SECTION ON CRITICAL CARE

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

January 2003

A Note from the Chair

by Michele Moss, MD

I would like to start this newsletter with a big "Thank you" and a big welcome. I want to thank our departing Executive Committee members, Brahm Goldstein and Stephanie Storgion. They have served on the Executive Committee for two terms each. Their contributions to the Executive Committee, the Section, and the AAP are innumerable. I also want to sincerely thank Tex Kissoon who is stepping down as Program Chair. Tex has served as Program Chair longer than anyone previously and has done an outstanding job. The most recent Section Scientific Meeting is an example. The two half day sessions on management of sepsis and shock were very good with some of the top experts in the field. I know all of them will continue to make contributions to our section.

I also want to welcome Don Vernon, Barry Markovitz, and Jim Fortenberry. Don and Barry are two new members of the Executive Committee and Jim is the new program chair. All of us on the Executive Committee look forward to working with all of them in the future.

The Pediatric Critical Care Coding Course developed by our section was given for the first time in San Diego prior to the Pediatric Critical Care Colloquium. In brief, it was a huge success. The size of the room available limited seating to just over 100 participants and we had a full house. The Course is going to be offered again in June just prior to the World Congress of Pediatric Intensive Care in Boston. Look for meeting brochures this spring.

In addition to the Coding Course designed for our section members, our section under the leadership of Steve Schexnayder has developed with input from the Council of Sections Action Groups a new course for subspecialty in-training fellows. It is sort of a "how to survive in academics" course that will include multiple topics of general interest to academic pediatric subspecialists. These topics include medical legal issues, time management, how to deliver bad news, and an overview of coding and documentation. The course will be offered for the first time next October in New Orleans just before the start of the annual National Conference and Exhibition (NCE). Look for more about this course in the spring newsletter.

The new CPT codes for pediatric critical care for children less than 2 years old and greater than 30 days are found in the new CPT 2003 book. There are also changes to the neonatal ICU codes. If you need a copy of CPT 2003 book, the AAP sells them on their Web site. There are currently some delays with the Center for Medicare and Medicaid Services publishing the Medicare physician fee schedule which usually is published in November but has been delayed until February 1st at the earliest. So although the codes are available to use January 1st, our carriers may not assign values until later. So the advice of the AAP coding and reimbursement folks is to check with your major carriers now to see how they are going to handle the situation.

The Executive Committee met in Boston during the annual NCE. As always it was a productive and energetic meeting.

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PEDIATRIC INTENSIVE CARE WORLD CONGRESS

4th World Congress on Pediatric Intensive Care
Hynes Convention Center
Boston, MA
June 8-12, 2003
http://www.pic2003.com

Look for information soon about the

Pediatric Critical Care Coding Course

to be held at the World Congress on Pediatric Intensive Care!

A Note from the Chair

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Our requested bylaws change was approved by the members. This change was designed to encourage participation in the section by critical care in-training fellows and pediatric residents. The change allows a minimal fee for residents including critical care fellows in training to join the section rather than paying the full amount. Also the change includes a position on the Executive Committee for a pediatric critical care fellow in training. This position will be elected in the fall. If you know of a fellow who would be interested in participating on the Executive Committee please let me or Stephanie Storgion know. Stephanie has accepted the position of chairman of the nominating and membership committee.

One of the difficult discussions at the meeting involved our section budget. Our section continues to be one of the most vital and viable sections in the AAP. We have enjoyed a solid reserve fund the past several years. The $10,000 New Investigator Research Award that is given every year was developed to use some of the reserve funds with the goal to replenish the fund with corporate donations. Donations from corporations for research in broad areas such as critical care have decreased markedly the past few years. Hence the fund has not been replenished. So this year is was decided to not give an award but to continue to work with the AAP to replenish the reserve fund. Hopefully, the award can be given again next year.

Dan Levin was awarded the section's Distinguished Career Award. Indeed Dan has had and continues to have a distinguished career in pediatric critical care medicine. He joins a truly outstanding group of prior awardees. Congratulations, Dan.

In closing, I want to thank the staff at the AAP who have helped us so much this past year including Linda Walsh and Carolyn Mensching to name just a few. Mostly I want to thank Sue Tellez who continues to be a great source of energy, enthusiasm, and knowledge for our section.

I want to wish all of you 

filled with plenty of energy for our patients, patience with their families, knowledge for our trainees, fully reimbursed new CPT codes, new PICU guidelines (look for them soon!), funded research grants and the time to do the research, good health, and lots of quality time with our families and friends. Mostly I wish us all 

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PCCM Fellowship Directors Report

Our last meeting was held in conjunction with the Critical Care Colloquium in San Diego on October 3, 2002. The attendance was excellent and we had a guest fellow Dr Nancy Tofil, a first year fellow from Birmingham, who sits on the RRC as a trainee representative. Her input was very important during a long discussion on the issues of the ACGME requirements on work hours that take effect in July of 2003. The requirements can be found on the ACGME Web site. There is an opportunity for a group to request an extension by 10% and we will look into the process by which we can request this extension for PCCM. The committee voted to send a letter to the ACGME acknowledging their efforts on the work hours issue and commending them for tackling this difficult issue. We also wanted to state that we wanted to be involved in future decisions regarding these types of trainee issues.

The 2003 match for fellows occurred on November 13, 2002 with about 75% (48) of the existing programs participating. Sixty percent of the participating programs filled through the match. There were 79 enrolled applicants with 94% of the applicants matching. The specific results can be accessed by going to www.nrmp.org and going to the fellow match site. We will be sending a survey to current fellows, those who just completed the match for 2003, and those who went outside the match to evaluate the opinion of the trainees on the match process. This is a critical issue as some very prominent programs did not participate in the match this year.

Michele Mariscalco, MD continues to lead the charge in trying to develop competencies for trainees in PCCM. A quick idea to put into place is to have all fellows participate as members on hospital committees that require intensivist members and other committees that are related to what we do in PCCM.

Finally, we continue to address the issues for recruitment and retention of trainees into our programs. Many of these issues are tied to the perception of pediatric housestaff of the work we do and the hours we spend. It is important that young housestaff not only see us in the PICU but also see how we function during time that we are not on service so that they can better assess what life as an intensivist really is like.

Our next meeting will be at the SCCM on January 30 at 7am in San Antonio. We look forward to seeing lots of you there.

Stephanie A. Storgion, MD
E-mail: Storgios@lebonheur.org

Drug Update – December 2002
Mary W. Lieh-Lai, MD

I. Medication Errors:

1. A patient receiving electroconvulsive therapy complained of severe discomfort during the procedure. Instead of *etomidate*, he had received *neostigmine*. Both drugs are packaged by Bedford Laboratories in the same size (10 mL vials) and both have black and gray lettering and numbers on the label.

2. Multiple magnesium errors: a physician ordered 2 g $MgSO_4$ q 4h – changed his mind, slashed out the "2" and wrote a "5" before it. The nurse read the order as 51 grams. The patient screamed that she had a feeling of paralysis and went into respiratory arrest. The patient's magnesium level was 16.7 mEq/L. In other incidents, the infusion pump was programmed to deliver 310 mL per hour instead of 30 mL/ hour. The patient was found in respiratory arrest with a magnesium level of 13.2. In yet another case, 10 mEq of magnesium was read as 10 mL of magnesium (equal to 40 mEq).

3. An order for Atarax syrup 6 mg PO q 6h. Because of limited space, "6 mg" was written below the word syrup. The tail of the "p" in syrup ran into the line below and was mistaken as a "1". The child received 2 doses of 16 mg Atarax.

4. A pharmacy reconstituted antibiotic suspensions with 10% formalin solution (3% formaldehyde + 15% methanol). Non-pharmacists working in the store had used empty gallon jugs of distilled water to prepare 10% formalin solutions for surgical centers. Formalin labels were attached to only one side of the jug, and the other side still had the "distilled water" labels on them.

5. Child was having elective tympanomastoidectomy. He was given what was thought to be an injection of 1% lidocaine with 1:100,000 epinephrine, following which, he arrested. Someone in the OR had poured 1:1000 epinephrine into medicine cups labeled "lidocaine with epinephrine", so the child was given 3 mg of 1:1000 epinephrine. The child arrested and died.

6. A premature infant was prescribed 7.4 mg loading dose of theophylline for apnea. The order was read as 7.4 mL (185 mg of theophylline). The child developed severe theophylline toxicity and died 36 hours later.

7. A patient was mistakenly given vincristine intrathecally instead of IV. The patient suffered paralysis and agonizing pain and died 10 weeks later.

8. A child in the ED developed respiratory arrest and was intubated following an IV antibiotic followed by a saline flush. The nurses in the ED had previously drawn up multiple syringes of saline flush for another child who had required vecuronium for intubation. A syringe containing vecuronium was mistakenly labeled as saline.

II. Warning:

1. Lidocaine is extensively absorbed (up to 35%) after topical administration to mucous membranes. Toxic levels have been reported when using large amounts of lidocaine for bronchoscopy.

2. If premixed IV bags are removed from the protective over wrap, the drug's concentration could increase over time as the fluid volume decreases due to evaporation.

3. Be careful with the abbreviation "AD" (aura dexter) – it has been mistaken as OD, QD, or "as directed."

4. Caution: overaggressive attempts to treat pain scores. A 24-year old died 24 hours after C-section. The nurses gave her repeated doses of fentanyl in response to every pain score. She was found in cardiac arrest and could not be resuscitated.

5. EMLA (eutectic mixture of local anesthetics): a 1-day old who was being prepared for circumcision developed methemoglobinemia (level 15.9%) after being given EMLA.

6. A 4-year old died after an adenoidectomy. The nurse was instructed to instill phenylephrine into the nose to decrease bleeding. A 0.5% solution of Neo-Synephrine® phenylephrine was used. The child developed hypertension and was given a beta-blocker. He developed respiratory distress and had a cardiac arrest and could not be resuscitated. Generally, lower concentrations of 0.125% or 0.16% phenylephrine are recommended for use as a nasal decongestant.

7. The use of valproate in children with urea cycle disorders: fatal hyperammonemic encephalopathy has been reported.

III. Recalls:

1. Cryolife – a human tissue-processing firm was ordered to recall all distributed human allograft tissues except allograft heart valves that have been processed by the company since

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Drug Update

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October 3, 2002. The FDA discovered violations in processing of human tissue, documenting bacterial and fungal contamination. Source of Information: Institute for Safe Medication Practices Newsletter.

IV. Safe Practice Recommendations in Children - Institute for Safe Medication Practices:

1. Limit verbal orders.
2. Require prescribers to always include the mg/kg dose.
3. Require nurses and pharmacists to independently check and document the dose calculation.
4. Monitor new personnel (nurses and physicians).
5. Provide posted references for commonly used medications.
6. Always provide the patient's weight in kilograms.

At the Children's Hospital of Michigan, we created a "Safe Practice Pocket Card" for distribution to physicians and nursing units. It has been very helpful in reminding prescribers of safe practices. **See next page for a reproduction of the Safe Medicine Prescribing Card.**

V. New Medication Error Study:
Kozer E, Schonik D, Macpherson A et al: Variables Associated with Medication Errors in Pediatric Emergency Medicine. Pediatrics 2002; 110-737-742.

Charts of 1532 children treated in the ED (Hospital for Sick Children) during 12 randomly selected days in 2000. Prescribing errors identified in 10.1% of the charts. Increased proportion of errors was correlated with the following: patients seen between 4 AM and 8 AM; medication ordered by a trainee; and patients seen during the weekends. Of the trainees, there was a higher error rate at the beginning of the academic year. There was also an increased error rate in the most seriously ill children.

Erratum: I would like to thank Dr David Polaner for pointing out an error in, of all places the "drug error" section of the March 2002 issue of the newsletter. I stated that "sufentanil is packaged in a much higher concentration than fentanyl." The correct statement should be "sufentanil is supplied in the same concentration as fentanyl (50 mcg/mL), but is 10 times more potent than fentanyl."

Join the SOCC ListServ for updates on Critical Care Codes and AAP Activities! Send an email message to cmensching@aap.org to join!

First Pediatric Critical Care Billing and Coding Course: A Great Success

Over 100 of our colleagues in pediatric critical care: physicians, nurses and billing professionals/administrators attended the course held in San Diego on October 2, 2002, on the eve of the Pediatric Critical Care Colloquium. The room was completely sold out. Unfortunately, many individuals who had attempted to register were disappointed that they could not be accommodated. The hotel had strict limitations on the number of individuals who could attend, and the planning committee had conservatively hoped for 75 registrants. In all, 108 participants attended!

The course was well received; with 91 folks feeling they had updated their knowledge in billing and coding, and 97 indicating that they would carry ideas back to their home practices. Most participants felt the length of the course was just right or too short, and a significant number requested additional time for questions.

We obtained helpful feedback and suggestions for future courses, many of which we hope to incorporate into our planning for the next course, tentatively scheduled to be held on the eve of the upcoming World Congress on Pediatric Critical Care in Boston, in June, 2003. Look for more information available soon.

2002 Research Award Winner

The Section on Critical Care is pleased to announce that Dr Melissa Campbell Evans from the Medical College of Virginia has been selected to receive the 2002 American Academy of Pediatrics' Section on Critical Care New Investigator Research Award. Her project is entitled "Use of Protein Synthesis Inhibitors for Metabolic Down-Regulation in Shock." Dr Evans' study will receive a grant in the amount of $10,000 and she will be invited to present the results of her work at the 2003 AAP National Conference & Exhibition in New Orleans during the Section's scientific session.

Dr Alice Ackerman chaired the grant application review panel whose members were Drs Stephanie Storgion, Tim Timmons, Dan Notterman and Tim Yeh. The grant proposals submitted this year were uniformly of exceptional quality, making the final decision an extremely difficult one. The annual award is supported by the Section membership through its dues process and past recipients have produced and presented excellent work.

Children's Hospital of Michigan

Safe Medication Prescribing Card

Practice	Intent	Misinterpretation	Safe Prescribing Practice
Zero after decimal point e.g., 5.0 mg	5 mg	Misread as 50 mg	Don't use a trailing zero
No zero before decimal point e.g., .5 mg	0.5 mg	Misread as 5 mg	Always use a leading zero
Letters and numbers together e.g., Inderal40 mg	Inderal 40 mg	Misread as Inderal 140 mg	Always use spaces to separate
> and <	Greater than and less than	Used opposite of intended	use GREATER THAN or LESS THAN
/ (slash mark) e.g., 5units/4units	separate two doses	Misread as the number "1"	Don't use a slash mark (/)
Use of Apothecary symbols	dram	dram misread as "3"	Use the metric system
Use of Apothecary symbols	Minim	Minim misread as "ml"	Use the metric system

Abbreviation	Intent	Misinterpretation	Safe Prescribing Practice
au	auro uterque (each ear)	Misread for OU –(oculo Uterque-(each eye)	Don't Use this Abbreviation
sub q	Subcutaneous	"q" misread for "every"	Use SUBCUTANEOUS or SUBCUT
sq	Subcutaneous	Misread for "sublingual (sl)"	Use SUBCUTANEOUS or SUBCUT
per os	Orally	Misread for "left eye (os)"	Use PO, BY MOUTH, ORALLY

Abbreviation	Intent	Misinterpretation	Safe Prescribing Practice
µg	microgram	Misread for mg	Use MCG
U or u	unit	Misread as zero or four	Use UNIT
IU	international unit	Misread as IV (intravenous)	Use UNIT
cc	cubic centimeters	Misread as "u" for units	Use ML
o.d. or OD	once daily	Misread for right eye (OD-oculus dexter)	Use DAILY
TIW or tiw	Three times a week	Misread as "three times a day"	Don't Use this Abbreviation
qd. or QD	every day	Misread as qid.	Use DAILY or EVERY DAY
Qn	Nightly or at bedtime	Misread as "qh" (every hour)	Use NIGHTLY
Qhs	Nightly at bedtime	Misread as every hour	Use NIGHTLY
q6pm etc.	Every evening at 6pm	Misread as every six hours	Use 6pm NIGHTLY
q.o.d. or QOD	Every other day	Misread as qd or qid if "o" is poorly written	Use EVERY OTHER DAY
x3d	for three days	Misread as "for three doses"	Use FOR THREE DAYS
BT	Bedtime	Misread as bid (twice a day)	Use NIGHTLY
ss	Sliding scale	misread	use SLIDING SCALE
ss	1/2 apothecary	Misread as "55"	use ONE-HALF or ½
D/C	Discharge or discontinue	Premature discontinuation of medications	use DISCHARGE and DISCONTINUE
ARA-A	Vidarabine	Cytarabine (ARA-C)	Never Abbreviate Drug Names
AZT	Zidovudine	Azathioprine	Never Abbreviate
CPZ	Compazine	Chlorpromazine	Never Abbreviate
DPT	Demerol/ Phenergan/ Thorazine	Diphtheria-pertussis-tetanus	Never Abbreviate
HCl	Hydrochloric acid	"H" misread as "K" (i.e., potassium chloride)	Never Abbreviate

Abbreviation	Intent	Misinterpretation	Safe Prescribing Practice
HCT	Hydrocortisone	Hydrochlorothiazide	Never Abbreviate Drug Names
HCTZ	Hydrochlorothiazide	Hydrocortisone	Never Abbreviate
LEVO	Levothyroxine	Levodopa or levofloxacin	Never Abbreviate
MgSO4	Magnesium sulfate	Morphine sulfate	Never Abbreviate
MSO4	Morphine sulfate	Magnesium sulfate	Never Abbreviate
MTX	Methotrexate	Mitoxantrone	Never Abbreviate
TAC	Triamcinolone	Tetracaine, ADRENALIN, cocaine	Never Abbreviate
ZnSO4	Zinc sulfate	Morphine sulfate	Never Abbreviate
Nitro Drip	Nitroglycerin infusion	Sodium nitroprusside infusion	Never Abbreviate
Norflex	Norfloxacin	NORFLEX (orphenadrine)	Never Abbreviate
PIT	PITOCIN (oxytocin)	PITRESSIN (vasopressin)	Never Abbreviate

Safe Practices for Prescribing Medications
Be careful when prescribing sound-alike medications (e.g., acyclovir, ganciclovir, valganciclovir)
Provide weight and age with all prescriptions
Don't use abbreviations for medications
Write prescription information in a printed, legible format rather than in cursive
Specify salt for all electrolyte prescriptions
Never use verbal orders for chemotherapy medications
Specify the exact dose (e.g., mg) rather than just the dosage form (e.g., vial, tablet, ampoule)
Never use felt tip pens or pencils with carbon copy order forms
Include the calculated dose and the mg/kg dose on the prescription
Write complete orders. Do not write ambiguous orders that require additional clarification (e.g., take as directed)
Include date/time, drug name, dosage form, dose, route, frequency, duration, and phone or pager number on all prescriptions and name of prescriber and nurse if applicable
Be careful when transcribing medication ordering information
Specify administration rate for all IV medications (e.g., TKO is not acceptable)
Orders should include a brief notation of purpose (e.g., cough), unless considered inappropriate by the prescriber

Reference: The Institute for Safe Medication Practices (www.ISMP.org) mcg/mL), but is 10 times more potent than fentanyl."

New and Revised CPT Codes for Patient Transport, Neonatal and Pediatric Critical Care, and Low Birth Weight Services

Starting January 1, 2003, there will be new and revised CPT codes for patient transport, neonatal and pediatric critical care, and low birth weight services. The descriptors will read as follows:

Pediatric Critical Care Patient Transport

99289 Critical care services delivered by a physician, face-to-face, during an interfacility transport of critically ill or critically injured pediatric patient, 24 months of age or less; first 30-74 minutes of hands on care during transport.

99290 Critical care services delivered by a physician, face-to-face, during an interfacility transport of critically ill or critically injured pediatric patient, 24 months of age or less; each additional 30 minutes (List separately in addition to code for primary service).

Neonatal and Pediatric Critical Care Services

99293 Initial pediatric critical care, 31 days up through 24 months of age, per day, for the evaluation and management of a critically ill infant or young child.

99294 Subsequent pediatric critical care, 31 days up through 24 months of age, per day, for the evaluation and management of a critically ill infant or young child.

99295 Initial neonatal critical care, per day, for the evaluation and management of a critically ill neonate, 30 days of age or less.

99296 Subsequent neonatal critical care, per day, for the evaluation and management of a critically ill neonate, 30 days of age or less.

(99297 has been deleted. To report, use 99296.)

Intensive (Non-Critical) Low Birth Weight Services

99298 Subsequent intensive care, per day, for the evaluation and management of the recovering very low birth weight infant (present body weight less than 1500 grams).

99299 Subsequent intensive care, per day, for the evaluation and management of the recovering low birth weight infant (present body weight of 1500-2500 grams).

CPT guidelines for the new/revised codes include:

- Codes 99293-99299 are reported only once per calendar day.
- Codes 99289-99290 and 99293-99296 are age-based codes, restricted to critically ill patients.
- Codes 99298-99299 are weight-based codes reported for patients who require intensive (not critical) care.
- Critical care services provided to neonates 30 days of age or less are reported with codes 99295 (initial (admit) day) and 99296 (subsequent day(s)).
- Critical care services provided to infants 31 days up through 24 months of age are reported with codes 99293 (initial (admit) day) and 99294 (subsequent day(s)). The hourly critical care codes (99291 and 99292) are reserved for reporting critical care services provided to children over 24 months of age.
- The services that are bundled into the hourly critical care codes (99291-99292) are also bundled into the pediatric critical care patient transport codes (99289-99290). Those services include: routine monitoring evaluations (eg, heart rate, respiratory rate, blood pressure, and pulse oximetry), the interpretation of cardiac output measurements (93561, 93562), chest x-rays (71010, 71015, 71020), pulse oximetry (94760, 94761, 94762), blood gases and information data stored in computers (eg, ECGs, blood pressures, hematologic data) (99090), gastric intubation (43752, 91105), temporary transcutaneous pacing (92953), ventilatory management (94656, 94660, 94662) and vascular access procedures (36000, 36400, 36405, 36406, 36410, 36415, 36540, 36600). Any services performed which are not listed above should be reported separately.
- The services that are currently bundled into the 2002 neonatal critical care codes (99295-99298) will also be bundled into the new and revised neonatal and pediatric critical care codes. Those services include: umbilical venous (36510) and umbilical arterial (36660) catheters, central (36488, 36490) or peripheral vessel catheterization (36000), other arterial catheters (36140, 36620), oral or nasogastric tube placement (43752), endotracheal intubation (31500), lumbar puncture (62270), suprapubic bladder aspiration (51000), bladder catheterization (53670), initiation and management of mechanical ventilation (94656, 94657) or continuous positive airway pressure (CPAP) (94660), surfactant administration, intravascular fluid administration (90780, 90781), transfusion of blood components (36430, 36440), vascular punctures (36420, 36600), invasive or non-

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New and Revised CPT Codes

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invasive electronic monitoring of vital signs, bedside pulmonary function testing (94375), and/or monitoring or interpretation of blood gases or oxygen saturation (94760-94762). Any services performed that are not included on this list should be reported separately.

While there will be new and revised codes for 2003, the Centers for Medicare and Medicaid Services (CMS) has delayed the release of the Medicare physician fee schedule (Resource-Based Relative Value Scale or RBRVS) final rule, which was originally due out November 1, 2002. The final rule publishes the relative value units (RVUs) for each CPT code. The delay has caused Medicare to push back its RVU implementation date to February 1, 2003. And that date could get pushed back even further as the final rule continues to be delayed. This means that while there will be new CPT codes starting on 1/1/03, your carriers may not implement values for the new codes until a later date.

Therefore, we are suggesting that you check with your carriers now to find out how they plan to handle this situation. They may require that you continue to report your services using the current codes (eg, continue to report the hourly critical care codes (99291-99292) for critically ill pediatric patients 31 days up through 24 months of age) until such time that the RVUs for the new codes become effective. Conversely, they may allow you to report the new CPT codes but may hold those claims until such time that the RVUs are implemented.

In an effort to provide some guidance as to how the codes may be reimbursed once 2003 RBRVS is published, below are the physician work RVUs that the Academy has requested {Note: Since all of the codes involve facility-based services, CMS will assign each code its own practice expense and professional liability insurance RVUs. Therefore, each code's total RVUs will most likely be higher than the figures below.}:

CPT Code	Requested Work RVUs
99289	4.80
99290	2.40
99293	16.00
99294	8.00
99295	18.49
99296	8.00
99298	2.75
99299	2.50

Linda Walsh will continue to keep you apprised of any developments with regard to the release of the final rule via the SOCC Listserv.

If you have any questions, please feel free to contact Linda Walsh at lwalsh@aap.org or 800/433-9016 ext. 7931.

SUMMARY PROGRESS REPORT AAP Section on Critical Care 2001 New Investigator Award

Vasopressin Antagonism Following Cardiopulmonary Bypass

Lara K. Primak, MD
Rainbow Babies and Children's Hospital

Cardiopulmonary bypass (CPB) produces fluid retention and vasoconstriction, which contribute to postoperative organ dysfunction. Antagonism of renal (V_2) and vascular (V_1) vasopressin receptors may attenuate these problems. Dr Primak studied different doses of conivaptan, a V_1/V_2 antagonist, on dogs exposed to hypothermic CPB without aortic cross-clamp or circulatory arrest. Dr Primak dosed conivaptan at the end of CPB. End points of her study were post-CPB urine flow (UOP), body weight, fluid compartments, and hemodynamics. Dr. Primak reported the results of her first 12 experiments at the annual meeting of the Section on Critical Care in Boston on October 20.

CPB was associated with significant baseline variability in hemodynamics, UOP, and fluid requirements. Post CPB, three animals were dosed 1.2 mg/Kg of conivaptan, three received 0.6 mg/kg, two received 0.3 mg/Kg, and four received sham. One animal in the 0.6 mg/Kg group had an abbreviated CPB run due to large fluid requirements to achieve just 25% of targeted CPB flow. All animals had the expected effects of CPB in terms of increased weight, positive fluid balance, and hemodilution. Dr Primak dosed conivaptan based on dry weights and considered the effect of fluid retention on actual conivaptan dose. She considered the effect of pre-dose fluid balance on UOP. She separated the effects of administered fluid from those of drug by multiple regression analysis.

The amount of fluid administered during CPB significantly influenced UOP in the five hours after CPB ($p=0.001$). Conivaptan also significantly increased UOP during this interval ($p=0.02$). A significant dose response was seen only at three hours post CPB, with no dose response on overall post-CPB UOP. Sodium, hematocrit, and urea nitrogen levels all rose in treated animals compared with controls. Body compartment analyses are ongoing.

Cardiac output declined overall with exposure to CPB. However, stroke volume was preserved in all but two animals, suggesting an absence of acute cardiac dysfunction. The two animals with decreased stroke volume had increases in peripheral resistance of greater than 100%. Post treatment, peripheral resistance declined in those two animals. Neither these or any other of the treated animals had hemodynamic deterioration due to conivaptan.

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CALENDAR OF EVENTS

http://www.pedsccm.org/

Meeting Title	Meeting Dates	Location	Contact
SCCM 32nd Critical Care Congress	1/28/03 - 2/2/03	San Antonio, TX	Information is at http://www.sccm.org/edu/32program/toc.html
1st Asia-Pacific Symposium on Pediatric Cardiac Intensive Care	2/20/03 - 2/21/03	Phuket Island, Thailand	Information is at http://www.pcicsasia.com
Pediatric Academic Societies' Annual Meeting	5/3/03 - 5/6/03	Seattle, WA	Contact Information: 281/419-0052 debbiea@aps-spr.org
4th World Congress on Pediatric Intensive Care	6/8/03 - 6/12/03	Boston, MA	http://www.pic2003.com
AAP Pediatric Critical Care Coding Course	To be held during the 4th World Congress	Boston, MA	http://www.aap.org/sections/critcare
AAP Fellows Course	10/30/03 - 11/1/03	New Orleans, LA	http://www.aap.org/sections/critcare
AAP National Conference and Exhibition	11/1/03 - 11/5/03	New Orleans, LA	http://www.aap.org

Do We Know How To Find You?

An important new service has been added to the online Member Directory. The "Membership Information Change Form" located within the Members Only Channel (www.aap.org/moc/memberservices/updatememberinfoform.cfm) has been added to provide you with an opportunity to view your address, demographic, and subspecialty information and update it at your own convenience. We understand that members are changing information more frequently. Now, each time you make a change, simply enter it into the form and our database will be updated the following day. This way, there will be no delay in receiving your member benefits.

The AAP online Member Directory, available through the AAP Members Only Channel at www.aap.org/moc, has recently been improved. With 15% to 20% of our member contact information in a state of change at any given time, the online Directory should be your primary resource to locate colleagues. Quite simply, it has the most accurate, up-to-the-minute contact information available.

With these new changes and enhancements, we believe we can further improve service to members and the public. However, it is also an important time for our members to check their address and demographic information for accuracy. In the next few weeks, please take the time to visit the Membership Information Change Form (www.aap.org/moc/memberservices/updatememberinfoform.cfm). If you prefer to contact us by phone or fax, you can do this by calling 800/433-9016, extension 5897 and providing one of our service representatives with your updated address information, or faxing your information to 847/228-7035.

Use of Drugs "Off Label" in Children

Prescribing of drugs for children that are not approved by the FDA for use in children unfortunately is commonplace in pediatric practice. The legal, regulatory, and ethical issues for the physician who must prescribe "off label" is best understood in the context of the laws that govern the development, approval, distribution and marketing of prescription drugs.

When the 1962 amendments to the U.S. Food Drug and Cosmetic Act were passed, it was the intent of Congress that drugs approved for human use in the U.S. be shown by well controlled studies to be safe and effective for the uses for which they were marketed. This is the law that has governed drug approval and use in the U.S. for the past 40 years and continues in effect to the present time. Under the FD&C Act, the FDA is charged with the responsibility for approval of therapeutic drugs marketed in the U.S. The FDA-approved prescribing information for an approved drug, including indications for use, dosing recommendations, and safety information, are contained in the official labeling for the drug. The label is a legal document that is published as the package insert and determines/limits the marketing claims that may be made for a drug.

Shortly after implementation of the 1962 FD&C amendments in 1965, it became obvious that loopholes in the law made it possible for companies to get drugs approved for adult use while not approving them for use in infants and children. Furthermore, once a drug was approved for marketing for any indication, there was little incentive for a company to seek approval for additional indications unless there was potential for a significantly expanded market. Because of this, approximately 80% of prescription drugs brought to market during the past 40 years have not been approved for children. Consequently, the approved labels do not contain dosing or safety information for children and contain disclaimers against use in children. Nevertheless, the majority of these drugs are therapeutically important for children as well as adults. This leaves the physician caring for children with the choice of denying patients access to valuable drugs or prescribing the drug "off label", e.g. prescribing the drug for an indication or age group not included or explicitly excluded in the approved labeling. More often than not, the physician opts for "off label" prescribing. In pediatric medicine, due to the paucity of drugs approved for children, "off label" use has become commonplace. What then is the physician's responsibility or legal culpability when prescribing "off label"?

First, it is important to understand that the FD&C Act governs the interstate commerce of a drug and does not regulate the practice of medicine. In other words, the approved label regulates the pharmaceutical company's marketing and distribution of the drug, including therapeutic claims, uses for which the drug is intended, and claims regarding the safety profile of the drug. Labeling is intended neither to preclude the physician from using his or her best medical judgment in the interest of the patient, nor to impose liability for failure to comply with labeling restrictions. "Off label" use of a medication does not necessarily imply deviation from an accepted standard of care and does not connote an illegal act on the part of the physician. "Off label" prescribing does NOT violate any section of the FD&C Act.

At the same time, in the absence of pediatric labeling, the physician who prescribes "off label" implicitly assumes increased responsibility for being knowledgeable regarding available authoritative scientific and medical information to support "off label" use and the extent to which such information is lacking. The lack of formal testing, approval and labeling of a drug for children increases the likelihood that there is inadequate information to safely and effectively prescribe the drug. Absence of pediatric prescribing information in the approved labeling places the onus on the physician to be familiar the best information available.

Although "off label" prescribing does not inherently increase a physician's exposure to claims of malpractice, is does impose an increased burden to justify and document justification for "off label" use. Indeed, a physician could conceivably be held liable in a malpractice action for a departure from accepted standards of care if he or she denied a patient access to generally accepted treatment solely because the use was not included in the official labeling of the drug.

It therefore, behooves the physician to be well informed regarding sources of pediatric prescribing information that is generally accepted as authoritative and that will support "off label" prescribing of specific drugs to pediatric patients. Examples of authoritative sources of information to support "off label" use include refereed articles in the medical literature, peer reviewed papers presented at scientific meetings, position statements by specialty societies, generally accepted current textbooks, and peer reviewed compendia such as the U.S. Pharmacopeia Dispensing Information (USP DI). The USP DI includes available pediatric data in their monographs even though the information may not be included in the approved labeling for the drug. The level of evidence supporting the information also is provided.

With the increased volume of pediatric studies being conducted under the incentives provided by the Best Pharmaceuticals for Children Act, the number of drugs with approved labeling for children will increase in the future and gradually reduce the number of drugs for which "off label" use is necessary.

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SUMMARY PROGRESS REPORT

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Dr Primak concluded these preliminary experiments confirmed the aquaretic effects of conivaptan in this model. High baseline variability and low numbers of experiments kept her from concluding whether a dose response occurred. The maximal dose effect on UOP at three hours coincides with the elimination half-life of conivaptan in these animals. Increased sodium levels might limit the practical dosing of vasopressin antagonists.

Dr Primak plans to repeat this protocol in more animals. She will repeat her power analysis using the preliminary data, grouping dogs by actual (rather than nominal) conivaptan dose. She foresees studying conivaptan in canine models of acute cardiac failure to better investigate hemodynamic effects.

Dr Moss and the assembled Section congratulated Dr Primak for her hard work and diligence. Her persistence and her adjustments to a difficult model impressed the group. Her experiments will continue with residual SOCC grant monies and other funding.

MEMBERSHIP DIRECTORY ON-LINE!

The AAP has added a link to the section membership roster on the Section's home page on the Members Only Channel. The roster will first appear as an alphabetical listing, and each member's name links to more detailed information about that person, including other section membership, chapter and district affiliation, and committee membership.

Be sure to contact the Membership Department at membership@aap.org should any of your information change, such as name, address, phone, fax or e-mail address. **You may also make the changes on-line on the Members Only Channel.** Just follow the link on the Section's home page!

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The LISTSERV® allows the AAP Staff to communicate with members through periodic e-mail messages.

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AAP CALL FOR ABSTRACTS

AAP National Conference and Exhibition
October 31-November 5, 2003
New Orleans, LA

Submission deadline:
April 14, 2003 for paper submissions
April 18, 2003 for electronic submissions
(Abstracts must be received by the dates listed.)

Section programs provide a forum for the discussion of clinical matters or research related to a particular subspecialty or special interest area. Submissions by AAP members and nonmembers are welcome; participation is open to health professionals in any field. (However, some sections require a sponsor for any papers whose authors do not include a member of the Section.)

The following Sections accept abstracts for presentation at the AAP National Conference and Exhibition. Abstracts are not accepted for general pediatrics or for other pediatric subspecialties or special interest areas not listed below.

- ✓ Administration & Practice Management
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- ✓ Transport Medicine
- ✓ Urology

Submit electronically from the AAP Web site http://www.aap.org under "Professional Education" (submission form will be available in mid- to late-January)

Print versions can be obtained by calling the AAP Faxback Service at 847-758-0391. Ask for Document 1201 (Abstract Form and Instructions)

Questions? Contact abstracts@aap.org, or Rebecca Marshall at 847-434-4079.

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