The Association Between The 39-week Rule and USA Term Stillbirth Rates: 
an update and a discussion of ethical implications

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Pennsylvania State University

Objectives:
1) Describe the 39-Week Rule, its history and the quality of its research basis.
2) Discuss the possibility that the 39-Week Rule may be causing many cases of term stillbirth
3) Consider the 39-Week Rule with respect to the three major medico-ethical principles (Beneficence, Autonomy, and Justice)

Objectives:
4) Introduce and briefly discuss a new concept:
   The “Weighted” Professional Responsibility Model of Medical Ethics
The Emperor’s New Clothes

Definitions:
Phases of term pregnancy -
- Early Term ~ 37w 0d – 38w 6d
- Full Term ~ 39w 0d – 40w 6d
- Late Term ~ 41w 0d – 41w 6d

Definitions:
Induction of labor
- the initiation of labor
......by artificial means*

* From Induction of Labor by Fields, Greene and Smith
(The McMillan Company, New York, 1965)
**Definitions:**

"Indicated" induction - a situation where the risk/benefit ratio for "delivery now" clearly outweighs the risk/benefit ratio for "delivery later."

**Definitions (2):**

**Indications for Delivery**
- Severe pre-eclampsia
- Eclampsia
- Severe fetal growth restriction (< 5%)
- Significant oligohydramnios (AFI <6)
- Rupture of membranes without labor
- Amniotic fluid infection ("chorioamnionitis")
- Failed antenatal testing
- Isoimmunization of pregnancy ("Rh disease")
- Post-term (>41w 6d gestation)
Definitions:

**Indicated induction** - a situation where the risk/benefit ratio for “delivery now” clearly outweighs the risk/benefit ratio for “delivery later.”

“Non-Indicated induction” - a situation where induction occurs in the absence of an indication (aka – “elective” induction).

Definitions:

**Indicated induction** = i-IOL

**Non-Indicated induction** = ni-IOL

Definitions:

**The 39-Week Rule** – an strict clinical guideline, currently “en force” throughout the USA, that states that “non-indicated” delivery should not occur prior to 39 weeks 0 days of gestation (i.e., not within, or before, the Early Term period of pregnancy).
King Harald V of Norway

QUEEN ELIZABETH II - Australia

King Willem-Alexander of the Netherlands
The Joint Commission

Medicare and Medicaid

39-Week Rule
EMPERORS AND KINGS AND QUEENS .....
....or KINGS AND QUEENS AND EMPERORS...news?..fake news?

39-Week Rule
A Careful Look at the 39-Week Rule:
- its basis,
- its apparent impact,
- and its concordance with modern medico-ethical principles.

Early Use of Labor Induction
- Soranus of Ephesus (100 A.D.) in Greece
- Ambroise Pare (16th century) in France
- Thomas James (1810) in Philadelphia
- Arguments about induction (1871-1920)
- Book on labor induction (1965) (Fields, Greene and Smith)

Modern Improvements to Labor Induction
- Foley Bulb… for cervical ripening
- Prostaglandin E1 and E2 for cervical ripening
- Misoprostol
- Dinoprostone
ACOG Advisory

“Assessment of Fetal Maturity Prior to Repeat Cesarean Delivery or Elective Induction of Labor”

September 1979

Due to the imprecision of LMP for pregnancy dating……a non-indicated delivery should not occur until least 39 weeks 0 days of gestation.

Early ACOG Technical Bulletin

“Induction of labor”
Number 217 – December 1995

• Induction should be performed only after an accepted “indication” can be identified.
• Accepted indications included both logistic factors and psychosocial issues.
• To ensure fetal maturity, an induced pregnancy should be at least 39 weeks 0 days.

This ACOG Technical Bulletin

“Induction of labor”
Number 217 – December 1995

Of note, the bibliography of this technical bulletin contained 34 citations, but no level 1 evidence (Randomized Clinical Trials, or “RCT”) comparing IOL to expectant management
ACOG Practice Bulletin

Induction of labor
Number 107 – August 2009

• States induction should be performed only after the “indication” is explained.
• List of indications include logistic factors including psychosocial issues, and “the list is not absolute.”
• States that in order to ensure fetal maturity, an induced pregnancy should be at least 39 weeks 0 days of gestation.

Of note, the bibliography of this bulletin was quite long [90 references]. It contained multiple observational studies but just one RCT that compared IOL to expectant management*. 

* Hannah ME – IOL as compared with serial antenatal monitoring in post-term pregnancy – NEJM 1999 – showed benefit to labor induction!

THEN……

Clark S.L et al – Neonatal and maternal outcomes associated with elective term delivery – AJOG 2009

Main, E – New perinatal quality measures from the National Quality Forum, the Joint Commission and the Leapfrog Group – Curr Opin Obstet Gynecol 2009

Oshiro B. – Decreasing elective deliveries before 39 weeks of gestation in an integrated health care system – Obstet Gynecol 2009
Normalization of Deviance

...a term used to describe the phenomenon in which individuals unknowingly persist in detrimental patterns of behavior based on a low frequency of individual adverse experience.
A California Toolkit to Transform Maternity Care

Elimination of Non-medically Indicated (Elective) Deliveries Before 39 Weeks Gestational Age

This collaborative project was developed by:

• March of Dimes
• California Maternal Quality Care Collaborative
• Maternal, Child and Adolescent Health Division, Center for Family Health
  California Department of Public Health

**NQF - ENDORSED VOLUNTARY CONSENSUS STANDARDS FOR HOSPITAL CARE**

Measure Set: Perinatal Care (PC)
Set Measure ID: PC-01
Performance Measure Name: Elective Delivery
Description: Patients with elective vaginal deliveries or elective cesarean sections at ≥ 37 and < 39 weeks of gestation completed

**Release Notes:**
Measure Information Form Version 2010A1

Joint Commission
**NQF-ENDORSED VOLUNTARY CONSENSUS STANDARDS FOR HOSPITAL CARE**

Measure Set: Perinatal Care (PC)

Set Measure ID: PC - 01

Performance Measure Name: Elective Delivery

Description: Patients with elective vaginal deliveries or elective cesarean sections at \( \geq 37 \) and \( < 39 \) weeks of gestation completed

Release Notes: Measure Information Form Version 2010 A1

Joint Commission

Strong Start for Mothers and Newborns Initiative: Effort to Reduce Early Elective Deliveries

Where Health Care Innovation is Happening

Financial Penalty
The 39-Week Rule
~ 2010 ~

The Emperor’s New Clothes

1. Observational Studies of Outcomes following Labor Induction
2. Observational Studies of Neonatal Outcomes as a Function of Gestational Age
1. Observational Studies of Outcomes following Labor Induction

2. Observational Studies of Neonatal Outcomes as a Function of Gestational Age

Observational Studies of Outcomes following Labor Induction:

ni-IOL vs. Spontaneous Labor

- Yeast JD et al. - Induction of labor and the relationship to C/S delivery. AJOG 1999
- Seyb ST et al. - Risk of C/S delivery with elective IOL in nullips. Ob Gyn 1999
- Cammu H et al. - Outcome after elective IOL in nullips. AJOG 2002

Observational Studies of Outcomes following Labor Induction:

ni-IOL vs. Spontaneous Labor

- More C/S
- More NICU
- More "Stuff"
Observational Studies of Outcomes following Labor Induction:

ni-IOL vs. Spontaneous Labor

**CONFOUNDING BY INDICATION?**

Observational Studies of Outcomes following Labor Induction:

ni-IOL *More Risk* vs. Spontaneous Labor

**CONFOUNDING BY INDICATION!**

Observational Studies of Outcomes following Labor Induction:

IOL vs. Spontaneous Labor

**IMPROPER MODELING!**
Proper Modeling of Observational Studies of Labor Induction:

Pregnancy @ 38-39 weeks

ni-IOL

Expectant Management (to a later time)
Proper Modeling of Observational Studies of Labor Induction:

Pregnancy @ 38-39 weeks

ni-IOL

Expectant Management

- Spontaneous labor
- i-IOL or ni-IOL
- Pre-labor Cesarean

Observational Studies of Outcomes following Labor Induction:

ni-IOL (delivery now!)

vs.

Expectant Management (delivery at later time...)

Recent Observational Studies using correct modeling:

<table>
<thead>
<tr>
<th>AUTHOR (Journal[s])</th>
<th>YEAR (S)</th>
<th>Possible impact of ni-IOL</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHENG et al (Am J Ob Gyn)</td>
<td>2012</td>
<td>Lower C/S Rate Lower Thick Mec Rate</td>
</tr>
<tr>
<td>Darney et al (Ob Gyn)</td>
<td>2013</td>
<td>Lower C/S Rate</td>
</tr>
<tr>
<td>Stock ET AL (British Med Journal)</td>
<td>2013</td>
<td>Lower Stillbirth Rates</td>
</tr>
</tbody>
</table>
Observational Studies of Outcomes following Labor Induction:

ni-IOL vs. Expectant Management

- Lower C/S
- Lower NICU
- Lower Stillbirth

Often fail to provide sub-group analysis:

1) Multiparous women
2) Women with intermediate risk factors
3) Women with a favorable cervix
4) Women of different races

Recent meta-analyses of randomized clinical trials (RCT's) show that IOL is beneficial!

<table>
<thead>
<tr>
<th>AUTHOR</th>
<th>YEAR (Yrs)</th>
<th>BENEFIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caughey et al (Ann Internal Medicine)</td>
<td>2009</td>
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</tr>
<tr>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Lower NICU Admit Rate</td>
</tr>
<tr>
<td><strong>LEVEL 1a EVIDENCE</strong></td>
<td></td>
<td><strong>Lower Term Stillbirth Rates (50% decrease!!!)</strong></td>
</tr>
</tbody>
</table>
Observational Studies of Outcomes following Labor Induction:

These studies fail to provide measures of association that are strong enough to support a claim of “CAUSALITY”:

1) Relative Risk (RR) > 3.0, or < 0.33
2) Odds Ratio (OR) > 4.0, or < 0.25

* Grimes DA and Schulz KF – Obstet Gynecol – October 2012

We need large (adequately powered) Randomized Clinical Trials (RCT’s) to compare birth outcomes following Labor Induction to birth outcomes following Expectant Management!

2. Observational Studies of Neonatal Outcomes as a Function of Gestational Age
Observational Studies of Neonatal Outcomes as a Function of Gestational Age

- Gouyon JB et al – Neonatal outcomes associated with singleton birth at 34-41 weeks of gestation – Perinatal Epidem 2010
- Kamath BD et al – Neonatal morbidity after documented fetal lung maturity in late preterm and early term infants – AJOG 2011

https://doi.org/10.1016/j.jpeds.2008.09.013
Observational Studies of Neonatal Outcomes as a Function of Gestational Age

Early Term Delivery associated with higher rates of:

- Low APGAR scores
- Respiratory Problems (minor and major)
- NICU admission
- Hospital readmission
- Small brain size
- 1-year infant mortality
- Impaired cognitive development
Observational Studies of Neonatal Outcomes as a Function of Gestational Age

An Arbitrary “Cut-Point” of 39w 0d

Inappropriate combination of weeks

Inappropriate combination of weeks - some studies even combined early term and late preterm in one group
Observational Studies of Neonatal Outcomes as a Function of Gestational Age

Selection bias - studies involving only infants delivered via elective repeat C/S should not be generalized to the setting of IOL*

* Tita A et al, Timing of Elective Repeat Cesarean Delivery at Term and Neonatal Outcomes NEJM 2009

Observational Studies of Outcomes following Labor Induction:

These studies fail to provide measures of association that are strong enough to support a claim of “CAUSALITY”*:

1) Relative Risk (RR) > 3.0, or < 0.33
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The Ecological Fallacy!
The Ecological Fallacy!

The measurement of what occurs naturally cannot be used to definitively predict what will happen after the intentional alteration of the natural order.

Observational Studies of Neonatal Outcomes as a Function of Gestational Age

The Ecological Fallacy! (measurement of “what is”)

Observational Studies of Neonatal Outcomes as a Function of Gestational Age

The Ecological Fallacy! (cannot predict “what will be”)

7/6/2017
Large RCT’s of *early-term* non-indicated labor induction have not been performed.

The association between the regular use of preventive labour induction and improved term birth outcomes: findings of a systematic review and meta-analysis

Authors: JM Nicholson, LC Kellar, GF Henning, AA Waheed, M Colon-Gonzalez, S Ural


Findings of the BJOG paper:

4 studies – 3 observational and one small RCT

**AMOR-IPAT Group**

1153 women exposed to the active management of risk

- overall IOL rate 39.0%
- ni-IOL rate 29.1% (~30% of these < 39w 0d)

**Usual Care Group**

1865 women exposed to usual care

- overall IOL rate 24.4%
- ni-IOL rate 5.8%
Findings BJOG paper:
AMOR-IPAT Group had lower C/S rate
- 5.7% vs. 14.4% ; RR 0.39, 95% CI 0.31-0.50

AMOR-IPAT Group had lower NICU admit rate
- 2.9% vs. 6.5% ; RR 0.45, 95% CI 0.31-0.65

AMOR-IPAT Group had lower weighted AOI score
- 2.8 vs. 6.1.

The 39-Week Rule
2010

Impact of the 39-Week Rule
1. Has it been successfully applied?
Impact of the 39-Week Rule

1. It has been successfully applied!

- Ebrenthal DB et al – Neonatal outcomes after implementation of the 39-Week Rule - Obstet Gynecol 2011
- Akinsipe DC et al – A systematic review of implementing an elective labor induction policy – JOGNN 2011

US State data - 2014

Births and nOL’s prior to 39 week 0 days significantly lower throughout the USA since 2010!

Impact of the 39-Week Rule

2. Has there been a reduction in USA primary C/S rates?


<table>
<thead>
<tr>
<th>Year</th>
<th>2006</th>
<th>2009</th>
<th>2012</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate</td>
<td>23.5%</td>
<td>23.8%</td>
<td>21.5%</td>
<td>21.8%</td>
</tr>
</tbody>
</table>

Impact of the 39-Week Rule
1. It has been successfully applied!
2. Mild reduction in USA primary C/S rates
3. Has it reduced NICU admission rates?

YES! - Ehrenthal DB et al – Neonatal outcomes after implementation of the 39-Week Rule - Obstet Gynecol 2011


Impact of the 39-Week Rule
1. It has been successfully applied!
2. Mild reduction in USA primary C/S rates.
3. Increased NICU admission rates!
4. Maternal mortality rates?
Impact of the 39-Week Rule

1. It has been successfully applied
2. Mild reduction in USA primary C/S rates.
3. No reduction in NICU admissions
4. Increase in Maternal Mortality Rates


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Impact of the 39-Week Rule

1. It has been successfully applied
2. Mild reduction in USA primary C/S rates.
3. No reduction in NICU admissions
4. Increase in Maternal Mortality Rates!
5. …and what about rates of term stillbirth?

---

Cumulative Probability of Antepartum Stillbirth increases as as a function of increasing gestational age at term

Risk of Antepartum Stillbirth at Term and after Term

<table>
<thead>
<tr>
<th>Gestational age</th>
<th>Probability of Stillbirth</th>
</tr>
</thead>
<tbody>
<tr>
<td>37 weeks</td>
<td>0.4/1000</td>
</tr>
<tr>
<td>38 weeks</td>
<td>0.8/1000</td>
</tr>
<tr>
<td>39 weeks</td>
<td>1.3/1000</td>
</tr>
<tr>
<td>40 weeks</td>
<td>2.2/1000</td>
</tr>
<tr>
<td>41 weeks</td>
<td>3.4/1000</td>
</tr>
<tr>
<td>42 weeks</td>
<td>5.3/1000</td>
</tr>
<tr>
<td>43 weeks</td>
<td>11.5/1000</td>
</tr>
</tbody>
</table>

What the 39-Week Rule does to some pregnancies…and populations

<table>
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<tr>
<th>Gestational age</th>
<th>Probability of Stillbirth</th>
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</tr>
<tr>
<td>43 weeks</td>
<td>11.5/1000</td>
</tr>
</tbody>
</table>

Ehrehthal:

Christiana, Delaware (2011) – Ob Gyn
Increase in 37/38 week stillbirth rate after imposition of the 39-Week Rule. Increase from 2.9 per 10,000 ➔ 9.1 per 10,000
p=0.32, RR 3.67
### Minnesota Data:

<table>
<thead>
<tr>
<th>YEAR</th>
<th>Stillbirth Rate/1,000</th>
<th>Average Rate/1,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>1.05753</td>
<td>1.07/1,000</td>
</tr>
<tr>
<td>2006</td>
<td>1.074611</td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td>1.099423</td>
<td></td>
</tr>
<tr>
<td>2008</td>
<td>1.091432</td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>1.033745</td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>1.198708</td>
<td>1.24/1,000</td>
</tr>
<tr>
<td>2011</td>
<td>1.183934</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>1.337754</td>
<td></td>
</tr>
</tbody>
</table>

Several studies found no association between the 39-Week Rule and higher rates of either stillbirth or perinatal morbidity/mortality:


**USA Fact:**

Between 2010 and 2016…

…there were no large studies assessing the impact of the 39-week Rule…

on USA term stillbirth rates…..
Term Stillbirth in the USA Following the Adoption of the 39-Week Rule: a cause for concern?

PRESENTED: SMFM – FEBRUARY 2016
Atlanta, GA

Timing of term birth in the USA 2007 - 2013

Rate of term stillbirth in the USA 2007 - 2013
Rate of term stillbirth in the USA 2007 - 2013

y = 0.0186x - 36.177
R² = 0.6247
USA Impact:

~ 400 additional term stillbirths in 2013 as compared to 2007!!!
The 39 week rule: impact on stillbirth and infant death
(Pilliod et al, AJOG, 2017)

<table>
<thead>
<tr>
<th></th>
<th>2008 – 2010</th>
<th>2011-2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Term Stillbirth Rate</td>
<td>0.09%</td>
<td>0.10%</td>
</tr>
<tr>
<td>Infant Death Rate</td>
<td>0.20%</td>
<td>0.17%</td>
</tr>
</tbody>
</table>

= 900 fewer infant deaths per year

More term stillbirths (+) 300
Fewer term infant deaths (−) 900
The 39 week rule: 
**impact** on stillbirth and infant death
(Pilliod et al, AJOG, 2017)

More term stillbirths (+) 300
Fewer term infant deaths (−) 900

Net “Impact” – 600 lives saved!

The probable reasons for decreasing 1-year infant mortality rate since 2010:
1. “Back-to-Sleep” programs
2. Avoidance of co-sleeping programs
3. “Shaken Baby” video programs
4. “Infant Car Seat” programs
5. Pertussis Immunization programs
6. Greater access to healthcare (ACA)
7. Lower threshold for NICU use

The impact of the 39-Week Rule on USA Term Stillbirth:
~ 300 - 400 more term stillbirths in 2013 as compared to 2007!!!
...and that will be the reality every year …
What would have happened were it not for recent “sleep on your side” advice and the recent subtle shift to less frequently allow pregnancies to go beyond 39 weeks?

What do we do with evidence that pregnancies with certain risk factors - factors that are not “indications” for delivery – may have an optimal time of delivery that is in the 37th or 38th week?

What do we do in the early term period when maternal intuition suggests something is wrong with the pregnancy?
What do we do when, at the ACOG Conference debate in 2016, both debaters concluded the delivery for all at 39 weeks would optimize birth outcomes?

The 39-Week Rule

2010
Medical Ethics

1. Beneficence
   • (non-maleficence)
2. Autonomy
3. Justice

Medical Ethics

1. Beneficence
Medical Ethics

1. Beneficence
   • (non-maleficence)

2. Autonomy

3. Justice
The Professional Responsibility Model of Ethics in Perinatal Medicine

A provider of medical care should commit to:
• Becoming scientifically and clinically competent
• Using his/her clinical knowledge and skills primarily for the clinical benefit of the patient
• Preserving medicine as a public trust and not a self-interested guild


The reliance on “evidence-based” clinical guidelines is stressed, and “deliberative clinical judgement” is used to “responsibly” reduce uncontrolled variation in clinical judgement and practice based on it, thereby improving the quality of both.


In the case presented, the Professional Responsibility Model is used to justify the refusal of a request by a pregnant women to have an early term ni-IOL.

The 39-Week Rule

2010

The “Weighted” Professional Responsibility Model of Ethics in Perinatal Medicine

Provider Issues

Patient Issues

Good evidence

Ambivalence

Borderline evidence

Strong beliefs
Whose Baby is it anyway?

Conclusions:
1. The 39-week Rule reflects very longstanding tensions about the optimal management of term pregnancy

Conclusions:
2. The 39-week Rule is not well supported by high-quality medical research – but it is the law of the land
Conclusions:
3. The adoption of the 39-week Rule has not been associated with a major change in the national cesarean delivery rate.

Conclusions:
3. The adoption of the 39-week Rule has not reduced the rate of NICU Admission.

Conclusions:
5. The adoption of the 39-week Rule has probably increased the number of “cases” of term stillbirth in the USA.
Conclusions:

6. The adoption of the 39-week Rule cannot be justified using the principle of Beneficence (because high-quality research does not exist, and existing evidence is inconclusive)

Conclusions:

7. The adoption of the 39-week Rule was an action, and the concept of non-maleficence was not adequately considered prior to the Rule’s adoption (vis-à-vis the increased risk of term stillbirth)

Conclusions:

8. The imposition of the 39-Week Rule, especially in the setting of strong patient beliefs, is in conflict with the concept of Autonomy
Conclusions:

9. Consider the use of a “weighted” Professional Responsibility Model of Ethics in Perinatal Medicine. This model suggests that the relative strength of available evidence be used to guide the way in which deliberative clinical judgement is applied, and that final clinical decisions reflect, in a balanced fashion, the relative strength of patient specific factors (beliefs, attitudes, feelings).

Conclusions:

10. In this case, the available evidence is relatively weak and the strict imposition of the 39-Week Rule cannot be justified. If a pregnant woman is provided with information concerning the potential risks of early term delivery, but has strong personal reasons to desire early-term delivery, then such a delivery should be allowed.
Thank You!