

Transmitted via email

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Dr. Christopher M. Zahn Interim Chief Executive Officer American College of Obstetrics and Gynecology 409 12th Street SW Washington, DC 20024

Dear Ms. Wurster and Dr. Zahn,

We are writing on behalf of the International Cesarean Awareness Network (ICAN) regarding ACOG and SMFM's <u>Interpregnancy care: Obstetric Care Consensus No. 8 (OCC #8)</u>. ICAN is a nonprofit organization with the mission to improve maternal-child health by reducing preventable cesareans through education, supporting cesarean recovery, and advocating for vaginal birth after cesarean (VBAC). ICAN has more than 100 chapters across the world and has provided daily education and support to pregnant and postpartum families since 1982.

ICAN has been a leader in sounding the alarm on the medically unnecessary high cesarean rate in the United States and other countries for more than four decades. We appreciate aspects of ACOG's <u>Practice Bulletin No. 205: Vaginal birth after cesarean delivery (PB #205)</u> for the many important updates included, as well as ACOG's highlighting the importance of informed consent and emphasizing that facilities capable of performing emergency deliveries should be offering Trial of Labor After Cesarean (TOLAC).

Unfortunately, even with these updates, supportive hospital-based TOLAC/VBAC care remains difficult to access in most of the United States. Our overall cesarean rate in the US is more than double what the World Health Organization (WHO) suggests it should be. In addition, racial disparities in maternity care lead to even higher total cesarean rates for affected groups. Regional differences in total cesarean rate can be up to four times WHO suggestions. Such high cesarean rates will not be safely reduced until TOLAC/VBAC care is accessible in all hospitals offering labor and delivery. One of the barriers to TOLAC/VBAC care is providers who impose



limitations around interpregnancy and interdelivery intervals based on their interpretation of OCC #8 which states,

Women with prior cesarean deliveries, and particularly those who are considering a trial of labor after cesarean delivery, should be counseled that a shorter interpregnancy interval in this population has been associated with an increased risk of uterine rupture and risk of maternal morbidity and transfusion. Evidence exists of increased risk of uterine rupture after cesarean delivery following delivery-to-delivery intervals of 18–24 months or less <u>43</u> <u>129</u>.

OCC #8 further mentions that, because interpregnancy and interdelivery intervals are a "potentially modifiable risk factor," patients can be counseled on *potential* benefits (emphasis added) of longer interpregnancy intervals during pregnancy planning.

But, instead of using this as intended for pregnancy planning, many providers are using this to "risk patients out" of care, specifically VBAC care. ICAN chapter leaders frequently hear from individuals in their support groups who are being denied TOLAC/VBAC care in hospital settings for non-evidence based reasons. In the past few years, since OCC #8 was published, we've seen an alarming increase in providers refusing to support TOLAC for individuals with shorter interdelivery intervals due to the providers' reading of OCC #8 and concern that the shorter intervals bring an unusually high uterine rupture risk.

In addition, as the name of OCC #8 is "Interpregnancy care," some providers are even confusing the recommended interdelivery interval with a required interpregnancy interval and are pushing repeat cesarean for those with less than 18 months *interpregnancy* spacing. Others are counseling patients that the risk of uterine rupture is very high with shorter interdelivery intervals, and are putting additional cumbersome labor requirements on these patients compared to those planning TOLAC with longer pregnancy spacing. Even though OCC #8 specifically mentions that placenta accreta spectrum risk increases alongside the number of cesareans, few maternity care professionals are providing that information in their counseling. This imbalance of information pushes many toward repeat cesareans and removes the chance for patients to give true informed consent.

This is not in alignment with ACOG's PB #205 (2019), which states only the following regarding interdelivery intervals:

Moreover, a shorter interdelivery interval (less than 19 months) and the presence of preeclampsia at the time of delivery also have been associated with a reduced chance of



achieving VBAC (56, 57). Conversely, women who have had a prior vaginal delivery are more likely than those who have not to have a VBAC if they undergo TOLAC (45, 58).

Besides the need for this paragraph to be edited for clarity by separating out the presence of preeclampsia as its own sentence and emphasizing the still relatively high success rate of VBAC for shorter interdelivery intervals in the cited study, ("*The VBAC success rate was 79.0% for patients with an interdelivery interval less than 19 months compared with 85.5% for patients with an interdelivery greater than or equal to 19 months (P = .12)"*), the practice bulletin's update makes clear that any concern with shorter interdelivery interval is not related to uterine rupture. Huang et al. (2002) found no difference in uterine rupture rates. At no point in the current VBAC Practice Bulletin does it mention that interdelivery or interpregnancy intervals less than 19 months (or any other range) are contraindicated for a TOLAC. And yet, that is how many providers have interpreted OCC #8.

Upon careful review, the four studies regarding VBAC that are referenced in OCC #8 are outdated and misleading, using questionable samples or methodologies. Two of the four studies were also referenced in ACOG's Practice Bulletin No. 54: Vaginal birth after previous cesarean delivery (2004) but were all removed starting in the 2010 update and are not referenced at all in PB #205. Additionally, there are several comparatively newer and well-designed studies on interdelivery interval that were not included in OCC #8, even though one of them is cited in PB #205. None of these other studies found an increased uterine rupture risk with shorter interdelivery intervals. We have detailed the issues with the studies cited in OCC #8 and provided examples of other studies in an analysis attached to this letter.

The ongoing harm that comes from providers' interpretations of OCC #8 is significant. While the OCC #8 was meant as guidance for pregnancy planning, it is instead being used to limit options for prenatal and birth care and is being cited by hospitals and providers as the reason they treat those with shorter interpregnancy intervals as "higher risk" for VBAC. Providers are using the recommendations intended for counseling those not yet pregnant as "policy" to limit choices in prenatal care for those who are, counseling patients against TOLAC or refusing to accept those patients if they do not consent to an "elective" repeat cesarean, leading to mandated surgery when other options are not available and increasing risks for any future pregnancies. It behooves ACOG to make it clear that current research does not support limiting VBAC for people with shorter interdelivery intervals.

We urge ACOG, SMFM, ACNM, and NPWH to correct OCC #8 by removing references to the outdated and poorly conducted studies related to interdelivery intervals and uterine rupture rates and, while not perfect, at a minimum align the sections related to prior cesarean delivery with ACOG's PB #205. ACOG should also make clear to its members that, after counseling about



the risks and benefits of VBAC, in the event of a shorter interdelivery interval, it is still the patient's right to choose VBAC and it is by no means contraindicated by current research.

We commend ACOG and its partners on efforts to improve maternal health through the Alliance for Innovation in Maternal Health (AIM) safety bundles including the safe reduction of primary cesareans and the focus on respectful care. We hope you will join us in ensuring hospitals, providers, and individuals seeking pregnancy care have access to current and quality evidence based information.

ICAN welcomes collaborative dialogue around this topic, and all other barriers to VBAC/TOLAC care, and cesarean support. We look forward to hearing from you regarding this letter. If you have any questions please contact us at <u>board@ican-online.org</u>.

Sincerely,

International Cesarean Awareness Network Board of Directors

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Analysis of Relevant Studies

Bujold et al. (2002), referenced in OCC #8, is very limited by the sample size of the shortest interdelivery interval group (≤12 months), which only included 21 people. The other groups contain 372 (13-24 months), 436 (25-36 months), and 698 (>36 months). There are 33 times the number of people in the largest interdelivery interval group than in the smallest. With such a small sample size in the ≤12 month group, the single uterine rupture that occurred could easily be an outlier, and the actual risk in a larger group could be much lower. In addition, the uterine rupture rates for the longer spacing groups are still higher than we generally see quoted in other studies. It is important to note this study looked at a single hospital between 1988-2000 and 78% of all their uterine ruptures occurred after 1994. Was this sudden increase due to a specific provider, a specific intervention like a cervical ripener, or a policy change? This study was included in the 2004 ACOG PB #54 almost 20 years ago but was removed thereafter for the 2010, 2017, or 2019 editions. Given the study is no longer deemed reputable for the PB #205, it should not be referenced in the interpregnancy consensus.

A second study referenced in OCC #8, Bujold and Gauthier (2010), retains the same limitations as the 2002 version from the same authors. In this study, they expanded the original sample by a few years then divided the groups a bit differently than in the 2002 version, due to other studies dividing at 18 months, and found those with under 18 months interdelivery intervals to have a 4.8% uterine rupture rate (n=188), over 24 months to have a 1.3% uterine rupture rate (n=1,323), and 18-24 months to have a 1.9% uterine rupture rate (n=257). Once again, the rates even for the "lower" risk groups are well above the uterine rupture rates of other studies - for example, Huang (2002) found a uterine rupture rate of 0.3% for the longer interdelivery interval. Additionally, this study mentioned that the risk of uterine rupture was more tied to the type of uterine closure in the previous cesarean and/or to the use of prostaglandins than to the interdelivery interval - the odds ratio (OR) for interdelivery interval <18 was 3.0, the OR for prior single-layer closure was 7.3, and the OR for use of prostaglandins was 3.9. So, in the study, uterine rupture was more highly associated with single layer closure and/or use of prostaglandins than interdelivery interval. Forty percent of the shortest interdelivery group had single layer closures vs. only 25% of the longer interdelivery group, a statistically significant difference. Given this is from a single hospital, it seems possible this could represent a provider or group who were doing a certain type of single layer closure with poor results. This study also does not appear in any of the ACOG Practice Bulletins for VBAC.

Shipp et al. (2001), referenced in OCC #8, also had limitations due to the type of sampling. Per ACOG's PB #205, while induction should remain an option for TOLAC, there is an increased risk of uterine rupture with induction, especially when using higher doses of pharmacologic induction



methods. But the risks related to induction were not well known at the time of this study's sample (1984-1996). In this study, 44.8% of people with uterine ruptures had been induced and only 18% of people who did not experience uterine rupture were induced. This means the uterine rupture group was 2.5 times more likely to have received pharmacologic induction methods that are now known to increase likelihood of uterine rupture. This study group was also the same one that, in another publication, found the uterine rupture rate for vaginal birth after two cesareans (VBA2C) to be 3.7% whereas other studies on VBA2C from the same time period generally quote 1.8%-2%, and studies with samples after 2000 have generally found even lower rates. As with the Bujold studies, this study sample came from a single hospital and calls into question whether policies or procedures used by this single hospital and/or a few obstetricians led to unusually increased uterine rupture rates.

Finally, Stamilio et al. (2007), the fourth study referenced in OCC #8, is based on unsound data. The study authors did not have access to actual interpregnancy interval (IPI) data as they only had access to the year of prior cesarean delivery, not the month or day. To attempt to examine IPI, they assigned January 1 as the cesarean delivery date for all participants' prior delivery, which led to the shorterest IPI group having a sample size of only 282, which was very small compared to the size of the whole study (over 13,000). There is only one mention of this estimate, found midway through the discussion section. In this mention, the authors reported trying July 1 instead of January 1 and having the size of the shortest IPI group increase significantly (from 282 to 1402) while the risk of uterine rupture rate in that group decreased (from 2.7% to 1.6%), a notable difference. The authors also stated that using the middle-of-the year estimate decreased the statistical significance of the difference in rates compared to the longer intervals. Instead of recognizing that the January 1 estimates might be inaccurate, they simply opted to use the January 1 estimate for their analysis to retain the appearance of statistical significance. By using January 1 as the delivery date, those with shorter IPIs but who had cesareans later in the year would be included in one of the the longer IPI groups, leaving the shorter IPI group largely limited to those with especially short IPI, largely those who delivered within the same year and/or experienced premature deliveries in their post-cesarean birth. Not having the actual prior delivery date for a study on interdelivery intervals is a major flag for a poorly-conducted, unreliable study. This study also does not appear in any current or past ACOG VBAC Practice Guidelines.

Meanwhile, there are high quality studies on interdelivery interval that were not included in OCC #8, but that show low uterine rupture rates for shorter interdelivery intervals. **Huang (2002)** showed no difference in uterine rupture rates between longer and shorter interdelivery intervals. While this study was similarly sized to those quoted in OCC #8, there were no uterine ruptures in the less than 19 month interval group and only three in the more than 19 month group (0.27%). This is the only study related to interdelivery interval that is included in the VBAC



Practice Bulletins from 2010 and later. The studies showing increased likelihood of uterine rupture with shorter interdelivery intervals were all removed after the 2004 version of the VBAC Practice Bulletin.

Ridgeway et al. (2004) found no difference in mean interdelivery interval between the uterine rupture group and the control group with no uterine ruptures. This is not mentioned by ACOG in regards to interdelivery interval, but was mentioned by Bujold.

Bujold also mentioned **Grobman et al. (2008)**, a study that attempted to create a prediction model for uterine rupture and examined several possible factors. While actual uterine rupture rates for short interdelivery intervals were not reported, their analysis found that interdelivery interval was not strongly enough associated with uterine rupture risk to be included in their model. Only prior vaginal birth (protective) and induction (increased risk) appeared to have strong enough effects on rates to include in the model.

The most recent study on interdelivery interval appears to be **Rao et al. (2022)**, which did not find a statistically significant difference in uterine rupture rates based on interdelivery interval. There were no ruptures at all in the shortest IDI group, though the high dividing line (24 months) and small sample size (n=28) make it difficult to apply to the discussion.

Finally, **Kessous and Sheiner (2013)** is more recent than most of the other studies (with the exception of Rao) and also found no statistical significance in uterine rupture risk between shorter and longer interdelivery intervals. Unlike Rao, this study included several groups with less than 24 month intervals and had a fair sample size for each group: the study had 3,176 participants, including 176 in the \leq 12 months group and 728 in the 13-18 month group. It is larger than the Bujold and Shipp studies mentioned in OCC #8 and, unlike the Stamilio study, is built around actual IDI data, not estimates. It focused on a single hospital, like the Shipp and Bujold studies, but the uterine rupture rates for all groups were much more in line with other reputable VBAC-related studies. The uterine rupture rates for the different interdelivery groups were 0.6% for the \leq 12 month group, 0.5% for the 13-18 month group, 0.3% for the 18-24 month group, and 0.2% for the more than 24 month group. The difference in uterine rupture rates between these groups was not statistically significant despite the larger sample sizes. All were in line with the rates already quoted in the VBAC practice bulletin for any interdelivery interval.



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