Volume 6, Issue 1, April 2011

HDSP CONNECTION

Connecting programs, events, resources, research and people in the Minnesota heart disease and stroke prevention community.

In this issue:

HDSP
Minnesota Heart Disease & Stroke Prevention Unit

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From the Editor:

I'm pleased to present the April issue of the Connection. This issue's focus is on peripheral artery disease (PAD) and its impact on the cardiovascular health of Minnesotans. The authors are leaders in the field and it's a pleasure to highlight the work they are doing to improve the quality of life for those with PAD.

~ Mary Jo Mehleich

Peripheral Artery Disease

How North Star State Values Underpin National Leadership in PAD Science, Public Health, and Advocacy

Alan T. Hirsch, MD
Professor of Medicine, Epidemiology and Community Health
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We recognize certain facts. Minnesota is cold. Minnesota has lakes. Minnesota is a collaborative, health-attentive, community-focused State.

The exact origin of this community focus is not known. Is it the weather? Perhaps. But other cold northern States are not health attentive like Minnesota. Their health is poor.

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Is it our particular immigrant tradition? Perhaps. But all States have strong immigrant origins, but do not collaborate. Public health approaches to cardiovascular disease prevention are poor.

For at least the past 150 years, Minnesotans have used their communities as a base to support creation of a "better life". Amongst the definition of a "better life", our goals have included a community-based focus on the prevention of disease. We work together to measure our health. We take unified steps to identify areas where we "fall short" of our goals and then take deliberate steps to resolve the "gaps" between what "is" and what "could be". The key operational concept that underpins our success is embodied in this concept of "community": Individuals best sustain their health and their dreams, not merely in isolation, but within a family, a town, a county, and a State. One cannot ideally prevent childhood diseases, avoid swine (H1N1) influenza, lower rates of avoidable hip fractures, or avoid a cardiac death by individual actions alone. We achieve these goals more effectively and efficiently by working together.

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The High Prevalence, Risk and Cost of PAD

The Inescapable Truth

Sue Duval, PhD
Assistant Professor, Division of Epidemiology and Community Health, University of Minnesota

Despite encouraging recent temporal trends in heart disease and MI rates in Minnesota and in the United States, the outlook for PAD is not likely to paint such a rosy picture.

The prevalence of PAD has been estimated in several population based studies, from which the consensus is that between 8 and 12 million Americans are currently living with PAD. It should be noted however that prevalence estimates depend very much on the population, diagnostic methods used, and whether symptoms were included in the definition of PAD. Estimates from several studies in the US which measured the ankle-brachial index (ABI) in adults have demonstrated a prevalence of PAD as low as 1-3% in those under 60 years to 11-29% in those over 60 years of age. In individuals over 75 years of age, PAD prevalence is commonly estimated to be 20%.

Risk factors associated with PAD include advancing age, cigarette smoking, diabetes mellitus, hypercholesterolemia, and hypertension. The risk of developing PAD is as much as three times higher for people who smoke as that of non-smokers.

Event rates in those with PAD are dramatically high. In a very large cohort of outpatients with vascular disease enrolled in the "REduction of Atherothrombosis for Continued Health" (REACH) Registry, one and 3-year rates of MI/stroke/vascular death/rehospitalization were 14.4 and 28.4%, respectively, for patients with symptomatic PAD. PAD case identification included individuals with known claudication (exertional muscle pain in the lower extremities) with an ABI of less than 0.90, a history of lower limb arterial revascularization, or a history of ischemic amputation.

The economic burden of PAD is very high, largely due to recurring hospitalizations and repeat revascularization procedures in many patients. Using US REACH data, mean total hospitalization costs, per patient, were $7,445, $7,000, $10,430, and $11,693 for patients with asymptomatic PAD, a history of claudication, lower limb amputation, and revascularization, respectively. Each year, the U.S. spends approximately $21 billion on PAD-related hospitalizations.

In Minnesota, we have an outstanding track record for surveillance of heart disease and cardiovascular risk factors. As one example, the Minnesota Heart Survey (MHS) provides cross-sectional snapshots of cardiovascular risk factors for the Minneapolis-St. Paul metropolitan population, which comprises over half the population of the state. Peripheral artery disease, with similar or worse outcomes and cost, should be elevated to a much higher profile as we strive to better understand the burden this disease presents to the people of Minnesota. When we do not measure the disease in our midst, we suffer needlessly. We can do better, as Minnesotans, for others in our communities who suffer from this debilitating disease. ■

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Cardiovascular Disease and PAD

Cardiovascular disease, despite major advances, remains one of the key killers of Minnesotans, as it is throughout both the United States and the world. In 2008, Minnesotans experienced over 54,000 acute heart disease hospitalizations. More than 20% of all deaths in Minnesota are due to heart disease. Minnesotans incurred over $1.7 billion in charges for inpatient hospitalizations due to heart disease in 2007 and more than $360 million due to stroke. Yet, heart attack and stroke are simply the names we give to the most obvious outcomes of the primary disease: atherosclerosis.

Lower extremity **peripheral artery disease** (PAD) represents one of the most common manifestations of systemic atherosclerosis and is defined as blockages in the major arteries that supply the leg. PAD represents one of the three major systemic atherosclerotic diseases, with a prevalence that is similar to that of coronary heart disease and ischemic stroke. Individuals with PAD may be asymptomatic, but often experience "**claudication**" as the primary ischemic symptom. Claudication is "angina of the legs", and is experienced as an exertional leg muscle fatigue, weakness, discomfort, or pain that occurs reproducibly with exercise. Current evidence documents that claudication is even more disabling than angina. While Minnesotans value their ability to walk independently, we do not routinely ask our patients about common PAD symptoms, as we might ask about exertional chest pain.

When PAD is permitted to progress without active medical treatment, foot or leg ischemia may become so severe that unrelenting symptoms are present at rest. Severe PAD leads to constant unremitting pain and skin ulcers do not heal. Without treatment, leg tissue death (gangrene) and amputation occur. This presentation of PAD is defined as **critical limb ischemia** (or simply, "CLI"). One could consider CLI to be the equivalent of a "leg heart attack". This analogy is apt for many reasons. For individuals with CLI, as for patients with a heart attack, prompt

Alan T. Hirsch, MD

arterial revascularization is essential. As well, the presence of CLI defines an extremely high short-term risk of heart attack and stroke, as coronary and cerebrovascular plaque is invariably present. The etiology of over 80% of amputations that occur in all developed nations (including those that occur in individuals with diabetes) are due to PAD and CLI. Yet, while the evidence base underlying this statement is true, no health system yet can provide standards of care for individuals with CLI, as we would for individuals with an acute MI or stroke. Thus, outcomes are poor and expenses are extremely high.

Cardiovascular Epidemiology

How could any individual or community be aware of its cardiovascular risk without the collection of data to define factors that promote disease (risk factors)? Similarly, it is imperative to measure the number of individuals affected by any disease (prevalence). It is mandatory to assess the efficacy and cost of treatment strategies (health service research and comparative effectiveness). The tools of cardiovascular public health are anchored in cardiovascular epidemiology. Professor Sue Duval has evaluated the prevalence, risk, and cost of PAD, both in Minnesota and nationally (see page 2). Epidemiology is not "dry statistics", but represents the sum of our community-defined knowledge base. Epidemiology defines the "health environment" in a manner as critical as the weather service defines the "atmospheric environment". When Doppler radar reveals that a storm path is likely to bring tornadoes to our towns, we take shelter. A cardiovascular epidemiologist serves as our "early warning system".

Nursing

The burden of PAD is at the family, city and state level. PAD is not merely "a blocked artery" that must be opened. The physical symptoms, emotional impact, and loss of independence can be profound. Vascular nursing, with leadership provided by Minnesotans, has defined this impact in a series of major regional and national contributions. Cindy Felty, Rita Clark, Carolyn Robinson, and Diane Treat-Jacobson, and others provided early recognition of these impacts of PAD. They have provided leadership to the non-profit, public-focused Vascular

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Disease Foundation and its Peripheral Arterial Disease Coalition. They have led a series of clinical and educational initiatives, including leadership of the national Society of Vascular Nursing (www.svnnet.org) to extend their knowledge to others. Dr. Treat-Jacobson has served as a pioneer in designing and evaluating methods by which exercise can modify PAD symptoms and preserve functional status (see page 7).

Primary Care

For patients with PAD to achieve a prompt community-based diagnosis, primary care clinicians (internal medicine and family practice, nurse practitioners and physicians assistants) must recognize the high PAD prevalence and ischemic risk, and have access to cost-effective treatment options. Dr. Tracie Collins has assessed how these goals can best be achieved in office-based care. As well, she has provided key insights into how community-based walking programs can be practically designed and be effective. Our health is surely the product of our individual behaviors. But mere old-fashioned advice from clinics to patients with PAD to "go home and walk" provides a proven method "therapeutic failure". Such advice is as effective as merely telling an obese patient to "go home and lose weight", while providing no resources to do so. Dr Collins has carefully examined how individuals with diabetes and PAD can definitely achieve improved functional status in a community-based walking program. She has provided leadership in revealing and reversing PAD health disparities.

State-based Public Health

Individuals are aware of their personal and family health. Physicians are aware of the health of the members of their practice. Health systems can measure the health of those who receive system-based care. But who takes stock of the cardiovascular health of the State itself? The Minnesota Department of Health (MDH) is charged with such evaluations. Yet, in this nation, only the State of Minnesota has – via the key leadership of Dr. Jim Peacock – measured rates of ischemic amputation as a manifestation of PAD. From such a county-based map, the risk and cost of PAD is now immediately apparent. Do you want to know how many legs were lost in the Twin Cities or in northwestern Minnesota? Do you want to know if these amputation rates have improved over the past decade? This central role of the MDH as a national leader merits our recognition. These new data are reviewed on page 5.

The North Star State as a PAD Leader

I do not know why leadership so often arises from my fellow Minnesotans. I do know that we all benefit from this leadership, from those who dream of a healthy community, and those on the front lines who work to make these dreams of good health a reality. You are one of these leaders. Peripheral artery disease is common in every Minnesota family, in every town, in every clinical practice, and in every health system. We seek your help to improve State-based PAD health.

There are many proven, cost effective, and easy strategies that might be employed to reduce the adverse health effects of PAD, and thus help us further lower the incidence of heart attack and stroke. This issue of Connections is designed to introduce you to a few of our PAD health heroes. With their leadership, Minnesota is now poised to serve as a national model for the prevention, detection, and optimal treatment of PAD. ■

Would you help?

Please find published resources and references on page 9.

Web-based PAD Patient Information Sources

- The Vascular Disease Foundation: www.vdf.org
- The National Heart, Lung and Blood Institute's "Stay in Circulation: Take Steps to Learn About PAD" Campaign: www.aboutpad.org
- The American Heart Association: http://www.heart.org/HEARTORG/Conditions/More/PeripheralArteryDisease/Peripheral-Artery-Disease-ATH_UCM_002082_SubHomePage.jsp
- The Peripheral Arterial Disease (PAD) Coalition: www.padcoalition.org

The Minnesota Ischemic Amputation Survey: Measuring Legs and Lives

James Peacock, PhD, MPH
Minnesota Department of Health, Heart Disease and Stroke Prevention (HDSP) Unit

The effort to better understand the burden of peripheral artery disease (PAD) in Minnesota has just begun, with work by the Minnesota Department of Health's Heart Disease & Stroke Prevention (HDSP) Unit. There is currently no national surveillance system to monitor trends in the most common cardiovascular and cerebrovascular disease events such as heart attack, sudden cardiac arrest, or stroke, let alone for ischemic amputations due to PAD. Working with a team from the University of Minnesota, the HDSP unit developed an algorithm for identifying one of the most serious clinical outcomes of severe PAD, the amputation of all or part of a leg due to critical limb ischemia.

The first statewide surveillance of lower limb amputations was conducted using 2005 through 2008 Minnesota Hospital Billing (UB) Claims Data, compiled by the Minnesota Hospital Association

and shared by the Health Economics Program at MDH. Lower limb amputations were identified through procedure codes present in the claims record for hospitalizations for either cardiovascular disease or diabetes, excluding those individuals with disease codes for trauma and certain cancers. **The overall annual age-adjusted amputation incidence for Minnesotans was 20.0 per 100,000 over the 4-year period, equating to more than 1,000 limbs lost each year.** While far short of the number of hospitalizations for heart attack (8,966 in 2008) or cerebrovascular disease (11,775 in 2008), the burden is still quite high.

Over the 4 years in the study period, the average estimated costs for inpatient hospitalizations with amputations rose from $19,230 to $21,015, ranging from $21 to $24 million in total costs per year. An analysis of national hospitalization data from the Healthcare Cost and Utilization Project (H-CUP) Nationwide Inpatient

Sample of 39.5 million hospital discharges estimated median hospital costs of $15,900 for amputation due to "circulatory system disorders", which compares well with our estimates. These cost estimates do not fully reflect the resources expended in managing this condition, as they only include costs for the hospitalization associated with the amputation events. This does not include any costs due to rehabilitation and care after discharge, or lost wages.

These results are currently under review for publication in a peer-reviewed journal, and represent, to our knowledge, the first attempt to quantify lower limb ischemic amputation in the general population. The HDSP unit will continue to support research, treatment, and awareness of PAD and lower limb amputations by maintaining this surveillance activity and providing annual updates on amputation trends in Minnesotans.

Walking Therapy *for* African Americans *with* Peripheral Arterial Disease

Tracie C. Collins, MD, MPH
Associate Professor, Department of Medicine Co-Director, Research Core, Center for Health Equity Investigator, Applied Program in Clinical Research and Program in Health Disparities Research University of Minnesota

Peripheral arterial disease (PAD) is atherosclerosis of the abdominal aorta and arteries of the lower extremities, is a common disease affecting 20-30% of adults > 50 years of age, or up to 12 million Americans. PAD disproportionately affects African Americans as compared to non-Hispanic whites. For example, in the Systolic Hypertension in the Elderly Program – a randomized trial of 4,736 persons age 60 years and older with hypertension – the prevalence of PAD was 23% for non-Hispanic white women, 25% for non-Hispanic white men, 38% for African American men, and 41% for African American women. In a national U.S. sample of 2,174 persons aged 40 years and older, African Americans were 2.8 times as likely as non-Hispanic whites to screen positive for PAD.

A reliable, non-invasive, bedside test to diagnose PAD is the ankle-brachial index (ABI), a ratio of systolic blood pressure in the ankle to systolic blood pressure in the arm. An ABI of less than 0.90 has been used to define disease. ABI levels have also been used to define PAD severity: 0.70-0.90 = mild, 0.41-0.69 = moderate, and < 0.41 = severe or critical. Persons with PAD may present with asymptomatic disease (without leg pain upon exertion) or with symptomatic disease (with symptoms of leg pain, fatigue, weakness, or numbness with walking). Further, symptomatic disease is categorized as either classic intermittent claudication (exertional calf pain that resolves within 10 minutes of rest) or atypical leg pain (pain in legs that is not classic intermittent claudication).

Modifiable risk factors for PAD are smoking, diabetes mellitus, hypertension, and dyslipidemia. Control of atherosclerotic risk factors is key to reducing the risk for adverse systemic events including heart attacks and strokes. Although aggressive risk factor control can reduce leg symptoms, the magnitude of the benefits from risk factor control does not approach that of walking therapy to improve lower limb function.

Walking therapy for PAD reduces walking impairment (i.e., a reduction in walking distance, speed, and/or stair climbing). There are two well recognized types of walking therapy: 1) supervised treadmill walking and 2) home-based walking. Efficacy studies demonstrate that supervised treadmill walking – walking conducted at a rehabilitation site with supervision by a trained clinician – improves treadmill walking distance in patients with PAD. However, the benefits of this approach are greatly attenuated by a lack of access to this therapy; very few sites in the U.S. offer supervised treadmill walking for patients with PAD. Also, Medicare does not reimburse for supervised treadmill walking for PAD. In addition, supervised treadmill walking imposes a high patient burden; patients must report to a rehabilitation site three times a week for six months under direct supervision by a clinician. Given the significant commitment, limited flexibility in scheduling, and potential transportation barriers, alternatives to supervised treadmill walking are needed. The second type of walking therapy is home-based walking – walking conducted outside of a rehabilitation site and with minimal, if any, supervision by

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a trained clinician. Home-based walking therapy is a more feasible approach to improving lower limb function in African Americans with PAD.

Compelling reasons to highlight walking programs for African Americans with PAD include the higher prevalence of PAD in this population. Additionally, PAD is more severe in African Americans than in non-Hispanic whites. In a study of 460 men and women age 55 years and older with PAD, mean ABI levels were lower – indicating more severe PAD – in African Americans than in non-Hispanic whites (0.60 vs. 0.66, p=0.001). In a PAD screening study involving an ethnically diverse population (conducted by Dr. Collins), 42% of African Americans had an ABI < 0.69, while only 28% of non-Hispanic whites had ABIs in this range. Multiple factors likely explain why African Americans have more severe PAD at the time of diagnosis. One reason is a reduced level of activity to minimize leg discomfort. In a cross-sectional study, lower levels of physical activity were positively related to ABI levels in a cohort of African Americans and whites. Further, African Americans with and without PAD have lower physical activity levels when compared to non-Hispanic whites. Thus, efforts are needed to identify effective walking interventions to improve walking ability and reduce functional limitations in African Americans with PAD.

FREEDOM TO WALK: EXERCISE FOR PATIENTS WITH PERIPHERAL ARTERY DISEASE

Diane Treat-Jacobson, PhD, RN, FAAN
Associate Professor, School of Nursing,
University of Minnesota

PAD causes functional disability

Many patients with peripheral artery disease (PAD) experience claudication, which is pain or discomfort caused by decreased blood supply to the leg muscles during physical activity. Claudication is often described as a cramping or aching in the calf, thigh or buttock that comes consistently with exertion and is quickly relieved by rest. Patients with claudication have significant functional disability, including moderate to severe limitation in walking ability. Thus, the treatment goals for patients with claudication are to relieve symptoms, improve walking ability and improve the patient's ability to complete activities of daily living.

Does exercise help patients with PAD?

There is a considerable body of research demonstrating that supervised exercise training is one of the most effective ways to improve symptoms of claudication and exercise performance in patients with PAD. Exercise that consists of repeated bouts of treadmill or track walking until moderate claudication is induced, has consistently been shown to result in an increase in the distance that patients can walk before the onset of claudication, as well as the distance that they can walk before pain forces them to stop. The evidence also indicates that having some level of supervision improves the

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benefits gained in these programs. The benefits can be seen as early as 4 weeks and patients continue to improve over 12 to 24 weeks of exercise training. The evidence is so compelling that patient care guidelines from the American College of Cardiology/American Heart Association as well as the Transatlantic Inter-Society Consensus (TASC) II Guidelines recommend a program of structured or supervised exercise as an initial therapeutic approach for patients with claudication. Such an exercise approach is so important, that new 2010 Performance Measures for the treatment of peripheral artery disease will measure whether clinicians and health systems do provide access to PAD exercise rehabilitation programs.

What type of exercise?

Traditionally, it has been thought that it was necessary for PAD patients to engage in weight-bearing (i.e. walking) exercise to achieve the greatest symptomatic relief. Improvement in claudication symptoms after repeated bouts of walking exercise training is thought to be primarily due to changes in the metabolism of the leg muscles, which is triggered by ischemia/rest cycles that occur during intermittent walking exercise. However, more recently, studies have demonstrated improvement in walking capability in patients with PAD following exercise that doesn't cause ischemia, including aerobic arm exercise. It is thought that improvement seen with this form of exercise is related to improvement in systemic cardiovascular function. One drawback of walking exercise is that it requires the patients to exercise into moderate claudication pain repeated times during each exercise session, which may limit tolerability in some patients. Aerobic exercise that does not rely on the lower extremities, such as arm ergometry or 'arm cranking', may be better tolerated in some patients, particularly those who are functionally very limited.

What exercise instructions should be given to PAD patients?

If a patient with PAD wishes to begin a walking program in an unsupervised setting, there are wonderful resources available through the Vascular Disease Foundation: www.VDF.org. these include:

- PAD Walking Instructional Brochure: http://www.vdf.org/pdfs/VDF_PAD_WalkingBro1010.pdf
- PAD Walking Log: http://www.vdf.org/diseaseinfo/pad/documents/WalkingLog3.pdf

Additional considerations include:

- It is not sufficient to simply tell patients to 'go out and walk'. They need more specific instruction.
- It is important not to instruct patients to 'walk through' their pain, as this is usually not possible.
- It is important to emphasize that each exercise session should consist of several bouts of walking until moderate claudication symptoms are experienced. Then the patient should rest, standing or sitting, until the symptoms subside and repeat this cycle until 30 minutes of walking time has been achieved. They should try to complete these sessions at least 3 and preferably most days of the week.
- Patients should gradually increase the speed or incline walked as their tolerance increases.
- Noting benchmarks helps patients realize the progress they are making.
- It is very important to wear comfortable, well-fitting shoes and to inspect the feet daily, especially after an exercise session.

Are supervised programs available for patients with PAD?

Unfortunately, despite the large amount of evidence demonstrating efficacy of supervised exercise to improve symptoms in patients with PAD, supervised exercise programs for PAD are not reimbursed by Medicare, and therefore participation in these programs usually requires the patient to self-pay. Lack of reimbursement has limited the number of existing programs that offer rehabilitation specifically designed for patients with PAD. As well, the Vascular Disease Foundation has recently published a PAD Exercise Training Toolkit, which was created to help currently existing rehabilitation programs develop a PAD exercise training program. This Toolkit is available at no charge at: http://www.vdf.org/professionals/exercisetoolkit.php

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Are there any on-going research studies for patients with PAD?

The following are ongoing clinical trials in the Twin Cities Metropolitan Area currently available for patients with PAD. These studies provide exercise interventions for patients with PAD at no charge to the participants.

- **EXERT: Exercise Training to Reduce Claudication: Arm Ergometry versus Treadmill Walking**

The goal of this study is to understand how people with claudication respond to different types of exercise. Exercise participants receive supervised exercise training three times per week for 12 weeks.

Principal Investigator: Diane Treat-Jacobson, PhD, RN, FAAN

Funding Agency: National Heart Lung and Blood Institute (NIH)

Contact Information: www.EXERTstudy.org; EXERT@umn.edu; 612-624-7614

- **Promoting Walking in African Americans with Peripheral Arterial Disease**

The purpose of this study is to determine the efficacy of a community-based walking protocol combined with motivational interviewing (PACE Plus) to increase walking distance in African Americans with PAD. The PACE Plus protocol will be delivered for 6 months, using both face-to-face visits and telephone contact.

Principal Investigator: Tracie Collins, MD, MPH

Funding Agency: National Heart Lung and Blood Institute (NIH)

Contact Information: 612-625-7223

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SPOTLIGHT

May is

High Blood Pressure Education Month

May is dedicated to increasing public awareness about high blood pressure a condition that affects over 76 million Americans. It is a good time for people to check their blood pressure and take steps to lower it if it's high.

For more information about high blood pressure please visit one of these websites:

- **American Heart Association** http://www.heart.org
- **Centers for Disease Control and Prevention** http://www.cdc.gov/Features/HighBloodPressure/
- **National Heart, Lung, and Blood Institute** http://www.nhlbi.nih.gov/health/public/heart/index.htm

Stroke Awareness Month

The purpose of Stroke Awareness Month is to raise public awareness about:

- **Signs and symptoms of stroke and the need to call 9-1-1,**
- **Managing stroke risk factors, and**
- **Improving the quality of life after stroke.**

For more information please visit one of these websites:

- **American Stroke Association** http://www.strokeassociation.org/presenter.jhtml?identifier=1200037
- **Centers for Disease Control and Prevention** (CDC) http://www.cdc.gov/Features/Stroke/
- **National Stroke Association** http://www.stroke.org/site/PageServer?pagename=sam

Upcoming Events

Minnesota Stroke Conference

June 13, 2011
Snelling Office Park (SOP) , St. Paul, Minnesota.

This conference brings together hospital staff and other partners to share best practice strategies and tools for improving stroke care in Minnesota hospitals. The conference will provide a networking opportunity for health care professionals, public health professionals and stroke advocates.

For more information please visit: http://www.mn-strokepartnership.org/conference.html

The 2011 Minnesota Rural Health Conference

June 27-28, 2011
Duluth Entertainment and Convention Center, Duluth, Minnesota

The Conference will take an in-depth look at federal and state health reform, Health Information Technology (HIT), quality, workforce and finance & reimbursement. Monday will focus specifically on Critical Access Hospitals (CAHs), with representatives from Minnesota's 79 CAHs and other CAH stakeholders. The Minnesota Rural Health Conference provides an opportunity to showcase creative solutions to challenges and encourages leadership for the future.

For more information please visit: http://www.health.state.mn.us/divs/orhpc/conf/2011/index.html

Please direct any comments, questions or suggestions for newsletter content to Mary Jo Mehelich at (651)201-5419 or mary.mehelich@state.mn.us

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