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Why ARRIVE should not thrive in Australia

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Why ARRIVE should not thrive in Australia



Published last week and surrounded by a flurry of commentary and social media was the ARRIVE trial. This trial was based on the hypothesis that elective induction of labour at 39 weeks would reduce perinatal mortality and morbidity. Across 41 hospitals in the United States, more than 6000 low-risk nulliparous women who were at 34 weeks 0 days to 38 weeks 6 days of gestation were randomised to either to induction of labour at 39 weeks 0 days to 39 weeks 4 days or to expectant management, which meant waiting beyond 40 weeks and 5 days to be induced but no later than 42 weeks and 2 days. The primary outcome was a composite of perinatal death and severe neonatal complications. The main secondary outcome was caesarean section. There were no differences in the primary outcome. Specifically, elective induction of labour at 39 weeks did not improve perinatal outcomes. However, induction of labour did significantly reduce the rate of caesarean section, by 4%. The authors of the paper were tempered in their conclusion, merely stating the finding in relation to the outcomes. However, the wider response has been much less tempered, including a statement from the American College of Obstetricians and Gynaecologists (released the same day as the full paper) that it is reasonable for obstetricians and health-care facilities to offer elective induction of labour to low-risk nulliparous women at 39 weeks gestation.² We are yet to see the formal response in Australia.

If the goal of earlier induction is to prevent adverse perinatal outcomes, then it is not surprising that many clinicians are drawn to the research. High-income countries around the world are struggling to reduce stagnated rates in perinatal mortality.³ For the US, this is particularly important given they have the highest rates of perinatal mortality among developed countries worldwide. Their rate of stillbirth of 3 per 1000 births >28 weeks places them 29th among 49 countries. Australia is ranked 15th. The neonatal death rate in the US, at 4 per 1000⁵ is double that of Australia's.⁶ Intuitively, earlier induction makes sense. If a pregnancy comes to an end, then the unborn baby will no longer be at risk. However, the ARRIVE trial shows us that, for healthy women with a healthy pregnancy, elective induction at 39 weeks does not improve perinatal outcomes. If the intent is to prevent adverse perinatal outcomes, then routine elective induction does not deliver. Women can be reassured that waiting is safe and appropriate.

But did we not already know that? Over the last two decades in Australia there has been an increasing left shift in pregnancy duration, i.e. towards shorter pregnancies. In 1991 the average gestation of birth was 39.2 weeks. In 2016 it was 38.6 weeks. This has largely been as a result of an increasing rate of induced labours,

from 19.5% to 31%. Despite this, the perinatal mortality rate has remained unchanged. 6

An important consideration, and ongoing debate, is whether induction of labour is associated with an increased risk of caesarean section. The ARRIVE trial suggests that it is not. On the contrary, elective induction was associated with a lowering of the risk of caesarean section. This is at odds with Australian population data. For example, in 2016 in one Australian state, the rate of caesarean section among nulliparous women undergoing induction of labour ≥37 weeks (Robson group 2) was 30%.8 Among similar women with a spontaneous onset of labour the rate of caesarean section was 16.5%. Outside of the controlled environment of a clinical trial, such as ARRIVE, it seems highly likely that a policy of routine elective induction of labour in nulliparous women would result in yet further increases in our overall rates of caesarean section.

There is also growing concern about increased longer-term harm associated with early term births. The educational and physical outcomes of Australian children born at 40 weeks and beyond are significantly better than those born before 39 weeks. Poorer child health and educational outcomes were also apparent, on average, in children whose labour was induced compared to those who went into labour spontaneously, irrespective of mode of birth. So not only does elective induction of labour at 39 weeks not confer any benefit on the child, it may cause harm. *Primum non nocere*.

Given the many differences in the provision of maternity services between the US and countries like Australia, the UK, New Zealand and Scandinavia, it seems likely that elective induction of labour at 39 weeks will not improve outcomes for women and their babies in these contexts. Our attention should turn to the countries where a reduction in the rate of stillbirth has occurred. For example, the UK has demonstrated a reduction of 20% in the rate of stillbirth following a whole-of-nation implementation of an evidence based bundle of care^{10,11} which has targeted the key risk factors for perinatal mortality. In addition, if all women in Australia had access to midwifery continuity care with consultation and referral to obstetricians as needed, there are likely to be significant benefits in terms of reduced preterm birth, less early stillbirth, more positive birth experiences. 12,13 Not to mention the cost savings to the health system 14 and a reduction in the caesarean section rate. 15,16

Finally, ARRIVE may have arrived in the maternity care lexicon, but we should exercise caution in widespread implementation especially in different contexts and settings. The disconnect

between efficacy in well controlled trials and effectiveness when the intervention is implemented into widespread practice has been well known since the 1980s.¹⁷ A focus on care approaches and interventions that are effective at optimising women's outcomes and experiences and reducing adverse outcomes, without increasing other harms at the population level and meet the needs of the women is required.

References

- Grobman W., Rice M, Reddy U, Tita A, Silver R, Mallett G, et al. Labor induction versus expectant management in low-risk nulliparous women. N Engl J Med 2018;379:513–23.
- ACOG. Practice advisory: clinical guidance for integration of the findings of the ARRIVE trial: labor induction versus expectant management in low-risk nulliparous women. American College of Obstetricians and Gynecologists;
 2018 Available from: https://www.acog.org/Clinical-Guidance-and-Publications/Practice-Advisories/Practice-Advisory-Clinical-guidance-for-integration-of-the-findings-of-The-ARRIVE-Trial.
- Lawn JE, Blencowe H, Waiswa P, Amouzou A, Mathers C, Hogan D, et al. Stillbirths: rates, risk factors, and acceleration towards 2030. *Lancet* 2016;387 (10018):587–603.
- Flenady V, Wojcieszek AM, Middleton P, Ellwood D, Erwich JJ, Coory M, et al. Stillbirths: recall to action in high-income countries. *Lancet* 2016;387 (10019):691–702.
- Rossen L. Quarterly provisional estimates for infant mortality, 2015-quarter 3, 2017. Atlanta, GA: Centers for Disease Control and Prevention; 2018.
- 2017. Atlanta, GA: Centers for Disease Control and Prevention; 2018.6. Australian Institute of Health and Welfare. Australia's mothers and babies 2016—
- in brief. Canberra: AlHW; 2018 Perinatal statistics series no. 34. Cat. no. PER 97.
 Lancaster P, Huang J, Pedisich E. Australia's mothers and babies 1991. Sydney: AlHW National Perinatal Statistics Unit; 1994.
- Hunt R, Davey M, Anil S, Kenny S, Wills G, Simon D, et al. Victorian perinatal services performance indicators report 2016–17. Melbourne: Safer Care Victoria, Victorian Government; 2018.
- Bentley J, Roberts C, Bowen J, Martin A, Morris J, Nassar N. Planned birth before 39 weeks and child development: a population-based study. *Pediatrics* 2016; 138(6).
- Widdows K, Reid HE, Roberts SA, Camacho EM, Heazell AEP. Saving babies' lives project impact and results evaluation (SPiRE): a mixed methodology study. BMC Pregnancy Childbirth 2018;18(1):43.
- 11. Healthcare Improvement Scotland. Scottish patient safety program maternity and children, end of phase report, August 2016. Scotland: HIS; 2016.

- Sandall J, Soltani H, Gates S, Shennan A, Devane D. Midwife-led continuity models versus other models of care for childbearing women. *Cochrane Database Syst Rev* 2016(9). doi:http://dx.doi.org/10.1002/14651858.CD004667. pub4 Art. No.: CD004667.
 Forster D, McLachlan H, Davey M, Biro M, Farrell T, Gold L, et al. Continuity of
- Forster D, McLachlan H, Davey M, Biro M, Farrell T, Gold L, et al. Continuity of care by a primary midwife (caseload midwifery) increases women's satisfaction with antenatal, intrapartum and postpartum care: results from the COSMOS randomised controlled trial. BMC Pregnancy Childbirth 2016;16 (1):28.
- 14. Tracy S, Welsh A, Hall B, Hartz D, Lainchbury A, Bisits A, et al. Caseload midwifery compared to standard or private obstetric care for first time mothers in a public teaching hospital in Australia: a cross sectional study of cost and birth outcomes. BMC Pregnancy Childbirth 2014;14:46.
- 15. McLachlan H, Forster D, Davey M, Farrell T, Gold L, Biro M, et al. Effects of continuity of care by a primary midwife (caseload midwifery) on caesarean section rates in women of low obstetric risk: the COSMOS randomised controlled trial. *BJOG* 2012;119(12):1483–92.
- Homer CSE, Davis GK, Brodie PM, Sheehan A, Barclay LM, Wills J, et al. Collaboration in maternity care: a randomised controlled trial comparing community-based continuity of care with standard care. Br J Obstet Gynaecol 2001;108(1):16–22.
- Flay B. Efficacy and effectiveness trials (and other phases of research) in the development of health promotion programs. Prev Med 1986;15(5):451–74.

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