

# CONGENITAL CARDIOLOGY TODAY

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## NEW AHA GUIDELINES FOR NUTRITION IN INFANTS, CHILDREN, AND ADOLESCENTS

By Samuel S. Gidding, MD

In 2005, the American Heart Association, with the endorsement of the American Academy of Pediatrics, updated cardiovascular nutrition guidelines for children.[1] The last such comprehensive nutrition overview was published in 1982. The purpose was to review the extensive literature published on the topic over the last 2 decades with particular attention paid to the current obesity epidemic, emerging research on the fetus and infant with respect to future cardiovascular disease, and important new research establishing the importance of a low cholesterol, low saturated fat diet in the management of elevated cholesterol. A critical feature of these guidelines is the inclusion of numerous tables designed to assist implementation of the recommendations; many are included in this synopsis and all are available on the American Heart Association website under scientific statements.

***“Though these guidelines are “new,” the recommended diet is not substantially different than that recommended in the very first American Heart Association Scientific Statement on this topic from the early 1960s and reemphasized over the ensuing decades”***

Though these guidelines are “new”, the recommended diet is not substantially different than that recommended in the very first American Heart Association Scientific Statement on this topic from the early 1960s and reemphasized over the ensuing decades. What is different is an emphasis on foods as opposed to “%s”, and recognizing that nutri-

tional value is inherent to specific nutrient dense foods as opposed to foods with little nutritional value other than as sources of calories (much fast food, sugar sweetened snack foods and soda, etc.). Emphasizing healthy food choices and portion size over elaborate calculations make the guidelines more user friendly and practical. Also new is the concept of discretionary calories, that is the number of calories left in the diet after you have consumed the food necessary to meet basic micronutrient requirements. Discretionary calories are tightly linked to daily energy expenditure. For the sedentary youth, there are actually only about 100 discretionary calories avail-

*Continued on Page 3*

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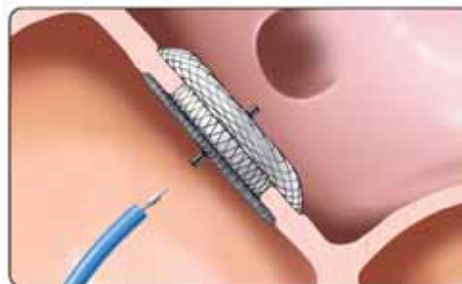
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able daily, that is 2 cookies, 8 oz. of soda, or less than half a candy bar. It is therefore, no surprise that today's inactive snack consuming child is tomorrow's high cardiovascular risk, insulin resistant adult.

Underlying the recommendations is the principle of primordial prevention, the prevention of the development of cardiovascular risk factors. Simple reflection will lead one to understand why children do not have advanced atherosclerosis; they generally do not smoke, do not have diabetes mellitus, participate in regular physical activity (at least until recently), and have blood pressure levels and lipid levels below thresholds associated with the cardiovascular risk (systolic blood pressure below 120 mmHg and LDL cholesterol below 110 mg/dl). The goal of primordial prevention is to maintain this low risk state. Whereas behavioral management is adjunctive therapy in adults with established risk factors, new research proves that most people never have to get these risk factors, or can at least control them if they maintain normal weight for height, get regular exercise, do not smoke, and eat properly. Since the early 1960s, the United States has halved its tobacco use rate, reduced passive smoke exposure more than 75%, and lowered serum cholesterol levels in adults from 240 mg/dl to

200 mg/dl. The obesity epidemic with concomitant decline in daily exercise threatens these trends.

### The Recommendations

Tables I and II provide the basic diet recommendations for children over 2 years of age as well as tips for implementation. The diet should rely on fruits and vegetables, whole grains, low fat and non-fat dairy products, beans, fish, and lean meat. A daily exercise recommendation of one hour of moderate level activity is included. Important differences between these recommendations and prior statements are the allowance of more liberal intakes of mono- and polyunsaturated fats as well as dietary sources of omega-3 fatty acids (e.g. the fat in fish) and emphases on specific foods that are nutrient dense while low in saturated fat, trans fats, and cholesterol. Limitation on the intake of sugar-sweetened beverages is strongly endorsed; infants over 4-6 months of age

**TABLE II. Tips for Parents to Implement AHA Pediatric Dietary Guidelines**

Reduce added sugars, including sugar-sweetened drinks and juices
Use canola, soybean, corn oil, safflower oil, or other unsaturated oils in place of solid fats during food preparation
Use recommended portion sizes on food labels when preparing and serving food
Use fresh, frozen, and canned vegetables and fruits and serve at every meal; be careful with added sauces and sugar
Introduce and regularly serve fish as an entrée
Remove the skin from poultry before eating
Use only lean cuts of meat and reduced-fat meat products
Limit high-calorie sauces such as Alfredo, cream sauces, cheese sauces, and hollandaise
Eat whole grain breads and cereals rather than refined products; read labels and ensure that "whole grain" is the first ingredient on the food label of these products
Eat more legumes (beans) and tofu in place of meat for some entrées
Breads, breakfast cereals, and prepared foods, including soups, may be high in salt and/or sugar; read food labels for content and choose high-fiber, low-salt/low-sugar alternatives

*This table was originally published as Table 2 in AHA's Scientific Statement, "Dietary Recommendations for Children and Adolescents A Guide for Practitioners—Consensus Statement From the American Heart Association -Endorsed by the American Academy of Pediatrics." See the end of this article for more detail.*

**TABLE I. AHA Pediatric Dietary Strategies for Individuals Aged >2 Years: Recommendations to All Patients and Families**

Balance dietary calories with physical activity to maintain normal growth
60 Minutes of moderate to vigorous play or physical activity daily
Eat vegetables and fruits daily, limit juice intake
Use vegetable oils and soft margarines low in saturated fat and trans fatty acids instead of butter or most other animal fats in the diet
Eat whole grain breads and cereals rather than refined grain products
Reduce the intake of sugar-sweetened beverages and foods
Use nonfat (skim) or low-fat milk and dairy products daily
Eat more fish, especially oily fish, broiled or baked
Reduce salt intake, including salt from processed foods

*This table was originally published as Table 1 in AHA's Scientific Statement, "Dietary Recommendations for Children and Adolescents A Guide for Practitioners—Consensus Statement From the American Heart Association -Endorsed by the American Academy of Pediatrics." See the end of this article for more detail.*

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should have no more than 4-6 ounces of real fruit juice a day and older children no more than 12 oz. (for those of you who cannot read between the lines that means virtually no soda, sports drinks, or other sugar-sweetened beverages).

The scientific basis for these recommendations is now strong. There are now 2 randomized controlled trials of dietary intervention in children: the DISC study which randomized over 600 8-11 year old boys and girls to either usual care or a low cholesterol, low saturated fat diet for 3 years and the STRIP study, a randomized diet intervention begun at 6 months of age in Finland. Both studies have shown beneficial results on lipid levels and established the safety of the recommended diets. There are now many meta-analyses of controlled diet interventions in adults showing efficacy of these recommendations for lowering cholesterol levels. There are numerous longitudinal studies showing the adverse impact on future risk of the acquisition of overweight and failure to participate in physical activity/having low levels of physical fitness.

**TABLE III. Parent, Guardian, and Caregiver Responsibilities for Children's Nutrition**

Choose breast-feeding for first nutrition; try to maintain for 12 months
Control when food is available and when it can be eaten (nutrient quality, portion size, snacking, regular meals)
Provide social context for eating behavior (family meals, role of food in social intercourse)
Teach about food and nutrition at the grocery store, when cooking meals
Counteract inaccurate information from the media and other influences
Teach other care providers (eg, daycare, babysitters) about what you want your children to eat
Serve as role models and lead by example; "do as I do" rather than "do as I say"
Promote and participate in regular daily physical activity

*This table was originally published as Table 5 in AHA's Scientific Statement, "Dietary Recommendations for Children and Adolescents A Guide for Practitioners—Consensus Statement From the American Heart Association -Endorsed by the American Academy of Pediatrics." See the end of this article for more detail.*

***"The guidelines review for the first time research on the earliest portion of life, from fetal life until about 2 years of age."***

There is a large gap between the current diets of children in the United States and these recommendations. Rather than belabor the obvious, I will just provide a few statistical jolts: one third of children <1 year of age have eaten French fries (the most popular vegetable in America with no close second), vegetable and fruit consumption actually declines from 1 to 2 years of age with one third of 19 to 24 month olds eating no fruit in a given day, and adolescents consume so much nutrient poor food that despite higher total caloric intake they do not meet minimum daily requirements for many micronutrients.

### Considerations for Specific Age Groups

Tables III, IV, and V (5, 6, and 7 in the document) discuss parent roles, the transition from weaning to table food, and strategies to get younger children to eat healthy. These tables provide strategies to use when counseling families about improving diet. A principle emphasized in the document and supported by current behavioral research is asking parents to teach children by engaging in the healthful activity themselves, that is "Do As I Do" as opposed to "Do As I Say". A second general principle is that children's foods are those that are nutritious. Snacks, sugar-sweetened drinks, sugar-

**TABLE IV. Improving Nutritional Quality After Weaning**

Maintain breast-feeding as the exclusive source of nutrition for the first 4-6 months of life
Delay the introduction of 100% juice until at least 6 months of age and limit to no more than 4-6 oz/d; juice should only be fed from a cup
Respond to satiety clues and do not overfeed; infants and young children can usually self-regulate total caloric intake; do not force children to finish meals if not hungry as they often vary caloric intake from meal to meal
Introduce healthy foods and continue offering if initially refused; do not introduce foods without overall nutritional value simply to provide calories

*This table was originally published as Table 6 in AHA's Scientific Statement, "Dietary Recommendations for Children and Adolescents A Guide for Practitioners—Consensus Statement From the American Heart Association -Endorsed by the American Academy of Pediatrics." See the end of this article for more detail.*



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sweetened cereals, and fast foods are discretionary only and NOT part of a regular diet. They exist to benefit their manufacturers, not children.

The guidelines review for the first time research on the earliest portion of life, from fetal life until about 2 years of age. There is now substantial emerging evidence that both the intrauterine environment and the first few months of life have an impact on future cardiovascular risk, though much remains to be learned. Important areas of research include impact of breast feeding on future risk, the development of taste preferences, the role of rate of early weight gain, and how eating behaviors are established. Tables III-V summarize much of this emerging science. Breastfeeding is emphasized for infants as the major source of nutrition. The transition from weaning to 2 years of age should be managed with the goal of providing nutrient dense foods as the major source of calories in the diet.

**TABLE V. Improving Nutrition in Young Children**

Parents choose meal times, not children
Provide a wide variety of nutrient-dense foods such as fruits and vegetables
instead of high-energy-density/nutrient-poor foods such as salty snacks, ice cream, fried foods, cookies, and sweetened beverages
Pay attention to portion size; serve portions appropriate for the child's size and age
Use nonfat or low-fat dairy products as sources of calcium and protein
Limit snacking during sedentary behavior or in response to boredom and particularly restrict use of sweet/sweetened beverages as snacks (eg, juice, soda, sports drinks)
Limit sedentary behaviors, with no more than 1 to 2 hours per day of video screen/television and no television sets in children's bedrooms
Allow self-regulation of total caloric intake in the presence of normal BMI or weight for height
Have regular family meals to promote social interaction and role model food-related behavior

*This table was originally published as Table 7 in AHA's Scientific Statement, "Dietary Recommendations for Children and Adolescents A Guide for Practitioners—Consensus Statement From the American Heart Association -Endorsed by the American Academy of Pediatrics." See the end of this article for more detail.*

As children get older, parental responsibility includes active role modeling for a healthy lifestyle. Peers, the media, and school assume increasing importance in shaping behavior. Interventions to improve nutrition thus require broader community based approaches as well as individual counseling.

### Therapeutic Life Style Changes

Table VI (10 in the document) provides consensus guidelines for the diagnosis of hypertension and dyslipidemia. Children with these disorders require diet counseling as part of their regular management. For hypertension the DASH program, available from the National Institutes of Health ([www.nih.gov](http://www.nih.gov))

**TABLE VI. Consensus Guidelines for Diagnosis of Hypertension and Dyslipidemia in Children**

Hypertension	Guideline
Prehypertension	Systolic or diastolic blood pressure >90th percentile for age and gender or 120/80 mm Hg, whichever is less
Stage 1 hypertension	Systolic or diastolic blood pressure >95th percentile for age and gender on 3 consecutive visits or 140/90 mm Hg, whichever is less
Stage 2 hypertension	Systolic or diastolic blood pressure >99th percentile + 5 mm Hg for age and gender or 160/110 mm Hg, whichever is less
Total cholesterol	
Borderline	≥170 mg/dL
Abnormal	≥200 mg/dL
LDL cholesterol	
Borderline	≥ 100 mg/dL
Abnormal	≥ 130 mg/dL
HDL cholesterol	
Abnormal	<40 mg/dL
Triglycerides	
Abnormal	≥200 mg/dL

*This table was originally published as Table 10 in AHA's Scientific Statement, "Dietary Recommendations for Children and Adolescents A Guide for Practitioners—Consensus Statement From the American Heart Association -Endorsed by the American Academy of Pediatrics." See the end of this article for more detail.*



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is a useful adjunct to the diet recommended herein. For those with elevated cholesterol, saturated fat and cholesterol intake should be restricted to <7% of total caloric intake and 200 mg/dl/day respectively.

### Final Thoughts

Physicians are perceived as the most reliable carriers of the health message. Therefore, we need to provide leadership not just in the office when communicating health information to individual patients, but in the community as well. We must provide the community with more than scientific research and clinical care. We must be effective advocates for good cardiovascular nutrition. If we do not assume this role, who will?

### Reference

1. Gidding SS, Dennison BA, Birch LL, Daniels SR, Gilman MW, Lichtenstein AH, Ratty KT, Steinberger J, Stettler N and Van Horn L. Dietary Recommendations for Children and Adolescents. *Circulation* 2005;112:2061-75.

~CCT~

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**Dietary Recommendations for  
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A Guide for Practitioners  
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**American Heart Association**

*Endorsed by*

*the American Academy of Pediatrics*

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(*Circulation*. 2005; 112:2061-2075)

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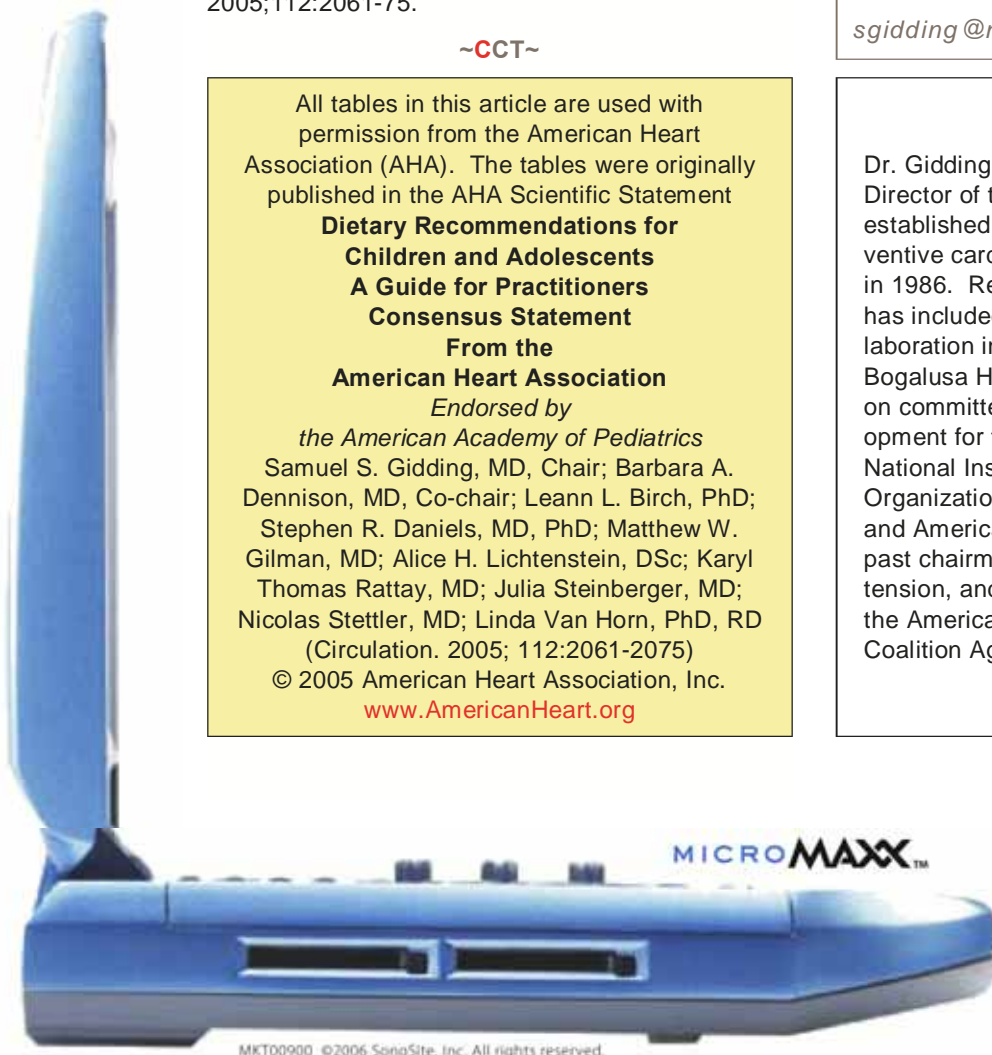
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Dr. Gidding is currently Outreach Services Director of the Nemours Cardiac Center. He established one of the earliest Pediatric preventive cardiology clinics in the United States in 1986. Research in preventive cardiology has included his own studies as well as collaboration in the DISC, CARDIA, PDAY, and Bogalusa Heart studies. He has participated on committee work/ consensus guideline development for the American Heart Association, National Institutes of Health, World Health Organization, American College of Cardiology, and American Diabetes Association, and is a past chairman of the Atherosclerosis, Hypertension, and Obesity in Youth subcommittee of the American Heart Association and Illinois Coalition Against Tobacco.



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## PEDIATRIC CARDIOLOGY IN IRAQ

By Kirk A. Milhoan, MD, PhD

As a volunteer pediatric cardiologist with the non-profit organizations For Hearts and Souls ([www.forheartsandsouls.org](http://www.forheartsandsouls.org)) and Samaritan's Purse's Children's Heart Project ([www.samaritan.org](http://www.samaritan.org)), I have screened children with congenital heart disease (CHD) in Mongolia, Kosovo, Uzbekistan, Mexico, Tibet, and Sudan. When I learned that I would be deployed to Iraq as a United States Air Force flight surgeon with the 332nd Aerospace Medicine Expeditionary Squadron, my hope was to be able to perform similar screenings there.

During the four months I was stationed at Balad Air Base, I was only able to see two children from the local community that had a diagnosis of congenital heart disease. The first child was a very cyanotic 7-month-old infant with unrepaired Tetralogy of Fallot and pulmonary atresia who, unfortunately, died two months after I saw her and the second child was an operable child with Tetralogy of Fallot. Toward the end of my tour of duty, my hope to see more children was fulfilled when I was invited by the Iraqi Ministry of Health and the National Iraqi Assistance Center (NIAC) to do a large-scale screening of children with known congenital heart disease to determine eligibility for surgical repair.

I was originally invited to screen at the Al-Bitar Cardiology Hospital in Baghdad, where all pediatric cardiac surgeries in Iraq are performed. However, due to the previous targeting of aid workers for abduction, Multi-National Force Iraq wanted the screening to take place

within the international zone in Baghdad. This allowed me to screen the children at the NIAC building, where patients are evaluated for medical care that requires referral out of Iraq. As I will explain later, this made it safer for me but more difficult for the locals.

---

***"As I started screening, I realized that the children they had for evaluation were some of the sickest children with the most complex heart disease."***

---

I was able to evaluate 57 children in two days. The evaluation included an exam with vitals, an ECG and, an echocardiogram. I had an Acuson Cypress and one medical tech, MSgt Antonio Rita, to assist me in evaluation. A number of Iraqi doctors were also present to help with translation and to observe the examinations and echocardiograms. The children came from a pool of about 1000 children known by the NIAC to have congenital heart lesions that could not be operated on in Iraq.

I thought that I would see many children with relatively benign disease, e.g., atrial septal defects and restrictive ventricular septal defects. As I started screening, I realized that the children they had for evaluation were some of the sickest children with the most complex heart disease. Of the 57 children I saw, 27 needed and could receive surgical repair without any further studies. There were 21 children who, due to the complexity of their disease and/or their age of presentation, would

require a cardiac catheterization prior to deciding whether surgical intervention was appropriate. There were six children who were poor surgical candidates and three children who did not need any intervention. The defects that I saw have been included in Table 1.

I was very impressed with the knowledge, professionalism, and diagnostic skills of the local Iraqi physicians. During the screening, I was able to talk with the Chief Physician and the Chief of Pediatric Cardiology from the Al-Bitar Cardiology Hospital about the state of congenital heart care in Iraq. The main problem with the provision of congenital heart care in Iraq is not from a physician training or ability standpoint, but rather from a limitation of equipment and supplies. Shortly after the fall of Saddam Hussein, many of the governmental hospitals, including the Al-Bitar Hospital, were looted, leaving them unable to perform even the most basic of services previously provided. Many Non-Governmental Organizations (NGOs) came in after stabilization and started helping to refurbish the hospitals. However, once aid workers started being abducted, most of the NGOs pulled their staff from Iraq. The US military hospitals often take care of emergency Iraqi civilian cases, but are not designed to care for children with complex congenital heart disease. The Iraqi surgeons are willing to do most pediatric cardiac operations except on the very young or very small, repairs requiring conduits, or complex multi-staged procedures, e.g., single ventricle palliation. I do not think that we will need to assist the Iraqi physicians and their patients for very long. Their motivation and the desire of the international health com-



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Table 1

Defect	Surgical Candidate	Diagnostic Catheterization Needed	Poor Surgical Candidate	No Surgical Intervention Needed
Restrictive VSD				2
Restrictive VSD, AI	1			
TOF s/p repair				1
DORV unobstructed pulmonary blood flow			2	
Tricuspid atresia, VSD, pulmonary atresia		1		
Unrestrictive VSD			2	
d-TGA, VSD unobstructed pulmonary blood flow		1	1	
DORV, mitral atresia			1	
d-TGA, IVS, s/p rashkind	4			
TOF	7			
Secundum ASD	1			
TOF s/p repair with RVOT obstruction	1			
DORV, PS	1			
l-TGA, VSD, PS	2			
VSD, moderate	1	1		
TOF, PA		8		
d-TGA, VSD and PS	1	3		
RHD, Mitral stenosis	1			
Coarctation of Aorta	1			
Sub AS, AS, and coarctation of the aorta	1			
TOF absent pulmonary valve	1			
DORV, hypoplastic LV		2		
Unbalanced AVC with LV hypoplasia, d-TGA and PS		1		
DORV, Taussig-Bing, Coarctation	1			
Complete AVC with pulmonary atresia		1		
DORV, pulmonary atresia		2		
Primum ASD	2			
Cyanosis with Pulmonary AVMs		1		

munity to bring Iraqi medical care to world class standards is very strong.

My experience was very rewarding and humbling as I was able to provide some degree of hope in the midst of a very difficult and dangerous transition in Iraq's history. Through the work of the non-profit organization Gift of Life, five children from the screening have already come to the US, been repaired, and returned to Iraq. Many more should be coming soon with the help of other non-profit organizations that specialize in finding care for children with congenital heart disease. After I had finished the screening, I was humbled to find out that for the parents to bring the children into the International Zone put their families at risk, as the insurgents often target those Iraqis that come and go through the International Zone checkpoint. In all my previous travels, I have seen many parents suffer much hardship and raise amazing amounts of money for their children to receive heart surgery. This was the first time I witnessed parents risking their very lives to save their broken-hearted children. I hope to return.

~CCT~



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## A PEDIHEARTNET PRIMER

By Laura Birek

PediHeartNet is an internet based mailing list exclusively for health care professionals involved in the treatment and care of children with heart disease. With over 2000 members, it provides a virtual meeting place for cardiologists, cardiac surgeons, and other medical professionals from over 60 countries.



Initially called PediHeart, the service was renamed PediHeartNet to differentiate from other entities that started to use its name. It has been a tool for quick and efficient information exchange on an extensive range of topics. The PediHeartNet mailing list was created by Drs. Adam Birek, a pediatric intensivist and anesthesiologist, and Kenneth Jue, a pediatric cardiologist at Children's Hospital Central California (formerly Valley Children's Hospital). As membership grew, PediHeartNet became an important forum for the exchange of ideas within the pediatric cardiology community. So far nearly 20,000 messages have been posted. Surveys and studies have suggested that PediHeartNet has a positive influence on clinical practice, that the quality of discussions is high and it is representative of the current thinking in Pediatric Cardiology and Cardiac Surgery.

With one simple email, members can immediately reach over 2000 medical

professionals. The most common topics of discussion are related to congenital and acquired heart disease. PediHeartNet has also been used to find specialists for patients moving to remote locations, to advertise training and job opportunities and for meeting announcements.

PediHeartNet is, and always has been, a free service relying on volunteer work plus support from UCSF-Fresno Medical Education Program, Children's Hospital Central California, and Springer-Verlag New York, the publishers of the Journal of Pediatric Cardiology.

PediHeartNet ran uninterrupted from 1994 to 2005. In December 2005, the server failed, and 11 years of continuous service was stalled until PediHeartNet was resurrected on January 9, 2006. Now, PediHeartNet is back up and running. However, it is possible some members may have been dropped inadvertently. If you were a member, but no longer receive PediHeartNet emails, you may sign up for a membership at [www.pediheart.net/howto.html](http://www.pediheart.net/howto.html). To join or learn more about PediHeartNet, please visit [www.pediheart.net](http://www.pediheart.net).

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## MEDICAL CONFERENCES

**Cardiology in Neonates and Infants**  
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[www.rbht.nhs.uk/cardiacMorphology](http://www.rbht.nhs.uk/cardiacMorphology)

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# USEFULNESS OF INTRA-OPERATIVE TRANSESOPHAGEAL ECHOCARDIOGRAPHY IN ASSESSMENT OF BIAURICULAR MYXOMA

By Javier Ozores Suarez, MD; Luis Bravo Pérez de Ordaz, MD; Alexander Gonzalez Guillen, MD

## Introduction

Primary cardiac tumors are rare lesions with an estimated incidence at necropsy ranging from 0.001% to 0.3%.[1] Myxomas represent less than 1.0% of all cardiac surgery cases[2], but they are the most common primary cardiac neoplasms, accounting from 30%[3] to 50% [4] of all primary cardiac tumors. The left atrium[4] is the site where they are most often discovered (85%), followed by the right atrium (7.4 %). Multiple locations occur in about 5 % of cases[5]. Biatrial myxomas are extremely rare, comprising only from 1.6 % [6] to 2.5 % [2] of cardiac myxomas.

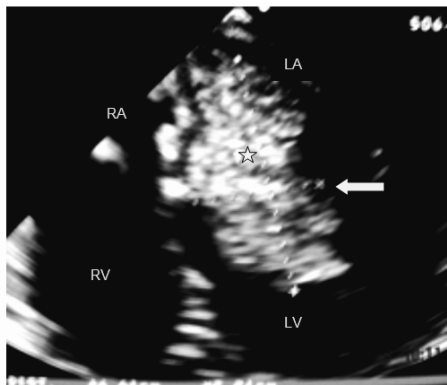


Figure 1. Transverse plane. Four chamber view. A big mass in the right atrium prolapsing into the left ventricle in diastole.

Tumor (star), Mitral valve plane (arrow), RA: Right Atrium, RV: Right Ventricle, LA: Left Atrium, LV: Left Ventricle.

The first echocardiographic diagnosis of an intracardiac tumor was made in 1959 [7]. Ten years later, the Mayo Clinic published an article entitled "Echocardiographic diagnosis of left atrial myxoma"[8] Today, echocardiography, especially transesophageal echocardiography (TEE), is the diagnostic procedure of choice for detecting and characterizing cardiac masses[3].

The aim of this paper is to describe the usefulness of intra-operative transesophageal echocardiography in assessment of multiple myxomas.



Figure 2. Longitudinal Plane. Mid-esophageal bicaval view. Tumor masses in both atria.

AI: Left Atrium, AD: Right Atrium, T: Tumors, VCS: Superior Vena Cava.

## Clinical Case

A 14-year-old girl was referred from her community doctor after detection of a cardiac murmur. She gave a history of progressively worsening fatigue and loss of appetite of 6 weeks duration. On



Figure 3. Longitudinal Plane. Mid-esophageal two-chamber view. The leaflets of the mitral valve are free of the left-sided tumor.

VI: Left Ventricle, VM: Anterior leaflet of Mitral Valve, T: Tumor.

examination all peripheral pulses were easily palpable, the right brachial blood pressure was 120/80 mmHg and the left brachial blood pressure was 130/80. Auscultation revealed a loud S1 and normal splitting of the second heart sound (S2), a loud P2, and a mid-diastolic rumble at the apex. The lungs revealed normal vesicular breathing.

Baseline investigations included hemoglobin 10g/dl, erythrocyte sedimentation rate (ESR) 105 mm in the 1st hour, and leucocytosis. Other markers of inflammation [C-reactive protein (CRP), anti-nuclear antibody (ANA) and rheumatoid factor (RF)] were negative. Chest X-ray showed a normal cardiothoracic ratio (0.50) and no pulmonary venous hypertension. On transthoracic echocardiography (TTE), both atrium and ventricles were within normal size. Contractil-



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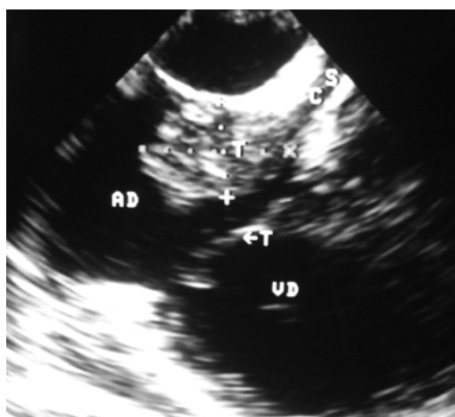


Figure 4. Transverse Plane. Modified four chamber view. Coronary Sinus drainage and the tricuspid valve are free of the tumor

AD: Right Atrium, VD: Right Ventricle, SC: Coronary Sinus, T: right sided tumor.



Figure 5. Tumors. Resection include the pedicle insertion place in the inter-atrial septum (arrows).

ity was also normal. The left atrium showed a pedunculated large tumor mass 15x45 mm in size, 0.62 area mass/ left atrium relation, attached to the inter-atrial septum. It was mobile and prolapsed across the mitral valve into the left ventricle (LV) during diastole and involved the anterior leaflet of the mitral valve. The mitral valve gradient was 10 mmHg mean. The right atrium contained a smaller pedunculated mass, measuring 19 x 16 mm, which involved the septal leaflet of the tricuspid valve. There was a 0.35 area mass/ left atrium relation and a gradient 5.7mmHg media across the tricuspid valve.

In the operating room, prior to surgery, TEE was performed with an Aloka machine and a biplane 8 mm diameter transducer.

In the transverse plane, mid-esophageal four chamber view, it was possible to see a left-sided mass measuring 2.3 x 1.3 cm which prolapsed in diastole into the left ventricle (Figure 1). The mid-

esophageal bicaval view (Figure 2) showed both atria have tumor masses: the right atrial mass (0.7 x 0.6 cm) was far away from the superior vena cava, and the left atrial mass was attached to the inter-atrial septum with a broad base of 0.5 cm. The mid- esophageal, two-chamber view demonstrated that the leaflets of the mitral valve were free of tumor (Figure 3). Finally, the coronary sinus drainage and the tricuspid valve were free of tumor as shown in Figure 4.

During the operation, standard aortic and bi-caval cannulation was performed. Cardiopulmonary bypass was established and the patient cooled to 31°C. After opening the heart, the left atrial tumor (2.1 x 1.1 x 0.8 cm) and the right atrial tumor (0.8 x 0.7 x 0.5 cm) were excised uneventfully (Figure 5), the atrial septal defect resulting from their resection closed with an autologous pericardium patch. After the patient was weaned from by-pass TEE examination showed no residual tumour, no inter-

atrial shunting and no valvular dysfunction.

The patient made an unremarkable recovery. She was in the intensive care unit for 16 hours and discharged from the hospital in four days.

Pathologic examination of the lesions confirmed a benign myxoma (Figure 6).

After 17 months, the patient remained asymptomatic with no residual tumor seen on echocardiography.

## Discussion

Due to the relative rarity of biatrial myxoma, there are few opportunities to see this disease. In our case, previous TTE showed a complex mass. Intra-operative TEE allowed us to assess and provide precise information about the size, shape, attachment, and mobility of these tumours, leading the surgeon to a safe and precise resection of the masses. Post resection, TEE allowed us to immediately confirm the success of the surgery. This case re-

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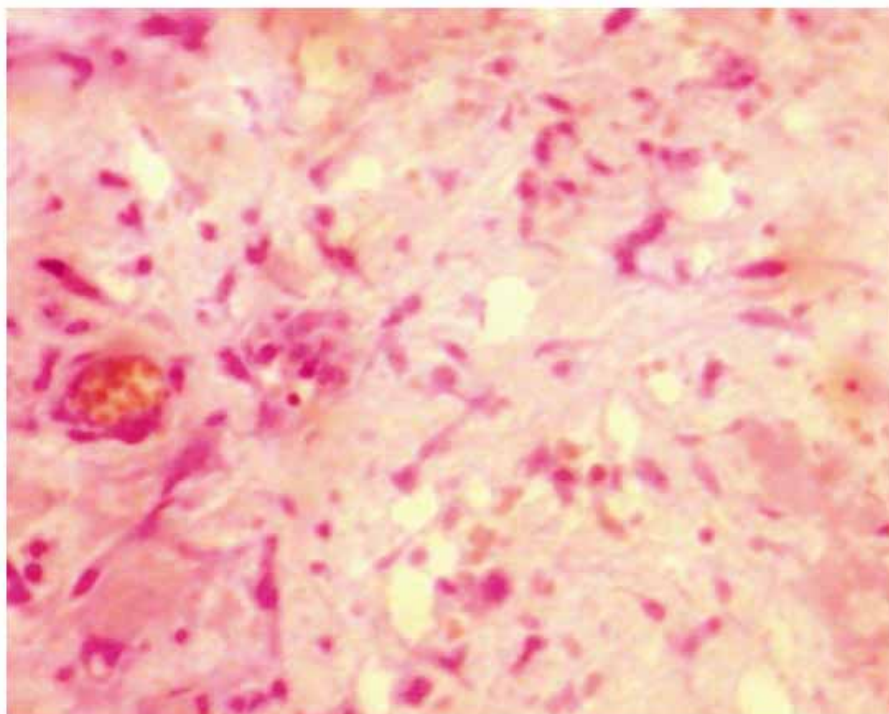


Figure 6. Photomicrograph of the stained sections of the myxoma showing the irregular stellate-shaped cells, histiocytes and vascular proliferation in a myxoid background (magnification H/E x 400).

emphasizes the importance of the use of intra-operative TEE and the need for careful visualization of all cardiac chambers in patients suspected of having a cardiac myxoma. These tumors may be multi-focal and complex.

With complete resection, the recurrence rates are less than 5%[9]. Recurrence has usually occurred within a 48-month period[10]. Patients should be followed up with serial echocardiography.

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**TO: Physicians Implanting the AMPLATZER® Septal Occluder**  
**FROM: Franck Gougeon, President/CEO, AGA Medical Corporation**  
**DATE: 2 January 2006**  
**SUBJECT: Hemodynamic Compromise with the AMPLATZER® Septal Occluder Importance of Proper Balloon Sizing Techniques**

This Tech Note is being reprinted by Congenital Cardiology Today to assist the pediatric cardiology community. Please contact AGA for an original copy of this Tech Note and any updates that may apply.

The purpose of this Tech Note is to draw your attention to a very important issue. There have been reports of tissue erosion associated with the use of the AMPLATZER Septal Occluder ("ASO"). This Tech Note will present the facts and offer recommendations to mitigate the risk of this remote, but nonetheless very serious, complication.

#### **Summary: Mechanism of Erosion**

- In the majority of patients suitable for ASO implantation, the anterior/superior atrial free wall (right or left) is in close contact with the device edge(s), especially with aortic/superior rim.
- If the ASO is not oversized compared with the native (static) diameter of the defect as determined by echocardiography, the device will re-adjust during normal cardiac function.
- If the device is oversized, the aorta compresses the waist (not the discs) which stretches the atrial free wall over the device discs, and the device edge may erode the free wall/aorta causing Hemodynamic Compromise.
- All adjudicated erosions occurred at the superior/anterior and aortic rim areas.

#### **Summary: Mitigating Erosion**

- Erosion is unlikely to occur if the diameter of the ASO device implanted is <1.5 times the native (static) diameter of the defect.

#### **Regulatory History**

The first adverse event was reported in 1998, three years after the introduction of the ASO. However, it was not until 2004 that a trend could be detected in the reports of Hemodynamic Compromise[1].

AGA Medical voluntarily convened a Review Board[2] to analyze all reports of Hemodynamic Compromise. The Review Board met for the first time in September 2002, and has met at least annually thereafter. The Review Board was given access to AGA Medical's internal files as well as all information AGA Medical had received from the physicians reporting the complaint (e.g., pre-procedure, procedure and post-procedure echocardiograms, catheterization lab reports, and surgical reports). At the March 2004 meeting, the Review Board concluded that there were enough patients (28 - worldwide) to detect a trend in the cases; that trend was oversizing in the presence of patients with deficient aortic and supe-

rior rims. The Review Board published a paper with their findings; a copy of which is attached for your reference.

#### **Incidence Rate**

To date, more than 97,000 ASO devices have been shipped worldwide. Because tracking is not required, AGA Medical can only estimate the number of ASO devices implanted. AGA Medical's current estimate of implanted devices is approximately 80,000 worldwide. AGA Medical tracks ASO implantation based on the number of implant registration cards (IRF) being returned to the company. IRFs are included in each ASO package. Physicians are strongly encouraged to return the IRF for each implanted ASO to AGA Medical so that a permanent patient ID card can be issued and the patient information logged in the company's registry.

Of the more than 97,000 ASO devices shipped, AGA Medical is able to confirm that approximately 35,000 have been implanted (number of IRFs returned to AGA to date). A total of 37 cases of Hemodynamic Compromise have been reported to date, 18 from overseas markets. The worldwide rate of Hemodynamic Compromise is therefore 0.11% or approximately 1 out of 1,000 confirmed ASO implants.

To date, there have been four reported deaths associated with the use of the ASO device and Hemodynamic Compromise. Each death has been thoroughly reviewed by our panel of experts and adjudicated as device or non-device related. Device related deaths include one patient who went into cardiac arrest post ASO closure in the presence of gross device oversizing; a second patient experienced cardiac tamponade but access to the cath lab was compromised and the equipment needed to treat the patient was unavailable. Non-device related deaths include one sudden death patient and one patient who developed a cardiac tamponade post ASD closure attributed (during autopsy) to a wire perforation during cardiac catheterization.

#### **Trends (US Data)**

Since its introduction in the United States in December 2001, AGA Medical has received 15,900 IRFs (confirmed implants) and 19 cases of Hemodynamic Compromise have been reported. The Review Board has adjudicated 14 cases as device related, 1 as non-device related and 4 as unknown.

The US rate of Hemodynamic Compromise is, therefore, 0.12% or approximately 1 out of 1,000 confirmed ASO implants.

AGA Medical has determined that the incidence of Hemodynamic Compromise due to device erosion is related to device oversizing. The practice of device oversizing is strongly discouraged. The following data compares the mean diameters of implanted ASO devices during the US clinical trial versus



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those implanted after market release that have resulted in Hemodynamic Compromise.

Although the data shows identical mean native ASD diameters, the balloon stretched diameter in the hemodynamic compromise series is almost 4mm larger and the ratio between native ASD size and device selection is 1.76 (or approximately 30%) larger than during the US controlled trial.

	ASD Diameter	Stretched Diameter	Device Size Implanted	Ratio
Clinical Trial	12.8 mm	17.2 mm	17.7 mm	1.38
Hemodynamic Compromise	12.7 mm	20.9 mm	22.3 mm	1.76

Prior to the Amin, et al article being published, AGA Medical sponsored physicians to speak at various meetings and AGA symposiums on the risk of oversizing. Since the Amin, et al article was published the reported incidence of Hemodynamic Compromise has decreased significantly.

With proper adherence to our panel recommendation, we are hopeful that this very serious complication will be mitigated.

#### Steps to Mitigate Risk of Erosion

AGA Medical recommends changes to physician practice which have been incorporated into the ASO Instructions for Use as follows:

##### 1. Defect/Device Sizing

- The use of echocardiographic imaging is required. Do not inflate the balloon beyond the cessation of the shunt (i.e., stop flow) or the visualization of a small waist in the balloon. DO NOT OVERINFLATE.
- Do not select a device size >1.5 times the ASD diameter as determined by echocardiographic imaging prior to balloon sizing.

##### 2. Patient Selection

- Certain patients may be at higher risk for complications such as tissue erosion and device embolization. If higher risk patients have devices implanted, closer follow-up is warranted. Higher risk patients include the following:
- Patients with deformation of the device at the aortic root.
- Patients with high defects (minimal aortic and superior rims).
- Patients with IVC rim deficiency (risk of device embolization).

##### 3. Follow-up

- All patients should be kept overnight for observation. A transthoracic echocardiogram (TTE) should be performed prior to discharge.

- Patients with any observed small pericardial effusion following device implantation should be closely monitored with serial echocardiograms performed until resolution of the pericardial effusion.
- Higher risk patients should be followed more closely, including clinical follow-up with echocardiogram one (1) week following device implantation.

#### 4. Patient Education

Reports of Hemodynamic Compromise reported in the US			
Year	Number of Implants	Reports of HC*	Rate
1998-2001	1,063	1	.10%
12-05-2001 (FDA approval)	199	0	-
2002	2,993	7	.23%
2003	3,815	9	.24%
2004	3,973	1	.02%
2005	3,857	1	.02%
<b>Total</b>	<b>15,900</b>	<b>19</b>	<b>.12%</b>
*Reported the year the device was implanted, not the year the reported event occurred.			

Educate patients about the risk and need for echocardiography with symptoms (i.e., chest pain or shortness of breath). Patients should be instructed to go to the emergency room if they experience symptoms.

Please contact your US Field Clinical Specialist or distributor should you have any questions on this Tech Note.

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1. Hemodynamic Compromise is defined as any report of hemopericardium, cardiac tamponade, erosion, fistulae, puncture, hole, laceration, pleural effusion, tear, edema, pinhole, pericardial effusion, and fissure.
2. Review Board members: Zahid Amin, MD, University of Nebraska/Creighton University, John L. Bass, MD, University of Minnesota, John P. Cheatham, MD, Ohio State University, William L. Hellenbrand, MD, Columbia University College of Physicians and Surgeons, Ziyad M. Hijazi, MD, University of Chicago, and Charles S. Kleinman, MD, Columbia University College of Physicians and Surgeons.

Sincerely,

Franck Gougeon  
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## THE SOCIETY OF PEDIATRIC CARDIOVASCULAR NURSES ADDRESSES PROFESSIONAL EDUCATION AT ANNUAL MEETING

By Kerry Cook, RGN, RN

The Society of Pediatric Cardiovascular Nurses (SPCN) is an international organization of over 400 nurses. Every year, in conjunction with the American Heart Association Scientific Sessions, SPCN offers an educational meeting. Professional education is always a pertinent topic. At the November 12, 2005 meeting in Dallas, members learned of a national program being developed in the United Kingdom that would be offered to all professionals working within, or having links to pediatric cardiology and cardiac surgery. The modules will be 'e' based and, therefore, accessible to staff all over the country. Kerry Cook, one of the program creators, presented information about this educational plan. The following is a summary of this innovative approach.

### **National Paediatric Cardiothoracic Education Programme - An Interprofessional Pathway by Kerry Cook, RGN, RN (child), BA (Hons); ITEC Dip, ENB 160, PGDip**

Traditionally in the United Kingdom (UK), specialist education was uniprofessional, with specific post registration courses being offered to nurses and doctors, but little being offered for other professionals allied to health. Unfortunately, the two nationally recognised courses (English National Board 160) for nursing staff both disbanded over 4 years ago, leaving the speciality lacking in educational opportunities. This resulted in the evolution of a staff group that have been poorly supported from a formal educational perspective with a potential negative impact on the care of the child and family.

In 2002 the Paediatric Cardiac Nurses Association UK (PCNA) began conducting a review of the educational situation nationally, with the aim of developing a course that would meet the needs of the staff and the service, whilst contributing to the development of national standards of care. At the same time, several national documents were published that recom-

mended an interprofessional approach to continued professional development, particularly the Kennedy Report following the Bristol Royal Infirmary Inquiry (DoH, 2001), the National Health Service Plan (DoH, 2001), and more recently, the National Service Framework (DoH, 2004). A feasibility study also suggested that nursing staff working in paediatric cardiac units across the UK wanted a course that was interprofessional as well as accessible, flexible and nationally available. The PCNA, therefore, concluded that any course developed should be innovative in its approach, taking into account the professional and personal barriers to education that individuals experience.

The result has been the development of an interprofessional programme that will be offered via blended learning approaches incorporating e-based learning and video/web streaming of didactic theoretical sessions delivered by the experts in the field. The PCNA is working closely with Coventry University, the British Congenital Cardiac Association (BCCA), representing mainly medics and other professional groups allied to medicine, and with patient groups such as the Children's Heart Federation.

Coventry University, which has recently been awarded Centre of Excellence in Teaching and Learning (CETL) and has a Centre for Interprofessional e-learning (IpeL), (<http://corporate.coventry.ac.uk/cms/jsp/polopoly.jsp?d=1654&a=11719>), hence offers excellent opportunities for developing relevant e-based materials, such as web-based interactive patient journeys, which will be an integral part of the programme. These patient journeys assist individuals to learn interprofessionally, with, from, and about each other (Barr, 2002). Course attendees will be assigned to a 'virtual learning set', a group of professionals from a range of backgrounds that will complete activities 'virtually' wherever they choose to access the web pages.

The BCCA have been working towards a



Andrea Torzone, Nurse Practitioner (Children's Medical Center - Dallas, TX.), Kas Sheehan, Nurse Practitioner (All Children's Hospital - St. Petersburg, FL.), Kerry Cook, Senior Lecturer (Coventry University - United Kingdom), and Connie Cephus, Nurse Practitioner (Texas Children's Hospital - Houston, TX).

National Core Curriculum for the Specialist Registrars over the last 2-3 years in the format of expert lectures. These are currently accessible either 'live' or via video streaming on Friday afternoons or, at a later date, with a password via [www.cardiacmorphology.com](http://www.cardiacmorphology.com). It is envisaged that individuals accessing the interprofessional programme will be able to access these and other lectures prepared specifically by the experts. These lectures will contribute to the taught (didactic) element of the course.

It has been proposed that the first module will be offered at degree level and will cover core clinical skills including normal anatomy and physiology, clinical examination, electrocardiography, echocardiography, radiology and cardiopulmonary bypass, in an attempt to ensure that all professionals have a similar knowledge base that will underpin their clinical care delivery. Subsequent modules may be offered as part of a Post Graduate Certificate and will include all aspects of CHD from anatomy and physiology, morphology, and

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aetiology, and following the patient journey through to discharge. National workforce clinical competences are currently in the development stage with Skills for Health, the health sector skills council of the UK [www.skillsforhealth.org.uk](http://www.skillsforhealth.org.uk).

Although this programme has been developed primarily as a national interprofessional pathway, the aim of the presentation to the SPCN at the American Heart Association Scientific Sessions in Dallas, Texas in November 2005 was to scope for international interest. This is an exciting and innovative approach to paediatric cardiothoracic education that will undoubtedly challenge the traditional boundaries of interprofessional working and will hopefully assist in enhancing the quality of care received by the child and family during what should become a more streamlined journey.

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The Society of Pediatric Cardiovascular Nurses (SPCN) gratefully acknowledges that the 2005 annual meeting was sponsored by Texas Children's Hospital and Children's Medical Center – Dallas. For more information on SPCN, please go to [www.spcnonline.com](http://www.spcnonline.com) or contact President, Gwen Fosse, at: DeVos Children's Hospital MC#117, 100 Michigan NE, Grand Rapids, MI 49445; Phone: 616-391-1369; fax: 616-391-8848; [gwen.fosse@spectrum-health.org](mailto:gwen.fosse@spectrum-health.org).



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