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# Evidence on: Inducing for Due Dates

Inductions for non-medical reasons have been on the rise in the U.S. and around the world over the last 30 years (<u>Little, 2017</u>). Increasingly, more pregnant people are being induced because they have reached their estimated "due date" of 40 weeks, or even when they have reached 39 weeks.

What are the benefits and risks of elective induction for mothers and babies *before* your estimated due date? What about *after* you've passed your estimated due date—is there a point where the risks of continuing the pregnancy greatly increase? Do a person's goals and preferences for their birth matter?

The purpose of this Evidence Based Birth® article is to look at the evidence on inducing labor for due dates.

This article was originally published in 2015 and last updated on February 24, 2020 by <u>Rebecca Dekker</u>, PhD, RN, and Anna Bertone, MPH.

## How often are pregnant people induced for going past their estimated "due date?"

According to the 2013 Listening to Mothers III survey, more than four out of ten mothers (41%) in the U.S. said that their care provider tried to induce their labor (<u>Declercq et al., 2013</u>). The researchers asked mothers to select the reasons that they were induced.

- Out of everyone who was induced, 44% said that they were induced because their baby was full-term and it was close to the due date.
- Another 18% said that they were induced because the health care provider was concerned that the mother was overdue.

In the U.S., the Centers for Disease Control (CDC) reported that 27% of pregnant people were induced in 2018 (<u>Martin et al., 2019</u>). But that number is probably low. It's likely that induction of labor is underreported in federal vital statistics (<u>Declercq et al., 2013</u>).

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## Glossary

- Estimated due date = Traditionally considered to be 40 weeks and 0 days after the last menstrual period
- Last menstrual period (LMP) = First day of the last period
- **Apgar score** = A quick test given to newborns to assess their health status (usually done at 1 and 5 minutes after birth)
- Stillbirth = Death in utero due to any cause after 20 weeks gestation
- **Neonatal death** = Death at <28 days after birth, further delineated into early neonatal (<7 days), and late neonatal (7-27 days)
- Perinatal death = Includes both stillbirth and neonatal death
- **Post-dates pregnancy** = A common term that means any pregnancy that goes past the estimated 40-week due date; however, it is imprecise and usually replaced with early/full/ late/post term
  - o Early-term is between 37 weeks 0 days and 38 weeks 6 days
  - o **Full-term** is between 39 weeks 0 days and 40 weeks 6 days
  - o Late-term is between 41 weeks 0 days and 41 weeks 6 day
  - o **Post-term** is 42 weeks and 0 days (294 days total) or later
- Medical induction = Starting labor with medical intervention before it begins on its own
- **Spontaneous labor** = A labor starting on its own rather than triggered by medical intervention
- **Medically indicated induction** = An induction for an accepted medical indication from a professional guideline
- Elective induction = Induction that is not medically indicated
- **Expectant management** = Waiting for labor to start on its own, usually with fetal and other testing to monitor the mother/baby's status
- Active management = Medical induction for due dates
- **Absolute risk** = The actual, or true, risk of something happening to you as an individual (e.g., a 15% chance of the outcome means it happens to 15 people out of 100)
- **Relative risk** = The risk of something happening to you in comparison to someone else (e.g., if your absolute risk is 15% and some else has an absolute risk of 10%, then your relative risk of the outcome is 50% higher than theirs)

**DISCLAIMER:** Nothing in this article shall be construed as advice from a healthcare provider (i.e. midwife, nurse, nurse practitioner, doctor or physician assistant). This article is strictly intended to provide general information regarding its subject-matter and may not apply to you as an individual. It is not a substitute for your own healthcare provider's medical care or advice and should not be relied upon by you other than upon the advice of your treating provider. If you need someone to examine you or discuss your pregnancy or baby's health, see a midwife, nurse practitioner, or doctor.

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## Why is there so much controversy about elective induction?

In general, inductions are considered medically indicated when there are accepted medical problems or pregnancy complications that make it less safe to continue the pregnancy. Labor inductions that do not have a clear medical reason (or indication) for taking place are considered "elective" inductions.

Elective inductions might occur for social reasons, like the provider wanting the birth to happen before he or she goes out of town, or other non-medical reasons like the mother wanting to be done with an uncomfortable pregnancy.

But the distinction between elective versus medically indicated induction is not always clear. Some providers consider induction for late and post-term pregnancy alone to be medically indicated because of the increased risks of complications that come with longer pregnancies (<u>Little, 2017</u>). In this article, we refer to induction without a medical indication as an elective induction, regardless of gestational age.

#### The challenge of choosing the right comparison group to study elective induction

For many years, the common belief was that elective inductions doubled the Cesarean rate, especially in first-time mothers.

However, in the 2010s, some researchers began to dispute the claim that elective induction doubles the risk of Cesarean. They argued that earlier studies—where elective induction showed a doubling in Cesarean rates—were flawed.

In the earlier studies, elective induction was compared only to spontaneous labor: people who were electively induced versus people who went into spontaneous labor. Excluded from these two groups were people who were not electively induced initially, but waited for labor and then ended up having inductions later on, some of which were medically necessary (and, thus, linked to a higher rate of Cesareans). For an example of this earlier flawed research, see this article by Yeast et al. 1999.

Previous studies compared Cesarean rates of these two groups only:



New researchers pointed out that we need to compare people who have elective inductions with the whole group of those who wait for spontaneous labor—whether or not they actually do have spontaneous labor.

This is a subtle difference, but an important one, because not everyone who waits for labor will actually have a spontaneous labor; some will develop complications that lead to an induction and increase their risk for Cesarean. The researchers argued that the comparison group must include these people as well.

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So, with this new understanding, someone in the wait-for-labor group who ends up being induced later in the pregnancy would **not** be considered inappropriate crossover between groups. This is because induction later in the pregnancy is a possible outcome with expectant management, just like going into spontaneous labor is a possible outcome.

This graphic shows how you would look at the two groups: the elective induction group versus the entire group of people who were not electively induced at that time—some of whom would, in fact, end up being induced later in the pregnancy.

In the 2010s, researchers said studies should include all groups:



Because of this flaw in the earlier studies, the researchers argued, those studies don't give us a true picture of the risks and benefits of elective induction between 39-41 weeks versus waiting for labor to start on its own ("expectant management"). Basically, when they started using the appropriate comparison group in studies, they no longer saw the increase in Cesareans with elective induction.

## Induction at 39 weeks versus waiting for labor

When someone gets closer or past their due date, they will often face the question about whether to induce labor or wait for labor to start on its own.

- Inducing labor for due dates is also known as "active management."
- Waiting for labor to start on its own, usually with fetal testing to monitor the baby's status, is called "expectant management."

Many researchers have tried to compare the risks and benefits of induction versus expectant management for pregnant people from 39 weeks to 42+ weeks of pregnancy.

## **Cautions about the evidence**

Before we begin discussing the evidence, it is important to note that there are some major drawbacks to the evidence that we have so far on induction versus waiting for labor to start:

1. Many of the clinical trials were carried out in countries or time periods with low Cesarean rates. So their research results may not apply to hospitals with high Cesarean rates that are associated with high rates of "failed inductions" due to non-evidence-based restrictions placed on laboring people. For example, does your hospital put strict time limits on the length of labor, not allow people in labor to eat or drink at will, or discourage mobility and position changes during labor? If so, then this evidence may not apply to you, because induction may be more risky (more likely to lead to a Cesarean) in your specific hospital!

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- 2. As we discussed, the appropriate comparison group for elective induction includes people who are induced later in the pregnancy together with those who go into labor spontaneously. Most researchers only report the results of the two study groups as they were originally assigned (those who were assigned to active management and expectant management), but it's also informative for us to look at the results for people who were actually induced or who actually went into spontaneous labor. For example, in the Hannah Post-Term trial (the biggest study about induction for post-dates), about one-third of mothers who were assigned to the induction group went into labor spontaneously before the induction. When you look at the breakdown of what actually happened to the people in the two groups (as we do below), it becomes apparent that Cesarean rates are only increased with expectant management when induction occurs later in the pregnancy, and not when mothers go into spontaneous labor later in the pregnancy.
- 3. In most studies, people in the expectant management group had many fetal tests, some of which may have showed possible signs of distress, and some of which turned out to be false positives (Menticoglou & Hall, 2002). This extra testing may have led to higher rates of Cesarean section for suspected fetal distress during labor in the expectant management group (Wood et al., 2014).

Another researcher said, "It may be that the results of our review reflect doctors' discomfort with delayed delivery in high-risk people that, once they are in labor, manifests as more frequent Cesarean sections: an example of research confirming the biases of the health care community" (Wood et al., 2014, pg. 682).

4. The induction protocols varied from study to study, and even within studies themselves. For example, in the Hannah Post-Term study, people in the active management group first received drugs to ripen the cervix, and then drugs to induce labor. Meanwhile, people in the expectant management group who ended up being induced did NOT have cervical ripening. It is known that medical induction without cervical ripening results in higher risk of Cesarean, so in this case, the expectant management group would have been at increased risk of Cesarean compared to the active management group.

## The ARRIVE study of 39-week inductions

In 2018, researchers published the results of the ARRIVE study (A Randomized Trial of Induction Versus Expectant Management), conducted to find out if elective induction of labor during the 39th week of pregnancy would result in a lower rate of death and serious complications for babies, compared to waiting until at least 40 weeks and 5 days for elective induction (<u>Grobman et al., 2018</u>). They also wanted to see if inductions had any effect on the risk of Cesareans.

This was a large study that took place across 41 hospitals in the United States. Researchers screened more than 50,000 people to see if they could take part in the study. People had to be giving birth for the first time with a single, head-down baby; be certain of the date of their last menstrual period; and have no major medical conditions.

They found 22,533 people who were eligible to be in the study, but only 6,106 of them (27%) agreed to participate. Researchers think that such a high refusal rate means there may be *selection bias*, where the study's findings among the trial participants do not reflect the overall eligible population (Carmichael and Snowden, 2019).

The researchers randomly assigned (like flipping a coin) 3,062 people to be induced at 39 weeks, and 3,044 people to expectant management. Expectant management meant you could wait for labor to begin on its own as long as birth occurred by 42 weeks and 2 days, or be induced for medical reasons at

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any time, or be induced electively after 40 weeks and 5 days. In other words, people in the expectant management group experienced a mix of spontaneous labor, induced labor for medical reasons, and electively induced labor.

Some people may wonder why the researchers did not simply compare elective induction with spontaneous labor. As we discussed, they could not compare those two groups, because spontaneous labor is not a certainty-it is possible someone may change their mind and wish to be induced electively, or require an induction for medical reasons.

#### What did the ARRIVE trial find?

They found that inducing labor at 39 weeks did not improve the primary outcome of death or serious complications for babies. Since stillbirths and newborn deaths are very rare at 39 and 40 weeks, the ARRIVE study (with 6,000 participants) was too small to tell if elective induction has an effect on this outcome. More babies received breathing support after expectant management (4.2% versus 3%) and had longer hospital stays, both of which could have been due to the higher rate of Cesareans with expectant management.

For mothers, induction at 39 weeks was linked to a lower rate of Cesarean compared to those assigned to expectant management (19% Cesarean rate versus 22%) and a lower chance of developing pregnancy-induced high blood pressure (9% versus 14%).

It's worth noting that the participants in this study developed high blood pressure after 38 weeks of pregnancy at unusually high rates, and researchers have questioned if the decrease in Cesareans with 39-week induction was mostly because of the mothers who got high blood pressure while waiting for labor after 39 weeks (<u>Carmichael and Snowden, 2019</u>). Hopefully, researchers will publish another study based on the ARRIVE data (called a secondary analysis) that will give us a better understanding of why 39-week induction led to a lower rate of Cesarean.

The mothers in the early induction group spent more time in the hospital in labor, but less time in the hospital postpartum. There was no difference in breastfeeding outcomes between groups. In both groups, 33% of babies were exclusively breastfeeding at 4 to 8 weeks after the birth and 31% were breastfeeding plus formula feeding.

Although this study may be helpful with making informed decisions, it does not mean "everyone" should be induced at 39 weeks. The ARRIVE study **did find** that inducing low-risk, first-time mothers with accurately estimated due dates at 39 weeks may help to lower the Cesarean rate from 22% to 19% if care providers follow the same induction practices as they did in this study. The study authors did not mandate a single protocol for induction or labor management, but it was recommended that providers follow best practices for induction, such as using cervical ripening for anyone who had an unfavorable cervix. The researchers think their finding on the Cesarean rate is explained by an increase in the risk of Cesarean the longer a pregnancy continues. Longer pregnancies mean more opportunities for potential complications to show up and an increasing willingness by providers to perform a Cesarean.

The ARRIVE study **does not** mean that elective induction at 39 weeks lowers the risk of Cesarean for every individual. Some mothers may not benefit from early elective induction, including:

• <u>Those who prefer to avoid medical interventions</u>. Many mothers would prefer to wait for labor to start on its own, if possible. This could be why so many people (73%) refused to participate in the study (although some may have refused because they knew they wanted early induction and didn't want to wait). Some mothers want to avoid cervical ripening drugs, synthetic oxytocin, or

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mechanical induction with a Foley catheter, where an inflatable balloon presses against the cervix to help start labor. They may also want to avoid other medical interventions that go along with induction, such as intravenous fluids, continuous fetal monitoring, and restrictions on freedom of movement.

- <u>Those whose care providers have high Cesarean rates with inductions</u>. In the ARRIVE study, providers knew they were participating in a research study looking at Cesarean rates, which can lower their Cesarean rate because they know they're being "watched." Providers were told to follow best practices for induction, and the researchers also recommended that mothers be given at least 12 hours in early labor before diagnosing a "failed" induction and ordering a Cesarean. Most providers in this study probably did follow these strict labor guidelines, because they were able to get a Cesarean rate of 19% with early induction in first-time mothers—this rate is unusually low, and not typical in many hospitals. For example, the average Cesarean rate after induction among low-risk, first-time mothers giving birth in 240 California hospitals was 32%, with some rates as high as 60% (Main and CMQCC, 2018).
- <u>Those choosing midwifery care</u>. Most of the people in this study were cared for by physicians (94%). Studies show that midwives achieve low rates of Cesarean without the regular use of elective induction. In the U.S., the Cesarean rate is about 5% at planned home births and 6% at midwifery-led birth centers (<u>Cheyney et al., 2014</u>; <u>Stapleton et al., 2013</u>). Hospitals with a higher percentage of midwife-attended births also tend to have lower rates of Cesarean; a recent study found a 15% Cesarean rate for hospitals that had more than 40% of their births attended by midwives (<u>Attanasio and Kozhimannil, 2018</u>).

An important limitation to the ARRIVE trial is that it was not designed to look at the practical implications of inducing everyone at 39 weeks. Increasing the number of elective inductions may increase costs and resources owing to a longer length of stay in the hospital before the birth. On the other hand, these costs could be offset by the costs required for expectant management (more prenatal visits, monitoring, or treating complications). Researchers have expressed concerns that filling beds with people choosing elective inductions could mean there is no space for those with severe preeclampsia or post-term pregnancy (Marss et al., 2019).

## Other ways to lower your risk of Cesarean besides elective induction at 39 weeks

The ARRIVE trial reported that people assigned to elective induction at 39 weeks had a Cesarean rate of 19% compared to a rate of 22% among those assigned to expectant management. That was the absolute risk of having a Cesarean, or how often Cesareans actually happened in each group. Absolute risk is the actual, or true risk of something happening to you. Relative risk is the risk of something happening to you in comparison to someone else, and you have to carry out a math formula to understand the reduction in relative risk. The relative risk of having a Cesarean was 16% less in the early induction group compared to the expectant management group.

Although the relative risk reduction was 16% with elective induction, studies have found a variety of even more effective ways to reduce the Cesarean rate that require significantly fewer resources. For example:

• People randomly assigned to continuous support during labor (such as with a doula) were 25% less likely to have a Cesarean (Bohren et al., 2017)

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• When people are assigned to a less-invasive type of fetal monitoring called hands-on listening (known as intermittent auscultation), they are 39% less likely to have a Cesarean compared to people assigned to continuous electronic fetal monitoring (Alfirevic et al., 2017)

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• Other comfort measures, such as walking around during labor, or planning a waterbirth, have also been shown in randomized trials to lower your risk of Cesarean by more than 16%

So, there are plenty of alternatives for people or facilities seeking lower risks of Cesarean that don't involve elective inductions.

## Other randomized, controlled trials on 39-week induction (*much* smaller than the ARRIVE trial)

Miller et al. (2015) conducted a trial at a U.S. military medical center. They randomly assigned 162 firsttime mothers with an 'unfavorable cervix' to induction at 39 weeks (with cervical ripening and Pitocin®) or waiting for labor until no later than 42 weeks.

Of the people assigned to induction at 39 weeks, 79 out of 82 people (96%) followed their assignment and were induced at 39 weeks. Of the people assigned to expectant management, 79 out of 80 (99%) followed their assignment, meaning that they weren't electively induced at 39 weeks; however, 44% gave birth after spontaneous labor and 56% gave birth after induction for medical reasons.

They found no difference in the rate of Cesareans between groups. To put it another way, elective induction at 39 weeks was not found to significantly increase or decrease the Cesarean rate. There was a high rate of Cesarean for labor arrest in the induction group (72% of Cesareans versus 36% in EM group), which suggests that it is important to have a protocol for "failed" induction that aims to prevent unnecessary Cesareans.

In the expectant management group, 13% of mothers were induced for high blood pressure disorders versus 0% of mothers in the 39-week induction group. This is more evidence that as the pregnancy progresses, there are more opportunities for complications to develop.

The main benefits of expectant management past 39 weeks were more spontaneous labor and a shorter hospital stay for mothers: about 10 hours shorter, on average, compared to the induction group.

Another randomized trial by Walker et al. (2016) assigned about 600 mothers from 42 hospitals in the United Kingdom to either inducing labor between 39 weeks 0 days and 39 weeks 6 days, or not inducing at 39 weeks and instead waiting up until 41-42 weeks before being induced. All of the participants in this study were over 35 years of age, so they called it the 35/39 trial. You can read more about this trial in our Evidence Based Birth<sup>®</sup> Signature Article on Advanced Maternal Age <u>here</u> (ebbirth.com/ama). In brief, there was no difference in Cesarean rates between the induction at 39 weeks group and the not-induced-at-39-weeks group. There was also no difference in any of the other birth complications for mothers or babies.

## Retrospective studies of 39-week induction in recent years

We found five retrospective studies conducted in the last five years that compared 39-week elective induction with expectant management. A retrospective study is one that looks back at events that took place in the past. Here, we're focusing on studies that compared 39-week elective induction with expectant management, not studies with inductions later in pregnancy, or those that grouped 39-41 week inductions.

Four of the studies found a lower Cesarean rate with elective induction at 39 weeks compared to expectant management and one study found no difference in the Cesarean rate between groups. All five of the studies found newborn benefits with elective induction at 39 weeks.

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The largest retrospective study (California data from over 360,000 births, <u>Darney et al., 2013</u>) found lower perinatal death with elective induction at 39 weeks (0% versus 0.2%). However, these studies are not randomized, so they have inherent flaws. For more details on these studies, see <u>Table 1, page 24</u>.

## Induction at 39 weeks versus waiting for labor

We considered the evidence discussed above in a broader context to develop the following list of potential Pros and Cons of 39-week elective induction.

Pros	Cons
<ul> <li>Avoid potential complications of continuing the pregnancy (e.g., developing a high blood pressure disorder, having a large baby)</li> <li>Lower Cesarean rate with first-time mothers under best practice "failed" induction protocol, which may prevent unnecessary Cesareans</li> <li>May prevent potential future stillbirth (although some would consider the absolute risk to be low until 41 weeks)</li> <li>Convenience, the ability to end an uncomfortable pregnancy</li> </ul>	<ul> <li>Potential for failed induction leading to a Cesarean</li> <li>Potential for medicalization of birth because of the induction (e.g., continuous fetal monitoring)</li> <li>Miss the hormonal benefits of spontaneous labor</li> <li>Longer time spent in labor</li> <li>Medically induced contractions may increase pain and make epidural-use more likely</li> <li>Potential uterine tachysystole (more than 5 contractions in 10 minutes, averaged over a 30-minute window; it can lead to a possible decrease in oxygen to the baby, fetal heart rate changes, and increased risk of uterine rupture)</li> <li>Increased risk of infection (with some methods)</li> <li>Cognitive benefits for babies during a continued pregnancy appear to increase until 40-41 weeks of pregnancy (so 39-week induction would miss this potential benefit)</li> </ul>

## Induction at 41-42+ weeks versus waiting for labor

Two large randomized, controlled trials on post-term induction came out in 2019. They both found that 41-week induction might improve outcomes for babies.

## The INDEX trial from the Netherlands

The trial from the Netherlands is called the INDEX trial, which stands for INDuction at 41 weeks, EXpectant management until 42 weeks (<u>Keulen et al., 2019</u>). It was a multicenter trial, conducted at 123 midwifery practices and 45 hospitals in the Netherlands, where midwives manage most pregnancies and births.

The researchers randomly assigned a total of 1,801 pregnant people to either induction at 41 weeks and 0 to 1 days or to expectant management and induction at 42 weeks and 0 days (if still no labor). In the Netherlands, labor is not usually induced before 42 weeks with an uncomplicated pregnancy, so they

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were able to get ethical approval to conduct this study. In the U.S., on the other hand, it is not standard practice to continue expectant management for as long as 42 weeks, so it would have been more difficult to get ethical approval to conduct the study there.

Pregnant people were enrolled into the study between 2012 and 2016. Mothers had to be healthy and pregnant with single, head-down babies. Everyone had to have a gestational age that was estimated with ultrasound before 16 weeks of pregnancy. They excluded anyone with a prior Cesarean, high blood pressure disorders, expected problems with the baby's growth, abnormal fetal heart rate, or known fetal malformations.

In both groups, cervical ripening and induction methods depended on local protocol. This is an important weakness of the study because, like the large Hannah Post-Term trial, individual providers in the INDEX trial may have managed labor inductions differently based on group assignment. The variation in induction methods used in the study also limits the study's *generalizability*, or ability to apply the results to the population at large, since care providers lack an induction protocol to replicate.

In the elective induction group, 29% of the participants had spontaneous labor before their induction and 71% were induced. In the expectant management group, 74% of the participants went into labor spontaneously before their planned induction and 26% were induced. Interestingly, the median decrease in length of pregnancy between groups was only two days. In other words, the median pregnancy was only 2 days shorter in the elective induction group, compared to the expectant management group.

#### What did the INDEX trial find?

#### For mothers:

- There was no difference in Cesarean rates (11% in both groups).
- There was no difference in a combined measure of bad outcomes for mothers (11%-14% both groups). This outcome, called the maternal composite adverse outcome rate, included excessive bleeding after birth (≥1000 mL), and/or manual removal of placenta, and/or severe tears, and/or intensive care admission, and/or maternal death. No maternal deaths occurred in either group. The researchers did not report on uterine rupture.

#### For babies:

- Babies in the elective induction group had a lower composite adverse outcome rate (1.7% versus 3.1%). For babies, this combined outcome included perinatal death, Apgar score <7 at five minutes, arterial pH <7.05, meconium aspiration syndrome, nerve injury, brain bleeds, or admission to a newborn intensive care unit (NICU). It was mostly the lower rate of Apgar score <7 at five minutes that contributed to the lower combined adverse outcome with the elective induction group (1.2% with elective induction versus 2.6% with expectant management). The authors note that there was no difference in rates of Apgar score of <4 at 5 minutes; however, the combined outcome was still significantly lower in the elective induction group if using Apgar score <4 at 5 min. and excluding fetal malformations.</li>
- One stillbirth occurred in the elective induction group at 40 weeks and 6 days (before the mother was induced) and two stillbirths occurred in the expectant management group (while the mothers were waiting for labor). One was to a first-time mother at 41 weeks and 3 days; her baby was small for gestational age. The other stillbirth was to an experienced mother at 41 weeks and 4 days; her placenta showed signs of infection. There were no newborn deaths in either group.
  - o There was no protocol for fetal monitoring (it varied by local guidelines), but fetal monitoring and assessment of amniotic fluid levels was typically performed between 41-42 weeks.

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In summary, the INDEX trial found that elective induction at 41 weeks resulted in similar Cesarean rates and fewer overall bad outcomes for babies compared to waiting for labor until 42 weeks. The absolute risk of a bad outcome (a combined measure of perinatal death, intensive care admission, or Apgar score <4 at five minutes) was low in both groups (1.7% versus 3.1%).

## The SWEPIS trial from Sweden

The SWEdish Post-term Induction Study (SWEPIS) garnered a lot of media attention with headlines like "<u>Post-term pregnancy research cancelled after 6 babies die</u>." Indeed, the researchers planned to enroll 10,000 mothers from multiple centers across Sweden but ended up stopping the study early (with about 1,380 people in each group) after their Data Safety and Monitoring Board found a significant difference in perinatal death between the groups (<u>Wennerholm et al., 2019</u>).

In Sweden, just like in the Netherlands, labor is typically not induced before 42 weeks with uncomplicated pregnancies and midwives manage most pregnancies and births. This study set out to compare elective induction at 41 weeks and 0 to 2 days versus expectant management and induction at 42 weeks and 0 to 1 day (if still no labor).

From 2015 to 2018, researchers enrolled healthy mothers with single, head-down babies. Gestational age had to be estimated with 1st or 2nd trimester ultrasound. They excluded anyone with a prior Cesarean, diabetes, low fluid levels, high blood pressure disorders, small-for-gestational-age babies, or known fetal malformations. There is a low stillbirth rate in Sweden, so they planned to enroll 10,000 people, but they ended up not needing nearly that many people to see a difference in perinatal outcomes between groups.

A big strength of the SWEPIS trial is that they defined an induction protocol, and the same protocol was used with the people assigned to elective induction <u>and</u> those assigned to expectant management who were induced for medical reasons or because the mother reached 42 weeks of pregnancy. If the mother's cervix was already ripe, they broke her water and gave her synthetic oxytocin as needed. If the mother's cervix was not ripe or the baby's head not engaged, they used any of the following: mechanical methods, misoprostol, prostaglandins, and/or synthetic oxytocin after ripening the cervix first.

In the elective induction group, 14% of the participants had spontaneous labor before their induction and 86% were induced. In the expectant management group, 67% of the participants went into labor spontaneously before their planned induction and 33% were induced. Similar to the INDEX trial, the median decrease in length of pregnancy between groups was slim—pregnancy in the elective induction group was, in general, only 3 days shorter.

#### What did the SWEPIS trial find?

#### For babies:

- The study was stopped early after five stillbirths and one early newborn death occurred in the expectant management group, out of 1,379 participants (4.4 deaths per 1,000). Zero deaths had occurred in the elective induction group, out of 1,381 participants. All five stillbirths in the expectant management group occurred between 41 weeks, 2 days and 41 weeks, 6 days. Three of the stillbirths had no known explanation, one was with a baby that was small for gestational age, and the other was with a baby who had a heart defect. The one newborn death occurred four days after birth due to multiple organ failure in baby that was large for gestational age.
  - The author mentions that when complications are present at the end of pregnancy (e.g., with the placenta, umbilical cord, or fetal growth) they may become increasingly important as the

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days of pregnancy progress, leading to a higher death rate with expectant management past 41 weeks.

- All of these perinatal deaths occurred with first-time mothers, which suggests that 41-week induction may be especially beneficial for first-time mothers. They found that it only took 230 inductions at 41 weeks to prevent one perinatal death. This is a much lower number than previously thought.
- If you recall, the INDEX trial did not find a significant difference in perinatal death between the induction group and the expectant management group (1 versus 2 deaths, respectively). This could be because SWEPIS is a larger study and better able to detect differences in rare outcomes like death. It could also be that there was better fetal monitoring of participants between 41 and 42 weeks in the INDEX trial, leading to fewer perinatal deaths. We can't be certain, because there were no fetal monitoring protocols in either trial. Finally, the participants in the SWEPIS expectant management group tended to give birth a little later than the participants in the INDEX expectant management group, and that might help to explain the higher perinatal death rate in SWEPIS.
- There was no difference in the composite perinatal outcome (2.2% to 2.4% in both groups). This combined outcome included perinatal death, Apgar score <7 at 5 min., pH less than 7, brain bleeds, brain injury from low oxygen, convulsions, meconium aspiration syndrome, ventilation after birth, or nerve injury. However, there was a significant difference in perinatal death alone.
- The elective induction group babies were less likely to be admitted to intensive care (4% versus 5.9%), they had fewer cases of jaundice (1.2% versus 2.3%), and fewer of them were big babies (4.9% versus 8.3%).

#### For mothers:

- There was no significant/meaningful difference in Cesarean rates (10-11% both groups).
- More mothers in the elective induction group had inflammation of the inner lining of the uterus usually due to infection, called endometritis (1.3% versus 0.4%).
- More mothers in the expectant management group developed high blood pressure disorders at the end of pregnancy (3% versus 1.4%).
- There were no cases of uterine rupture in either group.
- Qualitative data found that people in the expectant management group struggled with negative thoughts, and they described feeling in "limbo" while they waited for either labor or a 42-week induction.

As we mentioned, fetal monitoring in this study was done per local guidelines. In other words, there was no study protocol for fetal monitoring during the 41st week of pregnancy. The mothers recruited in the Stockholm region (about half the people in the study) had ultrasound measurement of amniotic fluid volume and abdominal diameter at 41 weeks, whereas such assessments were not regularly performed at the other centers. Importantly, none of the six deaths occurred in the Stockholm region of Sweden, where this type of fetal monitoring was performed. This means that the results of the SWEPIS study may not apply equally to mothers who receive fetal monitoring at the end of pregnancy. Also, since all of the perinatal deaths occurred to first-time mothers, the study results may not apply equally to experienced mothers.

## 2018 Cochrane meta-analysis on elective induction versus waiting for labor

In a 2018 Cochrane review and meta-analysis, researchers compared people who were electively induced to those who waited for labor to start on its own (<u>Middleton et al., 2018</u>). They included 30 randomized, controlled trials (over 12,000 mothers) comparing a policy of induction at or beyond term

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versus expectant management. The trials took place in Norway, China, Thailand, the U.S., Austria, Turkey, Canada, the U. K., India, Tunisia, Finland, Spain, Sweden and the Netherlands.

Most of the data (about 75%) came from trials of induction that took place at 41 weeks or later. This meta-analysis came out too early to include the large ARRIVE trial of 39-week induction or the two large 2019 trials (INDEX and SWEPIS) on 41-week induction. The Hannah Post-Term trial, which we will describe in detail, was the largest trial included. The Cochrane authors considered the overall evidence to be moderate quality.

**What did they find?** A policy of induction was linked to 67% fewer perinatal deaths compared to expectant management (2 deaths versus 16). The Hannah Post-Term trial excluded deaths due to fetal malformations, but some of the smaller trials did not. If we exclude the three deaths from severe fetal malformations, then there was one death in the induction group and 14 deaths in the expectant management group. Overall, the number needed to treat was 426 people with induction to prevent 1 perinatal death. Specifically, there were fewer stillbirths with a policy of induction (1 stillbirth versus 10). The absolute risk of perinatal death was 3.2 deaths per 1,000 births with a policy of expectant management versus 0.4 deaths per 1,000 births with a policy of induction.

A policy of induction was also linked to slightly fewer Cesareans compared to expectant management (16.3% versus 18.4%).

Fewer babies assigned to induction had Apgar scores less than 7 at 5 minutes compared to those assigned to expectant management. There were no differences between groups in the rate of forceps/ vacuum birth, perineal trauma, excessive bleeding after birth, total length of maternal hospital stay, newborn intensive care admissions, or newborn trauma.

They were not able to find differences between timing of induction (<41 weeks versus ≥41 weeks) or by the state of the cervix for perinatal death, stillbirth, or Cesarean. The authors concluded that individualized counseling might help pregnant people choose between elective induction at or beyond term or continuing to wait for labor, and that providers must honor their values and preferences. We need more research to know who would or would not benefit from elective induction and the optimal time for induction is still not clear from the research.

## The famous Hannah "Post-Term" study

Before INDEX and SWEPIS were published, one of the most important studies that was done on inducing for post-dates is the Hannah et al. 1992 Post-Term study. This study was published in the New England Journal of Medicine.

Because it was such a large study, even larger than the recent INDEX and SWEPIS trials, the Hannah Post-Term study controls most of the findings in the Middleton et al. (2018) meta-analysis described above.

Between the years of 1985 to 1990, a group of researchers enrolled 3,407 low-risk pregnant people from six different hospitals in Canada into the Hannah Post-Term study.

Participants were included if they had a live, single fetus, and were excluded if they were already 3 or more centimeters dilated, had a previous Cesarean, had pre-labor rupture of membranes, or had a medical reason for induction. Unlike the INDEX and SWEPIS trials that induced everyone who had not given birth by 42 weeks and 0 to 1 days, the people assigned to expectant management in the

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Hannah Post-Term study were monitored as long as 44 weeks. The study took place in the six Canadian hospitals between the years 1985 and 1990.

At around 41 weeks, participants were randomly assigned to either induction of labor or fetal monitoring (expectant management).

In the induction group:

- Labor was induced within four days of entering the study (usually about 4 days after 41 weeks).
- If the cervix was not ripe (< 3 cm dilated and <50% effaced), and if the fetal heart rate was normal, participants were given prostaglandin E2 gel to ripen the cervix.
- A maximum of 3 doses of gel were given every 6 hours. If this did not induce labor or if the gel was not used, participants were given IV oxytocin, had their waters broken, or both. They could not receive oxytocin until at least 12 hours after the last prostaglandin gel dose.

In the monitored (expectant management) group:

- Participants were taught how to do kick counts every day and had nonstress tests 3 times per week.
- The amniotic fluid level was checked by ultrasound 2-3 times per week.
- Labor was induced if the nonstress test was nonreactive or showed decelerations, if there was low amniotic fluid (deepest pocket <3 cm), if complications developed, or if the mother did not go into labor on her own by 44 weeks.
- If doctors decided that the baby needed to be born, mothers did not receive cervical ripening instead, they either had their water broken and/or IV oxytocin, or had a Cesarean without labor.

#### What did researchers find in the Hannah Post-Term study?

In the induction group, 66% of people were induced, and 34% went into labor on their own before the induction. In the monitoring group, 33% were induced and 67% went into labor on their own.

There were two stillbirths in the group assigned to wait for labor and zero in the group assigned to induction, but this difference was not statistically significant. This means that we can't be sure if it happened by chance or was a true difference between groups.

The findings on Cesarean rates differ depending on which set of numbers you compare.

You can look at the outcomes for the two original groups—the people randomly assigned to induction and those assigned to fetal monitoring—or you can look at the breakdown of what actually happened to the people in the two groups. In other words, what happened to the people who were actually induced or actually went into spontaneous labor?

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#### What happened in the original, randomly assigned groups?

If you look at what happened in the two original groups (random assignment to elective induction and expectant management groups), the overall Cesarean rate was lower in the elective induction group (21.2% versus 24.5%), even after taking into account whether this was the mother's first baby, her age, and cervical dilation at the time of study entry.



There was also a lower rate of Cesareans for fetal distress in the elective induction group versus the expectant management group (5.7% versus 8.3%).

#### But what happened to people who were actually induced or actually went into labor on their own?

If instead of considering the results according to how participants were assigned—to the elective induction and or expectant management groups—you look at what actually happened to the people who were induced or who actually went into spontaneous labor, this is what you will see (Hannah et al., 1996):





So, we see two very interesting things here: people who went into spontaneous labor, regardless of which group they were originally assigned, had a Cesarean rate of only 25.7%. But if people in the expectant management group had an induction, their Cesarean rate was much higher than all of the other groups—42%!

The same pattern holds true when you look at experienced mothers (people who had given birth before):



#### So what do these numbers mean?

Important details from the Hannah Post-Term study are hidden when you only look at the results according to random group assignment. The reported main findings were that a policy of fetal monitoring and expectant management increases the Cesarean rate.

But a closer look at the findings reveals that only the people who were expectantly managed but then had an induction later in the pregnancy had a really high Cesarean rate. People who were expectantly managed and went into labor spontaneously did NOT have higher Cesarean rates.

One possible explanation for the high Cesarean rate seen in the people who were assigned to expectant management and then ended up getting an induction is that the people in this group may have been at higher risk for Cesarean to begin with, since a medical complication could have led to the induction. The people who were assigned to expectant management and never developed a complication requiring induction were the lower risk people, the ones less likely to give birth by Cesarean.

Another factor that could have contributed to the high Cesarean rate in this group is the issue that we discussed previously—that doctors might have been quicker to call for a Cesarean when assisting the labors of people with medical inductions who had longer pregnancies.

So, if someone is considering expectant management after 41 weeks, one of the benefits is that if they go into labor on their own, they will have a relatively low risk of Cesarean. But one of the risks is that longer pregnancies mean more opportunities for potential complications to show up and if an induction becomes necessary, the risk of a Cesarean with that induction is nearly doubled, from 25.7% to 42%.

## Policy of routine induction before 42 weeks is still controversial

The authors of a systematic review from 2019 raise concerns that routine induction prior to post-term puts a large number of pregnant people at risk of harmful side effects from induction (<u>Rydahl et al.,</u> <u>2019a</u>). This review came out too early to include the SWEPIS and INDEX trials.

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Unlike the Middleton et al. (2018) Cochrane review, these review authors applied stricter criteria to the studies they included. They restricted the studies to only those published within the last 20 years, with low-risk participants, and comparing routine induction at 41 weeks and 0 to 6 days versus routine induction at 42 weeks and 0 to 6 days. Altogether, they included three observational studies, two randomized controlled trials (RCTs), and two "quasi-experimental" studies (which means they compare groups in a way that isn't truly random).

Combining the two RCTs with the two quasi-experimental studies, there was one perinatal death in the 41-week induction group and six deaths in the 42-week induction group (a perinatal death rate of 0.4 versus 2.4 per 1,000). The finding was not statistically significant. These same studies showed no difference in Cesarean rates between groups; however, the authors did report that one observational study found an increase in the Cesarean rate with the 41-week induction group.

It remains to be seen whether the INDEX and SWEPIS trial results will lead to changes in national policy in the Netherlands and Sweden to recommend routine induction by 41 weeks instead of 42 weeks.

Back in 2011, Denmark changed its national policy from recommending induction at 42 weeks, 0 days, to 41 weeks, 3 to 5 days. A recently published study compared birth outcomes before the change in policy (2000-2010) versus after the change (2012-2016) (<u>Rydahl et al., 2019b</u>). The study looked back at all births in Denmark between 41 weeks, 3 days and 45 weeks, 0 days of pregnancy. Over 150,000 births were included in the dataset.

They didn't find any difference in stillbirths, perinatal death, or low Apgar scores comparing the period before versus after the policy change. Perinatal death was already declining before the policy change in 2011, and it continued the downward trend without an additional impact from the 2011 policy change. There was also no impact on the rate of Cesareans or the use of forceps/vacuum.

After the policy change in 2011, however, they did see a significant increase in labor inductions and uterine ruptures. During 2011, the rate of people induced at 41 weeks, 3 days jumped from 41% to 65% and the rate of uterine rupture went from 2.6 to 4.2 per 1,000. The majority of uterine ruptures (73%) occurred among mothers with a previous Cesarean. Unfortunately, we can't tell from this study whether the uterine ruptures are occurring among people with a prior Cesarean who are being induced—only that the rate of uterine rupture jumped up after the policy change, and that most occurred among mothers with a previous Cesarean.

The researchers expressed concern about the increase in harm without evidence of benefits from a policy of earlier induction. Why did the intervention fail to lower perinatal deaths in Denmark? It could be that the rate was already low in Denmark (and on a downward trend) so there was little opportunity to prevent additional deaths. It could also be that waiting until 41 weeks, 3 days to induce was a few days too late to make a difference. The SWEPIS and INDEX trials found that even a few days after 41 weeks made a significant difference in birth outcomes.

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## Induction at 41 weeks versus waiting for labor

Pros	Cons
<ul> <li>Lower risk of stillbirth, especially among those with risk factors for stillbirth such as being pregnant with your first baby. The absolute risk of stillbirth is (Muglu et al., 2019):</li> <li>4 out of 10,000 pregnancies at 39 weeks</li> <li>7 out of 10,000 pregnancies at 40 weeks</li> <li>17 out of 10,000 pregnancies at 41 weeks</li> <li>32 out of 10,000 pregnancies at 42 weeks</li> <li>Lower risk of baby receiving intensive care unit admission, having jaundice, or being a big baby</li> <li>Lower risk of Cesarean, may depend on practice setting and could be that risk only increases while waiting for labor if an induction becomes necessary for medical reasons</li> <li>Lower risk of a mother developing a high blood pressure disorder at the end of pregnancy</li> <li>Cognitive benefits for babies during a continued pregnancy appear to increase only until 40-41 weeks of pregnancy</li> <li>Convenience</li> </ul>	<ul> <li>Potential for medicalization of birth because of the induction (e.g., continuous fetal monitoring)</li> <li>Potential for failed induction leading to a Cesarean</li> <li>Potential uterine tachysystole (more than 5 contractions in 10 minutes, averaged over a 30-minute window)</li> <li>Potential increase in risk of uterine rupture with medical induction, especially among people with a previous Cesarean</li> <li>Miss the hormonal benefits of spontaneous labor</li> <li>Increased risk of mother getting inflammation of the inner lining of the uterus (endometritis)</li> <li>Medically induced contractions may increase pain and make epidural-use more likely</li> </ul>

## What about people who are planning a VBAC?

Many people who are planning a vaginal birth after Cesarean (VBAC) are told they must go into labor by 39, 40, or 41 weeks or they will be required to have a repeat Cesarean or induction.

Research has shown that only about 10% of people who reach term will spontaneously give birth by 39 weeks (Smith, 2001; Jukic et al., 2013). So, if a hospital or physician mandates repeat Cesareans for people who have not gone into labor by 39 weeks, this means that 90% of people planning a VBAC with that hospital or physician will be disqualified from having a spontaneous VBAC. Also, some hospitals and providers will not provide inductions with VBACs, which means some people who reach the required deadline will only have one option– repeat Cesarean.

There is actually no evidence supporting hard-stop "must-give-birth-by-39-weeks" or "give-birth-by-40-weeks" rules for people planning a VBAC.

In 2015, researchers looked at 12,676 people who were electively induced at 39 weeks for a VBAC, or had expectant management for a VBAC (Palatnik & Grobman, 2015).

Elective induction at 39 weeks was associated with a higher chance of VBAC compared to expectant management (73.8% versus 60-62%), but there was also a higher rate of uterine rupture in the elective induction group (1.4% versus 0.4-0.6%).

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For people who chose not to be induced, the risk of uterine rupture was fairly steady at 39 weeks (0.5% uterine rupture rate), to 40 weeks (0.6%), to 41 weeks (0.4%).

The first large meta-analysis to specifically look at the link between weeks of pregnancy and likelihood of VBAC was published in 2019 (<u>Wu et al., 2019</u>). It included 94 observational studies with nearly 240,000 people attempting labor for a VBAC. Interestingly, they found that gestational week at birth was not linked to having a VBAC— whether someone gave birth at 37 weeks, 39 weeks, or 41 weeks—it didn't make a difference to whether someone had a VBAC or a Cesarean birth after Cesarean.

## Are there any benefits to going past your due date?

One of the major benefits of going past your due date and awaiting the spontaneous start of labor is the hormonal benefit of experiencing spontaneous labor. In her book <u>Hormonal Physiology of Childbearing</u> (http://bit.ly/14NyRHE), Dr. Sarah Buckley reviewed the research on the hormonal benefits of spontaneous labor.

Based on the available evidence, Dr. Buckley concluded that:

"Overall, consistent and coherent evidence from physiologic understandings and human and animal studies finds that that the innate, hormonal physiology of mothers and babies—when promoted, supported, and protected—has significant benefits for both in childbearing, and likely into the future, by optimizing labor and birth, newborn transitions, breastfeeding, maternal adaptations, and maternalinfant attachment" (Executive Summary, page 9)

Another benefit of going past your due date and experiencing spontaneous labor is that you can avoid the potential risks of a medical induction, which may include experiencing a failed induction (possibly leading to a Cesarean), uterine tachysystole (uterine contractions that are too close together and may decrease blood flow to the baby), and adverse effects of other interventions that often occur with an induction, such as epidural anesthesia and continuous fetal monitoring (NICE Guidelines, 2008).

Although anecdotally it has been said that later term and post-term babies have an easier time with breastfeeding, we were not able to find any research on that subject.

There may be cognitive benefits for babies when the pregnancy continues to 40-41 weeks (<u>Murray et al.,</u> <u>2017</u>). A study of Scottish schoolchildren found that the need for special education was highest among children born before 37 weeks (preterm babies), and then there was a continuous decrease in the need for special education until a low point at 41 weeks, after which the risk quickly rose again (<u>MacKay et al.,</u> <u>2010</u>).

## Is it safe for someone to wait for labor to begin on its own, if that is what they prefer? How long is it safe to wait?

When pregnant people go past their estimated due dates, it is appropriate for them and their care provider to discuss the benefits and risks of elective induction and expectant management.

Most research articles and guidelines say that because there are benefits and risks to both options, the pregnant person's values, goals, and preferences should play a part in the decision-making process.

It is important for expectant families to be aware of the growing research evidence showing worse health outcomes for those who wait for labor after 41 weeks of pregnancy instead of being induced at 41 weeks, especially among first-time mothers and those with additional risk factors for stillbirth.

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Ultimately, after receiving accurate, evidence-based information and guidance from their health care provider, pregnant people have the right to decide whether they prefer to induce labor, or wait for spontaneous labor with appropriate fetal monitoring.

## How should people and their care providers talk about the risk of stillbirth?

It can be difficult for health care providers and expectant parents to discuss the risk of stillbirth. Research on health care decision-making suggests that one of the best ways to frame the risk of stillbirth is to use the following techniques (Perneger & Agoritsas, 2011; Fagerlin et al., 2011).

- 1. Present risks in actual or "absolute" numbers (as opposed to relative risk)
- 2. Talk about both potential gains and losses
- 3. Offer a visual if possible
- 4. Focus on the absolute difference between two risks

So, in a real life situation, this might look like:

"At 41 weeks, out of 10,000 pregnant people, about 17 will have a stillbirth. This means 9,983 won't have a stillbirth.

In comparison, at 42 weeks, out of 10,000 pregnant people, about 32 will have a stillbirth. This means 9,968 won't have a stillbirth. Here is a picture to help give you an idea of what this means.

So an extra 15 people out of 10,000 might avoid a stillbirth by being induced at 41 weeks. For the other 9,985 women, it won't make a difference."

Then circle/highlight the additional 15 to show the difference.

## What do the guidelines say?

- The Ontario Midwives Association has a really comprehensive, easy-to-understand set of guidelines. To download the free PDF, click <u>here</u> (https://bit.ly/2wx0gR8).
- To download the Society of Obstetricians and Gynaecologists of Canada guidelines (Canada), click <u>here</u> (https://bit.ly/32caL8k).
- In 2019, ACOG reaffirmed their 2014 <u>recommendations</u> (https://bit.ly/2P8H07P) on post-term pregnancy. ACOG recommends that induction of labor should take place between 42 weeks 0 days and 42 weeks 6 days, and that induction at 41 weeks can also be considered. If a person planning a VBAC goes post-term, this does not mean they have to have a repeat Cesarean.

Also, ACOG released new practice guidelines that address the ARRIVE trial findings (<u>ACOG/SMFM, 2018</u>). They concluded that it is reasonable to offer elective induction to low-risk, first-time mothers at 39 weeks of pregnancy. However, they urge care providers to first consider three important factors: the values and preferences of the pregnant woman, the staffing and facility resources available (to assist longer labors), and the protocol for "failed" induction. Specifically, as long as there are no complications, early labor can last 24 hours or more and oxytocin can be given for 12 to 18 hours after breaking the mother's water before the induction is considered a failure.

• The American College of Nurse-Midwives (ACNM) also released a press statement in response to the ARRIVE trial saying that they continue to promote normal healthy physiologic birth and a woman's right to make decisions during pregnancy (<u>ACNM, 2018</u>). They expressed concern that many women may not desire elective induction and proposed that costs might be better spent on less invasive but more effective approaches to reduce Cesarean rates, such as continuous labor support from a doula.

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## What's the bottom line on elective induction versus waiting for labor?

- Current research evidence has found that elective induction at 39 weeks does not make a difference in the rate of death or serious complications for babies. For mothers, induction at 39-weeks was linked to a small decrease in the rate of Cesarean compared to those assigned to wait for labor (19% Cesarean rate versus 22%).
  - o We have heard from people who are surprised at this finding, since for so long elective induction was thought to increase the Cesarean rate. It's largely a matter of the new research using the appropriate comparison group for elective induction (now including medical inductions in the expectant management group). It would be interesting to see secondary analyses published on who *actually* was induced versus who *actually* had spontaneous labor for every study (like we saw with the Hannah Post-Term trial). But from a decision-making perspective, it is most helpful to consider the results according to original group assignment (active versus expectant management), since spontaneous labor is not a guarantee with expectant management.
  - o It's important to keep in mind that there are plenty of alternatives for people or facilities seeking lower risks of Cesarean that don't involve elective inductions.
- Elective induction at 41 weeks and 0 to 2 days could help to reduce stillbirths and poor health outcomes for babies, especially among first-time mothers.
  - Importantly, two large randomized, controlled trials published in 2019 both found benefits to elective induction at 41 weeks instead of continuing to wait for labor until 42 weeks. One of the studies found fewer perinatal deaths with 41-week induction and the other found fewer poor health outcomes for babies (e.g., intensive care unit admission, low Apgar scores) with 41-week induction.
  - Neither trial found an increase in the risk of Cesarean or forceps/vacuum during birth with 41-week induction compared to continuing to wait for labor until 42 weeks. Both of these trials took place in countries that follow the Midwifery Model of Care, and the overall Cesarean rates were low (only 10-11%).
  - o An earlier study called the Hannah Post-Term study found that waiting for labor after 41 weeks greatly increased the risk of Cesarean for people who ended up needing an induction for medical reasons, but not for people who went into labor on their own.
- People can talk with their care providers about the pros and cons of waiting for spontaneous labor or elective induction at 39 weeks and 41-42 weeks (see Pros/Cons lists above). This conversation should take into account the mother's preferences, personal birth history, risk factors for stillbirth, chances of a successful induction (how "ripe" the cervix is, also known as the Bishop score"), the facility's Cesarean rate with induction, and alternatives.
  - The <u>Bishop score</u> (https://bit.ly/2V4aYbQ) that helps to determine if you are a good candidate for induction is based on five factors:
    - 1. How dilated (or open) is your cervix?
    - 2. How effaced (or thin) is your cervix?
    - 3. How soft is your cervix?
    - 4. How far forward is your cervix?
    - 5. How far down the birth canal is your baby's head?
- None of the research evidence looked closely at birthing people's experiences or preferences. These non-medical factors are very real when it comes to individual decision-making. For example, the experience of being induced (potentially more painful contractions, tethered to wires for monitoring and IV fluids, confined to bed) may not make much of a difference to someone planning

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a birth with an epidural, but it can make a huge difference to someone planning to use movement and other comfort measures during an unmedicated birth. On the other hand, someone who has experienced miscarriages or stillbirth in the past may have a strong preference for elective induction in order to lower the absolute risk of stillbirth by any means necessary. **All of these experiences and preferences are valid.** 

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#### **References**

- Alfirevic, Z., Devane, D., Gyte, G. M., et al. (2017).
   "Continuous cardiotocography (CTG) as a form of electronic fetal monitoring (EFM) for fetal assessment during labour." Cochrane Database Syst Rev 2: CD006066.
- American College of Nurse Midwives (2018). ACNM Responds to Release of ARRIVE Trial Study Results: Acknowledges Quality of Study but Raises Concerns about Potential for Misapplying Results. Accessed online December 1, 2019.
- American College of Obstetricians and Gynecologists (2014, Reaffirmed 2019). Committee opinion no. 146: Management of Late-Term and Post-Term Pregnancies. Obstet Gynecol 124, 390-396.
- American College of Obstetricians and Gynecologists/ Society for Maternal-Fetal Medicine (2018). Practice Advisory: Clinical guidance for integration of the findings of The ARRIVE Trial: Labor Induction versus Expectant Management in Low-Risk Nulliparous Women. Accessed online December 1, 2019.
- <u>Attanasio, L. and Kozhimannil, K. B. (2018</u>). Relationship Between Hospital-Level Percentage of Midwife-Attended Births and Obstetric Procedure Utilization. J Midwifery Womens Health. 63(1):14-22
- <u>Bohren, M. A., Hofmeyr, G. J., Sakala, C., et al. (2017)</u>. Continuous support for women during childbirth. Cochrane Database of Systematic Reviews, Issue 7. Art. No.: CD003766.
- Buckley, S. J. (2015). Hormonal Physiology of Childbearing: Evidence and Implications for Women, Babies, and Maternity Care. Washington, D.C.: Childbirth Connection Programs, National Partnership for Women & Families, January 2015.
- 8. <u>Carmichael, S. and Snowden, J. M. (2019</u>). The ARRIVE Trial: Interpretation from an Epidemiologic Perspective. J Midwifery Womens Health, 64(5):657-663.

- <u>Cheyney, M., Bovbjerg, M., Everson, M. A., et al. (2014)</u>.
   "Outcomes of care for 16,924 planned home births in the United States: the Midwives Alliance of North America Statistics Project, 2004 to 2009." J Midwifery Womens Health 59(1): 17-27.
- <u>Darney, B. G., Snowden, J. M., Cheng, Y. W., et al. (2013)</u>. Elective induction of labor at term compared with expectant management: maternal and neonatal outcomes. Obstet Gynecol, 122(4), 761-9.
- 11. <u>Declercq, E. R., Sakala, C., Corry, M. P., et al. (2013)</u>. Listening to MothersSM III: Pregnancy and Birth. New York: Childbirth Connection.
- Fagerlin, A., Zikmund-Fisher, B. J., & Ubel, P. A. (2011). Helping patients decide: Ten steps to better risk communication. J Natl Cancer Inst 103(19): 1436-1443.
- Grobman, W. A., Rice, M. M., Reddy, U. M., et al. (2018). Labor induction versus expectant management in low-risk nulliparous women. N Engl J Med;379:513-23.
- Keulen, J. K., Bruinsma, A., Kortekaas, J. C., et al. (2019). Induction of labour at 41 weeks versus expectant management until 42 weeks (INDEX): multicentre, randomised non-inferiority trial. BMJ, 364, I344.
- 15. <u>Little, S. E. (2017</u>). Elective Induction of Labor: What is the Impact? Obstet Gynecol Clin N Am 44; 601–614
- MacKay, D. F., Gordon, C. S., Dobbie, R., et al. (2010). Getsational Age at Delivery and Special Education Need: Retrospective Cohort Study of 407,503 Schoolchildren. PLoS Med 7(6), e1000289.
- 17. <u>Main, E. and the CMQCC Leadership Team (2018)</u>. California Maternal Quality Care Collaborative: Comments on the Arrive Trial.
- Marrs, C., La Rosa, M., Caughey, A., et al. (2019). Elective Induction at 39 Weeks of Gestation and the Implications of a Large, Multicenter, Randomized Controlled Trial. Obstet Gynecol. 133(3), 445–450.

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- Martin, J. A., Hamilton, B. E., Osterman, M. H. S., et al. (2019). Births: Final Data for 2018. National Vital Statistics Reports. Vol. 68 No. 13.
- Middleton, P., Shepherd, E. and Crowther, C. A. (2018). Induction of labour for improving birth outcomes for women at or beyond term. Cochrane Database of Systematic Reviews, Issue 5. Art. No.: CD004945
- Miller, N. R., Cypher, R. L., Foglia, L. M., et al. (2015). Elective Induction of Labor Compared With Expectant Management of Nulliparous Women at 39 Weeks of Gestation: A Randomized Controlled Trial. Obstet and Gynec. Vol. 126, No. 6: 1258-64.
- Muglu, J., Rather, H., Arroyo-Manzano, D., et al. (2019). Risks of stillbirth and neonatal death with advancing gestation at term: A systematic review and meta-analysis of cohort studies of 15 million pregnancies. PLoS Med 16(7), e1002838.
- Murray, S. R., Shenkin, S. D., McIntosh, K., et al. (2017). Long term cognitive outcomes of early term (37-38 weeks) and late preterm (34-36 weeks) births: A systematic review. Wellcome open research, 2, 101.
- Palatnik, A. and Grobman, W. A. (2015). Induction of labor versus expectant management for women with a prior cesarean delivery. Am J Obstet Gynecol 212(3): 358 e351-356.
- Perneger, T. V. & Agoritsas, T. (2011). Doctors and patients' susceptibility to framing bias: a randomized trial. J Gen Intern Med 26(12): 1411-1417.
- <u>Rydahl, E., Eriksen, L. and Juhl, M. (2019a</u>). Effects of induction of labor prior to post-term in low-risk pregnancies: a systematic review. JBI database of systematic reviews and implementation reports, 17(2), 170–208.

- 27. <u>Rydahl, E., Declercq, E., Juhl, M., et al. (2019b</u>). Routine induction in late-term pregnancies: follow-up of a Danish induction of labour paradigm. BMJ Open, 9, e032815.
- Smith, G. C. (2001). Use of time to event analysis to estimate the normal duration of human pregnancy. Hum Reprod 16(7): 1497-1500.
- Stapleton, S. R., Osborne, C., and Illuzzi, J. (2013).
   Outcomes of care in birth centers: demonstration of a durable model. J Midwifery Womens Health, 58(1): 3-14.
- Walker, K. F., Bugg, G. J., Macpherson, M., et al. (2016). Randomized Trial of Labor Induction in Women 35 Years of Age or Older. N Engl J Med 374;9: 813-22.
- Wennerholm, U. B., Saltvedt, S., Wessberg, A., et al. (2019). Induction of labour at 41 weeks versus expectant management and induction of labour at 42 weeks (SWEdish Post-term Induction Study, SWEPIS): multicentre, open label, randomised, superiority trial. BMJ, 367, 16131.
- Wood, S., Cooper, S., et al. (2014). Does induction of labour increase the risk of caesarean section? A systematic review and meta-analysis of trials in women with intact membranes. BJOG 121(6): 674-685; discussion 685.
- <u>Wu, Y., Kataria, Y., Wang, Z., et al. (2019)</u>. Factors associated with successful vaginal birth after a cesarean section: a systematic review and meta-analysis. BMC Pregnancy Childbirth, 19(1), 360.
- Yeast, J. D., et al. (1999). Induction of labor and the relationship to cesarean delivery: A review of 7001 consecutive inductions. Am J Obstet Gynecol 180:628-33.

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## Table 1. Retrospective studies of elective induction at 39 weeks versus expectant management

Darney et al. (2013)	<ul> <li>Retro study of linked hospital- vital stats data in CA, 2006 (n=362,154).</li> <li>Included everyone without a prior CS and compared eIOL at each term GA (37-40 wks) with EM.</li> </ul>	<ul> <li>Odds of CS lower with eIOL across all GA and parity.</li> <li>Nullips at 39 weeks' (n=2,186 eIOL, 74,115 EM). CS rate was 23% with eIOL and 28% with EM. Respectively, 0% vs. 0.2% perinatal mortality, 4.2% vs. 6.3% NICU admissions, 1% vs. 1.7% respiratory distress, 8% vs. 11% macrosomia. No difference: jaundice, forceps/vacuum, 3rd/4th degree tears.</li> </ul>
Gibson et al. (2014)	<ul> <li>Retro study using Consortium of Safe Labor data (19 U.S. hospitals, 2002-2008, n= 131, 243).</li> <li>Included low-risk women and compared eIOL with EM at 37- 41 weeks'.</li> </ul>	<ul> <li>Risk of CS was lower at each week of GA with eIOL vs. EM regardless of parity and Bishop score. Unfavorable nullips at 39 weeks = 24% vs. 39% CS. Also less maternal infection and better newborn 'composite' outcome with eIOL regardless of parity or cervical status.</li> <li>No difference in perinatal mortality with Consortium of Safe Labor study data.</li> </ul>
Lee et al. (2016)	<ul> <li>Retro study of term, singleton, vertex births among obese women (BMI 30+) in CA in 2007 (n=74,725)</li> <li>Linked hospital-vital statistics data</li> </ul>	<ul> <li>Odds of CS were lower with eIOL vs. EM at 39 weeks' for nullips (30% vs. 35%) and for multips with a prior vaginal birth (5% vs. 9%). Less chorio for nullips at 39 weeks' with eIOL. Less macrosomia with eIOL for nullips and multips at 39 weeks.</li> <li>No difference in forceps/ vacuum, brachial plexus injury, respiratory distress syndrome, or severe tears.</li> <li>No data on perinatal mortality</li> </ul>

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Gibson et al. (2016)	<ul> <li>Retro study that looked at the weekly risk of developing a hypertensive disorder among low-risk term pregnancies with EM</li> <li>Used Safe Labor Consortium data, 2002 – 2008 (n=114, 651). Excluded people with a history of hypertension, Type 2 diabetes, CVD, planned CS</li> <li>In each week, compared people who had eIOL with those who had EM</li> </ul>	<ul> <li>The risk of developing a hypertensive disorder (with associated mother/baby morbidity) goes up with each additional week of pregnancy.</li> <li>Risk of CS lower at 39 weeks' with eIOL</li> </ul>
Knight et al. (2017)	<ul> <li>Retro study that included nullips aged <b>35 and over</b> who gave birth in NHS hospitals in England, 2009-2014 (n=77,327)</li> <li>They excluded people with hypertension, diabetes, cardiac and lung disease)</li> </ul>	<ul> <li>No difference in CS or forceps/ vacuum between groups at 39 weeks'</li> <li>Found that IOL at 40 weeks was linked to less perinatal death (0.08% vs. 0.26%). 562 IOL at 40 weeks to prevent 1 perinatal death. However, they found no difference in perinatal death between groups at 39 weeks'.</li> </ul>

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