FACILITATORS AND BARRIERS TO IMPLEMENTATION OF STEMI GUIDELINES IN RURAL AREAS

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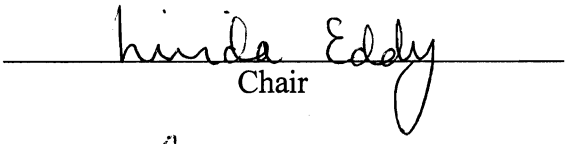

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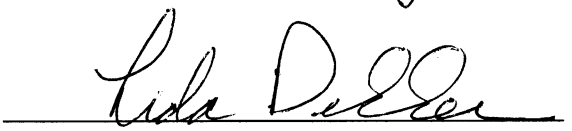

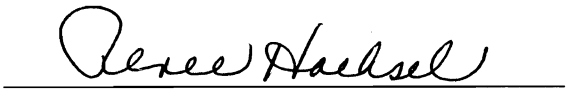

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Key words: Rural, Facilitators, Barriers, STEMI Guidelines

ABSTRACT

Background and Objective:
The implementation of STEMI guidelines and early reperfusion therapy with fibrinolytics or PCI improves short-term and long-term STEMI patient outcomes. Identifying concepts that facilitate the development of systems and guidelines along with identifying barriers that hinder development of systems and guidelines is important for the rural nurse implementing STEMI guidelines. The purpose of this paper is to examine the facilitators of, and barriers to, developing specific strategies for implementation of ST-Elevation Myocardial Infarction (STEMI) guidelines in a rural area.

Theoretical Framework:
The theoretical framework applied was the concept of Evidence Based Practice (EBP). EBP guides nurses in making clinical decisions based on evidence from comprehensive research and their own clinical experience. The use of EBP uses the best current evidence to make decisions about care related to individual patients. Applying this framework to the development of systems and guidelines for STEMI care within a region allows for use of best evidence and practice.

Findings and Conclusions:
Remaining current with innovative technology and current guidelines associated with improved patient outcomes creates challenges for rural nurses. Having systems and guidelines in place within a region can aid nursing to develop standards of practice and add consistency to practice that results in improved outcomes for patients by improving care delivered to STEMI patients. The use of systems to implement reperfusion therapy in STEMI patients has demonstrated improvement in short and long-term patient outcomes. Using standard protocols within the system has the ability to decrease door-to-balloon and door-to-needle time, which improves effectiveness. Identifying concepts that facilitate the development of systems and guidelines along with identifying barriers that hinder development of systems and guidelines is important for the rural nurse implementing STEMI guidelines. After identification of agency-specific facilitators and barriers, rural nurses can begin to develop a specific plan related to implementing the guideline in their communities.

TABLE OF CONTENTS

Facilitators and Barriers to Implementation of STEMI Guidelines in Rural Areas

Introduction

Rural nurses pride themselves in remaining current with innovative technology and the latest guidelines associated with improved patient outcomes. Challenges associated with implementation of new standards and practices in rural areas are common for nurses employed in these areas. Time spent reviewing guidelines, forming new policies and procedures, training, and implementing new programs can be long processes. Lack of input from other departments and lack of access to information from tertiary facilities has the potential to impede processes. Having systems and guidelines in place within a region can aid nursing to develop standards of practice and add consistency to practice resulting in improved patient outcomes.

Knowledge of rural populations and related health care disparities is important when developing systems and guidelines within a region. Twenty percent of the U.S. population lives in rural areas (Agency for Healthcare Research and Quality [AHRQ], 2006). Rural residents are poorer and older than residents living in urban areas (National Rural Health Association [NRHA], 2006). Rural residents, if poor, are often not covered by Medicaid. Health care coverage and prescription drug coverage provided by employers is less available (Rural Assistance Center [RAC], 2007). Barriers associated with accessing high quality health care impact rural areas. Distance from health care delivery sites and lack of physicians are two such barriers (Agency for Healthcare Research and Quality [AHRQ], 2005). The majority of emergency response systems and types of hospitals also create barriers in the rural community. Emergency medical and fire systems in rural communities operate from the volunteer model (Health Resource Services Administration [HRSA], 2006). Recruiting potential workers to staff

emergency and fire systems is challenging. Time away from the job and family makes many individuals hesitant about joining fire and emergency medical response teams (HRSA).

Many hospitals in rural areas are Critical Access Hospitals (CAH). These hospitals must be located in a rural area and meet specific requirements. Critical Access Hospitals must provide twenty-four emergency service, but medical staff can be off-site with a thirty to sixty minute response time (Rural Assistance Center [RAC], 2007).

Rural residents are more likely to die from heart disease, have a chronic illness such as diabetes, or have higher rates of obesity than urban residents (National Rural Health Association [NRHA], 2006). In 2001, the Agency for Healthcare Research and Quality (AHRQ) reported inpatient deaths from acute myocardial infarctions higher in rural areas than urban areas (AHRQ). These statistics indicate a need to have systems and guidelines in place within rural settings that address specific challenges associated with providing care to those presenting with acute myocardial infarction.

ST-Elevation MI's

Occlusion of coronary arteries by thrombus formation causes a rapid sequence of events that results in ischemia of the myocardium distal to the occlusion. The myocardial cell membrane is altered, causing disruption of vital electrolytes to the myocardial cell. Myocardial contractility is depressed and life-threatening dysrhythmias can result (Phipps, Monahan, Sands, Marek, & Neighbors, 2003). Lack of oxygen enriched blood causes ischemia to surrounding muscle. When oxygenation is not restored, tissue death ensues, causing myocardial muscle death (Cantwell et al., 2005). Electrocardiograms (ECGs) are critical in diagnosing myocardial infarction. Ischemic changes are reflected in ST segment changes that are apparent on the ECG.

ST segment elevation indicates ongoing ischemia. If progression of ischemia continues, myocardial infarction results (Phipps et al.).

In 2004, the American Heart Association (AHA) published a comprehensive set of guidelines for the management of patients with ST-elevation myocardial infarctions. These guidelines include pathological and epidemiological considerations of ST-Elevation Myocardial Infarction (STEMI) as well as considerations prior to onset of STEMI, treatment until discharge, and long-term management (Antman et al., 2004).

The goal of the guidelines is to limit total ischemic time to 120 minutes, with a "door-to-balloon" time of 90 minutes (Antman et al., 2004). Door-to-balloon time is a reflection of the time frame when the patient enters the emergency department to the minute when the physicians inflate the balloon during the Percutaneous Coronary Intervention (PCI) procedure. Performed in a cardiac catherization lab, PCI is balloon angioplasty (May, 2007). Knowledge of the guidelines, especially those associated with the acute phase of STEMI's will aid in developing strategies for implementation of STEMI guidelines in rural areas.

Purpose

The purpose of this paper is to examine the facilitators of, and barriers to, developing specific strategies for implementation of ST-Elevation Myocardial Infarction (STEMI) guidelines in a rural area.

Conceptual Framework

Understanding the concepts used to form pathways and make decisions are critical to nursing process and research. The concept of Evidence Based Practice (EBP) is used to guide nurses in making clinical decisions based on evidence from comprehensive research and their own clinical experience (Yoder-Wise & Kowalski, 2006). EBP uses the best current evidence to

make decisions about care related to individual patients (McEwen & Wills, 2002). Applying this framework to the development of systems and guidelines for STEMI care within a region allows for use of best evidence and practice regardless of geographic location.

The six step practice model suggested by Rosswurm and Larrabee helps nurses make changes based on evidence. The model allows nurses to use a six-step framework to discover new solutions and change the solutions into evidence based practices (Yoder-Wise, 2003). The six steps include: "(1) assessing the need for change, (2) linking the problem with the interventions and outcomes, (3) synthesizing the best evidence, (4) designing a change in practice, (5) implementing and evaluating the practice change, and (6) integrating and maintaining the practice change" (Yoder-Wise, 2003, p.193). These steps can be applied to numerous situations, including STEMI care in rural settings.

Literature Review

The search engines of Pro-Quest and Ovid were used to locate literature related to STEMI guidelines and the use of systems. Key words used in the literature search included STEMI, guidelines, systems, facilitators, barriers, myocardial infarction, and rural. Nineteen relevant articles were found and these were used for the preparation of this review due to their applicability.

Trauma Systems

A brief examination of state trauma systems indicates that implementation of systems of care can have positive impacts on critically injured patients. A developed trauma system is an organized system in which critically injured patients are triaged and transferred to appropriate levels of care immediately. While the underlying infrastructure is complex, states have developed trauma system policies that are effective (Nathens, Jurkovich, Rivara, & Maier, 2000).

Mullins and colleagues found that organization of a trauma system on a statewide level could decrease the risk of death for critically injured patients (Mullins, Mann, Hedges, Worrall, & Jurkovich, 1998). In several states where trauma systems were implemented Nathens and colleagues demonstrated a 9% reduction in global injury mortality (Nathens et al., 2000). The data indicates the use of systems within a region can be effective when developing strategies for implementing STEMI guidelines.

STEMI Guidelines

STEMI guidelines created by the American College of Cardiology/American Heart Association (ACC/AHA) utilize evidence-based methodologies (King III et al., 2008). The diagram (Table 1) represents the class of recommendation and level of evidence. This illustrates how the ACC/AHA colleagues provide estimates for treatment effect and certainty of the treatment effect with benefits outweighing the risks within the recommended guidelines (King III et al.). Treatment indications are presented in the following guidelines.

Guideline One: patient education in early recognition of STEMI symptoms. Individuals with symptoms of STEMI, such as shortness of breath, nausea, diaphoresis, lightheadedness, chest pain or discomfort with or without radiation to the arms, back, jaw, or neck, should be transported by ambulance instead of family or friends. The 911 call should take place 5 minutes after the onset of symptoms (Antman et al., 2004).

Guideline Two: Emergency Medical System (EMS) activation. Activation of 911 triggers dispatch, which notifies EMS. EMS response time to scene varies depending on the distance EMS has to travel. Transport back to the hospital will also vary. It is important to remember the goal of 120 minutes for total ischemic time (Antman et al., 2004). EMS with the 12-lead ECG capabilities should run and interpret results as soon as possible and notify the

receiving hospital. If the receiving hospital is not capable of PCI and EMS is proficient in administering fibrinolytic therapy, patients who qualify for fibrinolytic therapy receive it within 30 minutes of EMS arriving on scene (Antman et al.). EMS without the capabilities of 12-lead ECGs and fibrinolytic therapy should limit their time on scene and return as soon as possible to the hospital.

Guideline Three: Awareness of the capabilities of the receiving hospital. The most important variable is determining if the receiving hospital is capable of performing PCI. If the receiving facility has PCI capabilities, patients presenting with STEMI should have a door-to-balloon time of ninety minutes (Antman et al., 2004). Hospitals without PCI capabilities, such as small rural hospitals, need specific steps in place that promote efficient transfer to appropriate facilities when the 90-minute treatment window is achievable and initiate fibrinolytics to appropriate candidates and initiate transfer when they will exceed the 90-minute time frame. Prior to treatment or transfer, a patient history targeted at previous myocardial ischemic episodes is recommended. Patients additionally need screening for bleeding risk, clinical cerebrovascular disease, hypertension, diabetes, and age and gender related differences. A physical examination, along with a 12-lead ECG should occur within 10 minutes of Emergency Department (ED) arrival (Antman et al.). Laboratory tests, including cardiac specific troponins should be performed as well as a portable chest x-ray. Decisions regarding medication selection need to be timely. Medications given must reflect the consensus of the receiving cardiologist. Recommendations of medications by the AHA are as follows for initial treatment: (a) Supplemental oxygen, (b) sublingual nitroglycerine 0.4mg every five minutes for total of three doses, then decision for intravenous nitroglycerine, (c) morphine sulfate 2-4mg intravenous every 5-15 minutes as needed for analgesia, (d) Aspirin 162-325 mg, chewed, (e) Oral or IV

beta-blocker to patients without contraindication,(f) reperfusion therapy with fibrinolytic medication or primary PCI (Antman et al.).

Systems of Care

Implementation of early reperfusion therapy with fibrinolytics or PCI improves short-term and long-term STEMI patient outcomes (Jacobs et al., 2006). Rapid reperfusion by primary PCI with S-T elevation myocardial infarctions proves to be the optimal strategy when performed within a specific time by trained professionals (Rokos et al., 2006). Approximately one third of STEMI patients in the United States do not receive any reperfusion therapy, even if contraindications are not present (Jacobs et al.). Of the patients who are treated with reperfusion therapy, only 40% have a door-to-balloon time of 90 minutes or less and fewer than 50% have a door-to-needle time of 30 minutes or less (Jacobs et al.). Door-to-needle time is a reflection of the time frame when the patient presents to the ED until the time of intravenous fibrinolytics. The use of systems has been shown to increase quality of care for STEMI patients while reducing mortality and morbidity (Jollis et al., 2007). While some areas, such as Minneapolis have developed systems, other areas have been slow to adopt and implement systems for the care of STEMI patients.

In Minnesota, the Minneapolis Heart Institute developed a system of care called the "Level 1 MI Program" with 29 community hospitals to provide PCI care to STEMI patients (Henry et al., 2005). With the use of committees, standardized protocols and an integrated transfer system were developed. The results show the effectiveness of the system. Prior to standardization, door-to-balloon time for patients undergoing direct PCI was 192 minutes. After standardization of protocols, the door-to-balloon time was 98 minutes (Henry et al.). Success relies on using a team approach with "cooperation between cardiologist, emergency physicians,

nurses, and the emergency medical system as well as various health care organizations" (Henry et al., p. 373).

In another area in Minnesota, the Mayo Clinic STEMI protocol was initiated with a PCI capable hospital and 28 regional non-PCI hospitals across three states. Some were located up to 150 miles away (Ting et al., 2007). A prospective, observational cohort study involving 597 patients with ST-segment elevation within 12 hours of symptom onset was analyzed. Patients were divided into three groups. Group A were patients who presented to the PCI capable hospital and were treated with primary PCI and group B were patients who presented to non-PCI hospitals with symptom onset greater that three hours and transferred for primary PCI. (Ting et al.). The two groups had a median door-to-balloon time of 71 minutes for group A and 116 minutes for group B. A door-to-balloon time of less than 90 minutes was achieved in 75% of group A and 12% of group B (Ting et al.). Group C were patients who presented to non-PCI hospitals with symptom onset less than three hours and were treated with full dose fibrinolytic therapy. These patients had a median door-to-needle time of 25 minutes, with 70% having a door-to-needle time of less than 30 minutes (Ting et al.). This study demonstrates the effectiveness of using a coordinated system of care for STEMI patients (Ting et al.).

Five regions in North Carolina implemented a system of care for STEMI patients that involved 65 hospitals. Each facility developed a coronary reperfusion plan with the input of physicians, nurses, technicians and administrators, which focused on the reperfusion process. Meetings and conference calls allowed for the development of a systematic plan (Jollis et al., 2007). Reperfusion times were measured for three months before implementation of the system. After the system had been in place one year, reperfusion times were again measured for three months. Significant improvements related to median reperfusion times were noted. Door-to-

needle time in non- PCI hospitals decreased from 35 minutes to 29 minutes, door-to-device time in PCI capable hospitals decreased from 85 minutes to 74 minutes, and door-in to door-out time in non-PCI hospitals decreased from 120 to 71 minutes (Jollis et al). While rates of non-perfusion remained unchanged in the non-PCI hospitals, rate of non-perfusion decreased from 23% to 11% in hospitals capable of performing PCI. The authors of the North Carolina study concluded state programs focused on regional systems could significantly improve quality of care for STEMI patients (Jollis et al.).

In the State of Washington, one small town in Eastern Washington worked in partnership with a large urban hospital to develop a system of care for their STEMI patients. After learning about the Minneapolis Heart Institute and their Level 1 program, this hospital identified five partners and set about developing a program for their STEMI patients (Washington Rural Health Association [WRHA], 2007). Objectives were identified and the program was developed with input from all partners. Standardized protocols were put into place at the rural and urban facilities. The first patient transferred from the rural hospital had a door to balloon time of 93 minutes. The second patient had a door-to-balloon time of 63 minutes (WRHA). Ongoing collection of data allows all partners to improve the processes if needed and collect data for further research (WRHA).

Developing Guidelines: Facilitators and Barriers

Facilitators to Effective Management

Identification of all participants in a region facilitates the development of guidelines in that region. Studies conducted in Minnesota, North Carolina, and Washington show that identification of all participants in a region provide quality STEMI care and decrease door-to-

balloon or door-to-needle time (Henry et al., 2005), (Ting et al., 2007), (Jollis et al., 2007), (WRHA, 2007).

The development of standardized protocols, while acknowledging the differences within regions facilitates the development of guidelines. Specific policies on reperfusion therapy within a region can decrease time to treatment of STEMI patients (Ting et al., 2007). Identifying areas where transportation options are limited or when travel time to PCI hospitals is prohibitive assists regions in developing specific guidelines, which allow for optimum treatment (Jollis et al., 2007).

Allowing emergency room physicians to activate PCI for patients presenting to the ED with STEMI plays an important role in developing guidelines. Putting policies in place where emergency room physicians activate the cath lab has the capability to decrease median door-to-balloon time. In a study by Kurz and colleagues of 172 STEMI patients who presented to the ED, emergency room physicians inappropriately initiated the cath lab in only one patient and decreased the mean door-to-balloon time from 131 to 91 minutes in their population during this time period (Kurz, Babcock, Sinha, Tupesis, & Allegretti, 2007). Kraft and colleagues (2007) conducted a retrospective before and after study for a period of one year. Door-to-balloon times were examined under the initial policy in which the emergency department physician had to page the cardiology nurse practitioner, then the interventionist before making the decision to page the cardiac catheterization laboratory team. Door-to-balloon times were then examined after a policy change in which the emergency room physician activated the cardiac catheterization laboratory at the same time he implemented the rest of the policy. The study demonstrated a decrease in door-to-balloon time of 41 minutes, confirming that activation of the cardiac

catheterization laboratory by the emergency room physician decreases door-to-balloon time (Kraft, Newman, Hanson, Anderson, & Bastani, 2007).

Developing a chest pain screening area for ED patients who arrive by private car can facilitate decreased length of stay in the ED (Novotny, 2006). In a study in Florida, one hospital developed a chest pain screening area for patients presenting with chest pain. The process facilitated rapid recognition of AMIs. In one month, 540 patients were seen in the chest pain screening area. Five patients were identified as STEMI patients and average arrival to PCI time was 66 minutes (Novotny). While rural facilities do not have these numbers of patients, processes can be put in place to identify patients with chest pain as soon as they are triaged or registered.

Education for hospital staff, emergency room physicians and primary care physicians is important when facilitating the development of guidelines in a rural area. Knowledge of capabilities and resources within the region facilitates the development of guidelines appropriate to the region (Henry et al., 2005). The New Jersey study documented that use of registered nurses as full-time regional coordinators was key to the overall success of the program (Jollis et al., 2007).

On-going quality improvement process facilitates the development of guidelines. Data from quality improvement processes can be used to develop and refine guidelines that reflect best practices for STEMI care (Henry et al., 2005). Data on pre-intervention times, intervention times, type of intervention, and post-intervention times can be collected from chart reviews. As an example, collecting data on door-to-needle time and identifying factors that impede the 30-minute period can help improve processes and patient care.

Barriers to Effective Management

The patient's ability to recognize their symptoms as cardiac in nature limits timely reperfusion therapy, which can be a barrier when developing guidelines. Educational programs in the community in which community members are taught to recognize symptoms and either contact the EMS or go directly to the hospital to reduce delays in treatments have not proven to be effective (Jacobs et al., 2006). In one study, which lasted eighteen months, concentrated interventions aimed at increasing knowledge of symptoms of myocardial infarctions and appropriate use of the EMS system showed only a slight increase in EMS utilization and no improvement in patient delays when seeking medical care (Nallamothu et al., 2007).

The emergency medical system can create barriers when developing guidelines for systems of care for STEMI patients. Currently, access to emergency personnel is available to greater than 95% of the population using the 9-1-1 system. Nine-one-one operators are the first contact when an individual calls 9-1-1 with chest pain (Moyer et al., 2007). Ambulance services utilize a variety of personnel including first responders, basic emergency medical technicians (EMT-B) intermediate emergency medical technicians (EMT-I) and paramedics. While EMT-Bs give basic care such as oxygen, first aid, Cardiopulmonary Resuscitation (CPR) and early defibrillation with an Automatic External Defibrillator (AED), paramedics are able to perform advance life support (ALS), including 12-lead ECGs, intubation, IV's, and medications. Approximately 10% of EMS systems have a 12-lead ECG capability, which leaves 90% of EMS systems with only AED or 3-lead ECG capabilities (Jacobs et al., 2006). The capability of performing 12-lead ECGs and having personnel available to interpret the results is valuable. Transport time, which may be long in the rural areas increases time to reperfusion of the heart (Jacobs et al.).

Not having organized systems for interfacility transfers can be a barrier to developing guidelines for STEMI care (Henry et al., 2005). In many areas, 911 calls are given preference over interfacility transfers. Interfacility transfers from small rural hospitals can be delayed due to many variables, including Emergency Medical Treatment and Active Labor Act (EMTALA) regulations and lack of EMS staff (Henry et al.).

Facilities within designated regions that do not provide similar types of care can act as barriers to developing guidelines in a rural area. If area hospitals have capabilities to perform PCI and physicians within facilities are unwilling to work together and collaborate, the ability to create an integrated system is lost (Henry et al., 2005). Confusion and delays develop when transporting patients with STEMI causing prolonged time to appropriate treatment.

Equipment costs cause barriers related to STEMI care in rural areas. Expanding the capabilities of EMS systems with new equipment is costly. Devices to obtain prehospital ECGs may cost up to $25,000 per machine (Nallamothu et al., 2007). Training personnel, maintenance of the devices and creating technology to transmit data from ambulances to the hospitals adds additional dollars. Community hospitals that elect to develop primary PCI programs must provide upfront investments. These investments in equipment and training can outweigh the cost-effectiveness of STEMI programs (Nallamothu et al.)

Nursing practice in rural areas can cause a barrier related to STEMI care. Distance from urban settings can cause professional isolation making it difficult for rural nurses to network with colleagues to discuss new treatments and care options (Beatty, 2001). Decreased reimbursement resulting in a low net gain for the health care institution can result in decreased funding for nurse education. Long work hours and family commitments leave nurses with little time for

professional development and opportunities to increase competence related to new protocols (Beatty).

Significance to Nursing

It is imperative that rural nurses identify the institutional and regional facilitators and barriers to programs when implementing STEMI guidelines within their community. After identification of agency-specific facilitators and barriers, the rural nurse can begin to develop a specific plan related to implementing the guidelines in the community. The guidelines are complex and the rural nurse must focus on the guidelines that are appropriate to the community and regional area. Identification of facilitators and barriers gives the rural nurse valuable information to use when working with regional partners in developing systems of care for STEMI patients. Coordination of ideas and resources between the PCI available tertiary centers and rural facilities requires knowledge of existing capabilities related to the facilities and surrounding areas. By early identification of facilitators and barriers, both rural and community agencies can focus their attention on collaboration and the development of guidelines that coordinate with tertiary care centers.

In the rural community, the nurse must be proactive and advocate for change in national guidelines that can lead to improved care. The rural nurse implementing change must involve all community members, including citizens, EMS, fire, and police as well as other nurses, physicians, and key administrative members of the community and hospital. The rural nurse must take the leadership role to create change associated with STEMI care. Strong leadership empowers others and creates change. The success of a STEMI program depends on it, as do the lives of the people affected with STMEI.

Summary

Keeping up with innovative technology and current guidelines associated with improved patient outcomes creates challenges for rural nurses. Time spent reviewing guidelines, forming new policies and procedures, training, and implementation can be long and costly processes. Having systems and guidelines in place within a region can aid nursing to develop standards of practice and add consistency to practice that results in improved outcomes by improving care delivered to STEMI patients. The use of systems to implement reperfusion therapy in STEMI patients has demonstrated improvement in short and long-term patient outcomes (Jacobs et al., 2006). Using standard protocols within the system has the ability to decrease door-to-balloon and door-to-needle time, which improves the effectiveness (Henry et al., 2005).

Identifying concepts that facilitate the development of systems and guidelines along with identifying barriers that hinder development of systems and guidelines is important for the rural nurse implementing STEMI guidelines. Facilitators to developing guidelines are (a) identifying of all participants in your region, (b) developing standard policies while taking into account the distance from the PCI hospital, (c) activating the catheterization lab by emergency room physicians with one phone call, (d) putting a process in place to identify chest pain patients on arrival, (e) educating all staff involved, and (f) implementing on-going quality improvement processes.

Barriers to developing guidelines include (a) lack of the patients' ability to recognize symptoms of heart attack, (b) less than optimal EMS systems, (c) a non-structured system for interfacility transfers, (d) failure to attain regional consensus on guidelines, (e) cost of equipment related to ECGs and the development of PCI programs in community hospitals, and (f) decreased opportunities for professional development related to nursing education and competence.

Future research needs to be directed at determining the specific facilitators and barriers that rural hospitals experience. Research also needs to determine the long-term effectiveness of developed systems related to rural facilities. Rural nurses have the ability to play a key role in the implementation STEMI guidelines. This plays an important role in the research process with the collection of data by nurses in rural areas.

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Table 1

Applying Classification of Recommendations and Level of Evidence

	CLASS I Benefit > > Risk Procedure/treatment SHOULD be performed/administered	CLASS IIa Benefit > > Risk Additional studies with focused objectives needed. IT IS RESAONABLE to perform procedure/ administer treatment	CLASS IIb Benefit ≥ Risk Additional studies with broad objectives needed; additional registry data would be helpful Procedure/Treatment MAY BE CONSIDERED	Class III Risk ≥ Benefit No additional studies needed Procedure/Treatment should NOT be performed/ administered SINCE IT IS NOT HELPFUL AND MAY BE HARMFUL
LEVEL A Multiple (3-5) population risk strata evaluated General consistency of direction and magnitude of effect	Recommendation that procedure or treatment is useful/effective Sufficient evidence from multiple randomized trials or meta-an	Recommendation in favor of treatment or procedure being useful/effective Some conflicting evidence from multiple randomized trials or meta-analyses	Recommendation's usefulness/efficacy less well established Greater conflicting evidence from multiple randomized trials or meta-analyses	Recommendation that procedure or treatment is not useful/effective and may be harmful Sufficient evidence from multiple randomized trials or meta-analyses
LEVEL B Limited (2-3) population risk strata evaluated	Recommendation that procedure or treatment is useful/effective Limited evidence from single randomized trial or nonrandomized studies	Recommendation in favor of treatment or procedure being useful/effective Some conflicting evidence from single randomized trial or nonrandomized studies	Recommendation's usefulness/efficacy less well established Greater conflicting evidence from single randomized trial or nonrandomized studies	Recommendation that procedure or treatment is not useful/effective and may be harmful Limited evidence from single randomized trial or nonrandomized studies
LEVEL C Very limited (1-2) population risk strata evaluated	Recommendation that procedure or treatment is useful/effective Only expert opinion, case studies or standard of care	Recommendation in favor of treatment or procedure being useful/effective Only diverging expert opinion, case studies, or standard or care	Recommendation's usefulness/efficacy less well established Only diverging expert opinion, case studies, or standard of care	Recommendation that procedure or treatment is not useful/effective and may be harmful Only expert opinion, case studies, or standard of care
Suggested phrases for writing recommendations:	Should Is recommended Is indicated Is useful/effective Is beneficial	Should Is recommended Is indicated Is useful/effective Is beneficial	May/might be considered May/might be reasonable Usefulness/effectiveness is unknown/unclear/uncertain or not well established	Is not recommended Is not indicated Should not Is not useful/effective/beneficial May be harmful

(King et al pg.263 2008)