraced this community approach to disaster preparedness and are partners with EMS in emergency preparedness.

"Responding to a major statewide disaster such as experienced on the Gulf Coast in 2005 is not a matter of if but when. 'Will North Carolina be ready?'"

Responding to a major statewide disaster such as experienced on the Gulf Coast in 2005 is not a matter of if but when. "Will North Carolina be ready?" is the question many emergency planners are asking. In the past 6 years, funding for preparedness equipment and activities has increased substantially thanks to the attention of the federal government in the wake of the 9/11 events. Planners have also embraced the notion that disaster preparedness must be scalable, flexible, and sustainable. Crossinstitutional planning between emergency responders, hospitals, community officials, and industry has resulted in more robust,

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comprehensive, and integrated plans that allow a community or region to react in concert to mitigate the effects of disasters.

As required by Homeland Security Presidential Directive-5, adoption of the National Incident Management System by all emergency responders (eg, hospitals, EMS, public health) has allowed for a common language and better communication among providers. Incident command uses the concept of management by objective and is task-oriented rather than person-oriented.

Mass-casualty incidents affect particular segments of communities, but disasters have consequences that are felt across entire communities and regions. An "all-hazard" approach to emergency preparedness has demonstrated the greatest potential for success. In an "all-hazards" model a standardized framework for disaster response is developed and followed with the ability to supplement response with specific entities such as decontamination as the incident dictates. While the federal government offers substantial assistance in the event of a disaster, this help may be days to weeks away and communities have to plan to be self-supporting for 72 to 96 hours.

Where Does North Carolina Stand?

North Carolina's emergency responders stand at the forefront of emergency preparedness compared to the rest of the nation. The North Carolina State Medical Response System (SMRS) is a joint partnership of the North Carolina Office of Emergency Management, the North Carolina Office of Emergency Medical Services, and the North Carolina Department of Public Health. Role modeling at the state level the partnerships that are most effective in emergency preparedness, the SMRS has set the standard for both regional and local level preparedness. Utilizing a comprehensive approach based around the administrative organization of the Trauma Program's Regional Advisory Councils, the SMRS has set up several layers of emergency preparedness. Through Health Resources and Services Administration (HRSA) grants, North Carolina has provided funding and other resources for individual counties to develop SMAT 3 teams. While not required, counties are encouraged to develop and maintain the training for SMAT 3 teams. At present, 25 counties have taken advantage of this opportunity. Primarily prehospital in orientation, these teams have the ability to rapidly set up technical decontamination systems to deal with weapons of mass destruction (WMD) or hazmat events. SMAT 3 teams also have the ability to assist with onsite medical care and triage in a mass casualty incident and are currently undergoing training to deal with blast injuries and structural collapse events.

Each of the 8 trauma regional advisory councils (RACs) in the state serves as the sponsor for a SMAT 2 team. These teams have the ability to support hospital based decontamination as well as provide care in a portable 50-bed medical facility that can be set up in either temporary shelters or fixed structures. Each facility is contained in a 55-foot tractor trailer (See Figure 1.) and can be used as a stand-alone acute care or alternate care facility. The units can be utilized in combination forming a larger medical facility with maximum surge capacity of 400 beds for our state. To form the SMAT 2 response, each hospital within a RAC commits a few staff members to support the SMAT operation based upon the size of the member hospital. SMAT 2 operations are thus enabled without compromising the staffing of any one medical facility. Members of the SMAT 2 team train with the system on an annual basis and, in addition to disasters, the units have been deployed to support events such as the Tall Ships sail in Beaufort last summer. Current purchases to augment the SMAT 2 operations include 2 portable digital field x-ray systems for the state, 3 pharmacy trailers, and a stock of portable ventilators.

The SMAT 1 is based at the Special Operations Response Team (SORT) headquarters in Winston-Salem. Containing a

The central concept of SMRS is that it is scalable and flexible. Incorporating assets at the local, regional, and state levels, the SMRS is able to mount an integrated common response with equipment, protocols, and training. At the core of this response is the State Medical Assistance Team program (SMAT) with tiered levels of team response. The SMAT layers are based out of county (SMAT 3), regional (SMAT 2), and state (SMAT 1) bases. This concept has been proven effective in responses to tornados and the recent Apex chemical plant fire as well as responses Hurricane to Katrina.



more robust decontamination capability to deal with large-scale WMD events, the SMAT 1 inventory includes a tractor trailerbased field hospital and an 80-bed special medical needs trailer, which allow set up of a special needs shelter in a fixed facility. The Special Operations Response Team also maintains a tractor trailer with basic medical supplies for deployment during disasters as well as a rapid deployment field medical unit.

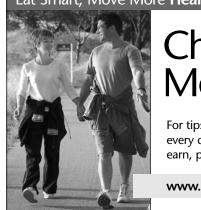
Carolinas Medical Center in Charlotte has developed and deployed under government funding a tractor trailer mounted intensive care unit and operating room facility called MED 1. Serving as the critical care area during the NC SMAT deployment to Waveland, Mississippi during the aftermath of Hurricane Katrina, the team has received extensive media coverage and accolades.

Public health has not been neglected in the process. Funding has been provided to increase training of public health agencies across the state and to upgrade laboratory facilities for the Division of Public Health to allow for timely diagnosis. Seven public health regional surveillance teams (PHRST) have been established and are operational, providing both technical support and epidemiological tracking for unusual diseases in our state. Lastly, the North Carolina Health Alert Network (NCHAN) uses a multimodel system for 24/7 distribution of health related information to health departments, medical facilities, and response agencies.

In a related function, the NC State Medical Asset Resource Tracking Tool (SMARTT) has been successfully deployed. It allows hospitals to enter bed status and availability in real time so that planners can use this information to allocate patients and assets during real events. The SMARTT system will eventually include EMS responders, special teams such as hazardous materials teams, and local clinics and physicians' offices.

Much has been done, but there is still much to do. Dealing with the special needs populations remains problematic and unsolved. Development of SMAT 4s to specifically address the special needs communities with input from home health agencies and nursing facilities is now underway along with a system to track medical records and medications for this population. Special needs equipment is being purchase and stockpiled. Dual use capability of special needs equipment is being pursued with home health agencies and community colleges across the state. Equipment can be used to train nursing and allied health professions students on a daily basis and, in an emergency, equipment would be used by the students and other health care providers to provide a special needs shelter on the campus in a coordinated manner, with all the necessary assets centrally located for the region.

North Carolina is extremely fortunate. Due to our cooperative approach, North Carolina is a leader in disaster response and states across the southeast are emulating our system of tiered response. We cannot rest on our laurels. We must continue to examine the risks and adapt our preparations. Finally, as practitioners we must realize that the victims we discuss are our patients. Therefore, we must take an active part in the preparation for and the provision of disaster medical care by volunteering to serve on a team, being certain that our practices can and do remain open in the event of a disaster or other incident in our communities, or being personally prepared with our families for disaster. Above all, we must remember that disaster response is really the ultimate team sport and that we are fortunate to be part of a top team. **NCMJ**



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Emergency Medical Communication in North Carolina: Past, Present, and Future Challenges

Carl C. Van Cott

If the best equipped ambulance arrives unannounced at the emergency room door and the hospital is unprepared for the arrival, the system has broken down and patients can be lost because of it. There must be good reliable communications between the person reporting the accident, the dispatcher of the appropriate vehicle and personnel, the police and fire departments (when called for), the hospital emergency department, the medical specialists available to the hospital, and those bigger hospitals (trauma centers) to which the patient might in some cases be sent directly.

This excerpt from the 1973 Report of the Legislative Research Commission to the General Assembly of North Carolina recognized the importance of emergency medical services (EMS) communications to the safety and quality of emergent care. Since its inception, EMS communications has made measured progress. This article explores some history, examines the current status of EMS communications, and highlights some of the future challenges faced in North Carolina.

An EMS communication system must be examined under two operational conditions: routine or day-to-day operations and disaster or larger scale emergency situations. For the local

systems to be effective, wide area standards for operations and equipment, radio frequencies, and technical requirements must be provided. These standards must be sufficient to ensure compatibility and interoperability throughout all systems statewide. Communication functions must also adapt if an emergency situation escalates. Communications must be capable of extending to adjacent counties, states, and national disaster management agencies. The establishment of interoperable systems requires time to develop and needs consistent financing and direction. System creation is an evolutionary process requiring understanding and acceptance. Common goals and language must exist to facilitate this development.

Public Access Communication

In the 1970s public access to emergency services was uncoordinated. Numerous telephone numbers were listed on the inside cover of local telephone directories for the various sources of EMS and rescue services. Callers seeking assistance were fortunate if they could identify the telephone number necessary for their needed emergency service; they may have had to call multiple phone numbers and choose between the various services and providers, thus being delayed in obtaining assistance.

"National long-term plans may convert all public safety communications to a common frequency band, but this will not be possible in the short term and requires interim systems to remain functional as the new systems and equipment become defined and available."

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Currently, public access to EMS is achieved through universally available 9-1-1 emergency telephone systems. Public Safety Answering Points (PSAPs) have been established in all 100 North Carolina counties and the state has progressed to being served fully by "Enhanced 9-1-1," also known as E9-1-1. Enhanced 9-1-1 enables a PSAP to determine the caller's location from data linked to the telephone number. Considerable effort has been expended in implementing these E9-1-1 systems. The introduction of new communications technologies has, however, created new challenges. For example, an estimated 70% of calls to PSAPs in North Carolina are now made from cellular telephones, but many PSAPs cannot accurately identify the location of the cellular telephone. Similarly, Voice over Internet (VoIP) telephones, also a popular new technology, do not automatically tie to the system that provides user location information. This requires the user to register the VoIP telephone to a location. These differences may cause delays and inaccuracies in dispatching emergency help, which can result in loss of life and property.

Cellular telephones also offer new advantages for EMS communication. They have features such as geographic positioning systems (GPS), digital picture and video transmission and reception capabilities, text messaging, and mapping capabilities. These new capabilities, however, are not utilized by most 9-1-1 centers. They could have considerable usefulness in the emergency dispatching system. Methods to utilize these new system capabilities for EMS systems should be explored. For example, a cellular caller could send pictures of a crash location or other emergency situation, in essence extending the eyes of the dispatcher to the emergency scene. Consider the range of possibilities when the cell phone device in the field can also receive messages or video from the 9-1-1 dispatcher. This could provide information on how to perform cardiopulmonary resuscitation (CPR) or other emergency procedures or even direct evacuations in preparation for an impending weather event or other large scale emergency.

Dispatch and Coordination Communication

In times past, virtually no training was provided to emergency dispatchers. Dispatching services were not recognized as having a high degree of importance and were not always provided 24 hours a day. Sometimes emergency telephone numbers changed from day to night depending on which person took the ambulance home that evening. Times have changed. Telecommunicators that function in a coordinated PSAP are generally required to have a minimum level of telecommunications training. There is increasing recognition of the important role telecommunicators play as the first of the first responders and the sole point of contact for all emergency services. The dispatcher is responsible for making the decision of what services are to be dispatched and for the coordination of all of the emergency functions and field responses. If this function is poorly performed, nothing else will go well in the response. Telecommunicators are rightfully assuming recognition in a new profession.

Emergency medical dispatch (EMD) training is available throughout North Carolina. Emergency medical dispatch certification is an advanced life support service that requires a medical director. Currently, 73 communications agencies or 63% of the approximately 115 emergency dispatch centers within the state have approved EMD programs.¹ These centers are trained to recognize life-threatening conditions and provide telephonic direction in medical emergencies such as childbirth and CPR.

Emergency medical services communications understanding must extend further to the educational requirements for all users of the system. This education must include training for the public on how and when to call for assistance and what to expect when they call. The dispatcher's training must include providing prearrival medical instructions. Field responders and hospital personnel need instruction on how to use their communications equipment. Methods must be developed to accurately and quickly exchange information about a patient's condition and treatment, and a standardized radio reporting template to present a patient to the emergency department must be developed. Finally, education must extend to licensing radio systems, maintaining the equipment, and testing the operational readiness of the entire emergency communications system.

Public Safety Answering Point operations should be encouraged to recognize the importance of certification and training programs. These certifications also extend to fire and law enforcement operations. Caller algorithms (flip cards and computer programs) for directions to provide assistance to callers must continue to be reviewed and expanded to a broadened array of programs and to additional medical conditions where early intervention can be critical. All emergency communications centers should have the ability to provide CPR instructions over the telephone. All emergency answering points should be able to provide information on the location of nearby automatic electronic defibrillators in high population areas such as malls, airports, fairs, and other public gathering places and to be able to provide instruction on the use of these devices to the caller.

Devices that provide mapping, location, and direction information to emergency events must be made commonly available to PSAPs, emergency response vehicles, and field responders. Vehicle GPS systems should be widely available to report to the PSAP the location of ambulances and to provide the dispatcher with information on the location of the closest units available to respond to any given situation. Coordination of emergency communications services between geographic areas such as cities and counties must become the rule and not the exception. There should be a common statewide approach to providing public safety services.

Medical Communication

In the early 1970s physician medical direction communication to field EMS units did not exist. Notification of an impending patient arrival via ambulance at a hospital was sporadic and information concerning a patient's condition was provided only as a local service option. In most instances it did not exist. Hospital radio systems operated on various radio frequencies with different channel designations. A statewide common hospital radio frequency was not available. Ambulance personnel making patient transports to out-of-county hospitals generally were not able to communicate after leaving their local service area.

A statewide common hospital very high frequency (VHF) was implemented in the later half of the 1970s and a standardized channel name was designated. During the 1980s and 1990s every ambulance and every hospital with an emergency department had a radio that operated on 155.340 MHz, now commonly called "340." A state publication entitled Dial Codes provided information about each hospital's radio frequencies and telephone and radio access numbers or codes. Ultra high frequency (UHF) "MED" radio systems were widely implemented and paramedic advanced life support communications systems were installed. These radio systems had the ability to transmit a patient's electrocardiogram to aid in patient care and treatment.

In the late 1990s wide area compatible hospital radio systems in parts of the state began to decline, both in numbers and in operational reliability. In part this was due to the lack of consistent funding to encourage hospitals and EMS agencies to install systems that met statewide standards and to the failure of hospitals to keep their radio equipment in prime operating condition. At times there was disagreement on who was responsible for providing the radio or maintaining the ambulance-hospital equipment serviced, especially when the services were under different administrative structures.

All hospitals in North Carolina with emergency departments currently have radios licensed on the state hospital 340 VHF frequency. Some of these radios have not been replaced or upgraded since the original installation 25 or more years ago. Even when functional, the single frequency hospital radio system is overloaded in metropolitan areas and during disaster situations.

Some counties and EMS agencies that previously had equipment operating on the state standard UHF MED channels have now removed these radios, electing not to repair or replace older radio equipment in favor of purchasing new 800 MHz systems. The expanded capabilities of the 800 MHz trunked systems, however, extend only to users that function within the same communications network. Compatibility between adjacent counties or to other communications systems may not exist or is difficult to achieve due to differences in the equipment when it is supplied by different manufacturers. Unless common direction and standards are consistently available, system designs may fail to maintain common statewide frequencies. This can result in situations where an ambulance transporting outside the county is not able to communicate with the receiving hospital or is unable to maintain contact en route. Cellular telephones appear to fill this communications gap, but they do not function when the telephone network becomes overloaded. This situation is common during disasters and can occur even during moderate traffic congestion situations.

The North Carolina Medical Communications Network (NCMCN) has been developed to provide common geographic wide area UHF radio coverage. The state network of radio repeater installations operates on two channels to increase connectivity between hospitals. The system functions both for routine radio communication and during disasters. The system serves as a redundant system to local EMS radio systems and as an interim system for disaster medical communication. By October 2007 NCMCN radios will be installed in all hospitals within North Carolina. Even with this advancement in statewide capabilities, channel capacity of the system is not sufficient to ensure communications during large scale emergencies or disasters. Additionally, there are currently insufficient numbers of ambulances equipped with UHF radios to ensure operational capability with the system.

Efforts are underway to create a new public safety statewide radio network in the 800 MHz spectrum. This system is the Voice Interoperability Plan for Emergency Responders or "VIPER" network. The system is intended for use by all emergency responders including law enforcement, fire, and EMS services.

A medical communications component has been added to the VIPER network to provide an additional layer of compatible medical radio operation to hospitals and EMS services. This component is designated the Viper Medical Network (VMN), and it provides another radio option for hospitals and EMS services. Funding to encourage wide participation in this system has not yet been identified. The first level of deployment of the VMN is underway through funding provided by the US Health Resources and Services Administration (HRSA). Eventually, it is envisioned that every hospital in the state will have access to its own "talk group" on the network, which will enable any hospital or ambulance to establish voice contact from anywhere within the state.

Complicating the advancement of the new VIPER system is the necessity to provide additional radios to ambulances. In the short term this could result in an ambulance being required to have up to three separate radios installed—one functioning on the hospital VHF 340 for communications on the statewide VHF hospital frequency and with its local dispatch operations, a second for the UHF NCMCN, and a third to participate in the VIPER VMN 800 MHz state trunked network. This amount of radio equipment is costly to acquire and maintain. Unfortunately, there does not appear to be any easy alternative. Some efforts are underway by the state and some counties to install gateway systems that will patch between various radio systems. For these systems to function, however, the radio coverage between the patched systems must be geographically coincidental. Until all systems statewide can be upgraded to a common band or to the VIPER system or until equipment becomes available to enable radio operation compatibility on the many systems and radio bands, multiple radios in hospitals and ambulances will continue to be required. Furthermore, alternative sources for equipment compatible with the VIPER network must be identified. Equipment is currently available from only a very limited selection of suppliers. Technical assistance and guidance regarding radio communications as well as the VIPER network must be made available to hospitals and EMS providers.

National long-term plans may convert all public safety communications to a common frequency band, but this will not be possible in the short term and requires interim systems to remain functional as the new systems and equipment become defined and available. There are already known technical situations and pending FCC actions that impact the development of these high capability systems. Developments of new capability systems and technology will keep EMS systems in a state of flux for years to come.

Implementation of an EMS communications system is an evolutionary process. Implementation requires a series of compromises and trade-offs made within the confines of time and funding. Directives, rules, laws, technology, motivation, and expectation all influence the outcome. Every aspect of the communications system must continually be revisited, evaluated, refined, refurbished, and improved to maintain North Carolina's readiness and ability to provide the services to respond and be prepared for the eventualities. **NCMJ**

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The Future of Emergency Medical Services Communications Systems: Time for a Change

Kevin K. McGinnis, MPS, EMT-P

Modern emergency medical services (EMS) are approximately 35 years old. The transformation of ambulances from "horizontal taxicabs" capable of little more than patient transportation to a system capable of sophisticated, life-saving, prehospital and hospital intervention has been dramatic. Emergency medical services communications systems have, by and large, not experienced similar transformation. Current and developing advances in communications technology could address this.

Immediate opportunities for EMS communications systems to integrate such advances exist, and more are evolving in the federal and national arenas. Incorporating broadband as a means of improving communications among EMS providers, between EMS, fire, and police, and between EMS and hospitals is one example. In affecting these advances, EMS has the potential to become the greatest user of public safety bandwidth and a very large user of federal communications funding.

There is no assurance that EMS will have access to such capabilities or funds. Additionally, EMS is not prepared to lobby for new resources and capabilities. First, we need to determine what information prehospital and hospital emergency care providers need, in what form, and at what stage in the course of an EMS patient care episode. It is the EMS community itself, including state and local government agencies responsible for EMS, that must organize to take advantage of these opportunities and capabilities.

Where We Are

The commentary by Carl Van Cott highlights the evolution of the existing EMS radio systems including the very high frequency (VHF) radio channels and ultra high frequency (UHF, in the 460MHz range; often called the "10 med channels") channels for ambulance to hospital (for reporting patient condition and seeking medical direction) and other communications. With the exception of electrocardiogram (EKG) biotelemetry sent over the UHF EMS channels, these communications were solely for voice use. Even today, the EMS communications system probably consists of 98% voice and 2% biotelemetry and other data transmissions.

Some local EMS systems have been solicited to participate in new or existing regionwide or statewide 700MHz and 800 MHz radio systems that are usually operated by law enforcement and/or government transportation agencies. These systems offer more voice channels for specializing communications but have significantly less transmission range, which makes them less practical in rural areas. Governmental owners of such systems solicit new users like EMS when the cost of maintaining an existing system becomes challenging. For rural EMS operations, this can be an expensive proposition. Erecting new antennae, for example, would be necessary. In addition, when urban EMS systems become integrated into 700/800 MHz systems, the

"Each segment in the EMS response presents potential delays. Each also presents opportunities to accelerate appropriate medical intervention through improved communications that enable some events, decision making, and actions to occur more simultaneously."

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specialty centers involved must often maintain VHF/UHF capabilities for communicating with ambulances coming in from outside of that area.

Broadband capacity at 2.4 MHz is a technology being provided by some municipalities for public internet access in urban environments. Municipalities are also encouraging public safety agencies to employ this technology. Broadband will become increasingly important to EMS as data communications are utilized more. Careful consideration, however, should be given when considering its use for mission-critical communications and for any communications involving confidential patient information. The unlicensed and public access characteristics of this system render its reliability and security suspect. Another broadband service at 4.9 MHz is reserved for licensing by public safety organizations. Use of this service is believed to alleviate reliability and security issues to a greater extent. Both 2.4 MHz and 4.9 MHz services are extremely short range and, thus, of use in primarily urban environments.

Where We Could Be

During an EMS emergency call today, events, decision making, and resulting actions largely occur on a sequential basis as new information is presented. In a rural car crash, for instance, the crash occurs, the crash is detected, EMS is called, EMS responds, EMS arrives and evaluates, additional resources are called (eg, extrication services, helicopter), additional resources respond, medical direction is sought and provided, treatment is administered, and the patient is transported. Each segment in the EMS response presents potential delays. Each also presents opportunities to accelerate appropriate medical intervention through improved communications that enable some events, decision making, and actions to occur more simultaneously. Delays during EMS calls can cost tens of minutes, if not hours, during the patient's "golden hour," the time from the crash event to when the patient arrives under a surgeon's scalpel.

In the future, through advanced automatic crash notification (AACN) systems in cars, standard equipment on many car models now produced, the crash event and location will be available to local EMS and other responders almost immediately. Current and future AACN features can also transmit change in velocity at crash, direction of impact, air bag deployment, seatbelt status, number of occupants, and rollover status. Future systems may include an "urgency algorithm" which notifies responders of the likelihood that an occupant was severely injured in the crash. Not only does this virtually eliminate the delay in detecting and locating crashes, but it allows prehospital and hospital providers to be immediately notified of all or severe crashes in their response/catchment areas. With appropriate protocols in place, simultaneous dispatch of ground and air ambulances and extrication services could then occur in severe crashes. Similarly, hospitals and trauma centers could notify their staffs to be ready and notify prehospital responders of their availability to take patients. One can imagine similar capabilities in "help, I've fallen and can't get up" devices for populations at risk.

When EMS responders arrive at the scene in the future, they

will be able to do more simultaneously. The initial provider at a car crash will make a quick, triaging assessment of each patient, placing and leaving a small electrocardiogram (EKG) and vital signs monitor on each, inserting each patient's emergency health record "smart card" into his personal digital assistant (PDA) or communications device, describing brief findings about each into a lip microphone which is translated to a text file, and shooting brief video of each through a shoulder or head camera. Each of these data streams goes into patient-specific data bases in the responder's PDA and is transmitted to a mobile data unit in the ambulance.

Once additional responders are assigned to patients, their devices are used to enter their identifications, monitor patient vital signs, and add new voice/text and video data into the respective patient-specific data files. The EMS scene coordinator, as well as yet to arrive EMS, extrication, and helicopter crews and the local and trauma center hospital staffs can access databases for updates on any or all of the patients' conditions. Field providers utilize PDAs or mobile data units like laptop or tablet computers. Hospital staff may use the same or desktop units. All are combination voice and data communications units. Looking at a screen with a patient's real-time vital signs, video image, and provider's notes, medical direction physicians can begin to anticipate more information they may want and orders they will give crews at the scene or en route to the hospital. As patients become assigned to specific EMS crews for transport to specific hospitals, access to their databases becomes limited to their prehospital and hospital providers. Best routing to a scene and then from scene to hospital by ground ambulance can be determined through local transportation agency real-time traffic monitoring databases.

The Technology Required

This vision for where we could be comes at a price and with risks. In April 2007 the Blackberry network crashed. Technology such as mobile data units, PDAs, and computers with integrated voice communications exist today, but these can be costly. Personal digital assistant-based emergency health record entry and reliable speech-recognition technology has been developed in military systems such as the Battlefield Medical Information System Tactical,¹ which is available for commercial licensure. Video and vital signs monitoring for one or multiple patients through miniaturized devices has been demonstrated by a research and development group coordinated through Johns Hopkins.² A number of EMS systems have piloted video use in ambulances

If hospital and prehospital emergency care and other public safety players involved in any EMS call maintain databases detailing the status and availability of their resources, it becomes theoretically possible to network them in a system that is accessible by the field PDAs and other devices described. Then we add to the network those databases created by public safety, advanced automatic crash notification, traffic and other control/dispatch centers that describe evolving car crashes, EMS call, traffic flow, and other system events. Finally added is the ad hoc patient databases created at the scenes of EMS calls, and these 3 components become a "network of networks" in which voice and data communications can exist. To complete the system picture, the screen of any of the data/voice communications devices could present a simple, map-like picture of the provider's response or catchment area. The screen would depict icons for all the relevant events occurring in real time (eg, car crashes, ambulance calls) and resources (eg, local hospital emergency department, EMS, fire rescue). By selecting an icon, an authorized user could then drill down on an event or resource to find out more about it. At the lowest level of a car crash event icon, one might find the patient video, vital signs, and provider notes data described earlier.

Federal and National Activities and Opportunities for State and Local Action

If EMS is going to participate in the type of data communications network described above, it must acquire communications frequencies with greater bandwidth than it has now. The VHF/UHF and 700/800MHz capabilities it now utilizes have bandwidth sufficient for voice communications and simple EKG biotelemetry. Sending text data (like provider's notes), real-time vital signs data, basic streaming video, higher definition video, and medical quality video require increasingly wider frequency bands to provide the speed of data transmission needed to send these files for real-time use. Transmitting a huge video file on one of today's EMS VHF frequencies would be slower than sending it by dial-up internet access. For vital signs transmission, at least wide-band capability would be needed, and for high to medical quality video, broadband is required. With multiple EMS crews sending data to various hospitals in any one area at the same time, the bandwidth required could well outstrip that available.

Congress and the Federal Communications Commission (FCC) have ordered analog television stations off a frequency band in the 700 MHz range (channels 60-69; 746 MHz-806 MHz). They have allocated some of this for public safety use and the FCC is now considering proposals for how it will be divided up when it is released in 2009. The remainder was to be auctioned in 2009 for commercial use with a billion dollars of the proceeds to go to public safety in states and locales for improving radio interoperability. Congress is likely to approve the expenditure of that \$1 billion to be spent this year. The National Public Safety Telecommunications Council, FCC, and US Department of Homeland Security (SafeCom Interoperability Program) websites can be monitored for progress.^{3,4,5} Despite the early availability of these funds, there are proposals before the FCC to give the remaining analog TV channel range to public safety for a national broadband network under the supervision of a public safety controlled consortium rather than auctioning them off for commercial use.

The SafeCom Program is constantly developing tools for state and local interoperability and system development efforts. Included in these are guidelines for the development of statewide interoperability executive committees. Such committees exist in most states by one name or another and should be targeted by EMS interests to seek inclusion for public safety broadband planning efforts and access to bandwidth.

The FCC has ordered that the VHF and UHF frequencies that include the traditional EMS frequencies be made even narrower by 2013. This means that where there once existed one narrow-band channel for use, there will be as many as four. Local EMS agencies that have been attracted to the current 700/800MHz system offerings in their states because of the availability of many open channels for EMS use may find that sticking with their VHF/UHF systems provides not only greater range and less expense but more voice channels in few years. **NCMJ**

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Spotlight on the Safety Net

A Community Collaboration Kimberly M. Alexander-Bratcher, MPH

Mecklenburg Emergency Medical Services Agency

Mecklenburg Emergency Medical Services Agency, better known as Medic, provides emergency and nonemergency paramedic level medical services to the citizens of Mecklenburg County. Medic is part of a unique partnership between Mecklenburg County, Carolinas HealthCare System, and Presbyterian Health Care/Novant Health. Since fiscal year 1997, Medic has reduced ambulance response times, implemented higher clinical standards, and reduced the taxpayer subsidy per call by half. The agency will answer more than 85 000 calls for medical help this year. Medic also conducts frequent community education programs on health, safety, injury prevention, and emergency-related issues.

In 1996, the Mecklenburg Board of County Commissioners and the county management staff worked closely with emergency medical services (EMS) management and leaders in both the medical and business communities to address the needs of the county's EMS department. Together, they were committed to meeting future needs in the ever-growing Charlotte-Mecklenburg community. The goal was and continues to be enhancement of Mecklenburg's emergency medical services to create a high-performance EMS system. A joint plan was also received by the community's two major hospital systems—the Carolinas HealthCare System and the Presbyterian Health Care System. In the fall of 1996, the Mecklenburg Board of County Commissioners decided to form a partnership with the two hospital systems to provide prehospital emergency medical care and transportation.

Medic maintains its own communication center known as Central Medical Emergency Dispatch (CMED). Central Medical Emergency Dispatch's 3 primary responsibilities are to: (1) prioritize and dispatch 9-1-1 requests for service and coordinate all EMS resources within Charlotte-Mecklenburg; (2) dispatch all Mecklenburg County volunteer fire departments; and (3) serve as the central warning point for two nuclear power facilities or other disasters that may occur. All requests for emergency services are handled via an enhanced 9-1-1 system. All 9-1-1 calls for Medic and/or county fire are routed to CMED by the Charlotte-Mecklenburg Police Department, which serves as the primary public safety answering point (PSAP). Central Medical Emergency Dispatch serves the community as the backup PSAP should there ever be a problem with the primary PSAP communications center. Efficient use of emergency medical resources is achieved by a state-of-the-art Computer Aided Medical Priority Dispatch System, global positioning satellite tracking equipment, onboard mobile status terminals, System Status Management programs, and nationally-certified emergency medical dispatchers who prioritize incoming calls and provide prearrival medical instructions to all 9-1-1 callers. Medic's CMED received national accreditation from the National Academies of Emergency Dispatch as a Center of Excellence in 2002.

At present, there are approximately 170 full-time and approximately 32 part-time field employees working at the paramedic or emergency medical technician (EMT) levels. There are also education and quality improvement staff, logistics team members, fleet maintenance workers, and human resource and financial staff. Medic currently responds to greater than 90% of all requests for emergency services within 9 minutes and 59 seconds. During any given 24-hour period, 150 to 300 calls are dispatched. Mecklenburg Emergency Medical Services Agency is the busiest EMS provider in North and South Carolina. In 2002, Medic units responded to over 70 000 calls (all responses) and conducted over 48 000 transports.

A new and innovative division at Medic is the Education and Simulation Center. Under the direction of Kevin Staley, Medic's Medical Services director, a state-of-the-art medical simulation center has been

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developed which includes multiple sound stages, high-fidelity mannequins, control rooms, digital reproduction capabilities, and review rooms. This resource affords EMTs and paramedics a unique and progressive methodology for their continuing education. Multiple scenarios have been developed and adopted that enhance the provider's ability to deliver evidence-based emergency medical care. Similar training is currently being adopted at medical universities and nursing schools across the country. A human gross anatomy lab has also been included in this center to enhance each provider's understanding of the anatomical relationships in the human body. Medic is in partnership with the Center for Prehospital Medicine at Carolinas Medical Center which provides full-time EMT-paramedic and EMT-basic courses of instruction throughout the year. These courses are open to the public as well.

The field of emergency medical service is rapidly evolving. The Mecklenburg Emergency Medical Services Agency is mirroring the larger changes being experienced throughout the medical marketplace as a whole. This model has been designed to ensure high quality clinical care, provide efficient and reliable EMS services at a reasonable cost to consumers, and provide the community with an operationally and financially stable system. Prehospital emergency medical care is in essence the provision of health care to those afflicted by unexpected illness or injury. While EMS is considered a public service, many will debate the notion of EMS being a component of public safety. Regardless, incorporating EMS into both health care systems and county oversight in the community strengthens the concept of health care delivery and ensures that citizens and visitors in the Charlotte-Mecklenburg community receive the highest level of quality patient care possible. As such, Medic is modeling a new design for the future of EMS.

Contributions from Tom Blackwell, MD, FACEP, medical director of Mecklenburg Emergency Medical Services Agency



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MEDICAL JOURNAL

Running the Numbers

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

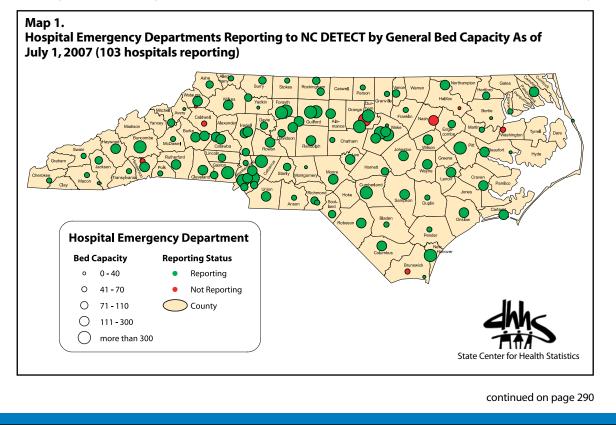
From the State Center for Health Statistics, NC Department of Health and Human Services http://www.schs.state.nc.us/SCHS

North Carolina Emergency Department Visit Data Available for Public Health Surveillance

The National Center for Health Statistics estimates there were 110.2 million emergency department (ED) visits throughout the United States in 2004 and has documented a steady increase in the number of ED visits over the past decade.¹ Secondary data from ED visit records are timely, comprehensive, population-based, and electronically available through hospital information systems. These data are increasingly in demand for use in biosurveillance and other public health surveillance efforts.

In North Carolina, 111 hospital-based EDs provide unscheduled acute patient care on a 24 hours a day, 7 days a week (24/7) basis. The North Carolina Emergency Department Database (NCEDD) project began in 1999 as a voluntary pilot project to demonstrate the ability to collect and standardize ED visit data from disparate hospital electronic information systems. In 2004 the North Carolina Division of Public Health partnered with the North Carolina Hospital Association and the University of North Carolina at Chapel Hill School of Medicine to create the North Carolina Hospital Emergency Surveillance System (NCHESS) and the provision of ED data for public health surveillance became mandatory.

As of July 1, 2007 93% (103 of 111) of hospital-based, 24/7 acute care EDs in North Carolina are providing visit data electronically at least once a day through NCHESS to be used by the North Carolina Disease Event Tracking and Epidemiologic Collection Tool (NC DETECT). (See Map 1.) NC DETECT is the web-based early



event detection and timely public health surveillance system in the North Carolina Public Health Information Network (See http://www.ncdetect.org.). The ED data in NC DETECT include all visits to North Carolina EDs: patients who were admitted to the hospital, transferred to another facility, discharged home or into law enforcement custody, or who left without being seen or against medical advice. NC DETECT uses the algorithms from the Early Aberration Reporting System (EARS) of the Centers for Disease Control and Prevention (CDC) to monitor several data sources for suspicious patterns. The reporting system also provides broader public health surveillance reports for emergency department visits related to hurricanes, injuries, asthma, vaccine-preventable diseases, occupational health, chronic diseases, and other topics.

For the purposes of biosurveillance, ED visits in North Carolina are grouped into syndromes based on analyses of the chief complaint, initial ED temperature, and history of the present illness (when available). The syndromes are based on the CDC's Syndrome Definitions for Diseases Associated with Critical Bioterrorism-associated Agents.²

NC DETECT serves more than 200 hospital-based and public health users at the local, regional, and state levels. All users must be approved by the North Carolina Division of Public Health before access to the system is granted. Depending on the assigned user role and data source, users have access to secure, web-based county and/or hospital views of the data and can access a variety of tabular and graphical reports. On several reports, users can specify the date ranges and can display the results by ICD-9-CM final diagnosis codes. Reports with dynamic mapping capabilities as well as an ad hoc query tool are under development.

As ED participation in NC DETECT approaches 100%, these data provide population-based analysis opportunities. The NC DETECT database will add approximately 3.5 million new ED visits each year when all hospital EDs are participating. Table 1 presents the distribution of primary diagnoses for the almost 3 million North Carolina

Major disease category*	ICD-9-CM code range	Number of visits	Percent distribution
All visits		2 977 543	100.0
Infectious and parasitic diseases	001-139	77 549	2.6
Neoplasms	140-239	10 563	0.4
Endocrine, nutritional and metabolic diseases, and immunity disorders	240-279	78 397	2.6
Mental disorders	290-319	112 427	3.8
Diseases of the nervous system and sense organs	320-389	122 958	4.1
Diseases of the circulatory system	390-459	124 264	4.2
Diseases of the respiratory system	460-519	249 851	8.4
Diseases of the digestive system	520-579	156 799	5.3
Diseases of the genitourinary system	580-629	124 667	4.2
Diseases of the skin and subcutaneous tissue	680-709	81 685	2.7
Diseases of the musculoskeletal system and connective tissue	710-739	201 680	6.8
Symptoms, signs and ill-defined conditions	780-799	595 237	20.0
Injury and poisoning	800-999	511 647	17.2
Supplementary classification	V01-V82	80 073	2.7
All other diagnoses	280-289 630-677 740-779	62 793	2.1
Unknown/Missing**		386 953	13.0

Table 1. nd Descent Distribution of Emorgancy Deportment Visits by Major Disease Category (Drimany

Includes invalid codes and blank diagnoses.

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ED visits reported for 2006. One in 5 ED visits received a primary diagnosis related to nonspecific symptoms and conditions (eg, fever, syncope, headache, chest pain) and a similar proportion have a primary diagnosis related to injury or poisoning. Many ED visits (13%) are submitted with missing or unknown primary diagnoses, including visits assigned invalid diagnosis codes.

A distinctive feature of the ED data in NC DETECT is their timeliness. Because the data are submitted and updated twice a day, they are particularly useful for surveillance and situational awareness in rapidly developing outbreaks or disasters. However, not all data elements are immediately available. Thus, early analyses of the data rely on the patient's presenting information, including demographics, chief complaint or reason for visit, history of the present illness, and initial vital signs, whereas analyses that require final diagnosis codes may need to wait 3 to 6 months to ensure acceptable levels of completeness.

NC DETECT allows public health epidemiologists and infection control specialists to significantly increase the speed of detecting, monitoring, and investigating public health events statewide. State and hospital-based epidemiologists monitor the biosurveillance syndromes daily to identify suspicious signals. Epidemiologists systematically review visit-specific information for detailed signal analysis and can also view syndromes and signals stratified by age groups. If an outbreak is suspected, additional investigation measures and appropriate notification can be quickly applied. In addition, rapid initiation of surveillance for new conditions and situations (eg, chemical explosion, peanut butter contamination) can be established by NC DETECT using keyword-based analyses of ED chief complaint and triage notes. These custom reports can be developed and disseminated in less than 2 hours.

All 111 North Carolina EDs are expected to be providing data to NC DETECT by the end of 2007. Efforts are underway to present reports of counts, percents, and population-based rates through the web-based reporting system. Additional users of the data are welcomed, based on application and authorization through the website and the North Carolina Division of Public Health. For further information, contact the authors at ncdetect@listserv.med.unc.edu or visit http://www.ncdetect.org.

REFERENCES

- 1 McCaig LF, Nawar EN. National Hospital Ambulatory Medical Care Survey: 2004 emergency department summary. Advance data from vital and health statistics; no 372. Hyattsville, MD: National Center for Health Statistics; 2006.
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Contributed by Anna E. Waller, ScD, and Amy I. Ising, MSIS, University of North Carolina, School of Medicine, Department of Emergency Medicine and Lana Deyneka, MD, MPH, NC Department of Health and Human Services, Division of Public Health, General Communicable Disease Control Branch

Scotland Memorial Hospital Emergency Center Improvements

n 2004 when Scotland Health Care System approved a project that would renovate and expand the Emergency Center at Scotland Memorial Hospital, it was decided the hospital would not borrow money for the project, but that funding would come from hospital reserves and fundraising—including grants. The health system approached The Duke Endowment with their plans and were awarded two grants of \$200 000 each to support the development of Scotland Memorial Hospital's vision for its emergency facility and the services it provides.

Scotland Memorial Hospital is a 104 acute care bed, not-for-profit, community-owned hospital in Laurinburg, North Carolina. Located in the Sandhills region of the state, the hospital serves the health care needs of citizens of Scotland, Robeson, Hoke and Richmond counties in North Carolina and Marlboro County, South Carolina. Built in 1983, Scotland Memorial Hospital's Emergency Center (EC) was a state-of-the-art facility at the time of the hospital's construction. With 6400 square feet, the EC was designed to accommodate 10 000 patients annually. With the exception of a small addition in 1986, the EC underwent no major changes or expansions in the next two decades, while the annual number of patients treated rose to approximately 23 000. This significant increase in patient visits overwhelmed available space and forced patients, equipment, and care into every corner of the EC.

Many patients presenting to the EC are sicker than in years past, requiring more time-consuming assessments and testing. In fact, nearly 20% of Scotland Memorial's EC patients require hospital admission in order to treat their illnesses. Over 60% of all inpatients are admitted through the EC. These numbers indicate that the EC has become the hospital's "front door." Compounding the problems caused by lack of EC space was that inpatient hospital beds were often full. The patients who need to be admitted from the EC had nowhere to go, thus exacerbating the Center's capacity limitations for patients requiring treatment.

To address the growing need, Scotland Health Care System approved a multifaceted project that included renovating and expanding the Emergency Center. The first grant from The Duke Endowment provided capital funding for the structural expansion of the EC. The EC increased from 6400 square feet to over 24 000 square feet along with growing from 14 curtained bays to 20 private rooms. Additionally, the new EC includes:

- A "fast track center" for nonurgent patients to receive care.
- A second triage and evaluation room to permit patients to be assessed more quickly.

- Two separate trauma rooms, offering greater privacy for patients and their families.
- An expanded waiting room.
- A separate pediatrics waiting area to protect children from the potentially traumatic experience of an EC waiting area.
- A modernized and expanded nurse's station that increases the visibility to patient rooms and houses computers and modern communication equipment.
- A quiet, private space for families coping with life-threatening illness, injury, or death of a loved one.

A second grant from The Duke Endowment helped fund the cost of hardware, software, and employee and physician training required for implementation of a new Emergency Center Patient Tracking and Information System that will go online August 14, 2007. This comprehensive system will result in increased patient safety and quality of care, improved provider efficiencies, and decreased patient waiting times. Benefits of a tracking and information system include:

- Identifying a patient's physical location and the status of his or her examination and diagnosis with the touch of a computer screen.
- Eliminating breakdowns in communication and long wait-times in the multi-step process of physician examination, order writing, and order completion.
- Reducing errors from illegible handwriting through touch screen technology.
- Diminishing misdirected lab requests and misplaced lab results.
- Monitoring and advising patients from outside of the EC through off-site access to patient records.

The expansion and renovation of the EC, along with the requisite changes, and the renovation of acute care bed space was a major project for Scotland Memorial Hospital. Through this initiative the citizens of the Scotland area receive quality, compassionate emergency care 24 hours each day, 7 days a week, in a facility that offers them privacy and security while accommodating the equipment and staff needed to serve them. The multifaceted project has had a significant impact on the health and economic well-being of Scotland Memorial Hospital and the community.

Karen Gainey, marketing coordinator, and Becca Hughes, foundation director, of Scotland Health Care System contributed to this profile.



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Call **1-800-969-8526** today to get free patient education materials about ACIPHEX for your practice!

ACIPHEX 20 mg is indicated for: treatment of daytime and nighttime heartburn and other symptoms of GERD; short-term, up to 4 weeks, treatment in the healing and symptomatic relief of duodenal ulcers; short-term, 4 to 8 weeks, treatment in the healing and symptomatic relief of erosive GERD; and maintenance of healing and reduction in relapse rates of heartburn symptoms of erosive GERD (controlled maintenance studies do not extend beyond 12 months).

Important Safety Information: In clinical trials the most common side effect assessed as possibly or probably related to ACIPHEX with a frequency greater than placebo was headache (2.4% vs 1.6% for placebo).

Symptomatic response to therapy does not preclude the presence of gastric malignancy. ACIPHEX is contraindicated in patients with known hypersensitivity to rabeprazole, substituted benzimidazoles, or to any component of the formulation. Patients treated with a proton pump inhibitor and warfarin concomitantly may need to be monitored for increases in INR and prothrombin time.

Please see brief summary of full prescribing information on adjacent page.



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BRIEF SUMMARY

Before prescribing ACIPHEX®, please see full prescribing information.

INDICATIONS AND USAGE

Healing of Erosive or Ulcerative Gastroesophageal Reflux Disease (GERD) ACIPHEX® is indicated for short-term (4 to 8 weeks) treatment in the healing and symptomatic relief of erosive or ulcerative gastroesophageal reflux disease (GERD). For those patients who have not healed after 8 weeks of treatment, an additional 8-week course of ACIPHEX® may be considered.

Maintenance of Healing of Erosive or Ulcerative Gastroesophageal Reflux Disease (GERD) ACIPHEX® is indicated for maintaining healing and reduction in relapse rates of heartburn symptoms in

patients with erosive or ulcerative gastroesophageal reflux disease (GERD Maintenance). Controlled studies do not extend beyond 12 months.

Treatment of Symptomatic Gastroesophageal Reflux Disease (GERD) ACIPHEX® is indicated for the treatment of daytime and nighttime heartburn and other symptoms associated with GERD.

Healing of Duodenal Ulcers

ACIPHEX® is indicated for short-term (up to four weeks) treatment in the healing and symptomatic relief of duodenal ulcers. Most patients heal within four weeks.

Helicobacter pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence ACIPHEX® in combination with amoxicillin and clarithromycin as a three drug regimen, is indicated for the treatment of patients with *H. pylori* infection and duodenal ulcer disease (active or history within the past 5 years) to eradicate *H. pylori*. Eradication of *H. pylori* has been shown to reduce the risk of duodenal ulcer recurrence. (See CLINICAL STUDIES and DOSAGE AND ADMINISTRATION in full prescribing information.) In patients who fail therapy, susceptibility testing should be done. If resistance to clarithromycin is

demonstrated or susceptibility testing is not possible, alternative antimicrobial therapy should be instituted. (See CLINICAL PHARMACOLOGY, Microbiology in full prescribing information and the clarithromycin package insert, CLINICAL PHARMACOLOGY, Microbiology.)

Treatment of Pathological Hypersecretory Conditions, Including Zollinger-Ellison Syndrome

ACIPHEX® is indicated for the long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome

CONTRAINDICATIONS

Rabeprazole is contraindicated in patients with known hypersensitivity to rabeprazole, substituted benzimidazoles or to any component of the formulation.

Clarithromycin is contraindicated in patients with known hypersensitivity to any macrolide antibiotic.

Concomitant administration of clarithromycin with pimozide and cisapride is contraindicated. There have been post-marketing reports of drug interactions when clarithromycin and/or erythromycin are coadministered with pimozide resulting in cardiac arrhythmias (QT prolongation, ventricular tachycardia, ventricular fibrillation, and torsade de pointes) most likely due to inhibition of hepatic metabolism of pimozide by erythromycin and clarithromycin. Fatalities have been reported. (Please refer to full prescribing information for clarithromycin.)

Amoxicillin is contraindicated in patients with a known hypersensitivity to any penicillin. (Please refer to full prescribing information for amoxicillin.)

WARNINGS

CLARITHROMYCIN SHOULD NOT BE USED IN PREGNANT WOMEN EXCEPT IN CLINICAL CIRCUMSTANCES

WHERE NO ALTERNATIVE THERAPY IS APPROPRIATE. If pregnancy occurs while taking clarithromycin, the patient should be apprised of the potential hazard to the fetus. (See WARNINGS in prescribing information for clarithromycin.)

Amoxicillin: Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and/or a history of sensitivity to multiple allergens.

There have been well-documented reports of individuals with a history of penicillin hypersensitivity There have been wen-oocumented reports of monotoals with a mistory of periculian hypersensitivity reactions who have experienced severe hypersensitivity reactions when treated with a cephalosporin. Before initiating therapy with any penicillin, careful inquiry should be made concerning previous hypersensitivity reactions to penicillin, cephalosporin, and other allergens. If an allergic reaction occurs, amoxicillin should be discontinued and the appropriate therapy instituted. (See WARNINGS in prescribing information for amoxicillin.)

SERIOUS ANAPHYLACTIC REACTIONS REQUIRE IMMEDIATE EMERGENCY TREATMENT WITH EPINEPHRINE. OXYGEN, INTRAVENOUS STEROIDS, AND AIRWAY MANAGEMENT, INCLUDING INTUBATION, SHOULD ALSO BE ADMINISTERED AS INDICATED.

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including clarithromycin and amoxicillin, and may range in severity from mild to life threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the istration of antibacterial agents.

Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by Clostridium difficile is a primary cause of "antibioticassociated colitis

After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to discontinuation of the drug alone. In moderate to severe cases, consideration should be given to management with fluid and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against *Clostridium* difficile colitis.

PRECAUTIONS

General

Symptomatic response to therapy with rabeprazole does not preclude the presence of gastric malignancy. Patients with healed GERD were treated for up to 40 months with rabeorazole and monitored with serial gastric biopsies. Patients without *H. pylori* infection (221 of 326 patients) had no clinically important pathologic changes in the gastric muccas. Patients with *H. pylori* infection at baseline (105 of 326 patients) had mild or moderate inflammation in the gastric body or mild inflammation in the gastric antrum. Patients with mild grades of infection or inflammation in the gastric body tended to change to moderate, whereas those graded moderate at baseline tended to remain stable. Patients with mild grades of infection or inflammation in the gastric antrum tended to remain stable. At baseline 8% of patients had atrophy of alrophy of glands in the gastric body and 15% had atrophy in the gastric antrum. At endpoint, 15% of patients had atrophy of glands in the gastric body and 11% had atrophy in the gastric antrum. Approximately 4% of patients had intestinal metaplasia at some point during follow-up, but no consistent changes were seen. Steady state interactions of rabeprazole and warfarin have not been adequately evaluated in patients. There have been reports of increased INR and prothrombin time in patients receiving a proton pump inhibitor and warfarin concomitantly. Increases in INR and prothrombin time may lead to abnormal bleeding and even death. Patients treated with a proton pump inhibitor and warfarin concomitantly may need to be monitored for increases in INR and prothrombin time

Information for Patients

Patients should be cautioned that ACIPHEX® delayed-release tablets should be swallowed whole. The tablets should not be chewed, crushed, or split. ACIPHEX® can be taken with or without food

Drug Interactions

Rabeprazole is metabolized by the cytochrome P450 (CYP450) drug metabolizing enzyme system. Studies in healthy subjects have shown that rabeprazole does not have clinically significant interactions with other drugs metabolized by the CYP450 system, such as warfarin and theophylline given as single oral doses, diazepam as a single intravenous dose, and phenytoin given as a single intravenous dose (with supplemental oral dosing). Steady state interactions of rabeprazole and other drugs metabolized by this enzyme system have not been studied in patients. There have been reports of increased INR and prothrombin time in patients receiving proton pump inhibitors, including rabeprazole, and warfarin concomitantly. Increases in INR and prothrombin time may lead to abnormal bleeding and even death.

In vitro incubations employing human liver microsomes indicated that rabeprazole inhibited cyclosporine metabolism with an IC₅₀ of 62 micromolar, a concentration that is over 50 times higher than the C_{max} in healthy volunteers following 14 days of dosing with 20 mg of rabeprazole. This degree of inhibition is similar to that by omeprazole at equivalent concentrations.

Rabeprazole produces sustained inhibition of gastric acid secretion. An interaction with compounds which are dependent on gastric pH for absorption may occur due to the magnitude of acid suppression observed with rabeprazole. For example, in normal subjects, co-administration of rabeprazole 20 mg QD resulted in an approximately 30% decrease in the bioavailability of ketoconazole and increases in the AUC and C_{max} for digoxin of 19% and 29%, respectively. Therefore, patients may need to be monitored when such drugs are taken concomitantly with rabeprazole. Co-administration of rabeprazole and antacids produced no clinically relevant changes in plasma rabeprazole concentrations.

In a clinical study in Japan evaluating rabeprazole in patients categorized by CYP2C19 genotype (n=6 per genotype category), gastric acid suppression was higher in poor metabolizers as compared to extensive metabolizers. This could be due to higher rabeprazole plasma levels in poor metabolizers. Whether or not interactions of rabeprazole sodium with other drugs metabolized by CYP2C19 would be different between extensive metabolizers and poor metabolizers has not been studied.

Combined Administration with Clarithromycin

Combined administration consisting of rabeprazole, amoxicillin, and clarithromycin resulted in increases in plasma concentrations of rabeprazole and 14-hydroxyclarithromycin. (See CLINICAL PHARMACOLOGY, Combination Therapy with Antimicrobials in full prescribing information.)

Concomitant administration of clarithromycin with pimozide and cisapride is contraindicated. (See **PRECAUTIONS** in prescribing information for clarithromycin.) (See **PRECAUTIONS** in prescribing information for amoxicillin.)

Carcinogenesis, Mutagenesis, Impairment of Fertility

In a 88/104-week carcinogenicity study in CD-1 mice, rabeprazole at oral doses up to 100 mg/kg/day did not produce any increased tumor occurrence. The highest tested dose produced a systemic exposure to rabeprazole (AUC) of 1.40 µg•hr/mL which is 1.6 times the human exposure (plasma AUC_{0" ∞} = 0.88 µg•hr/mL) at the recommended dose for GERD (20 mg/day). In a 104-week carcinogenicity study in Sprague-Dawley rats, males were treated with oral doses of 5, 15, 30 and 60 mg/kg/day and females with 5, 15, 30, 60 and 120 mg/kg/day. Rabeprazole produced gastric enterochromaffin-like (ECL) cell 5, 15, 30, 60 and 120 mg/kg/day, habeptadoe produced gastic entercentrating (ECE). Centry hyperplasia in male and female rats and ECC cell carcinoid tumors in female rats at all doses including the lowest tested dose. The lowest dose (5 mg/kg/day) produced a systemic exposure to rabeptazic (AUC) of about 0.1 µg+hr/mL which is about 0.1 times the human exposure at the recommended dose for GERD. In male rats, no freatment related tumors were observed at doses up to 60 mg/kg/day producing a rabeprazole plasma exposure (AUC) of about 0.2 µg•hr/mL (0.2 times the human exposure at the recommended dose for GEBD)

Rabeprazole was positive in the Ames test, the Chinese hamster ovary cell (CHO/HGPRT) forward gene mutation test and the mouse lymphoma cell (L5178Y/TK+/-) forward gene mutation test. Its demethylated-metabolite was also positive in the Ames test. Rabeprazole was negative in the *in vitro* Chinese hamster lung cell chromosome aberration test, the *in vivo* mouse micronucleus test, and the *in vivo* and *ex vivo* rat hepatocyte unscheduled DNA synthesis (UDS) tests.

Rabeprazole at intravenous doses up to 30 mg/kg/day (plasma AUC of 8.8 ug+hr/mL, about 10 times the human exposure at the recommended dose for GERD) was found to have no effect on fertility and reproductive performance of male and female rats.

Pregnancy

Teratogenic Effects. Pregnancy Category B: Teratology studies have been performed in rats at intravenous doses up to 50 mg/kg/day (plasma AUC of 11.8 µg•hr/mL, about 13 times the human exposure at the recommended dose for GERD) and rabbits at intravenous doses up to 30 mg/kg/day (plasma AUC of 7.3 µg•hr/mL, about 8 times the human exposure at the recommended dose for GERD) and have revealed no evidence of impaired fertility or harm to the fetus due to rabeprazole. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers

Following intravenous administration of ¹⁴C-labeled rabeprazole to lactating rats, radioactivity in milk reached levels that were 2- to 7-fold higher than levels in the blood. It is not known if unmetabolized rabeprazole is excreted in human breast milk. Administration of rabeprazole to rats in late gestation and during lactation at doses of 400 mg/kg/day (about 195-times the human dose based on mg/m²) resulted in decreases in body weight gain of the pups. Since many drugs are excreted in milk, and because of the potential for adverse reactions to nursing infants from rabeprazole, a decision should be made to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother. Pediatric Use

The safety and effectiveness of rabeprazole in pediatric patients have not been established.

Use in Women

Duodenal ulcer and erosive esophagitis healing rates in women are similar to those in men. Adverse events and laboratory test abnormalities in women occurred at rates similar to those in men.

Geriatric Use

Of the total number of subjects in clinical studies of ACIPHEX[®], 19% were 65 years and over, while 4% were 75 years and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

ADVERSE REACTIONS

Worldwide, over 2900 patients have been treated with rabeprazole in Phase II-III clinical trials involving various dosages and durations of treatment. In general, rabeprazie treatment has been well-tolerated in both short-term and long-term trials. The adverse events rates were generally similar between the 10 and 20 mg doses

Incidence in Controlled North American and European Clinical Trials

In an analysis of adverse events assessed as possibly or probably related to treatment appearing in greater than 1% of ACIPHEX® patients and appearing with greater frequency than placebo in controlled North American and European trials, the incidence of headache was 2.4% (n=1552) for ACIPHEX® versus 1.6% (n=258) for placebo.

In short and long-term studies, the following adverse events, regardless of causality, were reported in ACIPHEX[®]-treated patients. Rare events are those reported in ≤1/1000 patients.

Body as a Whole: asthenia, fever, allergic reaction, chills, malaise, chest pain substernal, neck rigidity, photosensitivity reaction. Rare: abdomen enlarged, face edema, hangover effect. Cardiovascular System: hypertension, myocardial infarct, electrocardiogram abnormal, migraine, syncope, angina pectoris, bundle branch block, palpitation, sinus bradycardia, tachycardia. Rare: bradycardia, pulmonary embolus, supraventricular tachycardia, thrombophlebitis, vasodilation, OTC prolongation and ventricular tachycardia. Digestive System: diarnea, nausea, abdominal pain, vomiting, dyspepsia, flatulence, constipation, dry mouth, eructation, gastroenteritis, rectal hemorrhage, melena, anorexia, choleiithiasis, mouth ulceration, stomatitis, dysphagia, gingivitis, cholecystitis, increased appetite, abnormal stools, collits, esophagitis, gloszistis, pancreatitis, proctitis. Rare: blody diarrhea, cholangitis, duodenitis, gastrointestinal hemorrhage, hepatic encephalopathy, hepatitis, hepatoma, liver fatty deposit, salivary gland enlargement, thirst. Endocrine System: hyperthyroidism, hypothyroidism. *Hemic & Lymphatic System:* anemia, ecchymosis, lymphadenopathy, hypochromic anemia. *Metabolic & Nutritional Disorders:* peripheral edema, edema, weight gain, gout, dehydration, weight loss. *Musculo-Skeletal System:* myagia, arthritis, leg cramps, bone pain, arthrosis, bursitis. Rare: twitching. *Nervous System:* insomnia, anxiety, dizziness, depression, nervousness, somnolence, hypertonia, neuralgia, vertigo, convulsion, abnormal dreams, libido decreased, neuropathy, paresthesia, tremor. Rare: agitation, amnesia, corfusion, extrapyramidal syndrome, hyperkinesia. *Respiratory System:* dyspnea, asthma, epistaxis, laryngits, hiccup, hyperventilation. Rare: apnea, hypoventilation. *Skin and Appendages:* rash, puritus, sweating, urticaria, alopecia. Rare: dry skin, herpes zoster, psoriasis, skin discoloration. *Special System:* cystitis, urinary frequency, dysmenorrhea, dysuria, kidney calculus, metrorrhagia, p

Laboratory Values: The following changes in laboratory parameters were reported as adverse events: abnormal platelets, albuminuria, creatine phosphokinase increased, erythrocytes abnormal, hypercholesteremia, hyperglycemia, hyperlipemia, hypokalemia, hyponatremia, leukocytosis, leukorrhea, liver function tests abnormal, prostatic specific antigen increase, SGPT increased, urine abnormality, WBC abnormal.

In controlled clinical studies, 3/1456 (0.2%) patients treated with rabeprazole and 2/237 (0.8%) patients treated with placebo developed treatment-emergent abnormalities (which were either new on study or present at study entry with an increase of 1.25 x baseline value) in SGOT (AST), SGPT (ALT), or both. None of the three rabeprazole patients experienced chills, fever, right upper quadrant pain, nausea or jaundice.

Combination Treatment with Amoxicillin and Clarithromycin: In clinical trials using combination therapy with rabeprazole plus amoxicillin and clarithromycin (RAC), no adverse events unique to this drug combination were observed. In the U.S. multicenter study, the most frequently reported drug related adverse events for patients who received RAC therapy for 7 or 10 days were diarrhea (8% and 7%) and taste perversion (6% and 10%), respectively.

No clinically significant laboratory abnormalities particular to the drug combinations were observed.

For more information on adverse events or laboratory changes with amoxicillin or clarithromycin, refer to their respective package prescribing information, ADVERSE REACTIONS section.

Post-Marketing Adverse Events: Additional adverse events reported from worldwide marketing experience with rabeprazole sodium are: sudden death; coma and hyperammonemia; jaundice; rhabdomoylosi; disorientation and delirium; anaphylaxis; angioedema; bullous and other drug eruptions of the skin; severe dermatologic reactions, including toxic epidermal necrolysis (some fatal), Stevens-Johnson syndrome, and erythema multiforme; interstitial pneumonia; interstitial nephritis; and TSH elevations. In most instances, the relationship to rabeprazole sodium was unclear. In addition, agranulocytosis, hemolytic anemia, leukopenia, pancytopenia, and thrombocytopenia have been reported. Increases in prothrombin time/INR in patients treated with concomitant warfarin have been reported.

OVERDOSAGE

Because strategies for the management of overdose are continually evolving, it is advisable to contact a Poison Control Center to determine the latest recommendations for the management of an overdose of any drug. There has been no experience with large overdoses with rabeprazole. Seven reports of accidental overdosage with rabeprazole have been received. The maximum reported overdose was 80 mg. There were no clinical signs or symptoms associated with any reported overdose. Patients with Zollinger-Ellison syndrome have been treated with up to 120 mg rabeprazole 0D. No specific antidote for rabeprazole is known. Rabeprazole is extensively protein bound and is not readily dialyzable. In the event of overdosage, treatment should be symptomatic and supportive.

Single oral doses of rabeprazole at 786 mg/kg and 1024 mg/kg were lethal to mice and rats, respectively. The single oral dose of 2000 mg/kg was not lethal to dogs. The major symptoms of acute toxicity were hypoactivity, labored respiration, lateral or prone position and convulsion in mice and rats and watery diarrhea, tremor, convulsion and coma in dogs.

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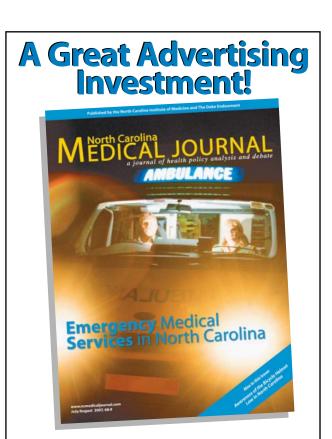
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