The need for appropriate language in the debate on medicalisation of pregnancy

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The need for appropriate language in the debate on medicalisation of pregnancy

Although the majority of pregnancies progress smoothly and result in the birth of a healthy baby, this is not always the case. Pregnancy can have severe complications, including stillbirth, affecting eight in 1000 pregnancies in France;[1] maternal hypertension, affecting 74 in 1000,[2] or neonatal death, affecting three in 1000. Obstetrics and midwifery are the fields of study focused on pregnancy, childbirth, and the post-partum period. They aim to identify, by screening or diagnosis, pregnant women at risk of complications and offer ways to prevent or treat complications to improve outcomes.

Recently, Richard Horton commented[3] on the FRENCH-ARRIVE trial (NCT04799912). This large, nationwide, randomised trial in France aims to replicate or refute the findings of the US ARRIVE trial.[4] The US trial showed that induction of labour in nulliparous women with uncomplicated pregnancies between 39 weeks (+0 days) and 39 weeks (+4 days) resulted in improved outcomes for the newborn baby than expectant management. Women induced also had lower rates of caesarean birth and hypertensive disorders of pregnancy.

Horton responds to a book by Claudine Schalck and Raymonde Gagnon[5] that posits "induction of labour without any medically justified reason can be considered nothing less than 'obstetric violence'". Of note, Horton highlights emotive quotes from the French authors 13 times (eg, "control" and "abuse" are a "form of domination over women"; the woman "has neither body, nor power, nor place, nor role in childbirth"). By contrast, he quotes the FRENCH-ARRIVE investigators twice. This, we think, reflects his bias in the debate for which he calls.

Horton's Comment deserves a rebuttal. The French research network Groupe de Recherche en Obstétrique et Gynécologie (GROG) is an excellent network that has done landmark trials that have improved care for mothers and babies. The FRENCH-ARRIVE study adds valuable obstetric knowledge to support decision making by women and their families. The best way to provide high-quality information for consumers and clinicians is with randomised controlled trials, such as ARRIVE and FRENCH-ARRIVE, and other studies, such as SWEPIS and INDEX, both of which assess induction at 41 weeks.[6]

We are particularly concerned that Horton implies pregnant women lack capacity to consent. This contention echoes historical, paternalistic, patriarchal, and prejudicial attitudes about women and begs the question why he believes their consent capacity is any different than any other individual in the context of a research trial? We contend this attitude additionally promotes the exclusion of pregnant women from research, with the resultant impairment of maternal and child health.

Suggesting that pregnant women should not be presented with information (eg, about the risks and benefits of an intervention, such as induction) and allowed to make decisions based on their own preferences and values is disrespectful. Instead, it is proposed that a higher authority should decide the philosophy to which they should adhere or the information with which they are permitted to engage. We would posit that just as it is problematic when women have interventions that they do not want, withholding information from women so they cannot make decisions for themselves as to what intervention (or non-intervention) is best for them is also problematic. In fact, in a recent UK law case, the judge upheld the right for women to have information about any material risk to make autonomous decisions about how to give birth.[7]

The debate about the medicalisation of pregnancy (and medicalisation of life in general) is important, but that debate should never be conflated with good research or used to impugn researchers and clinicians who address important questions in an appropriate and ethical manner. In fact, GROG and other research networks have identified many interventions that are ineffective; these studies have protected women from the possible harm of such interventions.[8,9]

Additionally, the use of terms such as "obstetric violence" from *The Lancet*'s Editor-in-Chief is unfortunate. Such inflammatory language shreds the ability for the nuanced, scientific debate that Horton is calling for. Similarly, we are surprised by the title of Horton's Offline, including the words "elles accusent", making a parallel between the FRENCH-ARRIVE study and the 1890's Dreyfus affair, a notable example of antisemitism in France. All in all, we welcome the debate that Horton wants to initiate, but, for reasons mentioned, we feel that this biased, provocative Offline comment is a false start.

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FRENCH-ARRIVE: a serious, evidence-free, and false accusation of unethical research

We—the investigators and Trial Steering Committee of the FRENCH-ARRIVE trial, members of the Groupe de Recherche en Obstétrique Gynécologie, representatives of the French College of Obstetrics and Gynecology, and Bordeaux University Hospital (appendix)—were stunned to read Richard Horton's[1] Comment spreading the erroneous accusations of Claudine Schalck and Raymonde Gagnon[7] claiming that the FRENCH-ARRIVE trial (NCT04799912) is scientific misconduct and unethical research that "obeys a pseudo-scientific rational logic" and is "a denial of what childbirth and motherhood mean to women". Schalck and Gagnon, who, like Horton, have never contacted us for accurate information about this trial, falsely suggest that the study provides the eligible women with incomplete information and that their "experiences, emotions, and subjectivity…are not taken into account".[1] As Horton pointed out, the rationale of the FRENCH-ARRIVE trial is based on the results of the ARRIVE trial.[8] That trial, done in the USA, showed a reduction of the composite adverse perinatal outcome (primary outcome) at the limit of significance, but a significantly lower frequency of caesarean births (secondary outcome). Based on this trial, the Society of Maternal-Fetal Medicine[2] stated that "[i]t is reasonable to offer elective induction of labor to low-risk nulliparous women ≥39 weeks 0 days of gestation".

The generalisability of this US study to populations with different characteristics or different contexts of care has been questioned in France and elsewhere.[3] The FRENCH-ARRIVE trial is being done precisely because we believe that additional evidence is required before elective induction of labour can be considered "a reasonable option"[3] for low-risk nulliparous women at 39 weeks or more of gestation and that one single multicentre trial, robust as it might be, is far from enough to implement such a medical intervention, especially when it is based on a positive result for a secondary outcome.[3] The FRENCH-ARRIVE trial is urgently necessary because practices have already changed, with labour induction rates increasing in many countries since the 2018 publication of the ARRIVE trial.

Contrary to the fact-free accusations made against us, we are particularly concerned about the implementation of a policy proposing routine labour induction for low-risk nulliparous women at 39 weeks or more of gestation, particularly because we have shown that induction of labour for medical reasons is an independent risk factor for post-traumatic stress disorders 2 months after vaginal childbirth.[4]

We therefore decided to test the hypothesis raised by the ARRIVE trial that elective induction of labour in low-risk nulliparous women at 39 weeks or more of gestation might reduce the

See **Online** for appendix