



FPQC Guidance Regarding the ARRIVE Trial Findings and Promoting Primary Vaginal Delivery (PROVIDE) Initiative: *What to Consider in Regards to Practice*

(Unanimously Approved by the PROVIDE Advisory Group on August 28, 2018)

WHAT IS ARRIVE?

The ARRIVE Trial findings have recently been published in the *New England Journal of Medicine* identifying positive benefits of electively inducing a select group of women at 39 weeks gestation. The study was a randomized controlled trial in university and university-affiliated community hospitals that compared labor induction at 39 weeks to expectant management up to 42 2/7 weeks among low risk nulliparous women. Cesarean births were significantly lower in the induction of labor group with a cesarean rate of 18.6% compared to 22.2% in the expectant management group. The FPQC Advisory Committee on PROVIDE has reviewed the findings as well as responses from ACOG, SMFM, ACNM, AWHONN, and CMQCC; FPQC supports the statements from these organizations relative to the generalizability of these findings to clinical practice and the cautions regarding implementation of policies supporting induction at 39 weeks. The committee primarily recommends that any newly established policies by hospitals support the facilitation and optimization of the chances for a safe physiologic vaginal birth.

HOW DOES THIS IMPACT PRACTICE?

After studying the ARRIVE Trial protocols and parameters, the PROVIDE Advisory Committee noted the following:

- The selection process for patients who will benefit from induction of labor at 39 weeks is rigorous. Of 50,000 patients screened for the study, 22,000 were eligible, and only 6,000 were accepted for inclusion in the trial. Inclusion and exclusion criteria, available in the study's Supplementary Appendix, should be studied and included in induction policies. Selection of patients is not simply a process of responding to a patient directed or physician directed request for induction.
- The protocols and recommendation for the definition of arrest used in the study were conducted in hospitals who have demonstrated a high degree of compliance with ACOG/SMFM recommendations and those utilized in PROVIDE. Adherence to those recommendations resulted in a baseline NTSV Cesarean rate of 22.4%.
- Patients undergoing elective induction of labor did experience a 30-40% increase in length of labor compared to patients who were allowed to enter labor spontaneously. This indicates that the management of labor is a critical factor for women both induced and expectantly managed.
- In order to prevent premature delivery, careful adherence to the criteria for consideration for elective induction must include confidence in the estimated dates for delivery, with first trimester ultrasonography confirmation for uncertain last menstrual periods.
- A strict definition for failed induction related to cervical ripening, labor duration, and labor management consistent with ACOG and PROVIDE guidelines (page 111) needs to be adopted and practiced to prevent a potential spike in cesarean rates.

FLORIDA SPECIFIC ISSUES

Prior to considering an elective induction of labor policy, hospitals should be prepared to address the following Florida specific concerns at their institution:

1. **The study population had a much lower baseline cesarean rate, indicating that their population is different or their hospitals manage labor differently.** Few Florida hospitals meet the rates of Cesarean section deliveries found in study hospitals. Only 14 of Florida's 115 delivery hospitals have rates less than 22.2% with a Florida hospital median rate of 29.4% in 2017, giving Florida one of the highest rates in the nation.
2. **In Florida, most cesareans for arrest of labor don't meet the ACOG recommended criteria.** Chart reviews conducted by Florida PROVIDE hospitals for a three-month baseline period found that only 40% of cesareans to low risk women (nulliparous, term, singleton, vertex pregnancies) met the ACOG guidelines for labor duration based on cervical dilatation; these are similar to guidelines followed by the ARRIVE study hospitals.
3. **Most Florida hospitals will require additional capacity to implement.** Florida hospitals report that they are challenged to provide the level of resources and staffing to support increased numbers of elective inductions while also providing the support for those that are medically or obstetrically indicated.
4. **Florida mothers need to have choice where possible.** Patient considerations are important and informed shared decision making is essential. Adequate counseling should include information about the risks, benefits, processes, and expectations for induction vs. awaiting spontaneous labor. Patients should be made aware that some induction and labor recommendations are not fully implemented in many Florida hospitals.

FPQC GUIDANCE

FPQC guidance to hospitals considering implementation of this research protocol is as follows:

- Determine your hospital's current compliance rate with ACOG guidelines for management of labor. If your hospital's NTSV rate is less than 25% and a thorough review determines that the majority of Cesarean sections were performed within ACOG labor management guidelines for labor progress and assessment of fetal well-being, proceed with feasibility studies. If your hospital does not meet the criteria, proceed with implementation of those guidelines prior to considering implementation of the ARRIVE research protocol.
- If your hospital does meet the criteria above, proceed with feasibility studies concerning how to implement such a protocol, including evaluation of your hospital's ability to:
 - Screen for adherence to published selection criteria prior to admission
 - Provide oversight of induction indications, prioritizing inductions for established medical indications over provision of elective inductions in low risk patients
 - Conduct budgetary analysis of costs of increased nursing needs
- If a protocol to allow elective induction of labor is initiated at your hospital, intensive chart review of the outcomes for these patients and ACOG guideline practices should be performed for at least 6—12 months after implementation of the protocol.

References:

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2. ACOG Practice Bulletin No. 107, Induction of Labor <https://www.acog.org/Clinical-Guidance-and-Publications/Practice-Bulletins/Committee-on-Practice-Bulletins-Obstetrics/Induction-of-Labor>
3. ACOG/SMFM Practice Advisory: Clinical guidance for integration of the findings of The ARRIVE Trial: Labor Induction versus Expectant Management in Low-Risk Nulliparous Women, <https://www.acog.org/Clinical-Guidance-and-Publications/Practice-Advisories/Practice-Advisory-Clinical-guidance-for-integration-of-the-findings-of-The-ARRIVE-Trial>
4. AWHONN Response to ARRIVE Trial, https://www.awhonn.org/page/arrivetrials?utm_source=awhonn_homepage&utm_campaign=ARRIVE%20Trial
5. ACNM Responds to Release of ARRIVE Trial Study Results: Acknowledges Quality of Study but Raises Concerns about Potential for Misapplying Results. August 9, 2018, <http://midwife.org/ACNM-Responds-to-Release-of-ARRIVE-Trial-Study-Results>
6. How to Apply the ARRIVE Trial To My Practice, Elliott Main, MD, Medical Director and the CMQCC Leadership Team, August 17, 2018, https://gallery.mailchimp.com/9d6c315d76cb931f29ad19466/files/964ba622-1a74-49b1-8f51-decd4c7490bb/Arrive_Trial_FINAL.pdf
7. International Cesarean Awareness Network (ICAN), www.ican-online.org, Patient Education Statement, <https://www.facebook.com/ICANonline/photos/a.425689387445927/2266222790059235/?type=3&theater>
8. FPQC Promoting Primary Vaginal Deliveries Toolkit, <http://health.usf.edu/publichealth/chiles/fpqc/provide/toolbox>