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## Safety of Cow's Milk-Derived Fortifiers Used with an All-Human Milk Base Diet in Very Low Birthweight Preterm Infants

Alan Lucas MD FMedSci, Maushumi Assad MD, MPH, Jan Sherman PhD, John Boscardin PhD, Steven Abrams MD

#### Abstract

Background: Very low birthweight (VLBW) preterm infants fed mothers own milk (MOM) need nutritional supplementation, traditionally achieved with cow's milk (CM) derived fortifier CMDF) and preterm formula (PTF) if MOM is insufficient. CM products have been associated with diverse major morbidities. The current recommendation is to preferentially replace PTF with donor milk (DM) to produce a 100% human milk (HM) base diet, usually fortified with CMDF. Objective: To identify whether CMDF, even when fed with a 100% HM base diet, is related to an increased risk of major morbidities.

Methods: We identified a randomized trial with an all-HM base diet, comparing CMDF with a fortifier derived from human milk (HMDF), and two additional studies of this design were generated from raw data as subgroup analyses of a randomized controlled trial and a quasi-experimental study. Using these studies, we calculated the impact of CMDF on major morbidities of death, necrotizing enterocolitis (NEC), retinopathy of prematurity (ROP), sepsis, bronchopulmonary dysplasia (BPD) and patent ductus arteriosus (PDA).

Results: Each study individually provided support for an increase in major morbidities with CMDF. Meta-analyses of pooled data showed that compared to HMDF, the CMDF group had large increases in NEC (RR=3.3; P=0.001), ROP (RR=2.2; P=0.007), PDA (RR=1.6; P=0.009), interruption of feeding (RR=3.4; P=0.001) and a positive mortality/morbidity index based on one or more of death, NEC, sepsis, ROP and BPD (RR=1.4; P=0.006).

Conclusions: Despite the increased use of HM in modern neonatal care as a base diet, we found a greater risk of critical morbidities with CMDF compared with HMDF. This burden of morbidity provides evidence that the benefits of an HM base diet, might be, in part, counteracted by multiple adverse outcomes relating to the use of CMDF.

**Key Words:** preterm infant feeding, cow's milk-derived fortifiers, human milk-derived fortifiers, neonatal morbidity, donor milk

Abbreviations: MOM: Mothers own milk, CM: Cow's milk, CMDF: Cow's milk-derived fortifier, PTF: Preterm fortifier, HMDF: human milk-derived fortifier, NEC: Necrotizing enterocolitis, ROP: Retinopathy of prematurity, PDA: Patent ductus arteriosis, BPD: bronchopulmonary dysplasia, NICU: Neonatal intensive care unit

#### Introduction

MOM is strongly recommended for very low birth weight (VLBW) preterm infants, but does not fully meet their nutritional needs, traditionally met by adding a CMDF to MOM, and when MOM is insufficient, by using a PTF. CM-based products have an important role in current neonatal practice in promoting growth, but evidence indicates that VLBW infants fed partly or wholly on CM products may have a greater risk of adverse outcomes relating to NEC1-4, late-onset sepsis (LOS) (5-8), mortality (7,8), ROP (7,9-11), BPD,(10,12), brain development (13,14), cardiovascular risk (15-17), bone health (18), atopic disease (19) and structural development of the heart, lungs and great vessels (20). It is unknown if these adverse outcomes relate to CM exposure, displacement of HM exposure, or both.

With increasing focus on using human milk in the NICU, official bodies (21,22) recommend using DM rather than PTF when MOM is insufficient, thus increasing HM exposure. Most units would then use a CMDF as the sole source of CM. Given the international emergence of this practice, testing the safety of CMDF, as used in this common practice, is critical. The ideal safety study is one where the base diet is 100% HM, and where it is possible to compare a CMDF versus an HMDF for a range of morbidities. However, remarkably few such studies have been undertaken. We identified only three studies of this design; the OptiMoM trial (9) together with two subgroup analyses of existing studies (1,10).

"Our hypothesis, based on historical evidence of adverse outcomes seen with CM products (cited above), is that even when the base diet is 100% HM, CMDF is associated with major morbidity."

Our hypothesis, based on historical evidence of adverse outcomes seen with CM products (cited above), is that even when the base diet is 100% HM, CMDF is associated with major morbidity. A large, well-powered, hypothesis-testing trial has not been done to test this comprehensively. However, since feeding an all HM diet with a CMDF is so prevalent, we considered that the combined analysis of morbid outcomes and mortality from the three studies identified, providing 453 subjects, should be evaluated as this is the largest dataset of its type and may help to guide practice and research.

#### Methods

Screening of PUBMED, MEDLINE, Google Scholar, and recent reviews, revealed only one study, the OptiMoM trial (2018) (9),

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that met our criterion of 100% human milk base diet with the experimental comparison of CMDF with a modern HMDF. However, we reanalyzed part of this study, and the authors later corrected the findings (see results). The other two studies – the Sullivan trial 2010 (1) and the Assad study 2014 (10) – were ones where we had access to raw data and could generate a subgroup with the desired design (100% HM base diet and experimental comparison of CMDF versus HMDF). We rejected a group of very small studies, notably those of Polberger et al (23) and Hagelberg et al (24) from before the modern HMDF era where investigative groups made non-standardized, clinically unavailable fortifier preparations from skimmed DM for physiological studies that were experimental precursors of current standardized HMDFs.

The three studies presented here are considered separately; and then combined in meta-analyses if two or all three studies included major individual morbidities, previously linked to CM exposure, including NEC, death, ROP, BPD, LOS, and PDA. A secondary outcome was feeding interruption (enteral feeding withheld 24 hours; FW24) since the increased need for parenteral nutrition (PN) with feed intolerance may increase morbidity.

"The three studies presented here are considered separately; and then combined in meta-analyses if two or all three studies included major individual morbidities, previously linked to CM exposure, including NEC, death, ROP, BPD, LOS, and PDA."

The original studies included here for further reanalyses and meta-analyses all received ethical approval. The OptiMoM trial was approved by the Human Research Ethics Board of each participating hospital; for the trial by Sullivan et al (2) Institutional Review Board (IRB) approval was obtained at each center; and for the Assad, study (3) approval was obtained from the IRB of the Herman and Walter Samuelson Children's Hospital.

#### OptiMoM trial (9)

This was a blinded, multicenter RCT from Canada comprising 125 infants <1250g birthweight, who received a base diet of MOM, plus DM as required, and were randomly assigned to CMDF or HMDF. The trial was powered for feeding interruption, but a secondary outcome was a dichotomous mortality/morbidity index, affirmative for any one or more of death, LOS, BPD, ROP or NEC (Bells stage II or greater) – each reported separately as well as part of the morbidity/mortality index. Partial BM fortification commenced at a feeding volume of 100ml/kg per day and full fortification at 140ml/kg/day.

#### Sullivan trial; subgroup analysis

The original trial (1), reported elsewhere, was a 3-limb, 12 center RCT (11 centers from the USA: one from Austria) including infants 500-1250g at birth. All infants received MOM. Groups HM100 and HM40 received HMDF (Prolacta Bioscience, USA), at feeding volumes of 100 mL/kg/day and 40 mL/kg/day, and both groups received standardized DM (Prolacta Bioscience) when MOM was insufficient. The CM group received CMDF (Enfamil, Mead Johnson, USA or Similac; Abbott Laboratories, USA) and a PTF if MOM insufficient.

We have recently reported25 an analysis of a subgroup from that trial in which the base milk was 100% mother's milk. Thus, the only difference between groups was whether HMDF or CMDF was added. Those randomized separately into the HM40 and HM100 were merged for analysis (no differences were seen based on the timing of initiation of feeds for any outcome), explaining why there were 82 subjects fed HMDF and 32 fed CMDF.

NEC was the principal outcome in our subgroup reanalysis, justified by the fact that it was a predetermined key outcome in the main trial (Clinicaltrials.gov reg. #NCT00506584.). Our further key outcome was a severe morbidity index: NEC surgery or death. Because mortality is high in those requiring surgery, death is logically included because of its censoring effect on the incidence of NEC surgery. Secondary outcomes included: BPD (7,10-12), ROP7,9-11, and sepsis (5-8).

#### Assad subgroup analysis

Assad et al. (2014) (10) conducted a single-center study in 293 preterm infants (mean gestation 28 weeks). The study is reported elsewhere (10). Three groups of infants were fed CM-based products and a 4th, EHM feeding. Two of the groups allowed a pre-post (quasi-experimental) comparison of an all HM base diet with CMDF pre-2012 versus an all HM base diet with HMDF post-2012. Since some original data analyses were from combined groups, our new 2-subgroup study required a reanalysis of primary data, allowing us to examine any association between fortifier type and multiple outcomes.

#### **Publication history**

The data in the Assad subgroup reanalysis, have not been published previously as an original manuscript. This analysis now also includes new data from the medical records for death and LOS that were not included in the analysis of the original Assad study (10). Both the Sullivan reanalysis and OptiMoM studies have been published (9,25) but have been further analyzed in this current study. None of the meta-analyses of the three studies combined have been previously published.

#### Type of human milk

The exclusive human milk group in the three studies all included both MOM and donor milk-derived fortifier. We note that in two of the three studies (Sullivan and Assad), the base diet in the CM group was only MOM, whereas in the OptiMoM trial, the base diet was MOM plus DM as required.

#### **Diagnosis of NEC**

In the OptiMoM and Sullivan trials, the diagnosis of NEC was made by radiologists, blind to the dietary assignment to improve diagnostic reliability, as described previously (2).

#### ROP

Two studies examined severe ROP (Sullivan(1) and OptiMoM(9)), and one examined all ROP (Assad10). For our meta-analyses, we elected to combine the three studies despite the heterogeneity. Previous studies have done this, and prior work shows both severe and all ROP are related to the use of CM(11) – as seen here when the studies were analyzed separately.

#### Statistical analysis

The baseline comparisons of categorical data used the chi-square test for homogeneity or Fisher's exact test for small cell sizes. Comparisons of baseline quantitative variables used the two-sample t-test. In considering whether fixed or random-effects models

would be most appropriate for our meta-analyses, we note the view of Borenstein et al (26). that if the number of studies is very small, as in this case, it may be impossible to estimate adequately between-study variance (tau-squared), rendering the fixed effect model the most viable option. In effect, we have treated included studies as the only ones of interest. Nevertheless, for the more major analyses, we also checked whether similar findings emerged with a random-effects model. We performed meta-analyses using REVMAN 5.3 software.

#### Results

Table 1 shows a lack of statistical evidence for differences in baseline characteristics between CMDF and HMDF groups within any of the three studies (P>0.05 in all cases).

Table 2 shows the relationship between fortifier type and outcomes for the three individual studies.

#### **OptiMoM trial (9)**

For all outcomes shown for OptiMoM in table 2, RR was greater in the CMDF group ranging from negligible for NEC stage II or greater, to 6.4 for severe ROP, a significant effect (P=0.04). There was also evidence for higher risk of sepsis with CMDF (RR=1.84; that is, an 84% increase in risk: P=0.07).

Additionally, the authors reported a dichotomous combined overall morbidity index, which was positive if the subject exhibited one or more of the following: death, NEC (stage II or higher), BPD, ROP or LOS. This aspect of the trial results is material, yet historically complex and clarified here,

The initial publication of the trial findings showed this morbidity index was not related to fortifier type: the incidence of a positive index in the CMDF and HMDF groups was almost identical at 49% and 48%. (9)

"However, we were concerned that this analysis was not an accurate representation of the data. Our own analysis utilized the authors' data on individual morbidities to calculate the average number of adverse events per subject. There were 31 adverse events in 64 subjects fed HMDF (0.48 events per subject); yet, for CMDF there were 45 adverse events among 61 subjects (0.74 events per subject)."

However, we were concerned that this analysis was not an accurate representation of the data. Our own analysis utilized the authors' data on individual morbidities to calculate the average number of adverse events per subject. There were 31 adverse events in 64 subjects fed HMDF (0.48 events per subject); yet, for CMDF there were 45 adverse events among 61 subjects (0.74 events per subject). Raw data were unavailable, but we did a provisional analysis of the overall morbidity data reported using a large sample z-test approximation to a Poisson distribution. The significance level was P=0.06 for the ratio of adverse events per case in the CMDF vs. HMDF group. The point estimate was an RR of 1.50 (95% CI: 0.95 to 2.37), that is, a 50% higher risk of a positive index in the CMDF group. Our analysis, while limited and hence provisional, nevertheless suggested that the CMDF group might prove disadvantaged for multiple morbidities.

The authors of the OptiMoM trial re-explored their findings and published a corrigendum (27), noting that there had been an overcounting of BPD cases resulting in their removal of 8 cases with a positive index selectively from the HMDF group. Thus, a revised version of the OptiMoM trial results now shows 23/64 subjects with a positive mortality/morbidity index in the HMDF group and 30/61 subjects in the CMDF group, reflecting, in our own analysis, an increased RR of having a positive index in the CMDF group of approaching 40% (RR 1.37; 95% CI 0.90-2.07) with an authors' adjusted P=0.07. The revised version is the version of the record at the journal website (direct link to AJCN).

#### Sullivan trial subgroup analysis (25)

Table 2 shows that use of CMDF was related to an increase in NEC compared to use of HMDF (RR=4.2; P=0.04); and also to a severe morbidity index of NEC surgery or death (RR=5.1; P=0.01) For BPD, sepsis, and ROP the relationship with fortifier type was not found.

#### Assad study reanalysis

The quasi-experimental pre-post subgroup analysis of Assad's study showed a major impact of fortifier type in those otherwise fed 100% human milk base diet.

Table 2 shows 7 outcomes in relation to fortifier type: death, lateonset sepsis, BPD, NEC, ROP, PDA, and FW24, all of which showed at an increase in risk in the CMDF group, and significantly so for NEC (RR=7.5:P=0.02); ROP (RR=2.5; P=0.001); PDA (RR=2.7; P=0.007); FW24 (RR=5.9; P=0.001).

In the original 4-limb Assad study, BPD incidence was significantly higher in those exposed to CM, but this subgroup analysis that allowed us to compare fortifiers was underpowered to study BPD; nevertheless, there was a 60% higher risk of BPD in the CMDF group (RR=1.6).

#### **Meta-analyses**

All three studies, Assad, Sullivan, and OptiMoM, contributed data for our meta-analyses of NEC, ROP. Death, BPD, and sepsis (all shown in Fig 1). Using fixed effect models, as planned, CMDF was associated with a higher risk of NEC (RR=3.3; P=0.008) and ROP (RR=2.4; P=0.001); with significance also shown in random-effects models (not depicted). In the CMDF group, there was also a more than doubling of the risk of death (RR=2.1; P=0.1); and a 32% higher risk of BPD (RR= 1.32; P=0.1). Both effects trended towards statistical significance. No overall effect of fortifier type was found for late-onset sepsis: the 80% and 30% increases in risk with CMDI in the OptiMoM and Assad studies were counter-balanced by a decreased risk in the Sullivan reanalysis

Two studies provided data for the impact of fortifier type on PDA, and our secondary outcome feeds withheld for >24 hours (FW24). Figure 2 shows the CMDF group had a higher risk of PDA (RR=1.6; P=0.009) and FW24 (RR=3.4; P=0.0001).

#### A meta-analysis of mortality/morbidity indices

In OptiMoM, those fed CMDF had a large, near 40% increase in the risk of a positive mortality/morbidity index compared to the HMDF group. (P=0.07) - see table 2. Because of the poten-

## Figure 1: meta-analyses for NEC, ROP, BPD, Death, LOS; all 3 studies contributed

#### Figure 1a NEC

-	CM		HM			Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% Cl	M-H, Fixed, 95% Cl
Assad 2014	11	127	1	87	20.5%	7.54 [0.99, 57.31]	
OptiMoM 2018	3	61	3	64	50.5%	1.05 [0.22, 5.00]	
Sullivan 2019	5	32	3	82	29.0%	4.27 [1.08, 16.84]	
Total (95% CI)		220		233	100.0%	3.31 [1.36, 8.07]	-
Total events	19		7				
Heterogeneity: Chi <sup>2</sup> =	2.84, df=	2 (P =	0.24); l² =	= 30%			
Test for overall effect: Z = 2.63 (P = 0.008)						Favours CM Favours HM	

#### Figure 1b ROP



#### Figure 1c BPD

	CM		HM			Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% Cl	M-H, Fixed, 95% Cl
Assad 2014	30	127	13	87	34.7%	1.58 [0.88, 2.85]	
OptiMoM 2018	18	61	16	64	35.1%	1.18 [0.66, 2.10]	
Sullivan 2019	11	32	24	82	30.3%	1.17 [0.65, 2.11]	
Total (95% CI)		220		233	100.0%	1.32 [0.94, 1.85]	
Total events	59		53				
Heterogeneity: Chi <sup>2</sup> =	0.65, df=	2 (P =	0.72); l² =	= 0%			
Test for overall effect:	Z = 1.60	(P = 0.1	1)				0.2 0.5 1 2 5 CM HM

#### Figure 1d Death

	Cows	Milk	Human	Milk		Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% Cl	M-H, Fixed, 95% Cl
Assad 2014	3	127	1	87	20.5%	2.06 [0.22, 19.43]	
OptiMoM 2018	4	61	3	64	50.5%	1.40 [0.33, 6.00]	
Sullivan 2019	4	32	3	82	29.0%	3.42 [0.81, 14.42]	+
Total (95% CI)		220		233	100.0%	2.12 [0.85, 5.31]	
Total events	11		7				
Heterogeneity: Chi <sup>2</sup> =	0.74, df=	2 (P =	0.69); l <sup>2</sup> =	0%			
Test for overall effect:	Z = 1.60 (	(P = 0.1	1)				Favours CM Favours HM

#### Figure 1e Late onset sepsis (LOS)

	Cows	Milk	Human	Milk		Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI	M-H, Fixed, 95% CI
Assad 2014	20	127	11	87	40.7%	1.25 [0.63, 2.47]	
OptiMoM 2018	14	61	8	64	24.3%	1.84 [0.83, 4.06]	
Sullivan 2019	5	32	20	82	35.0%	0.64 [0.26, 1.56]	
Total (95% CI)		220		233	100.0%	1.18 [0.76, 1.83]	-
Total events	39		39				
Heterogeneity: Chi <sup>2</sup> = Test for overall effect:	3.02, df = Z = 0.73 (	2 (P = (P = 0.4	0.22); I² = 7)	34%			0.1 0.2 0.5 1 2 5 10 Favours CM Favours HM

# Figure 2: meta-analyses where data on 2 out of the 3 studies were available. Outcomes were PDA, and the secondary outcome: feeds withheld >24 hours

#### Figure 2a PDA

-	CM		HM			Risk Ratio			Risk	Ratio		
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% Cl			M-H, Fixe	ed, 95% Cl		
Assad 2014	28	127	7	87	28.0%	2.74 [1.25, 5.99]						
Sullivan 2019	18	32	38	82	72.0%	1.21 [0.83, 1.78]			-	┢┻╾		
Total (95% CI)		159		169	100.0%	1.64 [1.13, 2.38]				•		
Total events	46		45									
Heterogeneity: Chi <sup>2</sup> =	4.02, df=	1 (P =	0.04); l <sup>2</sup> :	= 75%				-			÷	4.0
Test for overall effect:	Z = 2.63 (	(P = 0.0	109)				U. I	0.2	Favours CM	Favours HM	э	10
Figure 2c Feed	withhe	eld >:	24 hoi	ırs								
	CM		HM			Risk Ratio			Risk	Ratio		
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% Cl			M-H, Fixe	d, 95% Cl		
		407	-		40.000	5 00 K0 40 44 071						

Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% Cl		M-H, Fixe	d, 95% Cl		
Assad 2014	43	127	5	87	40.3%	5.89 [2.43, 14.27]				_	
OptiMoM 2018	14	61	9	64	59.7%	1.63 [0.76, 3.49]		-			
Total (95% CI)		188		151	100.0%	3.35 [1.90, 5.92]			•		
Total events	57		14								
Heterogeneity: Chi² = 5.00, df = 1 (P = 0.03); I² = 80%									1 1	н Л	100
Test for overall effect:	Z = 4.16	(P < 0.0	1001)				0.01	Favours CM	Favours HM	1	100

Figure 3: Meta-analysis of morbidity indices in the OptiMoM, Assad, and Sullivan studies, A positive index is defined as one or more of death, sepsis, NEC, ROP and BPD. The index was based on the one published in the OptiMoM corrigendum (27), and equivalent indices (based on the same 5 outcomes) were derived from raw data in the Sullivan and Assad reanalysis.

	CM		HM			<b>Risk Ratio</b>	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI	M-H, Fixed, 95% CI
Assad 2014	60	127	25	87	40.1%	1.64 [1.13, 2.40]	
OptiMoM 2018	30	61	23	64	30.3%	1.37 [0.90, 2.07]	
Sullivan 2019	16	32	39	82	29.6%	1.05 [0.69, 1.59]	<b>_</b>
Total (95% CI)		220		233	100.0%	1.39 [1.10, 1.75]	•
Total events	106		87				
Heterogeneity: Chi <sup>2</sup> =	2.49, df=	2 (P =	0.29); l <sup>2</sup> =	= 20%			
Test for overall effect:	Z = 2.74 (	(P = 0.0	06)				Favours CM Favours HM

tial clinical importance of this, we derived the same index for the Assad and Sullivan studies based on the raw data (one or more of NEC, sepsis, BPD, ROP, or death). Fig. 3, shows a significant 40% higher risk of a positive mortality/morbidity index in the CMDF group (RR=1.4; P=0.006) when the three studies were combined in a meta-analysis.

#### Discussion

We found strong evidence that using CMDF, even with a 100% HM base diet, was associated with an increased risk of major neonatal morbidities. This finding is consistent with previous studies, including RCTs, cohort studies, systematic reviews, and metaanalyses, which indicated that feeding CM based products (PTF and CMDF) was associated with increased risk of multiple major neonatal morbidities (1-12). In each of the three studies, analyzed separately, individual adverse outcomes were increased in the CMDF groups. When the studies were combined in meta-analyses, a clearer pattern of increased risk emerged for CMDF, most strongly expressed for NEC, ROP, PDA and FW24, and a dichotomous mortality/morbidity index based on death, late-onset sepsis, NEC, ROP or BPD.

One factor that may have an important bearing on these findings is that even with a 100% HM base diet, CM protein consumption of VLBW infants is still unexpectedly high. The current guideline that trades use of PTF for the use of DM is focussed on maximizing HM intake to improve outcomes. Yet, this practice also increases the use of fortifier – most commonly CMDF. We estimate a VLBW baby targeted to receive 4g protein/kg/day would obtain only 50% of this from 160 ml/kg per day of mother's preterm milk

Parameter	HMDF	CMDF						
OptiMoM trial								
Number of subjects	64	63						
Sex(female)	39/64 (61%)	34/63 (54%)						
Race (non-European)	37/64 (59%)	44/63 (71%)						
Antenatal steroids	56/64 (88%)	56/63 (89%)						
Apgar at 5 min	7.4 (SD 2.1)	7.3 (SD 2.3)						
Gestation (weeks)	27.9 (SD 2.7)	27.5 (SD 2.3)						
Birthweight (grams)	887 (SD 208)	889 (SD 196)						
SGA at birth	13/64 (20%)	16/63 (25%)						
Sullivan trial re-analysis								
Number of subjects	82	32						
Sex (female)	47/82 (57.3%)	15/32 (46.9%)						
Race (black)	16/82 (19.5%)	3/32 (9.4%)						
Antenatal steroids	15/82 (18.3%)	6/32 (18.8%)						
APGAR<7	8/82 (9.8%)	6/32 (18.8%)						
Gestation (weeks)	$27.3 \pm 2.2$	$27.1 \pm 1.8$						
Birthweight (grams)	$937 \pm 199$	$938 \pm 190$						
SGA at birth	10/82 (12.2%)	3/32 (9.4%)						
Assad	study re-analysis							
Number of subjects	87	127						
Sex (female)	34/87 (39%)	64/127 (50%)						
Race (black)	53 (61%)	85/127 (67%)						
Gestation (weeks)	27.7 (SD 2.7)	28.3 (SD 2.8)						

Statistical tests used: t-test for quantitative variables and chi-square/Fisher's exact test for categorical variables; all comparisons between groups were non-significant (p>0.05)

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Parameter	HMDF	CMDF	RR <sup>1</sup>	P-value <sup>2</sup>				
Total number subjects (453)	233	220						
OptiMOM trial								
Number of subjects	64	61						
ROP (severe)	1 /62 (1.6%)	6 /59; 10.%)	6.4	0.04				
Late onset sepsis	8 /64 (13%)	14/61 (23%)	1.8	0.073				
Death	3 /64 (4.7%)	4 (6.6%)	1.4	0.65				
BPD	16/64 (25%)	18/61 (30%)	1.2	$0.73^{3}$				
NEC (Bells stage II or greater)	3/64 (4.7%)	3/61 (4.9%)	1.0	0.95				
NEC all stages	3/64 (4.7%)	6/61 (9.8%)	2.1	0.27				
Feeds withheld 12h (FW12h)	17/64 (27%)	20/61 (33%)	1.2	0.343				
Feeds withheld 24h (FW24h)	9/64 (14%)	14/61 (23%)	1.6	0.193				
Positive morbidity index <sup>4</sup>	23/64 (36%)	30/61 (49%)	1.4	$0.07^{3}$				
Sullivan RCT – subgroup reanalysis								
Number of subjects	82	32						
NEC (Bells Stage II or greater)	3/82 (3.7%)	5 (15.6%)	4.2	0.04				
NEC surgery or death	3 /82 (3.7%)	6/32 (18.8%)	5.1	0.01				
Death only	3/82 (3.7%)	4/32 (12.5%)	3.4	0.10				
Proven sepsis	20 /84 (24.4%)	5/32 (15.6%)	0.6	0.45				
BPD	24/84 (29.3%)	11/32 (34.4%)	1.2	0.60				
ROP (grade 3 or 4)	6 /84 (7.3%)	2/32 (6.3%)	0.9	1.0				
Assad study – subgroup group reanalysis								
Number of subjects	87	127						
NEC (Bells stage II or greater)	1/87 (1.1%)	11/127 (8.7%)	7.5	0.02				
ROP	11/87 (14%)	40/127 (32%)	2.5	0.001				
BPD	13/87 (15%)	30/127 (24%)	1.6	0.20				
PDA <sup>5</sup>	7/87 (8%)	28/127 (22%)	2.7	0.007				
Feeds withheld 24h (FW24)	5/87 (6%)	43/127 (34%)	5.9	0.001				
Late onset sepsis	11/87 (13%)	20/127 (16%)	1.3	0.66				

<sup>1</sup>*RR* = relative risk of adverse outcome in the CMDF group

<sup>2</sup>*chi-square/Fisher's exact test* 

<sup>3</sup>adjusted P value based on multivariate logistic regression model

<sup>4</sup>Positive mortality/morbidity indxex = one or more of: ROP, sepsis, death, BPD, NEC stage II or greater <sup>5</sup>Data on PDA collected in original database but not published in the original Assad Study

Death 1/87 (1.1%) 3/127 (2.4%)	2.2	0.89
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of average composition (28) and only around 40% of this intake from 160 ml/kg of typical DM. The rest of this protein requirement must be from CMDF. Thus, babies fed HM as recommended may derive more protein from CMDF than HM, perhaps accounting for the apparently large adverse impact of CMDF.

"We found strong evidence that using CMDF, even with a 100% HM base diet, was associated with an increased risk of major neonatal morbidities."

An aspect of note was the variation between studies in the diversity of outcomes related to the use of CMDF. The OptiMoM trial showed that compared to the HMDF group, those fed CMDF had a strong trend to a near 40% increase in the proportion of subjects with a positive morbidity index, based on diverse morbidities. The Assad reanalysis illustrated this diversity of adverse outcomes with CMDF even more strikingly. Nevertheless, conversely, in the Sullivan reanalysis, the dominant effect of CMDF was in relation to NEC, NEC surgery, and death: whereas sepsis, ROP and BPD appeared unaffected. A likely possibility is that this simply reflects random variation in small individual studies, and hence justifies our approach in using meta-analyses to combine the data,

One finding in our trial that deserves attention is the hitherto unexplained higher risk of patent ductus in those fed CMDF. This was observed here in a meta-analysis of two of our three studies but has been previously reported by Hair and co-workers7, who found a highly significant increase in the risk of PDA in those exposed to CM products versus an exclusive human milk base diet. This requires further investigation.

Many studies lack the power to detect significant effects on the outcomes studied. To increase power, dichotomous morbidity indices are often used where having one or more of a group of adverse outcomes is treated as a positive result. In the OptiMoM trial, a mortality/morbidity index was used (one or more of death, NEC, sepsis, ROP, or BPD); and the CMDF group had a 40% increased risk of a positive index, based on the most serious common outcomes in neonatal care. Yet because P=0.07, the authors rejected this as "not significant" (27). However, Amrhein et al. in a seminal 2019 Nature paper (29), with 800 signatories, argue that P values have been misused, that P should not be a dichotomous variable with an arbitrary cut off value such as 0.05 and cannot be used to determine that findings are 'not significant,' particularly with large RRs, since this may result in incorrect rejection of key findings. Because of the potential clinical importance here, we conducted a meta-analysis of this same mortality/morbidity index for all three of our studies (n=453 versus 125 in OptiMoM alone: fig 3). The increased risk of having a positive index in the CMDF group remained at 40%, but now, in this more powered analysis, P=0.006.

Our secondary outcome and a primary one in OptiMoM (9) was the interruption of feeds – a major problem that increases the need for PN and its associated morbidity. In OptiMoM, feed interruption was measured as feeds withheld for 12 hours (FW12) but also as FW24. The increased risk for feed interruption for 12 and 24 hours in OptiMoM in the CMDF group was sizeable at 22% and 63%, respectively, but rejected as not significant. In OptiMoM, CM was introduced late (see below), which could have reduced the power of the study. Since FW24 was measured in both OptiMoM and Assad, a more robust meta-analysis was possible, showing a 3.4-fold increase in FW24 (P=0.0001) with the use of CMDF (see figure 2); an effect size potentially of considerable clinical significance.

#### Limitations

Our study is not a conventional systematic review or meta-analysis of published evidence and could not be conducted according to conventional guidelines. For 2 of our three studies (Sullivan and Assad), these could not be searched since they did not preexist but were created from subgroup analyses of the raw data from the original studies; and we accept there might be further, suitable raw datasets that could be correspondingly analyzed.

Two of our studies were subgroup analyses, theoretically more prone to chance imbalances between groups; greater morbidity in the CMDF group might simply have reflected chance generation a higher risk population. The evidence is strongly against that. Our studies, conducted in different years and centers, consistently showed greater morbidity in those fed CDMF. Baseline risk factors were well balanced between groups in each study. Also, much evidence links CM exposure to the same adverse outcomes shown here.

The NEC incidence amongst our three studies deserves some comment. The most modern of the three studies (OptiMoM) showed a particularly low incidence of NEC with no difference between randomized groups. Whilst we agree that future studies will resolve if this is an exceptional finding or not, we would note that the adverse effects of CM may be ameliorated by delaying its introduction into the diet (though with corresponding downsides for growth and requirement for PN). In the OptiMoM trial, the mean age of introduction of CM was late at day 17 (9), compared to the possibility of receiving CM in the early part of the first week in the Sullivan trial (1). The incidence of NEC in the Sullivan reanalysis was higher than commonly seen today, even in very small infants. However, the key point is that despite the heterogeneity in feeding practice, age of study, etc., our meta-analysis indicates a major increase in NEC in those assigned CMDF vs. HMDF: 8.6% incidence vs. 3.0% (derived from the data in figure 1).

"Our secondary outcome and a primary one in OptiMoM (9) was the interruption of feeds – a major problem that increases the need for PN and its associated morbidity."

Our study does not address the use of liquid CMDF used now in the US, though powder-based fortifiers are used in many countries and the three studies here. Whether liquid fortifiers by displacing about 1/6th of the MOM or DM volume with a fortifier could further increase any adverse impact of CMDF has received little attention. It would be hard to explore if HMDF, which is also a liquid, commercially derived from pasteurized DM, could have any measurable impact on the outcome by displacing a significant volume of MOM when the available volume is high. However, overall, compared to VLBW infants exposed to CM products, those fed on an EHM diet including HMDF, studied by us here and by other groups (1-3,7,10) have in general significantly lower morbidities

Finally, our findings apply to intact protein fortifiers in widespread international use. We do not consider here partially or extensively hydrolyzed fortifiers, now often used in the US (30-32). Such fortifiers have been compared with each other with some differences but not with HMDF and not studied for the broad range of morbidities reported to be differentially affected by CM vs. HM exposure. Moreover, the hypothesis that using hydrolyzed CM protein in feeds for preterm infants would overcome the adverse effects of intact CM products is unproven, and not supported conceptually by a recent Cochrane review (33), albeit focussed on hydrolyzed formulas rather than fortifiers.

#### Conclusion

Current recommendations to maximize human milk intake in preterm infants have been enthusiastically implemented internationally, but without adequate research on the impact of the CM component of the diet with this new regime. This now needs scientific attention. We have identified three studies all with some form of experimental design that show individually, and collectively in meta-analyses, that VLBW preterm infants fed CMDF with an otherwise 100% human milk base diet had a significant increase in major morbidities some of which may reduce survival or have significant adverse post-neonatal effects. This burden of morbidity, indicated by the findings, provides evidence that the benefits of an HM base diet, might be in part counteracted by multiple adverse outcomes relating to the use of CMDF- and this needs further research attention. Our study demonstrated a significantly lower burden of morbidity with HMDF. Finally, the use of CMDF is designed to meet nutrient needs, yet our study emphasizes further the increasingly recognized potential importance of non-nutritional impacts of diet on clinical course and health outcomes in this highrisk population.

"We have identified three studies all with some form of experimental design that show individually, and collectively in metaanalyses, that VLBW preterm infants fed CMDF with an otherwise 100% human milk base diet had a significant increase in major morbidities some of which may reduce survival or have significant adverse post-neonatal effects. "

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#### Author Contributions

**Professor Alan Lucas** conceived and initiated the study; analyzed raw data; and wrote the paper

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- **Dr Maushumi Assad** provided her raw data (Assad study) and assisted us with the understanding of her database, She read and commented constructively on the manuscript
- **Professor Jan Sherman** was our advisor on evidence-based medicine. She performed all the meta-analyses and provided the data for figures. She read and advised on the manuscript.
- Dr. John Boscardin was our statistician who advised on: the statistical analysis, interpretation of data and data presentation
- **Professor Steven Abrams** key collaborator involved in every aspect of the study and made major intellectual input.

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# SHARED DECISION-MAKING PROTECTS **MOTHERS + INFANTS DURING COVID-19**

KEEPING MOTHERS + INFANTS TOGETHER

Risks of separation Risk of and trauma horizontal infection

Means balancing...



## **EVIDENCE**

We encourage families and clinicians to remain diligent in learning up-to-date evidence.

### PARTNERSHIP

SHARED DECISION-MAKING

What is the best for this unique dyad?

#### S EEK PARTICIPATION H ELP EXPLORE OPTIONS A SSESS PREFERENCES R EACH A DECISION





#### TRAUMA-INFORMED Both parents FEAR

- - GRIEF
  - UNCERTAINTY

## LONGITUDINAL DATA

We need to understand more about outcomes for mothers and infants exposed to COVID-19, with special attention to:

MENTAL HEALTH



- POSTPARTUM CARE DELIVERY

NEW DATA EMERGE DAILY.

NANN AND NPA ENCOURAGE PERINATAL CARE PROVIDERS TO ENGAGE IN CANDID CONVERSATIONS WITH PREGNANT PARENTS PRIOR TO DELIVERY REGARDING RISKS, BENEFITS, LIMITATIONS, AND REALISTIC EXPECTATIONS.

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# **Omegaven**<sup>®</sup> (fish oil triglycerides) injectable emulsion



**The first and only fish oil emulsion** for pediatric patients with parenteral nutrition-associated cholestasis (PNAC) in the U.S.<sup>1</sup>

A source of calories and fatty acids in pediatric patients with PNAC

Patients receiving Omegaven achieved age-appropriate growth

Omegaven-treated patients experienced improvement in liver function parameters

#### Limitations of Use

- Omegaven is not indicated for the prevention of PNAC. It has not been demonstrated that Omegaven prevents PNAC in parenteral nutrition (PN)-dependent patients.
- It has not been demonstrated that the clinical outcomes observed in patients treated with Omegaven are a result of the omega-6: omega-3 fatty acid ratio of the product.

#### Contraindications

• Omegaven is contraindicated in patients with known hypersensitivity to fish or egg protein or to any of the active ingredients or excipients, severe hemorrhagic disorders due to a potential effect on platelet aggregation, severe hyperlipidemia or severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglyceride concentrations greater than 1000 mg/dL).

Please see Brief Summary of Prescribing Information for Omegaven on the reverse side.



#### OMEGAVEN (fish oil triglycerides) injectable emulsion, for intravenous use

#### BRIEF SUMMARY OF PRESCRIBING INFORMATION

This brief summary does not include all the information needed to use Omegaven safely and effectively. Please see full prescribing information for Omegaven (fish oil triglycerides) injectable emulsion for intravenous use at www.fresenius-kabi.com/us.

#### INDICATIONS AND USAGE

Omegaven is indicated as a source of calories and fatty acids in pediatric patients with parenteral nutrition-associated cholestasis (PNAC).

Limitations of Use:

Omegaven is not indicated for the prevention of PNAC. It has not been demonstrated that Omegaven prevents PNAC in parenteral nutrition (PN)-dependent patients.

It has not been demonstrated that the clinical outcomes observed in patients treated with Omegaven are a result of the omega-6: omega-3 fatty acid ratio of the product.

#### DOSAGE AND ADMINISTRATION

Prior to administration, correct severe fluid and electrolyte disorders and measure serum triglycerides to establish a baseline level. Initiate dosing in PN-dependent pediatric patients as soon as direct or conjugated bilirubin levels are 2 mg/dL or greater. The recommended daily dose (and the maximum dose) in pediatric patients is 1 g/kg/day. Administer Omegaven until direct or conjugated bilirubin levels are less than 2 mg/dL or until the patient no longer requires PN.

#### CONTRAINDICATIONS

Omegaven is contraindicated in patients with known hypersensitivity to fish or egg protein or to any of the active ingredients or excipients, severe hemorrhagic disorders due to a potential effect on platelet aggregation, severe hyperlipidemia or severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglyceride concentrations greater than 1,000 mg/dL).

#### WARNINGS AND PRECAUTIONS

- Risk of Death in Preterm Infants due to Pulmonary Lipid Accumulation: Deaths in preterm infants after infusion of soybean oil-based intravenous lipid emulsions have been reported in medical literature. Autopsy findings in these preterm infants included intravascular lipid accumulation in the lungs. The risk of pulmonary lipid accumulation with Omegaven is unknown. Preterm and small-for-gestational-age infants have poor clearance of intravenous lipid emulsion and increased free fatty acid plasma levels following lipid emulsion infusion. This risk due to poor lipid clearance should be considered when administering intravenous lipid emulsions. Monitor patients receiving Omegaven for signs and symptoms of pleural or pericardial effusion.
- Hypersensitivity Reactions: Omegaven contains fish oil and egg phospholipids, which may cause hypersensitivity reactions. Signs or symptoms of a hypersensitivity reaction may include: tachypnea, dyspnea, hypoxia, bronchospasm, tachycardia, hypotension, cyanosis, vomiting, nausea, headache, sweating, dizziness, altered mentation, flushing, rash, urticaria, erythema, fever, or chills. If a hypersensitivity reaction occurs, stop infusion of Omegaven immediately and initiate appropriate treatment and supportive measures.
- Risk of Infections: The risk of infection is increased in patients with malnutrition-associated immunosuppression, long-term use and poor maintenance of intravenous catheters, or immunosuppressive effects of other conditions or concomitant drugs. To decrease the risk of infectious complications, ensure aseptic technique in catheter placement and maintenance, as well as in the preparation and administration of Omegaven. Monitor for signs and symptoms of early infections including fever and chills, laboratory test results that might indicate infection (including leukocytosis and hyperglycemia), and frequently inspect the intravenous catheter insertion site for edema, redness, and discharge.
- Fat Overload Syndrome: A reduced or limited ability to metabolize lipids accompanied by prolonged plasma clearance may result in this syndrome, which is characterized by a sudden deterioration in the patient's condition including fever, anemia, leukopenia, thrombocytopenia, coagulation disorders, hyperlipidemia, hepatomegaly, deteriorating liver function, and central nervous system manifestations (e.g., coma).
- Refeeding Syndrome: Administering PN to severely malnourished patients may result in refeeding syndrome, which is characterized by the intracellular shift of potassium, phosphorus, and magnesium as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop. To prevent these complications, closely monitor severely malnourished patients and slowly increase their nutrient intake.
- Hypertriglyceridemia: Impaired lipid metabolism with hypertriglyceridemia may occur in conditions such as inherited lipid disorders, obesity, diabetes mellitus, and metabolic syndrome. Serum triglyceride levels greater than 1,000 mg/dL have been associated with an increased risk of pancreatitis. To evaluate the patient's capacity to metabolize and eliminate the infused lipid emulsion, measure serum triglycerides before the start of infusion (baseline value), and regularly throughout treatment. If hypertriglyceridemia (triglycerides greater than 250 mg/dL in neonates and infants or greater than 400 mg/dL in older children) develops, consider stopping the administration of Omegaven for 4 hours and obtain a repeat serum triglyceride level. Resume Omegaven based on new result as indicated.
- Aluminum Toxicity: Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Preterm infants are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum. Patients with impaired kidney function, including preterm infants, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.
- Monitoring and Laboratory Tests: <u>Routine Monitoring</u>: Monitor serum triglycerides, fluid and electrolyte status, blood glucose, liver and kidney function, coagulation parameters, and complete blood count including platelets throughout treatment. <u>Essential Fatty Acids</u>: Monitoring patients for laboratory evidence of essential fatty acid deficiency (EFAD) is recommended. Laboratory tests are available to determine serum fatty acids levels. Reference values should be consulted to help determine adequacy of essential fatty acid status.
- Interference with Laboratory Tests: The lipids contained in Omegaven may interfere with some laboratory blood tests (e.g., hemoglobin, lactate dehydrogenase, bilirubin, and oxygen saturation) if blood is sampled before lipids have cleared from the bloodstream. Lipids are normally cleared after a period of 5 to 6 hours once the lipid infusion is stopped.

#### ADVERSE REACTIONS

The most common adverse drug reactions (>15%) are: vomiting, agitation, bradycardia, apnea and viral infection.

#### **Clinical Trials Experience**

The safety database for Omegaven reflects exposure in 189 pediatric patients (19 days to 15 years of age) treated for a median of 14 weeks (3 days to 8 years) in two clinical trials.

Adverse reactions that occurred in more than 5% of patients who received Omegaven and with a higher incidence than the comparator group are: vomiting, agitation, bradycardia, apnea, viral infection, erythema, rash, abscess, neutropenia, hypertonia and incision site erythema. Patients had a complicated medical and surgical history prior to receiving Omegaven treatment and the mortality was 13%. Underlying clinical conditions prior to the initiation of Omegaven therapy included prematurity, low birth weight, necrotizing enterocolitis, short bowel syndrome, ventilator dependence, coagulopathy, intraventricular hemorrhage, and sepsis.

Twelve (6%) Omegaven-treated patients were listed for liver transplantation (1 patient was listed 18 days before treatment, and 11 patients after a median of 42 days [range: 2 days to 8 months] of treatment); 9 (5%) received a transplant after a median of 121 days (range: 25 days to 6 months) of treatment, and 3 (2%) were taken off the waiting list because cholestasis resolved.

One hundred thirteen (60%) Omegaven-treated patients reached DBil levels less than 2 mg/dL and AST or ALT levels less than 3 times the upper limit of normal, with median AST and ALT levels for Omegaven-treated patients at 89 and 65 U/L, respectively, by the end of the study.

Median hemoglobin levels and platelet counts for Omegaven-treated patients at baseline were 10.2 g/dL and 173 x  $10^{9}$ /L, and by the end of the study these levels were 10.5 g/dL and 217 x  $10^{9}$ /L, respectively. Adverse reactions associated with bleeding were experienced by 74 (39%) of Omegaven-treated patients.

Median glucose levels at baseline and the end of the study were 86 and 87 mg/dL for Omegaven-treated patients, respectively. Hyperglycemia was experienced by 13 (7%) Omegaven-treated patients. Median triglyceride levels at baseline and the end of the study were 121 mg/dL and 72 mg/dL for Omegaven-treated patients respectively. Hypertriglyceridemia was experienced by 5 (3%) Omegaven-treated patients.

The triene:tetraene (Mead acid:arachidonic acid) ratio was used to monitor essential fatty acid status in Omegaven-treated patients only in Study 1 (n = 123). The median triene:tetraene ratio was 0.02 (interquartile range: 0.01 to 0.03) at both baseline and the end of the study. Blood samples for analysis may have been drawn while the lipid emulsion was being infused and patients received enteral or oral nutrition.

#### Postmarketing Experience

The following adverse reaction has been identified with use of Omegaven in another country. Life-threatening hemorrhage following a central venous catheter change was reported in a 9 month-old infant with intestinal failure who received PN with Omegaven as the sole lipid source; he had no prior history of bleeding, coagulopathy, or portal hypertension.

## To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC, at 1-800-551-7176, option 5, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

#### DRUG INTERACTIONS

Prolonged bleeding time has been reported in patients taking antiplatelet agents or anticoagulants and oral omega-3 fatty acids. Periodically monitor bleeding time in patients receiving Omegaven and concomitant antiplatelet agents or anticoagulants.

#### USE IN SPECIFIC POPULATIONS

 Pregnancy: There are no available data on Omegaven use in pregnant women to establish a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Animal reproduction studies have not been conducted with fish oil triglycerides. The estimated background risk of major birth defects and miscarriage in the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

 Lactation: No data available regarding the presence of fish oil triglycerides from Omegaven in human milk, the effects on the breastfed infant, or the effects on milk production. Lactating women receiving oral omega-3 fatty acids have been shown to have higher levels of omega-3 fatty acids in their milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Omegaven, and any potential adverse effects of Omegaven on the breastfed infant.

 Pediatric Use: The safety of Omegaven was established in 189 pediatric patients (19 days to 15 years of age). The most common adverse reactions in Omegaven-treated patients were vomiting, agitation, bradycardia, apnea and viral infection.

• Geriatric Use: Clinical trials of Omegaven did not include patients 65 years of age and older.

#### OVERDOSE

In the event of an overdose, fat overload syndrome may occur. Stop the infusion of Omegaven until triglyceride levels have normalized and any symptoms have abated. The effects are usually reversible by stopping the lipid infusion. If medically appropriate, further intervention may be indicated. Lipids are not dialyzable from serum.

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# UV-A in the NICU: New Technology for an Old Challenge

#### JA Brons MSc, R White MD, MS Rea PhD

#### Abstract:

Healthcare-associated infections (HAIs) are a serious concern in the NICU. Alternatives or supplements to manual cleaning are increasingly being explored, including ultraviolet (UV) disinfection technologies. A recently-developed hybrid lighting system technology, designed to provide both visible white light and disinfecting UV-A ( $\lambda$  max = 366 nm) radiation, was retrofitted into a hospital newborn intensive care unit (NICU). The UV-A dosing was set to levels calculated to be safe for continuous adult occupation. The results showed that eight-hour exposures of 3 W m-2 on counter surfaces were effective for suppressing bacteria that commonly cause HAIs in the NICU. Although UV-A is not as effective at inactivating viruses as UV-C, it is safe for use while space is occupied, making it a promising technology for consideration in certain areas of the NICU.

#### Keywords: Ultraviolet UV-A germicidal disinfection irradiation; No-touch cleaning; Healthcare-acquired infections (HAIs); Newborn intensive care unit (NICU)

#### Introduction

Approximately 1 in 25 patients in the United States contract healthcare-associated infections (HAIs).(1) Patients are particularly at risk if the previous patient in that room had an infection.(2, 3) Standard cleaning procedures usually involve the manual application of detergents, and disinfectants.(4) The efficacy of these manual cleaning procedures can vary considerably among hospitals.(5, 6) In fact, less than 50% of the patient room surfaces are properly cleaned.(1)

Given the incomplete effectiveness of manual cleaning, alternative, so-called, no-touch methods have been examined with the expectation that decontamination of room surfaces will improve when the human element has been removed. Among these notouch methods, the efficacy of short-wavelength optical radiation, from ultraviolet (UV) to blue light (100 to 410 nm), has been studied.(7-9) Short wavelengths can inactivate pathogens through two main mechanisms, depending upon the wavelength, duration, and amount of optical radiation(10) as well as the type of pathogen. The direct mechanism involves alterations to DNA or RNA following absorption by UV-C so that the pathogen can no longer replicate. The indirect mechanism involves the absorption of UV-C, UV-B, UV-A, or blue light by chromophores inside or outside the pathogen. These radiation-altered chromophores cause secondary reactions, which, like the direct mechanism, can inactivate replication, but more commonly, they produce chemical reactions that disable the virus, bacterium, or fungus. The efficacy of a given UV dose (intensity x duration) against a given pathogen depends upon the presence or absence of a cell wall, the thickness of the cell wall, and the type of nucleic acid.(11) Generally, airborne viruses require lower doses for inactivation than bacteria and fungi, by one or two orders of magnitude. COVID-19, for example, is a single-stranded RNA virus with relatively high cell wall transmissivity to UV-C. In contrast, many bacteria and especially fungi, have double-stranded DNA and low cell wall transmissivity to UV-C (e.g., Candida paraposilosis).

UV-C produced by low-pressure discharge lamps (Xmax ≈ 254 nm) been used for many decades to inactivate airborne pathogens. More recently, it has been implemented on mobile platforms that move about the hospital room through remote control to disinfect surfaces. The advantage of UV-C technologies for minimizing HAIs is that effective dosage can be achieved with short time durations (<1 hour);(12) the disadvantage of UV-C is that the optical radiation must be applied when the hospital room is unoccupied. For UV-A and blue light applications, several hours of Exposure may be needed to reduce pathogen presence effectively, but, depending upon the wavelength and dose, people can occupy the room without harm. It should be emphasized, however, that all UV technologies are line-of-sight technologies. This means that disinfection can only occur from direct irradiation by the UV source. This works well for airborne pathogens, but those pathogens on shadowed surfaces, such as under a cabinet, will not be affected during UV application.

"With regard to human safety, Exposure to UV-A can cause erythema of the skin (reddening). For wavelengths longer than about 350 nm, however, erythemal effects are negligible.(13) Exposure to short wavelengths longer than about 380 nm can cause permanent damage to the retina; this phenomenon is known as blue light hazard.(14)"

With regard to human safety, Exposure to UV-A can cause erythema of the skin (reddening). For wavelengths longer than about 350 nm, however, erythemal effects are negligible.(13) Exposure to short wavelengths longer than about 380 nm can cause permanent damage to the retina; this phenomenon is known as blue light hazard.(14) Unlike erythemal effects, which depend upon irradiance on the skin, the radiance of the source imaged on the

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retina must be minimized to avoid the blue light hazard,(14, 15) So unless the source is extremely bright, little damage to the retina will occur from blue light exposure. According to industry standard safety recommendations(16) then, exposures to UV-A wavelengths between about 350 and 380 nm can be considered safe for humans at doses that would still be effective for reducing HAI pathogens. Safe exposures of UV-A for infants has not, however, been defined.

The present field study was designed to evaluate a hybrid lighting technology that could provide both visible white light and UV-A optical radiation. The site for the study was a recently-built newborn intensive care unit (NICU). The researchers assessed the efficacy of UV-A exposure for mitigating pathogens found in this unit. Occupant exposure safety was implemented by applying published safety limits(16) for UV-A exposures and confirmed through radiometric measurement. For more information about this study, see Brons et al.(17)

#### **Study Site**

This field study was conducted in the NICU at Memorial Beacon Children's Hospital in South Bend, Indiana, USA. This 39-bed NICU provides an advanced level of care for babies born prematurely or with a critical illness. The facility was designed and built in 2017 to minimize an institutional appearance. For example, rather than caring for multiple babies in one ward, premature babies have private patient rooms (Figure 1). These patient rooms include a private lounge, sleeping, and bathing facilities for each family. Each patient room has a separate sink and counter surface for families and medical staff. The sink and counter area in the patient rooms were the primary focus for assessing UV-A mitigation of pathogens because these high-touch areas are most likely to contain HAIs. The study was conducted in six of the NICU patient rooms (Figure 1).

#### Cleaning

Nurses work 12-hour shifts, either 07:00 to 19:00 or 19:00 to 07:00. At the start of each shift (morning and night), nurses clean

the sink and counters (PDI Super Sani-cloth germicidal disposable wipes). Once a day, environmental cleaning crews attempt to sanitize the many surfaces in each patient room, including the sink area (Diversey Oxivir 1 Wipes); environmental cleaning staff are not responsible for cleaning the counters.

"Each patient room has a separate sink and counter surface for families and medical staff. The sink and counter area in the patient rooms were the primary focus for assessing UV-A mitigation of pathogens because these high-touch areas are most likely to contain HAIs."

#### Methodology

#### Hybrid Luminaires

The hybrid luminaires ("Lumination" LBU 22 Disinfection Series D-Light, manufactured by GE Current, a Daintree company) were surface mounted in the patient rooms above the counter and sink areas after the existing luminaires in that area were removed. The hybrid luminaires had two circuits that could be operated independently (Figure 2). White light was provided by conventional light-emitting diodes (LEDs) controlled by the occupant using a dimmable wall switch. The UV-A LEDs were controlled by the manufacturer on a separate circuit using a remotely programmed time clock; the UV-A circuit was set to operate on Wednesdays and Thursdays for 8 hours (09:30 to 17:30). The spectral power distributions (SPDs) of the two luminaire channels are shown in Figure 3. The hybrid luminaires produced a diffuse intensity distribution.



Figure 1. Typical patient room sink and counter, before retrofit with a hybrid lighting system; each patient room serves one family and their infant(s).



Figure 2. Typical sink and counter space with the hybrid lighting system, providing white light (left) UV-A (center) and both (right). The UV-A and the white light could be energized with separate circuits.



Figure 3. Relative SPDs of the two hybrid lighting LED channels, UV-A ( $\lambda$ max = 366 nm) and white light

#### **Radiation Safety**

The manufacturer's recommendations for implementation safety relied on IEC standard 62471:2006, "Photobiological safety of lamps and lamp systems."(16) Standard 62471 gives thresholds for near-UV (UV-A; 315-400 nm), far-UV (actinic; 200-400 nm), and blue light (300-700 nm) exposures. For near UV, the irradiance limit is 10 W m-2 on the skin or at the eyes for 8 hours.

Following photometrically realistic simulations, confirmed by physical measurements, UV-A radiation emitted by the hybrid lighting system was limited to 10 W m-2 at 6 ft (2 m) above the finished floor plane, corresponding to an eye height of a very tall person. This safety limit corresponded to a UV-A irradiance level of approximately 3 W m-2 at the counter and sink heights of 3 ft (1 m) above the finished floor plane. Because Standard 62471 does not provide safety guidelines for exposures longer than 8 hours

in a single day, the duration of UV-A operation for this study was limited to 8 continuous hours per day.

#### Curtains

Despite the fact that the UV-A output was set at levels deemed safe for adults,(16) extra precautions were taken to keep direct UV-A irradiance off the infant patients during the study. Weale showed, for example, that infants' crystalline lenses transmit more UV-A than older people; thus, greater protective measures were needed for this population.(18) Short, blackout-type curtains were hung in the six patient rooms (Figure 4); the bottom of these curtains was 5 ft 5 in (1.65 m) above the floor. In addition to curtains, nursing personnel were ordered to drape baby bassinets/incubators when occupied (Figure 4).





Figure 4. Examples of curtains in two of the six patient rooms; shown in foreground of left image is a baby incubator draped in fabric.

#### Measurements

White-light illuminance and UV-A irradiance measurements were obtained at three locations in patient rooms: the sink, the nearby counter, and the far end of the counter. These were the same locations where the adenosine triphosphate (ATP) samples were collected (see Protocol, below).

Similar white-light illuminance levels were available at the sink before and after retrofit (600-700 lx). At patient room counters, illuminance levels at full output were higher after the retrofit (800 lx) than before the retrofit (450 lux).

As previously noted, the radiometric measurements confirmed the simulated irradiance level of 3 W m-2 at the primary locations (sink and counter). The measurement protocol focused on these primary locations; ancillary surfaces (e.g., counter inpatient rooms) far from the hybrid luminaires naturally had lower UV-A irradiance levels. Because the infant incubators were not close to the hybrid luminaires, extensive UV-A measurements were not undertaken of incubator interiors, but as shown in Figure 5, even when the curtains were retracted, and the incubator was directly in line with the UV-A source, the fabric inside the incubator did not fluoresce like those fabrics outside the incubator. This indicates that the visually transparent cover did not transmit UV-A. Figure 5: When curtains were retracted, the fabric on the exterior of this incubator did fluoresce, but the interior did not; this suggests that the incubator transparent cover did not transmit UV-A.

"When curtains were retracted, the fabric on the exterior of this incubator did fluoresce, but the interior did not; this suggests that the incubator transparent cover did not transmit UV-A."

#### Protocol

A one-week protocol was repeated three times in spring 2019. The white light from the hybrid luminaires provided illumination to the counters and sinks all three weeks. The UV-A radiation from the hybrid luminaire was operated for 8 hours on Wednesdays and Thursdays each week. Adenosine triphosphate (ATP) samples were collected at sink and counter locations mornings, evenings, and midnight in three occupied patient rooms and one vacant patient room.

#### **Inoculated Culture Plates**

In a separate protocol, to directly assess the efficacy of the UV-A exposures, three pathogen types were selected for study based upon the following three criteria:

- A. A pathogen previously identified as present in this NICU
- B. A pathogen identified in 2014 by the Centers for Disease Control and Prevention (CDC) as among the top 10 pathogens of concern for HAIs(19)
- C. A pathogen identified by the NICU Director as particularly problematic





Figure 5: When curtains were retracted, the fabric on the exterior of this incubator did fluoresce, but the interior did not; this suggests that the incubator transparent cover did not transmit UV-A.

The pathogens selected for the follow-up study were:

- 1. Enterococcus faecalis (E. faecalis), a bacterium that causes, most commonly, urinary tract infections. This bacterium is particularly resistant to antibiotics.
- 2. Staphylococcus aureus (S. aureus), a bacterium associated with upper respiratory infections.(20)
- 3. Escherichia coli (E. coli), a diverse group of bacteria that can cause a variety of maladies, including severe dehydration.

Cultures of a given pathogen type were divided into two groups. A control group was placed on culture plates covered with a transparent, UV-blocking cover, and an intervention group was placed on culture plates covered with the usual borosilicate, UV-transparent cover plates (Figure 6). The two groups were placed at the same locations that were selected for the previous ATP sampling. The hybrid lighting system with the UV-A source energized was operated continuously for 8 hours at approximately 3 W m-2.

Results

**ATP Sampling** 

ATP samples were obtained from three surfaces in 3-4 patient rooms for each of the three weeks. An analysis of the daily change in ATP counts was undertaken. After 8 hours of the UV-A application on Wednesdays there was a statistically significant reduction in ATP counts, with further, statistically significant reductions after 8 hours of UV-A application on Thursday. Importantly, on Friday, there was a statistically significant increase in ATP counts.

#### **Inoculated Culture Plates**

Student's one-tail t-tests comparing the UV-transmitting (intervention) and the UV-blocking (control) cultures showed statistically significant CFU reductions for E. faecalis (t,5 = -1.98, p = 0.05), S. aureus (t,3 = -3.52, p = 0.02) and E. coli. (t,3 = -12.58, p = 0.0005). Figure 7 shows these results in terms of percent CFU reduction; this shows the differential impact of the UV-A intervention relative to the control.

#### Discussion

#### **ATP Sampling**

ATP samples are routinely collected in the many units of Memorial Hospital as an inexpensive technique for quality assurance of their cleaning procedures. The hospital NICU studied here is



Figure 6. Inoculated culture plates at patient room sink (left) and counter (right); borosilicate glass covered all test plates, and additional orange-colored UV-blocking film covers each control group.

very clean, as reflected in the low ATP counts obtained during this study. Indeed, over the three weeks of the study, ATP counts were rarely over the threshold for cleanliness in this hospital. In fact, the NICU Director reported that his unit consistently receives internal recognition as one of the most consistently clean units in the hospital. To better gauge the level of cleanliness in the NICU, ATP spot checks of public areas in the hospital were sampled; those results supported the inference that this NICU is particularly clean.

"From an experimental perspective, low ATP counts made it difficult to assess the pathogen mitigation efficacy of the UV-A radiation from the hybrid lighting system. Nevertheless, support for the effectiveness of this hybrid lighting technology for killing bacteria was obtained from an analysis of the daily change in ATP counts. Without the UV-A radiation, there was no statistically reliable change in ATP counts, but there were statistically significant reductions in ATP counts following the UV-A exposures. "

From an experimental perspective, low ATP counts made it difficult to assess the pathogen mitigation efficacy of the UV-A radiation from the hybrid lighting system. Nevertheless, support for the effectiveness of this hybrid lighting technology for killing bacteria was obtained from an analysis of the daily change in ATP counts. Without the UV-A radiation, there was no statistically reliable change in ATP counts, but there were statistically significant reductions in ATP counts following the UV-A exposures. And, importantly, stopping the UV-A treatment led to a significant increase in ATP counts. After the COVID crisis abates, future demonstrations of the hybrid lighting technology are planned for hospital units with greater bio-burden. Significant reductions in pathogen counts after UV-A exposures should then be related to a reduction in HAI incidence.

#### **Inoculated Culture Plates**

The inoculated cell culture analysis was important for a variety of reasons. First, this NICU was particularly clean, making it difficult

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Figure 7. Average CFU percent reduction (1-(Intervention/Control)) following 8-hour exposures of  $\approx$ 3 W m-2 of UV-A; error bars indicate standard deviation.

to demonstrate the efficacy of the UV-A applications. Second, ATP samples do not differentiate pathogens that might cause HAIs from other organic materials. Third, a side-by-side comparison of cell culture growth, ambient lighting with and without UV-A, must be conducted to demonstrate that UV-A exposures affect pathogen growth unambiguously. Specifically, the side-by-side test conducted here showed that important pathogens identified by the CDC as problematic sources of HAIs and ones actually found in the NICU were directly abated by the UV-A applications actually used in the present field study.

#### Conclusions

The field study described here was the first to examine the efficacy of UV-A for reducing pathogens in the context of a working hospital. The hybrid lighting system used in the present study could independently emit visible white light, UV-A radiation, or both. A series of analyses support the inference that the UV-A radiation will reduce the burden of HAIs in doses set to minimize negative health effects for adult occupants (max = 10 W m-2 for 8 hours). The hybrid lighting system is safe to operate in occupied spaces under the radiation restrictions described here, but long-term and collateral effects on materials, and people need to be carefully tested before it should be widely adopted.

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## Fellow Column: Self-Adherent Elastic Wrap Dressing Injury in a Neonate

Federica C. Williams, MD, Shabih Manzar, MD

#### Summary:

Due to delicate skin, injuries secondary to the use of peripheral intravenous (PIV) catheters are not uncommon in neonates. We present a case of hand injury secondary to the use of a tight elastic band used to secure the PIV.

Keywords: Hand injury, elastic dressing, neonate

#### Case:

The newborn male infant was born to a 19-year-old G1P1001 female at 38 weeks 6 days gestation by vaginal delivery. Apgar Scores were at 1 and 5 minutes were 8 and 9, respectively. Mother had adequate prenatal care with pregnancy complicated by anemia in the third trimester, pyelectasis, and echogenic intracardiac focus on prenatal ultrasound (resolved on subsequent ultrasounds). Mother was admitted to the Labor Unit and developed increasing temperatures approximately 7 hours prior to delivery. The maximum temperature was 101.3F, 1.5 hours before delivery. She was started on ampicillin and gentamicin. She was also given acetaminophen once prior to delivery. She was GBS negative; therefore, she did not require penicillin prophylaxis. Delivery was augmented by vacuum extraction. Skin to skin was deferred, and the baby was taken to the newborn nursery.

The baby transitioned without any significant signs of infection except an initial temperature of 102.4F that decreased to 98.7F in one hour. He remained afebrile thereafter. A septic workup was collected (complete blood count with differential, CRP, and blood culture), and intravenous antibiotics were initiated (ampicillin and gentamicin).

"The use of self-adhesive elastic wraps has helped in securing these IV sites. Unfortunately, the proper care and surveillance of the site are critical to optimizing care and outcomes. In the nursery, IV sites are not monitored as frequently as in the NICU, which can possibly endanger the infant with potential complications."

#### **Newborn Nursery Course:**

While preparing for discharge after 48 hours of monitoring and antibiotics, the IV was removed from the right hand. The right hand (specifically the thumb) was noticeably swollen and blistered with what appeared to be a constriction injury from the self-adherent elastic wrap holding the IV in place (Figure- Day 1a-d). A decision was made to hold the discharge and watch the patient overnight in the nursery. Overnight, at least one of the blisters was noted to have ruptured and drained yellow fluid. The swelling worsened and became tenser; however, some of the bruising and the thumb indentation improved. A subsequent decision was made to transfer the baby to the NICU for antibiotics and further workup with labs and cultures.

#### NICU course:

The infant was started on IV vancomycin, which was switched to oral Clindamycin. The infant continued to tolerate oral feedings well. A gradual improvement was noted (Figure Day 2, 3, and 5). The wound service was consulted, and they concurred with the plan. The infant was discharged home on day 5 of life on oral Clindamycin with close follow up.

#### Discussion:

A spectrum of cases has been reported ranging from swelling, ischemia, and gangrene in association with bandage and dressings. (1-5) In our case, we noted local effects in the form of irritation and blister formation. Fortunately, we were able to decompress it in time, saving the baby from any untoward complications. Maintaining a usable IV site is a work of art. The use of self-adhesive elastic wraps has helped in securing these IV sites. Unfortunately, the proper care and surveillance of the site are critical to optimizing care and outcomes. In the nursery, IV sites are not monitored as frequently as in the NICU, which can possibly endanger the infant with potential complications.

There is plenty to learn from this unique care. Surveillance of the IV site must take priority. Protocols may need to be adjusted for site checks every four to six hours instead of twelve hours. Ac-



Figure 1: Showing the progression and improvement over time (Day 1 to 5)

Day 5: At discharge



Day 3: Infant is the NICU

Day 2 (a-b): Infant admitted in the NICU





Day 2-a

Day 1 (a-d): Infant in the nursery



Figure

curate and thorough documentation must also take place. This is key because the patient remained stable clinically, and there were no signs of infection, distress, or instability noted in labs or vitals. Finding other ways to secure these IV sites is also of utmost importance to prevent future constriction injuries that could lead to amputation from digital ischemia.

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- Submission should be from a resident, fellow, or NNP in training.
- Topics may include Perinatology, Neonatology, and Younger Pediatric patients.
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# SAFETY IN THE NICU

New tubes, new problems?

A new tubing design meant to eliminate tubing misconnections has introduced new challenges for the NICU population. Pediatric

providers must deliver medication in small volumes to tiny patients with high levels of accuracy. The new tubing design, known as ENFit<sup>®</sup>, could present dosing accuracy and workflow challenges.



#### DOSING ACCURACY

 The moat, or area around the syringe barrel, is difficult to clear. Medication can hide there, inadvertently increasing the delivered dose when the syringe and feeding tube are connected; patients may receive extra medication.

#### **INFECTION RISK**

• The moat design can increase risk for infection if residual breast milk or formula remains in the moat and transfers to the feeding tube.

#### WORKFLOW ISSUES

 Increased nursing workflow is seen with additional steps for clearing syringe moats, cleaning tube hubs, and using multiple connectors.

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# Examining the Benefits of Paternal Involvement and Breaking the Myths Surrounding Fathers

Barb Himes, IBCLC



#### Saving babies. Supporting families.

First Candle's efforts to support families during their most difficult times and provide new answers to help other families avoid the tragedy of the loss of their baby are without parallel.

#### Introduction

Sudden Unexplained Infant Death (SUID), which includes Sudden Infant Death Syndrome (SIDS) and accidental suffocation and strangulation in bed (ASSB), remains the leading cause of death for babies one month to one year of age, resulting in 3,600 infant deaths nationwide each year. This is despite the National Institute of Health's Back to Sleep campaign launched in 1994, based on sale sleep guidelines from the American Academy of Pediatrics (AAP), which led to an initial 50% reduction in the SIDS mortality rate.

That this remains the case is an indication of the complexities involved in maternal and infant health, both behavioral and physical. First Candle was a part of the Back to Sleep campaign collaboration and has made the AAP guidelines -- supine sleep on a firm surface, alone, with no bed-sharing or extraneous bed sharing -- the foundation of its Straight Talk for Infant Safe Sleep training program, working with community agencies and health care providers to educate families about the importance of an infant safe sleep environment. changed, but SUID rates have also quadrupled since 1984 and are three times greater in Black communities, and research and observation reveal implicit bias in the health care community as a barrier, coupled with cultural and socioeconomic factors that favor bed-sharing and other at-risk sleep environments.

This bias may tend to be maternally focused, but it may also lead practitioners to disregard the potential importance of fathers.

#### The Value of Paternal Involvement

Paternal involvement has been shown to have an impact on pregnancy and infant outcomes, (1) including a positive effect on maternal health behaviors and reduced risk of preterm birth, low birth weight, and infant mortality up to one year after birth. But fathers may be overlooked, especially in Black families.

As an illustration, breastfeeding has been associated with a reduction in SIDS deaths (2) and research also indicates that paternal involvement can have a positive effect on breastfeeding, (3) but Black infants are 21% less likely to have ever been breastfed than any other ethnicity, and only 68% of Black women try breastfeeding after giving birth, compared to 85.7 % of white women and 84.8 % percent of Hispanic women. In Michigan, for example, 77.3% of Black women start breastfeeding, and 35.2% continue to three months.(4)

"Paternal involvement has been shown to have an impact on pregnancy and infant outcomes, including a positive effect on maternal health behaviors and reduced risk of preterm birth, low birth weight, and infant mortality up to one year after birth. But fathers may be overlooked, especially in Black families."

Peter M. Williams, BPA, CHW, CLC, a Fatherhood Community Health Worker in the Detroit Health Department, is addressing this first-hand, through community outreach regarding the role of fathers and working with fathers themselves.

Not only has the national SIDS death rate not substantially

"There are misconceptions about fathers, especially those in Black



Did you know that premature and low birth weight babies have a 4x greater risk for SIDS?

At First Candle we're educating parents, grandparents and caregivers about safer sleep to make sure all babies reach their first birthday. Learn more at firstcandle.org communities," Williams said. "The birthing process has been traditionally mom-focused, with dads seen as a sort of on the edge of things and maybe not interested in becoming involved."

Williams has conducted focus groups with fathers, where they tell him they want to be involved with the children at the outset, but that they also needed help in navigating the system.

"Back then,' fathers were expected to wait down the hall during delivery, and if they were allowed in, they were expected to stay out of the way and watch. Now they can be invited into the delivery room and may even cut the umbilical cord," he said. "But the keyword here is invited. Men familiar with the traditional viewpoint around childbirth may feel pregnancy and childbirth is a womenowned realm and may feel they need permission to participate."

"Williams has conducted focus groups with fathers, where they tell him they want to be involved with the children at the outset, but that they also needed help in navigating the system."

This includes involvement from the outset, in prenatal meetings all the way through the birthing process and maternal and infant support through the first year of life and beyond.

"If they have brought the mother in for her prenatal check-up but are sitting in the waiting room, ask them if they would like to join the meeting. And then talk to them when they are there and enlist their partnership," Williams said.

"For instance, the number one reason women stop breastfeeding is they think they are not making enough milk for the baby because the infant seems constantly hungry," he said. "But we know it is because a newborn baby's stomach is the size of a cherry. A father can help reassure the mother that she is doing everything all right. He can be a source of strength and protection for her during both delivery and the post-natal period, by understanding what is happening and what she and the baby need. And he is there to claim his own dad and baby feeding and bonding time."

Williams also leads Daddies' Café, supported by the WIC Division of the Detroit Health Department. The all-male meetings include a discussion on infant safe sleep and a presentation on breastfeeding basics, as well as open discussion.

"Until you learn more about breast milk, you believe what you hear in ads that say formula is the next best thing," Williams said. "Since a dad's primary responsibility is to protect and provide, when dads know more about breastfeeding, they are better equipped to assist from day one."

Williams notes that what the fathers his program works with come to understand is straightforward:

• You and your opinions matter.

- Your baby deserves the health benefits of breastfeeding.
- Mom is more likely to breastfeed and do so for longer, with your support.
- You are in a position to protect the skin-to-skin, nursing, and bonding space for mom at both the hospital and at home.
- You should also make time for your own skin-to-skin contact, nursing, and bonding time.

#### The Role of the Health Care Provider in Recognizing Bias

Since the gatekeeper for access to paternal involvement may be health care providers, it is important for the pre- and perinatal health care community to:

- Recognize and understand your own biases. (For example, Teaching Tolerance offers a self-test on hidden bias.) (5)
- Determine if you have misconceptions about dad's role and his role at the hospital.
- Reflect on men's wants and needs in this process.
- Be careful not to automatically marginalize or exclude them from participation.
- Understand that men might not always say upfront what they want.

We know from our work with Peter Williams and other colleagues who are doing paternal outreach, and from the barriers we uncover in our Straight Talk for Infant Safe Sleep, that empathy and inclusion for fathers and partners are central factors to gaining acceptance of infant safe sleep and breastfeeding practices, and therefore central to reducing infant mortality in the first year of life.

Information on First Candle and its <u>bereavement support services</u> can be found on the <u>First Candle website</u>. The Grief Support Line is 1-800-221-7437.

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Disclosure: The author is the Director of Education and



Bereavement Services of First Candle, Inc., a Connecticut not for profit 501c3 corporation.

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In January, heaven gained a new angel -Laura Reno.

Laura was a SIDS mom and a guiding force at First Candle.

She worked tirelessly to end SIDS and was a source of comfort for many of our berieved families.

Laura will be greatly missed.



Through the darkness of my grief I light a candle to show the world my love for you.

At First Candle we provide bereavement support to the over 27,000 families who will experience the loss of a baby every year.

We need your support. Click here to help.



# The Survey says RSV



What you need to know about RSV



Really Serious Virus

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# 3

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Let them know the difference they are making in our babies' lives. Write a note, send an email, or deliver a gift to show them that you appreciate them.



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#### This project is a collaboration between



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### **Raising Global Awareness of RSV**

Global awareness about respiratory syncytial virus (RSV) is lacking. RSV is a relatively unknown virus that causes respiratory tract infections. It is currently the second leading cause of death – after malaria – during infancy in low- and middle-income countries.

The RSV Research Group from professor Louis Bont, pediatric infectious disease specialist in the University Medical Centre Utrecht, the Netherlands, has recently launched an RSV Mortality Awareness Campaign during the 5<sup>th</sup> RSV Vaccines for the World Conference in Accra, Ghana.

They have produced a personal video entitled "Why we should all know about RSV" about Simone van Wyck, a mother who lost her son due to RSV. The video is available at <u>www.rsvgold.com/awareness</u> and can also be watched using the QR code on this page. Please share the video with your colleagues, family, and friends to help raise awareness about this global health problem.





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### Flying Blind Why Are We Not Recognizing Air Trapping (Even with "The Jet")

Rob Graham, R.R.T./N.R.C.P.

I dedicate this column to the late Dr. Andrew (Andy) Shennan, the founder of the perinatal program at Women's College Hospital (now at Sunnybrook Health Sciences Centre). To my teacher, my mentor and the man I owe my career as it is to, thank you. You have earned your place where there are no hospitals and no NICUs, where all the babies do is laugh and giggle and sleep.

The path to chronic lung disease (CLD) in the premature infant is not a path at all; it is a map. As in ancient times, all roads lead to CLD, the Rome of pulmonary outcomes. While some of these paths can be avoided some of the time, and (one hopes) some paths can be avoided all of the time, rarely does one path alone lead to CLD.

We can leave runaway inflammatory responses to pharmacists and physiologists to treat or one day prevent, but mechanical ventilation is a key trigger in that response. As clinicians, we often have little training and relatively crude tools at our disposal to assess the presence of gas trapping. Along with inadequate evidence to support what become "gut feelings" about mechanical ventilation over the course of a career, and then there are institutional biases.

Medicine has used and learned from the aviation industry to improve safety, emulating checklists, for example. What we have been slower to adopt is the attitude in the proverbial cockpit; that is speaking up when something is wrong or does not look right, even if it means taking over from the right-hand seat.

"The military, top-down style of leadership in medicine lingers even today; trainees and new hires are reluctant to question the "old guard" even when their guts are telling them they should be."

This change from the culture of "the Captain is God" was necessitated by many crashes which, when analyzed, could have been prevented if a subordinate, seeing something wrong, had voiced their concern and/or taken over flying the plane. The military, topdown style of leadership in medicine lingers even today; trainees and new hires are reluctant to question the "old guard" even when their guts are telling them they should be. In the vernacular of respiratory therapy, we call it "drinking the Kool-Aid®." There is all too much of the drink to go around; it is nutritionally void, an impediment to safety and progress, and serves the field of medicine no better than it did aviation.

My tombstone will undoubtedly read, "It is gas trapping," for the words cross my lips more times than I can count. July has arrived with its requisite new crop of fellows and residents. I will sound like a broken record.

It is my firm belief that gas trapping is one of the most significant contributors to CLD. Physics dictate how much gas can travel through a tube in a given amount of time; playing with pressure will increase volume, but will not change the time at which it can deliver it. That is the time constant.

A myriad of factors contributes to gas trapping in the micro-premature infant. The predominant one is the tiny radius of their airways; another is the minute volume required to ventilate and oxygenate using conventional modes of ventilation (CV). As the rate is increased, the ventilation cycle shortens, leaving less time both to fill the lungs and to empty them. If the volume is increased either by adjusting target volume or increasing pressure, the time required for that volume to exit remains constant, but the time available for that to happen gets shorter. Larger volumes create shear stress, which in turn triggers an inflammatory cascade. High pressures easily damage fragile conducting airways, creating places for gas to escape on entry where it lies trapped in the pleural cavity without contributing to ventilation. Eventually, it forces the diaphragm down, giving the appearance of hyperinflation on chests films. (figure 1)



Figure 1: Chest film showing hyperinflation, however, note the haziness of the lung fields. Decreasing PEEP resulted in a marked increase in FiO2 requirements, which dramatically decreased when PEEP was increased, suggesting gas trapping. MAP <10 (Image used with permission.)

Adherence to proper lung-protective ventilation strategies can mitigate this damage. The most important is the "open lung" approach to ventilation. This ideal can only be achieved by assessing and providing sufficient mean airway pressure (MAP) to maintain functional residual capacity (FRC), which maintains optimum compliance. It is important to revisit this regularly, as even the most careful CV causes damage that may impact compliance. As compliance decreases, more MAP is required to maintain it and to maintain airway patency. This only works until cardiovascular compromise occurs, and as MAP increases, so does the risk of impairing cerebral blood return.

"As compliance decreases, more MAP is required to maintain it and to maintain airway patency. This only works until cardiovascular compromise occurs, and as MAP increases, so does the risk of impairing cerebral blood return."

In CV, the problem with increasing MAP (usually by increasing PEEP) is that peak inspiratory pressures often rise as well, increasing the risk of airway rupture. This is where high-frequency modes offer help. Both high-frequency oscillation (HFO) and high-frequency jet ventilation (HFJV) pressures rapidly attenuate as they progress down the airways, and both modes are effective in removing  $CO_2$ .

Time is not on our side when ventilating with HFO. Here gas trap-

ping is the most common problem, whether from "pinch points" created using high amplitude and inadequate MAP or because the typical 1:2 inspiratory/expiratory (I:E) ratio does not provide enough time for gas to exit, even with active exhalation. (figure 2) Decreasing frequency can help, but without the ability to monitor delivered volumes, it is risky; careful adjustment of amplitude is required so as not to give too much volume. If I:E ratio can be adjusted independently, increasing to 1:3 may help if it is a matter of expiratory time, provided the resulting increased amplitude does not create pinch points.

What about HFJV? With a fixed inspiratory time (Ti) and I:E ratio as high as 1:12, much more time is available both for expiration and spontaneous breathing. Gas traveling in both directions simultaneously (called bi-directional double-helical flow) in HFJV also helps.

Speaking of spontaneous breathing, it is worth noting that air trapping can occur on nasal CPAP and even a spontaneously breathing infant, as can CLD.

The proximity of the jet ventilator's pressure port and the algorithm used to interpret it provide us an approximation of what positive end-expiratory pressure (PEEP) is at the distal endotracheal tube (ETT). As the value of PEEP measured on the jet ventilator approaches the value set on the slave ventilator, gas trapping is highly suspected. Should jet-measured PEEP be higher than set, gas trapping is definitely occurring.

With these extra tools, why do I say we are flying blind? In HFJV, the machine reports estimated distal ETT pressure, which gives an average view of the situation. It cannot, however, tell you if re-

### CHOKE POINTS may develop when:



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gional gas trapping is occurring. Regional gas trapping eventually leads to the same outcome as overall gas trapping; regional hyperinflation impedes upon adjacent areas. This, in turn, collapses airways (particularly on expiration) and creates gas trapping in them as well. In the end, the picture is the same.

A new ventilator (Drager VN-500®) used as a slave for the jet ventilator perplexed users because the slave machine's measured PEEP was lower than set PEEP. It was thought at first that there was a flaw in the jet ventilator, an unseen leak in the circuit, or a problem with the slave machine itself. It turned out none of those were the case.

PEEP is, by definition, the pressure at the end of expiration, and before inspiration occurs, the lowest pressure present. This is what the slave machine was accurately reporting; the lowest pressure sensed in the circuit. Why was this so different than what the jet was reporting?

The jet measures the pressure between jet breaths. The slave machine reports the lowest pressure it senses. Because the jet breath creates a momentary decrease in pressure behind it, entrainment occurs, much like a truck passing by with a tail of debris swept up and briefly following it. There is no broom; it is the relative vacuum created as the truck passes. This raises the possibility that gas trapping is occurring earlier than we have previously thought.

"That an extreme micro-prem is experiencing gas trapping should be assumed unless proven otherwise; the consequences are too dire."

That an extreme micro-prem is experiencing gas trapping should be assumed unless proven otherwise; the consequences are too dire. Anti-gas trapping measures should be taken early, predominantly lower rates with HFJV and preferably lower frequencies in HFO if available devices provide volume monitoring. Sufficient PEEP in HFJV and MAP in HFO are vitally important.

Chest imaging is a clumsy tool in the assessment of air trapping. At first, the lungs may look wonderful, even over-inflated, as trapped volume steadily increases. The appearance of hyperinflation often leads clinicians to decrease distending pressure. This is only helpful if the lungs are actually hyperinflated from that pressure; if gas trapping is the culprit, the results are not good. As extra-luminal gas collects in the pleural space, it begins to compress airways and alveoli alike. Compromised airways lead to more gas trapping and more apparent hyperinflation, creating a vicious cycle. Eventually, imaging shows completely de-recruited "whited out" lungs. It is a double whammy at this point since the lungs are most prone to injury during the re-recruitment process, and atelectasis will likely have triggered a cytokine cascade.

There are clinical signs when gas trapping may be occurring. The appearance of hyperinflation with low PEEP/MAP (PEEPS < 7-8 in HFJV or MAP < 8-9 with HFO) is one. These pressures are unlikely to cause hyperinflation: consider MAP in CV is considerably higher. Paradoxically, it is probably more PEEP/MAP the lungs require, not less. Another is amplitude or inspiratory pressure. Should more amplitude or peak pressure be required to maintain ventilation after PEEP/MAP has been decreased, it is a clear sign that compliance has been compromised, and previous settings should be restored.

Fear of pressure remains common in clinical practice. It is worth remembering that there is a considerable difference in MAP between CV and HVO or HFJV. In the "old days," infants were typically started on a rate of 60, peak pressure of 20 cmH₂O, PEEP of 5 cmH<sub>2</sub>O, and Ti of 0.4 seconds. These settings produce a MAP of approximately 11 cmH<sub>2</sub>O. A MAP of 10 cmH<sub>2</sub>O is a typical starting point using HFO, lower than pressures previously used initially with CV. Furthermore, with high-frequency modes of ventilation, the lungs are subjected to far lower shear forces due to rapid pressure attenuation and smaller volumes. In a unit using high-frequency modes exclusively, such as the one I practice in, we have forgotten about the typical CV MAP. The way MAP is achieved is more relevant when discussing lung damage than the number itself, particularly if aiming for ventilatory efficiency. (see June's column) PEEP is the safest, most effective way of providing, maintaining, and increasing MAP.

It is unlikely we will ever be able to eliminate gas trapping in our tiniest patients. The best we can do is acknowledge it and the danger it presents, and act appropriately to minimize injury.

Disclosures: The author receives compensation from Bunnell Inc for teaching and training users of the LifePulse HFJV in Canada. He is not involved in sales or marketing of the device nor does he receive more than per diem compensation. Also, while the author practices within Sunnybrook H.S.C. this paper should not be construed as Sunnybrook policy per se. This article contains elements considered "off label" as well as maneuvers, which may sometimes be very effective but come with inherent risks. As with any therapy, the risk-benefit ratio must be carefully considered before they are initiated.

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- Access to RSV preventive treatment for all premature infants as indicated on the FDA label
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August 9, 1996 - April 3, 2010



Each year, the Emily Shane Foundation SEA(Successful Educational Achievement) Program provides academic and mentoring support to over 100 disadvantaged middle school students who risk failure and have no other recourse. We have served over 700 children across Los Angeles since our inception in the spring of 2012. Due to the COVID-19 outbreak, our work is in jeopardy, and the need for our work is greatly increased. The media has highlighted the dire impact online learning has caused for the very population we serve; those less fortunate. **We need your help now more than ever to ensure another child is not left behind.** 

> Make a Difference in the Life of a Student in Need Today! Please visit <u>emilyshane.org</u>

### Sponsor a Child in the SEA Program

The average cost for the program to provide a mentor/ tutor for one child is listed below.



1 session	\$15
1 week	\$30
1 month	\$120
1 semester	\$540
1 year	\$1,080
Middle School	\$3,240

The Emily Shane Foundation is a 501(c)3 nonprofit charity, Tax id # 27-3789582. Our flagship SEA (Successful Educational Achievement) Program is a unique educational initiative that provides essential mentoring/tutoring to disadvantaged middle school children across Los Angeles and Ventura counties. All proceeds directly fund the SEA Program, making a difference in the lives of the students we serve.



### NPA Position Statement: Coping During COVID-19 Free Resources for Your NICU from the National Network of NICU Psychologists (NNNP)

Sage N. Saxton, PsyD, Allison G. Dempsey, PhD

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

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



Educate. Advocate. Integrate.

The National Network of NICU Psychologists (NNNP), a recently reorganized suborganization of the National Perinatal Association, has over 65 members across 19 states. The NNNP strives to be the leading voice and resource for mental health services in NICU settings. We believe that national collaboration among NICU psychologist is essential to state-of-the-art education, clinical research, and advocacy for policy development and change. As a group, we provide mentorship to those entering our profession and advocate for the role of psychologists and other mental health professionals in the NICU setting.

In response to the emergent infant, caregiver, and staff/provider mental health needs in the midst of the COVID-19 pandemic, we have created three handouts to promote wellness for NICU families and providers. The handouts cover the following topics: "Bonding with Your Baby During the COVID-19 Pandemic," "Caregiv-

Readers can also follow NEONATOLOGY TODAY via our Twitter Feed ONEOTODAY ers Need Care Too During The COVID-19 Pandemic," and "Helping Children and Families Cope With Having a Baby in the NICU During the COVID-19 Pandemic". We hope you use these tools to support improved models of care in your NICUs during this time. Please feel free to distribute it widely.

These handouts are also available on our website: <u>www.nationalperinatal.org/psy-chologists</u>

Members of the NNNP are also hosting/ attending regular peer mentoring calls to discuss topics related to mental health services in NICUs during the pandemic. We invite any psychologists working in the NICU and/or related settings to join the NNNP. If interested in joining our efforts, please visit our website <u>www.nationalperinatal.org/psychologists</u>

Disclosure: The National Perinatal Association <u>www.nationalperinatal.org</u> is a 501c3 organization that provides education and advocacy around issues affecting the health of mothers, babies, and families.

NT





FREE RESOURCES FOR YOUR NICU

Newly-Validated Online NICU Staff Education



Transform Your NICU

### Caring for Babies and their Families: Providing Psychosocial Support to NICU Parents

based on the "Interdisciplinary Recommendations for Psychosocial Support for NICU Parents."

Contact sara@mynicunetwork.com for more information.

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- National Perinatal Association
  - Patient + Family CarePreemie Parent Alliance





nationalperinatal.org/psychologists

## BONDING WITH YOUR BABY

### DURING THE COVID-19 PANDEMIC



Being separated from your baby is challenging no matter the circumstances. Being separated because your baby needs intensive care in the NICU especially stressful.

Now, because of the risks of COVID-19 infection are so serious, the **rules about visitation** have changed. **When you visit the NICU things will not look the same** as they did before the pandemic. We are all doing our best to learn what we need to do to stay safe and protect each other.



#### Life is also different outside of the NICU. Daily routines

have changed. Meeting our basic needs is harder. The people we go to for love and support may be far away. We understand this, but we want you to know that you and your baby will be ok.

You and your baby have a special bond. This bond gives your baby a sense of security, forms the basis for learning and development, and sets the stage for future healthy relationships.

This bond and attachment will continue to grow even if you sometimes have to be apart.

### HERE ARE SOME IDEAS FOR BONDING WITH YOUR BABY DURING THE COVID-19 PANDEMIC.



### WHEN YOU'RE AT THE HOSPITAL

- Touch your baby. When you touch your baby it releases positive hormones for both of you that decrease stress and increase feelings of attachment. You and your baby's medical team can figure out the best way to touch your baby based on their medical condition. It may be supportive touch, bundled holding, or skin-to-skin care (also called kangaroo care).
- **Do as much of your baby's routine care as possible.** Each time you help your baby by changing their diaper, feeding them, bathing them, taking their temperature, or doing mouth care you will feel more connected to your baby. Ask for help as needed as you get more comfortable doing these care tasks.







### WHEN YOU'RE AT THE HOSPITAL continued

- Have a "mindfulness moment" with your baby. While you are touching your baby, focus in on one body part at a time, such as baby's hands. Notice each detail of how they look and feel while you are touching them. Pay attention to the smell of your baby's skin. Look at each tiny nail and finger one at a time. Take your time as you look at and appreciate each little part.
- Talk to your baby. Babies recognize their parents' voices and find them comforting. Talking to your baby can help you feel more connected. Talk about your day or what you see baby doing.
- **Create a hello and good-bye routine.** Each time you come to the NICU greet your baby in the same way with a gentle touch and kind words. Before you leave, read your baby a book or sing them a favorite song, and again offer a special, loving touch.



- **Take pictures of your baby** each time you visit to document this moment in time and see their progress. You can share these pictures with the people who love them and use them to think about baby when you are away from the hospital.
- Exchange scent cloths. Scent cloths are a piece of fabric that you use to pick up someone's scent. You can use two square or heart shaped pieces of fabric, or any other piece of cotton fabric that has been washed in scent-free detergent.



Keep one near your skin, tucked in your shirt, to pick up your scent. Leave one in the isolette or crib to pick up baby's scent. **Then swap the cloths so baby has one that smells like you, and you take the one home that smells like baby.** Babies have a well-developed sense of smell and recognize their parents this way. **Smelling your scent will comfort your baby when you are away.** 

• Bring a family picture or sibling's drawings to keep near your baby's bed space. Even though baby is not looking at the pictures it can help bring your family closer to baby and reminds everyone who sees it who they are helping to take care of.

### WHEN YOU'RE AT THE HOSPITAL continued

 Teach people about your baby's likes and dislikes. Partner with your baby's nurse and create a list of what you have noticed that your baby likes and does not like. This could include use of a pacifier for support, comforting touch your baby likes, and care tasks that are harder for baby, so staff knows to provide more support at these times.





### WHEN YOU'RE AWAY

- Your baby will not forget you! Many NICU parents worry that their baby will forget them if they are not at the hospital. Remember that your baby will always recognize you when you return based on your scent, voice, and familiar touch. Your baby knows the difference between you and the NICU staff based on these differences. Remind yourself that babies do not have a sense of time. They live in the moment and do not have an awareness of how long it has been since your last visit. As a parent it is hard to be away, but remember that your baby is not able to think about or worry about the time in between visits.
- Sleep with the scent cloth that smells like your baby. This will help you feel connected and has been shown to give a boost to parents' mood. Parents and siblings could all benefit from a scent cloth that smells like baby.
- Check in with NICU staff between care times. Ask for specific information about your baby's changes and activities that will help you understand what your baby's day is like. This may be by phone, video chats, or notes.
- Ask NICU staff to play a voice recording you make for baby. Record yourself talking, singing or reading to baby and ask the staff to play it during baby's daily routine.



In order to be there for your baby when you visit, it is essential to give some priority to your own self-care while you are away from the hospital.

#### Everything you do for yourself will directly benefit your baby.

You may not be able to engage in complete self-care in an ideal way right now, but improving even a little on each of these will help:

- Get as much sleep as possible. If you are pumping, ask your lactation consultant about having at least one longer stretch between pumps. Build up your sleep a little at a time. Having a set bedtime and bedtime routine can help a lot. Avoid screen time in the hour before bedtime.
- Remember to eat meals, and when you cannot eat meals, try high protein snacks.
- Have a water bottle always near to help you drink more water.
- Try one of these activities for 5-15 minutes during the day:
  - Practice deep breathing.
  - Create mindfulness exercises.
  - Go for a walk outside if possible, keeping social distance from others.
  - Take a warm bath or shower.
  - Listen to music.
  - Read a favorite book or magazine.
  - Draw or work on a coloring book.
  - Make time for your hobbies. Knit. Cook. Play games.
  - Connect virtually with a friend or another NICU parent.
  - Help someone. Ask someone for help.

### **MY SELF-CARE GOAL:**



- Ask NICU staff if seeing baby by video is possible while you are away.
- **Start a scrapbook for your baby.** Either a digital or physical scrapbook with pictures of baby's journey can help you feel connected to baby and incorporate baby's journey into your family's story. Add writing to the journal, including things that are personal for baby like how you picked baby's name, your baby's personality, and their characteristics.
- Journal about baby. Journaling can take many different forms, and can be done in a regular notebook, your phone notes, or an app (e.g. MyPreemie or My NICU Baby).
  Some ways to use a journal to help you feel closer to your baby could include:



- Write a letter to baby. Tell baby what is going on in life right now, your feelings about being separated from baby, and your hopes and dreams for the future.
- **Document** your baby's changes and developments.
- Write down a favorite quote or spiritual passage that provides guidance and reassurance.
- Write down your questions for your baby's care team, and anything that circles around and around in your mind about baby's condition.

### **NOTES:**

Find more resources at nationalperinatal.org/psychologists

### Being separated from your baby can feel unnatural and difficult.

Remember that your role in baby's life is very special and unique.

While the hospital staff is providing your baby with important medical care, **only you as your baby's primary caregiver can fill the role of parent**.

You are helping your baby feel safe and secure in a way no one else can.

Remember that you are still serving in that role even if you cannot be physically present every day.

### Your and your baby's safety come first.

It is okay during this pandemic if you need to take time apart in order to ensure everyone in your family remains safe.

### **PEOPLE AND RESOURCES THAT CAN HELP:**

Mental Health

Case Management

Community Resources

Financial Assistance

Peer Support



### HELPING CHILDREN AND FAMILIES COPE wITH HAVING A BABY IN THE NICU

### DURING THE COVID-19 PANDEMIC

Having a baby in the NICU and other children at home poses challenges even when the world is not in the middle of a pandemic. Managing the additional stressor of COVID-19 can be extremely difficult for families with NICU babies.

Here are some ways you can **help your children at home cope** with the double stressor of having a sibling in the hospital and the COVID-19 pandemic. Many of the principles related to helping your older children cope with a baby in the NICU are the same ones that can help them cope with COVID-19.

### cope ital ed to e the

### DURING ANY TRAUMATIC SITUATION, SOME OF OUR MOST BASIC NEEDS MUST BE MET:

• Coping with the unknown: It's hard to feel safe when you don't know what will happen. This is true for both your baby's NICU stay and the COVID-19 pandemic. Coping with the unknown is incredibly stressful, but can be made more bearable by talking about what we do have control over - and sharing the burden together in loving and supportive relationships. This is true for children and adults.



• **Physical safety:** Explain that the reason that you can't visit the NICU together or as often is that the hospital is keeping things safer for the babies, families, and staff.



### Remind your children that the baby is getting the care they need from professionals in the NICU.

Even though it's hard to be separated, the NICU is a safest place for the baby to be right now. Similarly, reassure your children that you and your family are all well and taking precautions to remain healthy. When the baby is ready to come home you will take care of them and the baby.

Explain to your children all the things you are doing to keep your family and our community safe, like washing our hands (for at least 20 seconds with soap and water), covering our coughs and sneezes, and staying home as much as we can. Remind children that if they get sick you will take care of them. Tell that that if you get sick people will help you.



• **Emotional safety:** A first and essential step involves sharing honest, accurate, and developmentally appropriate information about the NICU and about COVID-19.

Kids can generally sense when there's a secret and often will not talk about something they think is off limits. Giving them **information** and the **opportunity to ask questions** and **talk about their thoughts and feelings** allows them to understand what is and isn't happening.

When things are unknown or unsayable **children often fear the worst**. This is why they need to talk things through in a safe space with a loving and comforting caregiver. Even the youngest children can understand that the baby was born too early, with a problem that needs special attention (cardiac, or other surgical problem) and they need time and medical help to get well enough to come home.



If the baby is very sick, you can tell siblings that you're not sure what will happen but that the baby is getting everything they need to help them get better to get better. **Our job is to do** everything we can to make sure the baby knows we love them - no matter what happens.

Similarly, **provide information about COVID-19 that is based on facts.** Choose where you will receive your information (CDC, NIH, WHO, AAP) and share the information that helps your child understand the symptoms, transmission, and ho to take preventive measures.

Check in with your children regularly to see how they are feeling and what new thoughts or questions they have about the NICU and COVID-19.

Your kids may need extra love, reassurance, patience, and gentleness right now. So will you. This is not easy. We will all have a hard time. It ok if you're feeling angry, frustrated, and sad. It's also ok to have times when you feel happy. **Do what you can to be a little extra gentle with yourself and everyone around you during this difficult time.** 

There are lots of ways to help your children at home feel connected to the new baby. Ask your NICU staff if there are ways to have virtual visits. **Ask if you can FaceTime with your baby from home** so your family can see, talk to, and read stories to the baby. The voices babies hear in utero can be comforting to them during the NICU stay.

Another option for older children is to **draw a picture** for the baby and send it to your NICU in a plastic ziploc bag (that can be disinfected as needed), or send **black and white photos** in plastic bags for the babies over 32 weeks to see their family members while helping with their eye development during this time.



### CAREGIVERS NEED CARE TOO

### DURING THE COVID-19 PANDEMIC

Healthcare providers are used to working under challenging, highpressure conditions, but you now face extraordinary circumstances at work, at home, and in the world at large.

You're worried about the safety of your patients, your family, and yourself. **These concerns are real, appropriate, and expected.** 

At a time when so many things are out of our control it's helpful to identify the things we can control even when the rest of the world feels uncertain.

It is more important than ever for you to care for yourself. The way you do this may look radically different from what you did in the past. You may need new strategies.



### HERE ARE SOME TIPS FOR STAYING GROUNDED DURING THIS UNIQUE TIME:

SOCIAL

#### Good health habits are critical.

Protect your sleep routines. Maintain good nutrition and hydration. Get sunlight and fresh air. It will help your body stay on track.

#### **Keep moving!**

Walk your dog. Take a movement break at work. Try a new online exercise class. Physical activity is an essential tool for managing stress and regulating moods.

#### Build a support system.

Look for ways to stay connected with friends and family, whether near or far. Show love by both giving and getting help.

#### Teamwork is key.

Talk with coworkers. Nurture those bonds. Your colleagues may be in the best position to understand the pressures you're facing.



#### Breathe.

Our breath is the only stress response we can control. Slow down and pay attention. Meditation and yoga are great ways to practice being aware of your body's needs.

#### **Practice self-compassion.**

Now is not the time to remodel your house or learn a new language. Maintaining the status quo is more than enough!

### Create predictability.

Embrace familiar routines that help you restore a sense of normalcy and stability.

#### **Re-center.**

Make time to reflect - and rejuvenate. Create physical and virtual spaces where you can surround yourself with the sights, sounds, and smells that ground you.



### Find more resources at nationalperinatal.org/psychologists

NNNP is a program of the National Perinatal Association.

ENVIRONMENTAL

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COVID-19

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### National Network of NICU Psychologists FREE for our NICU COMMUNITY

- Helping Children and Families Cope
- Bonding with Your Baby
- Caregivers Need Care Too



#### Download at www.nationalperinatal.org/psychologists



www.nationalperinatal.org/psychologists

### FREE RESOURCES for your NICU

- Helping Children and Families Cope
- Bonding with Your Baby
- Caregivers Need Care Too

**OVID-19** 



## SHARED DECISION-MAKING **PROTECTS MOTHERS + INFANTS**

**DURING COVID-19** 

### **KEEPING MOTHERS + INFANTS TOGETHER**

Means balancing the risks of...

- HORIZONTAL INFECTION
- SEPARATION AND TRAUMA



### **EVIDENCE**

We encourage families and clinicians to remain diligent in learning up-to-date evidence.

### PARTNERSHIP

What is the best for this unique dyad?

SHARFD **DECISION-MAKING** 

S EEK PARTICIPATION **H** ELP EXPLORE OPTIONS A SSESS PREFERENCES **R** EACH A DECISION **F** VALUATE THE DECISION





### **TRAUMA-INFORMED**

Both parents and providers are confronting significant...

- FEAR
- GRIEF
- UNCERTAINTY

### LONGITUDINAL DATA

We need to understand more about outcomes for mothers and infants exposed to COVID-19, with special attention to:

MENTAL HEALTH
POSTPARTUM CARE DELIVERY



NEW DATA EMERGE DAILY. NANN AND NPA ENCOURAGE PERINATAL CARE PROVIDERS TO ENGAGE IN CANDID CONVERSATIONS WITH PREGNANT PARENTS PRIOR TO DELIVERY REGARDING RISKS, BENEFITS, LIMITATIONS, AND REALISTIC EXPECTATIONS.

### Partnering for patient-centered care when it matters most.



Association of



nationalperinatal.org nann.org

## **NICU** Awareness



### Educate. Advocate. Integrate.

### **Did You Know?**

Most NICU babies have special needs that last longer than their NICU stay. Many will have special health and developmental needs that last a lifetime. But support is available.

Learn about the programs in your community. Seek out other families like yours. Then ask for help. Working together we can create a community where our children will grow and thrive.

### Special Health Needs

Babies who have had a NICU stay are more likely to need specialized care after they go home. **Timely follow-up care is important.** 

NICU babies have a higher risk for re-hospitalization. So every medical appointment is important. Especially during cold and flu season when these babies are especially vulnerable to respiratory infections.

### Who Can Help

- pediatricians
- neonatal therapists
- pulmonologists
- neurologists
- gastroenterologists
- cardiologists
- nutritionists
- CSHCN Programs for Children with Special Health Care Needs

### Special Developmental Needs

### Any NICU stay can interrupt a baby's growth and development.

Needing specialized medical care often means that they are separated from their parents and from normal nurturing.

While most NICU graduates will meet all their milestones in the expected developmental progression, It is typical for them to be delayed. This is especially true for preterm infants who are still "catching up" and should be understood to be developing at their "adjusted age."

### Who Can Help

- IBCLCs and lactation consultants
- Early Childhood Interventionists
- developmental pediatricians
- occupational therapists (OTs)
- physical therapists (PTs)
- speech therapists (SLPs)
- WIC Special Supplemental Nutrition Program for Women, Infants, and Children
- social workers and case managers

### Special Educational Needs

Every child has their own unique developmental needs and **every student has their own unique and special educational needs**.

Take advantage of the services and support that can meet your child where that are and help them reach their future educational goals.

Call your local school district to request a free educational evaluation. Learn about all the available programs and support.

### Who Can Help

- Preschool Program for Children with Disabilities (PPCD)
- Special Education programs under the Individuals with Disabilities Education Act (IDEA)
- educational psychologists
- speech therapists (SLPs)
- occupational therapists (OTs)
- reading specialists





## Online NICU Staff Education Program

### Caring for Babies and their Families: Providing Psychosocial Support in the NICU

WWW.MYNICUNETWORK.COM



Looking to improve NICU staff skills in communicating with and supporting parents?

This educational program works!

Read the study by Hall et all in Advances in Neonatal Care, published online in 2019.

### **COMING SOON!**

Ask us about our 2-lesson Annual Refresher Program, developed to maintain annual nursing competencies

Continuing education credits provided by



#### NATIONAL PERINATAL ASSOCIATION PROTECT YOUR FAMILY FROM **RESPIRATORY VIRUSES CORONAVIRUS** flu coronavirus COVID-19 RELIABLE pertussis RSV **RESOURCES:** CDC: 2019 Novel Coronavirus • The Lancet: COVID-19 and pregnancy WASH YOUR HANDS often with soap and MotherToBaby: Coronaviruses warm water. • WHO: Emerging respiratory viruses SOA Serinatal STAY INFORMED. GET VACCINATED www.nationalperinatal.org for flu and pertussis. Ask about protective injections for RSV. Readers can also follow NEONATOLOGY TODAY COVER COUGHS via our Twitter Feed AND SNEEZES. Sneeze and cough **@NEOTODAY** into your elbow. USE AN ALCOHOL-BASED HAND SANITIZER. **STAY AWAY** FROM SICK PEOPLE Avoid crowds.

Protect vulnerable babies and children.



www.nationalperinatal.org

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# DID YOU KNOW? Postpartum dependence of fathers



### www.nationalperinatal.org/mental\_health

### THE BRETT TASHMAN FOUNDATION

The Brett Tashman Foundation is a 501©(3) public charity. The mission of the Foundation is to find a cure for Desmoplastic Small Cell Round Tumors (DSRCT). DSRCT is an aggressive pediatric cancer for which there is no cure and no standard treatment. 100 percent of your gift will be used for research. There is no paid staff. To make your gift or for more information, go to "TheBrettTashmanFoundation.org" or phone (909) 981-1530.

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### The Gap Baby: An RSV Story



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



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

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

www.infanthealth.org



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Peer Reviewed

### **COVID-19 Update: Impact on Children's Hospitals**

Gavin Clingham, Director of Public Policy, and the AfPA Governmental Affairs Team, Alliance for Patient Access (AfPA)

The Alliance for Patient Access (allianceforpatientaccess.org), founded in 2006, is a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care. AfPA accomplishes this mission by recruiting, training and mobilizing policy-minded physicians to be effective advocates for patient access. AfPA is organized as a non-profit 501(c)(4) corporation and headed by an independent board of directors. Its physician leadership is supported by policy advocacy management and public affairs consultants. In 2012, AfPA established the Institute for Patient Access (IfPA), a related 501(c) (3) non-profit corporation. In keeping with its mission to promote a better understanding of the benefits of the physician-patient relationship in the provision of quality healthcare, IfPA sponsors policy research and educational programming.

# Alliance of Patient Access

Now several months into the COVID-19 pandemic in the United States, health care experts are beginning to learn more about the virus's health implication and how it spreads. We are also learning more about the impact on the health care system.

Congress has acted several times to provide funding and equipment to health care providers, hospitals, and others impacted by this crisis. Are Children's hospitals getting their share?

#### Impact on Health Care System

At the very time hospitals and health care providers are most needed, these very systems are being starved of the resources required to ensure ongoing quality care. That challenge is particularly acute for Children's hospitals.

Many states have issued orders suspending elective medical procedures forcing hospitals to cancel or delay care. States have also issued stay at home orders, and many patients have been reluctant to seek treatment, concerned about being exposed to COVID-19 in a hospital setting. Further, the costs of testing and PPE have increased in all medical settings.

These factors combine in reduced revenue and increased costs to the very facilities that are most needed during this crisis.

#### **Federal Response**

Recognizing the strain on the health care system, Congress and the Department of Health and Human Services (HHS) responded by providing new large federal funding resources to augment funding that these facilities already receive.

To date, Congress appropriated more than \$175 billion for hospitals and other providers nationwide to prevent, prepare for, and respond to COVID-19. Eligible expenses include lost revenues from canceled procedures, building new structures or retrofitting existing buildings, purchasing supplies, training staff, and other COVID-19-related costs.

"To date, Congress appropriated more than \$175 billion for hospitals and other providers nationwide to prevent, prepare for, and respond to COVID-19. Eligible expenses include lost revenues from canceled procedures, building new structures or retrofitting existing buildings, purchasing supplies, training staff, and other COVID-19related costs."

In March, Congress passed The Coronavirus Aid, Relief, and Economic Security (CARES) Act that provided an initial \$100 billion, and then Congress added \$75 billion to the fund through the next legislative package, the Paycheck Protection Program Increase Act of 2020.

HHS has been distributing this needed funding, but the formula mainly used reflects a facility's existing Medicare population as well as the number of COVID-19 patients treated. Unfortunately, this distribution does not adequately reach Children's hospitals due to their different patient and payor environment. This mismatch is despite the reality that Children's hospitals have seen the

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same treatment restrictions and reduction in services performed.

#### Impact on Children's Hospitals

Children's hospitals differ from other for-profit and non-profit hospitals in that they do not treat the Medicare population to the same extent. In fact, Medicaid is the payor for more than 50% of all **patient volume.** 

Because Children's hospitals do not provide care for older adults, they do not benefit from remediation through Medicare, either in the form of relief from the sequester, increased reimbursement for COVID-19 patients, or access to Medicare advance payments.

According to The Children's Hospital Association, as of June: "Of the more than \$190 billion in COVID-19 relief funding allocated to health care providers to date, children's hospitals have received less than 1%. This number is alarming and puts at risk the important role they serve in our communities."

https://www.childrenshospitals.org/Newsroom/Press-Releases/2020/HHS-Distribution-of-CARES-Act-to-Date-Has-Overlooked-Our-Nations-Childrens-Hospitals

"According to The Children's Hospital Association, as of June: "Of the more than \$190 billion in COVID-19 relief funding allocated to health care providers to date, children's hospitals have received less than 1%. This number is alarming and puts at risk the important role they serve in our communities."

#### Support for Children's Hospitals

Support for providing direct funding to these facilities is growing. Industry associations such as the Children's Hospital Association are joining with individual hospitals to make their case to elected officials that support is badly needed and should be provided. This advocacy has resulted in numerous Congressional led letters to Senate and House leadership and directly to HHS Secretary Azar.

https://www.childrenshospitals.org/Issues-and-Advocacy/Medicaid/Letters-and-Testimony/2020/COVID19-funding-for-childrens-





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#### hospitals-support-letters

The letters request that existing funding be made available to Children's hospitals, but also that new funding be provided in the next legislative package.

#### Conclusion

Children's hospitals play an essential role in our health care system and treat and care for our most vulnerable children. They are also the only health care sector not to receive significant federal funding support during the COVID-19 crisis.

These hospitals face the same fiscal challenges as other facilities, increased costs, limits on elective procedures, and the public's reluctance to seek care during the pandemic and need support. Congress will consider a new aid package this month and should ensure the entire health care system receives the necessary support to maintain robust care.

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#### The author has not indicated any disclosures.



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### NATIONAL PERINATAL ASSOCIATION

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RELIABLE RESOURCES:

- CDC: 2019 Novel Coronavirus
- The Lancet: COVID-19 and pregnancy
- MotherToBaby: Coronaviruses
- WHO: Emerging respiratory viruses

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### Respiratory Syncytial Virus is a

# Really Serious Virus

Here's what you need to watch for this RSV season



Association

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### PROTECT YOUR FAMILY FROM RESPIRATORY VIRUSES

flu 📕

coronavirus





WASH YOUR HANDS

often with soap and warm water.

GET VACCINATED

SOA

for flu and pertussis. Ask about protective injections for RSV.



# +

### COVER COUGHS AND SNEEZES.

Sneeze and cough into your elbow.

USE AN ALCOHOL-BASED HAND SANITIZER.



### STAY AWAY FROM SICK PEOPLE

Avoid crowds. Protect vulnerable babies and children.



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# Respiratory Syncytial Virus:

How you can advocate for babies this RSV season



Survey Says: RSV



#### But Parents are Unprepared.

themselves "very well" prepared to prevent RSV

Only 18% know "a lot" about RSV

RSV EDUCATION & AWARENESS CAN HELP After parents learned more about RSV, they were:



64

\*See the NPA's evidence-based guidelines at www.nationalperinatal.org/rsv

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NEONATOLOGY TODAY www.NeonatologyToday.net July 2020

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### Regarding AAP Guidance for School Re-Opening, An Open Letter to Dr. Goza

Julia Koehler, MD

Boston, July 5, 2020

Dear Dr. Goza,

I hope this message finds you well. Thank you so much for your tireless work for our Academy and on behalf of all children in this time of enormous challenges.

I am writing as the chair of the Immigrant Health Committee of the Massachusetts Chapter of the AAP, and as a Pediatric Infectious Disease specialist. I was also a founding member of the Immigrant Health Special Interest Group and a member of its national steering committee. I am writing today to respectfully express serious concerns around our Academy's document, "COVID-19 Planning Considerations: Guidance for School Re-entry. June 25, 2020" (Guidance).

*"I am writing today to respectfully express serious concerns around our Academy's document, "COVID-19 Planning Considerations: Guidance for School Re-entry. June 25, 2020" (Guidance)."* 

My major concerns are:

- 1. That assumptions about SARS-CoV-2 infections in pediatric populations, for which evidence is insufficient at best, are stated as facts in this guidance;
- 2. That the guidance lacks consideration of the stark differences between schools in wealthy and in white school districts compared to those in poor, Black, Native American or immigrant communities; and
- 3. That the guidance was written without engaging other professionals in the schools, with whom we as pediatricians will do well to maintain a mutually informative, supportive, and respectful dialog.

This AAP Guidance has been used as the basis of a school reopening plan for Massachusetts that was published on 6/25/20. The Massachusetts school reopening plan raised alarm in immigrant communities and among teachers. Of this plan, a Black teacher said that she "feels that she and her colleagues are again being used as subjects in a Tuskegee-like experiment." I hope as an Academy we can reconsider and create a revised school reopening guidance more firmly based in scientific rigor, and that promotes racial justice by protecting the communities that have been <u>hardest hit by COVID-19</u>, (1) whose parents now fear that their children will be infected in school and will bring the virus home.

The physical presence of children in school is certainly a crucial goal. But achieving this goal at the expense of the protection of children, and by extension of their families and communities, from infection with SARS-CoV-2, will only further exacerbate the devastatingly unequal harm, by income, race, and ethnicity, that the pandemic has inflicted across the country. School districts in poor and in Black, Native American, and immigrant communities will most likely avail themselves of the justification provided by our Academy's Guidance to space desks as close as 3 feet together and to bring large numbers of students into single classrooms, thereby increasing the potential for viral transmission. 493 educators have already been laid off in Massachusetts in 3 under-resourced school districts alone, and the AAP Guidance will now be used to support holding classes with 30 or more students by the fewer remaining teachers. Educators in these classrooms will be placed at risk, while in wealthy towns parents will most likely ensure that students return to class only when physical distancing of at least 6 feet (as recommended by the CDC) and small class sizes of 10-15 students can be strictly adhered to - the strict adherence to a specific size of student groups that the guidance discourages.

A revised guidance document would include considerations delineated in the following.

Regarding concern # 1, those assumptions about SARS-CoV-2 infections in pediatric populations, for which evidence is insufficient, are stated as facts: a low risk of infection and disease in children is claimed in the guidance. The experience of the last six months does, in fact, show that children are more likely to be asymptomatically infected and are much less likely to develop severe acute COVID-19 than adults. However, the consequences of asymptomatic infection of children, some of whom develop radiographic evidence of pneumonia, are not yet known. Concern for CNS sequelae of infections with endemic coronaviruses has been raised. (2) As we now know, a small number of SARS-CoV-2 infected children go on to develop a life-threatening inflammatory state, MIS-C, (3) whose long-term sequelae remain to be discovered. Also, as endemic coronaviruses often co-infect children with other respiratory viruses, (4) we do not yet know how co-infection with SARS-CoV-2 and viruses like influenza, metapneumovirus and RSV will impact children when school openings and the beginning of the cold season coincide.

Very rare complications like MIS-C and open questions about asyet-unknown long-term sequelae will be less relevant when viral transmission in the community is low. In school districts with high viral transmission, however, risk-benefit considerations will need to reflect a higher likelihood of rare events. A one-size-fits-all state-



ment cannot reassure parents who want their children to learn and to be safe, and who are torn between their need to get back to work and fear of their child and their family being harmed by the coronavirus contracted in school.

The fact that children become infected with SARS-CoV-2 at substantial rates was underscored by one of the largest detailed studies from China with known index cases that introduced infections into families. Despite being one of the largest, this recent study (5) still comprises only 43 infected children <14 years of age among 314 families with children experiencing exposure to an index case. In this study, the incidence of infection in children exposed to an index case was 13% versus 21% in exposed adults; the infection rate of children hence was 60% that of adults, which cannot be dismissed as insignificant.

"In this study, the incidence of infection in children exposed to an index case was 13% versus 21% in exposed adults; the infection rate of children hence was 60% that of adults, which cannot be dismissed as insignificant."

Since daycare centers and schools were closed in jurisdictions experiencing significant COVID-19 outbreaks, the potential for children infected in these settings to bring SARS-CoV-2 into their families is not known. Large-scale studies investigating the likelihood of transmission from infected children to other children and adults are still lacking. Attempting to estimate the infectivity of children for their contacts, because of an impending government decision regarding reopening of schools, a prominent virology laboratory in Germany recently found that respiratory tract viral loads of children and adults did not differ; (6) previously, the same group had found that viral load detected by <u>RT-PCR correlated</u> with infectivity for tissue culture cells. (7) These workers concluded that children may be as infectious as adults to their contacts.

Concerningly, a <u>research paper published in our Academy's jour-</u> nal, (8) cited by a <u>commentary</u>, also in <u>Pediatrics</u>, (9) draws a sweeping conclusion from very weak data. Specifically, the researchers, as well as the commentators, concluded that transmission rates of SARS-CoV2 from children to adults are low. This conclusion was based on findings of 39 COVID-19-symptomatic hospitalized children, whose family members were queried for the timing of COVID-19-symptom onset. In 3/39 children, all household members developed symptoms after the index child. This result was stated as "In only 8% (3/39) of households did the study child develop symptoms prior to any other HHC (household contact)." However, the report's Figure 1 shows that in another five children, adult household contacts became symptomatic simultaneously with or after the index children. Hence in total 8/39 (20%) children's adult household contacts' symptoms began at the same time or after those of the index children. And in another six children, household pediatric siblings became symptomatic before the index children. The investigators did not state actual days of symptom onset relative to the index child cases; only "before, simultaneously and after" were recorded. It is known that the incubation period of COVID-19 can be substantially longer in children than in adults. One of the first reports on pediatric CO-VID-19, (10) which appeared on 2/28/20, already noted a longer incubation period in children compared with adults. This observation was confirmed in subsequent investigations, most recently in Hua et al., (5) where children's COVID-19 incubation periods ranged from 5 to 21 days, with a mean of 9 days, i.e., ~4 days longer than the mean incubation time typically observed in adults. Hence conclusions on directionality of viral transmission between children and adults cannot be based on timing of symptom onset, especially when the information regarding this timing is as vague as in Posfay-Barbe et al. In other words, a girl who became symptomatic after her parent became sick may still have infected the parent during her asymptomatic incubation period. As recently noted in a Perspectives article in the journal Science, "infected individuals can be highly contagious for several days, peaking on or before symptoms occur." (11) It is estimated that 79% of CO-VID-19 patients in Wuhan, whose infection was documented by testing, were infected by asymptomatic individuals with unknown infection status. (12)

Of note, as mentioned before, the SARS-CoV-2 transmission events examined by Posfay-Barbe et al. occurred during a time period in Geneva, Switzerland, when schools were closed. Even disregarding its small sample size and failure of the investigators to record symptom onset days of the study subjects, the setting of this study precludes simple extrapolation of its findings to communities in which schools are open.

The statement in the guidance (p.2), "children may be less likely to become infected and to spread infection," hence is insufficiently supported by the available data. Similarly, the statement "evidence suggests that spacing as close as 3 feet may approach the benefits of 6 feet of space, particularly if students are wearing face coverings and are asymptomatic" (p. 2 of the guidance) marshals thin theoretical considerations alone, but has no basis in epidemiological studies: such studies do not exist.

The statement, "infection via aerosols and fomites is less likely," (p. 4 of the guidance) is not accurate, and equating these two

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THE BRETT TASHMAN FOUNDATION

The Brett Tashman Foundation is a 501©(3) public charity. The mission of the Foundation is to find a cure for Desmoplastic Small Cell Round Tumors (DSRCT). DSRCT is an aggressive pediatric cancer for which there is no cure and no standard treatment. 100 percent of your gift will be used for research. There is no paid staff. To make your gift or for more information, go to "TheBrettTashmanFoundation.org" or phone (909) 981-1530. modes of transmission generates confusion. Infection via fomites has, in fact, not been demonstrated convincingly, though its theoretical risk is the basis for the ubiquitous and appropriately cautionary, exhortations for hand washing, as well as the mandate to sanitize surfaces in the guidance. In contrast, there is a <u>large body</u> <u>of evidence</u> supporting viral transmission via aerosols. (13) Aerosol transmission is highly significant, according to many researchers, like the authors of a recent epidemiologic study published by Proceedings of the National Academy of Sciences entitled <u>"Identifying airborne transmission as the dominant route for the spread</u> <u>of COVID-19"</u>. (14) This point has been stated for scientific as well as lay audiences for months. (11)

The consensus around airborne transmission of SARS-CoV-2 that is now accepted among nationally recognized Infectious Disease experts is reflected in their responses to interview questions like that published 7/3/20 in the Washington Post, e.g. Dr. Anthony Fauci's of the NIAID and Dr. Elizabeth Connick's of University of Arizona responses <u>regarding eating in restaurants</u>: "Fauci: We don't do anything inside. I don't eat in restaurants. (15) We do get takeout. Connick: No, no restaurants. I avoid any closed space with a lot of people, particularly when it's people whose risk I don't know. I think the biggest risk is being in a closed space and breathing the same air that other people are breathing, and also not wearing masks. I wouldn't go even if they were wearing masks."

Similarly, standard expert advice regarding social gatherings, as in a <u>7/3/20 article in the New York Times</u>, emphasizes that outdoor gatherings are much safer than those held indoors. (16) This would make no sense if aerosol transmission did not play a significant role in SARS-CoV-2 infection, since aerosols containing SARS-CoV-2 are quickly diluted by air currents outdoors, but indoors can build up to high densities over time.

The significant risk of aerosol transmission from asymptomatically infected children or school staff should also inform the revision of statements like "strict adherence to a specific size of student groups (eg, 10 per classroom, 15 per classroom, etc) should be discouraged" (p.2, Guidance) and "the risk reduction of reducing class sizes in elementary school-aged children may be outweighed by the challenge of doing so" (p.3, Guidance). Limiting student group sizes while keeping classrooms well ventilated through open windows and doors, in fact, can play a possibly significant role in risk reduction. The challenge of doing so is posed by the stark resource deprivations from which poor school districts suffer. These deprivations are due only to political decisions that have normalized structural racism and class-based withholding of educational resources. Accepting them as given legitimizes not only the educational losses that millions of children in this country suffer but now may even force these children and their families to accept an increased infection risk with SARS-CoV-2 as the price for going to school at all.

Regarding concern # 2, that the guidance lacks consideration of the stark differences between schools in wealthy and in white school districts compared to those in poor, Black, Native American or immigrant communities, the guidance itself cites "growing concerns about systemic racial inequity" (p. 9). Hence as an Academy, we would do well to guard against implicitly facilitating harsh further systemic racial inequity by which some children will be far less protected from infection than others. <u>As Dr. Martin Luther King said</u>, "Of all the forms of inequality, injustice in health is the most shocking and the most inhuman." (17) Justifying less safe school environments for poor, Black, Native American, and immigrant children by setting a bar that is significantly lower than precautions that high-income white school districts and their parents will likely enforce inflicts an injustice in health that I am certain runs counter to the intentions of the Academy.

Regarding concern #3, we as pediatricians would do well to include the professionals that work in schools impacted by the Academy's Guidance in the conversation and to establish respectful and mutually informative dialogs. Pediatricians' own children are unlikely to attend the under-resourced schools whose further deprivation this guidance may be used to justify. Lacking first-hand information, we may easily overlook the facts on the ground that require advocacy for drastically improving resources for these schools, including the higher staff-to-student ratio required for safe school environments in the pandemic. Teachers, school nurses, and other educators must be our partners in the endeavor to create a protective and fruitful educational environment for all students. Of note, their children are our patients too and will suffer if their parents become ill with COVID-19. In this way, we can contribute to the work to relieve the harsh neglect and starvation for resources that poor Black, Native American, and immigrant school children have suffered unrelentingly over the past century.

Detailed guidance on how schools can be made safer for students and staff, acknowledging that COVID-19 transmission risk can never be completely eliminated, is available from multiple sources, e.g., in the June 5 publication of the Harvard School of Public Health "Schools for Health: Risk Reduction Strategies for Reopening Schools" (available at <u>https://schools.forhealth.org/</u> wp-content/uploads/sites/19/2020/06/Harvard-Healthy-Buildings-Program-Schools-For-Health-Reopening-Covid19-June2020. pdf). (18) Making schools safer for all children will not be possible in many communities with current funding formulas. Now is the time to invest in schools, their buildings, and their staff, contributing to remedy the deeply unjust underfunding of so many children's education while addressing the employment losses that are

"Now is the time to invest in schools, their buildings, and their staff, contributing to remedy the deeply unjust underfunding of so many children's education while addressing the employment losses that are devastating the nation."

#### devastating the nation.

In summary, the truly crucial goal that students attend classes in person would best not be pursued by providing justification for conditions in schools that run counter to CDC recommendations, scientific evidence or consensus of nationally respected Infectious Disease experts and that parents in wealthy school districts are



unlikely to accept. Let us not accept lower safety standards that can be unjustly imposed on the communities already hardest hit by COVID-19. Scientific rigor ought not to be sacrificed in pursuit of expediency along the path of least resistance. Cautious school reopening accompanied by a simultaneous collection of data, and readiness to modify practices in response to research results, will best satisfy both the need for children to be present in school and their right to stay safe. As pediatricians, let us start with the best interests, health, and well-being of all children and continue to advocate until their needs are met, partnering with other professionals that share our goals. If this requires confronting entrenched systemic racism and class-based deprivation, we as pediatricians can muster the moral courage to do so, since we are tasked with

"As pediatricians, let us start with the best interests, health, and well-being of all children and continue to advocate until their needs are met, partnering with other professionals that share our goals. If this requires confronting entrenched systemic racism and classbased deprivation, we as pediatricians can muster the moral courage to do so, since we are tasked with standing up for the rising generations."

standing up for the rising generations.

Based on these considerations, I respectfully ask the appropriate bodies of our Academy to reconsider the document "COVID-19 Planning Considerations: Guidance for School Re-entry. June 25, 2020." In the meantime, I will ask my chapter to withdraw the endorsement of the Massachusetts guidelines based on this document. Please consider this an open letter as I intend to share it broadly with others for whom these issues may be relevant.

Thank you very much in advance for your consideration of this message. I look forward to hearing from you.

Sincerely,

Julia Koehler, MD Associate Physician in Pediatrics Division of Infectious Disease, Boston Children's Hospital Assistant Professor of Pediatrics, Harvard Medical School

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#### The author has no conflicts to disclose

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Compiled and Reviewed by Mitchell Goldstein, MD Editor in Chief

## Experimental COVID-19 vaccine safe, generates immune response

NIH-sponsored Phase 1 trial tested mRNA vaccine.

#### Tuesday, July 14, 2020

An investigational vaccine, mRNA-1273, designed to protect against SARS-CoV-2, the virus that causes coronavirus disease 2019 (COVID-19), was generally well tolerated and prompted neutralizing antibody activity in healthy adults, according to interim results published online today in The New England Journal of Medicine. The ongoing Phase 1 trial is supported by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. The experimental vaccine is being co-developed by researchers at NIAID and at Moderna, Inc. of Cambridge, Massachusetts. Manufactured by Moderna, mRNA-1273 is designed to induce neutralizing antibodies directed at a portion of the coronavirus "spike" protein, which the virus uses to bind to and enter human cells.

The trial was led by Lisa A. Jackson, M.D., MPH, of Kaiser Permanente Washington Health Research Institute in Seattle, where the <u>first participant received the candidate vaccine</u> on March 16. This interim report details the initial findings from the first 45 participants ages 18 to 55 years enrolled at the study sites in Seattle and at Emory University in Atlanta. Three groups of 15 participants received two intramuscular injections, 28 days apart, of either 25, 100 or 250 micrograms (mcg) of the investigational vaccine. All the participants received one injection; 42 received both scheduled injections.

In April, the trial was expanded to enroll adults older than age 55 years; it now has 120 participants. However, the newly published results cover the 18 to 55-year age group only.

Regarding safety, no serious adverse events were reported. More than half of the participants reported fatigue, headache, chills, myalgia or pain at the injection site. Systemic adverse events were more common following the second vaccination and in those who received the highest vaccine dose. Data on side effects and immune responses at various vaccine dosages informed the doses used or planned for use in the Phase 2 and 3 clinical trials of the investigational vaccine. The interim analysis includes results of tests measuring levels of vaccine-induced neutralizing activity through day 43 after the second injection. Two doses of vaccine prompted high levels of neutralizing antibody activity that were above the average values seen in convalescent sera obtained from persons with confirmed COVID-19 disease.

A <u>Phase 2 clinical trial of mRNA-1273</u>, sponsored by Moderna, began enrollment in late May. Plans are underway to launch a Phase 3 efficacy trial in July 2020.

Additional information about the Phase 1 clinical trial design is available at <u>clinicaltrials.gov</u> using the identifier <u>NCT04283461</u>. This trial was supported in part by the NIAID grants M1AI148373 (Kaiser Permanente Washington), UM1AI148576 (Emory University) and UM1AI148684 (Infectious Diseases Clinical Research Consortium). Funding for the manufacture of mRNA-1273 Phase 1 material was provided by the Coalition for Epidemic Preparedness Innovations (CEPI).

#### Article

LA Jackson et al. A SARS-CoV-2 mRNA vaccine — preliminary report. New England Journal of Medicine. DOI: 10.1056/NEJ-Moa2022483 (2020).

#### Who

NIAID Director Anthony S. Fauci, M.D., and John Beigel, M.D., associate director for clinical research, Division of Microbiology and Infectious Diseases, NIAID, are available to discuss the results of this trial.

NIAID conducts and supports research—at NIH, throughout the United States, and worldwide—to study the causes of infectious and immune-mediated diseases, and to develop better means of preventing, diagnosing and treating these illnesses. News releases, fact sheets and other NIAID-related materials are available on the <u>NIAID website</u>.

About the National Institutes of Health (NIH): NIH, the nation's medical research agency, includes 27 Institutes and Centers and





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## THE FIFTH ANNUAL BRETT TASHMAN GOLF TOURNAMENT AND LUNCHEON

Dear Friends,

Due to COVID-19, the foundation's golf tournament and luncheon scheduled for July 18, 2020 has been cancelled.

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Institute/Center National Institute of Allergy and Infectious Diseases (NIAID)

Contact: Anne A. Oplinger 301-402-1663

NT

American Academy of Pediatrics, Section on Advancement in Therapeutics and Technology

Released: Thursday 12/13/2018 12:32 PM, updated Saturday 3/16/2019 08:38, and Sunday 11/17/2019 1020

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- Access to and ability to submit research abstracts related to advancing child health through innovations in pediatric drugs, devices, research, clinical trials and information technology; abstracts are published in Pediatrics.

AAP members can join SOATT for free. To activate your SOATT membership as an AAP member, please complete a short application at <u>http://membership.aap.org/Application/AddSectionChapterCouncil</u>.

The Section also accepts affiliate members (those holding masters or doctoral degrees or the equivalent in pharmacy or other health science concentrations that contribute toward the discovery and advancement of pediatrics and who do not otherwise qualify for membership in the AAP). Membership application for affiliates: <u>http://shop.aap.org/aap-membership/</u> then click on "Other Allied Health Providers" at the bottom of the page.

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

Mitchell Goldstein, MD, FAAP, Section Chairperson, <u>MGoldstein@llu.edu</u> and

Christopher Rizzo, MD, FAAP, Membership Chairperson and Chair Elect, <u>criz-</u> <u>zo624@gmail.com</u>

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visit <u>www.aap.org</u>. Reporters can access the meeting program and other relevant meeting information through the AAP meeting website at <u>http://www.aapexperi-</u> <u>ence.org/</u>

NT

### Placenta lacks major molecules used by SARS-CoV-2 virus to cause infection

NIH study may help explain why the virus has rarely been found in fetuses or newborns of women with COVID-19.

Tuesday, July 14, 2020

#### What

The placental membranes that contain the fetus and amniotic fluid lack the messenger RNA (mRNA) molecule required to manufacture the ACE2 receptor, the main cell surface receptor used by the SARS-CoV-2 virus to cause infection, according to a study by researchers at the National Institutes of Health. Their findings appear in the journal eLife.

These placental tissues also lack mRNA needed to make an enzyme, called TM-PRSS2, that SARS-CoV-2 uses to enter a cell. Both the receptor and enzyme are present in only miniscule amounts in the placenta, suggesting a possible explanation for why SARS-CoV-2 has only rarely been found in fetuses or newborns of women infected with the virus, according to the study authors.

The researchers, led by Roberto Romero, M.D., chief of the Perinatology Research Branch at NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), found that the placenta contains molecules that previous studies have suggested as potential routes for SARS-CoV-2 infection, including the CD147 receptor and the enzymes cathepsin L and Furin. They also detected in placental and membrane tissue a type of macrophage (immune cell) that has the ACE2 receptor. However, they noted that there is little evidence showing that infected macrophages could spread the SARS-CoV-2 virus to the placenta, membranes and fetus in normal pregnancy.

Finally, the researchers found that the placenta contains large amounts of receptors used for infection by Zika virus(link is external) and cytomegalovirus(link is external), which are both known to carry serious health risks when passed from a women to her fetus during pregnancy.

#### Who

Study author Roberto Romero, M.D., chief of the NICHD Perinatology Research Branch, is available for comment.

#### Article

Pique-Regi, R. Does the human placenta express the canonical cell entry mediators for SARS-CoV-2? eLife. 2020.

About the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD): NICHD leads research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all. For more information, visit <u>https://</u> www.nichd.nih.gov.

About the National Institutes of Health (NIH): NIH, the nation's medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov.

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Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

#### Contact

Robert Bock or Meredith Daly 301-496-5133

NT

Iodine exposure in the NICU may lead to decrease in thyroid function, NIH study suggests

lodine solutions are commonly used as disinfectants to prepare the skin for surgical or other procedures.

Tuesday, July 7, 2020

Exposure to iodine used for medical procedures in a neonatal intensive care unit (NICU) may increase an infant's risk for congenital hypothyroidism (loss of thyroid



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At First Candle we're educating parents, grandparents and caregivers about safer sleep to make sure all babies reach their first birthday. Learn more at firstcandle.org function), suggests a study by researchers at the National Institutes of Health and other institutions. The authors found that infants diagnosed with congenital hypothyroidism following a NICU stay had higher blood iodine levels on average than infants who had a NICU stay but had normal thyroid function. Their study appears in The Journal of Nutrition.

"Limiting iodine exposure among this group of infants whenever possible may help lower the risk of losing thyroid function," said the study's first author, James L. Mills, M.D., of the Epidemiology Branch at NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD).

<u>Congenital hypothyroidism</u> is a partial or complete loss of thyroid function. The thyroid, located in the throat, makes iodinecontaining hormones that regulate growth, brain development and the rate of chemical reactions in the body. Treatment consists of thyroid hormone therapy and must begin within four weeks after birth or permanent intellectual disability may result.

In the United States, all infants are routinely screened for the condition by collecting a small sample of blood from an infant's heel and analyzing it for thyroid stimulating hormone. Infants with a high level of thyroid stimulating hormone are referred for further testing.

To conduct the study, the researchers analyzed blood spots for their iodine content. They compared blood iodine levels from 907 children diagnosed with congenital hypothyroidism to those of 909 similar children who did not have the condition. This included 183 infants cared for in the NICU — 114 of whom had congenital hypothyroidism and 69 who did not.

Overall, the researchers found no significant difference between blood iodine concentrations in those who had congenital hypothyroidism and those in the control group. Because very high or very low iodine levels increase the risk for congenital hypothyroidism, they also looked at those infants having the highest and lowest iodine levels.



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Children with congenital hypothyroidism were more likely to have been admitted to a NICU than those without congenital hypothyroidism. When the researchers considered only those infants with a NICU stay, they found that the group with congenital hypothyroidism had significantly higher iodine levels than those without the condition who also had a NICU stay. Similarly, those with congenital hypothyroidism and a NICU stay tended to have higher blood iodine than children with the condition who did not have a NICU stay.

The researchers were unable to obtain information on the medical procedures the infants may have undergone during their time in the NICU. Iodine solutions are commonly used as disinfectants to prepare the skin for surgical or other procedures. Preterm infants absorb iodine more readily through their skin than older infants. Iodine also is given internally for imaging procedures used in infants.

The researchers said that the higher iodine levels seen among infants with congenital hypothyroidism and a NICU stay may have resulted from exposure to iodine during a medical procedure. Because of this possibility, they cautioned NICU staff to use disinfectants that do not contain iodine whenever possible and to avoid exposing infants to iodine unless absolutely necessary.

About the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD): NICHD leads research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all. For more information, visit <u>https://www.nichd.nih.gov</u>.

About the National Institutes of Health (NIH): NIH, the nation's medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov.





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#### Institute/Center

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

Contact Robert Bock or Meredith Daly <u>301-496-5133</u>

### Experts identify steps to expand and improve antibody tests in COVID-19 response

NIH workshop attendees review capabilities, limits of SARS-CoV-2 serology testing.

Media Advisory

Tuesday, June 23, 2020

#### What

More than 300 scientists and clinicians from the federal government, industry and academia published a report of their conclusions and recommendations on COVID-19 serology studies online in Immunity. The group gathered for an online workshop in May to discuss the role of serology testing in understanding and responding to the COVID-19 public health crisis and to explore strategies to address key scientific knowledge opportunities and gaps in the emerging field. Serology tests for COVID-19 are designed to detect antibodies(link is external) against SARS-CoV-2, the virus that causes CO-VID-19. While such tests do not diagnose active infection, they can indicate prior infection with SARS-CoV-2 that may have been missed because a person did not experience significant symptoms or access testing while infected.

The COVID-19 Serology Studies workshop was convened by an interagency working group comprised of experts from the U.S. Department of Health and Human Services — including scientists at the National Institute of Allergy and Infectious Diseases (NIAID), the National Cancer Institute (NCI), and the National Heart, Lung and Blood Institute (NHLBI), parts of the National Institutes of Health, as well as the Centers for Disease Control and Prevention and the Biomedical Advanced Research and Development Authority — and the Department of Defense. Attendees assessed efforts to better understand the implications of serology test results, to produce and validate test kits, and to quantify undetected cases of SARS-CoV-2 infection.

Attendees recommended that additional research is needed to determine if and to what extent a positive antibody test means a person may be protected from reinfection with SARS-CoV-2. Attendees emphasized that until such data is available, serology tests should not be used as a stand-alone tool to make decisions about personal safety related to SARS-CoV-2 exposure. Researchers are now pursuing studies in humans and in animal models to better understand SARS-CoV-2 immunity. Attendees noted that such understanding could help identify optimal donors of convalescent plasma that potentially could be used to help treat those with severe COVID-19.

Researchers from NCI reviewed progress in their <u>effort to independently validate</u> <u>SARS-CoV-2 serology tests</u> on behalf of the <u>U.S. Food and Drug Administration</u>. Attendees also proposed strategies to expand the accuracy and capacity of these tests to distinguish between naturally acquired and vaccine-induced antibodies, which will be critical to evaluating COV-ID-19 vaccine candidates.

Both community-based and large-scale <u>serology surveillance</u> efforts — such as the <u>RESPONSE</u> study sponsored by NI-AID and NHLBI — are collecting critical data to improve epidemiological models and inform public health decision-making. Ideally, attendees noted, federal partners will expand this activity to establish an interactive serological database that will help public health officials monitor and quickly respond to changes in SARS-CoV-2 infection patterns.

#### Article

A Lerner et al. COVID-19 Serology Studies Workshop: Meeting Report. Immunity DOI: 10.1016/j.immuni.2020.06.012 (2020).

Who

Cristina Cassetti, Ph.D., deputy director of NIAID's Division of Microbiology and Infectious Diseases, is available for comment.

NIAID conducts and supports research — at NIH, throughout the United States, and worldwide — to study the causes of infectious

About the National Institutes of Health (NIH): NIH, the nation's medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit www.nih.gov.

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#### Institute/Center National Institute of Allergy and Infectious Diseases (NIAID)

Contact NIAID Office of Communications 301-402-1663

ΝΤ

Pediatricians, Educators and Superintendents Urge a Safe Return to School This Fall

Science and community circumstances must guide decision-making; funding is critical

For Release: 7/10/2020

Washington, DC—The American Academy of Pediatrics (AAP), American Federation of Teachers (AFT), National Education Association (NEA) and AASA, The School Superintendents Association, join together today in the following statement on the safe return of students, teachers, and staff to schools:

"Educators and pediatricians share the goal

of children returning safely to school this fall. Our organizations are committed to doing everything we can so that all students have the opportunity to safely resume in-person learning.

"We recognize that children learn best when physically present in the classroom. But children get much more than academics at school. They also learn social and emotional skills at school, get healthy meals and exercise, mental health support and other services that cannot be easily replicated online. Schools also play a critical role in addressing racial and social inequity. Our nation's response to COVID-19 has laid bare inequities and consequences for children that must be addressed. This pandemic is especially hard on families who rely on school lunches, have children with disabilities, or lack access to Internet or health care.

"Returning to school is important for the healthy development and well-being of children, but we must pursue re-opening in a way that is safe for all students, teachers and staff. Science should drive decision-making on safely reopening schools. Public health agencies must make recommendations based on evidence, not politics. We should leave it to health experts to tell us when the time is best to open up school buildings, and listen to educators and administrators to shape how we do it.

"Local school leaders, public health experts, educators and parents must be at the center of decisions about how and when to reopen schools, taking into account the spread of COVID-19 in their communities and the capacities of school districts to adapt safety protocols to make in-person learning safe and feasible. For instance, schools in areas with high levels of COVID-19 community spread should not be compelled to reopen against the judgment of local experts. A onesize-fits-all approach is not appropriate for return to school decisions.

"Reopening schools in a way that maximizes safety, learning, and the well-being of children, teachers, and staff will clearly require substantial new investments in our schools and campuses. We call on Congress and the administration to provide the federal resources needed to ensure that inadequate funding does not stand in the way of safely educating and caring for children in our schools. Withholding funding from schools that do not open in person fulltime would be a misguided approach, putting already financially strapped schools in an impossible position that would threaten the health of students and teachers.

"The pandemic has reminded so many what we have long understood: that educators are invaluable in children's lives and that attending school in person offers children a wide array of health and educational benefits. For our country to truly value children, elected leaders must come together to appropriately support schools in safely returning students to the classroom and reopening schools."

#### ###

#### About the American Academy of Pediatrics

The American Academy of Pediatrics is an organization of 67,000 primary care pediatricians, pediatric medical subspecialists and pediatric surgical specialists dedicated to the health, safety and well-being of infants, children, adolescents and young adults. For more information, visit <u>www.aap.org</u> and follow us on Twitter @AmerAcadPeds





#### About the American Federation of Teachers

The AFT represents 1.7 million pre-K through 12th-grade teachers; paraprofessionals and other school-related personnel; higher education faculty and professional staff; federal, state and local government employees; nurses and healthcare workers; and early childhood educators.

#### About the National Education Association

The National Education Association is the nation's largest professional employee organization, representing more than 3 million elementary and secondary teachers, higher education faculty, education support professionals, school administrators, retired educators, students preparing to become teachers, healthcare workers, and public employees. Learn more at <u>www.nea.org</u>

#### About AASA

AASA, The School Superintendents Association, founded in 1865, is the professional organization for more than 13,000 educational leaders in the United States and throughout the world. AASA's mission is to support and develop effective school system leaders who are dedicated to equitable access for all students to the highest quality public education. For more information, visit <u>www.aasa.org</u>.

NT

Media Contact: Devin Miller 202-347-8600 dmiller@aap.org

American Academy of Pediatrics, American Academy of Family Physicians, American College of Physicians and American Medical Association Statement on Official Withdrawal of U.S.

## from the World Health Organization

The following statement is attributable to: AAP President Sally Goza, MD, FAAP, AAFP President Gary L. LeRoy, M.D., AMA President Susan R. Bailey, M.D., and ACP President, Jacqueline W. Fincher, MD, FACP

For Release: 7/7/2020

"The Trump administration's official withdrawal from the World Health Organization (WHO) puts the health of our country at grave risk. As leading medical organizations, representing hundreds of thousands of physicians, we join in strong opposition to this decision, which is a major setback to science, public health, and global coordination efforts needed to defeat COVID-19.

"The WHO plays a leading role in protecting, supporting, and promoting public health in the United States and around the world. The agency has been on the frontlines of every global child health challenge over the last seven decades, successfully eradicating smallpox, vaccinating billions against measles, and cutting preventable child deaths by more than half since 1990. Withdrawing from the WHO puts these investments at risk and leaves the United States without a seat at the table – at a time when our leadership is most desperately needed.

"As our nation and the rest of the world face a global health pandemic, a worldwide, coordinated response is more vital than ever. This dangerous withdrawal not only impacts the global response against COVID-19, but also undermines efforts to address other major public health threats. The American Academy of Pediatrics, American Academy of Family Physicians, American College of Physicians and American Medical Association strongly oppose this short-sighted decision. We call on Congress to reject the Administration's withdrawal from the WHO and make every effort to preserve the United States' relationship with this valued global institution. Now is the time to invest in global health, rather than turn back."

#### ###

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The American Academy of Family Physicians, founded in 1947, represents 136,700 physicians and medical students nationwide. It is the largest medical society devoted solely to primary care. Family physicians conduct approximately one in five office visits -- that's 192 million visits annually or 48 percent more than the next most visited medical specialty. Today, family physicians provide more care for America's underserved and rural populations than any other medical specialty. Family medicine's cornerstone is an ongoing, personal patient-physician relationship focused on integrated care. To learn more about the specialty of family medicine, the AAFP's positions on issues and clinical care, and for downloadable multi-media highlighting family medicine, visit www.aafp. org/media. For information about health care, health conditions and wellness, please visit the AAFP's award-winning consumer website, www.familydoctor.org.

The American Medical Association is the physicians' powerful ally in patient care. As the only medical association that convenes 190+ state and specialty medical societies and other critical stakeholders, the AMA represents physicians with a unified voice to all key players in health care. The AMA leverages its strength by removing the obstacles that interfere with patient care, leading the charge to prevent chronic disease and confront public health crises and, driving the future of medicine to tackle the biggest challenges in health care.

The <u>American College of Physicians</u> is the largest medical specialty organization in the United States with members in more than



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145 countries worldwide. ACP membership includes 159,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

Media Contact: Devin Miller 202-347-8600 dmiller@aap.org

NT

## CDC updates, expands list of people at risk of severe COVID-19 illness

Risk for pregnant women is updated

#### Press Release

For Immediate Release: Thursday, June 25, 2020 Contact: Media Relations (404) 639-3286

Based on a detailed review of available evidence to date, CDC has updated and expanded the <u>list of who is at increased risk for</u> getting severely ill from COVID-19.

Older adults and people with underlying medical conditions remain at increased risk for severe illness, but now CDC has further defined age- and condition-related risks.

As more information becomes available, it is clear that a substantial number of Americans are at increased risk of severe illness – highlighting the importance of continuing to follow preventive measures.

"Understanding who is most at risk for severe illness helps people make the best decisions for themselves, their families, and their communities," said CDC Director Robert Redfield MD. "While we are all at risk for COVID-19, we need to be aware of who is susceptible to severe complications so that we take appropriate measures to protect their health and well-being."

#### COVID-19 risk related to age

CDC has removed the specific age threshold from the older adult classification. CDC now warns that among adults, risk increases steadily as you age, and it's not just those over the age of 65 who are at increased risk for severe illness.

Recent data, including an <u>MMWR published</u> <u>last week</u>, has shown that the older people are, the higher their risk of severe illness from COVID-19. Age is an independent risk factor for severe illness, but risk in older adults is also in part related to the increased likelihood that older adults also have underlying medical conditions.

#### COVID-19 risk related to underlying medical conditions

CDC also updated the <u>list of underlying</u> <u>medical conditions</u> that increase risk of severe illness after reviewing published reports, pre-print studies, and various other data sources. CDC experts then determined if there was clear, mixed, or limited evidence that the condition increased a person's risk for severe illness, regardless of age.

There was consistent evidence (from multiple small studies or a strong association from a large study) that specific conditions increase a person's risk of severe COVID-19 illness:

Chronic kidney disease

- COPD (chronic obstructive pulmonary disease)
- Obesity (BMI of 30 or higher)
- Immunocompromised state (weakened immune system) from solid organ transplant
- Serious heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies
- Sickle cell disease
- Type 2 diabetes

These changes increase the number of people who fall into higher risk groups. An estimated 60 percent of American adults have at least one chronic medical condition. Obesity is one of the most common underlying conditions that increases one's risk for severe illness – with about 40 percent of U.S. adults having obesity. The more underlying medical conditions people have, the higher their risk.

CDC also clarified the list of <u>other conditions</u> that **might** increase a person's risk of severe illness, including additions such as asthma, high blood pressure, neurologic conditions such as dementia, cerebrovascular disease such as stroke, and pregnancy. An MMWR published today further adds to the growing body of research on risk by comparing data on pregnant and nonpregnant women with laboratory-confirmed SARS-CoV-2 infection. Pregnant women were significantly more likely to be hospitalized, admitted to the intensive care unit, and receive mechanical ventilation than nonpregnant women; however, pregnant women were not at greater risk for death from COVID-19.

## Protecting yourself, your family, and your community

Every activity that involves contact with others has some degree of risk right now. Knowing if you are at increased risk for severe illness and understanding the risks associated with different activities of <u>daily living</u> can help you make informed decisions about which <u>activities</u> to resume and what level of risk you will accept. This information is especially critical as communities begin to reopen.

Everyone should continue to do their part to implement prevention strategies, such as focusing on activities where social distancing can be maintained, washing your hands frequently, limiting contact with and disinfecting commonly touched surfaces or shared items, and wearing a cloth face covering when you are around people you do not live with, especially when it is difficult to stay 6 feet apart or when people are indoors. By taking these steps, you can help protect yourself, your loved ones, and others around you, including those most vulnerable to severe illness.

CDC will continue to update and share information about risk for severe illness as more information becomes available. For more in-



formation on how to prevent getting sick with COVID-19, visit CDC's website at <u>https://www.cdc.gov/coronavirus/2019-ncov/prevent-get-ting-sick/index.html</u>.

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#### U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

CDC works 24/7 protecting America's health, safety and security. Whether disease start at home or abroad, are curable or preventable, chronic or acute, or from human activity or deliberate attack, CDC responds to America's most pressing health threats. CDC is headquartered in Atlanta and has experts located throughout the United States and the world.

ΝΤ

## COVID-19 Can Be Transmitted in the Womb, Reports Pediatric Infectious Disease Journal

Case Study Provides Evidence of Intrauterine Transmission of SARS-CoV-2 from Mother to Infant

10-Jul-2020 11:50 AM EDT, by <u>Wolters Kluwer Health: Lippincott Wil-</u> liams and Wilkins

"Newswise — July 10, 2020 – <u>A baby girl in Texas – born prematurely</u> to a mother with COVID-19 – is the strongest evidence to date that intrauterine (in the womb) transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) can occur, reports <u>The Pediatric Infectious Disease Journal</u>, the official journal of <u>The European</u> <u>Society for Paediatric Infectious Diseases</u>. The journal is published in the Lippincott portfolio by <u>Wolters Kluwer</u>.

The findings "suggest in utero transmission" of COVID-19 from an infected mother to her infant, according to the case report by Julide Sisman, MD, and colleagues of The University of Texas Southwestern Medical Center, Dallas.

"Numerous infants have now been delivered to pregnant women diagnosed with SARS-CoV-2, with the majority of these infants without respiratory illness or positive molecular evidence for SARS-CoV-2," comments Amanda S. Evans, MD, one of the lead authors of the new study. "Our study is the first to document intrauterine transmission of the infection during pregnancy, based on immunohistochemical and ultrastructural evidence of SARS-CoV-2 infection in the fetal cells of the placenta."

#### First Documented Intrauterine Transmission of COVID-19

The authors report on an infant delivered to a mother diagnosed with COVID-19, who also had type 2 diabetes. The infant was born at 34 weeks' gestation after the mother had premature rupture of the membranes. The baby was born "large for gestational age" (LGA) – an important complication in infants of diabetic mothers. She was

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And only 10% of NICUs surveyed connect parents with non-hospital support.

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See what they found by emailing info@grahamsfoundation.org to request a free copy of the 2017 whitepaper, "Reaching Preemie Parents Today" (*Heather McKinnis, Director, Preemie Parent Mentor Program, Graham's Foundation*).

You may be surprised to see what NICUs are doing right and where their efforts are clearly falling short.

Graham's Foundation empowers parents of premature babies through support, advocacy and research to improve outcomes for their preemies and themselves.



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treated in the neonatal ICU due to prematurity and possible SARS-CoV-2 exposure.

The infant appeared initially healthy, with normal breathing and other vital signs. On the second day of life, she developed fever and relatively mild breathing problems. "It is unlikely that the respiratory dis-

tress observed in this infant was due to prematurity since it did not start until the second day of life," the researchers write.

The baby tested positive for SARS-CoV-2 infection at 24 and 48 hours after birth. She was treated with supplemental oxygen for several days but did not need mechanical ventilation. COVID-19 tests remained positive for up to 14 days. At 21 days, the mother and infant were sent home in good condition.

The researchers examined the placenta, which showed signs of tissue inflammation. In addition, specialized tests documented the presence of coronavirus particles as well as a protein (SARS-CoV-2 nucleocapsid protein) specific for the COVID-19 virus in fetal cells of the placenta. Together, these findings confirmed that the infection was transmitted in the womb, rather than during or after birth.

Although data on COVID-19 remain very limited, "Intrauterine transmission of SARS-CoV-2 appears to be a rare event," Dr. Sisman and colleagues conclude. They highlight several urgent priorities for further research, including the mechanisms and risk factors of in utero SARS-CoV-2 transmission and the outcomes of congenital COVID-19 in infants.

"We wanted to be very careful of our interpretation of this data, but now is an even more important time for pregnant women to protect themselves from COVID-19," comments Dr. Evans. She adds, "The CDC has thoughtful guidance on ways to reduce risk of infection." (See https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/pregnancy-breastfeeding.html)

Two additional case reports in PIDJ also describe "vertical" transmission of SARS-Co-V2 from mother to infant occurring under different circumstances. Together, the three cases highlight the important but difficult distinction between virus transmission occurring before or during/after delivery (intrauterine versus intrapartum), according to a commentary led by George K. Siberry, MD, of the US Agency for International Development and Associate Chief Editor of PIDJ. Dr. Siberry and coauthors write: "As these cases illustrate, evaluation for vertical - and especially intrauterine - SARS-CoV-2 infection can be challenging, and assessment is often limited by lack of optimal testing of appropriate specimens obtained at specific timepoints."

Click here to read "Intrauterine Transmission of Sars-Cov-2 Infection in a Preterm Infant."

DOI: 10.1097/INF.000000000002815

###

#### About The Pediatric Infectious Disease Journal

The Pediatric Infectious Disease Journal® (PIDJ) is a complete, upto-the-minute resource on infectious diseases in children. Through a mix of original studies, informative review articles, and unique case reports, PIDJ delivers the latest insights on combating disease in children - from state-of-the-art diagnostic techniques to the most effective drug therapies and other treatment protocols. It is a resource that can improve patient care and stimulate your personal research. The Pediatric Infectious Disease Journal is the official journal of the European Society for Paediatric Infectious Diseases.

## PROTECT YOUR FAMILY FROM RESPIRATORY VIRUSES

#### flu coronavirus

pertussis



WASH YOUR HANDS

## often with soap and

warm water.

#### GET VACCINATED

SOAF

for flu and pertussis. Ask about protective injections for RSV.



## COVER COUGHS AND SNEEZES.

Sneeze and cough into your elbow.

USE AN ALCOHOL-BASED HAND SANITIZER.





## STAY AWAY FROM SICK PEOPLE

Avoid crowds. Protect vulnerable babies and children.



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#### About The European Society for Paediatric Infectious Diseases

Now in its 36th year, <u>The European Society for Paediatric Infectious</u> <u>Diseases</u> (ESPID) forms the basis for European investigators interested in infectious diseases in children and infection prevention in childhood. The society is engaged in a number of activities including the organisation of multicentre trials, international exchange of infectious disease fellows, and an annual meeting. Membership includes subscription to <u>The Pediatric Infectious Disease Journal®</u> in addition to many other benefits.

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#### NATIONAL PERINATAL ASSOCIATION

## Update: CORONAVIRUS

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According to the data in The Lancet, even when mothers were infected

## No virus was detected in:

- NASOPHARYNGEAL SWABS OF THE BABY
- AMNIOTIC FLUID
- CORD BLOOD
- BREASTMILK



Keeping Your Baby Safe

during the COVID-19 pandemic

## How to protect your little one from germs and viruses

Even though there are some things we don't know about COVID-19 yet, there are many more things that we do know. We know that there are proven protective measures that we can take to stay healthy.

#### Here's what you can do...

#### Wash Your Hands

- This is the single, most important thing you can do to stop the spread of viruses.
- Use soap.Wash for



Use alcoholbased sanitizers

#### Provide Protective Immunity

Hold baby skin-to-skin.

 Give them your breast milk.
 Stay current with your family's immunizations



/ F.

## Limit Contact with Others

- Stay home when you can.
- Stay 6 feet apart when out.
- Wear a face mask when out.
- Change your clothes when you get home.
- Tell others what you're doing to stay safe.

#### Take Care of Yourself

- Stay connected with your family and friends.
- Sleep when you can.
- Drink more water and eat healthy foods.
- Seek mental health
   support.

Immunizations Vaccinations save lives. Protecting your baby from flu and pertussis lowers their risks for complications from coronavirus.

#### Never Put a Mask on Your Baby

- Because babies have smaller airways, a mask makes it hard for them to breathe.
- Masks pose a risk of strangulation and suffocation
- A baby can't remove their mask if they're suffocating.

#### If you are positive for COVID-19

- Wash with soap and water and put on fresh clothes before holding or feeding your baby.
- Wear a mask to help stop the virus from spreading.
- Watch out for symptoms like fever, confusion, or trouble breathing.
- Ask for help caring for your baby and yourself while you recover.

## We can help protect each other.

www.nationalperinatal.org/COVID-19



Peer Reviewed

## Neonatology Solutions NICU Directory: The Directory is finally completed!

Scott Snyder, MD

## solutions

To help our individual AAP Districts, we have created District Summary pages within the Directory that include information about all NICUs in the AAP's 10 Districts across the United States (Canadian data is still forthcoming). The summaries also include content on open neonatology positions, upcoming conferences, fellowship programs, and links to District websites where they exist.

"We are hopeful that the Districts with active Neonatal/Perinatal sections find these summary pages helpful for their members. As always we welcome feedback and suggestions on how to ensure this is a useful and valuable resource for our field."

We are hopeful that the Districts with active Neonatal/Perinatal sections find these summary pages helpful for their members. As always we welcome feedback and suggestions on how to

NATIONAL PERINATAL ASSOCIATION

## Update: CORONAVIRUS

COVID-19

According to data published in The Lancet

Because of the risk of developing severe pneumonia, pregnant women and newborn babies should be considered key at-risk populations.





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ensure this is a useful and valuable resource for our field.

https://neonatologysolutions.com/aap-district-viii/

Suggestions for additional content can be sent via the easy-touse links on the website or email me directly at <u>Scott@Neona-</u> tologySolutions.com.

https://neonatologysolutions.com/state-summary/

We would like to provide a humble 'thank you!' to the 5,368 new users of Neonatology Solutions since our inception just 11 months ago!

Stay healthy!"

Thank you!!

References:

1. <u>https://neonatologysolutions.com/explore-nicus-and-pro-grams/</u>

The author is a principal of Neonatology Solutions, LLC.

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**Corresponding Author** 



Scott Snyder, MD, FAAP System Medical Director St. Luke's Neonatology Founder Neonatology Solutions, LLC Scott Snyder <u>Scott@neonatologysolutions.com</u>

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3690+ Beds

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Vermont Oxford Members

85

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#### AAP District VIII

Map	Satellite		167 NIC	:Us
North Pacific Ocean Google States	0	Canada Ca	Level IV 14 States within District 12	Nec Fello
Alaska		4 NICUs		101
Arizona		27 NICUs		660-
Colorado		33 NICUs		681-

Alaska	4 NICUs	101 Beds
Arizona	27 NICUs	660+ Beds
Colorado	33 NICUs	681+ Beds
Hawaii	3 NICUs	176 Beds
Idaho	10 NICUs	199 Beds
Montana	7 NICUs	108 Beds
Nevada	12 NICUs	343 Beds
New Mexico	6 NICUs	202 Beds
Oregon	9 NICUs	298 Beds
Utah	25 NICUs	473 Beds
Washington	27 NICUs	531 Beds
Wyoming	4 NICUs	19 Beds
Website		

AAP District VIII Section on Neonatal-Perinatal Medicine





## Service Antional Perinatal Association NICU AWARENESS MONTH

nationalperinatal.org/NICU\_Awareness



## WE NEED MORE RESEARCH

We have valuable data to help us deliver the best NICU care for small and premature babies. But we still need more data to help us optimize care for the rest of our bables who are admitted to the NICU.

Educate. Advocate. Integrate.

# **COVID-19**

## FREE for our NICU COMMUNITY

- Helping Children and Families Cope
- Bonding with Your Baby
- Caregivers Need Care Too



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## Interpreting Umbilical Cord Blood Gases: Uteroplacental Insufficiency

#### Jeffrey Pomerance, MD, MPH

Uteroplacental insufficiency can be caused by many factors. These include critical maternal anemia or oxygen desaturation, maternal hypotension, excessive uterine activity with hypertonus, certain maternal medications and drugs, abnormalities of the uteroplacental vasculature, placental infarcts, placental abruption, and uterine rupture without an expulsion. The case below illustrates typical umbilical cord blood gas findings in severe uteroplacental insufficiency.

The comparative reliability of bicarbonate versus base deficit as a marker of metabolic acidosis is also addressed here.

#### **Case 8: Uteroplacental Insufficiency**

The mother was a 19-year-old, gravida 3, para 1, aborta 1, with an intrauterine pregnancy at approximately 32 weeks by poor dates with preterm labor and diffuse abdominal pain for four hours. There was a history of cocaine use, last taken on the day of admission. Uterine contractions, occurring every minute, were associated with recurrent late decelerations with almost every contraction on the FHR (fetal heart rate) monitor. With the cervix three cm dilated and 70% effaced, the mother underwent an emergency cesarean section. An abruption involving 50% of the placental surface was found at surgery. Thick meconium was noted at the delivery of a 2500 g female infant with Apgar scores of 1, 2, and 4 at one, five and 10 minutes, respectively.

Cord blood gas results were as follows (presented without base deficits):

	Umbilical Vein	Umbilical Artery
рН	6.83	6.79
Pco <sub>2</sub> (mmHg)	100	110
(KPa) Po (mmHa)	10.33	8
(kPa)	1.33	1.07
HCO <sub>3</sub> <sup>-</sup> (mmol/L)	16	16

*"If one were to rely upon this information alone, one would conclude that the severe acidosis is essentially all respiratory in origin. This interpretation would be erroneous, as the following information demonstrates."* 

#### Interpretation

In both the umbilical venous and arterial samples, the pHs are severely acidotic, and the PCO<sub>2</sub>s are very severely elevated. The bicarbonate (HCO3<sup>-</sup>) of 16 mEq/L in the umbilical venous sample is at the lower end of normal, and the bicarbonate of 16 mEq/L in the umbilical arterial sample is marginally low. If one were to rely

upon this information alone, one would conclude that the severe acidosis is essentially all respiratory in origin. This interpretation would be erroneous, as the following information demonstrates.

#### Bicarbonate versus Base Deficit/Base Excess

Cord blood gas results (providing both bicarbonate and base deficit) were as follows:

	Umbilical Vein	Umbilical Artery
рН	6.83	6.79
Pco <sub>2</sub> (mmHg)	100	110
(kPa)	13.33	14.67
Po <sub>2</sub> (mmHg)	10	8
(kPa)	1.33	1.07
HCO <sub>3</sub> (mmol/L)	16	16
BD (mmol/L)	23	25

Had you been texting at the moment these base deficits came to your attention, without doubt, you would have texted, "OMG!" Now it becomes clear that in addition to very severe respiratory acidosis, there exists a concomitant very severe metabolic acidosis in each sample. The base deficit is defined as the amount of base required to titrate the sample to a pH of 7.40 at a PCO<sub>2</sub> of 40 mmHg at 37° C. Base excess is defined as the amount of acid required to titrate the sample to a pH of 7.40 at a PCO2 of 40 mmHg at 37°C. Base deficit, unlike bicarbonate concentration, also takes into account the hemoglobin concentration. Base deficit (or base excess) is a far more satisfactory and clinically useful way to assess the non-respiratory (metabolic) portion of acid-base balance than is bicarbonate. Base deficit corrects for an elevated (or depressed) PCO<sub>2</sub> resulting in an increased (or decreased) bicarbonate value. Below, the venous and arterial cord gases each have been "normalized" to a PCO2 of 38 and 49 mmHg (the mean normal venous and arterial PCO2s), respectively, as is done artificially by the equation used to calculate the base deficit in blood gas analyzers. Then it can be seen that bicarbonate "falls," revealing the underlying metabolic acidosis quite as well as does the base deficit.

	Umbilical Vein	Umbilical Artery
рН	7.00	6.92
Pco <sub>2</sub> (mmHg) <i>(kPa)</i>	38 5.07	49 6.53
Po <sub>2</sub> (mmHg) <i>(kPa)</i>	10 <i>1.</i> 33	8 1.07
HCO <sub>3</sub> <sup>-</sup> (mmol/L)	8.9	9.5
BD (mmol/L)	23	25

These values were obtained by using the Siggaard-Andersen Alignment Nomogram provided below. As long as two values are provided, using a straight edge, all the other data can be obtained. In this case, the PCO2 and the base deficit are placed on a straight line. For the venous umbilical cord blood gas, a straight line (line A) is extended from the PCO2 of 38 mm Hg, found on the right edge of the nomogram and base excess (negative base deficit) of 23 mmol/L, found in the wing-shaped part of the nomogram (using hemoglobin of 15 g/100 mL found at the bottom of the wing-shaped part of the nomogram). The pH and the bicarbonate can then be read off the nomogram in the center and near left parts of the nomogram, respectively. The same approach is then used for the arterial umbilical cord blood gas. The results appear in line B in the nomogram.

"In some hospitals, in a cost-containment effort, only an umbilical artery sample is obtained. However, unless both umbilical venous and umbilical arterial samples are obtained, one cannot be certain that the only sample obtained is indeed from an umbilical artery."

As can be seen from the equation below, an increase or decrease in  $CO_2$  will result in a reciprocal increase or decrease in  $HCO3^{-1}$  (bicarbonate).

 $CO2 + H_2O \leftrightarrow HCO_{3^-} + H +$ 

If one were to rely upon bicarbonate as a guide to the degree of metabolic acidosis, what initially appeared to be a borderline bicarbonate value would be revealed, as efficient ventilation begins, to be a severe metabolic acidosis with low bicarbonate values. Base deficit permits metabolic acidosis to be appreciated before PCO<sub>2</sub> is normalized by automatically correcting for deviations of PCO<sub>2</sub> from "normal." Therefore, it is the more reliable parameter to follow when a PCO<sub>2</sub> significantly deviates from average. If the PCO<sub>2</sub> is at or near a normal value, it makes no difference whether one uses bicarbonate or base deficit to determine the degree of metabolic acidosis.

A significantly depressed PCO<sub>2</sub> is uncommon in umbilical cord blood gases, except when the mother either spontaneously hyperventilates or is hyperventilated under general anesthesia. For a mother's hyperventilation to lower fetal PCO<sub>2</sub>, the uteroplacental circulation must be unimpeded. If the PCO<sub>2</sub> is artificially decreased by exposure to an air bubble, calculated bicarbonate is low, but the base deficit is unaffected. As a general rule, the base deficit should be used in the interpretation of metabolic acidosis or alkalosis. For this reason, information on the base deficit will be provided, and bicarbonate values will be omitted as additional cases are presented.

The umbilical cord blood gas values in this case show combined severe metabolic acidosis and severe respiratory acidosis. The history of diffuse abdominal pain, maternal cocaine use , and very frequent uterine contractions all suggested placental abruption, which indeed was the correct diagnosis. Placental abruption and excessive uterine activity both have the potential to critically diminish the oxygen available to the fetus, as reflected in the recurrent late decelerations. "Late decelerations are smooth, gradual, symmetrical decreases in FHR beginning at or after the peak of the contraction and returning to baseline only after the contraction has ended," and are associated with more than 50% of contractions. In any given sequence, they are both recurrent and proportional to the amplitude and duration of the underlying contraction, and the drop from baseline to nadir must be greater than 30 seconds. As umbilical arterial blood moves through the intervillous space, uteroplacental insufficiency leads to a poor exchange of carbon dioxide and oxygen, resulting in umbilical venous blood with higher than normal PCO<sub>2</sub>, and lower than normal PO<sub>2</sub>, and little or no correction of any underlying metabolic acidosis. As the fetus receives "under-ventilated" and under-oxygenated blood from the umbilical vein, FHR decelerations and respiratory and metabolic acidoses progress as the fetal heart rate baseline rises. Elevated PCO<sub>2</sub> and depressed venous PO<sub>2</sub>, together with approximately equal derangements of both umbilical venous and arterial base deficits, are the hallmarks of uteroplacental insufficiency.

Thick meconium is very unusual in premature deliveries but is quite common in term or post-term infants. Additionally, maternal cocaine use increases the risk of intrauterine growth restriction. Either this is a large for gestational age 32-week infant, a 36-38 week average for gestational age infant, or a small for gestational age term or post-term infant. The third scenario seems most likely.

#### **Key Points**

- The base deficit reflects metabolic acidosis or alkalosis better than bicarbonate in the presence of either high or low PCO<sub>2</sub>.
- The hallmarks of uteroplacental insufficiency are elevated PCO2 and depressed venous PO2 together with approximately equal derangements of both umbilical venous and arterial base deficits.

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Disclosure: The author has no disclosures.

#### NT



## Siggaard-Andersen Alignment Nomogram



## NCfIH National Coalition for Infant Health

Protecting Access for Premature Infants through Age Two

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



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- **Increased emotional support resources** for parents and caregivers suffering from PTSD/PPD
- Access to RSV preventive treatment for all premature infants as indicated on the FDA label
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## Why PREMATURE INFANTS Need Access to an EXCLUSIVE HUMAN MILK DIET



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## The Genetics Corner: Congenital Microcephaly and a Region of Homozygosity on Chromosome 1 that was not Reported on the Prenatal Chromosome Microarray

Cynthia Haag MS, Daisy Hernandez MS, LGC, Robin Dawn Clark MD

#### **Case History:**

A genetics consultation was requested for a 6-day old male with prenatally diagnosed IUGR, microcephaly, and bilateral talipes equinovarus. A fetal MRI demonstrated agenesis of the corpus callosum, severe lateral and third ventriculomegaly, and extensive parenchymal thinning. The mother had an amniocentesis with normal oligo-SNP chromosome microarray (CMA) results: arr(1-22) x2,(XY)x1, and negative PCR for CMV and Toxoplasma gondii. She was a 27-year old G3P1011, who denied teratogenic exposures or travel outside of the country. Parents, who denied consanguinity, reported that they were both from the same small town in Mexico.

"A genetics consultation was requested for a 6-day old male with prenatally diagnosed IUGR, microcephaly, and bilateral talipes equinovarus. A fetal MRI demonstrated agenesis of the corpus callosum, severe lateral and third ventriculomegaly, and extensive parenchymal thinning."

The infant was born at 36w5d gestation, after spontaneous rupture of membranes with clear amniotic fluid, by vaginal delivery in the vertex presentation. APGAR scores were 81 and 95. Birth weight 2041 g (2nd percentile), birth length 40.6 cm (<1st percentile), head circumference 27 cm (Z score -4 SD). A repeat CMA, which was sent to the same cytogenetic laboratory as the prenatal test, identified a long contiguous region of homozygosity (ROH) on chromosome 1, of approximately 21.4 megabases (Mb). Upon further request, the laboratory gave a verbal report of additional regions of homozygosity on chromosomes 2, 4, 11, and 16, indicating that the parents likely had a distant common ancestor. A trio whole-exome sequencing test identified a homozygous (likely causative) variant, c.929T>G/p.Leu310Arg, in MFSD2A. This gene, which is located within the ROH on chromosome 1, is responsible for an autosomal recessive form of primary microcephaly (MCPH15, MIM 616486) that matches this baby's phenotype.

#### Assessment and Counseling:

CMA is the first-tier diagnostic test for patients with multiple congenital anomalies. It can be performed prenatally or postnatally. A single nucleotide polymorphism (SNP) CMA uses SNPs to detect

DNA copy number gains or losses at high resolution. It can also detect regions of homozygosity (ROH, or absence of heterozygosity, AOH) when the copy number is normal. ROH are stretches of identical DNA shared by the maternally-derived and paternally-derived copies of a chromosome pair. ROH are not necessarily associated with a genetic disease, but they may pose an increased risk for autosomal recessive disorders when a common ancestor carried an autosomal recessive trait that was then passed on by both parents to an affected child. ROH occur when parents are closely related (consanguineous), or more distantly related as members of a reproductively isolated group, as in this case. ROH can also be caused by uniparental disomy (UPD), which occurs when only one parent contributes both copies of a chromosome pair (in whole or in part). When UPD involves an imprinted chromosome region that is differentially expressed based on the parent of origin, it can cause a significant genetic disorder (e.g., Prader-Willi syndrome).

The laboratory that performed both the prenatal and postnatal CMAs in our patient clarified the discrepancy in their reports when we called asking for more details. This lab uses different reporting standards for prenatal and postnatal microarray studies. Their prenatal microarray report is designed to limit information of uncertain significance. They report terminal ROH >5 Mb or interstitial ROH >10 Mb when they occur on chromosomes that cause imprinting disorders consistent with UPD (e.g., chromosomes 6, 7, 11, 14, 15). Multiple ROH that make up greater than 10% of the genome are also reported prenatally, as this indicates close consanguinity, a first or second-degree relationship between the parents. In postnatal microarrays, ROH is reported when it makes up >2% of the genome or when a terminal ROH is >5 Mb, or an interstitial ROH is >10 Mb on an individual chromosome regardless of its imprinting status. Because the largest ROH in our patient was on chromosome 1, which is not imprinted, and was therefore of uncertain significance, it was not reported on the prenatal microarray. When we called the laboratory, they released five additional ROH that were not included in the postnatal CMA report as these did not meet those postnatal reporting criteria.

"Because the largest ROH in our patient was on chromosome 1, which is not imprinted, and was therefore of uncertain significance, it was not reported on the prenatal microarray. When we called the laboratory, they released five additional ROH that were not included in the postnatal CMA report as these did not meet those postnatal reporting criteria." This case raised several concerns and made us question when we should repeat a microarray that had been normal prenatally and when we should contact the laboratory seeking more information. Ultimately, the gene of interest in our patient was located in the initially unreported ROH on chromosome 1p34.2. Had the mother's obstetricians had access to this information prenatally, it is possible that a definitive prenatal diagnosis might have been possible using autozygosity mapping - which means looking at the genes in the region of homozygosity for candidates that match the phenotype in question. It is unclear how this information might have been used by the parents, but the question is moot because a definitive diagnosis was not possible until after delivery. The conservative reporting standards of the laboratory, in this case, serve the ideal of "doing no harm" by not offering information prior to delivery that might be misconstrued as pathogenic but at the cost of reducing options for the family, paternalistically withholding data and delaying the diagnostic process. The lab's lack of transparency conflicts with the family's right to autonomy, their clinicians' right to data, and the expectation by all parties of full disclosure. The laboratory's policy may not give sufficient weight to the fact that the amniocentesis was performed at a cost, both financial and in terms of risk to the pregnancy, which reflects the high importance that the parents placed on making a prenatal diagnosis. There was also no way for the neonatologists to know that there was more information to be had by repeating the microarray after delivery. In fact, up until this point, it had not been routine for us to repeat a microarray after delivery when the prenatal microarray was normal. We should admit here that the fact that the microarray was repeated postnatally was considered (at least by RDC) to be an error, unnecessary and even wasteful testing. Now that opinion seems less defensible.

The cost of withholding the information about the ROH may not be readily apparent, because we made a likely diagnosis with a genomic test (exome). This might argue that the lack of timely information about the ROH on chromosome 1 was not critical to the diagnostic process. However, the exome results took about four months and were very costly. We likely would have succeeded at a lower cost, and with a quicker turn-around-time had we been able to narrow our focus to candidate genes within the ROH and had we had that information in good time. The consequences of the lab's prenatal microarray reporting policy must include the stress of delayed diagnosis on the family, the cost to the patient of delays in offering meaningful treatment or surveillance, and the cost to the hospital of a redundant microarray and overly broad and expensive exome testing.

There are no professional standards or guidelines for reporting CNVs or ROH on microarrays, either prenatally or postnatally. Each laboratory determines its own reporting protocols. To document the variability in reporting standards that exist for prenatal

and postnatal microarrays, we performed an informal telephone survey on a convenience sample of 10 cytogenetic laboratories. The results are summarized in Table 1. Among these ten labs, none had the same reporting criteria, even though many were similar. Furthermore, 8 of the 10 had different reporting standards for prenatal and postnatal microarrays, usually reporting less information prenatally. Knowing this, a clinician could reasonably expect that a "normal" prenatal microarray might not meet the criteria for the same "normal" interpretation when reported postnatally

Loss-of-function variants in MFSD2A are associated with autosomal recessive primary microcephaly, type 15 (MIM# 616486). The mechanism seems to be disruption of transport of the necessary omega-3 fat, docosahexaenoic acid, DHA, across the blood-brain barrier. This condition is characterized by a spectrum of severe microcephaly, structural brain anomalies, a paucity of white matter, hypotonia, spasticity, and intellectual disability with absent speech. Although the homozygous missense variant in MFSD2A in this child has been classified as of uncertain significance (VUS), c.929T>G/p.Leu310Arg, we considered it to be likely causative. This homozygous variant has not been reported in the literature, disease/mutation databases, or in allele frequency databases (gnomAD). The amino acid position is highly conserved through evolution, and in silico analyses predict this alteration has a deleterious effect on protein function. This variant is located at the 5' border of transmembrane domain 6; it has been hypothesized that variants in these transmembrane domains may interfere with substrate binding. The four other pathogenic variants in this gene reported in association with this phenotype are novel missense variants found in highly conserved residues in or at the border of the aforementioned transmembrane domains. At least 3 of these variants have had functional studies that show reduced or absent transporter activity. These findings suggest that this variant has a pathogenic consequence Taken together. We are in the process of investigating the CNS phenotype with more imaging studies.

Wang et al. (2015) demonstrate that ROH occur frequently and have clinical utility by reflecting parental relatedness, ascertaining autosomal recessive diseases, and unraveling UPD. In their study of over 14,500 consecutive oligo-SNP chromosome microarrays, these authors found that 6% of oligo-SNP microarrays harbored one or more ROH >10 Mb, of which 78% involved multiple regions, indicating identity by descent (consanguinity). Of the ROH involving single chromosomes, about 10% demonstrated UPD. Autosomal recessive disorders were confirmed in seven of nine cases from eight families because of the finding of a suspected gene within an ROH.

Our survey found a variety of reporting criteria among ten commercial and academic cytogenetic laboratories and different stan-



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Laboratory	Prenatal Microarray Reporting Criteria	Postnatal Microarray Reporting Criteria
Commercial Lab A	Del >1 Mb, Dup >2 Mb Total percentage of ROH is reported when >5% of the genome Single terminal ROH >3 Mb or single interstitial ROH >10-20 Mb are generally reported, dependent upon chromosomal location	Del >50 kb, Dup >400kb ROH >3% of the genome Single terminal ROH >3 Mb or single interstitial ROH >10-20 Mb are generally reported, depen- dent upon chromosomal location
Commercial Lab B	At least 1 gene is included in CNV and Del >1 Mb, Dup >2 Mb AOH of unknown significance when greater than 5 Mb (terminal) and 10 Mb (interstitial) on imprinted (UPD-associated) chromosomes Total percentage of ROH is reported when >10% of the genome	Del >200 kb, Dup >500 kb ROH >2% of the genome
Commercial Lab C	<b>Del &gt;1 Mb, Dup 2 MB</b> ROH >8 MB multiple chromosomes or consan- guinity	Del >200 kb, Dup >500 kb Or >50 kb when CNV is in a clinically signifi- cant region ROH >8 MB when multiple chromosomes are involved or consanguinity
Commercial Lab D	CNV that is likely benign is not reported AOH >5 Mb	CNV that is likely benign may be reported AOH >5 Mb
Academic Lab A	<pre>CNVs: Del ≥1 Mb, Dup ≥2 Mb, or smaller CNV in clinically significant regions ROH ≥5 Mb, reporting threshold ~10 Mb Total percentage of ROH is reported when ≥5% of the genome</pre>	CNVs: <b>Del ≥200 kb, Dup ≥400 kb</b> or smaller when CNV is in a clinically significant region ROH ≥5 Mb, reporting threshold ~10 Mb ROH ≥5% of the genome
Academic Lab B	CNV >50 kb AOH >5 Mb	Same as prenatal criteria
Academic Lab C	CNV > 400kb if VUS or >25 kb if pathogenic >400 kb VUS clinician determined AOH >3 Mb on a single chromosome or >1.5% of the genome	Same as prenatal criteria

Table 1. Prenatal and postnatal microarray reporting criteria

**Boldface** is used for reporting standards that are different for prenatal and postnatal microarrays AOH absence of heterozygosity (AOH=ROH), CNV copy number variant, Del deletion, Dup duplication, kb kilobase, Mb megabase, ROH region of homozygosity (AOH = ROH), VUS variant of uncertain significance



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dards for prenatal and postnatal microarrays in 80% of those labs. When the prenatal and postnatal reporting standards differed, the tendency was to limit the reporting of CNVs and ROH prenatally. The challenges associated with the lack of uniform standards for reporting ROH among laboratories have been described by others (Grote et al., 2012). Our case reinforces the need for prenatal disclosure of ROH when an autosomal recessive disorder is suspected. Meanwhile, we are considering how best to unlock any hidden data that might exist in "normal" prenatal microarray reports. It will likely include more frequent communication with the cytogenetics lab and more repeat postnatal microarrays. We are also exploring more productive ways of partnering with the lab going forward. For instance, we asked whether the lab would be willing to report all ROH prenatally for autozygosity mapping when there is a high index of suspicion for an autosomal recessive disorder, which could be indicated on the test requisition form.

#### **Practical Applications:**

- 1. Understand that cytogenetic reporting criteria for prenatal and postnatal microarrays have not been standardized.
  - 1. Reporting algorithms vary between laboratories.
    - 1. Many cytogenetic laboratories also have different reporting criteria for prenatal and postnatal chromosome microarrays.
    - Know your cytogenetic laboratory's microarray reporting protocols
- 2. After a normal prenatal microarray, consider repeating the test postnatally, especially when the infant has unexplained congenital anomalies, low birth weight, or poor feeding.
  - 1. Another option: contact the cytogenetic laboratory that reported the normal prenatal microarray results and ask for a reinterpretation using postnatal reporting standards.
- 3. Review regions of homozygosity (ROH) reported on the chromosome microarray, to identify candidates genes when an autosomal recessive disorder is suspected

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### **2020 Infant Health Policy Summit**

Susan Hepworth, Mitchell Goldstein, MD

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Protecting Access for Premature Infants through Age Two

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

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

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

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

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## National Statistics Respiratory Syncytial Virus

## **About Respiratory Syncytial Virus**

Respiratory syncytial virus, or RSV, is a contagious seasonal respiratory virus that can cause bronchiolitis and pneumonia. It is also the leading cause of hospitalization in babies less than one year old.<sup>1</sup> RSV can be deadly for premature infants and at-risk infants with congenital heart disease or chronic lung disease.

Preventive treatment called palivizumab can protect infants from RSV, but national claims data shows certain babies aren't getting access to this FDA-indicated therapy.

## National Health Plan Coverage & Access

A national data supplier provided palivizumab claims for Medicaid and commercial health plans across the nation from January 2019 through December 2019.



"Gap" Babies Commercial Plans Denied 40% Medicaid: 25%



Medicaid: 25% **"In-Guidance" Babies** Commercial Plans Denied **25%** Medicaid: **14%**  Health plans deny 40% of palivizumab prescriptions for premature infants born between 29 and 36 weeks gestation.

One in every four prescriptions is denied for infants who should qualify for coverage under standard insurance policies.

This includes severely premature infants born before 29 weeks gestation, babies born before 32 weeks gestation who have chronic lung disease, and babies born with congenital heart disease.







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## RSV AWARENESS: A National Poll of Parents & Health Care Providers

Respiratory syncytial virus, or RSV, is far from the common cold. It can lead to hospitalization, lifelong health complications or even death for infants and young children. **In fact, it is the leading cause of hospitalization in children younger than one.** 

Yet a national poll of parents and specialty health care providers reveals a startling divide in attitudes toward the virus. While both groups acknowledge RSV as a significant concern, the two populations vary widely in their reported ability to meet RSV's threat head-on. Health care providers vigilantly monitor for the virus, which they report seeing regularly in their practices. Parents, however, feel unequipped to protect their young children.

Meanwhile, specialty health care providers overwhelmingly report that health plan rules and insurance denials block vulnerable infants' access to preventive RSV treatment. Such barriers can put unprepared parents at a double disadvantage. The survey does suggest, however, that education can embolden parents to seek more information about RSV and take steps to protect their children.

## KEY FINDINGS

#### Preparedness

Parents of children age four and under report that understanding of RSV is lacking. That leaves them less than fully prepared to prevent their young children from catching the virus. Specialty health care providers reiterated these concerns; 70% agreed that parents of their patients have a low awareness of RSV. Meanwhile, specialty health care providers themselves actively monitor for RSV. They reported that:



#### SPECIALTY HEALTH CARE PROVIDERS

They treat RSV as a priority, "often" or "always" evaluating their patients (80% doctors; 78% nurses)

During RSV season, they are especially vigilant about monitoring patients for symptoms or risk factors for RSV (98%).

#### PARENTS

Only 18% said parents know "a lot" about RSV, reflecting an awareness level that's roughly half that of the flu

Only 22% of parents consider themselves "very well prepared" to prevent RSV.



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## Clinical Pearl: COVID-19 in the Neonatal Population: Review of Current Literature

Kenneth Kellner, MD

#### What is COVID-19?

Many members of the Coronaviridae family exist, and usually, Coronaviruses cause mild respiratory disease or diarrhea. (1) Towards the end of 2019, COVID-19 emerged in local hospitals in Wuhan, China. Initial investigation suggested cases were associated with exposure at a local seafood market where many varieties of live animals were available for sale. On February 11, 2020, the World Health Organization (WHO) announced the standard format: Coronavirus Disease-2019 (COVID-19). The same day, the International Committee on Taxonomy of Viruses (ICTV) named the virus SARS-CoV-2. SARS-CoV-2 was first isolated in bronchoalveolar lavage fluid of three patients at a Wuhan hospital on December 30, 2019. (2)

SARS-CoV-2 is a member of the  $\beta$ -CoV family. The Coronavirus (CoV) family are enveloped, positive-sense, single-stranded RNA viruses. Four subfamilies exist:  $\alpha$ ,  $\beta$ ,  $\gamma$ , and  $\delta$ . Human CoV infections are caused by  $\alpha$  and  $\beta$ -CoVs. SARS-CoV-2 is a member of the  $\beta$ -CoV family. (2)

The spike (S) protein of coronaviruses facilitates viral entry into target cells. Entry depends on the binding of the surface unit of the S protein to a cellular receptor. SARS-CoV-2 utilizes angiotensin-converting enzyme 2 (ACE2) as the entry receptor. (1)

#### Is COVID-19 vertically transmitted from mother to neonate?

A systematic review published in May 2020 aimed at studying vertical transmission of SARS-CoV-2. A review of 22 studies comprising 83 neonates born to mothers diagnosed with COVID-19, both via cesarean delivery (CS) and vaginal delivery (VD), revealed three positive confirmed cases of SARS-CoV-2 in neonates via nasopharyngeal swab real-time polymerase chain reaction (RT-PCR). Another six patients had elevated virus-specific antibody levels but negative PCR testing. Without positive RT-PCR tests of amniotic fluid, placenta, or cord blood, there is a lack of evidence for intrauterine vertical transmission. In addition, there is no convincing evidence that CS is safer than VD. (3)

Another systemic review of 49 studies and 666 neonates demonstrated 28 infants (28/666, 4%) had confirmed COVID-19 infection. A total of 291 women delivered vaginally, and 8/292 (2.7%) of these neonates tested positive for SARS-CoV-2. Three hundred and sixty-four women delivered via CS, and 20/374 (5.3%) of these neonates tested positive. This study demonstrates neonatal COVID-19 infection is uncommon, usually asymptomatic, and the rate of infection is not significantly lower when babies are born via CS versus VD. Importantly, rate of neonatal infection does not appear to be significantly different comparing infants who were allowed to breastfeed, room-in with or come into contact the mother versus infants who were separated from mom or formula feed. (4)

"The National Registry for Surveillance and Epidemiology of Perinatal COVID-19 Infection (NPC-19) includes 176 centers in the United States thus far with an aim to monitor data and outcomes of mother/ infant dyads when mothers test positive for COVID-19."

The National Registry for Surveillance and Epidemiology of Perinatal COVID-19 Infection (NPC-19) includes 176 centers in the United States thus far with an aim to monitor data and outcomes of mother/infant dyads when mothers test positive for COVID-19. These data were last updated on June 5. 2020. and now includes 747 mother/infant dyads. Of 747 mothers who tested positive for COVID-19, 508 (68.6%) were asymptomatic, 191 (25.8%) were symptomatic, and 42 (5.7%) were admitted for COVID-19 treatment. Twenty-five infants thus far have had at least one positive test for COVID-19. Of these, 14 were separated from mom after birth, and 11 were non-separated. Of 232 mothers with clinical illness, 182 infants were separated, and six were presumptive positive (infection rate of 3.3%). Fifty infants both to mothers with clinical illness roomed in with mother, and 1 of these infants tested positive (2% infection rate). A total of 500 asymptomatic women tested positive for COVID-19, and 212 of these infants were separated from mom. Of these 212 separated infants, three tested positive (1.4%). 288 infants born to asymptomatic women roomed in, and ten of the infants tested positive (3.4%). (5)

As further data are published, the information gathered will likely lend more answers to the question of vertical transmission. Based on the data currently published, it is apparent that CS is not necessarily safer than VD. Likewise, the argument can be made that neonates rooming in with mother—whether mom is symptomatic or asymptomatic—do not infer a higher risk of infection versus infants who are separated.

#### A Convincing Case Report of Potential Vertical Transmission:

A recent case report suggests the possibility of vertical transmission. The infant was born to a 40-year-old woman with active SARS-CoV-2 infection in Toronto, Canada. Mother had a history of familial neutropenia, gestational diabetes and had frequent bacterial infections during pregnancy treated with antibiotics. She presented with myalgia, dry cough, and fever and tested positive for SARS-CoV-2 via reverse transcriptase-polymerase chain reaction (RT-PCR). This mother did not require respiratory support. Due to worsening maternal coagulopathy, urgent CS was performed at 35+5 weeks gestation. There was



an artificial rupture of membranes at delivery, clear fluid, and delivery of a neonate with Apgar scores of 9 and 9 at one and five minutes, respectively, with a birth weight of 2.93kg. Contact and droplet precautions were observed in the operating room. Nasopharyngeal swabs of the neonate were positive on the day of birth, post-natal day of life (DOL) 2, and DOL 7. Neonate's plasma tested positive on DOL 4, and stool tested positive on DOL 7. Five random placenta specimens showed areas of infiltration by inflammatory cells and early infarction. (6)

In the same case, mother and newborn were transferred to a negative pressure room, mom attempted breastfeeding with precautions, and the neonate was kept two meters away from mom between feeds. The infant was then transferred to the Neonatal Intensive Care Unit (NICU) for hypoglycemia and neutropenia. The infant was eventually discharged home on DOL 4. In this case, congenital infection is supported by the fact that the neonate was not in contact with the mother's vaginal secretions, membranes were intact before birth, and there was no skin-to-skin contact with mother prior to collection of the first PCR test. Of note, mother tested positive via nasopharyngeal swab and also tested positive in breast milk and vaginal secretions. 6 If this case truly represents vertical transmission, it is likely the mother's immunocompromised state and disseminated infection played a significant role in the transmission of SARS-CoV-2 to the neonate.

#### Can COVID-19 be Transmitted Via Breast Milk?

A study from Germany in May 2020 examined breast milk from two nursing mothers infected with SARS-CoV-2. After nipple disinfection, milk was collected with pumps and tested for viral loads via RT-PCR. Four samples from mother number one tested negative. SARS-CoV-2 RNA was detected in the milk of mother number two at days 10, 12, and 13 after delivery. Subsequent samples collected from mother two were negative. Both newborn one and two tested positive for COVID-19 on DOL 8 and DOL 11, respectively. It is unclear whether the newborn born to mother number two was infected via mother's breast milk or via another mode of transmission. (7) Further studies are needed in which mother's milk is tested for SARS-CoV-2, and the neonate is tested and followed clinically over time in order to determine if breast milk is a source of vertical transmission from mother to neonate.

#### Is the Placenta Affected by Maternal COVID-19 Infection?

A recent study from Northwestern University examined placentas of 16 mothers infected with SARS-CoV-2. Fifteen were live births in the third trimester, and one was delivered in the second trimester after intrauterine fetal demise. Compared to controls, third trimester placentas were significantly more likely to show maternal vascular malperfusion (MVM). MVM is a pattern of placental injury indicating abnormalities in oxygenation in the intervillous space and is associated with adverse perinatal outcome. (8)

#### Does COVID-19 Adversely Affect Neonates?

A recent case study reports a term neonate born after an uncomplicated pregnancy. On the second day after delivery, the mom developed a fever and tested positive for SARS-CoV-2 via PCR. On the same day, the infant also tested positive. Initially, the infant was asymptomatic, but after 48 hours of isolation in the same room as mother, the baby developed perioral cyanosis and a poor suck without other signs of respiratory distress. Complete blood count and C-reactive protein were reassuring. The baby's oxygen saturation was 88% on room air; the remainder of vital signs were within normal limits. Arterial blood gases demonstrated hypoxemia. An echocardiogram excluded a cardiac cause of cyanosis. The infant was started on empiric ampicillin and gentamicin, blood culture resulted showed no growth, and the infant tested negative for other respiratory viruses via PCR. The chest radiograph revealed mild ground-glass opacities. The infant required high flow nasal cannula (FiO<sub>2</sub> 30%). Weaning to room air was accomplished after 50 hours of NICU admission. This case indicates that infection with SARS-CoV-2 may result in significant hypoxemia in the neonate. (9)

This update of clinical information regarding aspects of the transmission and effects of COVID-19 infection in mothers and their newborn infants reflects the almost daily availability of new information for providers.

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# Medical Legal Forum: High Reliability in Health Care - An Introduction

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"The very first requirement in a hospital is that it should do the sick no harm" – Florence Nightingale.

Contemporary healthcare is "...the most complex undertaking in human history" - Peter Drucker

### Background:

Healthcare workers face quite a challenge. They must try to take the safest possible care of patients while working in extraordinarily complex systems. The High-Reliability theory offers insight into this dilemma. Increasing reliability has the potential to not only improve outcomes but also to decrease a hospital's liability.

"Hippocrates may have first addressed preventable harm in healthcare, and there have continually been attempts to try to find better systems. In the last few decades, increasing attention has been paid to the challenge of medical errors."

Hippocrates may have first addressed preventable harm in healthcare, and there have continually been attempts to try to find better systems. In the last few decades, increasing attention has been paid to the challenge of medical errors. Countless books and articles have been written about the problem and the search for meaningful and sustainable solutions. Contributing factors include complex systems, distractions, culture, routine rules violations, and misaligned incentives.

Charles Perrow addressed challenges in complex systems in his classic 1984 book, Normal Accident. The book was primarily focused on other high-risk industries, such as the nuclear industry, chemical manufacturing, and commercial aviation. However, healthcare has similarities to other high consequence industries. In Normal Accident, Perrow outlined the three components of catastrophic failure:

- 1- Complex systems
- 2- A culture of "blame the victim."
- 3- High productivity pressures

Anyone working in the healthcare industry can evaluate for

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themselves if the three elements listed above apply to their own job.

*"The term "high-reliability organization" has been used since at least the 1980s. A landmark contribution was made in 2001 when Weick and Sutcliffe published the first edition of Managing the Unexpected."* 

The term "high-reliability organization" has been used since at least the 1980s. A landmark contribution was made in 2001 when Weick and Sutcliffe published the first edition of Managing the Unexpected. These authors described the common themes in organizations that had found ways to improve outcomes in complex systems. A brief summary of their findings has been referred to with the acronym "FSORE."

- 1- Preoccupation with failure
- 2- Reluctance to simplify
- 3- Sensitivity to operation
- 4- Commitment to resilience
- 5- Deference to expertise

As with any acronym or brief summary, "FSORE" is an oversimplification of the elegant themes developed by Weick and Sutcliffe. Managing the unexpected became a blueprint for contemporary efforts for organizations to become a so-called "HRO."

There have been subsequent editions of the book, and the principles above have been extensively refined. Increasingly, the principles of HRO are being applied at hospitals.

### Introductory Concepts to Improve Reliability

As in any methodology, it is critical to understand the terminology. The current pandemic has ushered in the increasing use of the vocabulary of HRO.

**Example 1**- a hospital worker actively infected with Covid-19 attempts to enter the hospital

### Precursors- attempt to prevent the "error" before it happens

Vaccine (theoretically, the worker may never become actively infected)

Education- widespread campaign to inform employees not to come to work if ill

# Barriers- if the "error" takes place, attempt to minimize/ prevent the harm

masks, PPE, screening employees at the entrance to the



hospital

redundancy- second "screener" confirms work done by the initial screener

recovery- take employees temperature and prohibit entry if the employee is febrile

Mitigation- if the harm takes place, attempt to limit the damage/downstream effects

ICU care

Anti-viral therapy

Attempt to protect staff and visitors from exposure to the patient

**Example 2-** NICU RN mistakenly attempts to attach milk feeding tube to UVC line

### Precursor-

Training (consider simulation labs)

Proctoring

Regular competency evaluation

### **Barriers**-

non-compatible connector (physical barrier),

follow the line to the patient (recovery),

two RN's confirm that the feeding is connected correctly (redundancy)  $% \left( {{\left[ {{{\rm{conf}}} \right]}_{\rm{conf}}} \right)_{\rm{conf}} \right)$ 

### **Mitigation-**

fluid resuscitation

blood pressure support

ICU care

### Take Home Messages:

- Attempt to understand common fail points and vulnerabilities in the system.
- Attempt to categorize the types of failures- communication, diagnosis, etc....
- It is generally advisable to invest in "precursors" such as vaccines, training, proctoring.
- Is it possible to prevent the "error" from taking place?
- If the error happens, is it possible to prevent the error from causing harm?
- Design robust and resilient systems so that "errors" do not get through to the patient.
- Attempts to realistically model the risk- will the human being comply with the rule/process?

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### **Disclaimer:**

This column does not give specific legal advice, but rather is intended to provide general information on medicolegal issues. As always, it is important to recognize that laws vary state-to-state and legal decisions are dependent on the particular facts at hand. It is important to consult a qualified attorney for legal issues affecting your practice.



### OPIOIDS and NAS When reporting on mothers, babies, and substance use LANGUAGE MATTERS



### I am not an addict.

I was exposed to substances in utero. I am not addicted. Addiction is a set of behaviors associated with having a Substance Use Disorder (SUD).



### I was exposed to opioids.

While I was in the womb my mother and I shared a blood supply. I was exposed to the medications and substances she used. I may have become physiologically dependent on some of those substances.



# NAS is a temporary and treatable condition.

There are evidence-based pharmacological and non-pharmacological treatments for Neonatal Abstinence Syndrome.



## My mother may have a SUD.

She might be receiving Medication-Assisted Treatment (MAT). My NAS may be a side effect of her appropriate medical care. It is not evidence of abuse or mistreatment.

### My potential is limitless.



I am so much more than my NAS diagnosis. My drug exposure will not determine my long-term outcomes. But how you treat me will. When you invest in my family's health and wellbeing by supporting Medicaid and Early Childhood Education you can expect that I will do as well as any of my peers!

Learn more about Neonatal Abstinence Syndrome at www.nationalperinatal.org



# Why PREMATURE INFANTS Need Access to an EXCLUSIVE HUMAN MILK DIET





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### Flight Decks and Isolettes: High-Reliability Organizing (HRO) as Pragmatic Leadership Principles during Pandemic COVID-19

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### Abstract

The COVID-19 crisis has created a physical environment where neonatologists and neonatal staff face exposure to an easily transmissible, potentially fatal infection in the course of their duties. Leaders cannot reject an assignment, such as a resuscitation of a newborn, because of risk. As in military operations, safety and capability cannot be separated from neonatal operations. Leadership models developed in stable environments do not fully translate to dynamic, uncertain situations where the leader and subordinates personally face threats; the type of environment from which the High-Reliability Organization (HRO) emerged. There must be a shift from the increasingly abstract, academic, and normative representation of HRO leadership to its original, more pragmatic frame that iteratively supports engagement. The purpose of this paper is to present HRO as leadership principles. bridging the gap between abstract theory and practice by bringing attention to HRO as a scientifically supported pragmatic leadership stance.

### Keywords: None

### Introduction

The uncertain and ambiguous behavior of COVID-19 taxed healthcare leaders who directed medical care, identified and treated the novel infection, and protected their staff while risking exposure to the potentially lethal virus themselves. During COVID-19, neonatologists faced the dual challenge of identifying and treating a previously unencountered disease while protecting themselves and others from contracting a highly infectious virus.

Leadership models developed by external observers bring clarity to leadership duties, introduce a macroscopic view, and assist in different levels of analysis. This approach directs leadership schemata toward organizational design and structure, maintains coherence with established leadership concepts, and ensures congruence with the organization's operations. Effective leadership buffers the organization from disruptions, yet cannot be tested until the rare, extreme situation. Leadership models do not incorporate the characteristics necessary for close in, quick identification and interpretation of weak signals, uncertainty, and ambiguous information. "A story always sounds clear enough at a distance, but the nearer you get to the scene of events the vaguer it becomes" (Orwell 2008 31).

Leadership models developed in safe, stable environments do not generalize well in circumstances where leaders and followers must personally face dynamic and unpredictable situations, actively avoid death, and consider outcomes that include lifethreatening disease or psychological injury (Kolditz 2006; Campbell, Hannah, and Matthews 2010). Stress responses, fear reactions, and threat reflexes then easily become misinterpreted as personal failings or emotional responses developing into subtle or hidden decrements in human performance and organizational operations.

Leadership models meet the purposes of the leader and organization with less emphasis on the needs of subordinates. Leadership for dangerous situations, by necessity, encompasses the point of view of subordinates, such as mutual sense giving (Dixon et al. 2017) and survival (Dixon 2014; Kolditz 2006). Followers must believe the leader's intent and actions will influence their well-being (Kolditz 2006)

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Leadership found in dangerous environments is similar to leadership in the organizations from which academicians codified HRO (TAM) and dangerous public safety environments (DvS, SDM). The purpose of this article is to identify salient leadership characteristics for HRO that support neonatal care during pandemic COVID-19. Responding to the admixture of threat and duty necessitates values directed toward well-being. Acting under time compression limits ethics analysis. The pragmatic stance for leadership must be grounded in practical wisdom.

Appreciation of the pragmatic leadership stance as integral HRO will support neonatologists bringing the benefits of HRO to the neonatal intensive care unit (NICU) and to their academic research. In this article, we will describe 1) the emergence of HRO principles from aerial combat operations and nuclear engineering, 2) leadership ethics and practical wisdom, 3) the dynamics of leadership, 4) leadership in extremis, and 5) The nature of the problem and environment

The emergence of HRO: The duality of safety and leadership

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During the roughly 30-year period from WWII through the Vietnam War, the Pacific Fleet had conducted most of the US Navy's combat operations, making death a part of operations and creating 'rules written in blood.' The exigencies of combat made it imperative for everyone to identify effective actions and retain what they learned. Aviation Safety is vital even during wartime, and operational accidents are thoroughly investigated. Safety in combat has an additional function; the avoidable operational loss causes shortages of men and planes one cannot afford and increases vulnerability to enemy activity. The pragmatic leader gives meaning to the adage "Safety through operations and operations through safety."

"The pragmatic leader gives meaning to the adage 'Safety through operations and operations through safety.""

After 1973, when the US Navy's involvement in the Vietnam War ended, the Navy established additional risk management and safety programs for greater attention to operational readiness. This included the development of what is now called HRO. A very significant decrease in aircraft and shipboard accident rates occurred over the next twenty years. Major aircraft accidents per 100,000 flight hours were reduced from seventeen to two. Nearly all accidents have some degree of aircrew or personnel error involved (the point where human intervention may prevent failure), contributing to the expansion of selection and training pipelines for all air wing and shipboard personnel, particularly in the top leadership positions.

During this time, the ten Nimitz-class nuclear aircraft carriers joined the fleet. Captains of a US Navy aircraft carrier are nuclear trained and, by an act of the US Congress, must be aviators. They now serve a three-year tour in carrier command after a nominal six years of prior qualifying assignments. In addition to the eighteen months of nuclear power and Naval Reactors training, the program includes a two-year tour as the Executive Officer of a nuclear carrier and command of a conventionally powered deep draft vessel. Thus, the nuclear aircraft carriers brought together three independent, otherwise disparate domains within a single individual: 1) aerial warfare experience with initiative, improvisation, and flexibility, 2) nuclear propulsion engineering experience with rigor, detail, and conformity to procedures; and 3) previous aircraft squadron and large ship command of complex organizations in demanding circumstances. This remains the standard.

Nuclear training in engineering and nuclear safety theory gave these Captains a greater appreciation of highly reliable operations and expanded their leadership capabilities. The training and professionalism of the nuclear propulsion engineers helped formed the basis for increased safety awareness and reliability of operations throughout the entire aircraft carrier and embarked air wing. HRO had emerged on the nuclear aircraft carrier by merging the emergency-type responses of aerial combat with the control-operator functions for a nuclear reactor. Diverse organizations adapted HRO to their specific environments. For example, wildland firefighting emphasized the emergency operations component, while civilian nuclear power programs emphasized the control operator style (Roe and Schulman 2015).

The USS Carl Vinson departed on a seven-month homeport change and around-the-world cruise less than a year after commissioning. As the first new carrier assigned to the Pacific Fleet in over twenty years, much of the pre-cruise aviation and ship logistic support was provided through the Pacific Fleet chain and awaited the ship in Diego Garcia, an island in the middle of the Indian Ocean. After a month of operational commitments in the Mediterranean Sea, and a port visit to the Ivory Coast in West Africa, Carl Vinson proceeded to the Indian Ocean. One of the authors, (TAM), reported as Captain to the ship in Perth, Australia, three months into the cruise. Over the next three years and two extended deployments, Carl Vinson operated free of aircraft accidents and major injuries, receiving significant aviation safety and operational readiness awards, including the Admiral Flatley Memorial Award for the best Navy-wide aircraft carrier and air wing safety record.

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Shortly after arrival in the ship's new homeport of Alameda, CA, RAdm Mercer invited the academicians from the University of California, Berkeley, onboard to research and evaluate the Navy's methods in ensuring safe and reliable aircraft and ship operations (Ford et al., 2003; van Stralen and Mercer 2015). The intense activity on the flight deck and in Air Operations during high tempo operations captured their attention. Navigation Bridge and Combat Information Center coordination in defending the ship and avoiding collisions and groundings were studied to a lesser extent. The academicians, therefore, had a somewhat restricted view of the hands-on leadership, including the Captain's presence throughout the ship, which made the complex organization function as a team. This led to a single level of analysis rather than a macroscopic view providing multiple levels of analysis. The initial data collection and research did not identify the effect of command and leadership on the organizational structure and culture of the carrier. The researchers focused on the flight deck and "experiences of not failing" ("error-free"), somewhat missing "the experiences of failing," resulting in the flight deck only level of analysis becoming codified as HRO.

Unconventional aspects of the pragmatic leadership stance, often misunderstood by outsiders, can hinder acceptance of HRO. For example, in the US Naval Special Warfare (NSW) community (aka Navy SEALs), enlisted (or relatively junior) personnel are often expected, and as necessitated by circumstances, to give commands to those senior to them, including officers, that must be followed. This may appear to negate the strong rules of relationships between officers and enlisted sailors, similar to the hierarchy in healthcare. But the behavior has a basis in experience. Because of the nature of their work, an enlisted sailor with proximity to the problem knows what needs to be done. They are often the individual that planned and was responsible for the success of one aspect of the operation. An officer on the mission, accountable for the overall operation, may not be in a position to act. Thus, a lowerranking individual with local knowledge gives urgent commands or directions to a higher-ranking individual (personal communication, Raymond C. Smith, RAdm, USN, retired). This is also, to a lesser degree, the operational norm for firefighting operations and combined fire-rescue ambulance physical rescues (DvS, SDM) but not nearly as accepted in healthcare (DvS). This forms the basis for

training all members to be "leader-leaders," and is certainly one example of appropriate "deference to expertise."

The military is viewed as hierarchal, but, for example, the Army's philosophy of 'mission command' empowers subordinates within the intent of the mission. The key point to understand is who has authority and responsibility. Regardless of their branch of service, whether Special Operations Forces (SOF) or conventional forces, a commander can delegate authority but not responsibility. Operators are expected to speak up and provide immediate directions or commands based on the circumstances, which aren't orders. Actual orders are legally binding

"Unrecognized fear caused defensive and offensive protective behaviors. Sustained threat reflexes such as fight, flight, and (hypervigilant) freeze interfered with team formation. The problem was present, staff were present, residents were present, but the intensivist was not, a recurring situation experienced by one of the authors (DvS)."

In a recently opened pediatric intensive care unit (PICU), "First do no harm," the classical safety dictum in healthcare, initiated a cortisol stress cascade in bedside staff during abrupt patient deteriorations, interfering with care. Executive functions, cognition, working memory, and declarative memory became impaired. Resident physicians and staff, with little or no experience in a PICU or with unanticipated patient deteriorations, hesitated to make decisions or take actions, other than known protocols. Unrecognized fear caused defensive and offensive protective behaviors. Sustained threat reflexes such as fight, flight, and (hypervigilant) freeze interfered with team formation. The problem was present, staff were present, residents were present, but the intensivist was not, a recurring situation experienced by one of the authors (DvS). To address these impairments, the two PICU attendings (one a former fire department paramedic and the other a former US Navy aviator and Vietnam War veteran) focused on decision-making and modulating the stress responses, fear reactions, and threat reflexes that inhibited engagement.

Professionals have requested information from the authors to "convince" their leaders to accept various safety models, including HRO. Misunderstanding HRO's leadership dimension contributes to conflict with existing leadership beliefs and subsequent rejection of portions, if not the entirety, of HRO. Not recognizing the leadership dimension obscures the qualities of HRO that extend leadership into the situation. Viewed as a leadership stance, HRO methods naturally integrate into the organization's structure, and leadership approaches. "Conversion" without the inherent leadership dimension, as with other reliability and safety models, and HRO becomes a market commodity rather than a readily attained, pragmatic leadership stance.

We also find leaders will profess their organization's HRO characteristics. Pragmatic leadership, derived from in extremis situations, has positive influences on subordinates when the leader is absent. From the perspective of HRO comprising attributes, each attribute necessitates a sort of melding of subordinates and leaders in various circumstances independent of the proximity of the leader. Interactions with these subordinates, far from the organization's central leaders, reveals the operational presence of pragmatic leadership.

### Leadership Ethics, Practical Wisdom, Phronesis

During a week of training for a select group of US Special Operations Command (USSOCOM) personnel, one of the first questions the medics asked one of the authors (DvS) was, "Do you have a relationship with your people?" People trust themselves to the leader who develops relationships with subordinates, genuinely cares about their welfare, is honest, and possesses integrity (Sweeney, Matthews, and Lester 2011). Threat and time compression generate unrecognized fear behaviors directed toward selfprotection, making these actions appear prudent in the moment. These are situations where subordinates look to the leader for decisions ensuring their welfare and the public good.

Subordinates will take a far harder path than imagined when they believe in the character and integrity of the leader, the reason we find these leader traits in Aristotle's Nicomachean Ethics (1140b5-7), public safety training ((Palmer, Hannah, and Sosnowik 2011), and American military colleges and universities (Palmer, Hannah, and Sosnowik 2011; Sweeney, Matthews, and Lester 2011; Olsen, Eid, and Larsson 2020). Phronesis – prudence or practical wisdom – is situational wisdom for contextual circumstances, context-dependent information, and the particulars of a situation. Phronesis guides rule selection appropriate for the situation at the moment of action. We are more familiar with rule-based knowledge independent of context: epistêmê (epistemology) and technê (technology).

Phronesis, adaptive and pragmatic toward the greater good, has three elements: (1) the person who possesses character; (2) the particular situation in context; (3) values for the community good. In Aristotle's words, phronesis is an intellectual virtue or characteristic "bound up with action, accompanied by reason, and concerned with things good and bad for a human being" (Nicomachean Ethics 1140b5-7). Phronesis, also called prudence, is the first of Aristotle's four Cardinal Virtues (Prudence, Justice, Temperance, and Fortitude).

The leader in dangerous contexts influences subordinates by modeling attitudes, values, and behaviors. While beliefs have a stronger influence on behavior, their greater specificity limits adaptability to uncertainty and ambiguity. Values have a stronger, more consistent effect on behaviors with less context-dependence. Attitudes influence behavior and are less specific, making them adaptive to varying contexts. Attitudes predispose us toward favor or disfavor (Banaji and Heiphetz 2010, 350), the notion of evaluation at their core (Petty, Wegener, and Fabrigar 1997, 611). Attitudes summarize and integrate cognitive and affective reactions (Crano and Prislin 2006).

Leaders stimulate people to act on their own at the interface with the problem. Compared to fixed administrative control leadership, flexible distributed leadership generates knowledge-creation. The pragmatic leader recognizes context, defers to expertise, and accepts local knowledge. Practical wisdom is the capacity to choose appropriate goals and successfully devise means to reach those goals (Halverson 2004). Phronesis leaders view the problems of the organizations as being solvable within local constraints.

Engagement combines theory and practice, while leadership translates theory to practice. Phronesis, as a leadership-engagement characteristic, imbues practice with ethics while closing the theory-practice gap. Phronesis, to Aristotle, is an embodied quality to one who instructs the novice, a leadership quality, and the greatest of his Cardinal Virtues.



### The dynamics of leadership

In the neonatal world, "resuscitation" evokes procedures, protocols, teamwork, and actions directed to correct the baby's physiological dysfunction. The neonatologist considers the cause, initiating event, complications of therapies, sequelae, and optimal means to lead the team toward success. Although leadership and bringing order to these contingencies go hand-in-hand, this views leadership from the leader's perspective rather than of the subordinate and resuscitation as a relatively linear activity from alarm to resolution. The 'dangerous context,' imminent and personal threat to the individual, can destabilize leadership.

Resuscitation is a series of overlapping and sequential contingencies that can be simple or complex. Team members work independently and interdependently as decisions migrate to the person with the necessary information and capability to act. The neonatologist leads from a position somewhere between a dispassionate observer and an active participant. For example, during a tense resuscitation, someone states, "I need help." Does that remark reflect a subordinate's performance or a leader's ability or both? It depends on whether it is top-down or bottom-up and on whether it is made from an observer outside the problem space or an active team member working within the problem space.

"From a pragmatic stance, it makes little difference because the leader and subordinate experience the same threats and constraints. Making sense of their continuously changing perceptions, participants have only discrete concepts to rely on (Weick 2011). Both leader and subordinates experience the gap between how they practice in the moment and the theories and concepts they use (Zundel and Kokkalis 2010). "

From a pragmatic stance, it makes little difference because the leader and subordinate experience the same threats and constraints. Making sense of their continuously changing perceptions, participants have only discrete concepts to rely on (Weick 2011). Both leader and subordinates experience the gap between how they practice in the moment and the theories and concepts they use (Zundel and Kokkalis 2010). Together, the leader and subordinate engage the uncertainty and ambiguity, experience the restrictions and threats, struggle with the gaps between discrete concepts and continuous perceptions, and make and remake a team in a continuously adaptive, iterative process. Collaboration makes the team and the HRO stronger when leader and subordinates face the situation together with shared strengths and inad-equacies.

The sense of uncontrollability and existential threat results in stress responses and fear reactions that go unrecognized, impairing human performance and interaction (van Stralen, Byrum, Inozu 2017 269-73). Increasing stress capacity, a distinct yet inadequately developed leadership dimension in civilian leadership models, is fundamental to pragmatic HRO leadership.

Healthcare adopted HRO theory as codified by academicians from studying aviation operations on US Navy nuclear aircraft carriers (Rochlin, La Porte, and Roberts 1987; Chassin and Loeb 2013). The absence of the leadership domain in the body of HRO literature appears to be due in part to early HRO studies' focus on the visible 'flight deck' embodiment of high reliability achieved on the nuclear aircraft carrier USS Carl Vinson (TAM) as opposed to the inherent leadership skills that enabled it. As HROs organize to detect and respond to subtle and nuanced shifts and variance in contexts, it would appear reasonable that a leader's intentions and commands, or an executive's directives, could organize a system or situation from the outside. The leadership dimension of HRO, particularly in the dangerous context, is part and parcel of every interaction comprising the five (5) characteristics of HRO.

### Leadership in extremis

The neonatologist often leads by entering the situation, sharing the same demands and threats as the team, characteristics of leadership in extremis (Kolditz 2006; Hannah et al. 2009; Campbell, Hannah, and Matthews 2010; Ramthun and Matkin 2014; Dixon et al. 2017). In this article, we will adapt the leadership characteristics missed by the early HRO researchers into leadership for routine operations. Combined, they produce a pragmatic leadership stance available for routine care yet capable of rapid expansion with an evolving emergency. Jim Denney, Capt., LAFD, a veteran of two Vietnam combat tours, stating "What you do in an emergency is what you do every day," had integrated into routine work the leadership stance he learned from combat and emergency operations. People will then coalesce into an emergency team without fear of labels such as "crying wolf." The pragmatic leadership stance makes leaders available to the team, though the formal leader is absent.

The pragmatic leadership stance takes place within the situation, taking advantage of natural internal processes that self-organize people and situations. Self-organization with intention creates adaptive improvisation and immediate responsiveness, driving engagement and action. Individuals sense and respond to weak signals, subtle and nuanced feedback, and misinterpreted noise to bring order and generate the structure. As a stance, pragmatic leadership demonstrates leadership in the world of practice, a mental position, and attitudes. HRO and leadership as abstract representations of work that is done "out there," a representation by academics, is the very object that has been turned into a normative frame that must be returned to its more pragmatic frame. Pragmatic leadership, iterative across levels of analysis and hierarchy, supports engagement, bridges the gap between theory and practice (Zundel and Kokkalis 2010; van Stralen 2020), entwines individuals into teams through heedful interrelating (Weick and Roberts 1993), and from teams to groups to the larger organization from which emerges the HRO. Reliance on leadership models developed in relatively stable systems, the use of a normative stance, and top-down implementation has restricted the extension of HRO into healthcare, as well as into any organization where the environment can abruptly change.

"I see HRO more as mitigating, getting through, lessening the impact of disruptive interruptions. What's failing, am I oversimplifying this, what am I doing, what do I have to work with, and who knows more than I do, all seem to me to be working to restore a workable cosmos," Karl Weick, personal communication.

### The nature of the problem and environment

We work with the embedded problem, an ill-structured or ill-defined problem (Simon 1973) embedded in the environment (van Stralen 2020). Leadership in dangerous contexts occurs where the environment contains or influences information (Maitlis and



Christianson 2014; Dixon et al. 2017; van Stralen, Byrum, and Inozu 2017 page 396) and objectives compete or conflict (Vogelaar, Van den Berg, and Kolditz, 2010). Such problems have no clear problem definition, their goal state is not defined clearly, and the means of moving towards the (diffusely described) goal state are not clear (Dörner and Funke 2017).

In a natural system, problems embed into the environment to disrupt structures and distort the system's internal logic. As the environment gains influence, the immediate world becomes nonlinear and indeterminate, well thought out plans begin to fail, and the problem becomes a High-Reliability Situation (HRS) (van Stralen, Byrum, and Inozu 2017 122-3). Because the system can compensate for disruptions before they become consequential, HROs imagine disruptions as an early herald of a process. People maintain vigilance to intervene for these early heralds of failure. Small or frequent errors easily appear as patterns, mistaken for legitimate processes, which then become normative.

"In linear terms, an error or nonconformance results from clearly identifiable root causes to create a consequence. When we include time and the environment, the geometry is more like two cones joined at their apexes."

In linear terms, an error or nonconformance results from clearly identifiable root causes to create a consequence. When we include time and the environment, the geometry is more like two cones joined at their apexes. Contingent elements, inconsequential by themselves, interact synergistically, obscuring root causes, some of which may provide contingent benefits. They begin to form a final common pathway at the apex, then expand into a subsequent cone of consequences with varying severity due to other contingent elements. Pragmatic leadership prepares subordinates for these situations:

- A system disruption obscures antecedent events, misleading leaders into thinking only a few variables have meaning or relevance, thus directing their focus on human action as the cause.
- Categorizing failures, by consequence, decreases their visibility and significance when different organizational programs conduct the investigation. A US Navy aviator described this decreased visibility for a single bearing failure: If caught during production, it is a process quality control problem. If returned to the machine shop, it is a production problem. If it leads to damage to a plane, it is a reliability problem. If it causes harm to a person, it is a safety issue. The organization would then study the same error but in different systems.

We speak of contingencies for precipitating events, but we rely on universal, context-free principles for a response. That is, the normative stance teaches and plans for a context-dependent event and relies on context-independent responses. Contingent information and contingent principles are less convenient to discuss. During an event, information may represent events for only a short time period, and principles may only apply or be contraindicated, for certain circumstances, for example, treatment of oxygen desaturation in a premature infant. The identification and use of contingent information and principles make HRO implementation difficult and HRO leadership important.

Acute respiratory failure gives contingent information that may necessitate mechanical ventilation. Stabilization produces new contingent information, yet when asked why the infant is receiving mechanical ventilation, staff often describe the initial information. Mechanical ventilation becomes a context-free principle rather than a treatment we modify for evolving contingencies. This scenario is a rough description of contingent information and contingent principles; it also manifests in the rigorous application of clinical pathways and protocols.

On the strategic level, objectives have a different meaning and longer time horizons. The cells and tissues of an adult change very little over weeks, yet the neonate's cells and tissues have a trajectory, actually, a dividing trajectory, to create different cells and tissues. The outcome of an action today does not fully appear for months or years.

We see this in the nature of the meaning we give feedback loops. We attribute greater importance to short feedback loops with their greater visibility and immediate appearance, common in the disciplines using procedures. The length of time for long feedback loops is affected by memory deficits, confound cause-and-effect interpretations, and are susceptible to later contingencies. Indirect feedback loops require experience, wisdom, and trust because of the vulnerability to new forces and uncertainty of outcome. Contingent feedback loops require monitoring as the feedback may not appear unless underlying conditions are met. And delayed feedback, more common in neonatology, reflects the results years later following actions today. Because a premature infant's tissues have not fully developed, the damage is not to a single cell line but potentially tissues, and damage to a few cells is damage to all the cells that would have developed. Feedback loops in neonatology, though immediate or short during a resuscitation, are generally delayed and indirect, making it difficult for observers to measure success.

### Words as lexical elements

The pragmatic leader knows that the types of "words" used to communicate – lexical elements – influence thinking and action. Neonatologists use "diagnosis words," and nurses use "treatment words." Businesses use rules and protocols as words. Academicians, operating in a stable environment, use concepts as words, connecting concept words to construct theories and ideas. SOF units, operating in unstable, hostile, denied, or discrete environments, use descriptions, contingents, and responses as their words, supporting accurate communication of information. The SALUTE Report (US Marine Corps Section 4, Pages 228-229), must be factual, based on actual observations, distinguishing between facts and opinions. The use of different lexical elements, the types of words used, can impede communication and change a concept. This is quite common between physician and nurse urgently presenting new information.

During an emergency, mild, uncontrollable stress impairs the use of abstractions for thought (Arnsten 2009), communication, and



problem-solving. The pragmatic leadership stance thinks in abstract concepts but speaks with concrete terms to overcome this impairment. Leadership from a distance readily excludes the environment, enabling misplaced emphasis on abstract concepts. Concepts are images of reality, but we must not mistake concepts for reality. Alfred North Whitehead (1926/1967 64) warns against this "fallacy of misplaced concreteness," mistaking the abstract for the concrete, accepting abstractions as the most concrete rendering of fact. Discrete, abstract concepts, in a reality of continuous perceptions, creates gaps subject to misspecification, misidentification, and misunderstanding (Weick 2011), gaps the pragmatic leadership stance works to close.

The change in lexical elements, from concrete descriptions of an aircraft carrier's flight deck to abstract representations and business words, changed the frame of HRO from an operational frame to a normative, business frame. "Work done out there" became a normative frame of HRO principles, transforming the meaning and use of significant lexical elements. Threat and capability became risk and risk management using the standards for risk developed by the International Organization for Standardization (ISO) (2009). (The following terms in quotations come from ISO 31000:2009).

- Plans and planning to prepare for contingencies became protocols and algorithms restricting operations.
- Assessing capabilities needed for a mission, an assignment that cannot be refused, became "risk" ("effect of uncertainty on objectives") and "risk-benefit assessment" ("decision-aiding techniques that weigh advantages against disadvantages in numerical terms").
- Increasing capabilities for mission requirements (training and materiel) became "risk management" ("coordinated activities to direct and control an organization with regard to risk").
- Safety, as an operational element, became a distinct element and cost within risk management.

Called to a resuscitation, does the neonatologist determine and manage risk, sacrificing safety to reduce work? We do not deny the inherent dangers of resuscitating. We want to draw attention to the dynamics of "what helps now, hurts later; what hurts before, helps now." That is, we use contingent principles that apply in specific situations. When we consider HRO to be a method for risk management and safety, we wash out the value that HRO brings to extend teams and organizations against adversity and into hostile situations.

"When we consider HRO to be a method for risk management and safety, we wash out the value that HRO brings to extend teams and organizations against adversity and into hostile situations."

The choice of lexical elements creates a structural change in thought and action. Leonhard Euler described how we gain knowledge from observation through the use of inductive processes (Pólya, 1954 3). Inductive processes require descriptive words in order to translate observations into thought, prompt intellectual synthesis, and extend thought and action into the environment. Calling this induction, even though accurate, brings to mind "generalizing" and the use of specific observation to make broad

generalizations. Observations, through inductive reasoning with caveats as introduced by Euler, "lead us continually to new properties which we all endeavor to prove afterward...We should take care not to accept as true, such properties (Euler 1915 459)" in (Pólya, 1954 3). Lexical elements supporting description, reliability, and "contingent facts" will prompt staff toward induction and the iterative proof and disproof necessary for accurate observation. Lexical elements supporting facts, concepts, and true-false statements will more likely prompt staff toward deduction and acceptance of information that has been "proved." The pragmatic stance of HRO builds on inductive processes, maintains vigilance, and follows Euler's dictum regarding the false character of observed novel properties. The lexical elements the leader uses and accepts determine whether subordinates search for new properties and evaluate whether concepts are able to support perceptions. The unease of induction drives the team to engage the problem while the security of certainty can slow, if not redirect, action.

We can paraphrase Weick's quote into induction or deduction:

- What's failing? Where do I need to look? versus "What did I (or someone) do wrong?"
- Am I oversimplifying this? "What direction can this go?" versus "Am I missing facts?"
- "What am I doing?" "Have my actions caused a response?" versus "Are we following the algorithm?"
- What do I have to work with? "How can we adapt our staff and resources?" versus "Do we have the right tools?"
- Who knows more than I do? "Who hasn't spoken up?" versus "Can we call a consultant?"

### The Problem

Organizations seeking to increase reliability and decrease error, look to cognitive processes, and classical problem solving that utilize deductive analysis, scientific logic, and critical thinking. Unintentionally, this supports certainty, disregards ambiguity, and supports deterministic, linear problem solving, more like puzzlesolving, where knowable information fits together to produce the right answer (Heuer 1999 62; Wolfberg 2006). The belief that knowable information enhances decision-making, rather than iterated hypothesis testing, contributes to the collection of more information and increased feeling of confidence but with little change in accuracy, a problem recognized in intelligence analysis. Here, the pragmatic leader models methods of rapid hypothesis testing to quickly gain accuracy (Heuer 1999 51-53).

Leadership can unintentionally become limited to ensuring compliance to standards, appropriate response, and the completion of work with loss of functional authority over subordinates. The idea of followership then makes sense. When this becomes the core support for performance, we lose the ability to respond to unexpected, uncertain, and ambiguous events. The inclusion of uncertainty widens the operational environment making available a fuller spectrum of analysis and pursuit of weak but salient signals. Problem-solving becomes a mystery-solving rather than puzzlesolving (Wolfberg 2006).

Approaching the problem as a mystery promotes engaging an undefined problem (Deiterly 1980) before the situation is fully identifiable or the ill-structured problem that is not defined, poorly structured, requires information in the environment not readily available, uncertainty regarding allowable operations, and does not have a clear goal (Simon and Newell 1958; Simon 1973; Pretz et al. 2003). Well-structured and defined problems, independent of context, are amenable to computational algorithms with allow-



able operations (Simon and Newell 1958; Pretz et al. 2003), commonly used for education and planning. The ill-structured problem relies on heuristics, a practical process to move toward a solution (Newell, Shaw, Simon 1957). Algorithms are for the amount of processing; heuristics are for complexity (Newell, Shaw, Simon 1957). Heuristics have now become linked to error, cognitive biases, and biased decision-making (Tversky and Kahneman 1974), yet error, as the "experience of failing," is instrumental in achieving safety. Short, negative feedback, sometimes called an error, denotes the boundary of performance, knowledge, and operations. Error corrects heuristic bias.

Pragmatic leadership takes responsibility to guide and support the engagement of the undefined or ill-structured problem. The act of engagement generates information, while the direction of engagement generates structures. Simplification to make the situation a well-structured problem obscures information, the reason for the "reluctance to simplify" in HRO. In fact, HROs are disposed to "complexify the problem" to aid the search for information within the environment. The pragmatic leadership stance, through engagement and judgment, guides the resolution of undefined or ill-structured problems.

When the problem "embeds into time," compensating for the perturbation, it becomes covert, identifiable only from weak signals. The pragmatic leader, cognizant of the importance of weak but salient signals, encourages reporting, aware that subtle expressions from the leader easily extinguish communication. In this covert, compensated phase, a focus area for safety, the problem is ambiguous, yet interventions are more effective, and complications, less likely. The overt, decompensated phase, the focus for "error" surveys, is readily categorized, but internal, invisible processes continue to penetrate and spread.

The nature of an evolving embedded problem does not lend itself to most leadership models. Leadership, from a distance, shifts thinking to decontextualized abstractions, focuses on principles, and reliance on discrete concepts. The pragmatic leadership stance of HRO engages the embedded problem, accepts the influence of the environment, monitors the performance of individuals and the team, and supports leader-leader actions.

### The Environment

The HRO operates within an open system where energy and resources exchange between the organization, the problem, and the environment. Knowledge and concepts developed in controlled research environments do not reliably support operations during the HRS. The environment affects the performance and capabilities of the leader and subordinates. Acknowledging the open environment and its increased interactions promote scalability within the organization from NICU to levels of administration.

### **Problem Dynamics**

Within a system, elements continuously and actively self-organize from local, nonlinear interactions. "Natural systems become structured by their own internal processes," and "the emergence of order within them is a complex phenomenon" F. Eugene Yates (Yates 2012 p xi). Energy and infectious agents enter or leave, and energy transforms into other forms, confounding our efforts to impose structure and stability. Novel properties, emerging from self-organization, are produced by interactions of the properties of the parts of the system. We cannot deduce these properties from observation of the individual units, making them unpredictable and unexpected (Salt 1979; Edson, Foin, and Knapp 1981). Rather, novel properties are discovered through direct observation. Engagement and inductive processes then identify and give meaning to the discovered novel or unexpected properties which the pragmatic leader further interprets for salience, relevance, and meaning.

Dynamic problems and "deference to expertise" demonstrate how leadership occurs long before it is needed. Confusion between "deferring" versus "delegating" expertise interfered with early acceptance of HRO by physicians (personal communication from a physician executive with a national patient safety organization). In the US Navy, command consists of those duties the Captain cannot legally delegate. In healthcare, the physician cannot delegate diagnosis, prescriptive authority, or surgical procedures (there are exceptions). The pragmatic leadership stance acts as a mentoring system during routine operations, preparing members to assist the neonatologist during an emergency or to assume responsibility. That is, the physician mentors the expert that the physician will later defer to. For example, veteran leaders can readily manage the acceleration of activity in a linear system. A surge of critical patients, however, bifurcates the linear system, predictability is lost, and the leader can manage one or none of the patients. Subordinate "experts," developed by the pragmatic leader, are now available to extend the neonatologist's leadership to each critically ill neonate. Pragmatic leadership has elastic deformation compared to yielding (plastic) deformation of normative leadership stances. The physician leader has increased the distance from which we can enact change by using the organic energy of the NICU through this model (Jason Amerson, MSG, USASOC, personal communication). The pragmatic leadership stance is constant "on-the-job-training" supporting staff to recognize and engage problems early.

### Bronchopulmonary Dysplasia as HRO

Bronchopulmonary dysplasia (BPD) emerged as a novel property (disease) from complex, nonlinear interactions between the elements of preterm birth, growth and development, pathology, treatment, and healing. Treatments influenced various contributing factors, with the caveat that treatment for one element exacerbated other factors, interfering with success and creating other novel pathologies (Northway, Rosan, and Porter 1967; Abman, Bancalari, and Jobe 2017). Success led to the intact survival of more infants at an earlier stage of gestation. Despite 50 years of knowledge and experience, the definition of the disease continues to be treatment rather than pathology, radiology, or injury markers (Jobe, 2016; Voynow 2017).

Weick's quotation in the introduction illustrates the elements of HRO in the progress of BPD and could also be applied to a dangerous context:

- What's failing? Premature babies are dying from lung disease.
- Am I oversimplifying this? BPD results from complex interactions of disease, health, treatment, and development.
- What am I doing? Treatments help or hurt or both.
- What do I have to work with? Improved use of, and alternatives to, mechanical ventilation. Identification of medications.
- Who knows more than I do? Chemists, physicists, surgeons, physiologists, engineers, nurses, dietitians, social workers, ethicists, and anyone with knowledge that extends effective care to the premature infant.
- All seem to work to restore a workable cosmos. Increased intact survival and extension of this success to smaller babies, restoring young families.

Over a 50-year period, infants live rather than die; without intellectual disability, they graduate from school; compete athletically



without physical disability, and children love and are loved instead of life-long mourning. HRO extends leadership, healthcare, and meaning into diseases once seemingly hopeless.

### **Elements of pragmatic leadership**

The pragmatic stance is not about the leader entering a difficult environment, but how the leader's behavior influences the wellbeing of subordinates, so they not only enter the environment but effectively perform (Kolditz 2006). Working the problem from within the situation, sharing threats and uncertainty as a participant, defines the pragmatic leadership stance. The ill-structured problem is a natural system that becomes ordered from internal processes, a self-organizing system. The team, and leader, must enter the system, becoming part of the internal processes that generate order. We cannot organize the situation and use commands and rules to resolve ill-structured problems from the outside like is possible with context-independent, well-structured problems.

"The neonatologist, using the pragmatic leadership stance, can improve performance and effective operations while reducing uncontrollable stress in the NICU for the benefit of the babies, families, and staff."

### Conclusion

HRO, as synthesized from aerial combat, nuclear engineering, and US Navy leadership, becomes a pragmatic stance to balance between emergency response and emergency prevention. HRO, as a pragmatic leadership stance, increases the mental and psychological capabilities of staff. It is the qualities of the HRO pragmatic leadership stance that enables the smooth implementation of HRO and supports identification and engagement of early heralds of failure. The neonatologist, using the pragmatic leadership stance, can improve performance and effective operations while reducing uncontrollable stress in the NICU for the benefit of the babies, families, and staff.

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# Why PREMATURE INFANTS Need Access to an EXCLUSIVE HUMAN MILK DIET



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Thomas A. Mercer, RAdm, USN (retired) Superintendent Naval Postgraduate School (Jan 1993-Sep 1995)





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ÍNOTES

# SAVE YOUR LIFE:

# **Get Care for These POST-BIRTH Warning Signs**

Most women who give birth recover without problems. But any woman can have complications after the birth of a baby. Learning to recognize these POST-BIRTH warning signs and knowing what to do can save your life.

POST-BIRTH WARNING SIGNS

Call 911 if you have:	<ul> <li>Pain in chest</li> <li>Obstructed breathing or shortness of breath</li> <li>Seizures</li> <li>Thoughts of hurting yourself or your baby</li> </ul>	
Call your healthcare provider if you have: (If you can't reach your healthcare provider, call 911 or go to an emergency room)	<ul> <li>Bleeding, soaking through one pad/hour, or blood clots, the size of an egg or bigger</li> <li>Incision that is not healing</li> <li>Red or swollen leg, that is painful or warm to touch</li> <li>Temperature of 100.4°F or higher</li> <li>Headache that does not get better, even after taking medicine, or bad headache with vision changes</li> </ul>	
Trust your instincts. ALWAYS get medical care if you are not feeling well or have questions or concerns. These post-birth warning signs	Tell 911 or your healthcare provider: "I had a baby onand I am having" (Specific warning signs) " can become life-threatening if you don't receive medical care right away because:	

- catching your breath) may mean you have a blood clot in your lung or a heart problem
- · Seizures may mean you have a condition called eclampsia
- · Thoughts or feelings of wanting to hurt yourself or your baby may mean you have postpartum depression
- · Bleeding (heavy), soaking more than one pad in an hour or passing an egg-sized clot or bigger may mean you have an obstetric hemorrhage
- episiotomy or C-section site may mean you have an infection
- · Redness, swelling, warmth, or pain in the calf area of your leg may mean you have a blood clot
- · Temperature of 100.4°F or higher, bad smelling vaginal blood or discharge may mean you have an infection

\_ Phone Number:\_

· Headache (very painful), vision changes, or pain in the upper right area of your belly may mean you have high blood pressure or post birth preeclampsia

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### Why Pregnant and Nursing Women Need Clear Guidance on THE NET BENEFITS OF EATING FISH





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# **Letters to the Editor**

From: Duncan, Ray, M.D. via NICU-NET <nicu-net@nicu-net.org> Sent: Wednesday, July 15, 2020 8:40:48 AM To: nicu-net@nicu-net.org <nicu-net@nicu-net.org> Cc: Duncan, Ray, M.D. <ray.duncan@cshs.org> Subject: [EXTERNAL] [NICU-NET] The future of NICU-NET

Dear friends and colleagues -

There seemed to be strong sentiment on the old NICU-NET list that it should continue after Yahoo Groups shut down, so we rehosted it on a different provider in November 2019.

There are, in theory, 3022 active subscriptions to NICU-NET with non-bouncing email addresses. However, in the 9 months since the list was replatformed, there has been no message traffic at all except for a few test emails.

On the other hand, the private Facebook group "NICU Professionals", which I also manage, and whose membership is limited to licensed caregivers (MD, RN, NNP, RT, OT, PT, etc.) is quite active with about 5000 members, and is adding another 25-50 members per day recently. Now, I personally have strong distaste for Facebook and its policies generally, and do not use it for social postings at all, but it does work pretty well for this purpose. It's an alternative option, if you are interested.

Otherwise, I'm open to suggestions, but unless NICU-NET shows some signs of life soon, I don't see any point in keeping the code blue going. If people are voting with their feet, so to speak, there seems to be no reason for the list to continue to exist. It does cost money for the hosting and the DNS names. It's not a lot, but if nobody is going to use it, I might as well not have that expense.

Stay safe and stay well!

Ray

Ray Duncan, MD, FAAP Executive Director, Tech R&D Enterprise Information Services Cedars-Sinai Health System ray.duncan@cshs.org

On Wed, Jul 15, 2020 at 2:04 PM Goldstein, Mitchell via NICU-NET <nicu-net@nicu-net.org> wrote:

Ray

I'm not a fan of Facebook either. I still don't have an account. I'll start to share Neonatology Today posts on NICU-NET. Perhaps it will stimulate discussion.



Regards MG

Mitchell Goldstein, M.D. Professor of Pediatrics, Loma Linda University School of Medicine Director, Neonatal ECMO Program Division of Neonatology, Department of Pediatrics Loma Linda University Children's Hospital 11175 Campus Street, CP 11121 Loma Linda, CA 92354 Office: 909-558-7448 Fax: 909-558-0298 Cell: 909-257-8573 Email: mgoldstein@llu.edu

From: Ray Duncan [raygduncan@gmail.com] Sent: Friday, July 17, 2020 10:04 To: NICU-NET discussion forum for neonatology professionals Cc: Goldstein, Mitchell Subject: Re: [NICU-NET] Re: The future of NICU-NET Mitch -

I'm not a fan of Facebook either, I find Zuckerberg and his cronies and their business model of "misinformation for profit" abhorrent.

However, it has 2 billion users, so it can't be ignored. Listservs like this one are really a vestige of the 60s and 70s UNIX and academic culture, pre-public-Internet. In general, the world has moved on.

I'm happy to keep NICU-NET going if it is used. Time will tell. But if months are going to go by without a single message being posted (as they have), then there's obviously no need for it to continue to exist. I am not in clinical practice anymore, so I sadly have no advice or current experience of my own to contribute.

Happy to wait a few more months and see what happens. Ironic that the only thing that has provoked any traffic at all on this list-serve is the prospect of it disappearing. But that fits with Elon Musk's corollary to Occam's Razor: "The most ironic explanation is the most likely."

Ray Duncan raygduncan@gmail.com

Dear Dr. Duncan and NICU-NET members,

NICU-NET has been an important part of the neonatal landscape for decades. All of the credit for its initial success and subsequent survival into out modern age of social media dominated interactions goes to Ray Duncan. Although there are many other ways that we may communicate, NICU-NET harkens back to a time when we did not have the immediacy of Zoom or the ability to stream countless instructional videos on You-Tube. It is text only and does not have a fancy interface, but it still has incredible reach.

Sign up for free membership at 99nicu, the Internet community for professionals in neonatal medicine. Discussion Forums, Image Library, Virtual NICU, and more..."

www.99nicu.org



I am not alone in emphasizing the importance of NICU-NET to our field. Subsequent comments to NICU-NET have emphasized the need for a simple, easy to use way of communicating that did not have the problems with hospital firewalls associated with other offerings from Facebook and Twitter. Moreover, although we all may have different political views, NICU-NET is platform agnostic: there is nothing controversial about a listserve. For its basic no nonsense approach to getting the word out, NICU-NET allows one to focus on the topic and not the political aspirations of the platform.

Clearly, NICU-NET has a place in our collective future. My hope is that we rise to Dr. Duncan's challenge and increase the traffic and interaction so that NICU-NET continues to be relevant for future generations of neonatologists.

Thank you Dr. Duncan for creating, fostering, sustaining, and supporting NICU-NET. Your perseverance is an enduring gift to our field. To that end, Neonatology Today will try to support NICU-NET in whatever way we can.

Sincerely,

mmmmil

Mitchell Goldstein, MD Editor in Chief







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The Corona Warriors



RSV is a respiratory virus with cold-like symptoms that causes 90,000 hospitalizations and 4,500 deaths per year in children 5 and younger. It's 10 times more deadly than the flu. For premature babies with fragile immune systems and underdeveloped lungs, RSV proves especially dangerous.

### But risk factors associated with RSV don't touch all infants equally.\*

\*Source: Respirator Syncytial Virus and African Americans

Caucasian Babies	Risk Factor	African American Babies
11.6%	Prematurity	18.3%
58.1%	Breastfeeding	50.2%
7.3%	Low Birth Weight	11.8%
60.1%	Siblings	71.6%
1%	Crowded Living Conditions	3%

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AFRICAN AMERICAN BABIES bear the brunt of RSV. Yet the American Academy of Pediatrics' restrictive new guidlines limit their access to RSV preventative treatment, increasing these babies' risk.

Af PA

### Erratum (Neonatology Today June, 2020)

ailable on Amazon

Neonatology Today has identified no erratum affecting the June, 2020 edition.

Corrections can be sent directly to LomaLindaPublishingCompany@gmail.com. The most recent edition of Neonatology Today including any previously identified erratum may be downloaded from www.neonatologytoday.net.

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### **Upcoming Medical Meetings**

9<sup>TH</sup>ICCN International Conference on Clinical Neonatology September 3 - 4, 2020 Turin, Italy https://www.mcascientificevents.eu/ iccn/

8<sup>th</sup> Annual Fall Conference on Current Concepts in Neonatal Care September 23 - 26, 2020 Napa, California https://www.emedevents.com/c/ medical-conferences-2020/8thannual-fall-conference-on-currentconcepts-in-neonatal-care

> PDA Symposium 2020 October 9 - 10, 2020 Location: Las Vegas, NV https://pdasymposium.org/

AAP National Conference & Exhibition October 18 - 20, 2020 American Academy of Pediatrics San Diego, California https://aapexperience.org/

4<sup>th</sup> Annual NeoHeart October 28 - 30, 2020 New York, New York https://neoheartsociety.org/ conference2020/

International Conference on Neonatology and Perinatology November 5 - 6, 2020 Cape Town, South Africa https://waset.org/neonatologyand-perinatology-conference-innovember-2020-in-cape-town

Miami Neonatology 2020: 44<sup>th</sup> International Conference November 15 - 18, 2020 University of Miami Miller School of Medicine Miami Beach, Florida http://pediatrics.med.miami.edu/ neonatology/international-neonatalconference/



Perinatal Care and the 4<sup>th</sup> Trimester: Redefining Care National Perinatal Association Aurora, Colorado http://www.nationalperinatal. org/2020conference

Hot Topics in Neonatology December 6 - 9, 2020 Organization: Nemours National Harbor, Maryland http://www.hottopicsinneonatology. org/

For up to date Meeting Information, visit <u>NeonatologyToday.net</u> and click on the events tab.

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# Academic Neonatologist Opportunity in Southern California

Loma Linda University Faculty Medical Group, Department of Pediatrics, Division of Neonatology, is seeking board certified or board eligible Neonatologists to join their team.

The Neonatal Intensive Care Unit (NICU) at Loma Linda University Children's Hospital is committed to providing the highest quality of family-centered medical care with our skilled, multi-disciplinary neonatal team. Our unit has 84 licensed beds for the most critically ill babies. As one of the few level 4 tertiary centers in Southern California, we are equipped to provide the highest level of care for newborns with the most complex disorders. Our facility has the largest Level IV NICU in California, serving approximately 25 percent of the state.

We have subspecialists in all medical and surgical areas that are available at all times and are supported by hospital staff with technical, laboratory, and service expertise. Pediatric neurologists work together with us in our NeuroNICU to diagnose, treat and monitor babies with neurologic injury or illness and we focus on providing neuroprotective, developmentally appropriate care for all babies in the NICU. Very specialized care is given in our Small Baby Unit to babies born at less than 30 weeks gestation. Babies at risk for developmental delay are followed up to 3 years in our High-Risk Infant Follow-up Clinic. Genetics specialists are available for evaluation and consultation.

Our Children's Hospital is designated as a Baby Friendly Hospital that supports breastmilk feeding for both

term and preterm babies. Neonatal Social Workers and Child Life Specialists are important members of our team. It is our goal to support babies and families in culturally sensitive ways as our patients come from many different ethnic and religious backgrounds.

Loma Linda is located in the center of Southern California. A sunny climate augments the cultural benefits of Los Angeles and Palm Springs and the year-round recreational opportunities of nearby mountains, deserts and beaches.

This opportunity is not eligible for a J1 Waiver.

### For more information please contact:



Kelly Swensen Physician Recruitment Coordinator kswensen@llu.edu



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# Nursing Opportunities



EOE/AAE



# Neonatal Nurse Practitioner

- Collaborative work environment
- Care of high acuity NICU patients
- State of the art technology
- 24/7 coverage provided by NNP team and Fellows

# Who We Are

With over 900 beds in four hospitals, we operate some of the largest clinical programs in the nation. We also offer the only Level I Regional Trauma Center and Children's Hospital in the Inland Empire servicing the largest county in the US. We lead in many areas of excellence; pediatrics, cardiac services, cancer treatment and research, mental health, chemical dependency, and other essential clinical disciplines. All this adds up to endless possibilities for our patients and for you.

Many Strengths. One Mission.

The Neonatal Intensive Care Unit (NICU) at Loma Linda University Children's Hospital is committed to providing high-quality, family-centered care with our highly skilled, multi-disciplinary neonatal team. Our unit has 84 licensed beds for the most critically ill infants and a new Tiny Baby Program focusing on improving survival and outcomes of extremely low birth weight infants (<1000g at birth). As one of the only level 3 tertiary centers in Southern California, we are equipped to provide the highest level of care for the most complex disorders. We have subspecialists in all medical and surgical areas that are available at all times and are supported by hospital staff with technical, laboratory, and service expertise.

At Loma Linda University Health, we combine the healing power of faith with the practices of modern medicine. We consist of a University, a Medical Center with four hospitals, and a Physicians Group. These resources have helped us become one of the best health systems in the nation.

# **Contact Us**

Please visit our website http://careers.llu.edu or contact Jeannine Sharkey, Director of Advanced Practice Services at jsharkey@llu.edu or (909) 558-4486.

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for flu and pertussis. Ask about protective injections for RSV.



# +

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### Neonatology and the Arts

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

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

Logos and trademarks will usually not qualify for publication.

This month we announce an expanded presence of the arts within Neonatology Today. We will feature artistic works created by our readers on one page as well as photographs of birds on another. This month's original artwork is from Larry Tinsley MD who has graced Neonatology Today with an amazing quilt with





Herbert Vasquez, MD, Associate Neonatologist, Queen of the Valley CampusEmanate Health, West Covina, CA

VasquezH1@gmail.com

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### Manuscript Submission: Instructions to Authors

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2. All material should be emailed to:

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

3. There is no charge for submission, publication (regardless of number of graphics and charts), use of color, or length. Published content will be freely available after publication. There is no charge for your manuscript to be published. NT does maintain a copyright of your published manuscript.

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

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

6. An abstract may be submitted.

7. The main text of the article should be written in formal style using correct English. The length may be up to 10,000 words. Abbreviations which are commonplace in neonatology or in the lay literature may be used.

8. References should be included in standard "NLM" format (APA 7<sup>th</sup> may also be used). Bibliography Software should be used to facilitate formatting and to ensure that the correct formatting and abbreviations are used for references.

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

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