The Birth of Tragedy

Extreme Prematurity, Value Pluralism, and Virtue

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September 30, 2019

I have no conflicts of interest to disclose.

Comments may reflect my research publications, CQI projects, and literature explorations.

My views do not necessarily reflect the opinions nor position of Providence St. Joseph Health.

There is but one truly serious problem in extreme prematurity - the rights of the pregnant woman and her existent family.

Does a pregnant woman who might deliver an extremely premature fetus/infant through no fault of her own, have the right to freely choose either NICU care or palliative comfort care?

"All the rest are games….."

Albert Camus, 1913-1960
The Myth of Sisyphus

Ding, Lemyre, Moore - *Acta Paediatrica, 2018*

Definitive neurodevelopmental impairment meta-analysis
15 cohorts, broad geographic representation, only births after 1995

Neurodevelopmental disability at minimum *4-10 years*
Moderate (2-3 SD below mean IQ) + Severe Disability (>3 SD below mean IQ) plus cerebral palsy, hearing, vision deficits

22 wks	23 wks	24 wks	25 wks
42%	41%	32%	23%

Four factors left out of nearly all extreme prematurity follow-up reports:

1. "Mild" neurodevelopmental impairment - developmental quotient 1-2 SD below the mean,….thus an IQ of ***70-84*** is considered a "mild deficit",…..what do families think?
2. ~***67%*** of "Normal" and "Mild NDI" children have significant behavioral, educational, and psychiatric diagnoses – autism, ADHD, anxiety, depression, learning disorders, special schooling needs,….
3. How much did the NICU stay cost? Mean LOS at 23 weeks is ***140 days***,…..minimally ***$600,000.***
4. How much did the family spend out of pocket the first ***4-5 years*** caring for the child?

Sample 100 infants 23 to 24 Weeks in the Vermont Oxford Network - 2018

92 were resuscitated

63/92 survived to discharge

22/63 have significant brain injury

27/41 w/o overt brain injury will have behavioral, educational impairments, e.g., autism

So,…just 13 of the original 88 infants will achieve full neurodevelopmental health

So,…just 13 of the original 88 infants will achieve full neurodevelopmental health

So,….just 14 of the original 92 resuscitated infants will experience full neurodevelopmental health.

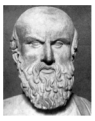
The Crux The Problem The Question

Because a woman is pregnant at 22, 23, 24, 25 weeks……

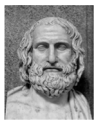
Is she morally required to have her premature fetus/infant resuscitated?,…should we at least obtain consent?

Therapeutic abortion is legal in some states at 22-25 weeks. And what about maternal morbidity from C/S?

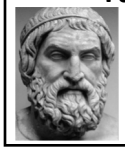
The issue is *NOT:* a) can these infants survive, b) can they be healthy, c) can neuro-impaired children rate their lives as good, d) do we have the resources to care for premies, e) we provide extraordinary measures of ICU care for sick children and adults,….



15%



If neonatologists resuscitate a 23-24 week extremely premature infant….



Families have a <u>one in seven</u> chance of raising a neurologically full-potential child.

Tragedy.

AAP Committee on Fetus and Newborn
2015 Clinical Report (*Pediatrics 2015, Cummings*)
Antenatal Counseling Regarding Resuscitation and Intensive Care Before 25 Weeks Gestation

1. **Periviability decisions should be consonant with the <u>parents</u>' wishes.**
2. **In most cases the approach should be <u>shared</u> decision making.**
3. **The primary goal of antenatal counseling is to provide parents with information that will aid ***<u>their</u>* decision making.**

2014 Executive Summary NICHD/ACOG/AAP/SMFM Joint Workshop (Raju T, *Ob Gyn*, *2014*)

"The goal of family counseling regarding anticipated or imminent periviable birth is to provide objective information in a compassionate manner, to permit <u>shared decision making</u> and to support the family."

***<u>Not a single</u>* national or medical society with periviability guidelines recommends NICU care at 22 weeks,…..and the vast majority do *<u>not</u>* endorse it at 23 weeks either.**

Yet, *<u>7 of 24</u>* NICHD NICUs actively resuscitate and apply NICU care to *<u>100%</u>* of all 22 and 23 week extremely premature fetuses/infants (*Rysavy, NEJM 2015*).

The "*University of Iowa Way*" – a yearly conference focusing on extreme premature NICU care hosted by one of the 7 NICHD NICUs that promote aggressive care for nearly all 22-24 weekers,….why?

Neurodevelopmental outcomes in premature infants <28 weeks are *NOT* improving,...and might be declining.

The single biggest misconception in neonatology - "*We keep making progress*!"

Author	Year	Time Period	Main Finding
Courchia	2019	1980-2015	***No improvement*** in NDI* in <750 g infants – single center
Myrhaug	2019	2000-2017	Meta-analysis - ***No improvement*** in NDI rates at 22-27 weeks
Rysavy	2019	2006-2011	Survival ***without*** moderate or severe NDI was 9%, 16%, 31%, 45%, 59% at 22-23-24-25-26 weeks – NICHD NRN
Brumbaugh	2019	2008-2016	***74%*** of surviving <400 g infants had ***moderate or severe NDI*** – NICHD NRN
Twilhaar	2018	1990-2008	Meta-analysis - ***No improvement*** in IQ deficit of <32 week infants

***NDI = neurodevelopmental impairment**

Author	Year	Time Period	Main Finding
Adams-Chapman	2018	2011-2015	Full scale evaluation showed ***no improvement*** in NDI – 22-27 weeks NICHD NRN
Spittle	2018	1991-2005	***Increasing motor impairment*** across three eras <28 weeks – Australia
Burnett	2018	1991-2005	***Executive function worse*** in <28 weeks than term controls and most notable in the recent era - Australia
Nakanishi	2018	2003-2012	22-24 weeks – ***no improvement*** in NDI with a ***rise in cerebral palsy*** – Japan
Cheong	2017	1991-2005	Neurosensory impairment rates ***no improvement***, and academic performance ***worsened*** <28 weeks - Australia

Proponents of aggressive NICU care for 22-25 week fetuses/infants cite a *single article* to infer "*things are improving*",….and neglect to mention the previous 10 manuscripts published in 2017-2019:

Younge NEJM 2017 – NICHD NRN – 22-24 week births
Three eras compared 2000-2003 2004-2007 2008-2011
Overall survival *without* neurodevelopmental impairment was just *16%* in 2000-03 and increased to *20%* in 2008-11.

***1%* of 22 week infants survived without NDI in 2008-2011**
***13%* of 23 week infants survived without NDI in 2008-2011**

Saroj Saigal Cohort Myth **– "*Brain injured former premies rate their lives the same as healthy term controls*."**

- **Ontario Canada - Predominantly white, middle class, 2 parent families with health insurance**
- ***397*** **infants born 1977-1982, 500-1000 grams, mean GA 27 weeks**
- **No mention of palliative care options, 218 deaths in the NICU not explained, 13 died post-NICU, 17 lost/refused follow-up**
- ***149*** **remained for comparison to term infants – initial reports showed no difference in job status, high school graduation, living independently, quality of life assessments**
- **The most recent report from Saigal (*J Peds 2016*) demonstrates meaningfully *poorer health related quality of life scores from teen age years through mid-30's*.**
- **Similar *lower* HRQoL scores have been reported from the UK (*Baumann, Pediatrics 2016*) and Norway (*Batsvik Acta Paed 2015*)**

How do we mediate a clash of "*moral values*" amongst a pregnant woman at 24 weeks, an obstetrician, a nurse, a neonatologist, a hospital administrator, and a family member?

.....it's a Protestant, a Jew, a Buddhist, a non-theist, a Catholic, and an Unitarian (one had a healthy premature infant, one a handicapped child, and one no children).

Deeply religious families of many faiths sometimes choose NICU care….
Deeply religious families of many faiths sometimes choose palliative care….

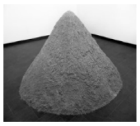
Non-theist families of many backgrounds sometimes choose NICU care….
Non-theist families of many backgrounds sometimes choose palliative care….

Virtually all ethical disputes hinge upon some combination of:

Lack of clarity regarding our personal *interests* that underlie our personal *position*.

Para-natural, religious, and/or cultural beliefs that differ.

Line of Demarcation disagreements



Sorites Paradox

"The Line of Demarcation"

What is a heap of sand?
When exactly is it dark?

If we cannot precisely define even the most concrete events, how can we define "quality of life",….or "suffering",….or "neurodevelopmental impairment"?

If we cannot concisely define a situation with clarity, accuracy, and fairness,…..then perhaps we ought not take inflexible positions.

We agree – There is a boundary at which a premature infant's neurologic impairments can be so significant that a family might prefer palliative comfort care.

We agree – It's uncertain at times whether NICU care will result in a reasonably healthy child, or a child with severe neurologic impairments.

We agree – Physicians, families, ethicists, society have *never* been able to determine an acceptable or fair ratio between the likelihood of the above two uncertainties.

Do you know what is omitted from almost every "periviability" publication?

Detailed account of the NICU deaths…?

How many days/weeks/months old were they…?

Why did they die…?

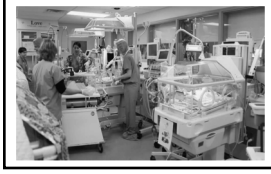
How many painful procedures did they have?

Was life support withdrawn? Comfort care?

What did the parents think months/years later?

***Uncertainty* means you are not sure what will happen. This, physicians understand.**

***Risk* is the product of: a) something harmful happening and, b) the probability it will happen. This, families understand.**



"The ability to hold two opposing ideas in your head and retain the ability to function is the surest sign of a first-rate intellect."

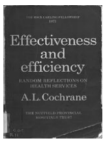
F. Scott Fitzgerald

1896-1940

EBM Triple Aim

Patient Preference and Values

Value Pluralism



Best Available Evidence

RCTs
Meta-analyses
Systematic Reviews
Observational Trials
Some Case Reports

Clinical Expertise

Big Picture Wisdom
Knowledge and Experience
Local Group Culture
CMGCHKURP Virtues

Providence St. Vincent Medical Center Periviability Guidelines – updated 2015

22 weeks	**Palliative Comfort Care provided. NICU Care not offered.**
23 weeks	**Palliative Comfort Care recommended. NICU Care provided if informed family so chooses via shared decision-making.**
24 weeks	**Palliative Comfort Care or NICU care provided if the informed family so chooses via shared decision-making.**
25 weeks	**NICU care recommended. Informed family may choose Palliative Comfort Care after clinical ethics consultation and clarity review with all parties.**
26 weeks	**NICU Care provided. Palliative Comfort Care not offered unless major anomaly or life-limiting condition is present.**

All periviability dialogue includes consideration of relevant conditions such as fetal weight, multiples, sex, ACS, plurality, maternal social and medical conditions, family culture and socio-economic factors, religion, and value pluralism.

138 infants palliative comfort care

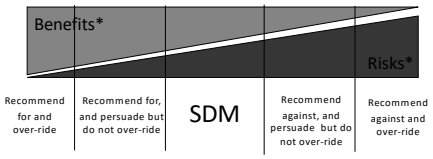
22 0/7 - 25 6/7 weeks

1996 – 2013

Not one single complaint or concern communicated to us related to PCC choice from the *pregnant woman*

Through 2018 "N" is now ~160

Kaempf et al, *J Perinatology, March 2016*



THE FUNDAMENTAL ISSUE

How do we decide if the rights and "*best interests*" of pregnant women and family are in agreement or conflict with the "*best interests*" of the infant?

How is the infant's "*best interest*" brain injury,…or death?

Are pregnant women obligated to agree to NICU care because (through no intention of their own) they might deliver an extremely premature infant?

Just my opinion:

The essence of periviability counseling is <u>not</u> to establish moral truth, <u>nor</u> to negotiate best interests models.

Our authentic purpose is to clarify the meaning of extremely premature birth to the pregnant woman and her family.

Is it permissible or relevant for a physician who is engaged with periviability "counseling" to mention that she/he is the parent of a premature infant?

Does that give them special moral authority?

Should every obstetrician be a woman?

Are the "best" oncologists those that have had cancer?

Is it problematic for a neonatologist who promotes resuscitation of 22-25 week premature infants to have an income >$600,000 per year and a bonus structure related to NICU census?

Is it a conflict-of-interest when an academic neonatologist who promotes resuscitation of 22-25 week infants to tout her principle research interests as IVH and brain injury?

Might a physician who promotes palliative care not be particularly skilled at 22-25 week care, or burned out, or on a fixed salary regardless of NICU census?

There is <u>no</u> state or federal law that mandates resuscitation of extremely premature infants. Both "*wrongful death*" and "*wrongful life*" lawsuits have occurred.

Baby Doe Laws
CAPTA
EMTALA
BAIPA

Value Pluralism

Isaiah Berlin

Human values are irreducibly diverse, often conflicting, and ultimately *<u>incommensurable</u>*.

Fundamental tenets of right and wrong are context dependent and *<u>hugely arguable</u>*.

Choices sometimes have to be made in which every available option involves *<u>some degree of loss or pain</u>*.

Value Pluralism is <u>not</u> relativism.

Relativism - "*You think two things are different, you are mistaken, they are actually equivalent.*"
Relativism is intellectually lazy.

Mary Warnock

Value Pluralism recognizes that there is *<u>no ultimate moral harmony,</u>* conflicts arise that ultimately cannot be reasoned or adjudicated without the risk of applying arbitrary power differentials or experimentation.

Prudential ethics

If you act "*morally*" because you expect external rewards,…are you virtuous?

Skin-in-the-Game

Beware of anyone who tells you what is "*moral*" or "*ethical*" who has no personal risk, no downside to the issue's resolution.

Health Care Pollution **Global Warming** **Medical Waste**

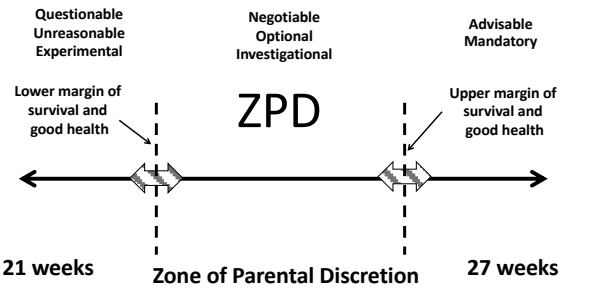
1 in 6 deaths globally are directly linked to the earth's degradation. If the healthcare sectors of USA, Canada, Australia, UK were a nation, it would be the #7 GHG emitter.

Take Home Thoughts

Formulate consensus periviability dialogue guidelines with decision aids.

Do this at your hospital via broad consensus; be inclusive of diverse sentiments.

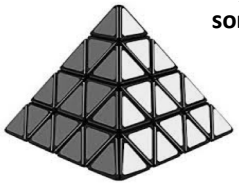
Read deeply – published consensus statements and guidelines, long term outcomes studies, parent viewpoints, history, moral philosophy, economics,….



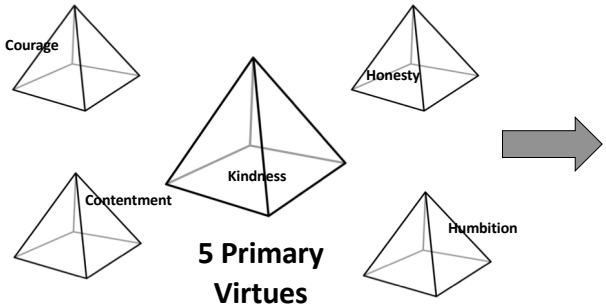
Kaempf JW, Acta Paed, 2017

Is there a common thread in the history of moral philosophy?

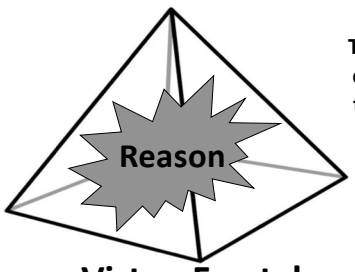
Can we agree on what is *virtuous*?



A fractal is an object or quality that displays <u>self-similarity</u> on all scales,….a process made of parts similar to the whole in some fashion.



5 Primary Virtues



Virtue Fractal

<u>Reason</u> **is at the core of the five primary virtues. The distinguishing feature of humanity is our ability to choose to *<u>understand</u>*.**

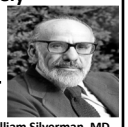
Every culture in every age has struggled with this truth. Power-based hierarchy resists….

<u>Tragedy</u> **is *<u>not</u>* "*right versus wrong*", nor "*right versus right*". Ultimate values conflict incommensurably; human history never shows eventual harmony.**

In neonatology, *<u>tragedy</u>* is borne of physicians, families, and society refusing to acknowledge and submit to biologic and social circumstances that *<u>neither intelligence nor courage</u>* can remedy.

Unrestrained interventions thrust upon extremely premature fetuses/infants despite high mortality, pain, and *<u>not-improving</u>* neurodevelopment is *<u>fundamentally tragic</u>*.

John Gray



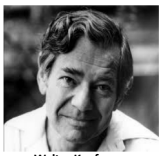
William Silverman, MD

The disempowerment of pregnant women and families from the informed choice of palliative care or neonatal intensive care is *not virtuous*.

Be ever wary of those who *end* moral controversies, rather than trying to *resolve* or *tolerate* moral disputes.

Authentic periviability shared decision making is distinguished by broad cultural knowledge and continual avoidance of power differentials and personal bias.

***Suffering* is inherent to every extreme prematurity option; accepting *tragedy* as life's distinction is born of wisdom and humility. Sympathetic honesty is a *virtue*, not an impiety.**



Walter Kaufmann

Thank you for all you do.

If you wish to be included in my "*EBM and CQI Article of the Week*" listserv,……no obligations, nothing commercial, 100% devoted to thinking, healthcare, literature, philosophy, and science, history,….

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I might be the luckiest man in the world.
Mickey, Josie, Grace, Caroline, Teddy...and #6 coming!