

# NEONATOLOGY TODAY

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## How Should States Approach Payment for Post-Discharge Donor Human Milk for Low Birth Weight Infants when Mothers can no longer Breastfeed? A Challenge for Medicaid Coverage

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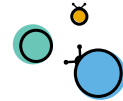
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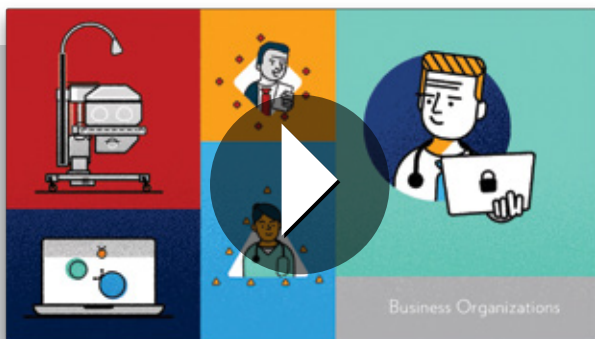
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# How Should States Approach Payment for Post-Discharge Donor Human Milk for Low Birth Weight Infants when Mothers can no longer Breastfeed?

## A Challenge for Medicaid Coverage

T. Allen Merritt, MD, MPA:HA, Stefanie Rogers, MD, Allison O'Brien, MD, Robert Pfister, MD, Cynthia McEvoy, MD, MCR, Howard S. Cohen, MD, Mitchell Goldstein, MD

According to the Centers for Disease Control and Prevention, 4 of 5 women giving birth in the U.S. provided some breast milk to their infant; however, only one in four were still exclusively breastfeeding their infants at 6 months of age (1). This report neither distinguishes between mothers of preterm versus term infants nor determines the number of weeks that women in these categories discontinue their breastfeeding or pumping breast milk. The American Academy of Pediatrics (AAP) recommends breastfeeding for all infants regardless of birthweight. With regard to babies born before term the AAP states that "all preterm infants should receive human milk" while recognizing that human milk should be fortified with protein, minerals, and vitamins to ensure optimal nutrient intake for infants weighing <1500 grams at birth. Appropriately fortified pasteurized donor human milk should be used if mothers own milk is unavailable or its use is contraindicated (2). It has been well established that use of premature mother's own milk or donor milk in the post-birth period improves neurodevelopmental outcomes, and decreases necrotizing enterocolitis and prevents sepsis (3,4).

Long term morbidity associated with preterm birth including growth restriction, intellectual disability, cerebral palsy, hearing and visual defects, chronic lung disease, feeding and digestive problems may, in part, be reduced by adequate nutrition in the post-discharge period. Harm reduction is associated with breastfeeding or use of human milk for necrotizing enterocolitis and neonatal sepsis. The American Academy of Pediatrics Committee on Nutrition recommends that human milk be supplemented (or fortified) with calcium (150 to 220 mg/kg/day), phosphorous (75-150 mg/kg/day), vitamin D (400 IU/day) and iron (2-4 mg/kg/day) to meet the increased metabolic needs and deficiencies as a result of preterm birth (5). Of randomized controlled trials of nutrient enriched milk or formula after discharge, six showed improved growth. Improved growth was accompanied by an increase in lean mass, not fat mass, and bone mineral content. (6) In a retrospective cohort study in Hong Kong growth rates of LBW and VLBW infants, infants fed breast milk overall growth was accelerated compared to those fed formula with fewer infants being classified as small for gestational age at discharge (7). Post-discharge nutrition needs may be met by human milk, human milk supplemented with post-discharge formula, vitamins and iron, or exclusively post discharge or some term formulas. Systematic reviews show a benefit in growth but minimal benefit on neurodevelopmental outcomes. Infants born at <1500 grams birth weight need close monitoring of growth parameters using validated growth curves (for prematurely born infants). Nutritional intake should be assessed at discharge and every 2 to 4 weeks thereafter until stable weight gain has been achieved. This strategy of monitoring requires individualization

as nutritional needs in LBW infants are wide ranging. Further complimentary food is advised to start not later than 6 months adjusted age (8).

***"In a large meta-analysis comparing donor breast milk to formula feeding of low birth weight infants there were nutritional advantages to the donor breast milk, in addition to a reduction in necrotizing enterocolitis, sepsis, and bronchopulmonary dysplasia.."***

### Supporting Evidence:

Evidence supports the use of donor human milk for LBW infants and especially those <1250 grams or very low birth weight (VLBW). Two published trials of growth in VLBW infants fed human donor milk and provided bovine human milk fortifier to supplement maternal milk found growth improved in those in which fortifiers were used to provide additional, protein and minerals. Schanler et al (9) found that a weight gain deficit of -3 g/kg/day was noted for infants fed maternal or donor milk compared to those fed formula, but no difference was noted between the donor and maternal breast milk groups. Length and head growth were similar across all three groups. In a second trial, Colaizy and colleagues (10) studied growth in VLBW infants fed varying proportions of maternal and donor human milk. Infants receiving >75% of the in-hospital diet as donor milk experienced a weight z-score change of -0.84 vs -0.56 compared to infants receiving 75% maternal milk (p=0.28). Infants in this trial also received levels of protein fortification in excess of those produced with manufacturer-directed bovine human milk fortifier use, through additional bovine HMF use or as a single component protein powders. Hair and colleagues (11) studied a similar cohort of VLBW infants fed an exclusive human milk diet, and reported that with early use and rapid advancement of human derived human milk fortifiers found that a weight gain of 24.8 g/kg/day can be achieved exceeding most recommendations. However, 43% of these infants were small for gestational age at discharge or 40 weeks post-menstrual age. The issue of what is the ideal fortifier for human milk (whether from mother's own milk or from donor milk sources) was also addressed Schanler et al (12) who found improved growth in the exclusively human milk (either mother's or donor) and human milk fortified group. Sullivan and coworkers (13) also demonstrated when used early in the life of low birth weight infants a reduction in necrotizing enterocolitis can be achieved with a non-bovine sourced fortifier. In a large meta-analysis comparing donor breast milk to formula feeding of low

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birth weight infants there were nutritional advantages to the donor breast milk, in addition to a reduction in necrotizing enterocolitis, sepsis, and bronchopulmonary dysplasia (14,15).

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***“Given these supportive evidence, when mothers can no longer produce adequate supplies of milk for their growing infant, or when socioeconomic factors strongly influence whether mothers can continue to breast feed their infant, donor human milk takes on added importance. ”***

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It should be noted that a recent Canadian trial comparing the effect of supplemented donor human milk with preterm formula for an infant’s initial 90 days or until initial discharge when mother’s milk was unavailable, showed minimally clinical important differences on the Bayley Scales of Infant and Toddler Development (3rd edition, Bayley III) at 18 months among infants in either group. In this study, mortality and morbidity index was similar as was growth-z scores between infants in both feeding groups (16). To date, the authors are unaware of any randomized trials comparing supplemented breastfeeding, donor milk, or formula in terms of growth and cognitive performance for LBW infants fed any of these nutrients for the first 6 months adjusted for gestational age.

Recent evidence also suggests that the health impact of human

milk on improving infant outcomes and reducing the risk of prematurity-specific morbidities appear to be linked to specific critical exposure periods post-birth during which the exclusive use of human milk and the avoidance of commercial formula may be substantially greater than previously recognized. (17-21) Given this supportive evidence, when mothers can no longer produce adequate supplies of milk for their growing infant, or when socioeconomic factors strongly influence whether mothers can continue to breast feed their infant, donor human milk takes on added importance.

**Donor Breast Milk Safety:**

Donor breast milk preparation, safety and usage options of banked donor breast milk have been carefully reviewed by the Committee on Nutrition Section of Breastfeeding, Committee of the Fetus and Newborn of the American Academy of Pediatrics. They concluded that the “use of pasteurized donor milk is safe when appropriate measures are used to screen donors and collect, store, and pasteurize the milk, and then distribute through established human milk banks” (22). The Northwest Mothers Milk Bank of Portland, Oregon meets all of these standards and was re-certified by the Human Milk Banking Association of North America. Donor mothers are carefully screened, a comprehensive medical history is taken, and milk monitored for potential adulteration. Transport to hospitals or to homes of discharged premature infants carefully accounts for the transit time, temperature, and uses commercial carriers of biologic products for delivery.

Prevalence of Low Birth Weight Infants and Breastfeeding in Oregon: From 2015-2017, 65-70% mothers in Oregon from 2015-2017 continue to breast feed their prematurely born infants weighing < 1500 grams at birth at the time of hospital discharge

**Table I Oregon total births, LBW births, Breastfeeding at Discharge, and Payer Source 2015-2017 (From the Oregon Center for Health Statistics 8/10/18)**

	2015		2016		2017	
	Medicaid	Other/Unk*	Medicaid	Other/Unk	Medicaid	Other/Unk
Total Births	20915	25187	20291	25686	19282	24332
LBW births	241	243	210	243	248	211
Discharged Alive	194	201	167	204	195	165
Breastfeeding At Discharge	131	130	112	143	130	112
% Breastfeeding at NICU discharge	67.5	64.7	66.1	70.1	66.7	67.8

\*Third party payer/unknown payer source

from NICUs (Table 1). This rate was not altered by insurance status (Oregon Health Plan versus Third Party Insurance (or unknown) (data prepared by Oregon Center for Health Statistics, 8/10/18). Women account for over 50% of the workforce in the United States and in Oregon 58.1% (23), and many working women must make critical choices regarding continuance of breastfeeding when returning to work. Returning to work is reported to negatively impact breastfeeding exclusively and its duration. While federal law protects some women, not all women have legal support to breastfeed or express milk at work. Further exemptions to federal law include limitations related to the employee's status, classification of employer, total number of employees and the employer's annual revenue. Both mothers of term and many preterm infants too frequently elect to wean early to return to work secondary to economic pressures to provide for their families. Thus, donor breast milk becomes crucial to keep infants on track with the benefits associated with human milk, when mothers either produce insufficient breast milk, or pumping and storage of their milk is not provided by their employer.

However, donor breast milk is modestly expensive especially for mothers on Medicaid. Their infants may further benefit from donor breast milk, even though the cost may be unaffordable to Medicaid beneficiaries. At an average cost of \$4.50 per ounce (data from the NW Mother's Milk Bank, personal communication 8/1/18), and with breast milk feeding volume increasing up to ~32 (~\$144 per day) to ~48 ounces per day (\$216 per day) until complimentary foods are introduced and tolerated for growing LBW infants, donor milk (or mother's own milk) with fortification can provide ongoing benefits to these growing infants.

In August 2018, only California, Kansas, Missouri, Montana, New York, Texas, Utah, and the District of Columbia have legislation or Medicaid or Health Department rules to provide donor breast milk as a Medicaid benefit for growing premature infants. (Table II) All of these Medicaid policies require a prescription by a licensed health care provider and documentation of medical necessity. These policies require informed consent with documentation that the risks of donor human breast milk have been discussed with the parent or guardian. Yet the risks of bovine based formula and fortification do not require similar consent. Policies also specify that donor milk must be obtained from a milk bank meeting quality standard established by each state, such as certification by the Human Milk Bank Association of North America. In Texas, the District of Columbia, and Utah there is a requirement for renewal of prior authorizations every 6 months. The HCPCS code 72101 (human breast milk processing, storage, and distribution only) is used for reimbursement of donor human breast milk. For inpatients, Texas requires that hospitals bill revenue code 220 (special charges with the procedure code T 2101), Code 89998 (enteral nutrition not otherwise classified) is used for outpatients,

Third party reimbursement (insurance coverage) is virtually non-existent placing a large financial burden on families when human milk is deemed medically appropriate for a vulnerable LBW infants after hospital discharge.

#### Cost/Benefit Analysis:

While a cost analysis comparing use of human milk versus formula in the initial Neonatal Intensive Care Unit stay has demonstrated benefit by avoiding costly complications (e.g. necrotizing enterocolitis, sepsis, and bronchopulmonary dysplasia) (15,24),

no cost/benefit analysis has been performed demonstrating cost benefit for breastfeeding or use of donor breast exclusively for infants from time of hospital discharge until 6 months.

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### ***“Cost reductions in expenses due to hospitalization from preventable morbidities may be achievable by using human milk.”***

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Unique to Oregon, through its federal waiver for Medicaid beneficiaries, is the Health Evidence Review Commission that evaluates the medical evidence and potential medical necessity for all health-related treatments, including nutritional supplements, for those citizens receiving the Oregon Health Plan (Oregon Expanded Medicaid), and to undocumented women delivering in Oregon and their infants. In a few instances use of donor breast milk from the Northwest Mother's Milk Bank (Portland, Oregon) has been approved primarily by Medicaid as “rescue therapy” for very low birth weight infants demonstrating intolerance to bovine-based formula, elemental formulas, or during infancy. (Nathan Roberts, Oregon Health Authority, Personal Communication July 1, 2018). These approvals are by “exception” and take a concerted effort by providers and advocates providing for short term payment after approval by the Medical Management Committee of the Oregon Health Authority. The advantages of such “rescue therapy” using donor breast milk or fortifiers has previously been reported. (25). Another group of infants likely to benefit from human milk are those infants with congenital bowel atresia, gastroschisis, omphalocele or infants with “short gut syndrome” usually occurring after surgical resection of bowel because of necrotizing enterocolitis. Infants with bowel anastomosis failures, or with long segment bowel atresia may also benefit; however no randomized trials have been conducted in these infants owing to the infrequent occurrence of these conditions. Although nutritionists and pediatric surgeons recommend breast milk for these infants. Other infants with severe bovine protein enteropathies may also benefit from donor breast milk. There are currently no determinations by the Health Evidence Review Commission regarding the medical benefit or necessity of human milk, donor breast milk or human milk fortifiers for this population of low birth weight infants. Given the abundant evidence supporting the medical benefit of mother's own milk or donor breast milk, it is imperative that especially for infants born <1500 grams at birth that Medicaid officials review the evidence and conclude that this is a medically necessary investment for the future of infants <1500 grams at birth. Clearly the expenditure of \$144 - \$216 per day [\$12,960-\$19,440 for 3 month's supply] for these vulnerable infants is justified based on medical necessity and unique individual circumstances (this assumes that the average mother ceases breastfeeding 3 months after NICU discharge). Although, the Women's Infants and Children's (WIC) program in all states provides discharge formulas for premature infants by physician prescription. WIC programs have no role in the provision of donor milk for growing premature infants despite the fact that nutritional benefits for breastfeeding mothers are approved.

There is low to moderately strong evidence for the medical benefit of donor breast milk using the evidence scale of Guyatt et al (26)

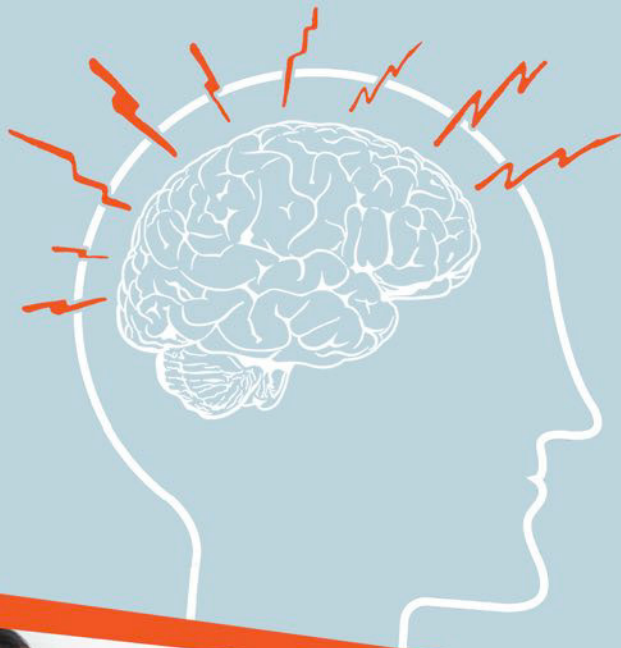
**Table II State or District of Columbia Specific Donor Human Milk Policies in Medicaid Programs**

<u>State</u>	<u>Medicaid Requirements</u>
California	<p>Eligibility: Donor milk usually used for infants in neonatal intensive care, or infants who are born to mothers whose breast milk is not considered consumable by their infant, infants who fail to thrive on formula, infants facing life-threatening diseases or conditions with failing immune systems, mother of multiple births who cannot meet the needs of her infants, mothers with insufficient supply during first week of life, infants of mothers who are unable to produce sufficient milk for her infants, infant adopted by families and believe in the value of breast milk. Straight MediCal will pay, but CCS MedicalTeams may deny by county of residence</p> <p>Documentation: inpatients may receive donor breast milk by a physician's order and a hospital request form to Mother's Milk Bank; Outpatients require a physician's prescription to the Mother's Milk Bank with a request for "Donor Breast Milk" specifically noting the required ounces per day, week, or month, and prescription must be signed by physician or nurse practitioner.</p> <p>Milk Bank Requirements: Only the Mother's Milk Bank of San Jose provides donor milk Reimbursement: Use of HCPCS code T2101; \$2.95 per ounce</p>
District of Columbia:	<p>Eligibility: Infants, age 0 to 11 months, provided all criteria are met including documentation of medical necessity and that formulas have not provided desired nutrition, human milk must be used to correct or ameliorate a condition or effect, re-evaluation every 6 months, and parent's consent. Prior Authorization must be completed by physician and expires at 12 months of age.</p> <p>Documentation: A treating physician must submit a Donor Human Milk form Every 6 months and declare medical necessity by written documentation</p> <p>Milk Bank Requirements: Enrolled as a Medicaid Provider in DC and certified by the Human Milk Bank Association of North America and meets standards adopted by Department of Health Reimbursement: Procedure Code T2101, \$3.30 per ounce</p>
Kansas:	<p>Eligibility: Infant is &lt;3 months of age, critically ill, and in the NICU and Milk ordered by a licensed physician and surgeon and the Kansas Department of Health and Environment has determined that the milk is medically necessary, informed consent of the parents or legal guardian</p> <p>Documentation: Prior authorization that uses the "best medical evidence and care and treatment guidelines consistent with national standards to determine medical necessity."</p> <p>Reimbursement: not determined.</p>
Missouri:	<p>Eligibility: Infant &lt; 3 months of age, critically ill, infant in NICU, human milk ordered by a physician, and the department of health determines that human milk is medically necessary, parent or guardian signs and dates informed consent indicating the risks and benefits of banked donor human milk.</p> <p>Milk Bank Requirements: The milk is obtained from a donor human milk bank that meets the quality guidelines established by the Department of Health.</p> <p>Prior Authorization: An electronic web-based prior authorization system using the "best medical evidence and care and treatment guidelines consistent with national standards" shall be used to determine medical need.</p>
Montana:	<p>Eligibility: Infants &lt;12 months of age who have been shown not to tolerate various formulas and for whom a physician demonstrates lack of growth. Testing of mothers for hypothyroidism, reduce prolactin levels, and encourages use of galactagogues</p> <p>Milk Bank Requirements: Donor human milk is obtained from the Montana Mother's Milk Bank Documentation: Physician's prescription and statement that infant has not tolerated formulas and growth chart records.</p> <p>Reimbursement: Montana Medicaid reimburses the Montana Mother's Milk Bank \$4.00 per ounce.</p>

**Table II State or District of Columbia Specific Donor Human Milk Policies in Medicaid Programs (continued)**

State	Medicaid Requirements
New York:	<p>Eligibility: Infants have a birth weight &lt;1500 grams; or have a congenital or acquired condition that places the infant at a high risk of developing necrotizing enterocolitis and/or infection, or have other qualifying condition(s) as determined by the Commissioner of Health or his/her designee. Coverage is for infants who are medically or physically unable to receive maternal breast milk or participate in breast feeding, or in cases where the mother is medically or physically unable to produce maternal breast milk at all or in sufficient quantities, or is unable to participate in breast feeding despite optimal lactation support. Medicaid managed care plans are required to cover inpatient use when medically necessary. Both donor breast milk and breast milk fortifiers are covered benefits.</p> <p>Milk Bank Requirements: Not specifically mentioned in law</p> <p>Documentation: Medical necessity is covered by the qualifying conditions</p> <p>Reimbursement: Not mentioned in law</p>
Texas:	<p>Eligibility: Inpatients age 6 months or younger, outpatients age through 11 Months and may be extended through 20 months with documentation of medical necessity. Hospitals must follow clinical recommendations for administering donor human milk to inpatients and maintain all applicable and appropriate medical necessity documentation in the medical record. For out-patients the requesting physician documents medical necessity and appropriateness, including why the particular patient cannot survive or gain weight on any appropriate formula, or any enteral nutritional product other than donor milk, a clinical feeding trial of an appropriate nutritional product has been considered with each authorization, the parent or guardian provides consent detailing the risks and benefits of using banked donor human milk, physicians must address the benefits and risks of using donor human milk, such as HIV, effects of pasteurization, nutrients, growth factors to parents. The physician must also address donor screening, pasteurization, milk storage, and transport of the donor milk. The physician can obtain this information for the donor breast milk bank. There is a maximum of 6 months per authorization that can be extended if medically necessary</p> <p>Milk Bank Requirements: Texas Medicaid enrolled donor milk bank, adheres to quality guidelines consistent with the Human Milk Bank Association of North America or others standards that may be adopted by Texas Health and Human Services Commission.</p> <p>Prior Authorization: Not required for inpatients, but required and must be renewed every 6 months.</p> <p>Reimbursement: For inpatients hospitals must bill revenue code 220 (special charges) with procedure code T2101; outpatients bill as "hospital service with the most appropriate outpatient type of bill. Bill must include number of ounces and reimbursed at \$2.00 per ounce. Outpatient procedure code 89998 and reimbursed at a maximum fee determined by HHSC or manual pricing, and billed to a Texas Medicaid enrolled donor milk bank.</p>
Utah:	<p>Eligibility: Member (patient) resides in a home setting with all of the following criteria being met: Medicaid eligible and age birth through 11 months, requesting provider is infant's treating practitioner, infant has completed a feeding trial, "requesting provider has addressed with the parent or guardian the benefits and risks of using donated milk, such as HIV, freshness, effects of pasteurization, nutrients, growth factors, the prescriber has provided information to parent or guardian information concerning donor screening, pasteurization, milk storage, and transport of donated milk., An informed consent signed and dated by the parents outlining the risks and benefits of donor breast milk must be included.</p> <p>Milk Bank Requirements: The Breast Milk Bank must be certified by the Human Milk Bank Association of North American and enrolled as a Utah Medicaid provider</p> <p>Prior Authorization: The treating physician will submit a prior authorization request, provide a Donor Milk Request Form, and documentation indicating medical necessity and why the mother cannot supply the breast milk. This request must be submitted every 6 months.</p>





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for Medicaid beneficiaries in Oregon and other states. In Oregon, the Northwest Mother's Milk Bank in Portland, Oregon has the capacity to serve these infants according to their Executive Director (Lesley Mondeaux, RNC, IBCLC, personal communication August 10, 2018). While benefitting approximately 900 LBW infants in Oregon's annually, this benefit may have a life long impact in terms of their optimal nutrition during a vulnerable part of their young lives. Cost reductions in expenses due to hospitalization from preventable morbidities may be achievable by using human milk.

#### Conclusion:

Low birth weight infants are susceptible to health conditions during their NICU hospitalization such as necrotizing enterocolitis, retinopathy of prematurity, death, disability, and neurodevelopmental delay. Composition of feedings has a critical role to play in the care of these infant critically ill infants and a reduction in some of these morbidities. Fortified breast milk has been demonstrated to improve many outcomes compared to formula feeding. Often mothers of premature infants are unable to produce sufficient milk to be used as the sole source of nutrition for their own infant(s) either while in the NICU or after hospital discharge. Pasteurized and fortified donor human milk and preterm formula are both used to feed LBW infants, both as in the NICU setting and as outpatients, who have insufficient maternal milk available to meet their nutritional need and for whom no maternal milk is available. No cost effectiveness analysis for the use of donor breast milk versus formulas designed for growing premature infants used exclusively post hospital discharge can be identified. However, as noted, the American Academy of Pediatrics strongly recommends human milk for all infants through their first six months. Donor breast milk using rigorous screening, processing, storage and transport methodologies is an excellent source of nutrition for these LBW infants and should be considered as a Medicaid benefit for low birth weight infants eligible for Medicaid in all States. In those states providing the benefit to Medicaid beneficiaries there are various eligibility criteria. Some states provide for both inpatient and post-discharge donor breast milk through 11 months of age. Others are more restrictive requiring documentation of medical necessity, renewal of prior authorizations every 180 days, and all require that donor breast milk be obtained from a Breast Milk Bank certified by the Human Milk Bank Association of North America. Reimbursement for breastmilk varies by state.

Premature labor and delivery are stressful events and education regarding the benefits of breastfeeding should begin during pregnancy and early pumping (with 6-12 hours after preterm delivery and continued 8-12 times per day until mother's milk supply is well established. (27) Ongoing encouragement with assistance by a lactation consultant is helpful in establishing both the milk supply and to provide ongoing education about the goal of breastfeeding for six months or more. Women experiencing a premature delivery may experience a decrease in milk production that can be countered by increased skin to skin time, stress reduction, and careful attention to diet, sleep, pumping schedules and when needed use of galactagogues. The transition from tube feedings to breast feeding in the NICU may also represent a challenge for some mothers of premature infants and usually occurs between 30-34 weeks gestation. This period of added "stress" to some mothers requires reassurance, not the least of which is the knowledge that should breast feeding not be possible for the entire 6 months an alternative source of breast milk,

using donor sources, may be available for their infant. Parental income should not be a factor in providing optimum nutrition for her growing infant. Overall there is low to moderate evidence of effectiveness of donor breast milk alone. When used, donor breast milk should be accompanied by use of a human milk based fortifier, protein, minerals, as well as, by the use of multi-vitamins especially Vitamin D. There is moderate evidence for improving growth of LBW infants and reducing some neonatal morbidities (necrotizing enterocolitis, sepsis, bronchopulmonary dysplasia, and possibly retinopathy of prematurity), and enhancement of neurodevelopmental performance in some, but not all studies.

There exists a significant disparity among the states regarding Medicaid benefits for coverage of donor breast milk and fortifiers that have been advocated by the American Academy of Pediatrics, thus a significant disparity exists in Medicaid benefits for some of the most vulnerable in our society. Parental income should not be a factor in providing optimum nutrition for growing premature infants.

*Acknowledgements: The opinions expressed here represent those of the author's and do not represent of the author's respective institutions.*

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# Commentary: Should Donor Breastmilk be Covered by State Benefit Programs?

Elba Fayard, MD and Carlos R. Fayard, PhD

Several states (Kansas, Texas, Missouri, New York, Montana, Utah, California) and the District of Columbia have declared that donor breast milk should be a benefit, based on prevailing evidence of medical effectiveness. California has taken the next step of advocacy as California Medicaid and California Children's Services have provided the benefit of donor breast milk to selected infants for nearly two decades. In addition to federal and state funds through Medicaid expansion, California also dedicates a significant portion of tobacco tax revenues, for healthcare of those 20 years or younger, through a system of state and county programs. These provide regulations and numbered letters with professional guidelines for evidence-based care determined by pediatricians.

Oregon on the other hand has championed its version of health-care reform by providing various forms of health care and alternative medicine to Medicaid beneficiaries through a federal waiver, using regional accountable care organizations and a fee for service program. Yet, as noted in the accompanying article, there still exist health care disparities that have to be addressed in Oregon. The article regarding coverage for donor breast milk both in the Neonatal Intensive Care unit and after discharge, as provided in some states, including California and the District of Columbia, highlights some of the social disparities that are evidenced in the care received by mothers and their infants.

Oregon's evidence based approach for services to be covered by Medicaid is similar to California's approach, but it does not provide for donor breast milk. While Oregon's approach to evidence based medicine may be lauded by some using a Health Evidence Review Commission (1) to examine medical evidence, it is noteworthy that, even though physicians have been appointed to the Commission (by the Governor), currently neither a board-certified pediatrician nor a neonatologist has been appointed to evaluate evidence of beneficial treatments for infants and children or to advocate for their health needs (2). Further, some important advances in Medicine have improved the lives of infants and children and have been approved without large multi-center randomized controlled trials.

There are infant heart transplants, Extracorporeal Membrane Oxygenation for diaphragmatic hernias, various treatments of autism, or therapies for infants with cerebral palsy. However, treatments without prior proof of efficiency such as acupuncture and chiropractic manipulation in children, and home delivery of infants by non-medical professional (despite documented increased mortality and morbidity) are benefits approved for payment (3) in Oregon. Greater than 120,000 children are Medicaid beneficiaries (4) and about half of infants delivered in Oregon are born to mothers on Medicaid. How Oregon honors the Medicaid coverage for these patients is of utmost importance.

Oregon Neonatologists and other physicians provide good evidence that human milk benefits infants born prematurely and <1500 grams or low birth weight infants. Provision of donor breast milk for LBW both in hospital and after discharge is but a first step in optimizing the health of infants throughout their first year. However, the real challenge is to support women that want to care for their infants during their first year. This can be done by providing paid Family Medical Leave for an entire 6-12 months, not 12 weeks! Giving mothers who choose to breastfeed an ample opportunity to do so and to nurture her baby during the first year of life without economic constraints will go a long way to increase children health.

It has been recognized that the social determinants of health play such a significant role in the ongoing health of infants and children. Perhaps the next goal for Oregon and other States, Commonwealths, District of Columbia, and territories of the US would be to fully implement paid maternal leave for 6 months to one year after an infant's birth. Being a champion for healthcare reform should not have to be in baby-steps, but rather in bold and determined efforts to eliminated the social disparities that exist for mothers in Oregon as well as in other states.

Oregon voters are being asked to determine whether tax dollars should pay for abortions (4), as currently authorized by state law. However, the real issue should be whether taxpayer's dollars should be spent to give an extra option to mothers who given choice, choose life and then want to breastfeed: women committed to caring for their infant during the first 6- 12 months after birth. To be true leaders in women's and children health means that we speak with our funds; dollars need to be focused from both the public and private sectors to honor both mothers and their babies, allowing for optimal care during the first year after birth, providing optimal nutrition to babies by their own mothers who will no longer have to return to work immediately because of financial pressures.

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[www.nationalperinatal.org](http://www.nationalperinatal.org)

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# Heart rate: the delivery room debate

Shabih Manzar, MD

## Neonatal Case

An infant is delivered vaginally at 24-week gestation infant with suspected abruption. (ie.) The case involved an premature male/female born to a 30 year old gravida 2, para 2 mother at 24 2/7 weeks gestational age. The mother presented to the labor and deliver unit with suspected of placental abruption. Mother was stable/or vaginal delivery was imminent. Infant was placed on external/internal electronic monitoring which showed that the baseline fetal heart rate was 140 bpm. Fetal tracing suggested a category 2/3. Incorporate the times of each stages of labor. What medications did mother receive? The NICU team was present for the delivery. Was there any assistance used by the OB team? Was there any delivery complications? Nuchal cords, ie. Was there delayed cord clamping or cord milking? At what time was the baby placed on the warmer. Infant was placed on warmer bed in the delivery room. Infant initially cried at birth and was vigorous/limp and not responsive. What resuscitation was initiated? At one minute of life what was the Apgar's? How was the heart rate obtained? What was the next step that the NICU team do? At five minutes/ten minutes/fifteen minutes/twenty minutes of life were the Apgars? Describe the resuscitation that took place until infant was viewed stable for transport to the NICU. The neonatology team started cardio-pulmonary resuscitation (CPR) and infant was then transferred to Neonatal Intensive Care Unit (NICU). The debate started between the Obstetric (OB)(was there concern for fetal acidemia and asphyxia?) and Neonatal teams regarding the heart rate of the infant at birth. The OB documented fetal heart rate 140 beats/min noted by cardiogram (CTG) soon before birth while the neonatology team noted no heart rate at birth using stethoscope. CPR was started per Neonatal Resuscitation Program (NRP) guidelines. Infant remained stable in NICU without any consequences of CPR (Figure 1). The case highlights on the need for more objective way of documenting heart rate at birth.

## Discussion

Auscultation is subject to human error and is often inaccurate especially in small premature infants at birth who is not vigorous<sup>1</sup>. There are three ways heart rate is assessed at birth; auscultation, palpating umbilical pulsations and pulse oximetry. There are three ways to assess the heart rate at birth: auscultation, palpating umbilical pulsations and through pulse oximetry. All these methods have potentials for error<sup>2</sup>. A pulse oximeter takes an average of 24 seconds to provide the heart rate, and its waveform depends upon heart contractility and skin perfusion<sup>3</sup>. Thus by using these methods, there remains a chance of over or under resuscitation.

The solution to this problem is to use ECG leads and cardiac monitor. The superiority of this method has been shown in recent report<sup>4,5</sup>. This method is able to ascertain heart rate

within 2 seconds. In complex resuscitation, such as in the case presented above, it is suggested by NRP Steering Committee to use ECG monitor<sup>2</sup>. Institutions have to make sure the ECG monitor is available in cases where:

- Auscultation is difficult and infant is not vigorous
- Pulse oximetry has unreliable signal
- PPV begins and a guide is needed for decision making
- When heart rate is low with poor perfusion and cardiac compression is started.

**“The solution to this problem is to use ECG leads and cardiac monitor.”**

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**Editor's Response:**

Dr. Manzar presents a compelling argument for the use of ECG leads in the delivery room. This thinking is in line with the current recommendations of the NRP steering committee of the American Academy of Pediatrics. However, there are several issues that must be reconciled before committing to the use of an ECG monitor in deference to a pulse oximeter.

First, the two devices measure different physiological phenomena. The ECG measures the electronic impulse of the nerve at the chest wall. The pulse oximeter measures the actual pulse at the level of the capillary bed of the hand or the foot. The pulse can be more closely associated with the rate of a beating heart.

Second, an ECG signal is not proof of a beating heart. Disassociation of the signal with muscular activity can occur at any time. In fact, there are many documented cases where heart activity has ceased

despite a relatively normal ECG (see reviewer references).

Third, a normal ECG rhythm and heart rate is now used as proof that a baby does not need resuscitation. The pulse oximeter which may be having difficulty picking up is disregarded. At the same time, cord pulsation and direct auscultation are "discouraged" by reliance on the ECG. In fact, if the oximeter is not picking up, this is clear evidence of poor peripheral perfusion pressure and/or disassociation. Auscultation is obligatory.

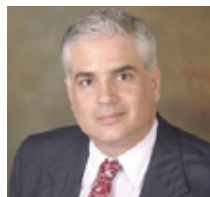
Finally, and conversely to the AAP argument, securing ECG leads first takes time away from securing a pulse oximeter in place, delaying the assessment of the true pulse rate.

Mitchell Goldstein, MD  
Editor in Chief

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# FROM THE NATIONAL PERINATAL INFORMATION CENTER

## How is the US doing with Perinatal Regionalization?

### Short Answer: Hard to Tell

Janet H. Muri, MBA

**The National Perinatal Information Center (NPIC) is driven by data, collaboration and research to strengthen, connect and empower our shared purpose of improving patient care.**

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Healthy People 2020 has sixty-four Maternal, Infant and Child Health (MICH) Objectives that have been developed and refined from previous Healthy People initiatives. MICH-33 Objective calls for the MICH community to “increase the proportion of very low birth weight infants born at Level III hospitals or subspecialty perinatal centers”.<sup>1</sup>

The HP 2020 target for this objective is a national average of 83.7% from a baseline rate of 75% in 2003-2006. The latest reported data on the Healthy People 2020 website shows a 2010 rate of 74.5% with a graphic showing “little or no detectable change” for this metric.

The data for MICH-33 come from an annual report submitted by the states and the District of Columbia through their Title V Information System (TVIS). The denominator is all VLBW infants born in the state for the year and the numerator is all cases from the denominator who were born at Level III or subspecialty perinatal centers. Identifying one national average for all the reporting states and DC suggests there are likely a number of states who have already achieved the target and those that fall well short.

We are hopeful that, yet to be measured, improvements over the last 7-8 years have been driven by initiatives such as the Health Engagement Networks (HENs), the national focus on population health and rapid consolidation of standalone hospitals into systems and Accountable Care Organizations (ACOs).

Unfortunately, a major problem with tracking this metric through HP 2020, aside from the data delay, is whether the numerator cases reported for each state are truly measuring the same population. Since the first *Toward Improving the Outcome of*

*Pregnancy (TIOP I)*<sup>2</sup> in 1976, the MCH community has had a relatively consistent definition of Level III and subspecialty perinatal centers, especially on the neonatal side. The dilemma is the degree of review, regulation and consistency with which the definitions are applied across states. Variations can make defining the number of Level III/ subspecialty perinatal centers even within a state a moving target.

The HP 2020 MICH-33 Objective and target rate supports the long term recognition, first expressed in TIOP I, that identifying and caring for at risk (mothers) and infants (regardless of VLBW status) has long term positive outcomes for the dyad, the family and society.

A national perinatal regionalization rate may be somewhat informative but there is no question that each state has an independent and vested interest in monitoring their own regionalization across the state and within state identified regions of care. For most states, Medicaid is the largest payer for maternal and child health services; knowing how efficient the referral and transport systems (antenatal and neonatal) function within the state is the fiduciary and public health responsibility of Medicaid state leadership. It also affords Medicaid substantial leverage in incentivizing providers to participate in an efficient system.

NPIC would like to propose a methodology for monitoring these regionalization patterns that uses a patient specific/more current statewide data set: the hospital discharge data set.

Most states assemble a discharge abstract data set that reflects all discharges from every hospital every quarter. This data set presents a rich opportunity for the state to analyze the location of high risk births across the state and within regions. States have all the tools to organize their regions of care and birthing facilities into their state-defined levels of care. Within those designations, using the discharge data set to identify location of birth for all high risk mothers and infants can help inform providers and state MCH leadership where there are opportunities for improvement not only in the delivery/birth location of high risk cases, but in outcomes and utilization as well. VLBW or compromised infants born at the wrong facility and not transferred immediately can translate into huge financial and quality liabilities for all those involved in MCH care.

Just a few of the questions that can be answered from the discharge data set include:

- What percent of VLBW infants are not born at Level III/ subspecialty perinatal centers and are there regions within our state that need our focused attention?
- If VLBW infants are born at non-Level III/subspecialty perinatal centers, how quickly are they transferred to a higher level of care?
- Are LBW and NBW infants with serious complications also being born at Level III/subspecialty perinatal centers?
- Are high risk moms being delivered at Level III/subspe-

cialty hospitals? If not, what are their differential outcomes and lengths of stay?

- What are the BW specific mortality rates across regions and within levels of care across regions?

All these analyses can also be done isolating the state's Medicaid population. NPIC's 2017 Perinatal Center Data Base, shows an average of 44.2% of all neonatal special care discharges were paid for by Medicaid with a range across our peer subgroups of 37.9% to 70.1%.

Medicaid leaders have great interest in fostering an efficient, high quality regionalized system. While state discharge data sets may not be as current as most would like, they offer a way to understand regionalization patterns within a state and identify opportunities for improving quality, utilization, outcomes and costs. Updating these analyses on a semi-annual/annual basis can measure whether progress toward a statewide HP 2020 target is within reach or has already been achieved.

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Janet H. Muri has been with the National Perinatal Information Center since 1986 and it's President since 2007. Ms. Muri oversees all collection, processing and analysis of clinical and financial data submitted by NPIC member hospitals and other state, federal and private data sources related to contract work. Ms. Muri was a contributing author to TIOP III Chapter 2: Evolution of Quality Improvement in Perinatal Care and has worked with a number of states in assessing regionalization using their statewide administrative data set.

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# Vitamin C During Pregnancy When Women Continue to Use Nicotine: Reversing the Adverse Effects on Lung Development

Lily Martorell-Bendezu, MD, Bryan T. Oshiro, MD, T. Allen Merritt, MD, MHA

*The National Perinatal Association (NPA) is an interdisciplinary organization that strives to be a leading voice for perinatal care in the United States. Our diverse membership is comprised of healthcare providers, parents & caregivers, educators, and service providers, all driven by their desire to give voice to and support babies and families at risk across the country.*

*Members of the NPA write a regular peer-reviewed column in Neonatology Today.*



In 2014, Oregon researchers showed that vitamin C (500 mg/day) supplementation to pregnant smokers improved the pulmonary function tests of infants and decreased wheezing through their first year, when compared to infants of pregnant smokers who received placebo (1). Several authors have reported on reduced pulmonary function among preterm and term infants whose mothers smoked during pregnancy (2-4). Reduced pulmonary function at birth has been associated with increased risk of asthma by 10 years of age (5). The potential benefit of vitamin C supplementation in improving long term health and decreasing disease burden can be significant as measured by the improvement in quality adjusted life years

(QALYs).

Hungarian Albert Szent-Györgyi discovered ascorbic acid's role as an anti-oxidant and was awarded the Nobel Prize in 1937. The curative powers for a host of human illnesses including asthma was advocated by Linus Pauling, twice a Nobel Laureate from Oregon (6). Pharmacokinetic data suggest that 500 mg of Vitamin C daily saturates Vitamin C receptors, maximizes plasma concentrations and conforms to the recommended daily allowance recommended for young women (7).

***“Evidence supports that much of the adverse effects of tobacco smoking during pregnancy on neonatal lung function is mediated by nicotine.”***

Evidence supports that much of the adverse effects of tobacco smoking during pregnancy on neonatal lung function is mediated by nicotine. Animal models have shown that nicotine appears to damage the DNA of proliferating cells in the fetal lung, which have low antioxidant capacity during most of pregnancy (8). Another animal model showed that nicotine affects lung development by increasing collagen expression around airways (9). Vitamin C was first shown in animal studies to mitigate deleterious effects of nicotine on pulmonary function. The harmful effects on the offspring of rhesus monkeys were prevented if mothers were supplemented with vitamin C (9). Although the exact mechanism by which Vitamin C mitigates the effects of nicotine on fetal lung function has not been determined, it is likely due to its antioxidant effects.

Harm reduction is a public health strategy initially developed in adults with substance-

abuse problems when abstinence was not feasible. Harm reduction approaches have been effective in reducing morbidity and mortality in these adult populations, and in recent years has been applied to sexual health education to reduce teen pregnancies and sexually transmitted disease, alcohol consumption and other risky behaviors. Harm reduction emphasizes the measurement of health, social and economic outcomes, as opposed to the measurement of drug (or other substances) consumption.

Ideally, tobacco smoking cessation and stopping all forms of nicotine should be the goal of prenatal counseling with the aim of reducing the health burden of nicotine on both the mother and fetus. While pregnancy appears to motivate about 50% of pregnant women to quit smoking before or during pregnancy (10), approximately 12% of American women continue to smoke tobacco during pregnancy. Cessation focused therapies including motivational interviewing, cognitive behavioral therapies, use of text messaging, and nicotine replacement therapies have been less than effective in persuading all pregnant women of the harm nicotine poses on her health and that of her fetus (11-13). Harm reduction strategies include, encouraging decrease exposure to nicotine if unable to stop is due to long term benefits to both mom and fetus. Smoking tobacco has dose dependent (#cigarettes smoked/day) negative effects on infant birth weight (-435 grams lower) in infants whose mothers smoked 11-40 cigarettes per day, and contributes to preterm birth (14). It is not known yet whether lung function is also affected in a dose dependent manner.

Use of alternative forms of nicotine delivery, such as electronic cigarettes and vaping, have increased substantially in recent years (especially among youth). However, there is minimal evidence that these alternatives reduce the detrimental health effects of nicotine exposure compared to traditional cigarettes. The promotion of electronic cigarettes as a method of harm



reduction has been falsely championed as a method to reduce cigarette smoking, when in fact, many pregnant women choose to combine both cigarette smoking and e-cigarette use rather than participate in cessation programs (15). Electronic cigarette use (or vaping nicotine) during pregnancy has similar harmful effects on newborn lung function. McGrath-Morrow and colleagues demonstrated convincingly that exposure of newborn mice to electronic cigarette vapors, 1.8% nicotine for 10 days after birth, impaired lung growth, diminished alveolar cell proliferation and decreased body weight 13% compared to vehicle (propylene glycol). Elevated plasma and urine cotinine levels correlated to the magnitude of fetal growth restriction (16)

The U.S. Preventive Services Task Force has concluded that current evidence is insufficient to assess the balance of benefits and harms of nicotine replacement products or other pharmaceuticals for smoking cessation during pregnancy (17). Conflicting evidence exists regarding whether nicotine replacement therapy increases abstinence rates of smoking during pregnancy. Further nicotine replacement therapy does not appear to increase the odds of permanent smoking cessation during the postpartum period or during breastfeeding (18).

A unique decision-analytic model used by Yieh et al (19) was designed to estimate costs for children exposed to nicotine during pregnancy and outcomes specifically related to the burden of asthma throughout childhood, asthma related deaths. In addition, this model provided estimated cost savings and improved QALYs for smoking pregnant mothers who received Vitamin C along with prenatal vitamins versus prenatal vitamins alone. The estimated benefits of Vitamin C (500 mg/day) along with prenatal vitamins were predicted to be \$5,947,200 in direct health care costs and \$31,420,800 over 18 years, an increase in QALYs by 19,200 for the 4 million infant born annually in the U.S and fewer deaths from asthma. In addition to the significant cost savings, the improvement in QALYs is noteworthy when considering the impact of asthma on a child's self-esteem and activities such as exercise, sports participation, school attendance. The additional burden of costs to parents in terms of loss of work, trips the emergency department, and medications cannot be underestimated and could be lessened using this strategy. The author's carefully describe limitations of their model and predictions, lead to new questions and where to next focus our efforts for harm reduction.

Based on these pilot data, how can the impact of this novel approach to harm reduction be proven to reduce asthma in childhood on a national or global scale? A large multicenter trial (with high power and stringent p-values) could be undertaken to demonstrate the effects of Vitamin C in addition to prenatal vitamins (given to smoking pregnant women) on pulmonary function of their newborns. These child cohorts would require follow up through 6 years to determine differences in asthma prevalence, needed medical services including hospitalization, and medications used to treat asthma. Alternatively, the strategy of Vitamin C (500 mg/day) supplementation for all pregnant women who smoke or use electronic cigarettes could be adopted, understanding that adults

tolerate up to 10 grams per day with minimal side effects and no known adverse drug-drug interactions (6).

Efforts to encourage smoking cessation by educating women that their use of nicotine in any form has adverse consequences on their fetus, baby, and child's life, especially the burden of asthma, requires greater public awareness. Clearly a combination of these approaches will require collaboration between pediatricians, neonatologists, obstetricians, maternal-fetal medicine specialists, and others who provide prenatal care or neonatal care or are involved in women's healthcare.

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***“Efforts to encourage smoking cessation by educating women that their use of nicotine in any form has adverse consequences on their fetus, baby, and child's life, especially the burden of asthma, requires greater public awareness..”***

---

The tobacco industry and their advertisers bear a substantial responsibility of the burden of childhood asthma in the U.S. Their advertisements need to be carefully vetted for accuracy and truth telling about the harms of tobacco and nicotine. Just as public health messages remind women that “alcohol and pregnancy do not mix,” use of cigarettes or vaping should equally be discouraged. Appropriate signage in the areas where nicotine containing products are sold should warn about its association with premature birth, low birth weight, sudden infant death syndrome, childhood wheezing and asthma.

Yieh, McEvoy and coworkers are to be commended for highlighting a significant public health problem of tobacco use during pregnancy. Vitamin C administration on a broader scale to women who continue to smoke during pregnancy, in addition to prenatal vitamins, iron supplementation, folic acid and consistent prenatal care provide opportunities to reduce long term harm to the most vulnerable. It is an attractive, inexpensive therapy, which can be started along with efforts to improve the diet of pregnant women to include foods with high ascorbic acid levels (citrus fruits and vegetables approaching 500 mg/day), and/or incorporating Vitamin C to current prenatal vitamin preparations.

All health care providers who take care of women during their reproductive years should stress effective harm reduction strategies by encouraging tobacco cessation when possible, recommending a healthy diet rich in ascorbic acid, and by prescribing Vitamin C along with prenatal vitamin supplements to mitigate the harm of nicotine to their babies and children. Why delay?

*Acknowledgement: Portions of this commentary were published as a requested editorial in The Journal of Perinatology by Dr. Merritt and copyrighted by Nature Publishing.*

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# National Black Nurses Association Announces Breastfeeding Resolution



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The National Black Nurses Association (NBNA) was organized in 1971 under the leadership of Dr. Lauranne Sams, former Dean and Professor of Nursing, School of Nursing, Tuskegee University, Tuskegee, Alabama. NBNA is a non-profit organization incorporated on September 2, 1972 in the state of Ohio. NBNA represents 150,000 African American registered nurses, licensed vocational/practical nurses, nursing students and retired nurses from the USA, Eastern Caribbean and Africa, with 92 chartered chapters, in 35 states.

The National Black Nurses Association's mission is "to represent and provide a forum for Black nurses to advocate and implement strategies to ensure access to the highest quality of healthcare for persons of color".

SILVER SPRING, MD, August 14, 2018, The National Black Nurses Association announces the passage of its resolution "National Black Nurses Association Promotes a Healthy Start: Supporting Exclusive Breastfeeding and the Provision of Human Milk for Newborns and Infants". The resolution was approved at the business meeting on August 3, 2018 during the NBNA 46th Annual Institute and Conference in St. Louis, Missouri.

"NBNA firmly believes that mother's breast milk is best for babies, providing important nutrients for a healthy baby", stated Eric J. Williams, DNP, RN, CNE, FAAN, NBNA President. "The data show and several major organizations advocate that breastfeeding contributes to the growth and development of infants and favorable health outcomes for both the baby and the mother."

## NBNA Resolution

National Black Nurses Association Promotes a Healthy Start: Supporting Exclusive Breastfeeding and the Provision of Human Milk for Newborns and Infants

Whereas, breastfeeding is the gold standard for infant feeding. Breastfeeding provides the optimal nutritional benefits for ideal growth and development,

Whereas, it is recommended that an infant is breastfed for at least the first year of life and exclusively for the first six months by the American Academy of Pediatrics, Department of Health and Human Services (DHHS), Association of Women's Health, Obstetrics and Neonatal Nurses, and American College of Obstetricians and Gynecologists,

Whereas, Healthy People 2020 has set national breastfeeding goals of 81% ever breastfed, 51.8% at six months, 30.7% at 12 months and 44.4% exclusive breastfeeding for 3 months,

Whereas, January 2011, the United States Surgeon General reiterated a public health goal of optimal breastfeeding practices and had a "Call to Action to Support Breastfeeding",

Whereas, Joint Commission has added exclusive breast milk feedings to its National Quality Measures to encourage hospitals and other health agencies to create a culture that consider and support parent's choice,

Whereas, the World Health Organization recommends breastfeeding for at least the first two years of life,

Whereas, breastfeeding has known health benefits and is linked to favorable health outcomes for babies, infants and children across the lifespan,



The National Perinatal Association (NPA) is an interdisciplinary organization that gives voice to the needs of parents, babies and families and all those interested in their health and wellbeing. Within NPA, parents and professionals work together to create positive change in perinatal care through education, parent programs, professional guidelines and events.

[www.nationalperinatal.org](http://www.nationalperinatal.org)

Whereas, infants who are breastfed have a significant reduction in risks of lower respiratory tract diseases, asthma, gastroenteritis, otitis media, atopic dermatitis, obesity, diabetes, childhood leukemia, sudden infant death syndrome, and necrotizing enterocolitis,

Whereas, breastfeeding has maternal benefits that include lower risks for hypertension, hyperlipidemia, postpartum depression, breast and ovarian cancer, and reduced risks for the development of cardiovascular disease and type 2 diabetes,

Whereas, breastfeeding reduces specific health outcomes and aids societies by reducing health cost,

Whereas, over 15 years ago, the Surgeon General issued a call to action to reduce racial and ethnic disparities in breastfeeding,

Whereas, racial disparities in breastfeeding persists; initiation rates among African Americans are significantly lower than their counterparts,

Whereas, increasing breastfeeding rates in the African American community can play a vital role in reducing poor infant health outcomes,

Whereas, structural and social changes are needed to improve breastfeeding education, support and resources in the African American community,

Whereas, there is a lack of racial and ethnic minority nurses in the lactation consultant industry,

Therefore, Be It Resolved: The National Black Nurses Association, Inc. (NBNA) believes in the promotion of breastfeeding, the protection of an individual's ability to breastfeed and increase breastfeeding support.

Therefore, Be It Resolved: The NBNA supports exclusive breastfeeding and use of human milk to promote a healthy start for all newborns and infants to one year of age.

Therefore, Be It Resolved: The NBNA calls for the diversification of the lactation profession.

Therefore, Be It Resolved: The NBNA encourages the use of lactation support persons such as Certified Lactation Counselors (CLCs), Certified Lactation Educators (CLEs), Breastfeeding Peer Counselors and International Board Certified Lactation Consultants (IBCLCs), to assist mothers, families and communities in meeting their breastfeeding goals.

Therefore, Be It Resolved: The NBNA calls for the use of racial and cultural sensitivity, and the use of racial equity lens as it pertains to lactation training, education and development of printed and visual material.

Therefore, Be It Resolved: The NBNA encourages the use of culturally informed and relevant breastfeeding interventions that focus on the needs and resiliency of mothers, families and communities.

Therefore, Be It Resolved: The NBNA promotes Medicaid reimbursement to hospitals that provide human milk as an alternative to commercial milk formula and promotes human milk equity

among African Americans and other underrepresented groups.

Therefore, Be It Resolved: The NBNA support documentation of exclusive breastfeeding as a part of the Electronic Medical Records of all newborns, infants and parents and the development of a patient centered environment that supports breastfeeding.

Sponsorship: NBNA Resolution Committee Exclusive Breastfeeding Taskforce (Requires original hand signatures)

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Approved at the NBNA Business Meeting on Thursday, August 2, 2018

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# Respiratory Syncytial Virus:

## How you can advocate for babies this RSV season

Track national data and trends at the CDC's website  
[www.cdc.gov/rsv](http://www.cdc.gov/rsv)



Identify babies at greatest risk



including those with CLD, BPD, CF, and heart conditions

Teach families how to protect



their babies from respiratory infections

Advocate for insurance coverage for palivizumab prophylaxis so more babies can be protected \*



Use your best clinical judgement



when prescribing RSV prophylaxis

Tell insurers what families need



and provide the supporting evidence

 National Perinatal Association

\*See the NPA's evidence-based guidelines at [www.nationalperinatal.org/rsv](http://www.nationalperinatal.org/rsv)

# Case Series Using the NAVA Catheter-Positioning Screen to Identify Cardiac Arrhythmias

Howard Stein MD, Kimberly S. Firestone MSc RRT and Nita Ray Chaudhuri MD

## Abstract

*Introduction: Diagnosis of arrhythmias can be challenging using the surface electrocardiogram (EKG). Previously, esophageal EKG (e-EKG) has been used to improve diagnostic acumen of various arrhythmias. Limitation to wide use of this technology has been the need for placement of a dedicated esophageal lead. Neurally Adjusted Ventilatory Assist (NAVA) utilizes a specialized esophageal catheter with electrodes that detect the electrical activity (Edi) of the diaphragm. Correct placement of the catheter relies on 4-lead e-EKG tracing evident on a catheter-positioning screen.*

*Objective: To validate the e-EKG seen on the NAVA catheter-positioning screen to diagnose arrhythmias.*

*Methods: This was a prospective observational single center study. Neonatal patients had recordings done as part of their ventilatory and cardiac management. Adult subjects were recruited from those already scheduled to undergo an electrophysiology study under general anesthesia. After induction of anesthesia, a NAVA Edi catheter was placed and screen captures of the arrhythmia were recorded.*

*Results: The following arrhythmias were identified: Premature atrial contractions, atrial flutter, atrial fibrillation, complete heart block, AV nodal re-entry, hyperkalemia, wandering atrial pacemaker and 3:1 heart block. These were compared to surface EKGs.*

*Conclusion: NAVA Edi catheters can be used reliably to identify different cardiac arrhythmias in patients using the retrocardiac EKG on the catheter-positioning screen. This approach offers an alternate way to diagnose and confirm arrhythmias in these patients.*

**Key Words:** esophageal EKG, electrical activity of the diaphragm, NAVA, arrhythmia, Edi

***“What this paper contributes to our knowledge: This study shows examples of various arrhythmias captured by the Edi catheter on the catheter positioning screen on the NAVA ventilator and correlates them to surface EKGs.”***

Background and significance of project

The accurate diagnosis of arrhythmias in ventilated patients is both challenging and critical for their proper management. Cur-

rent techniques are typically limited to surface EKG, which is dependent on the presence of a persistent arrhythmia, and telemetry, whose accuracy relies on various operator factors and can often be noisy due to patient movement and electrical interference. Esophageal electrocardiography (e-EKG) has been shown to possess excellent sensitivity for atrial signals and may improve signal quality compared to conventional surface EKG.<sup>1-6</sup> P-waves are often hidden by ventricular electrical activity in surface EKG recordings so the close proximity of the esophageal electrodes to the posterior atrium and left ventricle provides greater signal strength resulting in larger P-waves (atrial activation) as well as an amplified QRS complex (ventricular activity).<sup>5</sup>

E-EKG has demonstrated utility in neonates and children for both diagnosis and treatment of atrial arrhythmias.<sup>3,4,7</sup> However, currently e-EKG is not used much clinically most likely due to the need to place an esophageal lead and the limited experience in interpreting the wave-forms despite previous descriptive studies.<sup>8-10</sup> Recently an e-EKG catheter was introduced as part of a new ventilatory mode.

Neurally adjusted ventilatory assist (NAVA) is a mode of mechanical ventilation which delivers airway pressure proportional to the electrical activity of the diaphragm (Edi) and synchronous with the patient's respiratory needs.<sup>11</sup> Edi is measured from an array of eight bipolar electrodes inserted into the lower end of a specialized nasogastric tube (sensors are placed above the feeding holes) and positioned in the lower esophagus at the level of the crural diaphragm. The specialized nasogastric tube (Figure 1) is placed like any other nasogastric tube by using the measurement of nose-ear-xiphoid distance for initial positioning. The position is then refined using a retrocardiac EKG, obtained from electrodes on the catheter, the waveforms of which can be seen on a dedicated catheter positioning screen on the Servo-I (Maquet Getinge Group, Rastatt Germany) as seen in Figure 2. The position of the

***“We postulated that the retrocardiac or e-EKG seen on the catheter-positioning screen has the potential for diagnosis of arrhythmias in ventilated patients.”***

diaphragm is determined along the electrode array. When the electrode array is in the correct position, the largest p-waves and QRS complexes should be in the upper lead and decrease in size to minimal or absent p waves and QRS complexes in the lower leads. The Edi signal is superimposed on the retrocardiac EKG as a blue color and should be on the second and third lead.<sup>12</sup>

Over the course of the past several years of using NAVA in the NICU, we have noted a number of cardiac arrhythmias on the

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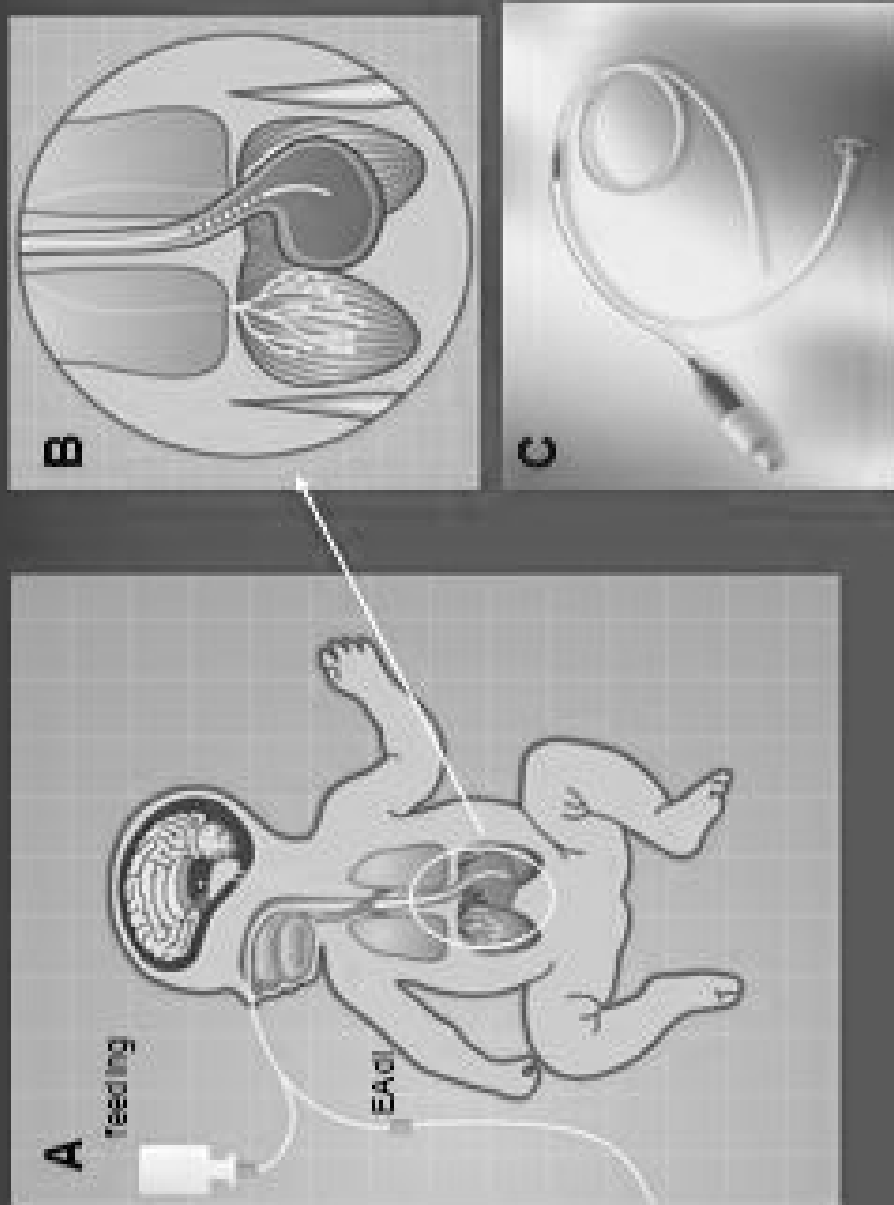


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# How do we measure EAadi?



Courtesy of Sodometry and Best

Figure 1: Positioning of the specialized nasogastric tube with electrodes above and below the diaphragm (reprinted with permission).

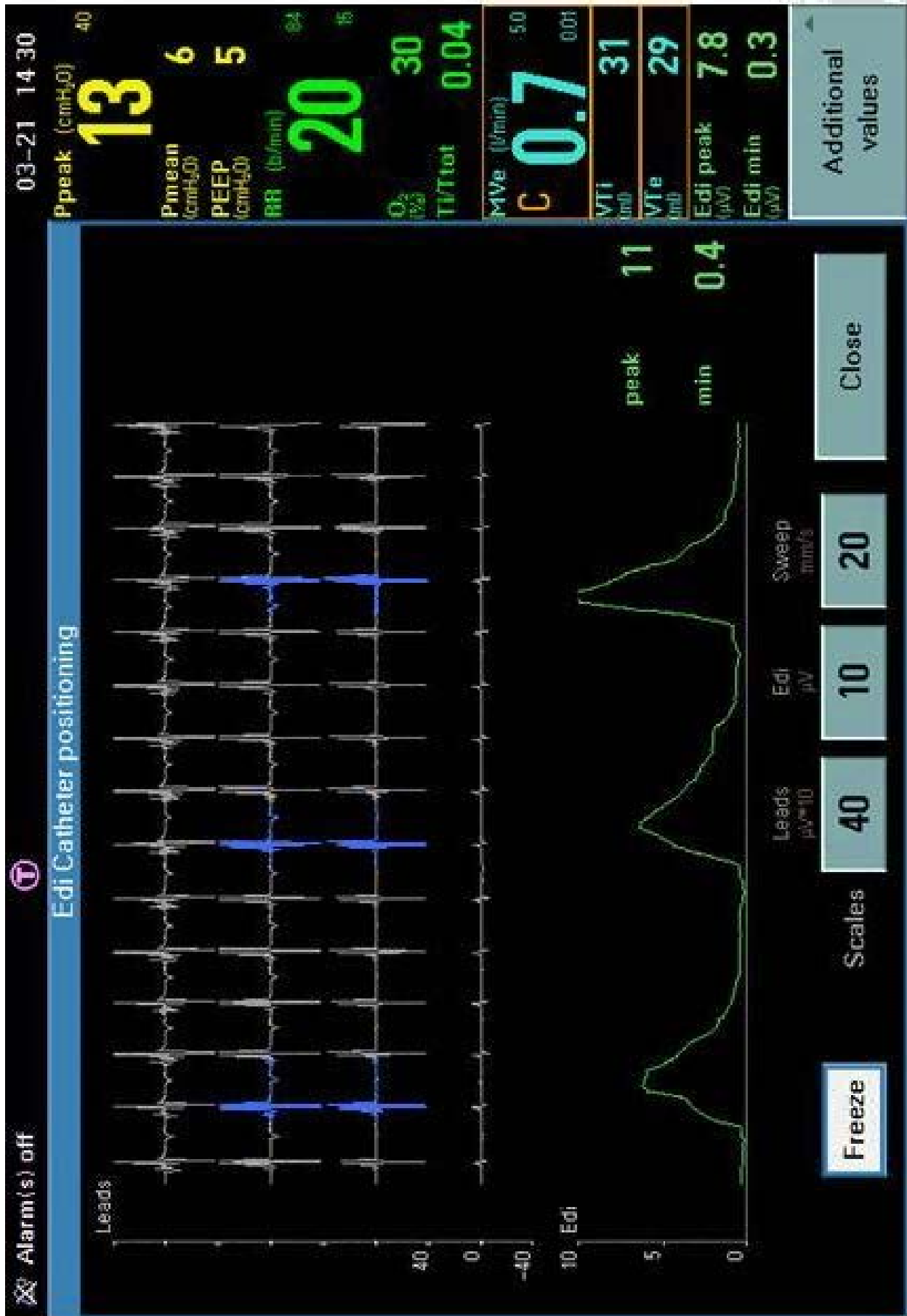
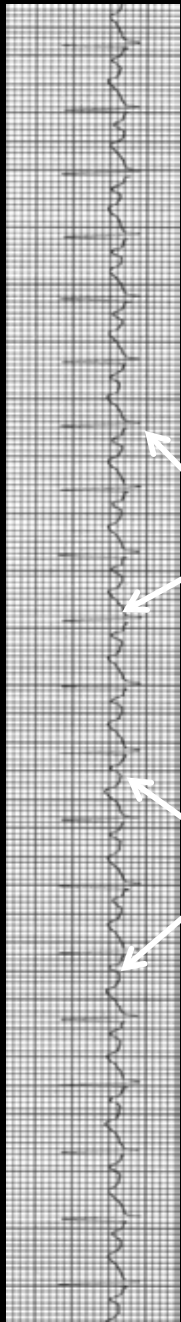


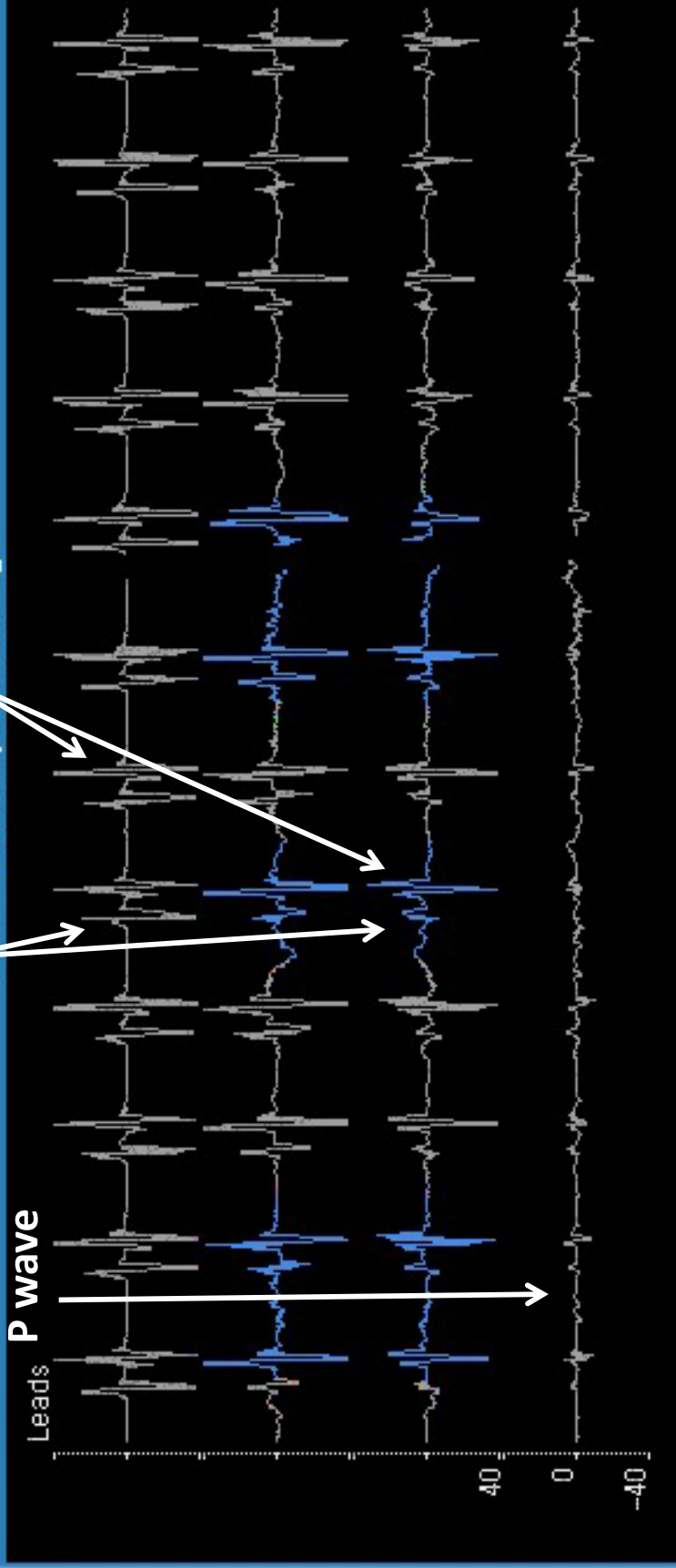
Figure 2: Edi nasogastric catheter-positioning screen on the Servo-I. Correct placement of the Edi nasogastric tube shows the retrocardiac EKG signal progressing from large p-wave and QRS complexes in the upper leads to small or absent complexes in the lower leads. The bottom tracing is the Edi signal and, when superimposed over the retrocardiac EKG tracing, is shown as a blue color (shown here as a brighter signal) and is ideally seen in the middle 2 leads. As long as the p-wave and QRS progression is from large in the upper leads to small in the lower leads, the blue color can drift to the upper and lower leads without affecting the Edi signal integrity.



P wave

QRS

EJi Catheter positioning



P wave

Leads

40

0

-40

Figure 3: Normal Sinus Rhythm - The retrocardiac p-waves look similar to surface EKG QRS complexes however, they become smaller from upper to lower tracings at a faster rate than the QRS complexes which remain evident in the lower leads. This is because the lower electrodes are further from the atria (tiny p-waves) but still close to the ventricles.



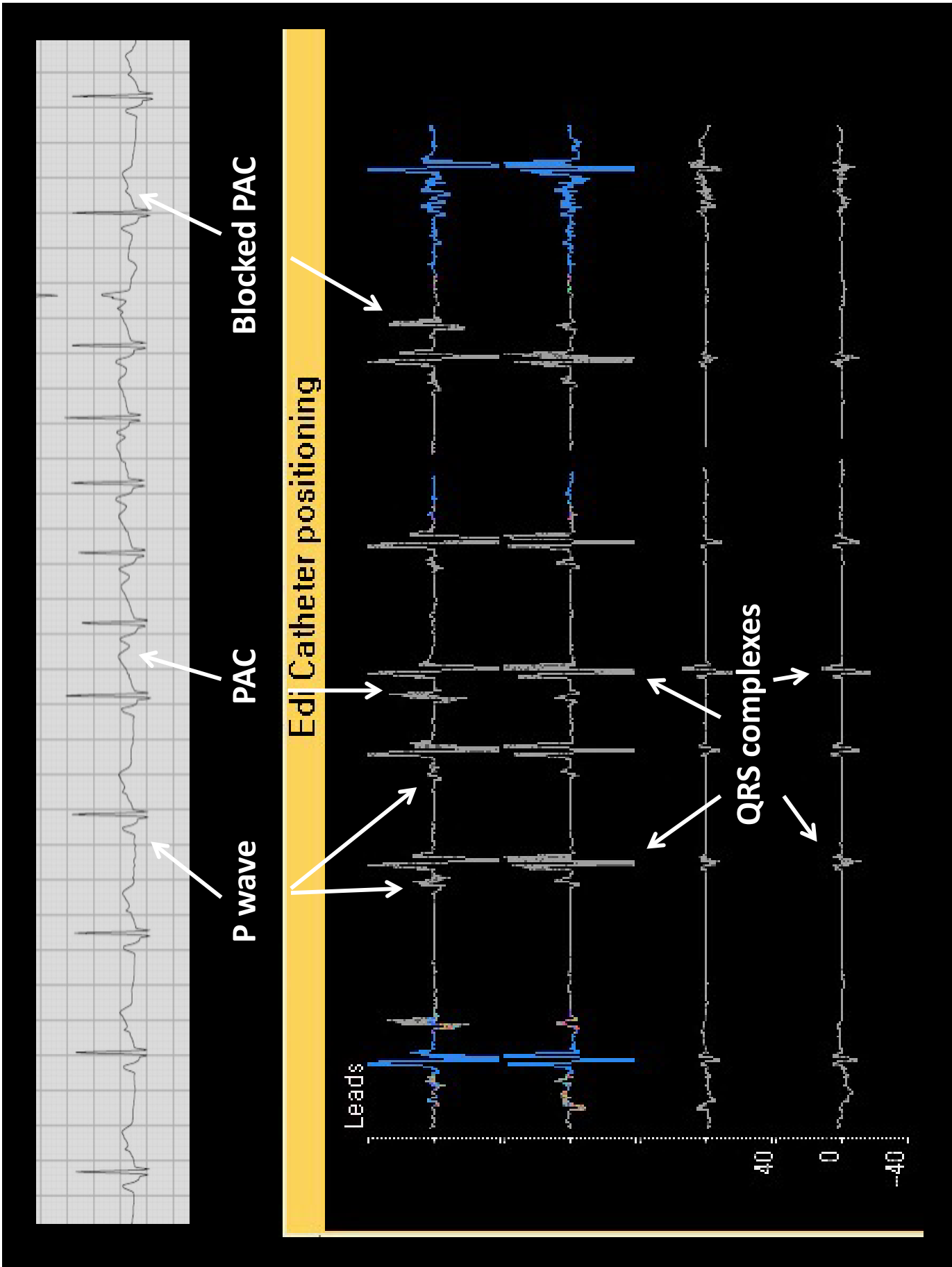


Figure 4: Premature Atrial Contractions (PAC) - P-waves evident in top 2 leads. QRS complexes evident throughout all 4 leads. The PAC and blocked PAC have similar morphology that both differ from the normal sinus p-wave.

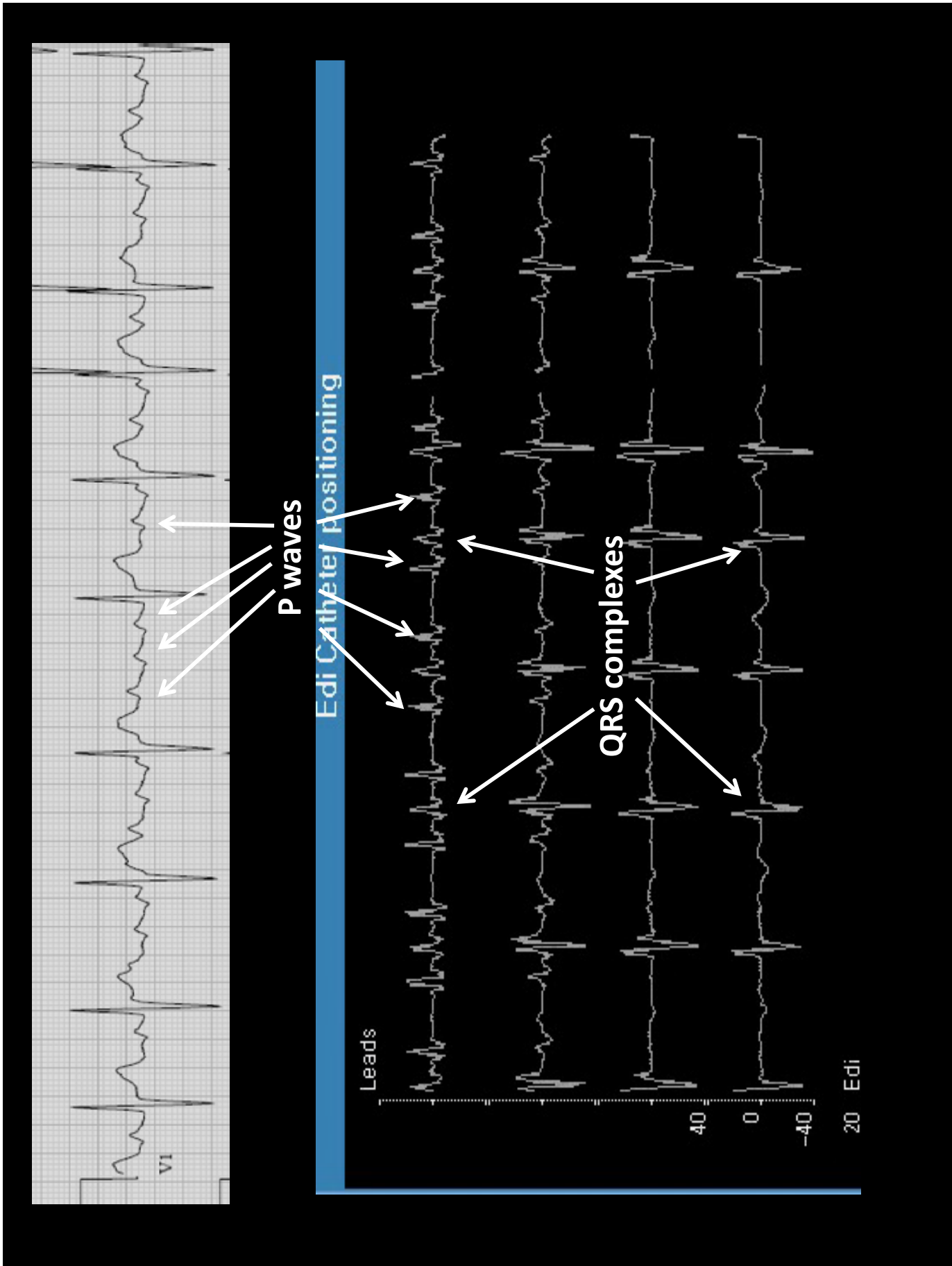


Figure 5: Atrial Flutter - P-waves have disappeared by the third lead while QRS complexes are evident in all 4 leads. QRS complexes follow every other p-wave consistent with 2:1 conduction. The surface EKG shows variable conduction.



Irregularly irregular RR intervals

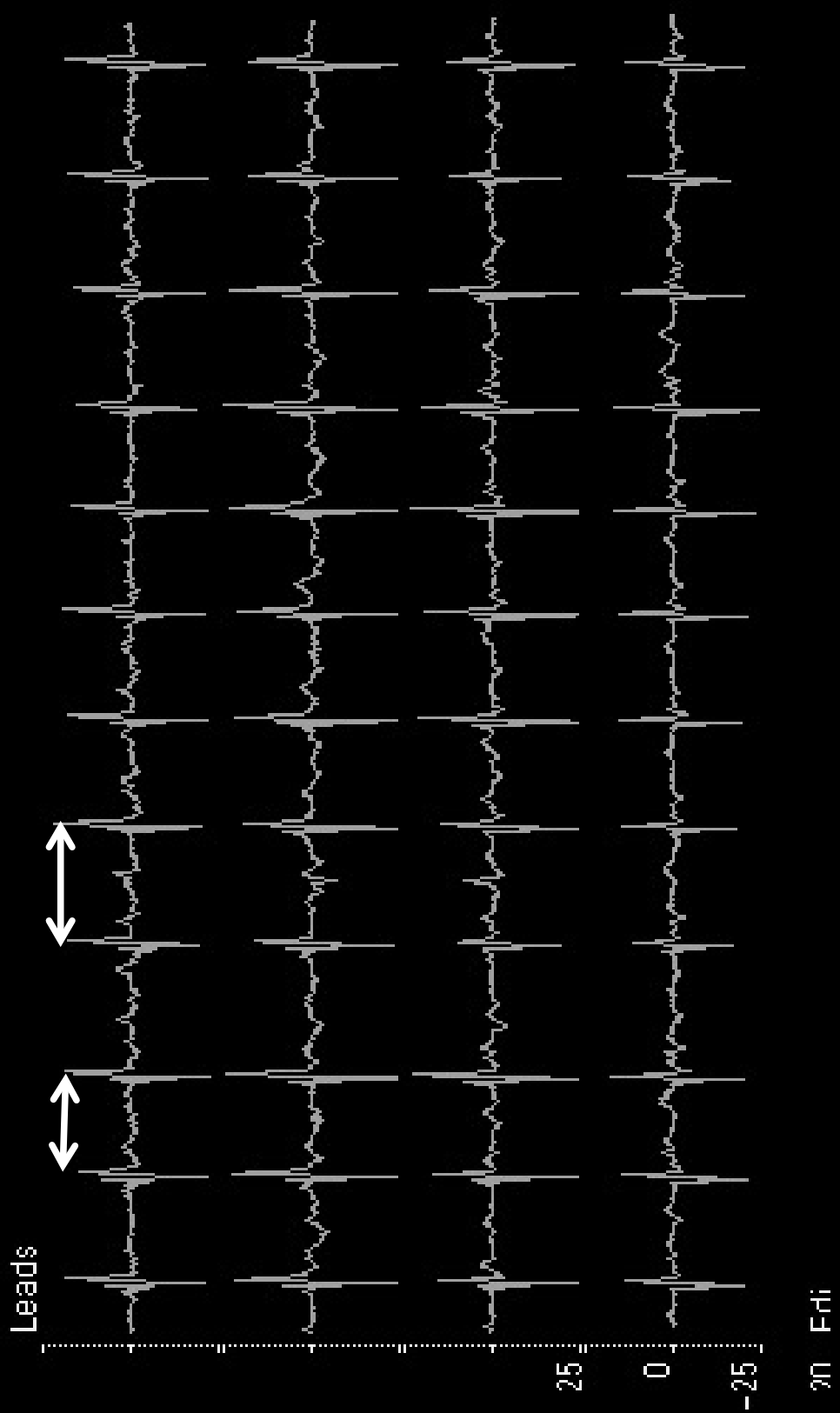


Figure 6: Atrial Fibrillation - Fibrillating baseline with irregularly irregular RR intervals.

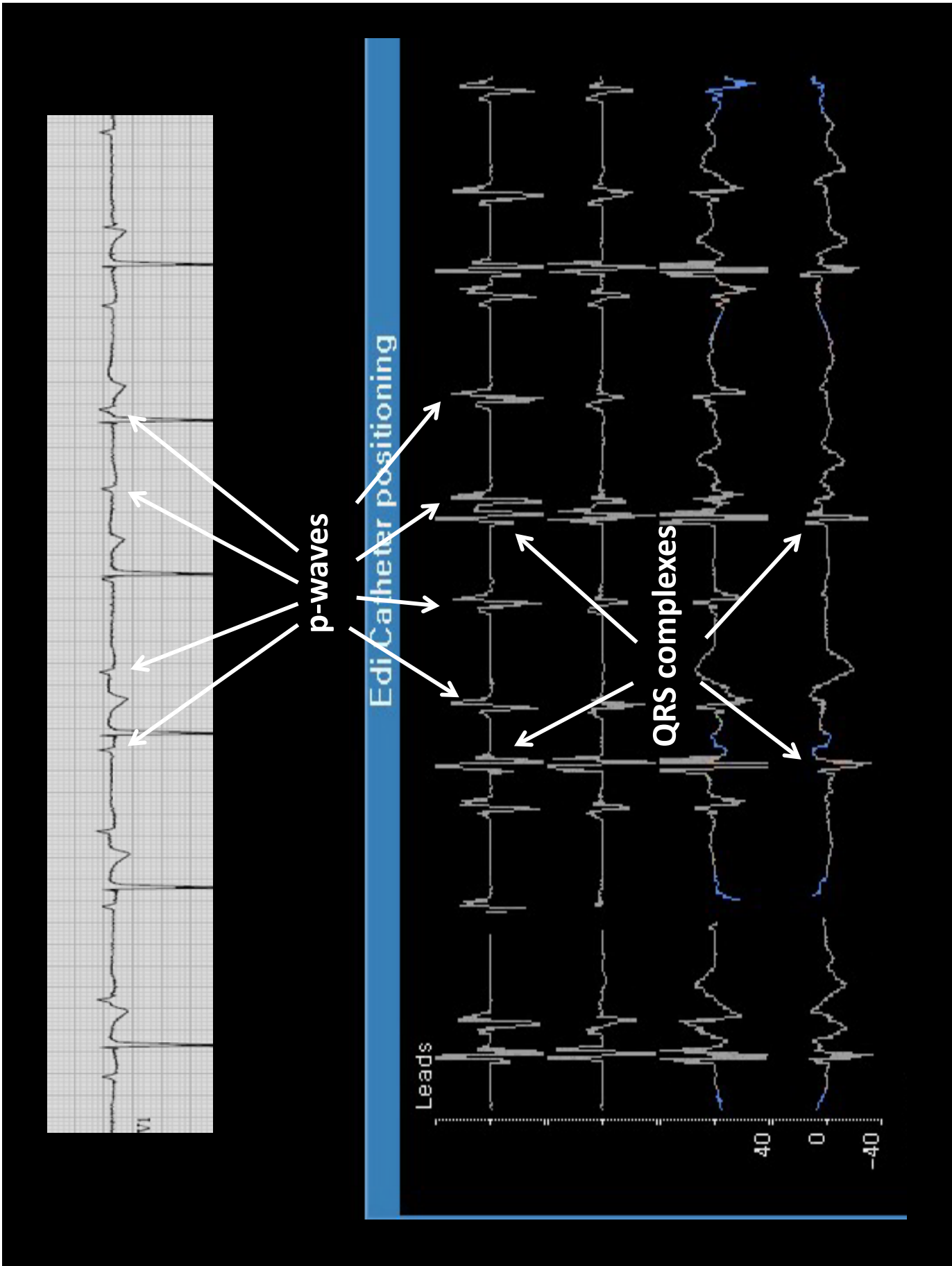


Figure 7: Complete Heart Block – unrelated p-waves and QRS complexes with atrial rate faster than ventricular rate.

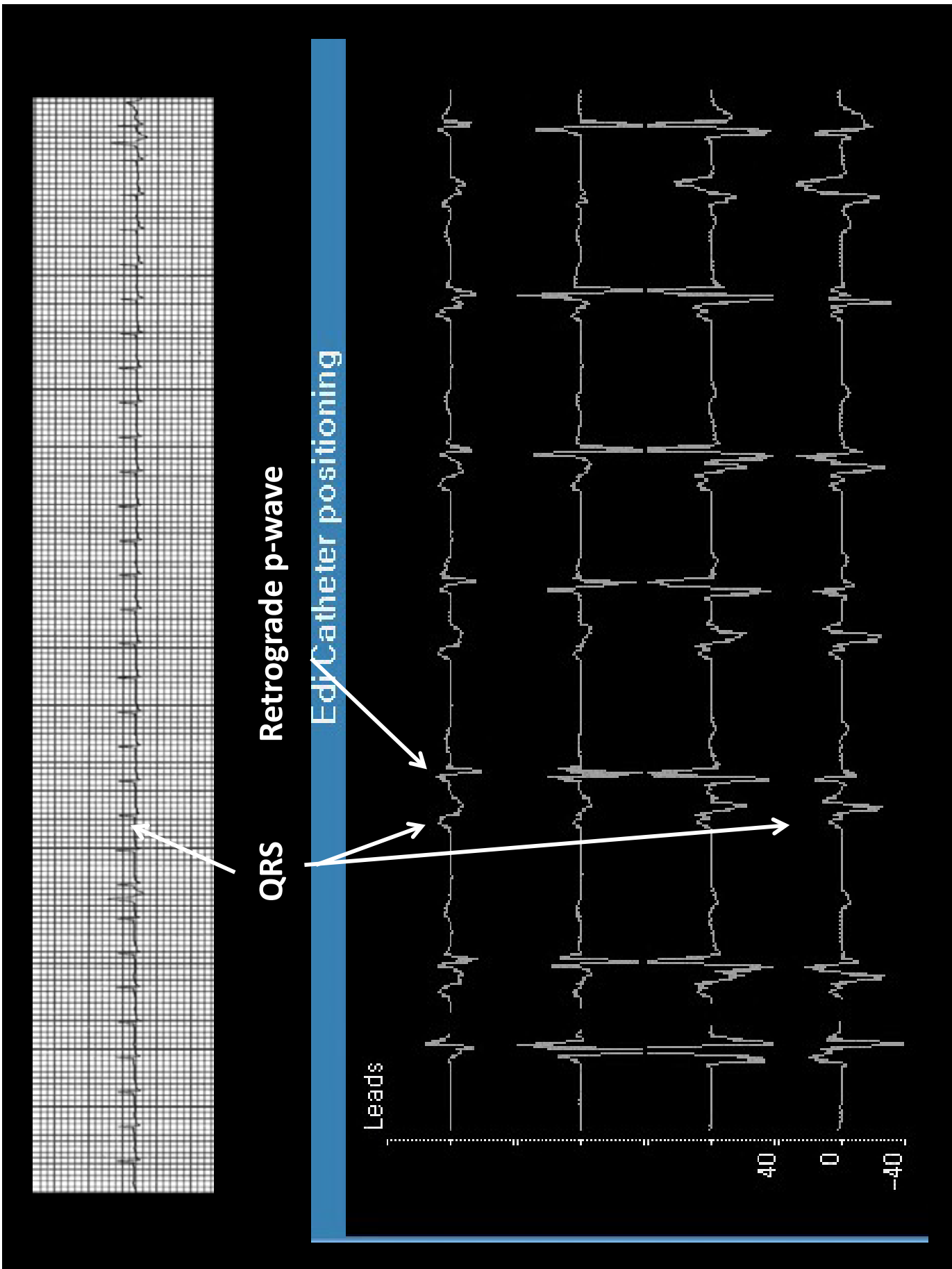


Figure 8: AV Nodal Re-entrant Tachycardia - Retrograde p-waves are evident following the QRS complexes.

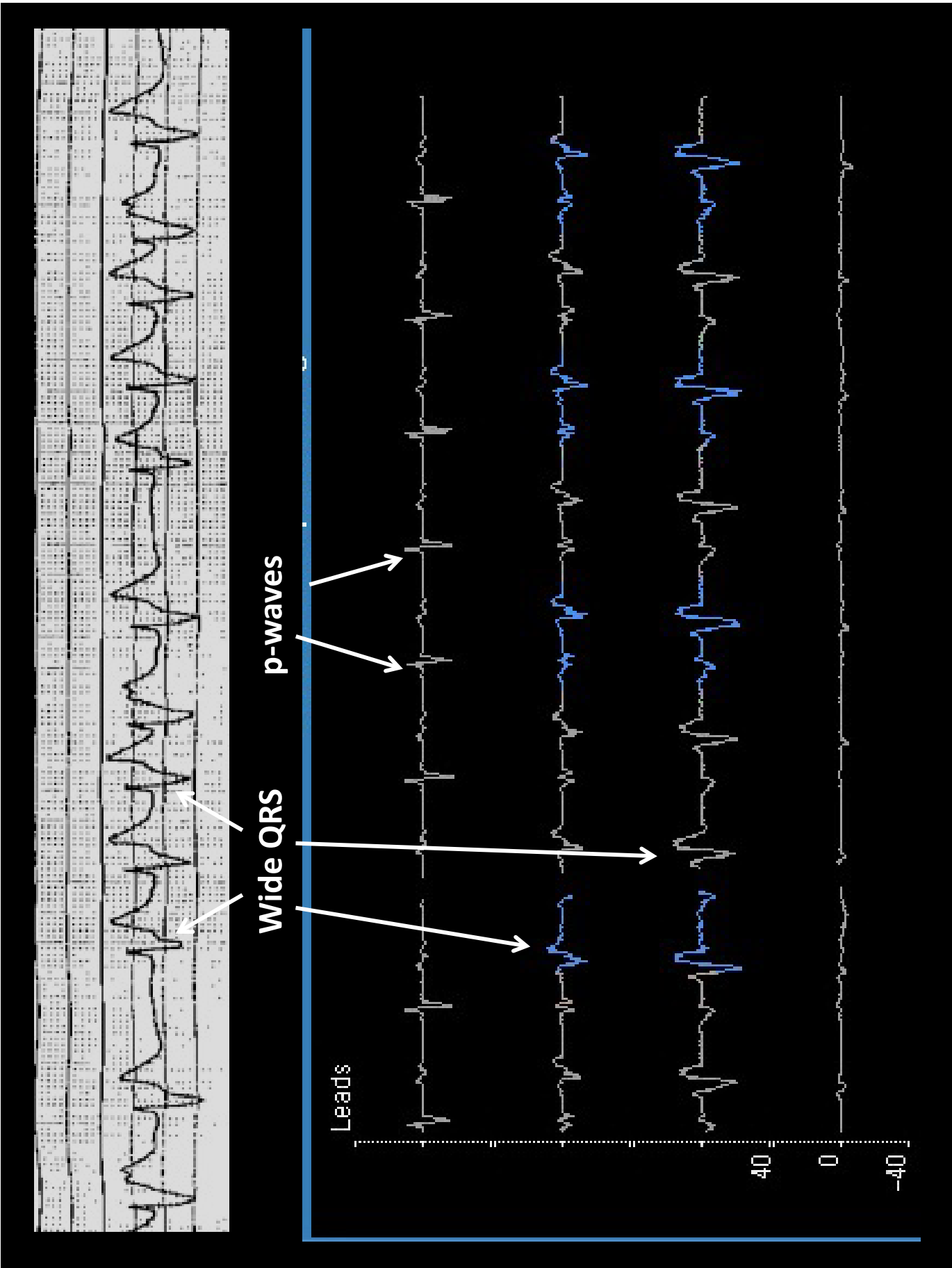
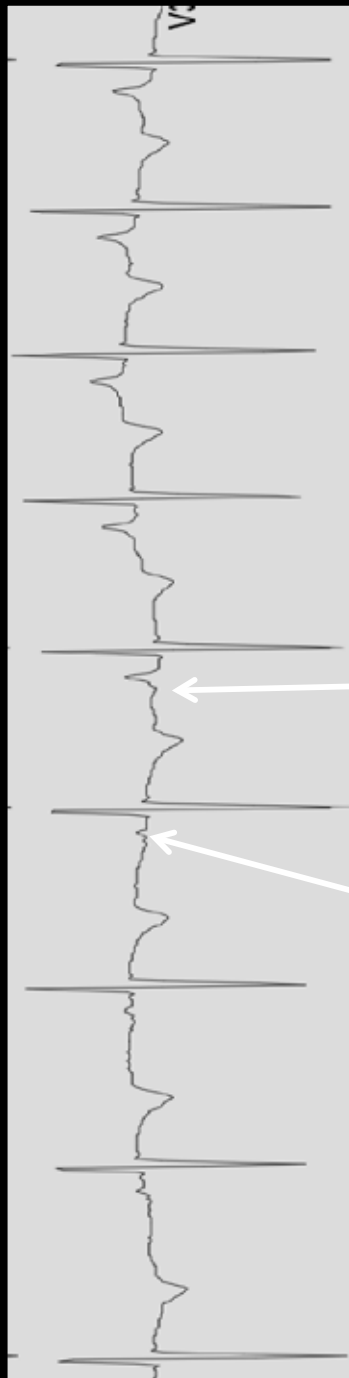


Figure 9: Hyperkalemia - Narrow p-waves evident in lead 1 and wide QRS complexes seen in lower leads.



p-waves of varying morphology

Edi Catheter positioning

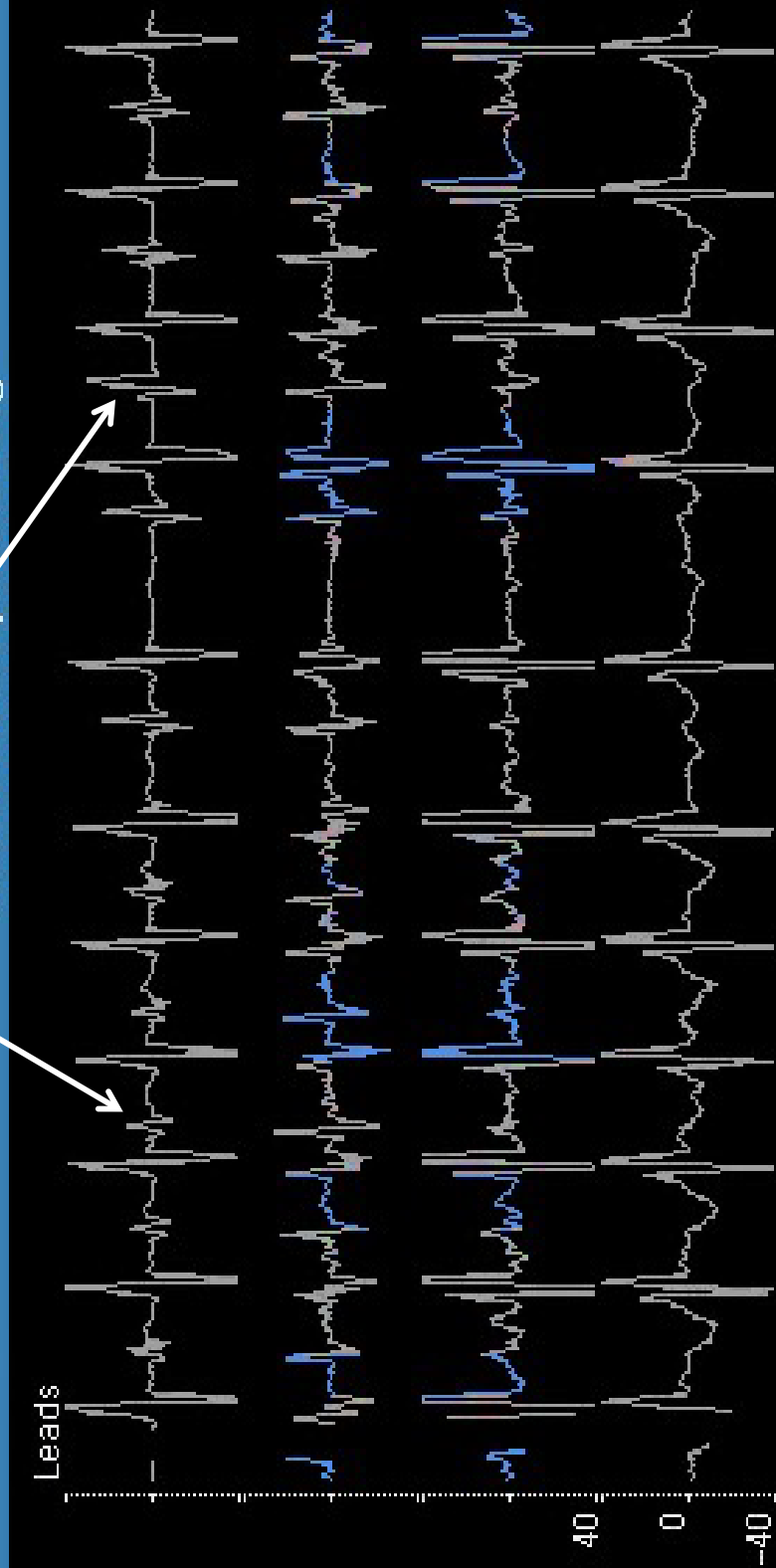
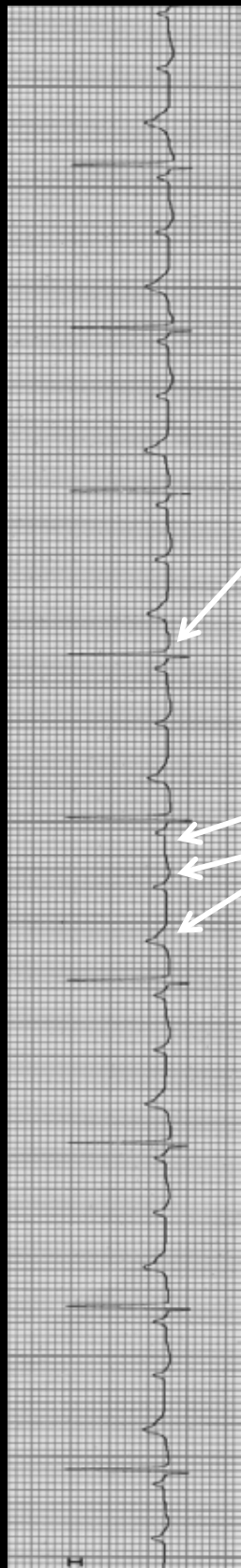


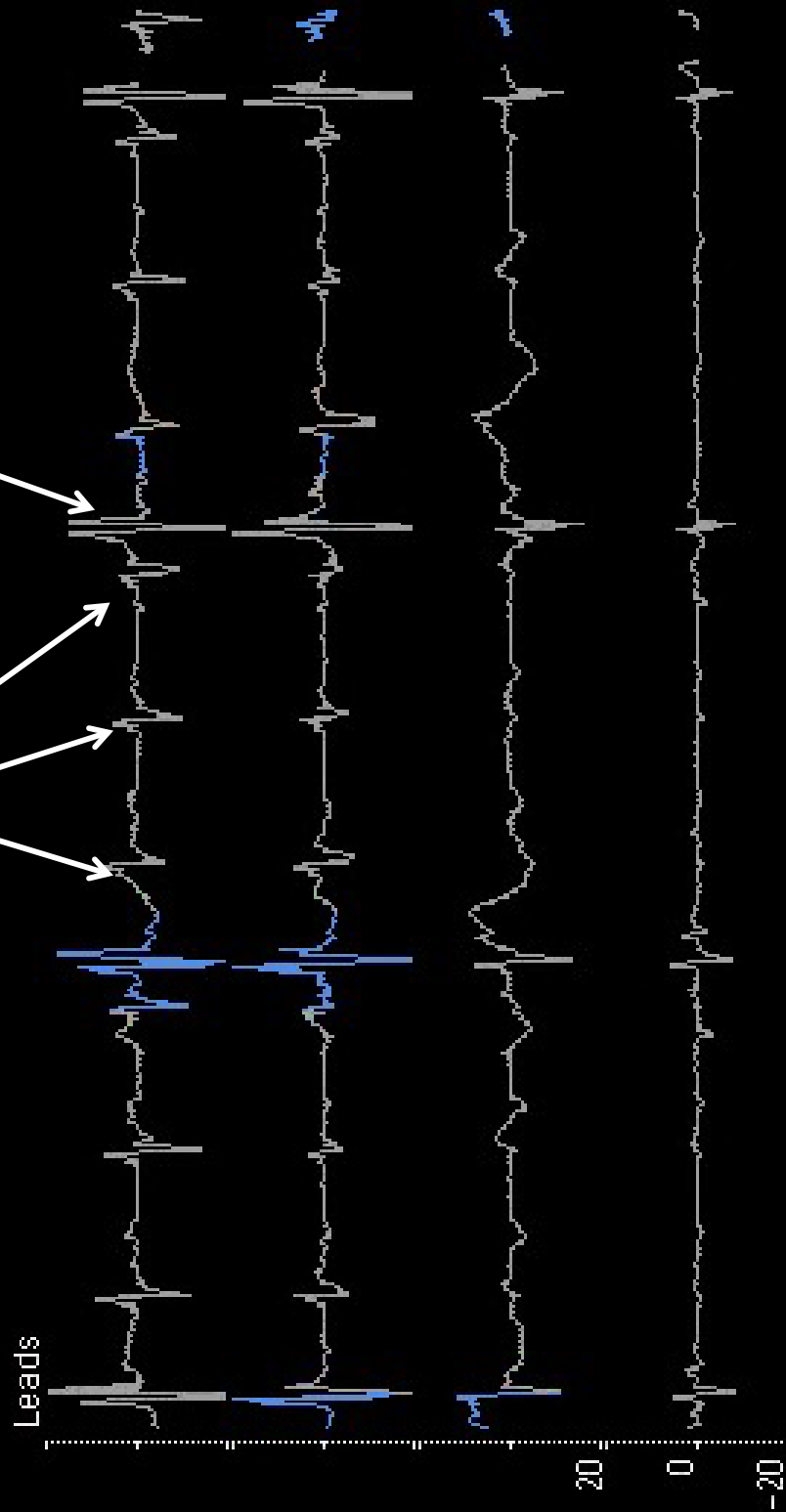
Figure 10: Wandering (multifocal) Atrial Pacemaker – p-waves with varying morphology. All followed by QRS complexes.



p-waves

QRS

### Eci Catheter positioning



Leads

20

0

-20

Figure 11: 3:1 Heart Block – 3 p-waves for each QRS complex.



catheter-positioning screen during catheter placement. We postulated that the retrocardiac or e-EKG seen on the catheter-positioning screen has the potential for diagnosis of arrhythmias in ventilated patients.

#### Purpose

The purpose of this study is to validate a high-fidelity novel method of diagnosing arrhythmias using the NAVA catheter-positioning screen in subjects who have a NAVA nasogastric tube in place.

#### Methods

##### Research design

This was a combination of a prospective observational single center study and a retrospective review of screen captures obtained during an arrhythmia.

##### Population and sampling methods:

The populations studied were adults with various arrhythmias who were already scheduled to undergo an electrophysiology study and-or ablation under general anesthesia, and neonates noted to have various arrhythmias during their hospital stay. IRB approval for both the prospective and retrospective components of the

---

***“Utilizing the retrocardiac e-EKG on the catheter-positioning screen expands the usefulness of the Edi catheter and has the potential for faster and more accurate diagnosis of cardiac arrhythmias”***

---

study was obtained.

In the adult population, appropriate informed consent was prospectively obtained and an Edi catheter was placed after the subject was successfully intubated. The lumen of the Edi catheter was used as a conventional nasogastric tube and electrodes were connected to the Servo-I ventilator that was used only as a monitor for this study. The position of the Edi nasogastric tube was refined using the catheter-positioning screen. During the course of the electrophysiology study various arrhythmias became evident and screen captures were saved. The Edi nasogastric tube was disconnected from the Servo-I during the ablation portion of the procedure to prevent inadvertent damage to the ventilator.

The retrospective population was neonates in the NICU on NAVA ventilation who were noted to have various arrhythmias. Screen captures were obtained as part of diagnosis and treatment.

#### Results:

Nine arrhythmias were captured on the NAVA catheter-positioning screen. Figure 3 shows normal sinus rhythm. Figures 4-11 demonstrate the features of various arrhythmias. These include premature atrial contractions (Figure 4 - neonate), atrial flutter (Figure 5 - neonate), atrial fibrillation (Figure 6 - adult), complete heart block (Figure 7 - neonate), AV node re-entry (Figure 8 - adult), hyperkalemia (Figure 9 - neonate), wandering atrial pacemaker (Figure 10 - neonate), 3:1 heart block (Figure 11 - neonate). Sur-

face EKGs were obtained from the same or other patients with comparable arrhythmias.

#### Discussion:

This is the first report to show the possibility of using the Edi catheter as an initial diagnostic tool to facilitate the diagnosis of arrhythmias in ventilated patients. It has been shown since the 1980's that e-EKG is useful for aiding in diagnosis of atrial dysrhythmias that are difficult to diagnose with a conventional EKG.<sup>1,2</sup> E-EKG showed an improvement in diagnostic capabilities for cardiac arrhythmias where a clear P-wave is needed.<sup>5</sup> This study shows, through a comparison of surface and Edi catheter tracings, the Edi catheter tracings can effectively identify multiple atrial arrhythmias.

It is important to note that the retrocardiac p-waves look similar to surface EKG QRS complexes however, they become smaller from upper to lower tracings at a faster rate than the retrocardiac QRS complexes which remain evident in the lower leads. This distinction will prevent confusion between the retrocardiac p and QRS complexes.

Recognizing various arrhythmias on the Edi catheter positioning screen provides rapid, additional information in those patients that already have Edi catheters in place for both invasive and non invasive ventilation. It is not meant to replace or supplant the use of the e-EKG catheter. The e-EKG catheter can be used in awake patients, if necessary, and does not require the patient to be intubated. It can also pace the patient, and potentially treat the arrhythmia.

The primary limitation of the study is that it was not clinically feasible to obtain surface EKG at exactly the same time as the screen shot was obtained (retrospectively collected in neonates and in adults, the proceduralist requested no EKG patches placed over the chest during the EP study) so surface EKGs were either obtained at the earliest possible time or from other patients with

---

***“Quick Look -- Current knowledge: Esophageal electrocardiography (e-EKG) has been shown to possess excellent sensitivity for atrial signals and may improve signal quality compared to surface EKG. NAVA ventilation uses a specialized Edi catheter with electrodes which are positioned using retrocardiac EKG waveforms seen on a positioning screen on the ventilator. These ventilator waveforms can be used to diagnose arrhythmias similar to e-EKG.”***

---

comparable arrhythmias. The limitation of the technology is that using the catheter-positioning screen, it is not currently possible to measure heart rate or intervals within this e-EKG. Therefore evaluation is not possible for Type 2 heart blocks, long QT or bundle branch blocks or to measure heart rate. T-waves are not evident

on this e-EKG so evaluations for ST changes are unavailable.

The Edi catheter currently provides a respiratory vital sign to assist the clinician with ventilator management. Utilizing the retrocardiac e-EKG on the catheter-positioning screen expands the usefulness of the Edi catheter and has the potential for faster and more accurate diagnosis of cardiac arrhythmias.

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Howard Stein and Kim Firestone have received speaker honoraria



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from Maquet Getting Group and Chiesi. Nita Ray Choudhury declares that she has no conflict of interest.

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# Policy Advocacy for Clinicians

## Tips for Advocating for Treatment Reimbursement

Alliance for Patient Access (AfPA) Government Affairs Team

*The Alliance for Patient Access ([allianceforpatientaccess.org](http://allianceforpatientaccess.org)), founded in 2006, is a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care. AfPA accomplishes this mission by recruiting, training and mobilizing policy-minded physicians to be effective advocates for patient access.*



Your role in reimbursement advocacy:

- Your objective: To assist payers in developing coverage and payment policies that enable patients to access appropriate treatments
- Policy advocacy is a natural extension of your role as a clinician:
  - ▶ You are already an advocate for your patients, responsible for finding the most appropriate treatment for your patients' medical conditions
  - ▶ When you pursue policy improvement, you take on another form of advocacy: helping to ensure that as many patients as possible can receive needed and appropriate treatment
- In reimbursement advocacy, your role is to:
  - ▶ Communicate the medical need to treat patients with appropriate therapies and demonstrate the clinical value of those therapies by:
    - Working with available reimbursement support services and procedures
      - Each carrier has different reimbursement services and procedures, and it is important to go

through the proper channels when disputing a claim or policy

- Communicating with payer decision-makers, which may include any or all of the following:
  - Meetings
  - Telephone calls
  - Letters
  - E-mails
- Preparing and delivering a persuasive argument
- Asking questions and gaining insights on details

Reimbursement Review:

- There are three components of reimbursement:
  1. Coverage
  2. Coding
  3. Payment
- Important concepts to understand:
  - ▶ “Coverage” means that a product or service is eligible for payment, but does not guarantee a particular amount
  - ▶ Having an assigned code does not guarantee coverage
  - ▶ Services without a specific code can still be covered
  - ▶ Coverage doesn't always negate the need for a prior-authorization
- Criteria for coverage: Before a treatment will be considered for coverage, the procedure or drug:
  - ▶ Must be included within the scope of benefits of the private payer's plan
  - ▶ Must not be considered investigational or experimental
  - ▶ Must be considered medically necessary
- What is the purpose of codes?
  - ▶ Codes allow you to communicate the service provided
  - ▶ Codes tell a payer the amount to pay for services provided
  - ▶ You need to understand correct coding and specific payer requirement for coding for procedures
    - Correct use of modifiers enables physicians to ac-

curately report the entire service provided

- How is payment determined?
  - ▶ Payment for services and physician administered drugs is usually linked to the codes reported
  - ▶ Payment for physician dispensed drugs is frequently determined by
    - A fee schedule maintained by the payer, or
    - The contract between the payer and the physician that identifies the method used to determine payment
- What is the difference between public and private payers?
  - ▶ Coverage policy by public payers is determined by national Medicare and Medicaid statute, policies and regulations. These guidelines must be followed by local CMS contractors and state Medicaid agencies; however, states are not always in compliance due to “regional interpretation.”
  - ▶ Coverage by private payers, while influenced by state in-

urance laws and Medicare policies, is primarily an issue of the benefits provided by the particular plan.

Tips on Preparing Your Case for Reimbursement:

- When working with payer decision-makers, it's important to:
  - ▶ Use patients who are beneficiaries to illustrate need
    - Compile data that meets the purpose of the audience to whom you're speaking; payer decision-makers are only concerned with their own beneficiaries – make them care about what you have to say
  - ▶ Provide an opportunity for patients to tell their stories – or be prepared to tell their story for them
    - Successful advocates use personal anecdotes to help explain why they are asking for reimbursement. Personal experiences provide a powerful point of reference for the issue being discussed and highlight why you are actively engaged in solving the problem.
  - ▶ Assemble your clinical data and evidence-based medicine as needed



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We are pleased to invite you to the 17th Congress of the European Society for Developmental Perinatal and Paediatric Pharmacology on

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- Tools to improve clinical trials in children and adolescents
- Treatment of serious infections in low and middle income countries

Registration and abstract submission will open on **October 01, 2018**

Registration for the newsletter and further information about the scientific programme are available on the website: [www.esdppp2019.org](http://www.esdppp2019.org)

- Create validation of your message by compiling studies and articles that support your case (AfPA can help)
- ▶ Do your homework, the Medical Director will expect it, so learn as much as you can about the payer:
  - Policies and procedures
  - Vision and mission
  - The decision-maker you're meeting
    - What has been his or her reaction to similar meetings in the past?
    - What types of information have swayed him or her before?
    - Has he or she voiced a negative opinion on this product or service in the past?
    - Does he or she have a personal familiarity with the medical condition you're treating?
- ▶ Be clear and specific with your request
- ▶ Expect a short visit. Payer decision-makers have limited time, so you will want to deliver a succinct, direct message. For example, a CAC meeting may offer only five minutes for you to speak. Your comments need to be brief and to-the-point.
- ▶ Offer to provide additional information where appropriate
- ▶ Involve your colleagues if necessary
- Five or ten physicians asking for a change in policy will always be more powerful than one
- What should you provide when making your case?
  - ▶ Name and credentials
    - Briefly highlight your credibility (job title, educational background)
  - ▶ Type of practice/specialty
  - ▶ Number of patients seen
  - ▶ Number of patients whose cases fit the severity criteria
  - ▶ Number of those patients you have treated with specific treatment in question
  - ▶ Details about success rates and a patient example
- ▶ Conclusion
  - Lead your audience to a conclusion that meets your purpose and conveys your specific request – arrive at a logical bottom line together
- After meeting with the payer by phone or in person, it's important to send a follow-up letter to:
  - ▶ Convey your appreciation
  - ▶ Provide any additional data requested
  - ▶ Confirm all that was agreed to in the meeting
  - ▶ If necessary, reiterate the case for reimbursement
  - ▶ Reconfirm and request the action that you want the payer to take
- Finally, remember that change does not occur overnight. Patience and persistence are important to remember for advocacy. After meeting with a payer decision-maker, it's important to:
  - ▶ Continue your follow-up at least once per month until the desired action is taken
  - ▶ Keep a written record of your contact
  - ▶ Write a letter of appreciation when a decision is made in your favor

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# Medical News, Products & Information

Compiled and Reviewed by Mitchell Goldstein, MD Editor in Chief

## Two consumer baby monitors show worrisome results in measuring vital signs

*CHOP researchers test pulse oximetry monitors in hospitalized infants.*

EurekaAlert!

Philadelphia, Aug. 21, 2018-- Researchers who tested two commercially available baby monitors are raising serious concerns about the accuracy of these products, which are marketed to parents, but are not regulated by the U.S. Food & Drug Administration (FDA).

"We evaluated how accurate these monitors were in detecting low oxygen levels in infants," said study leader Chris Bonafide, MD, MSCE, a pediatrician and safety expert at Children's Hospital of Philadelphia (CHOP). "One monitor detected those levels when they occurred, but was inconsistent; the other never detected those levels when they occurred." The team also evaluated pulse rate accuracy in the babies, and found that the monitor that never detected low oxygen levels also often falsely displayed low pulse rates.

Bonafide and colleagues, including CHOP neonatologist Elizabeth Foglia, MD, MSCE and co-authors from the ECRI Institute, a nonprofit research organization that evaluates medical devices and practices, published a report today in the *Journal of the American Medical Association (JAMA)*.

Last year, the researchers wrote an opinion piece in *JAMA* raising concerns about consumer use of physiological baby monitors being broadly marketed to parents. They argued that such products may cause undue anxiety to parents, with no evidence of medical benefits for healthy infants. "We previously discussed the consensus in the pediatric community that there is no medical reason to electronically monitor vital signs in healthy babies at home," said Foglia. "Our new study adds serious concerns about the accuracy of these consumer monitors, when we compared them to a standardized hospital monitor in a cohort of sick infants."

In the current study, the team studied 30 infants, six months old and younger, hospitalized in CHOP's Cardiology and General Pe-

diatrics units between July and December 2017. Each baby wore an FDA-approved reference monitor (the Masimo Radical-7) on one foot and a consumer monitor on the other foot.

The consumer monitors were the Owlet Smart Sock2 and the Baby Vida, the only two currently marketed smartphone-integrated consumer baby monitors that use pulse oximetry--a measure of the blood's oxygen levels. The scientists analyzed hypoxia (low oxygen levels) and bradycardia (slow pulse rate), comparing results between the reference monitor and each consumer monitor.

While testing the Owlet, the reference monitor reported hypoxia in 12 patients, and the Owlet reported at least one simultaneous hypoxia reading in all 12 patients. However, at least once during hypoxia, the Owlet also erroneously indicated that five of those 12 infants had normal oxygen levels. Across all the data points, the Owlet's overall sensitivity was 88.8 percent--it detected hypoxia, but not consistently. "If something is going wrong with a sick infant, you would want to know that 100 percent of the time," said Bonafide.

Testing of the Baby Vida monitor showed that none of the 14 infants who experienced hypoxia according to the reference monitor had simultaneous hypoxia readings on Baby Vida--a sensitivity of 0 percent, a serious flaw. In addition to missing hypoxia, the Baby Vida monitor also falsely displayed bradycardia in 14 patients who had normal pulse rates, a high rate of false positives. "False positives raise the possibility of unintended consequences," said Foglia. "Parents who see an abnormally low pulse rate reading might call 911, or unnecessarily rush their baby to an emergency department."

###

*The authors caution that as more vital sign monitors enter a largely unregulated marketplace, physicians and parents need to be aware that these machines may trigger unwarranted alarm.*

*Funding for this study came from Children's Hospital of Philadelphia.*

*Christopher P. Bonafide, et al, "Accuracy of Pulse Oximetry-Based Home Baby Monitors," *Journal of the American Medical Association*, Aug. 21, 2018.*

*Media can receive an embargoed copy of the paper by emailing JAMA Network Media Relations at [mediarelations@jamanetwork.org](mailto:mediarelations@jamanetwork.org)*

*About Children's Hospital of Philadelphia: Children's Hospital of Philadelphia was founded in 1855 as the nation's first pediatric hospital. Through its long-standing commitment to provid-*

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NT

## American Academy of Pediatrics, Section on Advances in Therapeutics and Technology Membership Drive (Originally posted in NT June, 2018)

American Academy of Pediatrics (AAP), Section on Advances in Therapeutics and Technology (SOATT) announces a membership drive

The American Academy of Pediatrics' Section on Advances in Therapeutics and Technology (SOATT) invites you to join our ranks! SOATT creates a unique community of pediatric professionals who share a passion for optimizing the discovery, development and approval of high quality, evidence-based medical and surgical breakthroughs that will improve the health of children. You will receive many important benefits:

- Connect with other AAP members who share your interests in improving

effective drug therapies and devices in children.

- Receive the SOATT newsletter containing AAP and Section news.
- Access the Section's Website and Collaboration page – with current happenings and opportunities to get involved.
- Network with other pediatricians, pharmacists, and other health care providers to be stronger advocates for children.
- Invitation for special programming by the Section at the AAP's National Conference.
- Access to and ability to submit research abstracts related to advancing child health through innovations in pediatric drugs, devices, research, clinical trials and information technology; abstracts are published in Pediatrics.

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Thank you for all that you do on behalf of children. If you have any questions, please feel free to contact:

Mitchell Goldstein, MD, FAAP, Section Chairperson, [MGoldstein@llu.edu](mailto:MGoldstein@llu.edu) and

Christopher Rizzo, MD, FAAP, Member-

ship Chairperson, [crizzo624@gmail.com](mailto:crizzo624@gmail.com)

NT

## Researchers Find Increased Risk of Birth Defects in Babies After First-Trimester Exposure to Lithium

*However, absolute risk is less than previously thought*

Newswise — (New York – June 18, 2018) — Researchers from the Icahn School of Medicine at Mount Sinai found an elevated risk of major congenital malformations in fetuses after first-trimester exposure to lithium, in the largest study ever to examine the risk of birth defects in lithium-exposed babies.

Nearly one and one-half times as many babies exposed to lithium during the first trimester experienced major malformations compared to the unexposed group (7.4 percent compared with 4.3 percent). In addition, risk for neonatal hospital readmission was nearly doubled in lithium-exposed babies compared to the unexposed group (27.5 percent versus 14.3 percent). However, lithium exposure was not associated with pregnancy complications or other delivery outcomes, such as pre-eclampsia, preterm birth, gestational diabetes, or low birth weight. In addition, the researchers found that the risk of birth defects in lithium-exposed infants was lower than previously thought, because previous studies did not look at large enough populations.

The study will be published online on Monday, June 18, at 6:30 pm EDT, in The Lancet Psychiatry.

The study examined the risk of congenital malformations such as heart defects and

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pregnancy complications in a meta-analysis of primary data from 727 lithium-exposed pregnancies compared to a control group of 21,397 pregnancies in mothers with a mood disorder who were not taking lithium. The data was taken from six study sites in Denmark, Canada, the Netherlands, Sweden, the United Kingdom, and the United States. The researchers also measured delivery outcomes and neonatal hospital readmissions within 28 days of birth.

Lithium therapy is widely recommended as a first-line treatment for bipolar disorder, which affects approximately 2 percent of the world's population. Lithium helps to prevent severe depression and mania. In the United States, bipolar disorder is more commonly treated with anti-psychotic drugs instead of lithium.

"Women should be informed on malformation risk in first-trimester exposed infants, but also about very high relapse risks for mental illness both during pregnancy and during the postpartum period," said the study's senior author, Veerle Bergink, MD, PhD, Professor of Psychiatry and of Obstetrics, Gynecology, and Reproductive Science, Icahn School of Medicine at Mount Sinai. "Given the well-documented effectiveness of lithium in reducing relapse in the perinatal period, some important clinical considerations are either to continue lithium in a lower dose during the first trimester or to restart lithium after the first trimester or immediately postpartum."

Other institutions involved in this study include Aarhus University in Denmark; Lundbeck Foundation Initiative for Integrative Psychiatric Research, in Denmark; Karolinska Institutet, in Sweden; University of Toronto, Scarborough, in Canada; Women's College Hospital in Toronto, Canada; University of Toronto in Canada; Institute for Clinical Evaluative Sciences in Toronto, Canada; Cardiff University in the United Kingdom; University of North Carolina at Chapel Hill School of Medicine; Indiana University; King's College London in the United Kingdom; Leiden University Medical Center in the Netherlands; and Eras-

mus Medical Centre in The Netherlands.

This study was supported by grants from the National Institutes of Mental Health.

#### *About the Mount Sinai Health System*

*The Mount Sinai Health System is New York City's largest integrated delivery system encompassing seven hospital campuses, a leading medical school, and a vast network of ambulatory practices throughout the greater New York region. Mount Sinai's vision is to produce the safest care, the highest quality, the highest satisfaction, the best access and the best value of any health system in the nation. The System includes approximately 7,100 primary and specialty care physicians; 10 joint-venture ambulatory surgery centers; more than 140 ambulatory practices throughout the five boroughs of New York City, Westchester, Long Island, and Florida; and 31 affiliated community health centers. The Icahn School of Medicine is one of three medical schools that have earned distinction by multiple indicators: ranked in the top 20 by U.S. News & World Report's "Best Medical Schools", aligned with a U.S. News & World Report's "Honor Roll" Hospital, No. 13 in the nation for National Institutes of Health funding, and among the top 10 most innovative research institutions as ranked by the journal Nature in its Nature Innovation Index. This reflects a special level of excellence in education, clinical practice, and research. The Mount Sinai Hospital is ranked No. 18 on U.S. News & World Report's "Honor Roll" of top U.S. hospitals; it is one of the nation's top 20 hospitals in Cardiology/Heart Surgery, Diabetes/Endocrinology, Gastroenterology/GI Surgery, Geriatrics, Nephrology, and Neurology/Neurosurgery, and in the top 50 in four other specialties in the 2017-2018 "Best Hospitals" issue. Mount Sinai's Kravis Children's Hospital also is ranked in six out of ten pediatric specialties by U.S. News & World Report. The New York Eye and Ear Infirmary of Mount Sinai is ranked 12th nationally for Ophthalmology and 50th for Ear, Nose, and Throat, while Mount Sinai Beth Israel, Mount Sinai St. Luke's and Mount Sinai West are ranked*

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## Marijuana Found in Breast Milk Up to Six Days After Use

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*Researchers report 63 percent of breast milk samples from mothers using marijuana contained traces of the drug.*

Released: 23-Aug-2018 11:05 AM EDT-  
Source Newsroom: University of California San Diego Health

Newswise — With the legalization of marijuana in several states, increased use for both medicinal and recreational purposes has been documented in pregnant and breastfeeding women. Although national organizations like the American Academy of Pediatrics recommend that breastfeeding mothers do not use marijuana, there has been a lack of specific data to support health or neurodevelopmental concerns in infants as a result of exposure to tetrahydrocannabinol (THC) or other components of marijuana via breast milk.

To better understand how much marijuana or constituent compounds actually get into breast milk and how long it remains, researchers at University of California San Diego School of Medicine conducted a study, publishing online August 27 in Pediatrics.

Fifty-four samples from 50 women who used marijuana either daily, weekly or sporadically — with inhalation being the primary method of intake — were examined. Researchers detected THC,

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the primary psychoactive component of marijuana, in 63 percent of the breast milk samples for up to six days after the mother's last reported use.

"Pediatricians are often put into a challenging situation when a breastfeeding mother asks about the safety of marijuana use. We don't have strong, published data to support advising against use of marijuana while breastfeeding, and if women feel they have to choose, we run the risk of them deciding to stop breastfeeding — something we know is hugely beneficial for both mom and baby," said Christina Chambers, PhD, MPH, principal investigator of the study, professor in the Department of Pediatrics at UC San Diego School of Medicine and director of clinical research at Rady Children's Hospital-San Diego.

The World Health Organization recommends exclusive breastfeeding for up to six months. Early breastfeeding is associated with a reduced risk of obesity, asthma and sudden infant death syndrome and with improved immune health and performance on intelligence tests. In mothers, breastfeeding has been associated with lower risks for breast and uterine cancer and type 2 diabetes.

Cannabinoids — marijuana's active compounds, such as THC — like to bind to fat molecules, which are abundant in breast milk. This stickiness has suggested that, in women who use marijuana, these compounds can end up in breast milk, raising concerns about their potential effects on nursing babies.

"We found that the amount of THC that the infant could potentially ingest from breast milk was relatively low, but we still don't know enough about the drug to say whether or not there is a concern for the infant at any dose, or if there is a safe dosing level," said Chambers, co-director of the Center for Better Beginnings at UC San Diego. "The ingredients in marijuana products that are available today are thought to be much more potent than products available 20 or 30 years ago."

The samples of breast milk used for the study were obtained from mothers who

joined the Mommy's Milk Human Milk Research Biorepository at UC San Diego, a program that focuses on looking at the numerous benefits of breast milk at the molecular level. Chambers and her research team collaborated with Skaggs School of Pharmacy and Pharmaceutical Sciences at UC San Diego to measure the levels of marijuana in the samples.

Chambers said the results are a stepping stone for future research. More studies need to be done, not only to determine the long-term impact of marijuana in breast milk for children, but more specifically: "Are there any differences in effects of marijuana in breast milk for a two-month-old versus a 12-month-old, and is it different if the mother smokes versus eats the cannabis? These are critical areas where we need answers as we continue to promote breast milk as the premium in nutrition for infants."

*Co-authors include: Kerri Bertrand, Nathan Hanan, Gordon Honerkamp-Smith, and Brookie Best, all at UC San Diego.*

*This research was funded, in part, by the Gerber Foundation and the National Institutes of Health (UL1TR001442).*

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## Here's Why It's Important to Support Your Breastfeeding Co-Workers

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*Breastfeeding support is essential.*

Released: 11-Jul-2018 10:05 AM EDT-Source Newsroom: Michigan State University

Newswise — Support from female co-workers may be even more important to new moms who are breastfeeding than getting encouragement from their significant others, close friends and relatives, says a new study.

According to Michigan State University and Texas Christian University researchers, the

more support women receive from their colleagues, the more successful they are in believing they can continue breastfeeding. While support from family or friends is important, surprisingly, co-worker support has a stronger effect.

The study, now published in the journal *Health Communication*, is the first to focus specifically on the effect female co-workers have on colleagues who want to continue breastfeeding by pumping milk at work.

"In order to empower women to reach their goals and to continue breastfeeding, it's critical to motivate all co-workers by offering verbal encouragement and practical help," said Joanne Goldbort, an assistant professor in the College of Nursing at MSU, who collaborated with lead author Jie Zhuang at TCU.

According to Zhuang, people may assume that women in the workplace automatically encourage one another, but that often may not be the case.

The study surveyed 500 working mothers. Eighty-one individuals indicated they had never breastfed, and 80 had stopped before returning to work. Of those who continued breastfeeding after returning to work, more than half chose not to stick with it between the first and sixth month. While the specific reasons participants stopped weren't tracked in the study, it did measure their thoughts and feelings around co-worker perception and stigma, as well as how uncomfortable they were about pumping milk at work.

Overall, the data suggested that the act of simply returning to work played a major role in their decision to quit breastfeeding but receiving colleague support was instrumental to those who continued.

The research also showed that more than a quarter of the women who originally decided to breastfeed made the decision because their place of employment created a helpful environment, such as providing a place to pump. Around 15 percent said they chose to continue breastfeeding after returning to work because they had co-workers or supervisors who directly motivated them to do so.

Goldbort indicated that multiple variables could play into why co-worker support is





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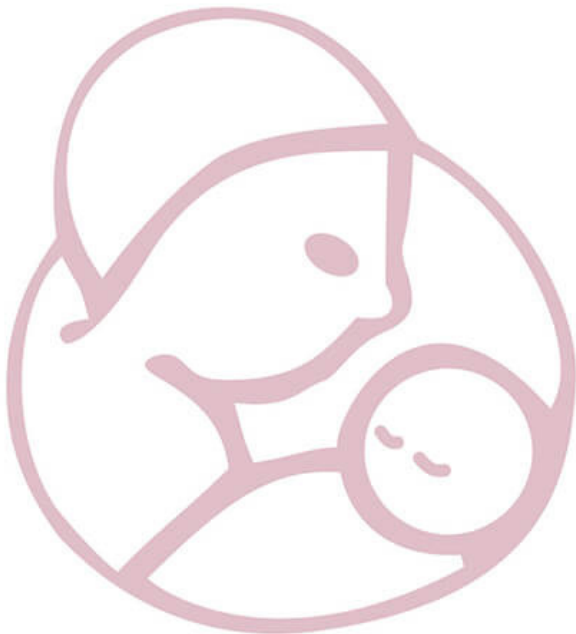
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viewed as equally important, if not more important, to working moms.

“One factor could be that simply spending the majority of their time during the day with co-workers necessitates more support for breastfeeding success,” she said. “In the workplace, a breastfeeding woman’s dependence on this is higher because she has to work collegially with co-workers, gain their support to assist with the times she’s away from her desk, and ultimately try to lessen the ‘you get a break and I don’t’ stigma.”

Recently, the United States opposed the World Health Assembly’s resolution to promote the use of breast milk over formula. This runs counter to years of research that shows breastfeeding has significant nutritional benefits for babies and their development. It also has many advantages for the mother. Yet the number of moms who choose to continue to breastfeed in the U.S. remains lower than health organization recommendations.

The World Health Organization and the Centers for Disease Control and Prevention suggest exclusive breastfeeding for the first six to 12 months and then continuing with supplementary feeding of solid foods up to two years of age or longer.

“If women know that co-workers and supervisors will support them in their breastfeeding efforts, it can make a big difference,” Goldbort said. “It really takes a village to breastfeed a baby.”

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## Baebies Announces CE Mark for SEEKER, an Innovative Newborn Screening Platform for Lysosomal Storage Diseases

Released: 21-Jun-2018 10:05 AM EDT

Source Newsroom: 70th AACC Annual Scientific Meeting Press Program

PDURHAM, N.C., July 31, 2017 – Baebies is pleased to announce that SEEKERTM, a high throughput newborn screening laboratory solution, now has CE Mark and available in Europe and other countries that recognize CE Mark. SEEKER quantitatively measures the activity of lysosomal enzymes from newborn dried blood spot specimens. Reduced activity of these enzymes may be indicative of Mucopolysaccharidosis Type I (MPS I), Pompe, Gaucher or Fabry disease.

Newborn screening for lysosomal storage diseases (LSDs) has gained interest worldwide with the increasing availability of effective treatment options and accessible screening methods. In addition, several recent studies have highlighted higher incidence rates for certain LSDs than previously reported. “SEEKER’s ease of use enables the platform to be used in virtually any newborn screening program,” says Jerry Walter, Founder and President of the National Fabry Disease Foundation. “More babies screened for LSDs means more babies identified and diagnosed through clinical follow-up.”

“As a company focused on newborn screening and pediatric testing, SEEKER’s CE Mark allows Baebies to build on the mission that everyone deserves a healthy start by expanding access to newborn screening to all babies around the world,” says Jan Østrup, a pioneer in neonatal screening product development and a member of the Baebies’ Scientific Advisory Board.

“We are delighted to announce CE Mark for SEEKER,” said Richard West, Co-Founder and Chief Executive Officer of Baebies. “There is a tremendous interest in SEEKER outside the US due to its simple implementation and we are actively engaged with several customers,” added West.

As countries start or expand newborn screening programs, labs are challenged

to find easy and cost-efficient ways to implement new assays. To address these needs, Baebies delivers SEEKER, a reliable, fast and easy to use solution for high throughput newborn screening. The pioneering platform features:

- Digital microfluidic technology which minimizes sample and reagent volumes.
- Minimal, easy to use equipment making installation and training quick and simple.
- All electronic workstation with no required daily maintenance so the platform is always up and running.
- Proprietary software that guides all skill levels through the minimal hands-on workflow.

*Baebies’ SEEKER received U.S. FDA authorization in February 2017 after a thorough review that included a clinical study of over 150,000 subjects, with no known false negatives reported. For more information on Baebies’ SEEKER platform, visit [www.baebies.com](http://www.baebies.com).*

About SEEKERTM

*SEEKER is a high throughput laboratory solution that quantitatively measures the activity of lysosomal storage enzymes from newborn dried blood spot specimens. As the first newborn screening platform for lysosomal storage disorders authorized by the U.S. FDA, SEEKER is designed for ease of use, simple implementation and no daily maintenance.*

About Baebies

*At Baebies our sole focus is to advance newborn screening and other pediatric testing worldwide. Baebies is guided by the vision that “everyone deserves a healthy start”. Baebies delivers innovative products and services to make life better for millions of babies. By bringing new technologies and new tests to the healthcare community, Baebies is providing hope to parents and the chance at a*

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## Researchers Launch New Study to Determine Benefit of Proactive Interventions in Reducing Premature Births

*Researchers are launching the first study of its kind involving up to 10,000 women that will use a new test to identify those at risk for premature birth, and, in those with high risk, to evaluate the impact of early interventions designed to prolong their pregnancy and reduce the rate of premature delivery.*

Released: 4-Jun-2018 12:05 AM EDT  
Source Newsroom: Intermountain Medi-

cal Center

**Newswise** — Researchers are launching the first study of its kind involving up to 10,000 women that will use a new test to identify those at risk for premature birth, and, in those with high risk, to evaluate the impact of early interventions designed to prolong their pregnancy and reduce the rate of premature delivery.

For the Prevent PTB study being conducted by researchers at Intermountain Healthcare in Salt Lake City, half of the 10,000 study participants will undergo normal medical screening to determine their risk of preterm birth. The other half will give a blood sample for Sera Prognostics' validated PreTRM test.

Previous research of more than 5,500 women found the PreTRM test accurately identifies pregnant women at high risk of preterm birth, even if they have no previous history or other signs of the condition, such as a shortened cervix.

"This is the first time we're able to use a blood test to identify the women at highest risk and start to intervene to prevent the preterm birth," said D. Ware Branch, MD, medical director of Intermountain Healthcare's Women and Newborns Clinical Program, who is principal investigator of the study.

Pregnant women will be recruited for the Prevent PTB study at five Intermountain

Healthcare hospitals in Utah: Intermountain Medical Center in Murray, Dixie Regional Medical Center in St. George, LDS Hospital in Salt Lake City, Utah Valley Medical Center in Provo, and McKay-Dee Hospital in Ogden. Salt Lake City-based Sera Prognostics is funding the research.

"We are pleased to see Intermountain leading clinical research with this important study. The Prevent PTB study is designed to show the benefits of early identification and proactive intervention in reducing preterm birth rates and improving the health of babies," said Gregory C. Critchfield, MD, MS, chair and CEO of Sera Prognostics. "By identifying more pregnancies where earlier, more proactive intervention is beneficial, society, families and, most importantly newborn infants, have the potential for better outcomes and lower healthcare costs."

Preterm birth is the leading cause of newborn death — and it can afflict babies who survive for the rest of their lives with blindness, deafness, cerebral palsy, developmental delays, and learning disabilities. Other long-term complications include chronic respiratory illness, seizures, and vision and hearing loss. Lifelong care for children with such conditions is expensive.

A March of Dimes national report found that preterm birth — defined as birth before 37 weeks of the normal 40 weeks — affects 15 million infants worldwide each



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year and causes 1 million deaths. Of almost 4 million babies delivered annually in the U.S., approximately 11 percent of births are preterm. The rate in Utah is slightly less.

“The biggest challenge we have in trying to treat preterm birth is we don’t know who’s going to have it,” said researcher Sean Esplin, MD, a maternal-fetal specialist at Intermountain Medical Center and director of research for women and newborn services for Intermountain Healthcare, who is a scientific founder of Sera Prognostics. “Out of every 100 pregnant women who come to my office, I know 10 of them will deliver early. But I don’t know which 10 to focus on, except for a few with a previous preterm birth, shortened cervix, or other risk factors. Otherwise, I have to wait until they come in with symptoms, and by then, it’s often too late to stop it.”

That’s why Intermountain Healthcare is using the PreTRM blood test to assess risk earlier. Previous published research shows that when blood is tested as early as 19 or 20 weeks gestation, PreTRM accurately predicts a woman’s chance of having a preterm birth by measuring and analyzing a pattern of proteins in the blood, focusing on two with high predictive performance.

“Of all the women who are pregnant, our current clinical methods identify fewer than half of those who eventually will give birth before 37 weeks,” said Dr. Branch. “We hope to show this test will identify a goodly proportion of the remaining patients to determine whether doing the test can enable interventions that prevent preterm births and/or improve neonatal outcomes among those who are born prematurely.”

The new Prevent PTB study will use such treatments on women who are carrying one baby and lack common symptoms, but are identified by the PreTRM test as being at high risk of preterm birth.

Women with a history of preterm birth, who are under age 18, or more than 21 weeks pregnant aren’t eligible for the study. Pregnant women enrolled in the study will be randomly assigned to the experimental group or a control group.

Women in the experimental group will receive the PreTRM blood test, and those found to be at high risk of preterm birth will undergo the study’s early, pre-emptive treatments to determine if they can reduce the number of preterm births and newborn deaths, and shorten hospital stays for premature babies.

Medical interventions used to reduce the likelihood of preterm birth or to lengthen gestation include injected or intravaginal progesterone hormone, which alone can reduce the risk of pre-term birth by 30 percent; use of a vaginal device to support the cervix or stitching the cervix shut until late pregnancy; visits to prematurity prevention clinics and weekly nurse contacts to check on expectant mothers’ symptoms; and baby aspirin to reduce inflammation.

Treatments to help babies who are born prematurely may include antibiotics, magnesium sulfate to reduce neurological disabilities and umbilical cord “milking” to push more oxygen-carrying red blood cells into premature babies just after delivery.

Women who are shown by the test to not be at high risk and those randomly assigned to the control group will receive normal obstetrical care, unless they later develop symptoms that require treatment for possible preterm birth at a high-risk obstetrics clinic.

The study design is adaptive, with readouts expected to occur sometime between 18 and 24 months.

If the study shows the PreTRM test and early intervention can reduce preterm births, the researchers hope to subsequently study whether that translates into fewer disabilities and lower healthcare expenses for premature babies.

“Every day a woman stays pregnant after 24 weeks saves \$10,000 in the cost of taking care of the baby,” Dr. Branch said. “Each year in the United States, we spend tens of billions of dollars taking care babies who are born too early. That’s why this study is so important.”

**NT**



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# The Genetics Corner: A Genetics Consultation for Microtia, ASD and IUGR

Subhadra Ramanathan, M.Sc., M.S and. Robin Clark, MD

## Case History:

A 16-day-old term Hispanic female infant with intra-uterine growth retardation (IUGR) was evaluated for right anotia and atrial septal defect. The infant was born vaginally at 38 weeks 2 days gestation to a G5 P4->5 37-year-old mother with pregestational diabetes and obesity prior to conception with a pre-pregnancy BMI of 45.9. Her hemoglobin A1c (HgbA1c) was 8.8% at 9-10 weeks gestation. She was initially on Metformin (1000 mg PO BID) but switched insulin late in the first trimester. Other teratogenic exposures were denied. The mother was diagnosed with pregnancy-induced hypertension at ~35 weeks' gestation.

Birth weight was 2296 grams (5 lb 1 oz, <3rd%ile), birth length was 44.5 cm, head circumference 30.5 cm (<3rd%ile). Absent right ear and sacral dimple were noted at birth. She was admitted to the NICU for poor feeding. An atrial septal defect was identified on echocardiogram. Chromosome microarray and chromosome analysis were normal.

On physical exam, the infant was small, alert and responsive. She had an absent external auditory meatus on the right, with two cartilaginous remnants of auricular tissue, corresponding to a rudimentary helix and lobule, and a preauricular tag. The left ear was normal. There were no epibulbar dermoids. The buccal fat pads were symmetric buccal without evidence of hemifacial microsomia. The mouth and palate were intact.

## Consultant's Report:

This baby's pattern of unilateral microtia and ASD, both common congenital anomalies, is compatible with poorly controlled maternal diabetes mellitus early in pregnancy. The mother had an elevated HgbA1c level and required insulin therapy in the first trimester. Her hypertension likely contributed to poor placental perfusion and IUGR.

Maternal diabetes is a well-known human teratogen associated with a wide array of congenital anomalies, which are collectively

referred to as diabetic embryopathy. This spectrum of congenital malformations and disruptions correlates with poor maternal glycemic control in the first trimester of pregnancy.<sup>2,5</sup>

The risk for anomalies in diabetic pregnancies is also modified by gene x gene and gene x environmental interactions. Obese women have children with a similar pattern of birth defects. The overall reported risk for birth defects is increased to about 10% in infants of diabetic mothers (IDMs) which is ~3 times the background risk of 3% in the general population.<sup>1</sup> The risk for malformations higher in women with pregestational diabetes and is inversely related to the degree of maternal diabetic control in the early first trimester, as measured by maternal serum HgA1c levels in the first trimester.<sup>3</sup>

Congenital anomalies in infants of diabetic mothers (IDM) can be seen in almost any organ system. The congenital anomaly that is most strongly and specifically associated with diabetic embryopathy is caudal regression due to sacral agenesis, ranging from sacral dysgenesis to sirenomelia (OR 26.4). The increased risk for anencephaly in IDM is more than tripled (Odds ratio, OR 3.39) and the risk is even higher for neural tube defects that are seen with additional anomalies (OR 7.99). Other relatively rare anomalies such as holoprosencephaly (OR 6) and heterotaxy (OR 7.48) are also strongly associated with poor glycemic control during pregnancy. Anomalies in the VATER spectrum (vertebral, anal, trachea-esophageal, renal) are also more common in infants of diabetic mothers.

However, as this case illustrates, many common congenital anomalies are also seen with greater frequency in offspring of diabetic mothers. Ear anomalies vary in frequency in the general population from 1/10,000 to 18/10,000. There is a higher prevalence of ear anomalies of ~1/1000 among certain ethnic groups: Hispanics, Asians, Native Americans and Andeans. The spectrum of relative risk for microtia/anotia/hemifacial microsomia among IDMs is 2.40-3.75.<sup>2</sup> This means that poorly controlled diabetic women who are from a high risk ethnic group have a child with ear anomalies in ~1/300 births. This is even more common than caudal regression, which occurs in 1-2/100,000 in the general population and in 1 in



Photo 1: Subtle asymmetry of eyes- infant unable to close right eye as well as left- implying weakness on right

Photo 2: Right microtia with cartilaginous remnant of auricular tissue. Absent external auditory canal.

350 IDMs. This means that for every infant with caudal regression who has a poorly controlled diabetic mother, we expect to at least one infant with an ear anomaly associated with maternal diabetes.

A similar calculation can be made for heart defects in infants of diabetic mothers. The general population risk for any cardiac anomaly is ~1/100. The overall OR for isolated cardiac defects among IDMs is 4.64 and for cardiac defects that are associated with other anomalies, the odds ratio is even higher: 10.77. The greatest differential in risk is for dextroposition of the great vessels associated with other anomalies (OR 71.97). This means that among infants of poorly controlled diabetic mothers, about 1 in 25 is expected to have an isolated heart defect. For every infant of a diabetic mother with an ear anomaly, we should expect to see roughly a dozen such infants with a cardiac anomaly.

These numbers should support an increased awareness of the wide variety of congenital anomalies associated with diabetic embryopathy. We should consider this diagnosis in infants with common malformations that are not always characterized as having the strongest association with maternal diabetes, yet are more prevalent because of their higher background rate.

The pathophysiology of diabetic embryopathy is complex and poorly understood. There is speculation that variable genetic or environmental factors, that influence gene expression patterns together with hyperglycemia, cause the different patterns of congenital anomalies associated with diabetic embryopathy. The perturbation of embryonic development in animal models is related to decreased cell proliferation/differentiation and increased cell apoptosis, mediated by altered gene expression in the diabetic milieu.<sup>4</sup>

The recurrence risk for diabetic embryopathy in a subsequent pregnancy born to a mother with pregestational diabetes, following an affected pregnancy, is increased to over 10%. This risk can be reduced by planning all future pregnancies to optimize diabetic control in the intergestational period, prior to any future conception, aiming for an ideal HgbA1c level between 5.7- 5.9. The tighter the level of glycemic control, the lower the potential risk to the pregnancy. Pregestational diabetic women should also take daily prenatal vitamins and supplemental folic acid (4 mg/day) starting at least one month prior to conception. This reduces the risk of congenital anomalies in subsequent pregnancies.

#### Practical Applications:

1. Document details of maternal diabetes mellitus in the prenatal history: dates and levels of HgbA1c, when and how diabetes was diagnosed, range and frequency of glucose levels, date of onset of insulin therapy, episodes of hypoglycemia.
2. Evaluate infants of diabetic mothers for congenital anomalies with an echocardiogram, head US, abdominal US, and radiographs when vertebral anomalies are suspected, etc.
  - o In IDMs who have one congenital anomaly, seek a second anomaly.
  - o Diabetic embryopathy is even more common among infants with multiple congenital anomalies.
3. Consider diabetic embryopathy when any congenital anomaly is present in an infant of a diabetic mother.
  - o Evaluate for other causes with microarray and chromosome analysis.
4. Counsel diabetic mothers to reduce the risk for diabetic embryopathy in a subsequent pregnancy by optimizing diabetic control between pregnancies with regular glucose checks,

modified diet, weight loss, exercise, regular medication use.

o Recommend monitoring diabetic control with regular HgbA1c levels prior to conception and early in subsequent gestations.

5. Recommend that diabetic women take a daily prenatal vitamin and a daily folic acid supplement of 4 mg, starting at least one month prior to stopping contraception.

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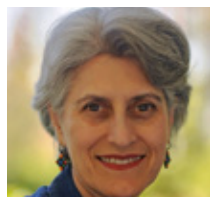
The author has no relevant disclosures.

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## Perinatal Substance Use

# 5 ways you can improve care during pregnancy and beyond

Pregnancy presents unique opportunities for patients to make positive changes in their substance use. When you become an informed provider you empower patients to make those changes.



### Educate Yourself

Learn more about the pharmacology of substance use. Promote evidence-based care by communicating with patients in a way that separates fact from fiction. Understand the cycles of sobriety and relapse so that you can help patients plan for their recovery. Advise on the risks associated with polysubstance use.



### Use the Right Words

Know the difference between substance use, substance misuse, and Substance Use Disorders (SUDs). Recognize that substance use is stigmatized and that stigma is a barrier to seeking care. Reject language that shames. Embrace the principles of Harm Reduction as a way to support any positive change.



### Screen Every Patient

Talking about substance use should be a routine part of everyone's medical care. Get comfortable discussing it. Ask questions and listen to what your patients have to say. You may be the first person to ever ask.



### Get Trained to Offer MAT

Medication-Assisted Treatment is the Standard of Care during pregnancy, but there are not enough providers. Contact SAMHSA to become an OTP\*. Make naloxone available to all your patients who use opioids.

\*opioid treatment program



### End the Stigma and Criminalization of Drug Use

Embrace people who use substances. Meet them where they are. Abide by your medical ethics. Practice beneficence. Promote public health. Advocate for decriminalization.

## Your Advocacy Matters

Learn more at [www.nationalperinatal.org](http://www.nationalperinatal.org)



## How to Care for a Baby with NAS



### Use the Right Words

I was exposed to substances in utero. I am not an addict. And my mother may or may not have a Substance Use Disorder (SUD).



### Treat Us as a Dyad

Mothers and babies need each other. Help my mom and me bond. Whenever possible, provide my care alongside her and teach her how to meet my needs.



### Support Rooming-In

Babies like me do best in a calm, quiet, dimly-lit room where we can be close to our caregivers.



### Promote Kangaroo Care

Skin-to-skin care helps me stabilize and self-regulate. It helps relieve the autonomic symptoms associated with withdrawal and promotes bonding.



### Try Non-Pharmacological Care

Help me self-soothe. Swaddle me snugly in a flexed position that reminds me of the womb. Offer me a pacifier to suck on. Protect my sleep by "clustering" my care.



### Support Breastfeeding

Breast milk is important to my gastrointestinal health and breastfeeding is recommended when moms are HIV-negative and receiving medically-supervised care. Help my mother reach her pumping and breastfeeding goals.



### Treat My Symptoms

If I am experiencing withdrawal symptoms that make it hard for me to eat, sleep, and be soothed, create a care plan to help me wean comfortably.

Learn more about Neonatal Abstinence Syndrome at [www.nationalperinatal.org](http://www.nationalperinatal.org)



## Still a Preemie?



*The National Coalition for Infant Health is a collaborative of more than 180 professional, clinical, community health, and family support organizations focused on improving the lives of premature infants through age two and their families. NCfIH's mission is to promote lifelong clinical, health, education, and supportive services needed by premature infants and their families. NCfIH prioritizes safety of this vulnerable population and access to approved therapies.*

Dear Colleagues,

We have all heard it. "But, she is so big, how can she be a preemie?" Premature babies are not just those that are admitted to the NICU. About 4 million babies are born each year in the United States. Of these, roughly half a million babies are born prematurely (<37 weeks) each year. Today, close to 1,500 babies in the United States (over 1 in 10) will be born prematurely (1-2).

Some babies are very small or sick and are admitted to the NICU. However, a lot more preemies are admitted to couplet care with mom in her room.

Family and friends expect that the baby will come home with the mom. The baby starts to have feeding problems in the hospital. Then, the bilirubin goes up and phototherapy is started. Despite never entering the NICU, this late premature baby may not go home for a week or more.

The mom and dad are frantic. Mom wants to breastfeed, but she has to go to the hospital each and every time she wants to feed her baby. She was given a breastpump prior to discharge, but the pump is not the same hospital grade pump that she used in the hospital. Her friends reassure her that it is okay to just give the baby formula. Meanwhile, without mom's breastmilk, the baby receives formula feeds, spits up more frequently, and is having trouble gaining weight.

Mom is distraught. She has not been able to bond with this baby the way she did with her first child. She is frequently sad. Her family does not understand. "What is there to be upset about? It is not like your baby is really sick?" The obstetrician wants to help. Mom is not going to breastfeed. So she gives her an anti-depressant.

***"All preemies face health risks, all deserve appropriate health coverage, and all need access to proper health care."***

By day three, the insurers are calling. One calls the clinician and asks why this 2500 gram baby is still not discharged home. Another in utilization review calls the father at work and explains how

## Still a Preemie?

*Some preemies are born months early, at extremely low birthweights. They fight for each breath and face nearly insurmountable health obstacles.*

**But that's not every preemie's story.**

### Born between 34 and 36 weeks gestation?

**STILL A PREEMIE**

*Just like preemies born much earlier, these "late preterm" infants can face:*



Jaundice



Feeding issues



Respiratory problems

And their parents, like all parents of preemies, are at risk for postpartum depression and PTSD.



### Born preterm at a "normal" weight?

**STILL A PREEMIE**

*Though these babies look healthy, they can still have complications and require NICU care.*

But because some health plans determine coverage based on a preemie's weight, families of babies that weigh more may face access barriers and unmanageable medical bills.



Picture: The new National Coalition for Infant Health Infographic.

the policy will not cover a well baby hospital stay past three days. "The family will be responsible for all of the costs from now on."

The parents speak with the clinician and an agreement is made to take the baby home with close follow up. The baby was started on a fortified infant formula to improve weight gain in the hospital. On the way home, the parents stop at the store to pick up the new formula. The supermarket doesn't have it, nor the drugstore neither the large wholesale store. One of their friends suggests goat's milk, another had good results with hemp milk.

Two weeks later, the parents finally have an appointment with the pediatrician. Unfortunately, the pediatrician is not doing well baby checks that day, and instead, the baby is seen by someone who does not know the baby's history. He re-assures the parents and explains that there should be no differences between this baby and their first child. Five minutes later, the parents are checking out.

## Born preterm but not admitted to the NICU?

Even if preterm babies don't require NICU care, they can still face health challenges.

Those challenges can extend through childhood, adolescence and even into adulthood.

STILL A  
PREEMIE



### Some Preemies



Will spend weeks in the hospital



Will have lifelong health problems



Are disadvantaged from birth

### All Preemies



Face health risks



Deserve appropriate health coverage



Need access to proper health care

**NCJH** National Coalition for Infant Health  
Protecting Access for Premature Infants through Age Two  
[www.infanthealth.org](http://www.infanthealth.org)

Across from them, another mom is bringing in her baby for an emergent visit. The baby is coughing and looks sick. Mom is worried, but she remembers what the doctor said. The parents go home. Although their baby has not regained birthweight, they are satisfied. Mom cannot remember discussing her concerns about prematurity or whether hemp milk should be used exclusively.

Two days later, the baby is sick with a cold. Mom is concerned. The baby's chest seems to be bouncing off the bed. Dad and mom go to the urgent care at 3 AM. The ER doctor starts an IV and broad spectrum antibiotics. Mom is crying; dad is stoic. They admit the baby to the general pediatrics ward. The nurse tells mom that her baby has Respiratory Syncytial Virus or RSV.

The insurer is calling again. He wants to know why the baby is re-admitted to the hospital. The parents are despondent. No one seems to understand. "Is this what it is going to be like forever, what went wrong?"

The answer is not always obvious. This baby is still a preemie. Not every premature baby goes to the NICU. Some have feeding problems, jaundice, and respiratory problems. Some spend weeks in the hospital. Some have lifelong health problems. And some are disadvantaged from birth.

All preemies face health risks, all deserve appropriate health coverage, and all need access to proper health care.

The National Coalition for Infant Health has created a new infographic designed to bring these concerns to light. The full graphic panel is on the facing page. Please download it from our website [www.infanthealth.org](http://www.infanthealth.org) and share it with a colleague, friend, or parent of a preemie.

*Mitchell Goldstein*

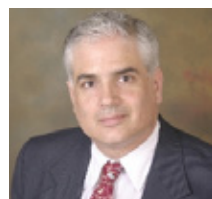
Mitchell Goldstein, MD  
Medical Director  
National Coalition for Infant Health

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The author has no relevant disclosures.

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#### National Coalition for Infant Health Values (SANE)

**Safety.** Premature infants are born vulnerable. Products, treatments and related public policies should prioritize these fragile infants' safety.

**Access.** Budget-driven health care policies should not preclude premature infants' access to preventative or necessary therapies.

**Nutrition.** Proper nutrition and full access to health care keep premature infants healthy after discharge from the NICU.

**Equality.** Prematurity and related vulnerabilities disproportionately impact minority and economically disadvantaged families. Restrictions on care and treatment should not worsen inherent disparities.

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# Still a Premie?

Some preemies are born months early, at extremely low birthweights. They fight for each breath and face nearly insurmountable health obstacles.

But that's not every preemie's story.

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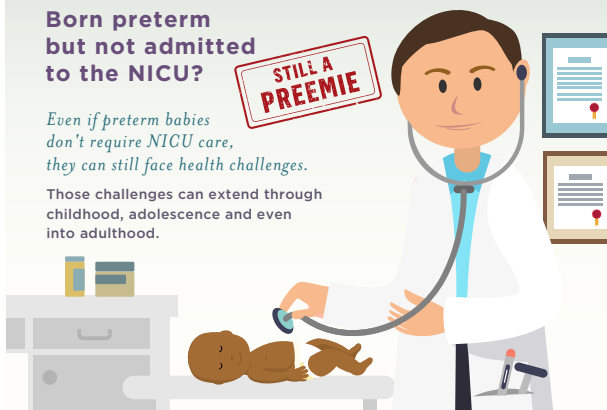
But because some health plans determine coverage based on a preemie's weight, **families of babies that weigh more may face access barriers and unmanageable medical bills.**

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### Some Premies



Will spend weeks in the hospital



Will have lifelong health problems



Are disadvantaged from birth

### All Premies



Face health risks



Deserve appropriate health coverage



Need access to proper health care

**NCFIH** National Coalition for Infant Health  
Protecting Access for Premature Infants through Age Two

[www.infanthealth.org](http://www.infanthealth.org)

**NCFIH** National Coalition for Infant Health

Protecting Access for Premature Infants through Age Two

A collaborative of professional, clinical, community health, and family support organizations improving the lives of premature infants and their families through education and advocacy.



## The National Coalition for Infant Health advocates for:

- **Access to an exclusive human milk diet** for premature infants
- **Increased emotional support resources** for parents and caregivers suffering from PTSD/PPD
- **Access to RSV preventive treatment** for all premature infants as indicated on the FDA label
- **Clear, science-based nutrition guidelines** for pregnant and breastfeeding mothers
- **Safe, accurate medical devices** and products designed for the special needs of NICU patients

[www.infanthealth.org](http://www.infanthealth.org)

# Perinatal/Neonatal Medicolegal Forum: Kernicterus

Jonathan Fanaroff, MD, JD and Gilbert Martin, MD

High reliability organizations (HRO) are defined by the Agency for Healthcare Research and Quality as “organizations that operate in complex, high-hazard domains for extended periods without serious accidents or catastrophic failures.” Examples include aircraft carriers, nuclear power plants, and commercial aviation. A core HRO principal is preoccupation with failure. When a bad outcome occurs, a detailed study known as a Root Cause Analysis (RCA) is performed in order to learn the root causes leading to that outcome with the ultimate goal of preventing future events. In neonatology, medical malpractice lawsuits can be one way to publicly learn about a poor outcome. Similar to an RCA, by analyzing what happened, lessons can be learned and applied that will hopefully prevent similar outcomes in the future. Let's look at a recent kernicterus case. Details have been taken from the complaint filed with the court by the plaintiffs.

## Alleged Facts

Kara Smalls, a 38 week 4040 gram female was born at 0921 on June 4th, 2014 via C-section. This was her mother Candice Smalls' second child, and her first baby had required phototherapy. Ms. Smalls' blood type was O and Kara was A. At 2 hours of life a bilirubin level was checked and was 5.5. Her skin color was noted as normal.

The next day (6/5) nurses noted Kara was “slightly jaundiced” and the following day (6/6) they noted “mild jaundice.” Kara was discharged Friday 6/6 at 49 hours of life with a follow up appointment set for June 16. Three days later on Monday (6/9) Kara's parents noticed that she was very lethargic, could not latch, had a shrill cry and was increasingly yellow. They called the clinic who told them to bring her in on Friday 6/13. But on Wednesday 6/11 Ms. Smalls called the clinic and left a message stating that Kara had a shrill cry, was arching her back, and seemed in pain. A nurse called back that evening, heard the history, and advised her to call the clinic in the morning.

The next day, Thursday 6/12 Kara is seen in clinic late that morning and is noted to be severely jaundiced. Her blood is drawn at 11:58 and she is sent home. The bilirubin results at 12:28 with a level of 33.4. Kara is diagnosed with kernicterus, a “severe and catastrophic” brain injury” that was “entirely preventable”

## Who was Sued?

The birth hospital, the clinic, the treating physician

## Allegations of Negligence

In this case the claim is that the defendants were ‘negligent’ by not providing Kara “with reasonable care [using] the degree of skill and learning ordinarily possessed and used by members of the medical profession in good standing engaged in the same type of service or specialty in the’ same location.” Specific care deficiencies included:

1. Not checking a repeat bilirubin level prior to discharge.
2. Ignoring the bilirubin level of 5.5 at 2 hours of life that put Kara at high risk for jaundice as well as the clinical evaluations where she was jaundiced.
3. Not recognizing the risk factors of siblings who required phototherapy and the potential ABO incompatibility.
4. Not treating Kara with phototherapy for jaundice.

5. Not scheduling a timely follow-up after discharge.
6. Not seeing Kara immediately on the multiple occasions when the family called with concerns.

## Case outcome

The case was filed July 2015. It went to trial February 2017 and 11/12 jurors found that the physician was negligent and 12/12 jurors found the hospital negligent. They also placed 85% of the liability on the physician and clinic and 15% on the medical center. Kara was given \$43 million in damages and her parents were given \$3.5 million in damages.

## Analysis

What can we learn from this case? Multiple ‘barriers’ are placed in an attempt to protect patients, but there are often weaknesses. James Reason proposed that errors result when a number of factors line up like holes in Swiss cheese to allow harm to reach the patient. There were a number of opportunities for better care in this case, including understanding risk factors for jaundice, interpreting the bilirubin level obtained and plotting it on a nomogram, and recognizing the limitations of visual exam to determine the bilirubin level. Additionally, when a parent calls with a concern in a newborn they need to be seen in a timely manner. It may be helpful to take some time and analyze the fact pattern in this case for yourself to determine additional opportunities that will help prevent this outcome from occurring in the future.

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*The authors have no conflicts of interests to disclose.*

**NT**

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# TOP 10



## RECOMMENDATIONS FOR THE PSYCHOSOCIAL SUPPORT OF NICU PARENTS

Essential evidence-based practices that can transform the health and well being of NICU families and staff

based on the National Perinatal Association's Interdisciplinary Recommendations for Psychosocial Support of NICU Parents

### 1 PROMOTE PARTICIPATION

Honor parents' role as primary caregiver. Actively welcome parents to participate during rounds and shift changes. Remove any barriers to 24/7 parental involvement and avoid unnecessary separation of parents from their infants.



### 2 LEAD IN DEVELOPMENTAL CARE

Teach parents how to read their baby's cues. Harness your staff's knowledge, skills, and experience to mentor families in the principles of neuroprotection & developmental care and to promote attachment.



### 3 FACILITATE PEER SUPPORT

Invest in your own NICU Parent Support program with dedicated staff. Involve veteran NICU parents. Partner with established parent-to-parent support organizations in your community to provide continuity of care.



### 4 ADDRESS MENTAL HEALTH

Prioritize mental health by building a team of social workers and psychologists who are available to meet with and support families. Provide appropriate therapeutic interventions. Consult with staff on trauma-informed care - as well as the critical importance of self-care.



### 5 SCREEN EARLY AND OFTEN

Establish trusting and therapeutic relationships with parents by meeting with them within 72 hours of admission. Follow up during the first week with a screening for common maternal & paternal risk factors. Provide anticipatory guidance that can help normalize NICU distress and timely interventions when needed. Re-screen prior to discharge.



### 6 OFFER PALLIATIVE & BEREAVEMENT CARE

Support families and NICU staff as they grieve. Stay current with best practices in palliative care and bereavement support. Build relationships with service providers in your community.

### 7 PLAN FOR THE TRANSITION HOME

Set families up for success by providing comprehensive pre-discharge education and support. Create an expert NICU discharge team that works with parents to find specialists, connect with service providers, schedule follow-up appointments, order necessary medical supplies, and fill Rx.



### 8 FOLLOW UP

Re-connect with families post-discharge. Make follow-up calls. Facilitate in-home visits with community-based service providers, including Early Intervention. Partner with professionals and paraprofessionals who can screen families for emotional distress and provide timely therapeutic interventions and supports.

### 9 SUPPORT NICU CARE GIVERS

Provide comprehensive staff education and support on how to best meet families' psychosocial needs, as well as their own. Acknowledge and address feelings that lead to "burnout."



### 10 HELP US HEAL

Welcome the pastoral care team into your NICU to serve families & staff.

SUPPORT4NICUPARENTS.ORG

## New Moms Need Access to Screening & Treatment for POSTPARTUM DEPRESSION



**1 IN 7 MOMS FACE POSTPARTUM DEPRESSION, experiencing**



Yet only 15% receive treatment<sup>1</sup>

### UNTREATED POSTPARTUM DEPRESSION CAN IMPACT:



### TO HELP MOTHERS FACING POSTPARTUM DEPRESSION



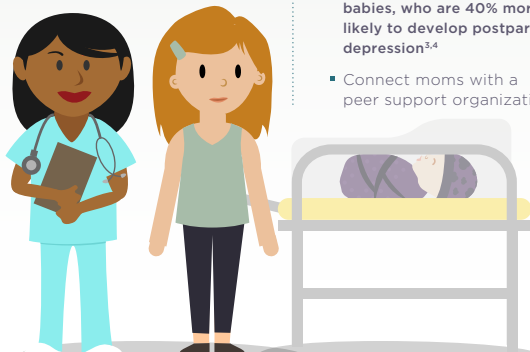
#### POLICYMAKERS CAN:

- Fund Screening Efforts
- Protect Access to Treatment



#### HOSPITALS CAN:

- Train health care professionals to provide psychosocial support to families... especially those with preterm babies, who are 40% more likely to develop postpartum depression<sup>3,4</sup>
- Connect moms with a peer support organization



**NCFIH** National Coalition for Infant Health  
Protecting Access for Premature Infants through Age Two  
[www.infanthealth.org](http://www.infanthealth.org)

<sup>1</sup>American Psychological Association. Available at: <http://www.apa.org/women/resources/reports/postpartum-depression.aspx>  
<sup>2</sup>National Institute of Mental Health. Available at: <http://www.nimh.nih.gov/health/publications/postpartum-depression-facts/index.shtml>  
<sup>3</sup>Journal of Perinatology (2015) 35, 229–236. doi:10.1097/01.jp.0000000000.00000.  
<sup>4</sup>Prevalence and risk factors for postpartum depression among women with preterm and low-birth-weight infants: a systematic review. Vigod SN, Vilgaard L, Dennis CL. Ross LE BJOG. 2010 Apr; 117(5):540-50.

## Las nuevas mamás necesitan acceso a la detección y tratamiento para LA DEPRESIÓN POSPARTO



**1 DE CADA 7 MADRES AFRONTA LA DEPRESIÓN POSPARTO, experimentando**



Sin embargo, sólo el 15% recibe tratamiento<sup>1</sup>

### LA DEPRESIÓN POSPARTO NO TRATADA PUEDE AFECTAR:



### PARA AYUDAR A LAS MADRES A ENFRENTAR LA DEPRESIÓN POSPARTO



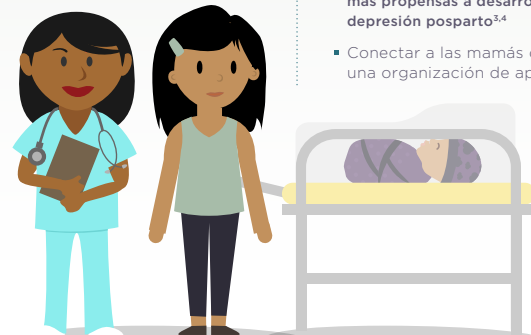
#### LOS ENCARGADOS DE FORMULAR POLÍTICAS PUEDEN:

- Financiar los esfuerzos de despistaje y diagnóstico
- Proteger el acceso al tratamiento



#### LOS HOSPITALES PUEDEN:

- Capacitar a los profesionales de la salud para proporcionar apoyo psicosocial a las familias... Especialmente aquellas con bebés prematuros, que son 40% más propensas a desarrollar depresión posparto<sup>3,4</sup>
- Conectar a las mamás con una organización de apoyo



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<sup>1</sup>American Psychological Association. Available at: <http://www.apa.org/women/resources/reports/postpartum-depression.aspx>  
<sup>2</sup>National Institute of Mental Health. Available at: <http://www.nimh.nih.gov/health/publications/postpartum-depression-facts/index.shtml>  
<sup>3</sup>Journal of Perinatology (2015) 35, 229–236. doi:10.1097/01.jp.0000000000.00000.  
<sup>4</sup>Prevalence and risk factors for postpartum depression among women with preterm and low-birth-weight infants: a systematic review. Vigod SN, Vilgaard L, Dennis CL, Ross LE BJOG. 2010 Apr; 117(5):540-50.

# Monthly Clinical Pearl: “BPD Spells” and Long-Term Follow-up of NICU Graduates

Joseph R. Hageman, MD

It always seemed to happen when I was on call. In the NICU, there were preterm twins who had become ventilator-dependent with bronchopulmonary dysplasia (BPD), and as cute as they were, they always seemed to decompensate on my calls. Once you finish your fellowship and become a board-certified neonatologist, you are supposed to know everything and be able to manage the most challenging clinical issues. But “BPD spells,” as we referred to them in the 1980’s, were challenging and frustrating. Were these spells secondary to bronchoconstriction? Then perhaps bronchodilators would do the trick? Perhaps we needed to manage their baseline disease better, and they needed a course of corticosteroids? How about infection as an etiology? Let’s cover them with antibiotics. We always monitored their fluid balance and also considered adding diuretics. We could not forget about optimizing nutrition as new lung growth would be healthier and better developed. How about supplemental oxygen to prevent episodes of intermittent hypoxemia, which might be related to pulmonary hypertension? Despite all of these treatment options, I recall thinking that these spells resolved independent of anything we did.

In the recent review about adjunctive therapies in patients with BPD by Maduekwe and DeCristofaro, the summary sentence states:

*“Fifty years after the initial descriptions of the disorder, BPD still remains one of the most frustrating complications of prematurity, carrying a significant physical, social and economic burden for the survivors and their families”.*

Although the incidence of “BPD spells” seems to have declined over time (for unknown reasons) and the clinical/radiographic BPD findings are different, we are still faced with similar challenges about how to manage these infants. Just after writing this blog with Dr. Dara Brodsky adding her comments, a new article appeared in the New England Journal of Medicine by Doyle and colleagues which examined long term follow up of pulmonary function of extremely low birthweight infants with non invasive respiratory support techniques and these children still had significant BPD (4). An editorial by Schreiber and Marks provides perspective about how complex the pathogenesis of BPD is as it involves a number of factors including: the immaturity of the lung and the lung’s response to inflammation, infection and oxygen toxicity (5). There is also still an element of barotrauma as well relative to the immature lung as long as positive pressure is used.

One method we used to utilize in our infants with severe BPD who were ventilator dependent was a negative pressure ventilator.

Somehow, this technique which is meant to mimic the normal physiology involved in spontaneous ventilation, is no longer being utilized. One new technique that is called “NAVA” or neutrally augmented ventilatory assistance which utilizes the neural impulse of the baby’s phrenic nerve to the diaphragm is another possible relatively gentle mode of ventilation which can be utilized in an intubated infant or using non invasive ventilator techniques (6). Schreiber and Marks also discuss the relative balance between avoidance of hyperoxia and episodes of intermittent hypoxemia in the pathogenesis of BPD (5). I agree that the pathogenesis of BPD is very complex and involves a combination of the immature lung as described by Jobe in his description of the “new BPD”. He describes the lung’s response to inflammation, infection, relative hyperoxia or oxygen toxicity, intermittent hypoxemia and vasoconstriction, and an element of barotrauma still. I still wonder about the contribution of changes in fluid balance related to the damaged lung and the patent ductus arteriosus.

Then we must also consider our therapy including interventions that decrease the development of BPD which include antenatal corticosteroids, strategic inhaled or intermittent systemic corticosteroid therapy, vitamin A, D or E therapy, antibiotic stewardship as it relates to the development of late onset sepsis or ventilator associated pneumonia with resistant organisms. It also seems that there may well be a genetic component as well as some infants seem to be at greater risk for the development of BPD (reference). In summary, it sounds simplistic but as we discuss the development of BPD we must consider genetic and environmental, and management components in the pathogenesis of this complex disease process.

Just to give the reader some hope and perspective, one of the twins is now a 29-year-old nursing orthopedic specialist; her brother is successful in business. One other long-term follow up experience I had in the last year was after a 34-year-old woman delivered a healthy term newborn and I received a call from my colleague. The last time I had seen this woman was in follow-up clinic when she was age 2 years.

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4. Maduekwe E, DeCristofaro JD. Adjunctive therapies in bronchopulmonary dysplasia. *NeoReviews*. 2017;18:e173-e179
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The author has identified no conflicts of interest.

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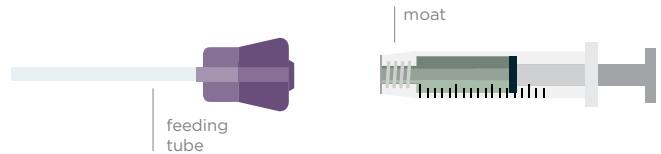
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 Summarize the pearl for emphasis.  
 No more than 7 references.  
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# Letters to the Editor

To the Editor (via email),

From: Shabih Manzar <shabihman@hotmail.com>

Subject: Letter to the Editor

Date: Tuesday 8/28/2018 11:53 AM

Letter to the Editor,

Dr. Goldstein,

Health care is a service-based discipline. Since managed care has been introduced, it has become a business. This model has changed the employment contract's language. The introduction of non-compete clause has become a standard. At one end the corporate has to protect their business competition, while at the other end, the physician has a distinct patient population and need in the community.

The problems with non-compete clause are two-folds. First, the verbiage is very legal and second it favors the company.

As noted very clearly, all items are in favor of the company. Certain clauses contained with these contracts refer to understandable standard business strategies protecting the employers' right to its clients or patients. The physician has no good choice should there not be prospects to stay long term for whatever reason. He/She can't provide any services in the area (medical, consultation, staff), can't own, manage, operate or control, and thus can't open a practice. The two options are: wait for the period of exclusion (1-2 years) or move out of the area of practice.

It is not easy to secure a job right away after losing one. Also, once physically and emotionally invested in a community, it is very difficult to move out, especially when kids are in schools and the housing market is tight.

There has to be a balance between protecting healthcare companies and physician interests. The language of non-compete clause should be structured in such away that protects both parties.

The intention of this letter is to address the issue of non-compete in healthcare employment contract and spark some discussion so that a favorable solution is sought.

Sincerely,

Shabih Manzar, MD

Independent Provider

Alexandria, LA

Email: [shabihman@hotmail.com](mailto:shabihman@hotmail.com)

Dear Dr. Manzar:

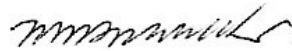
Thank you for your comments. The loss of a job is always challenging. The practice of neonatology is somewhat unique in that within a given geographical area, there may not be a lot of options for employment. Unlike other professions in the medical field, not every hospital has a NICU. Although the non-compete distance may be negotiated, it is often a moot point if the next NICU is over 50 miles away.

The legality of restrictive covenants has been questioned especially in situations where the contract results in a restraint of trade. Depending on the locality, the law varies considerably on this topic. Challenging a contract takes time, financial resources, and considerable patience. Providing for a family, worrying about a house payment, paying for tail insurance and making good on medical school debt are factors that need to be considered before committing to a course of action.

The most consistent advice is to have the contract reviewed by legal counsel prior to agreeing to the terms. Even the best job may not last forever; it is important to know your options and have an exit strategy if things do not work out.

I agree that this is an important topic and invite additional comment from our readers.

Sincerely,



Mitchell Goldstein, MD  
Editor in Chief

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**The National Coalition for Infant Health advocates for:**

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- **Access to RSV preventive treatment** for all premature infants as indicated on the FDA label
- **Clear, science-based nutrition guidelines** for pregnant and breastfeeding mothers
- **Safe, accurate medical devices** and products designed for the special needs of NICU patients

**Erratum (Neonatology Today August, 2018)**

Neonatology Today has not identified any erratum affecting the August, 2018 edition. Corrections can be sent directly to [LomaLindaPublishingCompany@gmail.com](mailto:LomaLindaPublishingCompany@gmail.com). The most recent edition of Neonatology Today including any previously identified erratum may be downloaded from [www.neonatologytoday.net](http://www.neonatologytoday.net).

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New York, NY  
<http://columbiacme.org/>

NANN's 34<sup>th</sup> Annual Conference  
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<http://nann.org/education/annual-meeting>

The Eighth Annual Fetal  
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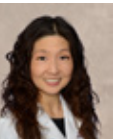
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Stephen Welty, MD - Seattle Children's Hospital

Robert White, MD - Memorial Hospital

T.F. Yeh, MD - John H. Stroger Jr. Hospital of Cook County and  
Taipei Medical University



## Neonatology and the Arts

This section focuses on artistic work which is by those with an interest in Neonatology and Perinatology. The topics may be varied, but preference will be given to those works that focus on topics that are related to the fields of Neonatology, Pediatrics, and Perinatology. Contributions may include drawings, paintings, sketches, and other digital renderings. Photographs and video shorts may also be submitted. In order for the work to be considered, you must have the consent of any person whose photograph appears in the submission.

Works that have been published in another format are eligible for consideration as long as the contributor either owns the copyright or has secured copyright release prior to submission.

Logos and trademarks will usually not qualify for publication.

This month's selection (see the next page) features a bag and mask ventilation system from the 1950's. It is a far cry from the sophisticated T-piece devices that we use today.

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## Manuscript Submission: Instructions to Authors

1. Manuscripts are solicited by members of the Editorial Board or may be submitted by readers or other interested parties. Neonatology Today welcomes the submission of all academic manuscripts including randomized control trials, case reports, guidelines, best practice analysis, QI/QA, conference abstracts, and other important works. All content is subject to peer review.

2. All material should be emailed to [LomaLindaPublishingCompany@gmail.com](mailto:LomaLindaPublishingCompany@gmail.com) in a Microsoft Word, Open Office, or XML format for the textual material and separate files (tif, eps, jpg, gif, ai, psd, or pdf) for each figure. Preferred formats are ai, psd, or pdf. tif and jpg images should have sufficient resolution so as not to have visible pixilation for the intended dimension. In general, if acceptable for publication, submissions will be published within 3 months.

3. There is no charge for submission, publication (regardless of number of graphics and charts), use of color, or length. Published content will be freely available after publication (i.e., open access). There is no charge for your manuscript to be published under open access

4. The title page should contain a brief title and full names of all authors, their professional degrees, their institutional affiliations, and any conflict of interest relevant to the manuscript. The principal author should be identified as the first author. Contact information for the principal author including phone number, fax number, email address, and mailing address should be included.

5. A brief biographical sketch (very short paragraph) of the principal author including current position and academic titles as well as fellowship status in professional societies should be included. A picture of the principal (corresponding) author and supporting authors should be submitted if available.

6. An abstract may be submitted.

7. The main text of the article should be written in formal style using correct English. The length may be up to 5,000 words. Abbreviations which are commonplace in neonatology or in the lay literature may be used.

8. References should be included in standard JAMA format. Bibliography Software should be used to facilitate formatting and to ensure that the correct formatting and abbreviations are used for references.

9. Figures should be submitted separately as individual separate electronic files. Numbered figure captions should be included in the main file after the references. Captions should be brief.

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