



# THE IHS PRIMARY CARE PROVIDER



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## Cardiac Rehabilitation and Secondary Prevention of Coronary Heart Disease in Native Communities

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### Introduction

Cardiovascular disease (CVD) accounts for nearly 60% of all deaths in the US each year and is the leading cause of death in native and non-native populations alike.<sup>1</sup> Historically, patients with cardiovascular disease had high rates of mortality and morbidity, and few treatment options. Patients were often disabled, with little hope of working or living normal lives. The Framingham study offered understanding into the etiology of CVD and spawned a movement towards risk factor management, advanced treatment options, and improved prognosis in patients with coronary artery disease (CAD).<sup>2</sup> This initiative has continued with targeted strategies aimed at the prevention of subsequent cardiovascular events and the maintenance and improvement of physical capabilities and mental health in patients with existing coronary heart disease.

Formal cardiac rehabilitation programs arose from this movement decades ago, focusing primarily on exercise, as the benefit of physical activity following coronary events became evident. Cardiac rehabilitation and secondary prevention programs have evolved over time into highly structured, medically supervised programs promoting exercise, risk factor modification, and psychosocial support. Such programs are now the standard of care in most urban communities, serving as an advocate for secondary prevention for patients with existing heart disease, and have been shown to reduce both death and disability.

In Native communities and similar rural settings, cardiac rehabilitation services are generally non-existent. After receiving high level cardiac care in urban tertiary medical centers, patients are often promptly discharged to rural communities without a full understanding of their diagnosis or concrete plans to adjust their lifestyles. Patients are frequently anxious about resuming daily activities and often have little support during this difficult time of transition. Cardiac rehabilitation programs are needed in Native communities to bridge this gap in care and address risk factor modification

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while educating and empowering patients. In Tuba City we recently started a cardiac rehabilitation program and hope to share our experiences, showing the benefit of implementing a culturally sensitive program, while offering assistance and encouragement for other Native communities to follow suite.

### Scope of the Problem

Although relatively rare in Native Americans a few decades ago, the rate of development of cardiovascular risk factors has increased significantly over this period.<sup>3</sup> Unfortunately, the age of onset of these risk factors is also decreasing, resulting in CVD incidence rates nearly double that of the general US population, and prevalence rates even higher than other ethnic and minority populations within the United States.<sup>3,5</sup> In addition, American Indians and Alaska Natives now appear to have the highest proportion of premature death when compared with whites, blacks, Asian/Pacific Islanders and the general US population.<sup>4</sup>

As a result of these trends, the numbers of acute myocardial infarctions, along with other acute coronary syndromes, and the need for coronary interventions, including coronary bypass surgeries and percutaneous interventions, are rapidly increasing. These events and procedures are often followed by the initiation of phase I cardiac rehabilitation programs in the referral tertiary care centers. Unfortunately, there is generally no cardiac rehabilitation follow-up available at rural Indian health care facilities for the vast majority of these patients to reduce their cardiovascular risk factors, improve the quality of their life, or prolong their life.

### Cardiac Rehabilitation and Secondary Prevention Defined

The American Heart Association (AHA) has defined cardiac rehabilitation and secondary prevention as “. . . a coordinated, multifaceted, intervention designed to optimize a cardiac patient’s physical, psychological, and social functioning, in addition to stabilizing, slowing, or even reversing the progression of the underlying atherosclerotic process, thereby reducing morbidity and mortality.”<sup>6</sup> It functions as a medically supervised program for cardiac patients initiated by physician referral and designed to assist with progressive exercise and activity. Goals include improved functional capability and quality of life and the alleviation or lessening of exercise related symptoms. Programs also serve to address lifestyle and risk factor modification while educating patients about the management of ischemic heart disease. Medicare and most private insurance programs cover cardiac rehabilitation programs.

### Evidence Reviewed: Mortality Data, Cost Effectiveness and Safety

It has been shown that cardiac rehabilitation programs save lives and positively influence cardiac risk factors. A recent evaluation showed reductions in all-cause and cardiac mortality for patients participating in cardiac rehabilitation

programs.<sup>7</sup> This meta-analysis was published in 2004 and included 48 trials and over 8900 patients. Compared with usual care, cardiac rehabilitation was associated with reduced all-cause mortality (odds ratio [OR] = 0.8) and cardiac mortality (OR = 0.74). It also showed greater reductions in total cholesterol level (weighted mean difference, -14.3 mg/dl), triglyceride level (weighted mean difference, -20.4 mg/dL), systolic blood pressure (weighted mean difference, -3.2 mm Hg) and lower rates of self reported smoking (OR = 0.64). Significant benefits in quality of life and exercise ability have been demonstrated in numerous studies as well.<sup>8</sup>

Cardiac Rehab has also been found to be cost effective. In several randomized, controlled trials, the cost effectiveness of cardiac rehabilitation was reviewed and, adjusted for the quality of life, was found to cost between \$4,950 - \$9,200 per year of life saved.<sup>9-11</sup> These figures compare favorably with other cardiovascular preventive interventions. Phase II interventions, the stage immediately post discharge from a tertiary care center, are most urgently needed in Indian country and are reimbursable by Medicaid and other insurance carriers.

Safety is a common concern for high risk cardiac patients after procedures and cardiac events. Despite the presence of significant cardiac disease and comorbid medical conditions in its patient populations, cardiac rehabilitation programs have been found to be safe, with very few cardiac events occurring in rehabilitation settings. A review of supervised programs showed the rate of cardiac arrest was 1 per 112,000 patient-hours, and the rate of non-fatal myocardial infarction was 1 per 294,000 patient hours. The overall mortality rate was 1 per 784,000 patient-hours.<sup>7,12</sup>

In summary, cardiac rehabilitation programs have been shown to save lives and positively influence both cardiac risk factors and quality of life. They have also been shown to be cost effective and safe.

### Program Eligibility

Currently the Centers for Medicare and Medicaid Services (CMS) recognize three diagnoses for entry into cardiac rehabilitation. The CMS website ([www.cms.gov](http://www.cms.gov))<sup>13</sup> lists the following guidelines defining criteria for reimbursable services:

1. Patients must be referred by a physician.
2. Services must be reasonable and necessary (documentation in the medical records supporting one of the following diagnosis):
  - Coronary artery bypass surgery within preceding 12 months
  - Myocardial infarction within preceding 12 months
  - Stable angina.
3. Program must be conducted in an area set aside for the exclusive use of the program while it is in session.
4. A provider must be available on site to address acute medical needs.

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## Phases of Cardiac Rehabilitation

Cardiac Rehabilitation is conventionally divided into four phases.<sup>14-15</sup> These four phases follow the patient from the immediate post-operative period through the maintenance phases of exercise and lifestyle modification.

*Phase I* includes the inpatient rehabilitative services that patients receive while hospitalized for a cardiac event or surgery. The goals of this phase are to assist with reintroducing ambulation and other activities of daily living and promoting healthy lifestyle changes. Phase I cardiac rehabilitation reimbursement is part of global inpatient billing but is not separately billable.

*Phase II* consists of monitored outpatient services. Patients participate in telemetry-monitored exercise programs guided by individualized physiologic profiles. Exercise workload increases progressively over time under the supervision of cardiac rehabilitation staff (physical therapists, nurses, or exercise physiologists). The program is performed three times per week for 12 weeks or 36 visits. This phase is administered in groups allowing patients exposure to individuals with similar medical conditions and the camaraderie of a shared experience. Phase II also incorporates an education component for lifestyle change. The educational model is achieved using a multidisciplinary curriculum presented by health professionals including dietitians, pharmacists, mental health professionals, physical therapists, nurses, and physicians. Topics target risk factor modification such as smoking cessation, regular exercise, management of hyperlipidemia, hypertension, and diabetes control. Additional emphasis is directed towards psychosocial issues including stress management, depression, and the cultural and spiritual aspects of healing. Phase II is reimbursable through Medicare and most insurance carriers.

*Phase III* is a community-based program usually with monitoring on a monthly basis and is most often exercise-based only. It is not currently reimbursable through Medicare; however, some insurance companies do pay for phase III.

*Phase IV* is also a community-based program for cardiac health maintenance. This phase is usually not conducted by medical personnel. Many health clubs offer services conducted by staff trained to work with individuals with stable cardiac or other chronic medical conditions for health improvement and maintenance. As with Phase III, these services are usually not reimbursable.

## Cardiac Rehabilitation: Nationally and Within Native Communities

Nationwide, cardiac rehabilitation programs are grossly underused, with only 10 - 20% of eligible patients participating.<sup>6</sup> Women, minorities, elderly, and people living in rural communities are notably underrepresented. With rare exception, rural Native community programs are nonexistent, leaving travel to urban centers as the only option for obtaining valuable cardiac rehabilitation services. Additional barriers to

care include low physician referral rates, inadequate third party reimbursement, and poor patient motivation.

## Tuba City Cardiac Rehabilitation Program

The cardiac rehabilitation program in Tuba City was designed using a multidisciplinary planning committee with technical support from the Native American Cardiology Program at the University of Arizona. The committee included physicians, nurses, physical therapists, dietitians, and hospital administrators. An initial QMAN search was carried out using RPMS and Medicare guidelines to estimate the number of eligible patients and need within our service unit. After confirming the community need and patient numbers, a business plan was established with hospital administration to determine the economic feasibility of such a program. The conclusion of the committee was that a cardiac rehabilitation program would meet the confirmed medical need of the community while being cost effective and financially feasible.

The template and guidelines for the program were derived using national guidelines from the American Heart Association and the American Association of Cardiovascular and Pulmonary Rehabilitation.<sup>14-16</sup> From the onset, emphasis was focused on providing rehabilitative services to cardiac patients using four main components. The four components included:

1. Safe, monitored, progressive **exercise** sessions
2. **Patient education** focusing on lifestyle modifications
3. **Camaraderie**, allowing socialization opportunities for patients who had gone through similar health events
4. Incorporation of **local cultural beliefs** including both Navajo and Hopi.

A mission statement was developed as follows:

“The mission of the cardiac rehabilitation department is to provide rehabilitative services to patients with coronary artery disease in a safe, culturally sensitive, and friendly environment by licensed professionals and to assist the patient with regaining their maximal level of function and independence.”

The program is currently housed in our physical therapy department and consists of three telemetry monitored, 30 - 45 minute exercise sessions per week with traditional cardiovascular equipment including treadmills and stationary bikes. Additionally, light resistance training and stretching are included during the warm-up and cool down phases of the exercise sessions. The program also includes classroom sessions for educational presentations. Each session is presented by a health care professional covering relevant topics from within their area of expertise. Topics include basic anatomy and physiology of the heart, activities of daily living, resuming sexual activity, smoking cessation, wound management for post-operative incisions, stress management, weight management, nutrition, hypertension, diabetes, and hyperlipidemia. Other topics include psychological roundtable discussions, depression screening, community exercise

education, common cardiac medications, and cultural and spiritual healing sessions.

The cardiac rehabilitation program at the Tuba City Regional Health Care Corporation is in the early phase of implementation. We have started initially with Phase II, as it is the only stage currently reimbursed by Medicare and because of facility space limitations. We hope in the future to expand our physical space and overall program to include Phases III and IV and extend services into our community wellness center.

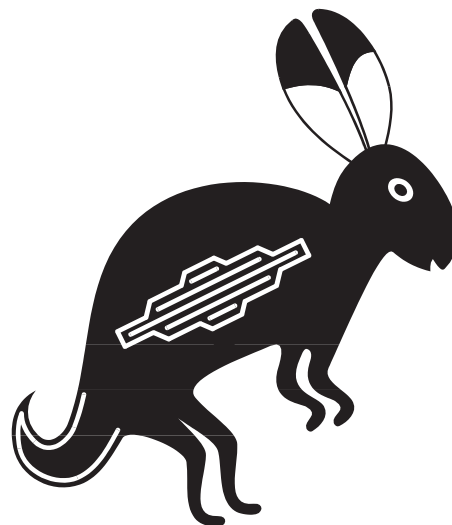
### Summary

Cardiac Rehabilitation programs have been shown to significantly reduce mortality and disability and positively influence existing cardiac risk factors in patients with coronary artery disease. These programs have also proven to be safe, cost effective, and largely covered by Medicare. In most urban communities, cardiac rehabilitation programs are the standard of care. Sadly, very few programs exist in Native communities. In Tuba City we have recently established a cardiac rehabilitation program, and we would like to share our experiences and offer assistance and encouragement to other Native communities.

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# Prevention of Childhood Hepatitis B Virus

*The following is excerpted from a letter released January 18, 2006 from John Ward, MD, Director of the Division of Viral Hepatitis, National Center for Infectious Diseases, Centers for Disease Control and Prevention, and Lance Rodewald, MD, Director of the Division of Immunization Services, National Immunization Program, Centers for Disease Control and Prevention*

We would like to bring to your attention revised immunization recommendations from the Advisory Committee on Immunization Practices (ACIP) to ensure that newborn infants are protected from hepatitis B virus (HBV) infection, a major cause of cirrhosis and liver cancer in the United States. The ACIP now recommends that, except on a case-by-case basis and only in rare circumstances, universal infant hepatitis B vaccination should begin at birth. Previously, the ACIP noted a preference for giving the first dose at birth, but also recommended that infants born to uninfected mothers could receive the first dose at age 1-2 months. To prevent HBV transmission among children at greatest risk for HBV infection, the ACIP also recommends that prenatal care providers, delivery hospitals, and health departments implement policies and procedures to identify and manage children born to infected mothers and mothers with unknown HBV infection status. The ACIP statement, including all of the revised recommendations, is available from CDC in the *Morbidity and Mortality Weekly Report*. A synopsis of the updated recommendations is provided below.

## Recommendations for Prenatal Care Providers

Management of all pregnant women:

- Test all pregnant women for hepatitis B surface antigen (HBsAg) during each pregnancy.
- Transfer a copy of the original laboratory report of the pregnant woman's HBsAg test result to the patient's medical record in the delivery hospital.
- Inform pregnant women of the importance of newborn hepatitis B vaccination.
- Vaccinate pregnant women who are at risk for HBV infection.

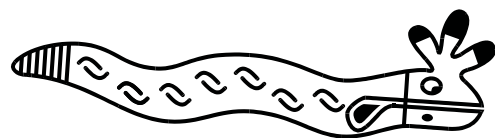
Management of pregnant women with chronic HBV infection:

- Inform HBsAg-positive women of HBV transmission risks and ways to prevent HBV infection, including the importance of postexposure prophylaxis for newborn infants and hepatitis B vaccination of household, sexual, and needle-sharing contacts.

- Refer HBsAg-positive women to an appropriate case-management program to ensure that their newborn infants receive timely postexposure prophylaxis and follow-up.
- Provide or refer HBsAg-positive women for appropriate medical management of their chronic HBV infection.

## Recommendations for Delivery Hospitals

- Implement standing orders to ensure that, except in rare circumstances (see statement for additional details), all newborns with birth weights of >2 kilograms receive hepatitis B vaccine before discharge.
- Implement policies and procedures to ensure that all infants born to HBsAg-positive mothers and all infants born to mothers with unknown HBsAg status are identified and receive appropriate immunoprophylaxis. These policies and procedures should include the following standing orders:
  - o Review HBsAg test results for all pregnant women at the time of admission for labor and delivery.
  - o Conduct HBsAg testing as soon as possible after admission for pregnant women who do not have a documented HBsAg result and for pregnant women identified as being at risk for HBV infection during pregnancy (e.g., >1 sex partner in the previous 6 months, evaluation or treatment for a sexually transmitted disease, recent or current injection-drug use, HBsAg-positive sex partner).
  - o Administer hepatitis B vaccine and hepatitis B immune globulin within 12 hours of birth to all infants born to HBsAg-positive mothers.
  - o Administer hepatitis B vaccine within 12 hours of birth to all infants born to mothers with unknown HBsAg status.
  - o Document on the infant's medical record the maternal HBsAg test results and the infant's hepatitis B immunization.



### Recommendations for Health Departments

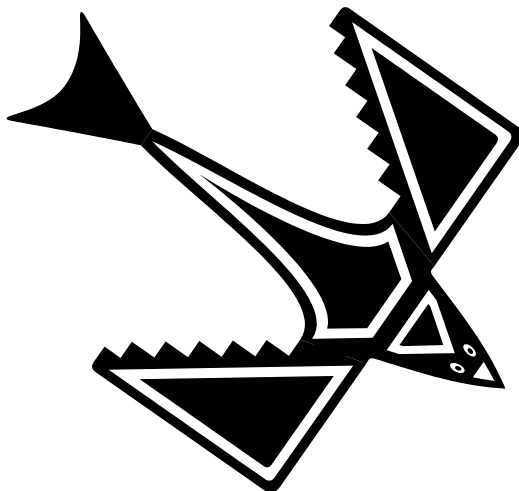
- Provide or assure case-management services to ensure that 1) all pregnant women are tested for HBsAg during each pregnancy, and 2) infants born to HBsAg-positive women and infants born to women with unknown HBsAg status receive recommended immunoprophylaxis and follow-up.

Before hepatitis B vaccination became routine in the United States, transmission of HBV infection perinatally and during early childhood caused an estimated 30% - 40% of chronic HBV infections. Approximately 25% of chronically infected children die prematurely from cirrhosis or liver cancer. The majority of chronically infected persons remain asymptomatic until the onset of cirrhosis or end-stage liver disease.

These recommendations update the ACIP strategy to eliminate HBV transmission in the United States. This strategy has been implemented with considerable success and has resulted in a substantial decline in hepatitis B incidence in the United States. However, challenges remain to eliminate

perinatal and childhood HBV transmission. In particular, CDC estimates that only about half of expected births to HBsAg-positive mothers are identified for case management, which is needed to maximize on-time delivery of postexposure immunoprophylaxis. In addition, errors in management of infants born to HBsAg-positive mothers and infants born to mothers with unknown HBsAg status have kept many of these infants from receiving appropriate immunoprophylaxis to prevent HBV infection.

On February 2, 2006, CDC hosted an Internet conference to discuss the new ACIP recommendations. This conference was intended for physicians, nurses, administrators, and other medical professionals, particularly hospital obstetrical and neonatal staff, prenatal care providers, professional organizations involved in perinatal care, and public health staff. You can visit the following website for replay and viewing of the slides: <http://www.cdc.gov/nip/ed/ciinc/#archive>. Additional resources may be found at the following website: <http://www.cdc.gov/ncidod/diseases/hepatitis/b/acip.htm>



## The 11th Annual Elders Issue

The May 2006 issue of THE IHS PROVIDER, to be published on the occasion of National Older Americans Month, will be the eleventh annual issue dedicated to our elders. Indian Health Service, tribal, and Urban Program professionals are encouraged to submit articles for this issue on elders and their health and health care. We are also interested in articles written by Indian elders themselves giving their perspective on health and health care issues. Inquiries or submissions can be addressed to the attention of the editor at the address on the back page of this issue.

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*Editor's Note: The following is a digest of the monthly Obstetrics and Gynecology Chief Clinical Consultant's Newsletter (Volume 4, No. 2, February 2006) available on the Internet at <http://www.ihs.gov/MedicalPrograms/MCH/M/OBGYN01.cfm>. We wanted to make our readers aware of this resource, and encourage those who are interested to use it on a regular basis. You may also subscribe to a listserv to receive reminders about this service. If you have any questions, please contact Dr. Neil Murphy, Chief Clinical Consultant in Obstetrics and Gynecology, at [nmurphy@scf.cc](mailto:nmurphy@scf.cc).*

## OB/GYN Chief Clinical Consultant's Corner Digest

### Abstract of the Month Results of a Well-Defined Protocol for a Trial of Labor After Cesarean

**Objective:** It has been claimed that a trial of labor after cesarean carries higher maternal and fetal risks than planned cesarean delivery. Because the management of such patients in our department differs from that described in some studies, and is perhaps more cautious, we hypothesized that the outcome may be better.

**Methods:** We identified women with one previous low uterine segment cesarean who had delivered a cephalic singleton infant at gestational age 34 weeks or more from January 2000 through May 2005. Our policy is to encourage such women to undergo a trial of labor unless cesarean delivery is indicated. Unless otherwise indicated, our policy is to wait for spontaneous labor. We do not use prostaglandins, and recommend cesarean delivery if the cervix is unripe (Bishop score < 6). We compared the outcome between women who underwent a trial of labor and women who underwent planned cesarean delivery.

**Results:** A trial of labor was attempted by 841 women (80% successful), and 467 underwent planned cesarean delivery. Uterine rupture was observed in one woman 18 hours after vaginal delivery. There was no difference in major or minor maternal morbidity. There was no serious neonatal morbidity. Among the planned cesarean patients, hospital stay was longer, and there were more admissions to the neonatal intensive care unit.

**Conclusion:** With our well-defined protocol, a trial of labor after cesarean seems to be as safe for the mother and infant as planned cesarean delivery, and the hospital stay is shorter.

Gonen R, et al. Results of a well-defined protocol for a trial of labor after prior cesarean delivery. *Obstet Gynecol.* 2006 Feb;107(2):240-5.

### OB/GYN CCC Editorial Comment

The Indian health system has just released a great new CME module on vaginal birth after cesarean delivery. The free online module offers many helpful resources for clinical management and public health decision making (e.g., should my facility provide VBAC?). The module highlights the Northern New

England Quality Improvement Network that has carefully looked at the literature and then applied it to clinical settings in New England. The CME/CEU module is available here at <http://www.ihs.gov/MedicalPrograms/MCH/M/VB01.cfm>.

*Northern New England Perinatal Quality Improvement Network risking system*

Low Risk Patient:

- One prior low transverse cesarean delivery
- Spontaneous onset labor
- No need for augmentation
- No repetitive FHR abnormalities
- Patients with a prior successful VBAC are especially low risk. (However, their risk status escalates the same as other low risk patients)

Medium Risk Patient:

- Induction of labor
- Pitocin augmentation
- Two or more prior low transverse cesarean deliveries. NB: "Two prior uterine scars and no vaginal deliveries" is listed as a circumstance under which trial of labor should not be attempted by the American College of Obstetricians and Gynecologists (ACOG Practice Bulletin No. 54, "Vaginal birth after previous cesarean delivery").
- < 18 months between prior cesarean delivery and current delivery

High Risk Patient:

- Repetitive non-reassuring FHR abnormalities not responsive to clinical intervention
- Bleeding suggestive of abruption
- Two hours without cervical change in the active phase despite adequate labor

Here is one suggested management system:

Low risk

- Notify pediatrics, anesthesia, and operating room crew of admission
- OB/GYN on campus during active phase
- Perinatal Guidelines of Care, ACOG, observed

Medium risk

- Notify Pediatrics, Anesthesia, and operating room crew of admission

- Operating room on campus in active phase or other plan if crew is busy

#### High risk

- OB/GYN, Anesthesia, and Pediatrics available
- No other acute care responsibilities
- Rapid decision to incision

#### Northern New England Perinatal Quality

#### Improvement Network:

<http://www.nnepqin.org/nneob/servlet/HomePage>.

Recommendations for TOLAC from the American Academy of Family Practice (TOLAC = trial of labor after cesarean delivery; VBAC = vaginal birth after cesarean delivery):

1. Women with one previous cesarean delivery with a low transverse incision are candidates for and should be offered a trial of labor. [SORT rating A].
2. Patients desiring TOLAC should be counseled that their chance for a successful VBAC is influenced by the following factors: [SORT rating B].
  - Positive factors (increased likelihood of successful VBAC):
    - o Maternal age less than 40 years
    - o Prior vaginal delivery (particularly prior successful VBAC)
    - o Favorable cervical factors
    - o Presence of spontaneous labor
    - o Nonrecurrent indication that was present for prior cesarean delivery
  - Negative factors (decreased likelihood of successful VBAC):
    - o Increased number of prior cesarean deliveries
    - o Gestational age greater than 40 weeks
    - o Birth weight greater than 4,000 g (8 lb, 13 oz)
    - o Induction or augmentation of labor
3. Prostaglandins should not be used for cervical ripening or labor induction, because their use is associated with higher rates of uterine rupture and decreased rates of successful vaginal delivery. [SORT rating B].
4. TOLAC should not be restricted to maternity care facilities with available surgical teams present throughout labor, because there is no evidence that these additional resources result in improved outcomes. [SORT rating C]. “Maternity care facilities” refers to birthing facilities with labor and delivery units that have the capacity to provide appropriate monitoring and to provide a timely cesarean delivery when needed. At the same time, it is clinically appropriate that a management plan for uterine rupture and other potential emergencies requiring rapid cesarean delivery should be

documented for each woman undergoing TOLAC. [SORT rating C].

5. Maternity care professionals need to explore all issues that may affect a woman’s decision (e.g., recovery time, safety). [SORT rating C]. No evidence-based recommendation can be made about the best way to present the risks and benefits of TOLAC to patients.

Adapted from Wall E, Roberts R, Deutchman M, Hueston W, Atwood LA, Ireland B. Trial of labor after cesarean (TOLAC), formerly trial of labor versus elective repeat cesarean delivery for the woman with a previous cesarean delivery.

The American Academy of Family Practice provides an evidence based approach to the trial of labor after cesarean. AAFP Recommendation # 4 is the most controversial: “TOLAC should not be restricted to facilities with surgical teams present throughout labor because there is no evidence that these additional resources result in improved outcomes. A management plan for uterine rupture and other potential emergencies requiring rapid cesarean section should be available and documented for each woman undergoing TOLAC. This recommendation differs from the current American College of Obstetrics and Gynecology (ACOG) guidelines and policy (grade C).”

#### AAFP Guidelines for TOLAC

Guidelines for TOLAC, based on patient-centered outcomes (morbidity, mortality, symptoms, cost, and quality of life), were developed by an AAFP Task Force and published on the AAFP Web site in July 2005. The guidelines apply to women with a history of one cesarean section and low transverse incision. The grade levels of the evidence used in the guidelines are as follows:

- Grade A: Good-quality studies with patient-oriented evidence
- Grade B: Inconsistent or limited patient-oriented evidence
- Grade C: Case series, consensus, usual practice or opinion

Seventy-six percent of women undergoing TOLAC are likely to succeed. Seven observational studies found a reduced success rate (63%) when induction with oxytocin or augmentation were used, and success was reduced even further to 51% if prostaglandins were used for induction. Risk for uterine rupture increased slightly with TOLAC when induction or augmentation were used.

Maternal death and infant mortality did not differ between TOLAC and repeated cesarean section. Infection rates were reported as higher with failed TOLAC than with repeated cesarean section (8% vs 3.5%). Risk for uterine rupture was estimated at 4.8 per 10,000 women with or without TOLAC. Risk for infant death from uterine rupture was reported at



1.5/100,000. There was no literature on quality-of-life issues related to VBAC.

Risk-assessment tools (two validated scoring systems were identified) were only partially useful in predicting successful vaginal delivery. Individual factors found to be associated with improved outcomes included demographic (younger than 40 years), delivery (spontaneous labor, nonrecurrent indication for delivery), medical (absence of diabetes) and cervical factors. Overall, teaching hospitals had a higher success rate with TOLAC than did community hospitals. The influence of TOLAC counseling on patient decision-making was unclear, as reported in one recent review. Dr. Wall suggested that additional factors to consider include perceived recovery time, presence of children at home, partner availability, perceived breastfeeding success, and safety.

### Future Research Agenda

Given the limitations of the existing literature, here are issues for a future research agenda:

- The definition of uterine rupture should be standardized. Definitions are currently inconsistent across studies. For example, uterine dehiscence is included within the definition for some studies, making comparisons across studies challenging.
- Validated instruments for measuring quality of life for mothers (including ability to care for the family after delivery) are not available. Long-term issues, such as pelvic floor function and, again, impact on families, are not considered.
- Development of decision support and shared decision-making tools is needed.
- Specific management plans appropriate for uterine rupture should be developed. It is not certain from the literature if more rapid intervention improves outcomes during labor.
- New technologies should be aimed at identifying women at high risk for TOLAC failure and should increase the ability to predict morbidity and uterine rupture (e.g., locating the placenta with imaging, or examining the thickness of the lower uterine wall).

### Subsequent Data

Vaginal delivery was attempted by 17,898 women, and 15,801 women had elective repeated cesarean delivery without labor. Symptomatic uterine rupture occurred in 124 women who underwent a trial of labor (0.7%). Hypoxic-ischemic encephalopathy occurred in no infants whose mothers underwent elective repeated cesarean delivery and in 12 infants born at term whose mothers underwent a trial of labor ( $P < .001$ ). Seven of these cases of hypoxic-ischemic encephalopathy followed uterine rupture (absolute risk, 0.46 per 1000 women at term undergoing a trial of labor), and two involved death of the infant.

The rate of endometritis was higher in women undergoing TOLAC than in women undergoing repeated elective cesarean

delivery (2.9% vs 1.8%), as was the rate of blood transfusion (1.7% vs 1.0%). The frequency of hysterectomy and of maternal death did not differ significantly between groups (0.2% vs 0.3%, and 0.02% vs 0.04%, respectively). The study concluded that TOLAC is associated with a greater perinatal risk than is elective repeated cesarean delivery without labor, although absolute risks are low. This information is relevant for counseling women about their options after cesarean section.

References are available upon request from [nmurphy@scf.cc](mailto:nmurphy@scf.cc).

### From Your Colleagues: Nancy Brannin, Santa Fe Oral Misoprostol for Cervical Priming in Non-Pregnant Women

I read about the misoprostol for hysteroscopy in the CCC Corner, and I wanted to pass along that the midwives on the ACNM clinical listserv just had a discussion about using it for two other purposes: 1) For IUD insertion in nulliparous women (including previous C/S but never dilated), one gives 400 mcg to take the night before the insertion, and it makes it much easier and less traumatic; and 2) EMBs, or even Paps, in postmenopausal women with stenotic cervices.

According to the authors, endometrial biopsy and hysteroscopy are important investigations in women presenting with abnormal vaginal bleeding. Endometrial biopsy is often performed as an outpatient procedure by endometrial aspiration. Difficulty in entering the internal cervical os may be encountered, especially in nulliparous women. The same problem may occur during hysteroscopy or dilatation and curettage. It is well known that use of a cervical priming agent is effective in reducing complications during cervical dilatation in pregnant women. However, its use in non-pregnant women is not well established. We compared oral misoprostol versus placebo for a cervical priming effect in non-pregnant women prior to hysteroscopy. The cumulative force required for cervical dilatation was significantly lower whereas the baseline cervical dilatation was significantly greater in the misoprostol group. We conclude that oral misoprostol is effective for pre-operative cervical dilatation in non-pregnant women.

Ngai SW, et al. Oral misoprostol for cervical priming in non-pregnant women. *Hum Reprod.* 1997 Nov;12(11):2373-5.

### Hot Topics: Obstetrics The Term Breech Trial Recommendations Should Be Re-Evaluated

*Results:* Most cases of neonatal death and morbidity in the term breech trial cannot be attributed to the mode of delivery. Moreover, analysis of outcome after two years has shown no difference between vaginal and abdominal deliveries of breech babies.

*Conclusion:* The original term breech trial recommendations should be withdrawn.

Glezerman M. Five years to the term breech trial: the rise and fall of a randomized controlled trial. *Am J Obstet Gynecol.* 2006 Jan;194(1):20-5.

## OB/GYN CCC Editorial Comment

This review joins a growing body of literature that raises serious questions about the Hannah term breech trial that concluded unequivocally that cesarean delivery was safer for breech babies. One of the major issues raised about the Hannah results was the short term nature of their follow-up. Other studies have shown outcomes after two years that show no difference between vaginal and abdominal deliveries of breech babies. We all need to critically follow this growing body of literature so that we can adequately counsel our patients.

## Gynecology Superiority of Liquid-Based Cytology for Cervical Screening Questioned

*Interpretation:* We saw no evidence that liquid-based cytology reduced the proportion of unsatisfactory slides, or detected more high-grade lesions in high-quality studies, than conventional cytology. This review does not lend support to claims of better performance by liquid-based cytology. Large randomised controlled trials are needed.

Davey E, et al. Effect of study design and quality on unsatisfactory rates, cytology classifications, and accuracy in liquid-based versus conventional cervical cytology: a systematic review. *Lancet*. 2006 Jan 14;367(9505):122-32.

## LEEP: Treatment of Cervical Neoplasia Linked to Preterm Births

*Conclusion:* Women with a history of LEEP, cold knife conization, and cryotherapy all independently have shorter cervical lengths than low-risk controls, and similar lengths to women with previous spontaneous preterm birth. Loop electrosurgical excision procedure and cold knife conization are associated with spontaneous preterm birth less than 37 weeks, and transvaginal ultrasonography predicts preterm birth in women who have had LEEP. *Level Of Evidence:* II-2.

Crane JM, et al. Transvaginal ultrasonography in the prediction of preterm birth after treatment for cervical intraepithelial neoplasia. *Obstet Gynecol*. 2006 Jan;107(1):37-44.

## OB/GYN CCC Editorial Comment

This is a recurrent finding. The CCC Corner has reported the same finding as recently as September 2004. To repeat, for young women, especially those who have not yet completed reproduction, LEEP may not be the best therapeutic option for treating CIN, especially of low malignant potential. Women who clearly require surgical intervention may be better served with other procedures, such as cryotherapy, or observation.

## Midwives Corner: Jenny Glifort, CNM and Marsha Tahquechi, CNM When Should We Clamp the Umbilical Cord? Preterm vs Term Infants

Philip and Saigal in their 2004 review article and in a 2004 Cochrane Review state that in 24 - 36 week infants, delaying cord clamping may be associated with fewer transfusions for

anemia or low blood pressure, and less intraventricular hemorrhage than early clamping. In addition, delayed clamping may help some infants in developing countries. On the other hand, delayed cord clamping should be avoided in infants of diabetic mothers, IUGR, and infants with cardiovascular or pulmonary conditions. In the majority of infants, e.g., near term and term infants, delayed clamping does not produce significant benefit/harm, but has been associated with unnecessary adverse effects in numerous small studies.

In addition, a 2005 Cochrane Review reported that in term patients, there does appear to be some potential benefit from the use of immediate placental cord drainage in terms of reducing the length of the third stage of labor. More research is required to investigate the impact of cord drainage on the management of the third stage of labor

## OB/GYN CCC Editorial comment

In June 2005, the CCC Corner previously reported fewer transfusions for anemia or low blood pressure, and less intraventricular hemorrhage in preterm infants with delayed cord clamping 30 -120 seconds. It should be noted that these findings and those reported by Philip and Saigal and the Cochrane Review are based on limited data, e.g., seven studies with 225 infants.

We should use caution in applying delayed cord clamping outside the setting of selected preterm infants. In addition, early cord clamping is associated with untoward effects in infants of diabetic mothers. Delayed cord clamping should not be applied universally, due to the lack of benefit in term, or near term infants. To further complicate the issue of delayed cord clamping, a second Cochrane Review reports potential maternal benefit from the use of placental cord drainage in terms of reducing the length of the third stage of labor.

I suggest we continue to follow the literature on this issue closely and apply delayed cord clamping only in the few selected preterm settings where clinically proven benefit has been documented.

### *Resources:*

June 2005 CCC Corner. Obstetric hot topics: slight delay in umbilical cord clamping better for preterm infants. [http://www.ihs.gov/MedicalPrograms/MCH/M/obgyn0605\\_HT.cfm#ob](http://www.ihs.gov/MedicalPrograms/MCH/M/obgyn0605_HT.cfm#ob).

Rabe H, Reynolds G, Diaz-Rossello J. Early versus delayed umbilical cord clamping in preterm infants. *The Cochrane Database of Systematic Reviews* 2004, Issue 4. Art. No.: CD003248.pub2. DOI: 10.1002/14651858.CD003248.pub2.

Soltani H, Dickinson F, Symonds I. Placental cord drainage after spontaneous vaginal delivery as part of the management of the third stage of labour. *The Cochrane Database of Systematic Reviews* 2005, Issue 4. Art. No.: CD004665.pub2. DOI: 10.1002/14651858.CD004665.pub2.

Philip and Saigal. When Should We Clamp the Umbilical Cord? *Neoreviews*.2004; 5: 142-154.

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## Liability in Triage: Management of EMTALA Regulations and Common Obstetric Risks

I am just following up on this topic from the December CCC Corner. The following information is paraphrased from Appendix D ACOG/AAP Guidelines for Perinatal Care, 5th Edition, pages 369-375.

Yes, in an EMTALA setting, a physician has to certify that a patient is in “false labor,” but a “qualified medical person” can sign that certification after consulting with a physician who authorizes the patient’s care. The physician must countersign the certification as contemporaneously as possible, e.g., 24 hours.

Further, it is the hospital that designates who is a “qualified medical person” to provide appropriate medical screening. The “qualified medical person” can be a non-physician, e.g., CNM, or RN, etc. If properly applied, a system of cooperation between the nurses, CNMs, and physicians can easily be devised and be in compliance with the EMTALA directives.

Adequate documentation is the key to success. Each facility should review the resources below. The L/D or triage team should come to agreement, and then implement a cohesive plan. In the meantime, the ACNM is working on changing the Federal regulations to allow CNMs to be able to diagnose “false labor” in EMTALA settings.

The ACNM is actively pursuing a revision of the above regulations. The Technical Advisory Committee met June 15 - 17, 2005. The Minutes reflect the ACNM proposed changes. The complete minutes can be found below, or contact Deanne Williams, Exec. Director, ACNM; or go to the Centers For Medicare and Medicaid Services website.

### Resources:

Midwives Corner, December 2005.  
[http://www.ihs.gov/MedicalPrograms/MCH/M/obgyn1205\\_Feat.cfm#MidWives](http://www.ihs.gov/MedicalPrograms/MCH/M/obgyn1205_Feat.cfm#MidWives).

Angelini DJ, Mahlmeister LR. Liability in triage: management of EMTALA regulations and common obstetric risks. *J Midwifery Womens Health*. 2005 Nov-Dec;50(6):472-8.

ACOG/AAP Guidelines for Perinatal Care, 5th Edition, pages 369-375, Appendix D. Contact ACOG’s Resource Center at (202) 863-2518.

## Injuries to the Brachial Plexus: Mechanisms and Management

The February Midwives Corner offers a follow up to last month’s shoulder dystocia column. Last month’s column focused on strategies to prevent shoulder dystocia. The “CCC deliver through maneuver” for shoulder dystocia prevention was also introduced.

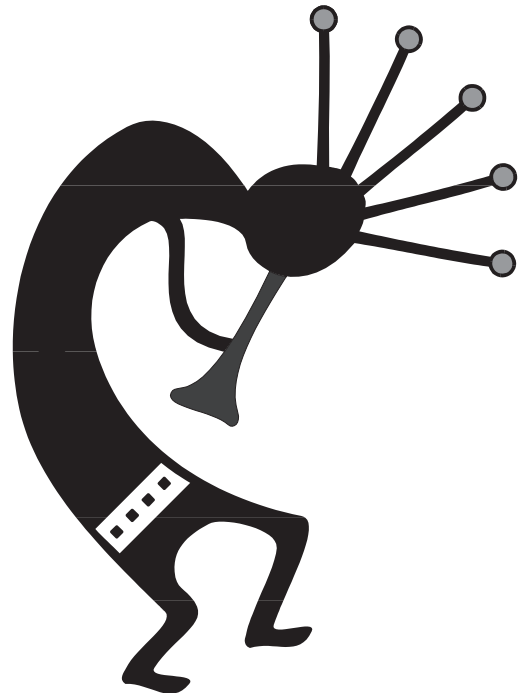
The following is an introduction to a two-part series on brachial plexus injuries that presents a comprehensive review of this complication of vaginal birth. Part 1 focuses on the fetal neuroanatomy and embryological development of the brachial plexus in relationship to the sequelae of physical disabilities

seen after an injury resulting from birth. Antenatal and intrapartum risk factors, as well as a classification of brachial plexus injuries are discussed.

Part 2 reviews the physical characteristics of brachial plexus injuries that result in the various palsies based on the severity of injury. Recommendations are made for the medical and nursing management of brachial plexus injuries and the long term outcomes for these infants.

Benjamin K. Part 1. Injuries to the brachial plexus: mechanisms of injury and identification of risk factors. *Adv Neonatal Care*. 2005 Aug;5(4):181-9.

Benjamin K. Part 2. Distinguishing physical characteristics and management of brachial plexus injuries. *Adv Neonatal Care*. 2005 Oct;5(5):240-51.



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This is a page for sharing “what works” as seen in the published literature, as well as what is being done at sites that care for American Indian/Alaskan Native children. If you have any suggestions, comments, or questions, please contact Steve Holve, MD, Chief Clinical Consultant in Pediatrics at [sholve@tcimc.ihs.gov](mailto:sholve@tcimc.ihs.gov).

## IHS Child Health Notes

### Quote of the month

“If you want to see what children can do, you must stop giving them things”

Norman Douglas

### Articles of Interest

Cardiovascular screening of student athletes. *Am Fam Physician*. 2000 Aug 15;62(4):765-74. <http://www.aafp.org/afp/20000815/765.html>

- Sudden cardiac death occurs in 1/200,00 high school athletes per year.
- The majority of sudden deaths are related to undiagnosed congenital cardiac anomalies such as hypertrophic cardiomyopathy (40%), coronary artery anomalies (20%), and increased cardiac mass (10%).
- Screening is problematic because of the low incidence and low risk of death: 200,000 athletes need to be screened to identify 1,000 with risk for sudden death for the 1 athlete who would die.
- Currently, there is no cost-effective battery of tests to identify all, or even most, of the dangerous cardiovascular conditions.
- Current consensus is to follow the 1996 screening guidelines of the Sudden Death Committee of the American Heart Association; these utilize a combination of personal history, family history, and cardiac exam.

Medical and legal issues in the cardiovascular evaluation of competitive athletes. *JAMA*. 2005 Dec 21;294(23):3011-8. [http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list\\_uids=16414949&query\\_hl=1&itool=pubmed\\_docsum](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=16414949&query_hl=1&itool=pubmed_docsum)

- Physician screening should adhere to the 1996 recommendations of the Sudden Death Committee of the American Heart Association.
- The recommendations state that pre-participation screening by history and exam is clinically justified but that routine non-invasive testing is not recommended due to the low yield and prohibitive cost.
- When cardiovascular abnormalities are identified or suspected, the athlete should be referred to a specialist for further evaluation. He/she should not be cleared until this evaluation is completed.

- Court decisions state that athletes can rightfully be disqualified from competitive sports if reasonable national guidelines are used.

### Editorial Comment

Despite a lack of compelling evidence to show that cardiovascular preparticipation screening is effective, it is recommended based on cost and medicolegal considerations and is required by nearly all high schools in the United States. While this method may be imperfect, the American Heart Association 1996 guidelines are considered the most practical and best available strategy for screening large populations of athletes. These guidelines have become the medical and legal standard for sports examinations in this country. The guidelines are listed in both articles. The American Family Physician article also has a sample physical exam and screening questionnaire that has become the standard form in many states.

One benefit of preparticipation sports exams is that physicians have an opportunity to evaluate and counsel adolescents who may not otherwise be seen for medical care. The sports exam is not intended to exclude athletes from participation but to maintain their health and safety. The exam should focus on ensuring the safety of the adolescent athlete and, to the extent possible, be used as an opportunity to counsel young athletes on the important health issues of adolescence.

### Infectious Disease Updates

#### Rosalyn Singleton, MD, MPH

RotaTeq™ (Rotavirus vaccine) newly licensed for infants.

The FDA just licensed a new Rotavirus vaccine, RotaTeq™ (Merck & Co., Inc.), to prevent severe gastroenteritis in infants. RotaTeq™ is a live, oral 3-dose vaccine to be given at 2, 4, and 6 months of age. The Advisory Committee on Immunization Practice is expected to decide on recommendations later this month.

Rotavirus causes an estimated 2.7 million episodes of gastroenteritis, 250,000 emergency room visits, and up to 55,000 hospitalizations per year in the United States. The licensure is based on a Phase III REST efficacy study, which involved 70,000 infants. RotaTeq™ prevented 98% of severe cases of vaccine-strain rotavirus and 98% of severe cases of any rotavirus strain. In addition, RotaTeq™ prevented 71% of rotavirus gastroenteritis of any severity. Unlike the ill-fated

RotaShield™ vaccine in 1999, RotaTeq™ was not associated with increased incidence of intussusception – there were 13 cases of intussusception in the vaccine group and 15 cases in placebo group.

### Editors Note

Rotateq is already approved for the Vaccine for Children Program that provides immunizations at no cost to AI/AN. However, as a practical matter, most states will probably not begin purchase of this vaccine until late summer or fall.

### Recent Literature on American Indian/Alaskan Native Health

#### Doug Esposito, MD

Race, genetics, and the biologic versus social determinants of health and health disparities.

The December 2005 issue of the *American Journal of Public Health* is devoted to exploring the controversial relationship between genes, race, and health disparities. This hotly debated issue is outlined in a collection of five articles, well worth study by anyone endeavoring to understand the basis for measured differences in health status of racially and ethnically distinct groups. What are the underlying determinants of health disparities? Are they a function of the inherent genetic makeup of groups and populations, or are they born out of socially imposed inequities and injustices in exposure and access to resources? This timely volume seeks to bring these issues into focus.

In “Bridging the Gaps between Race and Genetics,” Michael Fine calls into question the existence of substantive data supporting the presence of genetic or biologic determinants of racially derived health disparities. He contends that an ever increasing body of evidence to the contrary exists. “Although considerable time and energy have been devoted to understanding the associations between genes,

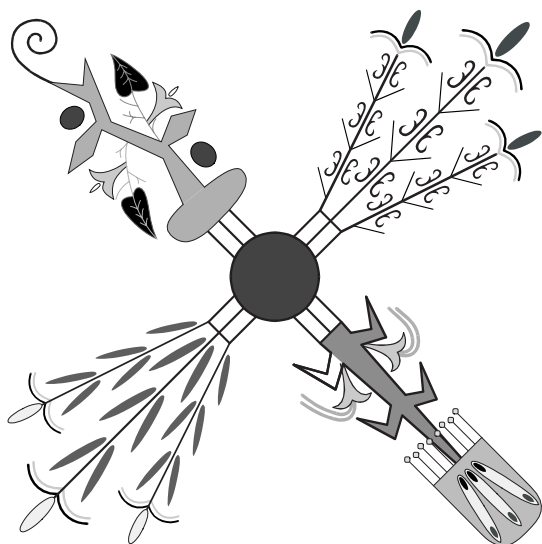
race, and health disparities over the past decade, there is currently abundant evidence that a multitude of other nonbiological, nongenetic factors contribute to health disparities. These well documented factors include diminished access to health care, low socioeconomic status, cultural preferences, low levels of health literacy, racial discrimination, poor doctor-patient communication, and environmental hazards and exposures. Despite the progress that has been made in understanding the genetic makeup of humans, genetics research does not yet have the capacity to explain or rectify observed racial disparities in health or health care. Thus, the jury remains out regarding the value of genes and genomics as tools for understanding and addressing health disparities.”

In their editorial “The Role of Race and Genetics in Health Disparities Research,” Fine, Ibrahim, and Thomas investigate the pros and cons of using a genetic definition of race in medical research. Central to the argument is whether race is a biologic, or conversely, a socio-cultural construct. It all boils down to how one uses genetic data and ethics/social justice to argue the case. Their contention is that insufficient evidence exists to support a genetic or biologic basis for race. Therefore, health disparities are more appropriately investigated and addressed through a thorough understanding of the interplay between environment, exposure, and access to resources as modulators of prevalence and outcomes of disease. Furthermore, they contend that there is no demonstrated role for “race-based genomics to reduce or eliminate such disparities.” On the contrary, they assert that such a view likely impedes progress toward the elimination of racial and ethnic health disparities.

In “Racializing Drug Design: Implications of Pharmacogenomics for Health Disparities,” Sandra Soo-Jin Lee, too, suggests the potential negative consequences of using a genetic/biologic definition of race on achieving health equity. His arguments are compelling as he points out that science’s continued attempts to strengthen the notion of a biologic basis for race likely will further strengthen “race as a naturalized, immutable biologic reality.” Or, in my own words, the medical and social institutionalization and ratification of biologically-based racism.

Thomas, *et al.* present a complex review of the ethical considerations of genomics in public health in “Genomics and the Public Health Code of Ethics.” Here, they lay out the differences and similarities between medical ethics and public health ethics. They then go on to define the ethical issues in genomics from both a medical and public health perspective. Most developed is a discussion of genomics and ethical concerns as they relate to the 12 principles of the Public Health Code of Ethics. A good article, but one I frankly had some trouble digesting!

Finally, Nancy Krieger eloquently argues in favor of considering race as a random concept born entirely out of historic and non-scientific fallacy in “Stormy Weather: Race,













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