

# NEONATOLOGY TODAY

News and Information for BC/BE Neonatologists and Perinatologists

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### UPCOMING MEDICAL MEETINGS

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**8<sup>th</sup> International Neonatal Nursing Conference 2013 - COINN 2013**  
Valvular & Congenital Interventions  
September 5-8, 2013; Belfast, Northern Ireland  
[www.coinn2013.com](http://www.coinn2013.com)

**Cell Technologies in Obstetrics, Gynecology, Neonatology and Pediatric Neurology**  
October 7, 2013; Kiev, Ukraine  
<http://cellconference.info/?lang=eng>

**24<sup>th</sup> Annual Neonatal Nurse Practitioner Symposium Critical Update and Review**  
October 15-19, 2013; Clearwater Beach, FL USA  
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## NEONATOLOGY TODAY

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## Safety and Quality: Are They Compatible?

By Mitchell Goldstein, MD and T. Allen Merritt, MD, MHA

Safety and quality are words that are often used interchangeably. Safety is a well-defined condition that incorporates a physical sense of well-being in addition to a feeling of being free of threat. Quality, on the other hand, is somewhat harder to define. Is it sufficient to say that the feeling of safety is a quality-based condition? Does quality require an evidence-based conclusion? In certain Third World countries, safety is only relative, and quality is not a term that is in common parlance. Within the field of Neonatology (Neonatal/Perinatal Medicine), we have always had to adapt to newer technologies that were not designed with evidence-based research on neonates, and use medications that never received a specific FDA indication for our fragile patients. The Electronic Medical Record (EMR) and Computerized Physician Order Entry (CPOE) have been touted as the panacea for decreasing medication errors. But does this actually apply to our patients? Increasingly, and with special reference to the field of neonatology, quality and safety are neither synonymous nor sequentially related.

### In the Beginning...

Over the centuries, large families ensured continuity. High infant morbidity and mortality was expected. Having a large number of children ensured that there would be enough hands to tend the livestock, as well as harvest the crops, and that the parents would have someone to take care of them when they were older. Safety and quality were clearly lacking. Sheer numbers (quantity of births) were used to overwhelm the odds imposed by infection, war, famine and im-

*“Safety is a well-defined condition that incorporates a physical sense of well-being in addition to a feeling of being free of threat. Quality, on the other hand, is somewhat harder to define. Is it sufficient to say that the feeling of safety is a quality-based condition?”*

precise medical intervention. For that matter, infant health intervention was neither a priority, nor achievable. The saying, “Don’t throw the baby out with the bath water,” derived from this period. The weekly bath was a communal affair with the adults and older children bathing first, and the infants bathing last. Notwithstanding, the infectious risk, a newborn being discarded with the murky bacteria infested sewage that served as bath water was a very real possibility.

After the first reference to Cesarean Section (715-673 BCE), it was not until the 1400’s that it was recognized that newborns have a soul. Neonatal endotracheal intubation was first documented in 1834. Gavage feeding was developed by 1850, and oxygen delivery to premature babies was “perfected” before the turn of the 20th century. Public interest in these technological marvels was high. PT Barnum and Martin Couney were among the first entrepreneurs with public displays of small babies. By keeping the

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babies warm and isolated from the public behind glass viewing walls, very small babies could be kept alive for long periods of time. These displays introduced the world of “neonatology” to the masses. In contrast, other less fortunate babies were sent home with instructions to feed by eye-dropper and keep warm by the hearth.<sup>1,2</sup>

By the turn of the 20th century, real technological advances were taking place. Alexander Graham Bell developed a negative pressure ventilator in the 1880’s. In 1898, Martin Conney demonstrated the feasibility of a large scale infant care enclosure (the first NICU), albeit in a circus environment. Continuous distending pressure was first attempted in 1912. In 1922, the first transport incubator was developed. In 1938, Dr. Gross performed the first ligation of a Patent Ductus Arteriosus. And, in 1960, the term “Neonatologist” was used for the first time. But, these efforts were isolated; there was no concerted national effort to improve neonatal care. What changed?<sup>1-4</sup>

### A Renaissance?

Patrick Bouvier Kennedy was born on August 7, 1963. By today’s standard, he was a late preterm baby, and would have had a greater than 99% chance of survival. In the early 1960’s, there was very little that could be done for premature infants with severe Respiratory Distress Syndrome (or even modestly severe RDS). President Kennedy boldly announced that the United States of America was to put a man on the moon before the end of the decade, yet medical technology and our understanding of neonatal physiology even with treatments such as “hyperbaric” oxygen could not save the President’s son.<sup>5</sup> The death of this infant galvanized a nation into action and provided the impetus for the establishment of what was then called the National Institute of Child Health and Human Development. Many charities including the March of Dimes refocused their efforts to place premature infants and birth defects at higher priority than in the past. The world’s basic scientists and academicians focused on infants and children invigorated research and teaching programs related premature births.

From that point onward, Neonatology advanced dramatically as a field of medicine. Neonatologists aggressively intervened for babies born prematurely, first at 32 weeks, then 28 weeks, then 25 weeks, and finally, 23 weeks and beyond. Indeed, neonatologists confronted every obstacle with innova-

tion, but often confused this misguided progress as quality. Guided by learned pioneers such as William Silverman, MD, mistakes were acknowledged along the way.<sup>6</sup>

A certain number of babies were bound to become blind from Retrolental Fibroplasia (RLF) or Retinopathy of Prematurity (ROP). Bronchopulmonary Dysplasia was a better alternative than certain death from Respiratory Distress Syndrome. Necrotizing enterocolitis had certain known causes, but a background rate was not avoidable. Nosocomial infection could be reduced by strict attention to hand-washing, and making sure that appropriate sterilization procedures were followed, but prevention of all of the circumstances that caused these problems was largely a problem with the logistics of taking care of an increasingly small and preterm population. As neonatologists, we trusted these aphorisms. The results were what they were. We tried our best – a euphemism for the “heroic” approach to patient care. A systems-based approach was not practical; it had not been invented. We could not use an evidence-based approach either; the evidence did not exist. This was an age of exuberance – No fetus could beat us. We were trying to find safety by trying everything we could with the newer technologies. Quality was clearly not present. Randomized control trials – we did not even know where to begin. The control group was a moving target. For the time, “knowing” the physiology was adequate, we presumed that our incomplete knowledge was somehow perfect. Worse still, we did not know the questions to ask. Medical error was inevitable.<sup>7,8</sup>

### Shades of Gray

We were dealing with a number of paradoxes. Neonates were by definition young. There was a lifelong potential for morbidity. There were increasingly large numbers of patients who we could care for as the limits of viability were continually forced downward, but resources were still not universally available. To most hospital systems, neonates were still a small focus. New NICU’s sprouted up in the fathers’ waiting rooms, supply areas, and closets across the country. The acuity was high, the remuneration was uncertain, and the technology needed to provide the care was still being developed. The small size of the patients precluded the use of certain larger pieces of equipment that were predominantly designed for larger children or adults. “Small” tolerances or acceptable errors that were permissible for larger patients

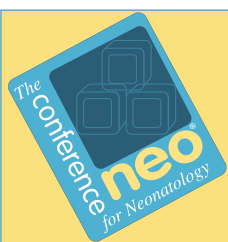
often exceeded the intended dose or volume for the neonate. As we improved our technology and developed standards, we needed to develop methods to deal with error.<sup>9-12</sup>

The traditional response to error or breaches in protocol has been to identify the responsible party and find an appropriate punishment. This model produces a new series of rules that add additional checks and balances to the system to prevent future errors. It is the framework of evidence-based medicine but is based on an exaggerated response to anecdotal missteps and does not address all potential causes of error. Indeed, the new rules created may be a source of additional error or produce circumstances that produce worse outcomes. Fear of discipline can produce errors in and of itself. Although errors are reduced, the potential for their occurrence remains.

Statistical Process Control (SPC) is a strategy that was introduced to achieve quality control in manufacturing processes. This system was originally introduced to American industry during the Second World War to improve aircraft quality during mass production. It was subsequently introduced to post-war Japan, and permitted companies like Toyota and others to outperform their international competition.

Basically, any manufacturing process is subject to seemingly random variations, which are said to have common causes; and non-random variations, which are said to have special causes. Management can usually determine special causes of manufacturing defects by consulting the workforce, but dealing with common causes is a management responsibility. Japanese manufacturers applied these techniques widely, and experienced new international demand for their products. A derivative strategy is Total Quality Management (TQM) and has been specifically tailored for the healthcare industry. Systems of care are evaluated for process issues that contribute to error. These steps include:

1. 改善 or Kaizen (constant good change), which focuses on Continuous Process Improvement (CPI) to make the process visible, repeatable, and measurable;
2. 当たり前品質 or Atarimae Hinshitsu (things are supposed to work the way they are designed) which emphasizes certain intangible effects on processes and ways to optimize and reduce their effects;



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3. 感性 or Kansei (a sensitivity or understanding), which examines the way the user applies the product, leading to improvement in the product itself;
4. 魅力的品質 or Miryokuteki Hinshitsu (things should have an aesthetic quality) broadens management concern beyond the immediate product.<sup>13,14</sup>

The important point here was to recognize the strength of a team working towards a common goal with the elimination of the usual barriers that interfere with processes designed to produce rapid improvements in quality while minimizing risk (i.e., producing safe outcomes). These efforts were based on Deming's Principles, shown in Table 1.<sup>13,15-17</sup>

**Table 1: Deming's Principles**

- |   |   |
|---|---|
| • Constancy of purpose.   | • Eliminate slogans, exhortations and targets.                      |
| • Take the lead in adopting the new philosophy.                             | • Eliminate management by the numbers, and management by objective. |
| • Cease dependence on inspection to achieve quality.                        | • Substitute leadership.  |
| • End the practice of awarding business on the basis of the cheapest costs. | • Remove barriers to pride in workmanship.                          |
| • Improve constantly.   | • Institute education and self-improvement.                         |
| • Institute training on the job.  | • Put everybody to work to accomplish the transformation.           |
| • Institute leadership.   |   |
| • Drive out fear.   |   |
| • Break down barriers between departments.                                  |   |

It is not hard to identify a common driving theme in these principles. Specifically, the goal is to eliminate provincial thinking and re-orient objectives towards a team-based approach. Although the language is from industry, it is clear that many of these objectives are related to our objectives in providing quality care. The elimination of hard targets, instead focusing on process, quality and continued improvement are embodied in our quality improvement, quality assurance, and team management processes. The elimination of hierarchical obstacles to reporting, care improvement, and the need for physician, nurse, therapist, and other care providers to work together towards a common goal of improving care are embodied in these principles.

Importantly, errors, whether they are unintentional or symptomatic of the process, can be avoided by identifying problematic systems and simply avoiding these systems. Vitamin K anaphylaxis associated with rapid intravenous administration can be avoided by not administering Vitamin K intravenously. There is the supposition that other methods of administration are equally effective. As long as there is a uniformly accepted effective alternative means of administration, error can be reduced.<sup>16,18,19</sup>

The cost-benefit analysis is a common favorite of purchasing departments. In a nutshell, this is the process of whether the total expected costs of an intervention are considered justified versus the total expected benefits. There is a monetary calculation of the initial expense versus the expected return. Monetary values may be assigned to less tangible effects such as risk, loss of reputation, market penetration, long-term strategy alignment, or in the case of the medical industry,

malpractice risk. Purchasing departments of hospitals have assumed a large amount of this risk.

Most physicians are separated from the actual purchasing of durable goods in the hospital. To some extent, this makes sense. If there are two equivalent suppliers of gauze, and there is no qualitative or quantitative difference between the two suppliers, the lower cost solution should be selected as the hospital supplier. These decisions are not always so simple. Suppose the choice is between two different pulse oximeters. Competitive purchasing principles dictate that there is no difference between measuring oxygen saturations between products. From the vantage point of a purchasing department, these are widgets. Moreover a purchasing department will often have certain financial incentives to prefer the widgets of a particular supplier over the widgets of another supplier. In some cases, achieving a certain percentage of purchases from a particular supplier can trigger a federally-sanctioned kickback that can reduce the total cost of care, at least in the short term.<sup>20,21</sup>

As we know, especially in the neonatal space, pulse oximeters, ventilators, and cardiac monitors may be durable medical equipment, but they are not mere "widgets." Value-based assessments of equipment that provides and may produce different clinical results should not be in the purvey of the hospital purchasing department. Often, the alternative equipment provides modes for adult and older pediatric patients but not neonates. In some cases, the alternative equipment can provide numbers or trends, but these results have not been validated. In other cases, the results are simply wrong or cannot be obtained. What effect does this have on long-term morbidity and mortality? As we learn from Deming's principles, awarding business based on low-cost is to be avoided.<sup>13</sup>

Ideally, this valuation process should nominally achieve a Pareto Optimization. Moving from one alternative allocation to another allocation without leaving individuals worse off produces this Pareto Optimization. Successive Pareto Optimizations can produce a situation that is better for everyone. However, a Kaldor-Hicks efficiency can leave some worse off. By way of this theory, an outcome is more efficient if those that are made better off could compensate those that are made worse off, leading to a Pareto optimal outcome (i.e., no one worse off). There are huge aggregation problems associated with disparity issues and the marginal valuation of a preemie. These issues are readily apparent in situations involving critical shortages of certain pharmaceuticals. Although there are a large number of premature babies born every year, not every baby requires Total Parenteral Nutrition (TPN). As a result, the market for the components that make up a neonatal TPN is comparably small. A number of varied trace elements and electrolyte solutions have to be individualized for each baby. Shortages occur when the pharmaceutical contracts are stripped to the bone by competitive marketing mandated by Group Purchasing Organizations that produce savings on the hospital side, but ultimately endanger the continued manufacture and supply of these vital components. These shortages, essentially error by design, create dilemmas with obvious solutions, but no practical way of achieving them. FDA interventions, although sometimes with cause, produce additional delay by not providing a mechanism for expedited approvals and retooling of factories to produce the components that are in short supply. Yes, quality is maintained, but the process is not safe.<sup>20,21</sup>

Our Food and Drug Administration (FDA) has long been the defender of American public quality. On the walls of the organization's main facility at 5600 Fishers Lane in Rockville, MD, the Thalidomide tragedy of the 1950's - 1960's is detailed and the diligence of Dr.



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Francis Kinsey is honored. While there were many women who were prescribed this compound worldwide, the teratogenic effects of this medication were mitigated here in the United States because of the FDA process of requiring certain studies from the manufacturer before approving the drug for use in pregnant women. This instance was perhaps the FDA's finest hour. The quality measures that had been put in place worked. Thalidomide was never approved. Thousands of babies were protected from the devastating limb altering effects (phocomelia) of the drug. Safety was maintained.<sup>22-24</sup>

### Back to the Dark Ages?

Compare this to the present day; the FDA continues to require certain quality measures from manufacturers. The results of a randomized control study must meet a criteria of  $p < 0.01$  as opposed to  $p < 0.05$ , which is used for most power analyses prior to initiating research and accepted by most major journals as a demonstration of probable effect. The FDA further adjudicates research by rejecting studies where the results were not obtained exclusively here in the United States, and will often recalculate "p" by including patients who were excluded for meeting pre-defined criteria. Only the results of randomized control trials can be considered according to the current metrics. What happens if equipoise cannot be maintained? Can we really justify not giving surfactant to a baby in order to demonstrate the clinical efficiency of a newer perhaps more efficacious surfactant? Can we limp on without FDA approval for a lifesaving medication that reduces cholestasis because the trial to demonstrate efficacy would mean that babies would have to die?<sup>25,26</sup> In its defense, the FDA explains that there is a mechanism for compassionate use of a medication, even without FDA approval. Patients can travel to other states that may have a center with a clinical trial with that medication or travel to other countries where the medication is approved because it is against FDA regulations to import a non-approved medication to the United States or transport it across state lines. Moreover, because these medications are considered experimental as they do not have FDA approval, most insurers and state Medicaid organizations will not pay for them or make arrangements for patients to have access to them. Again, the quality is maintained. This is "beautiful science, but bad medicine."<sup>27-29</sup>

We can be our own worst enemies. Everyone likes a discount and has a good idea of what something "should" cost. In fact, it is regarded as a form of quality control to have an appropriate price performance ratio. Because of FDA rules requiring license and approval of certain manufacturing processes, even if the process is "off-patent," our pharmaceuticals cost more than the comparable product purchased from any of a number of the other first world manufacturers of pharmaceuticals. Often times, the strength of the US market and the broad need for a particular drug bolsters the demand to the point that it becomes financially feasible to supply the drug to the masses. Unfortunately, especially with a drug that is "off patent" (without patent protection), this does not always apply to neonates. When a certain manufacturer sold its manufacturing process for a particular off-patent medication, and then retooled the plant where the medication was made, this led to widespread shortage of the medication. The total US market for the medication was probably less than five kilograms. When the new manufacturer announced pricing of the product that was in line with its production, FDA recertification, research, development, and licensing costs, but many times the cost for the product supplied by the original manufacturer, neonatologists were outraged. A paper in *Pediatrics* compared the cost of the medication to products available in other countries. Politicians quickly rallied to the cause. A number of lawsuits were filled. The company



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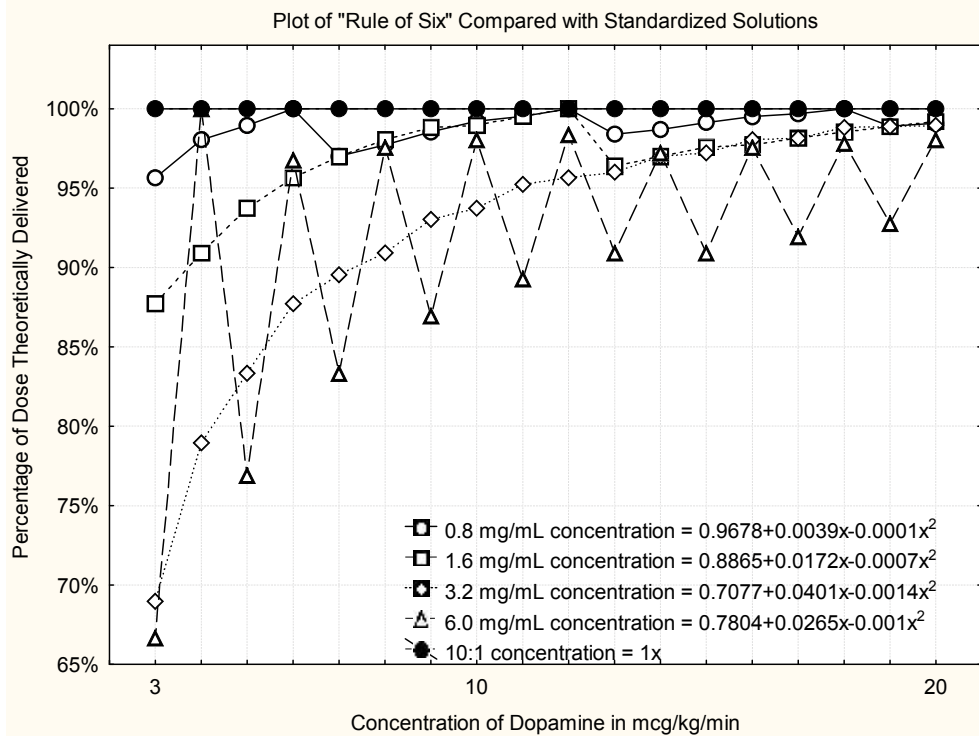
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no longer exists. What incentives do pharmaceutical manufacturers have to produce medications for neonates? Orphan drug laws and incentives cannot cover all situations. Whether these are time-trusted medications like Ampicillin or Indomethacin, trace elements for Total Parenteral Nutrition (TPN), or novel pharmaceuticals such as Palivizumab, at some point, if the financial incentives are removed, there will be no further distribution, no further development, and no practical way of caring for our most fragile patients safely.<sup>30</sup>


Proprietary Information Systems (IS) along with Computer Physician Order Entry (CPOE) are part of the new healthcare reform. As we struggle to find meaningful use, there are a number of quality measures that enhance care. The elimination of non-standard abbreviations, reconciliation of medications and doses, and fingertip drug monographs should generate improved outcomes. With respect to neonates, there are a number of processes that need refinement. First, most of these systems are adult-centric. This means that weights are reported in kilograms instead of grams. Early versions of one IS program insisted on rounding all of its entries to either 1 kilogram or 0 kilograms for the extremely low birth weight baby that was born under 500

grams. Although 0.004 kg and 4 grams refer to the same quantity, the fact that all neonatal weights are significant to three digits after the decimal point invites errors in rounding and dose calculation. Although there is a national incentive to eliminate leading and trailing zeros, standardization on a kg based weight system perpetuates this issue. These systems are largely designed along an adult analogy. Neonatal models of care must often be "hand crafted" or adapted from existing adult models. Alarms and alerts may not be changeable. Subjective sections based on patient response are propagated to neonatal data collection. Neonates do not have an aggregate smoking history and do not speak any language, let alone English. However, one of the most vexing and annoying problems with these systems is that they impose adult validated quality measures and calculations and ignore existing technology that has been shown to produce safe outcomes. Legacy programs that have been developed over years of research and perfected for neonates suddenly are no longer part of the greater CPOE solution. In the name of quality, these tools must be adapted to the point that they lose all or part of their usefulness or are discarded entirely in favor of unproven solutions.<sup>31-34</sup>

With neonates, this supposition of safety further breaks down with the imposition of standardized solutions. Widely praised as a way of improving care by eliminating the need to calculate and prepare a unique solution for every patient, several standardized concentrations are prepared for every medication that will be administered as an infusion. One can no longer look at the pump rate per hour and know the intended dose. Instead, the pump provides a numerical output which identifies the patient, the drug, and the intended dose.

On the surface, this appears to be an improvement; and for adult and larger pediatric patients, it may well be. Using the so called "rule" of six, which was developed because of its ability to safely deliver a known drip concentration in a 10 to 1 ratio, different solutions were calibrated for the individual weight. Whether the baby was 500 grams or 4000 grams, 0.5 mL/hr on the pump meant that the baby was receiving 5 mcg/kg/min of Dopamine. In the adult world, there were some advocates of a system similar to this, but there was a more concentrated effort to create "standardized" solutions. In this manner, the pharmacist would only have to create a certain number of solutions for the hospital. The CPOE system would "pre-select" the solution based on the situation and a "smart pump" would be programmed with the bar code information and the dose would be delivered.

Early models created standardized solutions that would exceed the total daily fluid for some of the smallest neonates. This led to the creation of more "appropriate" solutions that could deliver the medication using smaller volumes. But does this really work with the existing "smart pumps?" Shown above left is a model of what happens with different standardized concentrations of dopamine or another inotrope that might be used with neonates. In this case, the doses have been calculated using a standardized formula applied to a 500 gram infant. Be aware that the lower concentrations, although more accurate, produce "solutions" where more than half of the daily fluids are given in an inotropic drip solution. The top line represents the 10:1 solution, the traditional standard. At every intended infusion rate, there is an exact correspondence to the dose. The same cannot be true with the quality based "standardized" solution. At lower doses, the most CPOE appropriate concentration is up to 35% off the desired dose. Worse still, dosing error is irregularly saw-toothed as the infusion amount



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increases. Rounding issues inherent in numbers beyond the capable range of the smart pump make it improbable that the correct dose will ever be delivered within less than a 5% error.<sup>35-37</sup>

Infant based quality systems cannot ignore the physiological difference between infants and adults. Although many adults may be big babies, babies are not little adults. This underscores the very real fact that a number of adult interventions are not weight-based. A Lasix 40 mg dose is considered appropriate for a 72 kg COPD patient as well as a 40 Kg patient with congestive heart failure. On the surface, it seems strange that a 32 kg weight difference would not be considered substantial enough to justify individualized dosing. After all, 32 kg is 5 times the weight of our largest patients. Relatively speaking, the 72 kg patient is not even twice the weight of the 40 kg patient. In the neonatal world, there is a 10 fold difference in weight between the 23 week 500 gram preemie and the 5000 gram term infant of a diabetic mother. The same metrics do not apply. The pharmacokinetics of many drugs are different. Whole body water composition is higher, surface area in proportion to weight is greater, and distribution volumes are less predictable. Neonates may as well be a different species.<sup>19,33,34,38</sup>

Safety has a different perspective in the adult world. Certainly, adult patients outnumber neonates and hospital-based solutions designed to improved quality and safety should perform according to specifications, but the issues that affect our small babies are as important as those that affect the adult patients. Quality must represent a process that produces an outcome that is likely to be viewed as desirable and not an outcome that conforms to a specific metric or idealized result. Percent compliance to order entry via CPOE, systems that are designed to protect consumers but instead produce lengthy delays in the availability of a potentially useful drug or product, and Kaldor-Hicks efficiencies that produce systems where neonates are clearly worse off do not represent improvements in the quality of care. In the search for refinement, "quality has been bastardized into something that it is not".<sup>39</sup> In the search for this new quality, we have commoditized people and created inefficiencies that stifle both the science and art of medicine. We have abandoned safety.

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- Optionally, a picture of the author(s) may be submitted.
- No abstract should be submitted.
- The main text of the article should be written in informal style using correct English. The final manuscript may be between 400-4,000 words, and contain pictures, graphs, charts and tables. Accepted manuscripts will be published within 1-3 months of receipt. Abbreviations which are commonplace in pediatric cardiology or in the lay literature may be used.
- Comprehensive references are not required. We recommend that you provide only the most important and relevant references using the standard format.
- Figures should be submitted separately as individual separate electronic files. Numbered figure captions should be included in the main Word file after the references. Captions should be brief.
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INOMAX® is a vasodilator, which, in conjunction with ventilatory support and other appropriate agents, is indicated for the treatment of term and near-term (>34 weeks) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension, where it improves oxygenation and reduces the need for extracorporeal membrane oxygenation.

Utilize additional therapies to maximize oxygen delivery with validated ventilation systems.

**Reference:** 1. Data on file. Hampton, NJ: Ikaria, Inc; 2013.

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## **INOMAX Important Safety Information**

- INOMAX is contraindicated in the treatment of neonates known to be dependent on right-to-left shunting of blood
- Abrupt discontinuation of INOMAX may lead to increasing pulmonary artery pressure and worsening oxygenation even in neonates with no apparent response to nitric oxide for inhalation

**Please see Brief Summary of Prescribing Information on adjacent page.**

# INOmax Total Care™

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# INOmax (nitric oxide gas)

## Brief Summary of Prescribing Information

### INDICATIONS AND USAGE

#### Treatment of Hypoxic Respiratory Failure

INOmax<sup>®</sup> is a vasodilator, which, in conjunction with ventilatory support and other appropriate agents, is indicated for the treatment of term and near-term (>34 weeks) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension, where it improves oxygenation and reduces the need for extracorporeal membrane oxygenation.

Utilize additional therapies to maximize oxygen delivery with validated ventilation systems. In patients with collapsed alveoli, additional therapies might include surfactant and high-frequency oscillatory ventilation.

The safety and effectiveness of INOmax have been established in a population receiving other therapies for hypoxic respiratory failure, including vasodilators, intravenous fluids, bicarbonate therapy, and mechanical ventilation. Different dose regimens for nitric oxide were used in the clinical studies.

Monitor for PaO<sub>2</sub>, methemoglobin, and inspired NO<sub>2</sub> during INOmax administration.

### CONTRAINDICATIONS

INOmax is contraindicated in the treatment of neonates known to be dependent on right-to-left shunting of blood.

### WARNINGS AND PRECAUTIONS

#### Rebound Pulmonary Hypertension Syndrome following Abrupt Discontinuation

Wean from INOmax. Abrupt discontinuation of INOmax may lead to worsening oxygenation and increasing pulmonary artery pressure, i.e., Rebound Pulmonary Hypertension Syndrome. Signs and symptoms of Rebound Pulmonary Hypertension Syndrome include hypoxemia, systemic hypotension, bradycardia, and decreased cardiac output. If Rebound Pulmonary Hypertension occurs, reinstate INOmax therapy immediately.

#### Hypoxemia from Methemoglobinemia

Nitric oxide combines with hemoglobin to form methemoglobin, which does not transport oxygen. Methemoglobin levels increase with the dose of INOmax; it can take 8 hours or more before steady-state methemoglobin levels are attained. Monitor methemoglobin and adjust the dose of INOmax to optimize oxygenation.

If methemoglobin levels do not resolve with decrease in dose or discontinuation of INOmax, additional therapy may be warranted to treat methemoglobinemia.

#### Airway Injury from Nitrogen Dioxide

Nitrogen dioxide (NO<sub>2</sub>) forms in gas mixtures containing NO and O<sub>2</sub>. Nitrogen dioxide may cause airway inflammation and damage to lung tissues. If the concentration of NO<sub>2</sub> in the breathing circuit exceeds 0.5 ppm, decrease the dose of INOmax.

If there is an unexpected change in NO<sub>2</sub> concentration, when measured in the breathing circuit, then the delivery system should be assessed in accordance with the Nitric Oxide Delivery System O&M Manual troubleshooting section, and the NO<sub>2</sub> analyzer should be recalibrated. The dose of INOmax and/or FiO<sub>2</sub> should be adjusted as appropriate.

#### Heart Failure

Patients with left ventricular dysfunction treated with INOmax may experience pulmonary edema, increased pulmonary capillary wedge pressure, worsening of left ventricular dysfunction, systemic hypotension, bradycardia and cardiac arrest. Discontinue INOmax while providing symptomatic care.

### ADVERSE REACTIONS

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The adverse reaction information from the clinical studies does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates.

Controlled studies have included 325 patients on INOmax doses of 5 to 80 ppm and 251 patients on placebo. Total mortality in the pooled trials was 11% on placebo and 9% on INOmax, a result adequate to exclude INOmax mortality being more than 40% worse than placebo.

In both the NINOS and CINRGI studies, the duration of hospitalization was similar in INOmax and placebo-treated groups.

From all controlled studies, at least 6 months of follow-up is available for 278 patients who received INOmax and 212 patients who received placebo. Among these patients, there was no evidence of an adverse effect of treatment on the need for rehospitalization, special medical services, pulmonary disease, or neurological sequelae.

In the NINOS study, treatment groups were similar with respect to the incidence and severity of intracranial hemorrhage, Grade IV hemorrhage, periventricular leukomalacia, cerebral infarction, seizures requiring anticonvulsant therapy, pulmonary hemorrhage, or gastrointestinal hemorrhage.

In CINRGI, the only adverse reaction (>2% higher incidence on INOmax than on placebo) was hypotension (14% vs. 11%).

Based upon post-marketing experience, accidental exposure to nitric oxide for inhalation in hospital staff has been associated with chest discomfort, dizziness, dry throat, dyspnea, and headache.

### OVERDOSAGE

Overdosage with INOmax will be manifest by elevations in methemoglobin and pulmonary toxicities associated with inspired NO<sub>2</sub>. Elevated NO<sub>2</sub> may cause acute lung injury. Elevations in methemoglobin reduce the oxygen delivery capacity of the circulation. In clinical studies, NO<sub>2</sub> levels >3 ppm or methemoglobin levels >7% were treated by reducing the dose of, or discontinuing, INOmax.

Methemoglobinemia that does not resolve after reduction or discontinuation of therapy can be treated with intravenous vitamin C, intravenous methylene blue, or blood transfusion, based upon the clinical situation.

### DRUG INTERACTIONS

No formal drug-interaction studies have been performed, and a clinically significant interaction with other medications used in the treatment of hypoxic respiratory failure cannot be excluded based on the available data. INOmax has been administered with dopamine, dobutamine, steroids, surfactant, and high-frequency ventilation. Although there are no study data to evaluate the possibility, nitric oxide donor compounds, including sodium nitroprusside and nitroglycerin, may have an additive effect with INOmax on the risk of developing methemoglobinemia. An association between prilocaine and an increased risk of methemoglobinemia, particularly in infants, has specifically been described in a literature case report. This risk is present whether the drugs are administered as oral, parenteral, or topical formulations.

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# Neonates with PDA and the Coding Capture

By Julie-Leah J. Harding, CPC, RMC, PCA, CCP, SCP-ED, CDIS

Patent Ductus Arteriosus, PDA, is a congenital heart defect often found in premature infants who are born well before their due dates.

Fetal blood circulation is different from a baby. As a fetus, the blood is oxygenated by the placenta vs. the lungs. The PDA is a conduit between the aorta and the pulmonary artery. When the baby begins to breathe upon delivery, the PDA should close allowing the blood to flow to its lungs to become oxygenated.

If the PDA remains open there are signs noted fairly quickly: respiratory distress, difficulty eating, poor growth, and/or a murmur is heard.

To report a PDA:

ICD-9 747.0  
ICD-10-CM Q25.0  
SNOMED CT 83330001

What is often not reported is the fact the baby is premature; remember to report the weight and gestation age along with the PDA:

ICD-9-CM 764.0-, Light for dates, Small for dates  
764.9-, Fetal growth retardation (IUGR)  
765.0-, Extreme immaturity of infant  
765.1-, Other preterm infants; *usually implies the birth weight of 1000-2400 grams*

A secondary code is required:

Weeks of gestation  
765.2- from unspecified to less than 24 weeks up to 37 or more weeks completed

The above codes all require a 5<sup>th</sup> digit – refer to your ICD-9 manuals to define the appropriate 5<sup>th</sup> and required digit.

ICD-10-CM P05.0-, Newborn light for gestational age  
P05.1-, Newborn small for gestational age  
P05.9 (no 5<sup>th</sup> digit required) Newborn affected by slow intrauterine growth  
P07.0-, Extremely low birth weight newborn  
P07.1-, Other low birth weight newborn

A secondary code is required:

Weeks of gestation  
P07.2-, Extreme immaturity of newborn (less than 28 completed weeks)  
P07.3-, Other preterm newborn (28 completed weeks or more but less than 37 completed weeks)

Like ICD-9-CM the above codes all require a 5<sup>th</sup> digit – refer to your ICD-10 Tabular List of Diseases and Injuries manuals to define the appropriate 5<sup>th</sup> and required digit. See the following examples:

<b>P05.1</b>	<b>Newborn small for gestational age</b> Newborn small-and-light-for-dates Newborn small for dates
<b>P05.10</b>	<b>Newborn small for gestational age, unspecified weight</b>
<b>P05.11</b>	<b>Newborn small for gestational age, less than 500 g.</b>
<b>P05.12</b>	<b>Newborn small for gestational age, 500-749 g.</b>
<b>P05.13</b>	<b>Newborn small for gestational age, 750-999 g.</b>
<b>P05.14</b>	<b>Newborn small for gestational age, 1000-1249 g.</b>
<b>P05.15</b>	<b>Newborn small for gestational age, 1250-499 g.</b>
<b>P05.16</b>	<b>Newborn small for gestational age, 1500-1749 g.</b>
<b>P05.17</b>	<b>Newborn small for gestational age, 1750-1999 g.</b>
<b>P05.18</b>	<b>Newborn small for gestational age, 2000-2499 g.</b>

<b>P07.0</b>	<b>Extremely low birth weight newborn</b> Newborn birth weight 999 g. or less
<b>P07.00</b>	<b>Extremely low birth weight newborn, unspecified weight</b>
<b>P07.01</b>	<b>Extremely low birth weight newborn, less than 500 g.</b>
<b>P07.02</b>	<b>Extremely low birth weight newborn, 500-749 g.</b>
<b>P07.03</b>	<b>Extremely low birth weight newborn, 750-999 g.</b>
<b>P07.20</b>	<b>Extreme immaturity of newborn, unspecified weeks of gestation</b> Gestational age less than 28 completed weeks NOS
<b>P07.21</b>	<b>Extreme immaturity of newborn, gestation age</b> Extremely immaturity of newborn, gestation age less than 23 wks, 0 days
<b>P07.22</b>	<b>Extreme immaturity of newborn, gestation age</b> Extremely immaturity of newborn, gestation age 23 wks, 0 days through 23 wks, 6 days
<b>P07.23</b>	<b>Extreme immaturity of newborn, gestation age</b> Extremely immaturity of newborn, gestation age 24 wks, 0 days through 24 wks, 6 days
<b>P07.24</b>	<b>Extreme immaturity of newborn, gestation age</b> Extremely immaturity of newborn, gestation age 25 wks, 0 days through 25 wks, 6 days
<b>P07.25</b>	<b>Extreme immaturity of newborn, gestation age</b> Extremely immaturity of newborn, gestation age 26 wks, 0 days through 26 wks, 6 days
<b>P07.26</b>	<b>Extreme immaturity of newborn, gestation age</b> Extremely immaturity of newborn, gestation age 27 wks, 0 days through 27 wks, 6 days

Documentation must be captured specifying the weight and gestational weeks.

Repair to the PDA can often be performed in an open procedure. This is reported with CPT: 33820, Repair of patent ductus arteriosus, by ligation. Sometimes the PDA repair is referred to as a PDA clipping or Ductal collateral ligation. Cardiovascular catheterization procedure is another intervention that can be performed via a coil or device implantation. This is reported with CPTs: 37204 and 75894 modifier 26.

Resource: CMS:

[www.cms.gov/Medicare/Coding/ICD10/2013-ICD-10-CM-and-GEMs.html](http://www.cms.gov/Medicare/Coding/ICD10/2013-ICD-10-CM-and-GEMs.html)

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# Medical News, Products and Information

## Survey of Physicians Suggests Tablets More Useful Than Smartphones

Two June reports from AmericanEHR Partners based on a survey of nearly 1,400 physicians suggests that tablets are of greater use for clinical purposes than smartphones.

“Mobile Usage in the Medical Space 2013” and “Tablet Usage by Physicians 2013” reveal that the most common activity of physicians who use an electronic health record (EHR) and use a smartphone or tablet is “sending and receiving emails.” The second most frequent activity among tablet users is accessing EHRs (51% daily). Just 7% of physicians use their smartphone to access EHRs. Among physicians who have an EHR, 75% use a smartphone and 33% use a tablet, but time spent on tablets is 66% higher than time spent on smartphones.

“These two reports provide useful insights into how physicians use technology to interact with patients, physician satisfaction with mobile devices and apps, and the differences of technology use within various user demographics,” said Thomas Stringham, co-founder of AmericanEHR Partners.

The top market share position is held by Apple®, with 55% of physicians using smartphones and 54% using tablets. Clinical app usage in a medical practice was much higher among smartphone users (51% daily) than tablet users (30% daily). The top five smartphone apps used in a medical practice were: Epocrates®, Medscape®, MedCalc®, Skyscape®, and Doximity®. The top five tablet apps used in a medical practice were: Epocrates®, Medscape®, Up To Date®, MedCalc®, and Skyscape®.

Only 28% of smartphone users and 18% of tablet users were “very satisfied” with the quality of apps for their profession.

“As the adoption of mobile devices increases, so do the expectations of clinical users,” Stringham said. “The health IT sector and app developers have an opportunity to improve the quality and usefulness of clinical mobile apps.”

Additional highlights from the “Mobile Usage in the Medical Space 2013” report include:

- Mobile phone usage by physicians who use an EHR: 77% use a smartphone, 15% use a regular mobile phone, and 8% use neither.
- About 75% of physicians use their smartphone to communicate with other physicians at least once weekly.
- About 70% of physicians use their smartphone to research medications at least once weekly.
- Of the physicians surveyed, about 25% who use a regular phone intend on pur-

chasing a smartphone within the next six months.

Additional highlights from the “Tablet Usage by Physicians 2013” report include:

- About 33% of EHR users and 25% of non-EHR users use a tablet device in their medical practice.
- Smaller practices, defined as three doctors or fewer, are likely to conduct a broader range of activities on their tablet, such as banking, communicating with patients, or taking photos for clinical purposes.
- About 33% of EHR users are very satisfied with their tablet device, while 44% are somewhat satisfied.
- About 33% of EHR users use a tablet to research medications daily.

## It Takes More Than Money: Preventing Maternal and Child Mortality

**Newswise** — The statistics on maternal, newborn, and child mortality around the world are staggering: 265,000 maternal deaths, 880,000 stillbirths, 1.2 million neonatal deaths, and 3.2 million infant and child deaths annually, the vast majority occurring in low-income countries.

Many maternal and child deaths are easily preventable, and the United Nations established eight Millennium Development Goals (MDGs) toward this objective and others among the world’s poorest people. The MDGs set ambitious targets to reduce by two-thirds the mortality rate for children under age five between 1990 and 2015, and to reduce the maternal mortality rate by three-quarters during the same period.

Recent initiatives to reach these goals call for research-based, low-cost interventions that can reduce mortality and morbidity and argue for additional funding to increase access to and coverage of these life-saving interventions. However, funding alone will not close the gap maternal and child mortality rates, wrote Alison M. Buttenheim, PhD, MBA, Assistant Professor, at the University of Pennsylvania School of Nursing in the *Maternal and Child Health Journal*.

“It will take more than funding to reduce maternal and child mortality around the world,” said Dr. Buttenheim. “It will take an understanding of how people make decisions about health-related behaviors.”

Even when high-quality, affordable products and services are available readily, use of them is often low, said Dr. Buttenheim. “Unfortunately, humans rarely behave as rationally as public health planners and providers hope we will. There are fundamental psychological forces that lead us to take actions that

we know contradict our beliefs or our long-term goals, but are hard to resist in the moment. Simple investments in child health, like immunizations or insecticide-impregnated bed nets, are no exception.” These insights into human behavior are drawn from Behavioral Economics—a field at the intersection of Psychology and Economics.

Behavioral Economics asks such questions as, “Which message is likely to be more persuasive: ‘If your child gets this treatment, her chance of surviving increases from 45% to 90%’ or ‘if your child gets this treatment, her chance of survival decreases from 90% to 45%’?”

“Among other things, behavioral economics encourages us to pay attention to how choices are framed,” explained Dr. Buttenheim. “Generally, messages framed as losses are more persuasive than those framed as gains or benefits from taking the same action.”

Recent studies found that messages framed as losses can induce stronger intentions toward such healthy behaviors as vaccinating children and purchasing water treatment systems in areas with poor filtration. “Training community health workers and clinic staff to incorporate loss frames into promotion campaigns for maternal and child health behaviors may boost healthy behaviors and the use of health services more than current approaches,” said Dr. Buttenheim.

“Behavioral economics illuminates the path toward real progress by improving our understanding of how individuals make choices under information and time constraints, and by offering new approaches to make it easier for individuals to do what is in their best interest and harder to do what is not,” she said. “Among poor and rich populations alike, human behavior is the common pathway to achieve health.”

## Children’s National Medical Center Unveils New Pain Medicine Care Complex

Pain is one of the main reasons people – children and adults – seek medical help. And yet, pain, especially in children, is still largely misunderstood. Nationally-recognized experts in pain medicine are for the first time directly applying research to improve clinical care for children using a Distract, Measure, Treat approach that is already showing results.

“Through a cost-effective, continuous loop where evidence drives clinical care, and clinical care drives research, Children’s National is advancing pediatric pain medical research to improve the lives of children and reduce health care costs,” said Julia Finkel, MD, Lead Principal Investigator of the Sheikh Zayed Institute for Pediatric Surgical Innovation and Vice Chief of the Division of Anesthesiology

# NEONATOLOGY TODAY

News and Information for BC/BE Neonatologists and Perinatologists

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## **NEO:** THE CONFERENCE FOR NEONATOLOGY

**FEBRUARY 20-23, 2014**

NEO: The Conference for Neonatology addresses cutting edge, yet practical aspects of newborn medicine. Educational sessions are conducted by many of the foremost experts, who address neonatal-perinatal topics for which they have become renowned.

**Target audience:** All neonatal-perinatal providers, including neonatologists, advanced practitioners and staff nurses.

**Topics include:**

- Getting Stareted on the Right Foot — The Early Care of the Critically Ill Neonate
- Respiratory Support 2014 — What Do You Do, When Do You Do It?
- Neurological Injury in the Neonate
- Nutrition and the Neonate
- The Fetal Patient

SPECIAL INTERACTIVE SESSION: Surviving the NICU — Parents' Perspectives



## **SPECIALTY REVIEW** IN NEONATOLOGY

**FEBRUARY 18-23, 2014**

Specialty Review in Neonatology, the leading review of its type in the country, is an intensive and comprehensive review of neonatal medicine. This course is an invaluable learning experience for those preparing for certifying examinations, as well as new or current fellows-in-training seeking an outstanding fundamental pathophysiology course in neonatal-perinatal medicine.

**Target audience:** Neonatologists, residents, fellows and advanced practitioners.

**Topics include:**

- Maternal-Fetal Medicine
- Neonatal Respiratory System
- Neonatal Cardiovascular System
- Neonatal Endocrinology
- Neonatal Nephrology
- Neonatal Infectious Diseases
- Central Nervous System

and Pain Medicine at Children's National. "Using our unique approach – Distract, Measure, Treat – we can dramatically improve patient outcomes in the short-term while simultaneously driving long-term research to transform how care is delivered to children in the United States and around the world."

According to data collected by Children's National, approximately one in four parents of patients treated at the hospital has to quit their job or reduce working hours to care for a child in pain. Frequently, these patients also are misdiagnosed or treated for another disease, and pain is not acknowledged as a unique diagnosis if not linked to a specific condition. Misdiagnosis, along with uncoordinated, inefficient care and lost work productivity, can drive up the cost of treating pediatric (and adult) pain within the United States' healthcare system.

"Until now, it has been impossible to quantitatively measure and monitor chronic pain in children," said Sarah Rebstock, MD, PhD, Clinical Director of the Pain Medicine Program and a Principal Investigator of the Sheikh Zayed Institute. "Children's National has developed a promising solution to this problem that applies objective measurement to video gaming therapy that is uniquely designed for pediatrics. The data we collect will enable us to optimize care for each individual patient we treat at the Pain Medicine Care Complex, while also evaluating the success of various treatments over time."

Children's National's pain medicine program is the first of its kind to use unique video gaming therapy, holistic therapeutic tools, and digital data collection to enable short and long-term measurement of patient progress. For the first time, physicians can quantitatively measure pain and assess treatment progress in pediatric patients – all within an environment that was specially designed for children and teens. The Complex features the following elements:

- **A Multi-Sensory Room (MSR)** in which a physical therapist uses video gaming therapy that distracts the patient, while simultaneously digitally measuring treatment progress through Kinect technology and a proprietary software application to gather patient data in real-time, which targets and tracks 24 musculoskeletal points in the body.
- **A high-tech, interactive POD bed** designed by renowned interior designer Alberto Frias that serves as a biofeedback environment, including heart rate monitors, soothing lights and music, and tools to monitor a patient's response to therapy and reduce patient anxiety.
- **State-of-the-art teleconference and telemedicine technology** allows the pain medicine experts at Children's National to diagnose and treat patients around the world.

The Pain Medicine Care Complex is part of the Sheikh Zayed Institute. The institute was

made possible by a \$150 million gift from the Government of Abu Dhabi to Children's National Medical Center.

### Mayo Clinic, US and European Researchers Find Heart Disorder Genetic Variants in Stillbirth Cases

**Newswise** — In a first-of-its-kind study, researchers from the US and Europe discovered genetic mutations associated with Long QT Syndrome (LQTS), a genetic abnormality in the heart's electrical system, in a small number of intrauterine fetal deaths, according to a study in the April 10 issue of the *Journal of the American Medical Association*.

Researchers conducted a molecular genetic evaluation (referred to as a postmortem cardiac channel molecular autopsy) in 91 cases of unexplained fetal death (stillbirths) from 2006-2012. They discovered the prevalence of mutations in the three most common LQTS-susceptible genes, KCNQ1, KCNH2 and SCN5A. Two of the most common genes were discovered in three cases (KCNQ1 and KCNH2); and five of the cases exhibited SCN5A rare non-synonymous genetic variants.

Intrauterine fetal death or still birth happens in approximately one out of every 160 pregnancies and accounts for 50% of all perinatal deaths. "We know that the post-mortem evaluation often has not been able to explain these deaths," says Michael J. Ackerman, MD, PhD, pediatric cardiologist at Mayo Clinic and co-study senior author along with Peter J. Schwartz, MD, PhD, of the University of Pavia, Italy. "Those of us who study LQTS and treat LQTS patients have often wondered whether LQTS may be the cause of some of these deaths."

In the study, more than 1,300 ostensibly healthy individuals served as controls. In addition, publicly available exome (the entire portion of the genome consisting of protein-coding sequences) databases were assessed for the general population frequency of identified genetic variances.

"Our preliminary evidence suggests that LQTS may be the cause for approximately 5% of otherwise unexplained stillbirths and points to the need for further large-scale studies," says Dr. Ackerman, Director of Mayo's LQTS Clinic and Windland Smith Rice Cardiovascular Genomics Research Professor. "With LQTS, when we know of its presence, it is a very treatable condition but still more work needs to be done to prevent the family's first tragedy from occurring."

In LQTS, which affects one in 2,000 people, the rapid heartbeats can trigger a sudden fainting spell, seizure, or sudden death. Life-threatening cardiac arrhythmias can occur unexpectedly, mainly during childhood or adolescence. Treatment can involve medication, medical devices, or surgery.

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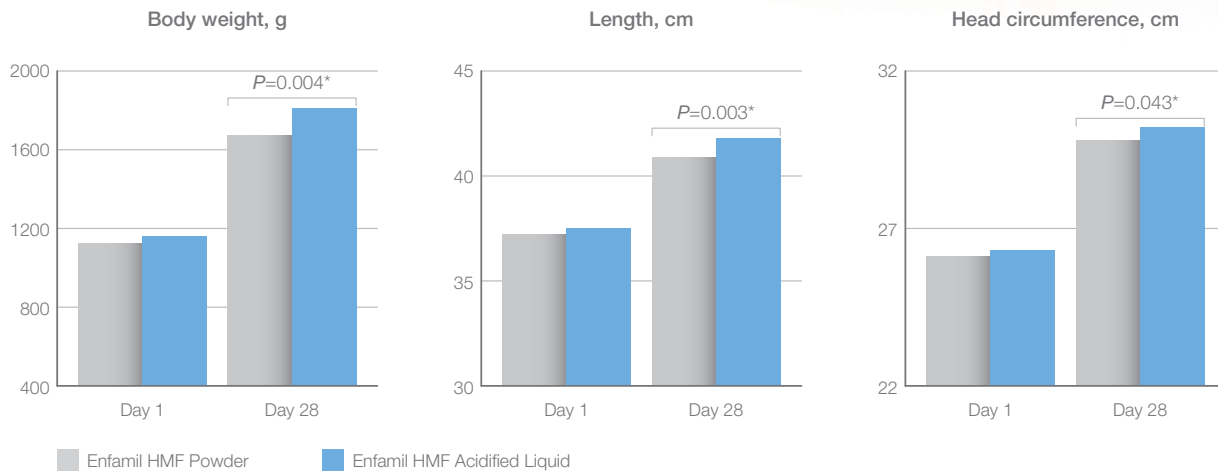
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