neonatal INTENSIVE CARE
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NEONATAL INTENSIVE CARE NEWS

Prolacta Reassures Hospitals of the Safety of Its Human Milk-Based Nutritional Products Amid COVID-19

Prolacta Bioscience, the world's leading hospital provider of 100% human milk-based nutritional products, notified hospital customers of the safety, quality, and continued supply of its human milk-based nutritional products. Prolacta's products are used by neonatal intensive care units (NICUs) throughout the world to address the nutritional crisis of prematurity. "We realize these are uncertain times and there are many questions surrounding the coronavirus. We are providing hospitals with the latest scientific data needed to make informed decisions," said Scott Elster, president and CEO of Prolacta Bioscience. "We also want to reassure these dedicated clinicians that the pandemic will not affect our commitment to supply their premature infants with life-saving nutritional products." The US Centers for Disease Control and Prevention (CDC), the Union of European Neonatal and Perinatal Societies (UENPS), and the European Center for Disease Prevention and Control (ECDC) have all issued statements either that SARS-CoV-2 (coronavirus) does not appear to be present in breastmilk and/or that breastmilk does not appear to be a source of disease transmission. Currently, data from China show an absence of detectable coronavirus in breastmilk. Chen et al. studied lactating mothers with coronavirus. Breastmilk of six of those mothers was tested for the presence of SARS-CoV-2. The virus was not found in any of the milk specimens tested. Kam et al. looked at breastmilk from one mother with coronavirus and this testing also failed to show the presence of the virus. Prolacta exceeds all state and federal regulations for human milk quality and surpasses the quality and safety standards of all currently operating milk banks. All Prolacta products are pasteurized using time and temperature profiles defined by the US Food and Drug Administration (FDA) in its Pasteurized Milk Ordinance (PMO) to ensure destruction of pathogens. Prolacta's pasteurization process has been independently validated using the same robust pathogen inactivation studies used in the biologics industry. This validation

Infants Born to Mothers With COVID-19 Appear Healthy

Infants born to mothers with COVID-19 appeared to be healthy with no clinical evidence of COVID-19, according to a case series from Wuhan, China. This early in the COVID-19 pandemic, little is known regarding infant and childhood infections and their clinical picture. Writing in Frontiers in Pediatrics, Dr Yalan Liu and colleagues from Tongji Medical College, Huang zhong University of Science and Technology in Wuhan describe the clinical course of four full-term infants born to pregnant women with COVID-19 infection during the third trimester. Three infants were born by cesarean section due to concerns about symptomatic maternal infection; the fourth was born by vaginal delivery. All infants were isolated from their mothers immediately after birth. All had 1-minute Apgar scores of 7-8 and 5-minute Apgar scores of 8-9. Three infants tested negative for COVID-19 in throat swab specimens by RT-PCR 72 hours after birth; the fourth infant's parents declined testing. Two infants were healthy and clinically normal, and two had transient rashes that resolved spontaneously. One infant developed transient tachypnea of the newborn requiring nasal continuous positive airway pressure, but his breathing became regular within three days. He was taking full formula on day 5 and was discharged from the neonatal intensive care unit on day 7. All four babies were doing well and receiving formula feeding at last follow-up. These findings, along with an earlier report, appear to indicate that vertical transmission of COVID-19, if it occurs, is rare.

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demonstrates that Prolacta's pasteurization provides appropriate bacterial killing and viral inactivation including enveloped viruses. Coronavirus is an enveloped virus. Studies of other epidemic coronaviruses, such as the virus responsible for the 2003 SARS epidemic and the virus responsible for the 2012 MERS outbreak, demonstrate that pasteurization is highly effective in inactivating these viruses. These studies were done in diverse carrier media such as plasma products and various animal milks in which the virus was found during epidemic infection. Only human milk products manufactured with the FDA-defined pasteurization process, such as Prolacta's, are clinically proven to be safe and improve health in the NICU. No published clinical data show similar results using human milk products treated by any other method. Prolacta operates the first and only pharmaceutical-grade manufacturing facilities for the testing and processing of human milk. Its two facilities have standard ISO-7 and ISO-8 cleanrooms totaling nearly 21,100 square feet. Prolacta modeled its stringent quality and safety protocols on those used in the plasma and blood industries. Prolacta has developed, validated, and implemented 19 donor milk screening tests to ensure the safety of its human milk-based nutritional products. Prolacta also has implemented the world's first nucleic acid amplification test (NAAT) capable of directly detecting the presence of infectious disease-causing pathogens and bacteria in donated breastmilk. Since 2018, all donor milk received by Prolacta has been tested using NAAT. "All Prolacta products, including pasteurized and nutrient-standardized donor milk, are manufactured in the same manner and undergo the same quality and safety protocols," said Elster. "We are maintaining a full inventory of finished product, as well as raw materials, and have multiple shipping partners to ensure deliveries continue as planned. Our team remains available to handle orders and any issues that arise."

Two NICU Items to Remember

To keep an eye on NICU visitor temperature readings, NOVAMED USA provides an easy answer with ACCUTHERM Forehead Liquid Crystal Temperature Indicators. Simply adhere to the forehead and within 15 seconds, core body temperature is indicated. Safe for even the most sensitive skin and can be worn up to 48 hours. Not made of natural rubber latex. Offered 100 pcs/ box for $95. www.novamed-usa.com For further inquiries: Email info@novamed-usa.com. Avoid NICU out-of-stock scenarios with NEOTEMP Skin Temperature Sensors from NOVAMED USA. This reliable USA manufacturer/distributor offers a complete range of sensors to match GE/Ohmeda, Draeger/AirShields, ATOM Medical and International Biomedical incubators and radiant warmers. Call upon their neonatal specialists to assist in matching your specific requirements. For further inquiries: Email neonatal@novamed-usa.com or visit www.novamed-usa.com.

St Luke's University Health Network One of the First in the World to Pilot Masimo SafetyNet

Masimo announced that St Luke's University Health Network (SLUHN) is one of the first institutions worldwide to use Masimo SafetyNet to monitor in-hospital patients, as the network seeks innovative solutions to care for the surge of patients infected by COVID-19. Masimo SafetyNet is an innovative, economically scalable cloud-based patient management platform designed to help clinicians care for patients remotely in hospital settings and in non-traditional settings and circumstances. The telehealth solution uses a tetherless, wearable single-patient-use

sensor to monitor patients with clinically proven Masimo SET pulse oximetry, and is designed to help manage the surge in COVID-19 patients while maintaining the safety of other patients and providers, allowing hospitals to expand patient remote monitoring into alternative care spaces, including overflow locations, emergency recovery facilities, and home care settings. Aldo Carmona, MD, St Luke's Senior Vice President of Clinical Innovation and Chairman of the Department of Anesthesia and Critical Care, said, "This technology is game-changing in light of the crush of demand on our hospitals during this COVID-19 pandemic. With this wearable device, we can create temporary, pop-up respiratory monitoring units as needed to meet the changing patient volumes and track employees' health in their homes if they have been exposed to COVID-19, the flu, or any other serious illness." Designed to track the blood oxygen saturation and respiration rate of patients who are hospitalized or quarantined at home, Masimo SafetyNet combines tetherless SET pulse oximetry with a proprietary remote data capture and surveillance platform accessible from a patient's Android or iOS smartphone or smart device. Monitoring key physiological data can help provide clinicians with an accurate snapshot of a patient's systemic health and facilitates awareness of the need for rapid execution of treatment decisions that can be life-saving. Patients are provided with a multi-day supply of single-patient-use sensors and access to the Masimo SafetyNet mobile app. With clinical feedback from St Luke's led by Dr Carmona and from University Hospitals led by Dr Peter Pronovost, Masimo SafetyNet has been designed for easy, intuitive use to provide customized, interactive CarePrograms that align with expert guidance on COVID-19. Monitoring data collected by the sensor is shared with the patient's smartphone using a secure Bluetooth® connection. Twice daily, or as directed, the CareProgram can be configured to actively notify patients to answer questions such as, "are you having trouble breathing?" and "what is your temperature?", and pushes these responses along with the monitoring data to clinicians for evaluation. CarePrograms are fully customizable to accommodate each institution's protocols, each patient's needs, and any changes in COVID-19 guidance – and can be updated through the cloud by providers even after being deployed, for maximum flexibility as situations evolve. In addition to COVID-19 CarePrograms, Masimo SafetyNet can be configured for more than 150 other CarePrograms for use with COPD, heart failure, oncology, and other patients.

On March 30, patients at St Luke's University Health Network Bethlehem diagnosed with COVID-19 were outfitted with Masimo SafetyNet. Non-COVID-19 patients are also being monitored with this system in general medical-surgical units. St Luke's plans to use the Masimo SafetyNet tetherless sensor and cloud-based surveillance system to monitor upwards of 2,000 hospitalized patients and lower acuity cases in the home. These may also include staff and patients who are quarantined at home with the virus. "Our patients at St Luke's have the most sophisticated and reliable respiratory

monitoring available anywhere," Carmona says. "We know that continuous physiologic monitoring with Masimo's Patient SafetyNet improves outcomes and saves lives. The ability to extend that capability to patients in non-traditional settings and at home during this crisis with Masimo SafetyNet is transformative. Only through our relationship with Masimo could this have been possible."

Joe Kiani, Founder and CEO of Masimo, said, "Masimo is proud to be able to work with St Luke's to help protect the health and safety of medical professionals and the patients they serve during this global pandemic."

Hy-Tape International's COVID-19 Response

Hy-Tape International wanted to let you know what we're doing in response to the Novel Coronavirus (COVID-19) outbreak to protect our staff and customers. We're following federal, state, and local government health advice to make sure our customers and our colleagues stay safe and we are putting all the necessary measures in place to ensure this advice is followed by everyone. This means that we have staggered our workforce to keep our numbers lower. That being said, we appreciate your patience when placing orders. There are many steps throughout the process that may experience delays that are out of our hands. Presently we are well stocked, orders are going out on, or close to on time. Our spirits are high, we know that everyone working hard to help during these times are doing their best, and we will continue to serve our clients, answer calls, and move ahead to do our part. Thank you for your continued support and if you have any questions or concerns, please call us 1-800-248-0101.

Non-traditional means of PEEP generation utilized in conjunction with the LifePulse Jet Ventilator

Given the current COVID-19 Pandemic, hospitals may be faced with inadequate numbers of conventional ventilators due to the reallocation to other patient units. Clinicians may need to utilize non-traditional methods for PEEP and Mean Airway Pressure generation for use with the LifePulse Jet Ventilator. Recommendations are below for these optional applications. We encourage you to call the hotline at 800-800-4358 (HFJV) should this situation arise. Alarms will only be activated by the LifePulse Jet Ventilator in all of the following set up scenarios. It is essential to respond to all alarms identified on the LifePulse HFJV. Use the PEEP display on the LifePulse HFJV to monitor PEEP. The following options are only recommended to be used on stable patients, as defined by the attending physician. Filter the exhaled gas in any of the following set up scenarios. Always provide proper humidification in any of the following set up scenarios. Option One: Traditional Invasive CPAP. Provide a blended gas source to a heated wire conventional ventilator circuit. At the interface on the distal end of the expiratory limb, utilize a PEEP valve. This set up would allow for the filtration of the exhaled gases, located before the PEEP valve. In addition, this option could also utilize a T-Piece Resuscitator to function as the PEEP valve and offer intermittent positive pressure breaths given via the clinician. NOTE: The position for some PEEP valves, ie, vertical versus inverted, will affect the PEEP value displayed on a pressure manometer. NOTE: During testing, we noticed an audible vibration when using a PEEP valve and filter together. This noise did not affect the functionality of this option. Option Two: Traditional Invasive Bubble CPAP. Provide a blended gas source to a heated wire circuit using a flowmeter. Place the distal end of the circuit in either sterile water or acetic acid bath, to generate the desired CPAP level. NOTE: Bubbles generated in the water column caused pressure fluctuations, which contributed to discrepancies between measured PEEP on the Jet and the set PEEP. Our recommendation, for this application specifically, is to use another pressure manometer for monitoring PEEP. Option Three: Utilizing a T-Piece Resuscitator. It is strongly suggested to utilize flows between 8-10 liters per minute. It is essential to heat and humidify the inspiratory gas by utilizing the manufacturer's recommended heated wire circuit. Option Four: Utilizing a T-piece circuit without the Driver. Similar to Option Three. In this option, there is a T-piece, with a PEEP valve, placed before the humidifier to set the desired Peak Inspiratory / Pop-Off Pressure. To deliver a manual breath, the T-piece resuscitator, located on the expiratory limb near the filter, is occluded by the clinician. WARNING: Having a PEEP Valve / Pressure Pop-Off, located at the humidifier, is critical in safely applying this option. The methods described in this Bulletin are valid only for the duration of the Declared Public Health Emergency. These alternate methods of providing PEEP have not been cleared through the FDA. These methods are only to be used if a conventional ventilator is not available to

LifePulse Jet Ventilator

provide PEEP or mean airway pressure. Although Bunnell Inc. has performed bench studies to confirm effectiveness and safety, full clinical validation with all set-ups has not been completed. If the patient is positive for Coronavirus or is suspected to be positive, we recommend the use of an expiratory filter or a traditional conventional ventilator.

NICU Comms Tools Available

Keriton is offering 6-months of access to our patient communication tools. Learn more: www.keriton.com/special_for_nicus. Keep families connected to the NICU with realtime, HIPAA-compliant push notifications, chat and photos: Private, two-way chat between staff and families; Broadcast updates to all families with push notifications; Send families secure photos of their babies; Easy to turn-on for WOWs and desktops too.

Major Infant Health Collaboration Announced

DuPont Nutrition & Biosciences (DuPont) announced a second collaboration with the APC Microbiome Ireland SFI Research Center (APC), a pioneer in the field of microbiome science, which focuses on microbes that live in and on the body and play a significant role in human health, based at University College Cork and Teagasc Moorepark. Representatives from both organizations attended an event Washington DC, to celebrate US-Ireland research and development collaborations, and to announce the 'Missing Microbes in Infants born by C-section' (MiMIC) project and its potential to improve infant health. The €6.3 million, four-year project will be funded jointly by DuPont and Science Foundation Ireland's Spokes program, a platform that is designed to deliver excellent research results and discoveries with industrial relevance to bring significant economic and societal impact. Martin J Kullen, PhD, Director of Probiotics and Microbiome Research at DuPont Nutrition & Biosciences said, "We are honored and privileged to be working with APC with the help of funding from Science Foundation Ireland on solutions and products that are key to our human microbiome platform. By working with the world's leading microbiome research institute in APC, we look forward to providing critical health offerings for key unmet needs around maternal and infant health as well as solutions for cognitive

health and well-being." The DuPont Human Microbiome Venture (HMV) was launched in 2017 to spearhead the development of next-generation microbiome solutions for improved health and wellness. Staying at the forefront of biotechnology innovation, HMV is designed to accelerate product development to complement its existing portfolio and build on DuPont's strong expertise in prebiotics, microbes, proteins and enzymes. "We are delighted to further develop our relationship with DuPont for the benefit of human health," said APC Director Prof Paul Ross. "APC Microbiome Ireland is a global leader, particularly in mother-infant and gut-brain areas of microbiome science, and this collaboration further strengthens our capabilities for advancing infant health and development." The population of bacteria in the gut develops over the first four years of life and plays a key role in human health. Establishment of a healthy gut microbiome in early life is influenced by birth mode, antibiotic use and nutrition, including breast milk components. Infant gut microbiota can be severely depleted in infants born by C-section or exposed to antibiotics. Breastfeeding can help improve microbiota composition. APC Microbiome Ireland SFI Research Centre is ranked No. 1 globally for research in antimicrobial and therapeutic microbes and is in the top five institutions in the world for microbiome research. "APC Microbiome Ireland has expanded the research and development capabilities of Ireland in an area of immediate relevance to the food and pharmaceutical sectors of industry," added Prof Catherine Stanton, Project Leader at APC Microbiome Ireland. "This project will allow us to identify the gut microbes in early life that play an important role in the short- and long-term health of individuals and will help to develop strategies to balance the microbiota following antibiotic exposure or C-section birth mode." Prof Mark Ferguson, Director General of Science Foundation Ireland and Chief Scientific Adviser to the Government of Ireland said, "Science Foundation Ireland strongly welcomes this collaboration between DuPont and APC Microbiome Ireland SFI Research Centre. SFI Research Centres such as APC Microbiome Ireland are making important scientific advances, attract top research talent to Ireland, enhancing enterprise and industry, training students with critical in-demand skills, and boosting Ireland's international reputation. We look forward to seeing the results of this industry partnership and its impact on public health." The Ireland-based research team also includes Prof Eugene Dempsey, Consultant Neonatologist at Cork University Maternity Hospital and Clinical Senior Lecturer, Dept. of Pediatrics and Child Health, APC Microbiome Ireland SFI Research Centre, as well as the INFANT Research Centre (UCC) and Prof John Cryan, who leads brain-gut-microbiome research at APC Microbiome Ireland SFI Research Centre.

Preeclampsia Linked to Neurologic Disease in Full-Term Babies

Full-term infants whose mothers had preeclampsia during pregnancy were more likely to develop a range of neurologic

diseases later on, according to a population-based cohort study in Norway. These included attention-deficit/hyperactivity disorder (ADHD), autism spectrum disorder (ASD), epilepsy, and intellectual disability, according to Bob Sun, MD, MA, of the University of Washington in Seattle, and colleagues. The study also showed an apparent association between preeclampsia and cerebral palsy (aOR, 1.30, 95% CI 0.94-1.80). "Preeclampsia is this giant question mark in medical research," study co-author Allen Wilcox, MD, PhD, of the National Institute of Environmental Health Sciences in Durham, North Carolina, said. "It's long been a fascinating enigma as to what causes it and what the effects are." Wilcox added that he was surprised to find such a broad range of neurologic outcomes related to preeclampsia. But despite the wide scope of neurodevelopmental outcomes linked to preeclampsia, the increased risk was small, he said in an interview. "The outcomes are rare, the increase in risk is rare in absolute terms, and even in relative terms." Ellie Ragsdale, MD, director of Fetal Intervention at University Hospitals in Cleveland, who was not involved in the study, said the research marks the first time preeclampsia has been linked to adverse neonatal outcomes when filtering out babies born preterm. "I think the idea that even when we get patients to full term, we're still seeing neurodevelopmental complications for babies, just solely from having preeclampsia, was sort of an eye-opener for everyone," Ragsdale said. Sun and co-authors noted that preeclampsia, a disorder of abnormal placentation, dysregulated vasculature, and inflammation, affects 4% of pregnancies. The condition is a leading cause of maternal morbidity and mortality, and is associated with adverse outcomes such as stroke, renal failure, elevated liver enzyme levels, and seizures. For the study, Sun and colleagues investigated the association between preeclampsia and a range of neurodevelopmental disorders in offspring. The researchers said they limited the analysis to term births to reduce the influence of preterm birth as a mediator between preeclampsia and neurodevelopment. The team analyzed all singleton births from 1999 to 2009 from the Medical Birth Registry of Norway, including all infants born at term, defined as at least 37 weeks gestation. In Norway, diagnostic criteria for preeclampsia included proteinuria and elevated blood pressure after 20 weeks gestation. All study participants were followed until 2014, providing a minimum of 5 years of follow-up for offspring. The researchers obtained neurodevelopmental diagnosis codes from national insurance data, and linked the information by each person's unique Norwegian identification number. The investigators assessed a range of neurological disorders, including cerebral palsy, ADHD, ASD, epilepsy, intellectual disability, and vision and hearing loss, and adjusted multivariable logistic analyses for participant age and sex, maternal age, parity, maternal marital status, and parental education levels and immigrant status. Of the more than 980,500 live births, approximately 29,000 of the children (2.9%) were exposed to preeclampsia during pregnancy. About 270 of these cases progressed to eclampsia. The birth cohort was around 49% female, and mean gestational age was 39.8 weeks. Full-term infants whose mothers had preeclampsia during pregnancy were more likely to develop a range of neurologic diseases later on, according to a population-based cohort study in Norway.

Don't Separate Moms With COVID-19 From Newborns, Experts Say

Separating mothers with COVID-19 from their newborns in the hospital to prevent viral spread interrupts breastfeeding, stresses mother and baby, and has other negative consequences that likely outweigh any benefit, experts on infant feeding warn. "Mamas need babies and babies need mamas. Sometimes we have to separate mamas from babies, but there's no good science to say that this is one of those times," said Dr Alison Stuebe, a distinguished scholar in infant and young child feeding and a professor in obstetrics and gynecology at the University of North Carolina Gillings School of Global Health in Chapel Hill. In cases where a pregnant woman has suspected or confirmed COVID-19, the US Centers for Disease Control and Prevention (CDC) initially advised hospitals to "consider temporarily separating the mother from her infant." On April 4, the CDC revised the guidance to emphasize the importance of skin-to-skin contact between mother and newborn and said the decision on separation should be made "on a case-by-case basis, using shared decision-making between the mother and the clinical team." The World Health Organization (WHO) and other groups say mothers with confirmed or suspected COVID-19 should room with their babies and should breastfeed, with the mother wearing a mask, washing her hands frequently and disinfecting surfaces, Dr Stuebe noted in a paper in Breastfeeding Medicine on the risks of mother-infant separation. "If mom is unable to take care of her baby and is in the intensive care unit, that's a whole different ball of wax," Dr Stuebe said. In that case, she said, a mother can be assisted in expressing milk for her infant if she wishes. But if a mother with COVID-19 is healthy enough to take care of her infant—and many have no symptoms, Dr Stuebe

noted—separation is not warranted. While the goal of separation is to prevent the baby from contracting the virus in the hospital, she writes, babies can still be exposed after going home. "Especially in the context of social distancing and travel restrictions, few families have the resources to isolate the infant at home, and it is highly plausible that other household members may be infected," she adds. "Hospital isolation may therefore delay, but not prevent, infant infection." Nursing strengthens the infant immune system in many ways, Dr Stuebe notes.

"Taking the baby away could hurt the baby. It could also hurt the mom," she said. "If you've got a mom with COVID and you take her baby away, you may make her worse." Finally, as she points out in her article, separation doubles the demand for personal protective equipment (PPE) and other key supplies on an already stressed health care system.

Support for Elective Induction of Labor at 39 Weeks in Some Low-Risk Women

There are benefits to electing to induce labor at 39 weeks gestation in low-risk women who have already given birth, according to two new studies. Dr Rachel Sinkey and colleagues from the University of Alabama at Birmingham took a look back at 3,703 low-risk multiparous women who each delivered a single baby between 39 and 42 weeks gestation. Of these, 12% delivered between 39 0/7 and 39 4/7 after an elective induction of labor and the remainder in the expectant-management group delivered at 39 5/7 weeks or later. Compared with expectant management, elective induction of labor was associated with fewer cases of a perinatal composite of death, neonatal respiratory support, 5-minute Apgar score of 3 or less, and shoulder dystocia (4.0% vs. 7.1%; adjusted odds ratio, 0.57; 95% confidence interval, 0.34 to 0.96). There were also fewer cesarean deliveries with elective induction of labor (5.1% vs. 6.6%; aOR, 0.60; 95% CI, 0.37 to 0.97), with no difference in other maternal outcomes (hypertensive disorders, chorioamnionitis, and operative vaginal deliveries) or admissions to neonatal intensive-care units. "I was intrigued by our findings, but am mindful that this was an observational study," Dr Sinkey commented by email to Reuters Health. "I believe this needs to be studied prospectively across various populations to learn more. Our promising findings can be included in counseling women on the pros and cons, but other studies have shown induction in nulliparous women results in longer times on labor and delivery (which were unavailable for this paper), which may not be desirable for some women. In sum, elective induction may be an option for multiparous women, but additional prospective studies are needed," said Dr Sinkey. In the other study, researchers analyzed US vital-statistics data for 5.4 million low-risk parous women who delivered single infants at 39 (54.4%), 40 (35.7%), or 41 (9.9%) weeks' gestation.

The overall rate of the composite neonatal adverse outcome (Apgar score less than 5 at 5 minutes, assisted ventilation for longer than six hours, neonatal seizure, or neonatal mortality) was 4.86 per 1,000 live births. The risk was higher in women who delivered at 40 weeks (adjusted relative risk, 1.18; 95% CI, 1.15 to 1.22) and 41 (aRR 1.59; 95% CI, 1.53 to 1.65) weeks gestation compared with 39 weeks.

The overall rate of the composite maternal adverse outcome (ICU admission, blood transfusion, uterine rupture, or unplanned hysterectomy) was 2.31 per 1,000 live births. This risk was also significantly higher with delivery at 40 weeks (aRR 1.15; 95% CI, 1.11 to 1.19) and 41 weeks gestation (aRR 1.50; 95% CI, 1.42 to 1.58) than at 39 weeks. "We hope that clinicians would accept that even among seemingly low-risk parous women, continuing pregnancy beyond 39 weeks is associated with multiple adverse outcomes to the newborn and themselves," lead authors Dr Han-Yang Chen and Dr Suneet Chauhan from McGovern Medical School at the University of Texas, in Houston, wrote in a joint email. "We also hope that the clinicians would share the data with the women they manage."

Guidance on Infant Symptoms, Cow's Milk Allergy Not Evidence-Based

Guidelines that suggest managing crying, vomiting and other common infant symptoms as cow's milk allergy (CMA) are not based on evidence, especially those suggesting that breastfeeding women exclude dairy products to address these symptoms, according to a new report.

"The level of cow's milk protein in human breastmilk of a women consuming large quantities of dairy foods in her own diet is not more than a 1 in 1 million dilution of cow's milk. So when breastfeeding women note that their diet seems to influence their infant's behaviour, the mechanism is unlikely to be allergy," Dr Robert J Boyle of Imperial College London, one of the article's authors, said.

"Severe symptoms in a formula-fed infant may be due to cow's milk allergy, but symptoms in a breastfed infant are very unlikely to be due to cow's milk allergy because micrograms of milk protein are not usually sufficient to trigger symptoms in a milk-allergic infant," he added. Prescribing of specialized infant formulas for CMA management has risen sharply in recent years, although there is no evidence that CMA prevalence has increased, Dr Boyle and his colleagues note. "The increase in specialized formula use might represent

an example of commercially driven overdiagnosis, where practitioners and parents are encouraged to consider CMA diagnosis and treatment for symptoms that are unlikely to be caused by CMA," they add. To investigate, the authors reviewed nine CMA guidelines from 2012-2019, including seven stating that CMA should be considered in infants with common symptoms. Seven of the guidelines recommended breastfeeding mothers exclude cow's milk to manage these symptoms. Three of the guidelines were supported by formula makers or marketing consultants, Dr Boyle and his team found, while 81% of guideline authors in total had reported conflicts of interest with formula companies. Dr Boyle and his team note that about 1% of infants have CMA confirmed by food challenge, while "troublesome" crying, vomiting and rashes are each reported in 15% to 20% of infants. "The practice of advising breastfeeding women to make dietary exclusions may cause harm by undermining confidence in breastmilk and in breastfeeding," Dr Boyle said. "There are already many milk allergy guidelines — locally, nationally and internationally," he added. "But they are too often influenced by companies that might profit from their recommendations and this is reflected in their guidance, which tends to focus on commercial products for managing cow's milk allergy and their role in relieving symptoms, with less attention given to alternative diagnoses and alternative management strategies." He added: "We think it is important that such guidelines are developed without the influence of companies that might profit from their recommendations; and that such guidelines take care to be supportive of breastfeeding as milk allergy guidelines have the potential to undermine breastfeeding."

High BP Early in Pregnancy Linked to Birth Risks

High blood pressure during the first trimester of pregnancy, or an increase in blood pressure between the first and second trimesters, is linked to higher risk for gestational hypertension and preeclampsia, a study indicates. Both conditions heighten the risk for maternal stroke as well as for premature birth, stillbirth, and low birthweight. Preeclampsia also increases the mother's risk for life-threatening seizures, the authors write. "We compared the frequency of hypertensive disorders of pregnancy, including preeclampsia and gestational hypertension, among women based on ACC/AHA [American College of Cardiology/American Heart Association] blood pressure category at a first trimester study visit and blood pressure trajectory between study visits in the first and second trimesters," they explain. The findings by Alisse Hauspurg, MD, with the Magee-Womens Research Institute at University of Pittsburgh School of Medicine in Pennsylvania, and colleagues suggest that this study may identify otherwise "low-risk" women who may be at risk for a hypertensive disorder of pregnancy (HDP). In 2017, the ACC/AHA recategorized blood pressure levels and lowered the threshold for a diagnosis of chronic hypertension. Hauspurg and colleagues wanted to study the new guidelines' relevance for pregnant women. "Considering that the prevalence of pre-gestational hypertension has been projected to double in women newly-designated as having hypertension based on the new ACC/AHA guidelines, understanding risk in this group is particularly relevant for clinicians," the authors write. Among women who had elevated blood pressure in the first trimester (120/80 to 129/80 mmHg), 30.3% developed an HDP, which represents a 42% higher risk than for women with normal blood pressure. Of women with stage 1 hypertension (130/80 to 130/89 mmHg), 37.8% developed an HDP, a risk 80% higher than that of women with normal blood pressure. Stage 1 hypertension was linked with more than 2.5 times the risk for preeclampsia with severe features (adjusted relative risk, 3.48; 95% confidence interval, 1.38 – 8.74). An increase in blood pressure between the first and second trimesters also raised the risk for a hypertensive disorder. Even for women whose blood pressure was normal during the first trimester, an increase in systolic blood pressure during in the second trimester raised the risk for a hypertensive disorder by 41% compared with women whose systolic pressure went down during that period. If the diastolic pressure went up, the risk was 23% higher compared with those whose diastolic pressure decreased during that time.

The researchers used data from the Nulliparous Pregnancy Outcomes Study: Monitoring Mothers-to-Be cohort, a prospective observational study of women who had not previously given birth and who had single pregnancies at eight clinical sites between 2010 and 2014. The 8899 women who were included had no known history of pre-pregnancy hypertension or diabetes. The authors hope the study will spur further research in hypertension among pregnant women.

Two-Step Screening Strategy for Biliary Atresia in Newborns Shows Promise

Newborn screening for biliary atresia using direct or conjugated bilirubin measurements has a high diagnostic yield, detecting all known infants with the rare liver disorder in a large cross-sectional study of infants born at 14 Texas hospitals. Timely diagnosis of biliary atresia is a "critical challenge in pediatric hepatology. Treating biliary atresia

in newborns earlier can delay or prevent the need for liver transplant; however, treatment typically occurs later because biliary atresia is difficult to detect during its early stages," the authors note. Dr Sanjiv Harpavat of Texas Children's Hospital in Houston and colleagues assessed the diagnostic yield of a two-stage screening approach for biliary atresia using direct or conjugated bilirubin measurements. In the first stage, all newborns were tested within the first 60 hours of life. A positive screen was defined as bilirubin levels exceeding derived 95th percentile reference intervals. Infants who screened positive in stage one were retested at or before the two-week well-child visit, with a positive screen defined as bilirubin levels greater than that seen in stage one or greater than 1 mg/dL. The study included more than 124,000 newborns and the two-stage screening approach identified all seven known infants with biliary atresia, with a sensitivity of 100.0% and a specificity of 99.9%, although the 95% confidence interval around the sensitivity was wide (56% to 100%), "and the study design did not ensure complete ascertainment of false-negative results," the authors note. The researchers also did a "pre-post" study of 43 infants who underwent the Kasai portoenterostomy for biliary atresia; 24 were treated before screening implementation and 19 infants were treated after screening implementation. They found that infants who underwent the Kasai portoenterostomy were significantly younger after than before screening was implemented (mean age, 36 days vs 56 days). "These findings may help inform decision-making about newborn screening for biliary atresia, although further research is needed from larger populations to obtain more precise estimates of diagnostic yield and to better understand clinical outcomes and cost-effectiveness of this screening approach," the researchers conclude.

COVID-19 Registry Tracks Pregnant Women, Newborns

A multidisciplinary team of researchers has created a national registry to study how COVID-19 affects pregnant women and their newborns. "Pregnant women are generally considered healthy, but they are also a vulnerable group, and we currently have no data on COVID-19 in pregnancy," co–principal investigator Yalda Afshar, MD, PhD, an obstetrician/gynecologist at UCLA Health, Los Angeles, California, said. "We expect this registry to provide data that will be critical in helping to improve care for pregnant women during this global pandemic," Afshar, a fellow with UCLA Biodesign, stated in a news release. The Pregnancy Coronavirus Outcomes Registry (PRIORITY) is enrolling pregnant women and those who have been pregnant or post partum within the past 6 weeks and who have either received a confirmed diagnosis of COVID-19 or are being evaluated for COVID-19. Women are being recruited through their healthcare provider. A study coordinator contacts the participants by telephone. Women can also join the registry on their own without a referral by visiting the registry website. The registry collects data on COVID-19 symptoms, clinical course, pregnancy, and neonatal outcomes and follows women from enrollment through the second and third trimesters and the postpartum period. The goal is to follow the mothers and babies for up to 1 year. Afshar noted that these kinds of registries often take months to design and to receive funding, but with COVID-19, "there was no time for that. We had to get it up and running ASAP." She said the team has been "blown away" by how quickly people have come forward to join the registry. Within 2 weeks of going live, the registry had enrolled more than 400 participants from across the United States. "At this rate, I think we will easily get 1000 participants in a month or so," Afshar said. "With the global reach of this disease, the findings resulting from this work have the potential to impact millions of lives in an entire generation," Johnese Spisso, CEO of UCLA Health, said in the news release.