Beneficence, Autonomy and the Ethics of the Current Restrictions on Early Term "Non-Indicated" Labor Induction

Introduction by Amber Goodyear

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Dr. James A. Nicholson obtained his undergraduate degree from Earlham College, Richmond, Indiana in 1977, his medical degree from the University of Pennsylvania in 1981, and completed his internship and residency with the Duke-Watts Family Medicine Residency Program in Durham, North Carolina in 1984.

Following his residency, Dr. Nicholson joined a private practice in North Grosvenordale, Connecticut. In 1997, Dr. Nicholson returned to the University of Pennsylvania to join the Department of Family Practice and Community Medicine. While pursuing a Master's Degree in Clinical Epidemiology, he published the AMOR-IPAT system of identifying pregnant women who would benefit from induction before 40 weeks of gestation. The publication was an editor's choice paper in the American Journal of Obstetrics and Gynecology. The AMOR-IPAT concept was further developed and followed-up with a prospective, randomized clinical trial (RCT) of AMOR-IPAT (the HUP-POP Trial). In 2012, Dr. Nicholson moved to the Hershey Medical Center of Penn State University in the Department of Family Medicine and Community Medicine, the Department of Obstetrics and Gynecology and the Department of Pediatrics.

HANDOUT FOR

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Definitions:

1. Term Stillbirth – the death of a fetus in utero on or after 37 weeks 0 days of gestation.
2. The 39-week rule – ..."Unless there is an accepted/approved "indication," a planned delivery should not occur prior to 39 weeks 0 days of gestation (ACOG 2009)."[1]
3. Accepted Indications for Early-Term labor Induction

Accepted Indications for Labor Induction
Late-term pregnancy (> 41 weeks 0 days of gestation)
Severe fetal growth restriction (fetus not growing, < 5%)
Rupture of membranes without labor
Severe pre-eclampsia (hypertension of pregnancy)
Chorio-amnionitis (amniotic fluid infection)
Failed antenatal testing (possible fetal compromise)
Significant oligohydramnios (AFI < 6)

Ethical Principles:

1. Beneficence – providers are expected to treat their patients in the best possible way – the corollary: *"Above All Do No Harm."*[2,3]
2. Autonomy – providers are expected to respect a patient's refusal of, *or request for*, a course of medical treatment.[2,3]

Talking Points:

1) The cumulative risk of term stillbirth increases with increasing gestational age.[4-8]
2) The 39-week rule[1] necessarily increases the gestational age of childbirth for some pregnancies.[9]
3) The 39-week rule is based only on observational studies and expert opinion.[1] It is not supported by high-quality evidence (i.e., it is not supported by randomized clinical trials [RCT's]). Observational studies comparing birth outcomes following labor induction to birth outcomes following spontaneous labor contain two major flaws: a) a type of bias called " confounding by indication",[10] and b) the use of an inappropriate comparison

groups[11-13] (the correct comparison group should be women who were not induced but were expectantly managed to a later gestational age...where they might develop spontaneous labor OR a complication requiring labor induction OR a "non-indicated" labor induction at a later gestational age). In addition, the observational studies that evaluate birth outcomes by week of gestational age find that outcomes are less good in the 37th and 38th weeks, and conclude that elective delivery prior to 39 weeks of gestation "should be avoided..." The conclusions of these studies reflect " ***the association fallacy***" – "that because two things share a property they are believed to be causally connected.[14]" In actuality, there are reasons that some pregnancies deliver 2-3 weeks prior to the due date that increase the risk of adverse outcomes irrespective of gestational age. Observational studies of childbirth outcomes as a function of gestational age cannot be used to determine whether the delivery of a pregnancy in the 38th week *by choice* will provide better or worse outcomes than the expectant management of that pregnancy to a later gestational age.

4) Furthermore, observational studies must meet at least two important benchmarks before their results can be considered to reflect an underlying "truth." First, the results must be statistically significant (p-value less than 0.05 [or 0.01], or 95% confidence interval that does not cross 1.0). This criterion is fairly easy to achieve, especially with large databases. Second, the results must demonstrate a fairly large *magnitude of association*, as measured in "Relative Risk" ("RR") or "Odds Ratio" ("OR").[15-17] The second benchmark is more difficult to achieve. " RR" should be greater than 2.0 (ideally greater than 3.0) and/or "OR" should be greater than 3.0 (and ideally 4.0).[16] In point of fact, none of the observational studies used to support the 39-week rule reported results that satisfy the second criteria.[1,18,19]
5) Several recent observational studies suggested, and several recent randomized controlled trials concluded, that "non-indicated" labor induction prior to the 39th week (e.g., in the 38th week) is more beneficial than harmful.[6,20-22] In contrast, there are no RCT's and no correctly modeled observation studies that show or suggest that "non-indicated" labor induction in the 38th week of pregnancy is harmful.
6) So.....there is no high-quality evidence supporting the 39-week rule. Hence, the ethical principle of beneficence cannot be used in its behalf. Furthermore, considering the concept of "above all do no harm," it is important to note that the strict application of the 39 week rule was an active intentional action (i.e., a "do") orchestrated by several influential national administrative bodies.[1,18,23-25] This action was done without high-quality research showing that it would not cause harm. Therefore, the concept of "above all do no harm" was not considered when the 39-week rule was developed and strictly instituted.

7) Clearly – in the USA today - if a pregnant woman desires to be induced in the 38th week but does not have an accepted "indication," then the strict application of the 39-week rule conflicts with the ethical principle of autonomy.[2,26]
8) Unfortunately, there is evidence that the implementation of the 39-week rule has increased the incidence of term stillbirth.[9,27,28]
9) It is possible in the USA today that a woman could have a balanced discussion with her provider about the risks and benefits of an early term labor induction, that she could request a pre-39 week labor induction, that she would have her request refused because of the 39-week rule, and that she could presents at a later date without a fetal heartbeat (i.e., with a term fetus that is no longer alive). There are anecdotal reports that this scenario is occurring in the USA.

Conclusions:

Because there is no high-quality evidence that supports the 39-week rule, because the 39-week rule was implemented before it was shown to be safe, because there is evidence that rates of term stillbirth have increased since the strict imposition of the 39-week rule, and because the strict application of the 39-week rule obstructs patient autonomy, it seems clear that the 39-week rule should be withdrawn, modified or made optional.

Addendum: *Argumentum ad populum* (appeal to widespread belief, bandwagon argument, appeal to the majority, appeal to the people) – where a proposition is claimed to be true or good solely because many people believe it to be so.

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