

Pediatric Forum



A journal of The Children's Medical Center of Dayton

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of Dayton*

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Pediatric Forum

is produced for the professional staff and referring physicians of The Children's Medical Center of Dayton by the marketing communications department. The purpose of Pediatric Forum is to provide information and news about pediatric health care issues and to provide information about clinical services and management issues of Dayton Children's.

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Educational objectives

- Articles will review commonly encountered clinical conditions and provide updates in pediatric medical and surgical care.
- Each individual article will have activity-specific learning objectives.

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CHILDHOOD OBESITY AND SLEEP DISORDERS

3

Objectives

Following the completion of this article, the reader should be able to:

1. Provide an overview of obesity related sleep disorders.
2. Enumerate other medical conditions that may develop from obesity.
3. Suggest management approaches for obesity related sleep disorders.

AN EMERGING PROBLEM

There is an emerging epidemic of obesity in children and adolescents worldwide.¹ Between 1980 and 2000, the prevalence of childhood obesity doubled among 6- to 11-year olds and tripled among 12- to 17-year-old children in the United States.² It is a recognized risk factor for the development of many adverse health outcomes.

Evidence suggests that obesity is modestly associated with obstructive sleep apnea syndrome (OSAS) in young children but strongly associated with OSAS in older children. Children with OSAS who were thought to be underweight with adenotonsillar hypertrophy are increasingly replaced by many who are overweight. The rising prevalence of childhood obesity is believed to be accompanied by an increase in

the incidence of OSAS and other sleep disorders as well as type 2 diabetes mellitus and insulin resistance, systemic hypertension, dyslipidemia, atherosclerosis, ischemic heart disease, depression and poor quality of life. Obesity in childhood increases the risk of obesity in adulthood.

Obstructive sleep apnea is characterized by temporary but intermittent episodes of upper airway obstruction resulting in cessation of breathing or reduction in tidal volume in sleep. Sleep disordered breathing (SDB) is a continuum of events ranging from benign snoring to the most severe OSA. Snoring, hypoventilation, hypoxemia, leading to sleep fragmentation, poor sleep, excessive daytime sleepiness, potentially poor school performance in children, inattention, hyperactivity, mood problems and poor quality of life are associated with OSA.

Weight gain increases fat deposition around the pharynx resulting in upper airway narrowing and collapse during sleep contributing to the development of OSA. Intermittent hypoxemia may amplify the adverse effects of adiposity, systemic inflammation and metabolic states associated with vascular disease and diabetes.³ In general, there are no sexual differences in prevalence of pediatric OSA as seen in adult OSA.

Pediatric OSA affects roughly 13 percent of 3- to 6-year olds and 2 to 3 percent of middle-school normal children, largely due to enlarged tonsils and adenoids, allergies, asthma and craniofacial abnormalities. The prevalence is reported to be two to four times

higher in blacks, Hispanics, prematurely born children and those from poor neighborhoods.

The exact role obesity plays in the incidence of pediatric OSA has been debated among researchers. From a recent Chinese study of 90 children aged 7 to 11 years, OSAS was identified in 32.6 percent of overweight children, compared to only 4.5 percent who had normal weight. Data from the Cleveland Family Study of 4- to 18-year olds also indicated that obese children are at a 4.6 fold increased risk for sleep apnea than normal weight children. A single percentage change in body mass index (BMI) is estimated to increase apnea hypopneic index (AHI) by 3 percent and a 10 percent increase in BMI increases AHI sixfold. Not inversely, weight loss (although beneficial) does not result in a comparative decrease in AHI.

Obesity is also a contributing cause of the obesity hypoventilation syndrome (OHS) which is well recognized in obese children. Evidence suggests that it is under-recognized, under-treated and associated with a significant increase in mortality. Obesity, hypercapnia, hypoxemia and excessive daytime sleepiness without intrinsic pulmonary disease are characteristics of OHS.

Repeated episodes of nocturnal hypercapnia and hypoxemia result in attenuation of hypercapnic and hypoxic drives during wakefulness, ventilatory drive during sleep and poor chest wall compliance. Individual predisposition depending on carbon dioxide re-



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sponse and amount of stress may be responsible because not every obese person develops OHS.

Both OSA and OHS may mediate components of the association between obesity, metabolic and cardiovascular morbidities, most likely by potentiation of inflammatory cascades. Sleep-disordered breathing (SDB) is associated with insulin resistance and dyslipidemia in adults and obese children, and seems to be determined primarily by the degree of body adiposity rather than by the severity of SDB.

Sleep duration may be an important regulator of body weight and metabolism. There is a complex relationship between obesity and sleep duration. Lifestyle changes over the last few decades, such as excessive television, video games, cell phones and computers have resulted in sedentary activities with children sleeping for fewer hours. In a recent study, participants with short sleep had reduced leptin and elevated ghrelin.⁴ Leptin reduces appetite and ghrelin increases it, possibly explaining the increased BMI observed with short sleep duration. In Western societies, where chronic sleep restriction is common and food is widely available, changes in appetite regulatory hormones as a result of sleep reduction may contribute to obesity leading to other sleep disorders.

The decline in sleep duration has paralleled a dramatic increase in the prevalence of obesity and diabetes, indicating a link between decreased sleep duration and increased insulin resistance in obese children.⁵ In addition, they spend proportionally less time in

REM sleep during which glucose utilization is higher than during non-REM sleep thus suggesting decreased glucose utilization (i.e., increased insulin resistance) with short sleep duration. Effects of sleep apnea, such as excessive daytime sleepiness (EDS) may lead to reduced physical activity, low energy and mood problems. In the Wisconsin Sleep Cohort Study, increased BMI was observed in people who usually slept for less than six hours. Levels of total cholesterol, HDL-cholesterol, triglycerides and blood pressure were inversely associated with sleep duration in adults.

It has been shown that OSA is present in more than 50 percent of a population of adult obese patients with a mean BMI higher than 40, particularly in women. Nocturnal hypoventilation seems to be present in more than 29 percent of severely obese population. Moreover, this study indicated that morbid obesity can be associated with excessive daytime sleepiness, even in the absence of sleep apnea. Neck circumference in men and BMI in women seem to be the strongest predictors of the severity of OSA in obese patients. Such studies have not yet been reported in children. The problem is that obese children may not have sleep complaints, but have comparatively higher percentage of abnormal polysomnograms which improved after tonsillectomy and adenoidectomy.

The interplay between obesity and respiratory function has implications on pulmonary function, sleep disordered breathing and asthma. Obesity-associated GERD can also lead to airway

inflammation and asthma. Severe obesity can restrict lung functions in childhood, although the extent of obstructive airway disease due to obesity in childhood is not clear. OSA leads to poor quality sleep which is, in fact, sleep deprivation. Sleep deprivation, upper airway edema and systemic inflammation associated with OSA could complicate asthma. Obese children with asthma tend to have more symptoms of asthma; particularly obese girls, have a greater likelihood of developing asthma later in life. Recent studies have found obesity, which is a significant risk factor for both OSA and asthma, to be associated with a systemic low-grade state of inflammation.

PREVENTION AND TREATMENT

Obesity-associated disorders require a multidisciplinary approach involving parents, pediatricians and primary care physicians, geneticists, nutritionists, endocrinologists, sleep physicians, as well as the media to curtail it.

Once obesity is diagnosed, a continuing effort should be taken to reduce weight gain. Childhood obesity prevention should be focused on the population at risk to eliminate factors influencing its development from the viewpoint of preventive medicine because it increases the risk of obesity in adulthood. Eating habits and dietary practices have to be modified to include increased intake of fruits, vegetables and fiber, and reduction of high-carbohydrate or sugar-containing beverages. Outdoor activities should be encouraged so that children should

indulge less in sedentary activities such as television, video games and computers. If all of these efforts fail and sleep problems develop, then some treatment approaches may be considered, including adenotonsillectomy, continuous positive airway pressure (CPAP) and bariatric surgery for patients who qualify for such procedures.

Adenotonsillectomy (T&A) is the first approach to manage OSA in obese children when indicated. Even though T&A may cure or improve sleep-disordered breathing in both obese and non-obese children, the outcome in obese children is less satisfactory. Disease resolution occurred in 77.5 percent of non-obese and only in 45 percent of obese children who underwent T&A, implying obesity, at the time of diagnosis, has a higher risk for persistent OSA after T&A.⁶

The optimal treatment for obesity hypoventilation syndrome is weight loss, but for most patients, it is hard to achieve. It improves most of the physiologic derangements believed to be involved in the pathogenesis of OHS; about 10 percent loss may lead to normalization of daytime PaCO₂, improvement in vital capacity, central ventilatory drive and voluntary ventilation. For those who have concomitant OSA, it also reduces the degree of sleep-disordered breathing and improves oxygen desaturations. Continuous positive airway pressure and bilevel positive airway pressure are effective treatments in some individuals and those with daytime hypoxia need oxygen added to the CPAP.

Progesterone has been used in treatment of OHS. However, it does not improve apnea frequency or symptoms of sleepiness. Side effects include hyperglycemia and alopecia, but adverse effects of long-term use are not known.

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CME Questions

1. Clinical symptoms of obesity hypoventilation syndrome (OHS) may mimic those of obstructive sleep apnea.
 - a. True
 - b. False
2. Obesity is associated with OSA in older children.
 - a. Modestly
 - b. Strongly
 - c. Not
3. Obese children with OSA may benefit from adenotonsillectomy.
 - a. True
 - b. False
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Objectives

Following the completion of this article, the reader should be able to:

1. Review indications for booster doses of meningococcal-conjugate vaccine in children and adolescents.
2. Discuss the reasoning surrounding the development of a 13-valent pneumococcal conjugate vaccine.
3. Describe the rationale behind the "cocoon" strategy applied to immunization of individuals with Tetanus-diphtheria-acellular pertussis (Tdap) vaccine.

INTRODUCTION

New vaccine products and new vaccine recommendations have appeared with increasing frequency in the recent past. The development of immunizations against a greater number of pathogens has greatly expanded the vaccine schedule for children. Vaccines, however, are not solely indicated for young children, but are part of an integrated continuum across other age groups. This article will review current vaccine developments.

MENINGOCOCCAL-CONJUGATE VACCINE (MCV)

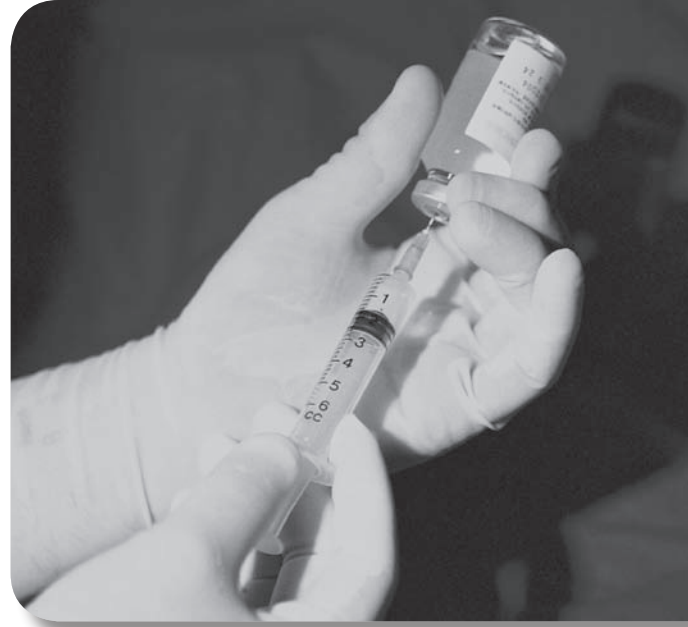
MCV has been recommended for adolescents aged 11 to 18 years (preferably at the 11 to 12 year preadolescent visit or for those entering high school). Either of two licensed vaccines can be used (minimum age 2 years for Menactra® and 11 years for Menveo®).

Based on October 2010 provisional recommendations from the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunizations Practices (ACIP), one should administer MCV at 11 to 12 years of age with a booster at age 16 years. The ACIP based this recom-

mendation on data indicating that protection conferred by MCV4 will wane in five years as opposed to the 10 years originally denoted by previous studies. For persons vaccinated at ages 13 to 15 years, administer a one-time booster dose five years after the first dose. Administer two doses of MCV at least eight weeks apart for children aged 2 to 10 years with persistent complement component deficiency and anatomic or functional asplenia, and one dose every five years thereafter. Persons with human immunodeficiency virus (HIV) infection should receive two doses of MCV at least eight weeks apart.

TETANUS TOXOID-REDUCED-DOSE DIPHTHERIA TOXOID-ACELLULAR PERTUSSIS VACCINE (TDAP)

For the past 60 years, there has been a dramatic decline in the incidence of pertussis in the United States. However, since 1990, there has been a 20-fold upsurge in the number of reported cases. The increase may be due to a variety of factors, including underimmunization of children, waning immunity in adolescents and young adults, administration of less antigenically potent childhood vaccines (DTaP) when compared to previous diphtheria-tetanus-pertussis (DTP) vaccines,



greater practitioner awareness of the disease in older age groups and improved diagnostic testing.

In California, more than 5,200 cases of pertussis during the first nine months of 2010 – the most reported in 60 years – have been reported. Adolescents and young adults account for the preponderance of cases. Such individuals may transmit infection to young infants. Children too young to have completed their primary vaccine series account for the majority of pertussis-related complications, hospitalizations and death. Approximately 60 percent of hospitalized cases were among infants less than 3 months of age. Of the nine reported deaths, eight were in infants less than 2 months of age. Commonly, the index case for the transmission of the organism is a family member, often a parent.

Practitioners should adopt a "cocoon" strategy that either vaccinates a mother immediately postpartum or the mother-to-be

in the second or third trimester if she has not been previously immunized. Other family members who will have contact with the infant after birth should also receive Tdap. Additionally, for the purposes of protecting the vulnerable young infant, adults aged older than 65 years who have or anticipate having a close contact with infants younger than 1 year (such as grandparents and health care providers) should receive a single dose of Tdap.

Tdap immunization is recommended at the 11-to 12-year visit. Children aged 7 to 10 years who are not fully immunized against pertussis should receive a single dose of Tdap. If additional doses of tetanus and diphtheria toxoids are necessary in children aged 7 to 10 years, refer to catch-up guidance available from the CDC. Tdap is preferred over the use of tetanus and diphtheria toxoid (Td) for wound management. Tdap can be administered regardless of the interval since the last tetanus and diphtheria containing vaccine.

PNEUMOCOCCAL VACCINE

Widespread heptavalent pneumococcal-conjugate vaccine (PCV7) use has remarkably reduced invasive pneumococcal infections (meningitis, bacteremia, pneumonia) and modestly reduced noninvasive disease (otitis media) due to vaccine strains (4, 6B, 9V, 14, 18C, 19F and 23F). However, infections caused by replacement strains have been increasingly reported. Serotype 19A, for example, was the most common isolate causing invasive pneumo-

coccal disease (IPD) among children in 2005.

A recently licensed 13-valent pneumococcal conjugate vaccine (PCV13) incorporates these emerging serotypes into its composition. The vaccine contains the pneumococcal polysaccharide capsular serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F. PCV13 is immunogenic with a safety profile comparable to PCV7.

Children aged 2 to 59 months should routinely be vaccinated with PCV13. A PCV series begun with PCV7 should be completed with PCV13. A single supplemental dose of PCV13 is recommended for all children aged 14 through 59 months who have received an age-appropriate series of PCV7. A single supplemental dose of PCV13 is recommended for all children aged 60 through 71 months with underlying medical conditions (asplenia, immunocompromising conditions and children with high risk conditions including cardiopulmonary disease, diabetes mellitus, cerebrospinal fluid leaks and those with cochlear implants) who have received an age-appropriate series of PCV7. The supplemental PCV13 dose should be administered at least eight weeks after the previous PCV7 dose.

INFLUENZA VACCINE

Annual influenza epidemics result in infections among persons in any age group. Rates of infection, however, are highest among children and rates of complications, hospitalizations and death highest in persons greater than 65 years, children less than 5 years and

persons of any age who have underlying medical conditions that increase the risk of complications from influenza. Influenza-related hospitalizations are substantially higher among children less than 2 years old compared with older children and similar to rates for other groups considered at higher risk for influenza-related complications (persons aged 2 to 64 years with chronic cardiopulmonary disorders, renal or hepatic dysfunction, diabetes mellitus; immunocompromised persons; pregnant women; those with conditions that compromise respiratory function or the handling of respiratory secretions; and older individuals over 65 years of age). During the H1N1 influenza pandemic, serious infection predominated among children and younger-aged adults, and resulted in serious illness among pregnant women. Importantly, children serve as very effective disseminators of influenza virus throughout the community.

The seasonal trivalent inactivated vaccine (TIV) and trivalent live attenuated influenza vaccine (LAIV) have both demonstrated efficacy and safety in adults and children. These vaccines given annually each contain influenza virus strains predicted to be prevalent in the upcoming influenza season, including influenza B types and influenza A subtypes. TIV contains inactivated virus, is administered by intramuscular injection and is approved for use in all children older than 6 months and in all adults. LAIV is given as a spray intranasally and is approved for persons aged 2 to 49 years. Persons at higher risk for complications of influenza infec-

tion because of underlying medical conditions should not receive LAIV. Children with a history of asthma should not receive LAIV.

All persons aged 6 months and older receive annual influenza vaccination. Since infants younger than 6 months of age cannot receive influenza vaccine, it is critical to immunize caregivers and household contacts of children in this very young age group. Protection of persons at higher risk of complications should continue to be a focus of efforts until routine universal vaccination of all persons less than 6 months old is achieved.

To attain optimal protection in young children, two doses of either TIV or LAIV vaccine separated by four or more weeks have been recommended for the first vaccination in those aged 6 months to 9 years who were previously unvaccinated with seasonal influenza vaccine. If a previously unvaccinated child in this age range received only a single seasonal vaccine in one year, then two doses are necessary for the following year. Only a single annual dose is recommended for children aged 9 to 18 years.

The emergence of a novel influenza virus in the H1N1 pandemic, however, resulted in modified recommendations for childhood vaccination for the 2010-2011 influenza season. For those 6 months to 8 years, two doses of the current vaccine are necessary for children who:

- ▶ Never received seasonal influenza vaccine before

- ▶ Were vaccinated for the first time in 2009-2010, but only received one dose
- ▶ Were previously vaccinated with seasonal influenza vaccine, but did not receive 2009 monovalent H1N1 vaccine

One dose may be administered to all others aged 6 months through 8 years.

HUMAN PAPILLOMA-VIRUS (HPV) VACCINE

A quadrivalent HPV vaccine HPV4 (Gardasil®) composed of HPV-11, -18, -6 and -11 virus-like particles and a bivalent HPV vaccine HPV2 (Cervarix®) containing HPV-16 and -18 virus-like particles are licensed for use in females. Both vaccines are highly efficacious against HPV 16- and 18-related cervical precancerous lesions. HPV4 also demonstrated high efficacy against HPV 6- and 11-related genital warts and HPV 16- and 18-related vaginal and vulvar precancerous lesions.

Routine vaccination with three doses of either vaccine is recommended for females aged 11 or 12 years and can be started at age 9 years. Ideally, vaccine should be administered before potential exposure to HPV through sexual contact. Vaccination is recommended for females aged 13 through 26 years who have not been vaccinated previously or who have not completed the three-dose series. Whenever feasible, the same HPV vaccine should be used for the entire vaccination series. If one does not know or have available the HPV vaccine previously administered, however, either HPV2 or HPV4 can be used to

complete the series to provide protection against HPV 16 and 18. For protection against HPV 6- or 11-related genital warts, a vaccination series with less than three doses of HPV4 might provide less protection against genital warts than a complete three-dose HPV4 series. It is important that vaccinated women continue with regular cervical cancer screening. HPV vaccines may be administered to immunocompromised individuals.

In 2010, HPV4 was licensed for administration to males aged 9 through 26 years to reduce their likelihood of acquiring genital warts caused by HPV types 6 and 11. Clinical trials documented efficacy in preventing genital warts and demonstrated an excellent safety profile. As with females, the vaccine is most effective when given before exposure to HPV through sexual contact.

CONCLUSION

We have progressed quite a distance in diminishing or almost eliminating the scourge of many vaccine-preventable diseases. One must be aware of these vaccine changes and additions, administer these effective tools in disease prevention, and educate the public on the importance of timely receipt of immunizations to prevent illness among both the pediatric population and other age groups.

Useful Immunization-related websites

- ▶ **Immunization Action Coalition**
<http://www.immunize.org>
- ▶ **CDC's immunization schedule for infants, children, adolescents, and adults**
<http://www.cdc.gov/vaccines/recs/schedules>
- ▶ **CDC's "Pink Book" – Epidemiology and Prevention of Vaccine-Preventable Diseases**
<http://www.cdc.gov/vaccines/pubs/pinkbook>
- ▶ **ACIP's "General Recommendations on Immunization"**
<http://www.cdc.gov/mmwr/PDF/rr/rr5515.pdf>
- ▶ **American Academy of Pediatrics Immunization Site**
<http://www.aap.org/immunization/>
- ▶ **Vaccine information Center, The Children's Hospital of Philadelphia**
<http://www.chop.edu/service/vaccine-education-center/home.html>
- ▶ **Institute for Vaccine Safety, Johns Hopkins Bloomberg School of Public Health**
<http://www.vaccinesafety.edu/>

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CME Questions

4. Booster doses of meningococcal-conjugate vaccine (MCV) for select individuals have been recently recommended. During a visit to your office today, who should receive a booster dose of MCV?
 - a. A 16-year-old girl who received her first dose of MCV at age 11 years.
 - b. A 10-year-old child with asthma.
 - c. An adolescent male with HIV-1 infection who received a dose of MCV three months ago.
 - d. A and C
 - e. All of the above

5. Immunization with Tetanus-diphtheria-acellular pertussis (Tdap) vaccine is indicated for which of the following individuals?
 - a. A respiratory therapist employed in a children's hospital.
 - b. A 68-year-old who plans to regularly visit his new twin grandchildren.
 - c. An 8-year-old child in a foster family who presents with records that note incomplete immunizations with most vaccines, including DTap (Diphtheria-Tetanus-acellular pertussis vaccine), when younger.
 - d. A and C
 - e. All of the above



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CHILDREN AND THEIR DEPLOYED MILITARY PARENTS: THE HIDDEN STRESS

You've seen the TV reports. You've read about them in newspaper and magazine articles. Active duty, Reserve and National Guard service members have deployed to Afghanistan since 2001 and to Iraq since 2003. What is only now getting more visibility are the effects of military parents' deployments on their children. The focus of this article is to understand this segment of the pediatric population and some of the research looking into unique issues that exist.

MILITARY PARENTS

Since the start of the wars, more than two million servicemen and servicewomen have deployed, a term used to describe a tour away from their home installation, to areas extending from the Horn of Africa to the Central Asia republics. Of this number, 793,000 have deployed more than once; for some, three or four tours. Active duty service members have 1.2 million "dependents" under 23 years of age and activated

Reservists and National Guard personnel have another 660,000.^{1,2} Between these two groups, 612,000 are children 5 years of age or younger. High "ops tempo," operations tempo, is a phrase many families live with. Their military mem-

ber has a job specialty needed more than others for combat operations, but for which numbers are limited. For these children, this means their parent has probably already deployed more than once and will likely deploy again. Military moms are more of a reality than ever before in the history of the United States military. A May 2007 report from the US Congress Joint Economic Committee (issued on Mother's Day) showed 342,000 women on active duty and in the Reserves, comprising 14.3 percent of the total force. Of these, more than 165,000 (48 percent) had already deployed at least once in support of operations in Afghanistan and Iraq. This same report noted 38 percent of women on active duty had children compared to 44 percent of men. However, 11 percent of all active duty women were single parents compared to only 4 percent being single fathers.

Many children grow up with parents who must travel and spend time away from home. For military children, however, deployment is more than just a period of absence. The parent is going where regular communication with them may be difficult and to an area media sources remind them regularly is one where people get injured or die.

Greg Gorman, MD, is a Navy pediatric nephrologist whose group used the enormous, worldwide Department of Defense health care claims database to look at the rate of children whose military parents accessed care. They studied these children's visits and ICD-9R diagnosis codes and linked them to their parent's de-

ployment records. The first study showed overall visits increased 7 percent and well-child visits 8 percent during the time a parent was deployed.³ The second, more extensive study analyzed records of over 640,000 children and more than 440,000 active duty parents for 2006 and 2007.⁴ Mental and behavioral health visits increased by 11 percent when a military parent deployed. Behavioral disorders increased 19 percent and stress disorders 18 percent. Rates especially increased in older children and children of married and male military parents.

THE "UNDER-5s"

This period is a time of critical developmental stages. Molinda Chartrand, MD, is an Air Force developmental-behavioral pediatrician, now stationed at a base in Germany. During her fellowship, she began studying this age group. One of her articles reported on 169 families with children at an on-base childcare center during May through December 2007.⁵ Using the Child Behavior Checklist (CBCL), two parental stress measures and the CBCL-Teacher Report as study tools, they controlled for parental stress and depressive symptoms. Within this group of children, the highest number behavioral symptoms were in 3-to 5-year olds who had a deployed parent. They showed increased externalizing behaviors with hitting, biting and hyperactivity being the most common.

Conversely, children aged 1-1/2 to 3 years with a deployed parent had significantly lower externalizing symptom scores. The authors acknowledged the study popula-

Objectives

Following the completion of this article, the reader should be able to:

1. Describe the scope of the issue involved including numbers and ages of children in military families affected by parental deployments.
2. Explain differences in emotional difficulties seen between preschool and school-age youth who have a parent deployed.
3. List resources available for military parents to help deal with effects of deployment on their children.

tion was from only one military installation, all were in organized childcare and because of the units' missions, the parents' deployment tours were shorter (average 3.9 months). By controlling parents' stress and depressive symptoms, however, the study suggested even young children were not spared the effects of deployment.

SCHOOL AGE

Children of military families are generally a robust, healthy group. There are more school age children than their under-5 counterparts, with all the stress and support structure that going to school provides. Eric Flake, MD, and Beth Ellen Davis, MD, Air Force and Army developmental-behavioral pediatricians, surveyed parents of children ages 5 to 12 at a large Army installation.⁶ Using standard checklists for child symptoms and parental stress indexes, they found one-third of families with a deployed parent were at high risk for psychosocial problems with the most significant predictor being the degree of parenting stress.

Anita Chandra, DrPHa, is a behavioral scientist and manager of the Behavioral and Social Sciences Group at the RAND Corporation. Her group presented information from phone interviews with 1,507 children (11-17 years) and their caregivers in a 2010 article.⁷ Controlling for family and service member characteristics, children with a parent deployed had more emotional difficulties than US norms. Older youth had a greater number of problems during deployment and girls demonstrated more problems during reintegration, when

the parent returned. For girls, post-deployment reintegration difficulties might be explained by changes related to roles they may occupy in the household when the military parent is away or connecting emotionally with an absent parent, usually the father. As found in other studies, the caregiver's mental health correlated with child well-being and the more time a parent was deployed or away, the greater the stressors of maintaining a healthy home life.

OTHER PARENT ISSUES

There is clear evidence of profound emotional impact of deployment, but the question remains: Does it translate into increased child maltreatment? One study looked at all substantiated cases, military and civilian, in the state of Texas from January 2000 to June 2003.⁸ In the majority of all cases, perpetrators were parents. The rate of occurrence for military families was 37 percent less than the civilian rate until October 2002. After October 2002, the rate of child maltreatment cases within military families doubled to 22 percent greater than for civilian families whose rate remained unchanged during the study period. During the same month, Congress authorized President Bush to use military force against Iraq. Prior to that, combat units in Afghanistan were principally special operations and air support units from installations mostly outside of Texas. The invasion of Iraq required entire armored and artillery divisions, including those from Fort Hood and Fort Bliss in Texas, suggesting the stressors of preparing to go, as

well as deploying, may contribute to child maltreatment.

Changes in personal protective equipment and forward deployed definitive medical care have allowed many injured soldiers to survive who in previous wars would have died. This has created a dramatic increase in the number of children with a parent disabled as the result of combat. Stephen Cozza, MD, at the Uniformed Services University Center for Traumatic Stress, wrote, "There is no such thing as an injured service member. We should be thinking injured family."¹ As of October 4, 2010, 5,712 service members have died in these two wars.⁹ By a 2010 RAND Corporation study, for an estimated 12,000 children, one of these service members was their parent. When an active duty parent dies, families often must or elect themselves to move away from the military installation and their new community may not recognize their needs.

WHERE IS THE HELP?

Early on, there was little formal assistance for anyone. Active duty units worked to build their own support structures and these evolved into what exist today. Deactivated Reserve or National Guard parents and families often had to deal with challenges on their own. While first a gradual response, there are now many proactive efforts to support children and their families.

Sesame Street has taken on this subject with a series of free videos ranging from preparing to deploy and "When Families Grieve," about parents who die while deployed. Military grass roots organizations include Military

OneSource, a web-based clearing house for information, and the National Military Family Association that sponsors Operation Purple Camp, a camp started in 2004 for children and teens whose parents deploy. The Department of Defense is helping fund the Purdue Military Family Research Institute that engages in research focused on these issues, including training interns who go to military installations around the world to meet with families.

What is our role as pediatricians? Most importantly, ask. The local children affected by parental deployments are not just those who receive care in the pediatric department at Wright-Patterson Air Force Base. If that parent is Army or Air Force Reserve or National Guard, the children were likely receiving their care in the civilian community before that parent was activated to deploy. Children of military families are resilient, but even for the strongest families, resiliency is waning as parents are called to deploy again and again. As with any clinical condition, being aware and understanding are the first steps in being able to help.

ADDITIONAL RESOURCES

www.sesameworkshop.org

www.militaryonesource.com

www.operationpurplecampinfo.com

www.mfri.purdue.edu

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CME Questions

6. The number of children with a parent on active duty, Reserve or National Guard is CLOSEST to:
 - a. 500,000
 - b. 660,000
 - c. 1.2 million
 - d. 1.8 million
7. A study of children at a military base childcare center found increased frequency of externalizing behavior symptoms in those aged 3 to 5 years. Examples of externalizing behavior symptoms include:
 - a. Less social interaction with the non-deployed parent
 - b. Decreased appetite
 - c. Hitting or biting
 - d. Prolonged crying after being dropped off at the childcare center
8. As discussed in the 2010 article by Chandra of 1,507 children ages 11 to 17 years with a parent who had deployed, which of the following is MOST correct?
 - a. The children in the study had the same frequency of emotional difficulties as expected for US age-equivalent norms.
 - b. Girls had more difficulties during the post-deployment, reintegration period.
 - c. Younger children had a greater number of problems during deployment than older youth did.
 - d. Length of time a parent was deployed did not seem to affect the degree of stress in the home.
9. In a study of child maltreatment cases in Texas, the rate of occurrence in military families increased to the same level as non-military (civilian) families beginning in October 2002.
 - a. True
 - b. False

Objectives

Following the completion of this article, the reader should be able to:

1. Review the purpose of the Black Box warning
2. Review ways to improve drug safety in pediatric patients.

WARNING: ASTHMA-RELATED DEATH

Long-acting beta₂-adrenergic agonists (LABAs), such as salmeterol, the active ingredient in SEREVENT DISKUS, increase the risk of asthma-related death. Data from a large placebo-controlled US study that compared the safety of salmeterol (SEREVENT[®] Inhalation Aerosol) or placebo added to usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol (13 deaths out of 13,176 patients treated for 28 weeks on salmeterol versus 3 deaths out of 13,179 patients on placebo) (see WARNINGS and CLINICAL TRIALS: Asthma: Salmeterol Multi-center Asthma Research Trial). Currently available data are inadequate to determine whether concurrent use of inhaled corticosteroids or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABAs.

Because of this risk, use of SEREVENT DISKUS for the treatment of asthma without a concomitant long-term asthma control medication, such as an inhaled corticosteroid, is contraindicated. Use SEREVENT DISKUS only as additional therapy for patients with asthma who are currently taking but are inadequately controlled on a long-term asthma control medication, such as an inhaled corticosteroid. Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy (e.g., discontinue SEREVENT DISKUS) if possible without loss of asthma control and maintain the patient on a long-term asthma control medication, such as an inhaled corticosteroid. Do not use SEREVENT DISKUS for patients whose asthma is adequately controlled on low- or medium-dose inhaled corticosteroids.

Pediatric and Adolescent Patients: Available data from controlled clinical trials suggest that LABAs increase the risk of asthma-related hospitalization in pediatric and adolescent patients. For pediatric and adolescent patients with asthma who require addition of a LABA to an inhaled corticosteroid, a fixed-dose combination product containing both an inhaled corticosteroid and a LABA should ordinarily be used to ensure adherence with both drugs. In cases where use of a separate long-term asthma control medication (e.g., inhaled corticosteroid) and a LABA is clinically indicated, appropriate steps must be taken to ensure adherence with both treatment components. If adherence cannot be assured, a fixed-dose combination product containing both an inhaled corticosteroid and a LABA is recommended.

WHAT ARE THEY?

A boxed warning is the most serious type of warning mandated by the US Food and Drug Administration (FDA) and is prominently featured in the labeling of drugs to alert prescribers about life-threatening adverse reactions or special problems.

WHERE DO THEY COME FROM?

Of 206 prescriptions reviewed, Beach et al¹ found that 29 percent of the warnings were based on clinical trial information; however 52 percent of the warnings were based on voluntary post-marketing reports by physicians caring for patients.

WHEN DO THEY APPLY?

1. When an adverse reaction is so serious in comparison to the drug's benefit that special consideration is necessary. Example: Salmeterol - when used without an inhaled corticosteroid - led to an

increased risk of asthma related death in the SMART study.²

2. When serious adverse reactions may be prevented or reduced by appropriate prescribing. Example: Valproic acid – Liver function tests should be followed to prevent serious hepatotoxicity.
3. When a drug requires mandatory restriction to ensure safe use. Example: Isotretinoin – Physicians must complete a certification program before prescribing, due to fetal abnormalities, spontaneous abortion and premature births when administered to pregnant females.

WHERE IS THE INFORMATION FOUND?

Boxed warnings can be found in the drug's Prescribing Information, the Physician's Desk Reference, the *Pediatric Dosage Handbook*, the Medication Resource Center on Dayton Children's website in the For Health Care Professionals section, the FDA's website and on websites of drug manufacturers. A website devoted to Black Box Warnings is <http://blackboxex.com>.

WHAT DO I DO WITH THIS INFORMATION?

Consider:

1. Do equally effective and safer alternatives exist?
2. Does the potential benefit of the drug outweigh the safety concern?

WHAT CAN I DO TO PROMOTE THE SAFE USE OF MEDICATIONS?

Report!

If a patient experiences a severe or unusual adverse reaction, physicians are encouraged to submit adverse drug reaction reports either directly on a standardized MedWatch form, available at <http://www.fda.gov/>

medwatch, or manually by downloading the form and sending it to the address on the form. If the patient is hospitalized at Dayton Children's, simply call the Adverse Drug Reaction (ADR) hotline at extension 3900. All serious and unusual reactions will be submitted to the Med Watch program.

HOW REPORTING CAN IMPACT SAFETY

Reporting adverse drug reactions in pediatric patients results in improved labeling. As of 2005, drug labels of 145 drugs were changed to include pediatric use information. These changes were due to studies requested by the health care community and conducted by drug companies who were granted marketing exclusivity by the FDA Modernization Act of 1997 and Best Pharmaceuticals for Children Act enacted in 2002. Although progress is being made, much more safety information regarding drug use in pediatric patients is still required.

REFERENCES

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Patricia Christoff, PharmD, AE-C

Patricia Christoff, PharmD, AE-C, is a clinical pharmacist and has been with Dayton Children's for 24 years. She graduated from The Ohio State University with a bachelor's degree in pharmacy, earned a doctorate in pharmacy and completed a post doctoral fellowship in pharmacokinetics from the State University of New York at Buffalo. She has special interest in the treatment of cystic fibrosis and asthma and has served on the Ohio Asthma Coalition for eight years.

CME Questions

10. The major source of adverse drug reaction information which result black boxed warnings is:
 - a. Post-marketing clinical trial information
 - b. Physicians caring for patients
 - c. Phase III clinical trials
11. The best ways to communicate a serious or unusual adverse drug reaction is to:
 - a. Report the reaction on a standardized MedWatch form at <http://fda.gov/medwatch>
 - b. Call the FDA Center for Drug Event Reporting.
 - c. Call the Western Ohio Poison and Drug Information Center at 1-800-762-0727.

PROGRAM EVALUATION

- Did the material presented in this publication meet the mission to enhance health care delivery in our region through education based on the essentials and policies of the Accreditation Council for Continuing Medical Education?
 Strongly agree Agree Neutral Disagree Strongly disagree
- Did the material presented in this publication meet the educational objectives stated?
 Met the stated objectives Did not meet the stated objectives
- Did the material presented in this publication have a commercial bias? Yes No
- Please rate the contents of this issue using the following scale: 1 = Poor, 2 = Fair, 3 = Good, 4 = Very good, 5 = Excellent
(Circle one response for each.)

	Poor				Excellent
Timely, up-to-date?	1	2	3	4	5
Practical?	1	2	3	4	5
Relevant to your practice?	1	2	3	4	5
- Please describe any changes you plan to make in your clinical practice based on the information presented in this program.

- Are there any other topics you would like to have addressed in this publication or future educational programs for health care providers?
 Yes No If yes, please describe: _____

- Please describe how you will incorporate information obtained from this publication into your practice _____

- Letter to the editor (may be published in next issue) _____

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- | | | | | | |
|-----|------|-------|---|---|---|
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| 2. | a | b | c | | |
| 3. | True | False | | | |
| 4. | a | b | c | d | e |
| 5. | a | b | c | d | e |
| 6. | a | b | c | d | |
| 7. | a | b | c | d | |
| 8. | a | b | c | d | |
| 9. | True | False | | | |
| 10. | a | b | c | | |
| 11. | a | b | c | | |

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NEW REFERRAL TOOLS AVAILABLE

The 2011-2012 Physicians Guide to Services and Fax Referral Book are now available and have been mailed to referring offices. Referral forms are also available electronically on our website, childrensdayton.org in the "For Health Care Professionals" section. For more information on these tools, or to request additional copies, call marketing communications at 937-641-3618, Kim Grant or Ruthie Laux, physician liaisons, at 937-641-3498.

Scoliosis screening in schools



Last fall, Dayton Children's orthopedic division began assisting area schools with scoliosis screening. So far, close to 10 percent of the 1,000 students have been recommended for follow-up care on positive screens. For information on screening or scoliosis for you or your patients and families, visit our website at childrensdayton.org or call 937-641-3618.

Dayton Children's welcomes new physicians



Jeanne Bobrer, MD



Hemanth Lingadevaru, MD



Navjyot Vidwan, MD

Jeanne Bobrer, MD, joins from after providing care in Dayton Children's emergency department and serving as director for several local medical facilities. She is board certified in pediatrics and has special interest in adolescent medicine and the special needs population.

Hemanth Lingadevaru, MD, MPH, joins from CS Mott Children's Hospital in Ann Arbor, Michigan, after completing a fellowship in pediatric critical care medicine. Dr. Lingadevaru also

earned a master's degree in public health from The University of Texas, School of Public Health in Houston. He is board certified in pediatrics and has special interest in sedation and analgesia.

Navjyot Vidwan, MD, joins after completing her pediatric residency and a fellowship in pediatric infectious disease at Cincinnati Children's Hospital Medical Center. Dr. Vidwan is board certified in pediatrics and has special interest in maternal-child health, global health and community outreach.

Laboratory Update

Virology/Infectious Disease Molecular Lab offers C. DIFFICILE BY PCR

Most labs perform a C. difficile screen, which is an EIA technology that detects the toxin itself. Unfortunately, C. difficile toxin is very unstable. The toxin degrades at room temperature and may be undetectable within 2 hours after collection. A recent study found pediatric patients had a 35% false positive EIA result when compared to the gold standard C. difficile PCR assay avoids these problems of false negatives and false positives. The assay detects the DNA in the bacteria responsible for producing the toxin, which is very stable. The C. difficile PCR has a sensitivity comparable to cytotoxin assay but with the speed of an EIA test.

Respiratory Infectious Disease Panel by PCR (RIDP)

We now offer a PCR that targets: adenovirus, human metapneumovirus (HMPV), rhino/enterovirus, influenza A (H1(2009) H1 (seasonal) H3), influenza B, parainfluenza 1,2,3, and respiratory syncytial virus (RSV).
Test code: RIDP
Specimen: Flocked nasal swab in viral transport

Reminder — These tests are performed 7 days per week. Specimens received before 1:00 pm will be ran and resulted that day. Questions? Call 937-641-5100.

Our outreach service will provide free specimen collection supplies and courier service for any testing to be performed at Dayton Children's. Call 937-641-3117 for more information.

Urology expands services



Venkata R. Jayanthi, MD

The department of urology, in collaboration with Nationwide Children's Hospital, is pleased to announce the expansion of urology services for infants, children and teens. Venkata R. Jayanthi, MD, will be providing care at Dayton Children's every Tuesday, including clinic and surgical services beginning February, 2011. Dr. Jayanthi is a full time pediatric urologist, is board certified in urology and has an added qualification to practice pediatric urology.

New camp for ill kids – refer your patients

Flying Horse Farms (FHF) is a camp for children with serious illnesses. This year, we aim to serve 1500 campers with cancer, heart disease, heart surgeries, Crohn's, asthma, arthritis, sickle cell, hemophilia, and other blood-related disorders. For most of these children, the typical summer camp experience is impossible but with FHF's state-of-the-art medical facilities and 24/7 medical staff, these campers can have a "spectacularly average" camp experience. If you know a child who would be a good fit for camp, please refer them so we may get the application process started. The 2011 camp schedule and camper applications can be found at <http://www.flyinghorsefarms.org/the-camp/how-to-enroll/>.

Dayton Children's Pediatric Summerfest

July
22 and 23,
2011



*Join your colleagues
for networking and
continuing medical
education, and bring
your family to enjoy
an indoor water park
and roller coasters at
King's Island.*

Topics include

- Immunization update 2011
- Management of the child with otitis media
- Approach to the child with Hematuria
- Caring for the adolescent with a concussion
- Obesity and diabetes
- Interactive cases in pediatric radiology

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