

Offline: FRENCH-ARRIVE—elles accusent

The accusation is direct and unflinching. The FRENCH-ARRIVE trial “obeys a pseudo-scientific rational logic” that is “a denial of what childbirth and motherhood mean to women”. Claudine Schalck and Raymonde Gagnon are both registered midwives. Their book, *When Inducing Labor Compromises a Woman’s Motherhood* (L’Harmattan, 2022), is one of the most remarkable denunciations of an ongoing research study ever published. It is also a sustained critique of the contemporary approach to obstetric care in many western nations today. Their analysis raises important questions about scientists’ ethical responsibilities to research participants, and more especially medicine’s attitudes to women.

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The original ARRIVE trial (A Randomised Trial of Induction Versus Expectant Management) was published in the *NEJM* in 2018 by William Grobman and colleagues. Over 6000 low-risk nulliparous women at 38 weeks to 38 weeks and 6 days gestation were randomised to labour induction or expectant management. The primary outcome was combined perinatal death or severe neonatal complications: the relative risk reduction in the induction group was 0.8 (95% CI 0.64–1.00). Caesarean delivery, the main secondary endpoint, was significantly lower among women undergoing induction (relative risk 0.84; 95% CI 0.76–0.93). Grobman et al comment that their results contradict observational reports of adverse maternal and perinatal outcomes after labour induction. They wrote that “the trial provides information that can be incorporated into discussions that rely on principles of shared decision making”. According to its record on ClinicalTrials.gov, the FRENCH-ARRIVE trial began in April, 2021, and is expected to complete by the end of 2023. The main sponsor is the University Hospital in Bordeaux, in collaboration with France’s Ministry of Health. The French investigators argue that “the expected benefits of elective labor induction at 39 weeks have to be confirmed in other settings outside [the] US before considering routine induction of labor for all low-risk nulliparous women at 39 weeks of gestation worldwide”. The primary outcome of FRENCH-ARRIVE is incidence of caesarean section. About 4200 women are anticipated to take part. Schalck and Gagnon begin their indictment with a quote from François Rabelais: “Science without conscience is but the

ruin of the soul.” They acknowledge that “Limiting the C-section rate has become an international public health issue.” But they point out that inducing labour without any medically justified reason can be considered nothing less than “obstetric violence”. In FRENCH-ARRIVE, the calculation is one of measured risks and benefits: “The experiences, emotions, and subjectivity of the pregnant women are not taken into account.” Induction of birth is not a benign intervention: Schalck and Gagnon argue that induction interferes with physiological birthing processes and breastfeeding. FRENCH-ARRIVE seems to reduce birth to a purely medical event. One might argue that women give their consent to take part in the study. But that consent may not be based on the fullest possible information. Schalck and Gagnon claim that the effects of the trial are minimised in the brochure describing the study. And what freedom do first-time mothers really have in the consent process when faced by a medical expert in the setting of a hospital? What this trial seems to do, they suggest, is to tell women where, when, and how they should give birth. In FRENCH-ARRIVE, “The uterus is seen as a machine used to produce and expel a baby within a certain period of time, under the supervision of medical personnel.” This situation of “control” and “abuse” is a “form of domination over women”. The woman “has neither body, nor power, nor place, nor role in childbirth”.

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There are unique French dimensions to these arguments. France has a chronic shortage of midwives, whose working conditions are increasingly unacceptable. Compared with Sweden, France has twice the maternal mortality rate and fewer than half the number of midwives per 100 000 livebirths. But there are also general questions posed by this critique of FRENCH-ARRIVE. Does the simultaneous activity of scientist and doctor create a dangerous conflict of interest? Is medical research an enterprise dedicated more to its idealised progress than to meeting the specific needs of a person at a particular place and time in the health system? Schalck and Gagnon have written a visceral condemnation of a single research study. But their “j’accuse” is far broader. It deserves serious scrutiny and discussion.

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