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A project to improve shared decision-making regarding the timing of induction of labor for people with healthy pregnancies at or beyond 39 weeks

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Dissertation

**A PROJECT TO IMPROVE SHARED DECISION-MAKING REGARDING THE
TIMING OF INDUCTION OF LABOR FOR PEOPLE WITH HEALTHY
PREGNANCIES AT OR BEYOND 39 WEEKS**

by

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Submitted in partial fulfillment of the
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“Women don’t need to find a voice. They have a voice, and they need to feel empowered to use it, and people need to be encouraged to listen.” – Meghan Markle

DEDICATION

I would like to dedicate this work to all the pregnant people all over the country and world who face this choice and the prenatal and birth care providers who partner with them to bring their babies into the world safely and with respect to their needs and desires. I would also like to dedicate this to my incredibly supportive partner and husband, Alec, my two “late” babies who were the inspiration and motivation for this topic in particular, Frida and Matías. Finally, I also dedicate this to my parents, Betsey and Richard Church, who taught me how to ask questions, seek more information, and communicate what I need and want clearly with others.

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I also want to thank my family, friends, classmates, and colleagues who are too numerous to name for all of their moral support and encouragement over these many years. I specifically want to thank my husband, Alec Peralta, and my children, Frida and Matías Peralta, for all of their patience and flexibility and understanding and support. I could not have done this without you.

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ABSTRACT

Background: Medical professional organizations in the U.S. recommend shared decision-making for routine labor induction in healthy term pregnancies. Shared decision-making is part of high quality, person-centered care and has substantial positive impacts. Despite these recommendations for, and impacts of, shared decision-making many people, especially people of color and those who are Medicaid-insured, do not experience shared decision-making concerning induction and according to a 2020 scoping review there are no patient decision aids on this topic.

Methods: We used quality improvement and qualitative methods to develop, test, and refine a patient decision aid on labor induction in healthy pregnancies at or beyond 39 weeks to support shared decision-making. We assessed shared decision-making primarily with these outcomes: patients' understanding of choices, pros and cons of choices, and their role as primary decision-maker. A quality improvement team developed an initial prototype and used Plan-Do-Study-Act cycles to get patient and

provider feedback. The decision aid was tested in three languages by providers across obstetrics, family medicine, and midwifery at a tertiary hospital and two community health centers in Boston, MA between September 2020 and December 2021.

Results: Shared decision-making on labor induction in healthy pregnancies was achieved. Across three Plan-Do-Study-Act cycles 24 pregnant people were interviewed. Most were people of color and Medicaid-insured. Many were recent immigrants and/or non-Native English speakers. Nearly all interviewees experienced shared decision making: 23/24 understood their role as the decision-maker. The majority could name two or three choices they had and pros and cons of different choices. Many described the process as empowering and positive. Nine medical providers tested the decision aid and gave feedback. Providers said using the tool helped improve the consistency and content of their counseling and reduce the role of bias.

Conclusion: A balanced, evidence-based decision aid can support patients and providers in achieving shared decision-making on induction. Quality improvement and qualitative methods were shown effective for decision aid development and can be applied to other topics within and beyond maternity care. Decision aids may be a meaningful part of efforts to improve equity when development, testing, and evaluation centers people with marginalized identities.

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LIST OF ABBREVIATIONS

ACNM	American College of Nurse Midwives
ACOG	American College of Obstetricians and Gynecologists
BUMC	Boston University Medical Campus
IPDAS.....	International Patient Decision Aid Standards
IRB	Internal Review Board
LTM II.....	Listening to Mothers II
LTMC	Listening to Mothers California
PDSA.....	Plan-Do-Study-Act
QI.....	Quality Improvement
WHO.....	World Health Organization

CHAPTER ONE: BACKGROUND

Overview

While many pregnancies culminate in spontaneous labor, and deliveries proceed without medical interventions, induction has become a common intervention in the United States (U.S.)^{1,2} and around the world. Approximately 646,000 pregnant people in the U.S. have a medical induction of labor each year with gestational length as the primary indication.^{3,4} Many researchers and clinicians hold differing viewpoints of when gestational age indicated induction should be done. However, most agree that appropriate counseling and shared decision-making should be practiced to support pregnant people in making decisions about induction.⁵⁻¹³ It is clear from national surveys that many pregnant people are not experiencing shared decision-making regarding labor induction.^{3,14} In maternity care, people of color and those who are Medicaid-insured are least likely to experience shared decision-making.^{15,16}

Decision aids are a common tool used to support efforts to implement shared decision-making¹⁷ but there are no up-to-date decision aids on induction for gestation age that meet international patient decision aid certification and quality criteria.¹⁸⁻²⁰ This project aimed to address this gap by adapting and updating a previously created decision aid on induction in prolonged pregnancy for use in all pregnancies at or beyond 39 weeks.

Induction of Labor in the U.S. for Gestational Timing Alone – Practice, Policy, and Evidence

The overall rate of medical labor induction has more than doubled since 1990¹ and was part of one in three (31.4%) births overall and 37.1 % of vaginal births in the U.S. in 2020.⁴ Data from Listening to Mothers in California (LTMC)ⁱ show that length of pregnancy is the most common indication (57% of respondents whose labors were induced)³ and suggest that each year approximately 646,000 people’s labors in the U.S. are primarily induced because they are at or beyond 39 weeks.ⁱⁱ

The American College of Obstetricians and Gynecologists’ (ACOG) guidelines state that induction “can be considered” at 41 weeks (beginning at week 41 and 0 days) and “is recommended” at 42 weeks (beginning at week 42 and 0 days) and that shared decision-making should be used in all cases.¹¹ The World Health Organization (WHO) recommends induction at 41 weeks and 0 days¹² and the American College of Nurse Midwives (ACNM) recommends induction by 42 weeks and 0 days with shared decision-making.¹³ However, data from LTMC show that national guidelines regarding the timing of induction based on gestation age are not being followed. For example, a third (35%) of respondents named being close to their due date as the reason for induction and the average gestational age of those pregnancies was 39 weeks 4 days. Another fifth (22%) said their provider was worried they were overdue; the average gestational age of those

ⁱListening to Mothers in California is a statewide, population-based survey, in English and Spanish, of the experiences, outcomes and views of 2,539 women who gave birth in California hospitals in 2016.

ⁱⁱThis number was calculated by taking the number of births with induction of labor (1,133,627)⁴ and then 57% of that number.³

pregnancies was 40 weeks 3 days.³

The ACOG guidelines are reflective of the current state of the evidence. The most recent Cochrane systematic review suggests that, compared with a policy of expectant managementⁱⁱⁱ, a policy of labor induction sometime between 39 and 42 weeks can result in reduced perinatal death, but that the absolute risk of perinatal death is small. The authors of the Cochrane review concluded that there is no clear optimal timing for induction once a pregnancy has reached 37 weeks. The review found a statistically significant reduction (a relative risk of 0.31) in perinatal death (all causes) and “probably” fewer cesarean sections (a relative risk of 0.90) with policies of induction.⁸

While the most recent Cochrane review is considered the best evidence we have on this topic, other researchers have critiqued its findings. For example, one limitation of the results is that over a third of the included studies were published prior to 1990, including some published in 1969 and 1975.⁸ Some studies in the meta-analysis include neonatal deaths related to congenital anomalies within their neonatal death counts, which are not associated with gestational age or induction. The largest and most dominant study within the meta-analysis was published in 1992 (with data from 1985–1990) with the expectant management group waiting until 44 weeks for induction, well outside of current practice in most countries.^{21,22} Additionally, the authors of the Cochrane review did not use the most up-to-date meta-analysis method for rare events (the beta-binomial regression method)²³ which could mean that the effect of an induction policy on perinatal

ⁱⁱⁱ Expectant management refers to a policy of waiting for spontaneous labor, often but not always with fetal monitoring especially after 41 weeks.

death (including stillbirth) is overstated.

The Cochrane review summarizes all randomized controlled trials published prior to July 7, 2019.⁸ The most recent studies included were four published in 2018 and 2019. The INDEX-study, a multicenter, randomized non-inferiority trial with 1,801 women in 123 midwife practices and 45 hospitals in the Netherlands, found a 1.4% difference in risk of adverse perinatal outcomes that favored induction at 41 weeks versus expectant management until 42 weeks. The absolute risk of severe adverse outcomes was low in both groups: perinatal mortality 0.1% vs. 0.2%, NICU admission 0.3% vs. 0.9%, and Apgar score <4 at five minutes 0% vs. 0.3%).²⁴ The ARRIVE trial, a multicenter, randomized controlled trial of 6,106 women found that induction of labor at 39 weeks and 0–4 days (versus expectant management) did not result in a lower frequency of a composite adverse perinatal outcome. However, it did result in a lower frequency of cesarean delivery and noted lower rates of gestational hypertension and preeclampsia as well as reduced need for neonatal respiratory support within the first 72 hours of life.⁹ The SWEdish Post-term Induction Study (SWEPIIS), a multicenter, open label, randomized, superiority trial of 2,760 women found that induction of labor at 41 weeks (compared with expectant management until 42 weeks) reduced perinatal mortality without increasing maternal outcomes like cesarean delivery and epidural anesthesia.²⁵ The final study specifically focused on pregnant people at or beyond 39 weeks with prolonged latent phase of labor in Malaysia. Patients whose labors were induced had the same rate of cesarean delivery as those who waited. There were no deaths reported in either arm of this study.²⁶

After the publication of the ARRIVE trial, a debate ensued regarding the study's application to practice. Some providers and researchers critiqued the study design and findings and suggested caution in adjusting practice based on its results. They noted threats to internal and external validity based on selection bias and the characteristics of the women and the facilities in the study.^{27,28} The authors of the ARRIVE trial published a meta-analysis that supported their findings.²⁹ Other researchers and providers supported the ARRIVE trial's findings and adoption, stating that all low-risk women should now be counselled on the safety of elective induction and its effect on reducing the rate of cesarean section rates when done at 39 weeks.³⁰ ACOG's practice advisory on clinical guidance for integration of the findings of the ARRIVE trial states that it is "reasonable for obstetricians and health-care facilities to offer elective induction of labor to low-risk nulliparous women at 39 weeks' gestation," but that the recommendation should be "conditional upon the values and preferences of the pregnant woman" and be a "collaborative discussion with shared decision-making."³¹

In addition to randomized controlled trials, a number of other studies with rigorous designs have been conducted to assess the impact of policies regarding the timing of routine induction in pregnancies on maternal and neonatal outcomes in low-risk singleton pregnancies at or beyond 39 weeks. Notably, three large studies have examined the effects of a policy change on country level outcomes, examining outcomes before and after a policy change. A study from Australia found no statistically significant differences between a policy of 41 weeks versus 42 weeks for induction on neonatal mortality, cesarean section rate, assisted vaginal deliveries, and admission to the NICU.³¹

A study that examined the policy in Denmark found that a countrywide policy of 41 weeks and 2–5 days vs. a policy of 42 weeks doubled the induction rate but did not change perinatal morbidity or instrumental delivery rates.³² A 2006 study from Hong Kong comparing a policy of 41 weeks versus 42 weeks found that duration of labor and intrapartum epidural analgesia increased with an earlier induction policy, but found no significant differences regarding mode of delivery, Apgar scores, or stillbirths.³³ Another, much smaller study (n=410) from Vienna compared women who reached 41 weeks and 3 days' gestation between January 2002 and April 2004 who were scheduled for induction of labor with vaginal prostaglandins compared with age- and parity-matched women with spontaneous onset of labor beyond term. In that study induction was associated with higher use of epidural analgesia, cesarean delivery, and vacuum extraction.³⁴

Conflicting results from studies on the optimal timing of labor induction along with many systematic reviews of the literature and meta-analyses have led to disagreement on the ideal timing for induction.^{6–8,22} The conflicts are further complicated by the many variables that might possibly affect the risks like maternal age or parity.^{35,36} Given the disagreement, conflicting results, and complexity, researchers and clinicians have concluded that providers should discuss options and pros and cons with pregnant people.^{8–10} The 2018 Cochrane review, for example, suggested that women should be offered “appropriate counseling to help choose between scheduled induction for a post-term pregnancy or monitoring without (or later) induction.”³⁷

Some countries have this type of counseling written into their guidelines. For

example, the French College of Obstetricians and Gynecologists' guidelines state that "in the absence of a specific disorder, induction of labor can be proposed in patients between 41+0 and 42+6 weeks," and note that the choice to prolong pregnancy "above 42+0 weeks appears to involve an increase in fetal risk, which must be explained to the patient and balanced against the potential disadvantages of induction."³⁸ The National Health Service guidelines in the United Kingdom state that at the 38 week prenatal visit pregnant people should be offered information about the risks associated with pregnancies that go beyond 42 weeks and their options (including membrane sweeping, induction of labor between 41 weeks and 42 weeks, and expectant management), as well as information about the process of, and risks associated with, induction, and alternative options if the person does not choose to have an induction, and what would happen if induction fails. The guidelines specifically state that healthcare professionals offering induction should allow the pregnant person time to discuss the information with their partner, encourage the person to seek out additional information, invite them to ask questions, and "support the [person] in whatever decision [they] make."³⁹

Induction is very common practice in the U.S. Researchers and providers disagree about the evidence on ideal timing for routine labor induction for healthy pregnancies at or beyond 39 weeks. ACOG, ACNM, and WHO guidelines suggest that induction should be recommended between 41 and 42 weeks and that shared decision-making should be used to counsel pregnant people. Data from LTMC suggest that many providers are recommending labor induction for gestational timing in weeks 39 and 40. There are no specific national guidelines in the U.S. regarding how counseling and shared

decision-making on induction for low risk pregnancies should be completed.

The Case for Shared Decision-Making for Labor Induction Solely for Gestational Timing

Shared decision-making is a helpful framework for considering how providers can “appropriately counsel” and support a patient’s decision of whether and when to induce labor when they have a healthy pregnancy at or beyond 39 weeks. Shared decision-making is defined as “a patient-centered [...] approach to the informed consent process that involves a discussion of the benefits and risks of available treatment options in the context of a patient’s priorities and values.”¹² Shared decision-making is most appropriate for decisions that require informed consent in which there are two or more reasonable medical options.⁴¹ The goal of shared decision-making is “high-quality decision-making by patients”^{42,43} which is defined by decisions that are both evidence-informed and values-congruent.⁴⁴ Shared decision-making is highly applicable to labor induction for gestational age due to the lack of medical certainty on precise optimal gestational timing and how strong a pregnant person’s values and preferences might be about whether and when to induce labor.

There is clear evidence that shared decision-making regarding whether and when to induce labor for a person with a healthy pregnancy at or beyond 39 weeks is not happening. Data from the Listening to Mothers III (LTMIII)^{iv} national survey show that

^{iv} Listening to Mothers III is a national quota sample of 2,400 English-speaking mothers aged 18–45 who gave birth in a U.S. hospital between July 1, 2011 and June 30, 2012.

one in five respondents felt that the final decision of whether to induce their labor or wait was neither made by them nor with them as a shared decision.⁴⁵ A substantial portion of mothers surveyed in LTMC described experiencing pressure from their provider to have their labor induced and that pressure increased with gestational age (10% felt pressure at 39 weeks, 17% at 40 weeks, 26% at 41 weeks, and 31% at 42 weeks.)³

Studies examining shared decision-making on similar topics (e.g., induction of labor with suspected macrosomia) suggest that women of color, women who have lower levels of education, and women who are publicly insured are significantly less likely to experience shared decision-making.^{15,16} This mirrors the more general finding of the 2019 National Healthcare Quality and Disparities Report of disparities between Black and White people who reported their providers only sometimes or never asked them to help make decisions when there was a choice between treatments. This disparity is worsening compared to prior years.⁴⁶

A recent systematic review of qualitative evidence regarding women's experiences and perceptions of induction of labor for healthy late or post-term pregnancy concluded that women with post-term pregnancies were less satisfied with their birth experiences and had significant unmet needs and expectations regarding labor induction.⁴⁷ A mixed methods study from 2013 found that women whose labors were induced were generally less satisfied with their care due to delays, staff shortages, neglect, pain, and anxiety about getting the induction started, the experience of it, and in relation to failed induction.⁴⁸ An online survey of women in Germany who gave birth at least once revealed that half of survey respondents had unmet needs for information and

decisional support regarding induction of labor. Most women wanted more information on induction, its indications, its alternatives, and more support with the decision process.⁴⁹ A recent qualitative study looked at pregnant women's views before and after induction regarding the conversation about induction and the information that was provided to the women. While a lack of informed decision-making came up in both sets of interviews, it was the top theme after the induction occurred. Women described not being told about risks associated with induction until after they arrived at the hospital for their induction, that they were not presented with information or options, and that induction was presented as a non-decision. Rather, it was simply something a provider told the women would happen. Even women who requested the induction of labor felt that they were unprepared for labor induction. A number of women were emotional and cried during the interviews as they described how little information they were given and how impossible it was for them to make a decision that was right for them without it.⁵⁰

The call to improve shared decision-making on the topic of induction for people with healthy pregnancies at or beyond 39 weeks includes a clear need for an evidence-based decision aid. Decision aids are widely viewed as helpful to supporting shared decision-making¹⁷ yet few have been made about labor induction and those that were are out of date. A 2015 review of decision aids and patient information about induction of labor in healthy pregnancies beyond term called for “the design of an evidence-based decision aid of good quality for late-term or post-term pregnancy.”¹⁹ The 2015 review found only two decision aids (that were in English or German) pertaining to labor induction for gestational age and only one decision aid from 2010 met “most” of the

International Patient Decision Aid Standards (IPDAS).^{19,51} A 2020 scoping review of prenatal care decision aids did not identify any focused on induction of labor.²⁰ This was in part because the 2010 decision aid was never updated and was no longer available for use in 2020.

IPDAS certification standards require a decision aid to show negative and positive features of options in equal detail, provide citations for included evidence, include a publication date and update policy, note levels of uncertainty regarding outcome probabilities, and provide information about the funding source for its development.⁵² The most recent IPDAS standards are included in Appendix 1. The 2010 decision aid, that met most IPDAS criteria was developed in Queensland, Australia by Dr. Rachel Thompson and called “Choosing how your labor will start.”⁵³

The absence of shared decision-making in prenatal care – and on labor induction for gestational age in particular – has a negative impact on pregnant people. A pregnant person’s involvement in decision-making is one of the biggest influencers of their satisfaction with their birth experiences.^{54,55} Involvement in decision-making increases their satisfaction with their provider and their birth overall^{56–59} as well as decreases depressive and post-traumatic stress symptoms after birth.⁶⁰ In addition, data from LTMIH and LTMC suggest that intervention rates are lower for those who do not perceive pressure for induction. They have lower rates of elective induction,^{3,61} epidural anesthesia in labor, and cesarean sections.³ This is reflective of the observational policy-related studies’ findings mentioned previously.^{31–34}

The evidence suggests shared decision-making should be applied to the topic of

labor induction for gestational timing alone. The development of an evidenced-based decision aid that meets IPDAS certification and quality criteria would support an effort to increase the number of pregnant people who experience shared decision-making on labor induction for gestational age. If shared decision-making is implemented it stands to have a positive effect on pregnant people, better meeting their need for information, and reducing negative experiences with their care.

This Project and its Contribution to the Field

This goal of this project was to address the gap in shared decision-making related to labor induction for gestational age and improve shared decision-making between prenatal care providers and pregnant people regarding induction of labor in healthy pregnancies at or beyond 39 weeks. To achieve that, the project aimed to adapt and update the 2010 decision aid and test implementation strategies to support its use. As part of the adaptation, the decision aid was broadened from one focused on post-term pregnancy (at or beyond 42 weeks) to include all healthy pregnancies at or beyond 39 weeks so that it would be applicable to more people facing the decision. It also reflected the newer evidence suggesting it is as reasonable a choice for someone to request an induction at 39 weeks as it is to decline one at 41 or 42 weeks.

Since pregnant people of color and those who have public insurance are the least likely to experience shared decision-making, I partnered with Boston Medical Center (BMC) and two of its affiliated community health centers for this project since their patient populations are primarily people of color who are Medicaid-insured.⁶²⁻⁶⁴ The

adapted version of this decision aid for use in all healthy pregnancies at or beyond 39 weeks is poised to make a significant contribution to the field of prenatal care and shared decision-making. Complementary implementation strategies further support the decision aid's use and understanding of how to implement shared decision-making on this topic.

A successful decision aid and set of implementation strategies have wide applicability and the potential to improve the quality of prenatal care for hundreds of thousands of pregnant people each year in the U.S. and around the world. At the project's conclusion, I created a guide to apply the process of improving shared decision-making on the topic of whether and when to induce labor for a person with a healthy term pregnancy to other settings since this is such a common decision in prenatal care.

The project's specific aims and deliverables were as follows:

Specific Aims:

- Adapt a patient decision aid for use in shared decision-making for induction of labor for people with healthy pregnancies at or beyond 39 weeks.
- Identify and test implementation strategies that support the use of the patient decision aid and shared decision-making for induction of labor for people with healthy pregnancies at or beyond 39 weeks.

Deliverables:

- An adapted patient decision aid for pregnant people and their prenatal care providers to use regarding induction of labor in healthy pregnancies at or beyond 39 weeks.
- A guide to application of the tool to other settings beyond pilot sites.

- A manuscript to submit to a peer review journal that summarizes the quality improvement process to adapt and refine the decision aid and identify and test implementation strategies to support its use in shared decision-making regarding induction.

CHAPTER TWO: METHODS

Overview

Quality improvement (QI) and qualitative methods were used to design and evaluate an evidence-based decision aid and complementary implementation strategies. Implementation science concepts provided an additional framework and strengthened the process. There were two main phases of the project. The first phase involved adapting and updating the 2010 decision aid, “Choosing how my labor will start” and expanding its scope to all healthy pregnancies at or beyond 39 weeks. It also involved determining initial implementation strategies for use of the decision aid. The second phase involved Plan-Do-Study-Act (PDSA) cycle testing to test and refine both the decision aid and its implementation.

At the outset, I formed a QI team. This involved recruiting and engaging four prenatal care providers across three main provider types (midwifery, obstetrics, and family medicine) at Boston Medical Center, a tertiary safety net hospital in Boston, Massachusetts. The QI team provided consistent leadership to the project and the providers on this team were key collaborators at all stages of the process.

Implementation Science & Quality Improvement Frameworks

Two models informed the methods and expected outcomes of this project: one from implementation science and the other from QI. The implementation science framework selected was the original Practical, Robust Implementation and Sustainability Model (PRISM).⁶⁵ This model (shown in Figure 1) fit the project well because it is informed by QI practice and equally considers the organizational and patient perspectives which are both critical in shared decision-making. It also considers the external environment (e.g., institutional policy, liability insurance) and the implementation and sustainability infrastructure (e.g., pre-existing and needed data systems, workflow processes, QI work) in which the tools are being implemented, both of which are highly relevant to this topic. PRISM bolstered the thoroughness with which the QI team examined different factors that would impact

the effectiveness of a given implementation strategy and its adoption and maintenance by other providers. Table 1 describes how PRISM concept-informed questions were posed to the QI team and informed patient interview guides.

Figure 1. PRISM Model

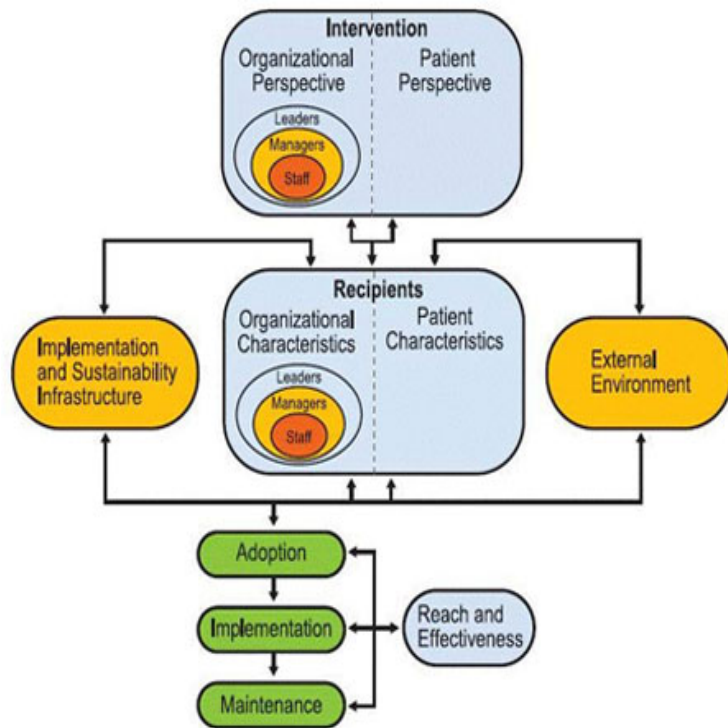


Table 1. How the Practical, Robust Implementation and Sustainability Model (PRISM) for Integrating Research Findings into Practice's Domains Inform the Project to Improve Shared Decision-making for Induction of Labor in People with Healthy Pregnancies

Table 1. How the Practical, Robust Implementation and Sustainability Model (PRISM) for Integrating Research Findings into Practice's Domains Inform the Project to Improve Shared Decision-making for Induction of Labor in People with Healthy Pregnancies	
PRISM Domain	Key Questions to Inform Implementation Strategy Identification and Testing
Organizational Perspective	Is the decision aid usable and modifiable without threatening essential elements of it? Will key BMC prenatal care providers and leaders be able to observe results (whether shared decision-making is happening, patient satisfaction)?
Patient Perspective	Does the decision aid address important barriers? Does it meet patient needs first and foremost? Does a patient understand when they have done well/what the goal is (i.e. the patient making an informed decision)?
Organizational Characteristics	What data gathering is possible within current systems? How can shared decision-making relate to meeting organizational expectations? What do staff see as perceived benefits of shared decision-making?
Characteristics of Patient Recipients	What characteristics of the patients (language, education level, culture) need to inform the tools? How do these hinder or help shared decision-making?
External Environment	How could environmental barriers to shared decision-making be addressed? How could facilitators be maximized?
Implementation and Sustainability Infrastructure	What are barriers and facilitators to adoption of the decision aid and implementation strategies? What is the process for dissemination of the decision aid to providers and pregnant people?

The QI framework used for this project was The Improvement Model⁶⁶ (Figure 2). This model focuses on three key questions: What are we trying to accomplish? How will we know that a change is an improvement? What change can we make that will result in improvement? The Improvement Model uses PDSA cycles as the mechanism for identifying and testing solutions. The Improvement Model guided the QI process to identify and test implementation strategies.

Figure 2. Improvement Model

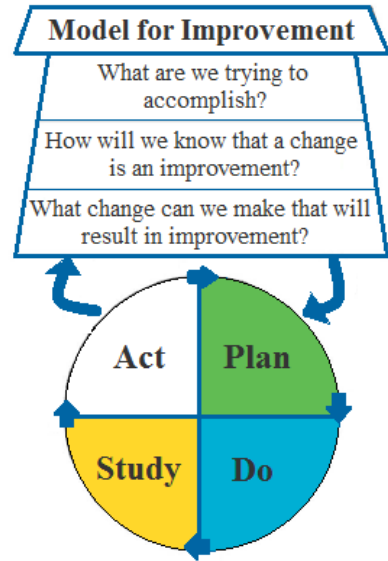
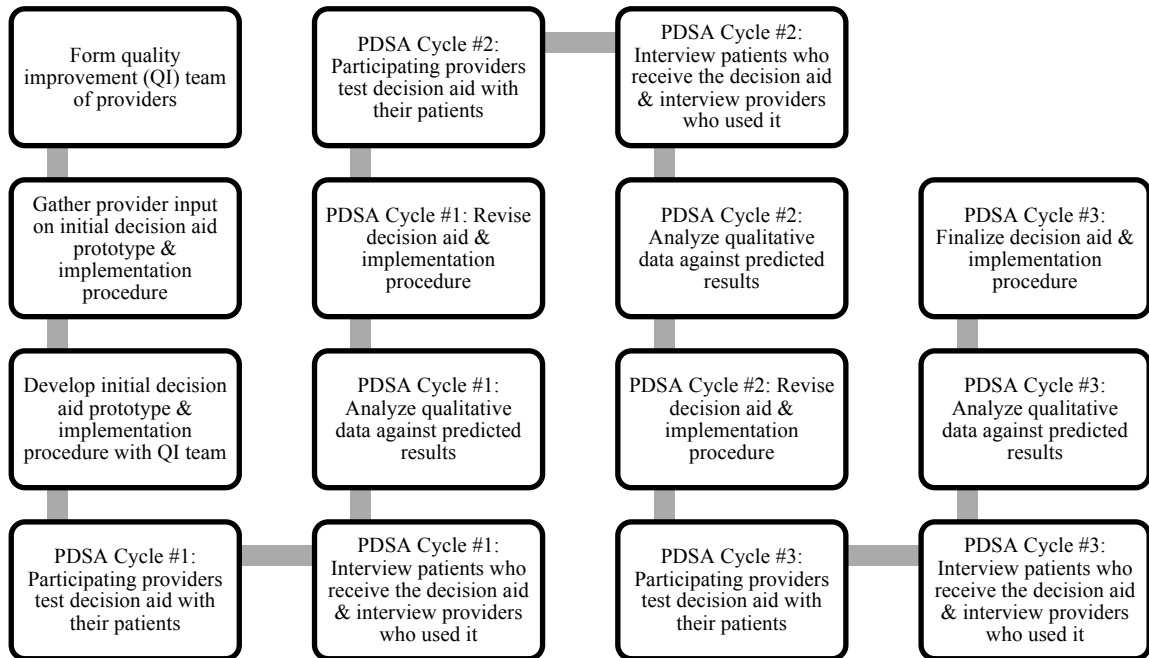


Figure 3 describes the main steps taken through the two phases of work from initial prototype development to PDSA cycle testing.

Figure 3. Plan-Do-Study-Act (PDSA) Cycle Testing Steps



Phase 1: Initial Prototype & Implementation Development

Prenatal care providers at the hospital were recruited to join the QI team.

Recruitment activities included attending pre-existing obstetrics team QI meetings and presenting the project at obstetrics, midwifery, and family medicine meetings.

Ultimately, four providers joined the QI team and were representative of the three primary types of prenatal care providers at the hospital (obstetrics, midwifery, and family medicine). The group first met to launch the team's work in early March 2020. Shortly thereafter, the COVID-19 pandemic hit Boston and the team meeting portion of the project was suspended until September 2020.

During the suspension of the project, I conducted a literature review and sought and received permission to revise the 2010 decision aid. I then updated the evidence within the aid with newer data from the July 2020 Cochrane review on the timing of induction of labor in healthy pregnancies at or beyond 37 weeks.⁸ I also added data about induction between 39 and 41 weeks that was not included in Dr. Thompson's decision aid and converted the relative risks reported in the Cochrane review to more patient friendly risk differences⁶⁷ using the GRADE system^v.^{68,69} As I drafted a starting prototype based on these changes, I checked for alignment with Boston Medical Center's guidelines on elective induction⁷⁰ and relevant patient education materials already in use.⁷¹

In September 2020 when meetings recommenced, I met with the QI team on a

^v The GRADE system is a method used to estimate a risk difference based on estimates of the baseline risk and the relative risk estimated from different sources. Since the risk difference was not reported in the Cochrane review, this technique was used to convert the relative risk to a risk difference so I could include absolute risks in the decision aid.

weekly basis to discuss the decision aid's content and formatting. Throughout the process we received feedback and perspectives on different drafts of the decision aid by taking them to regular obstetrician, midwife, and family medicine provider group meetings and meeting one-on-one with providers across provider types including nurse practitioners. The QI team made edits and changes based on feedback and at key points checked the decision aid against IPDAS certification and quality criteria⁵² and for a reading level of grade 6 or lower in alignment with other hospital patient education standards.

One change in the methods that came out of one-on-one provider input sessions was to translate the decision aid into Spanish and Haitian Creole during the pilot phase. Originally we had planned to first test it in English and then translate it into other languages, but many providers felt that this plan was inequitable and that using the tool in these other languages during the pilot phase would be crucial to the tool serving more pregnant people and relating to the hospital's goals of equitable care.

The aim for this phase of the project was a testable prototype of the decision aid. Once the decision aid had reached a place where all four providers on the QI team agreed that it was ready to be tested with providers, it was translated into Spanish and Haitian Creole and we entered the PDSA cycle phase of the project.

Phase 2: Plan-Do-Study-Act Cycles

While we finalized the first testable prototype and pursued translation, we began to use QI tools to identify implementation barriers, facilitators, and strategies for

implementation for our first PDSA cycle. Simultaneously, I went back to provider meetings to recruit additional providers to pilot the decision aid and to raise awareness that the pilot was about to begin. I also sought and received Boston University Medical Campus Internal Review Board (BUMC IRB) approval for patient interviews associated with the project including an approved recruitment and interview protocol. The protocol included video call or phone interviews as opposed to in-person interviews due to the ongoing COVID-19 pandemic and was approved in December 2020.

The QI tools used to set up the first PDSA cycle included process mapping, an analysis of barriers and solutions, and a prioritization matrix exercise to organize implementation strategies (see Appendix 2). First, the group completed process maps of the current and ideal states of how a provider and patient decide on if and when a patient will have labor induction to identify problems and their root causes, barriers, facilitators, and possible solutions. Next, the QI team assessed the ease and impact of each proposed solution and prioritized implementation strategies within a prioritization matrix according to their relative potential impact and ease. We then used the Institute for Healthcare Improvement's PDSA Worksheet to set up the PDSA cycles.⁷² Using this worksheet, we defined our aim and planned the first test of change (see Table 2). The QI team then revisited the worksheet at the end of each PDSA cycle to assess whether we met our goal, what we had learned, and what test of change we needed next. We repeated this process for every PDSA cycle.

Within this process we agreed to measure our progress on shared decision-making as follows:

- Patients will understand there is a choice to make
- Patients will be knowledgeable about pros and cons of each choice
- Patients will feel like the decision was one they made or they shared with their provider

These two outcomes were chosen because of their alignment with the definitions of shared decision-making noted in the Background chapter and to IPDAS decision aid certification and quality criteria^{51,52} (see Appendix 1). These two key aspects (knowledge of choices, pros and cons, and decision making role) also would address the biggest gaps in counseling related to poor patient experience as noted in Moore et al 2016, the qualitative review that interviewed pregnant women after induction counseling and then after birth that was noted in the Background section.⁷³ We operationalized these outcomes as follows:

- When asked what the pros and cons of different choices were, patients would name at least two different choices they had and name at least one pro or con about each choice.
- When asked whose decision they thought it was to have labor induction, patients would say it was theirs or a joint decision with their provider

In addition to achieving patient specific outcomes, we wanted to design a tool and process that was feasible and acceptable to providers. We agreed to operationalize provider acceptability to providers describing the decision aid as helpful to them practicing shared decision-making. (See Table 2 for more detail on how PDSA cycles were set up.)

Table 2. PDSA Cycle Set up

Table 2. PDSA Cycle Set up			
PDSA Cycle (Dates)	1 (April–June 2021)	2 (July–September 2021)	3 (October–December 2021)
Aim	Acquire qualitative data from at least six patients and from at least four providers who used the decision aid to understand its usefulness and effect on shared decision-making within an 8 week timeframe.		
Test of Change Protocol (italics denotes changes between cycles)	<p>A: Between the 37–40 week visit the provider:</p> <ul style="list-style-type: none"> Clarifies patient values/main questions Reviews laminated copy of decision aid with patient Answers questions and agrees to next steps (when to revisit, decide, etc.) Gives paper copy of decision aid and/or print decision aid in after-visit summary If decision made: provider supports the decision and helps patient carry it out <p>B: If decision not made in A revisit and discuss between 38–42 week visit(s)</p>	<p>A: Between the 36–39 week visit the provider:</p> <ul style="list-style-type: none"> Clarifies patient values/main questions Reviews laminated copy of decision aid with patient or briefly discuss it and ask patient to review paper copy at home for later discussion Gives paper copy of decision aid and/or print decision aid in after-visit summary Answers questions and agrees to next steps (when to revisit, decide, etc.) If decision made: provider supports the decision and helps patient carry it out <p>B: If discussion not had and/or decision not made in A revisit and discuss between 37–42 week visit(s)</p>	<p>A: Between the 36–39 week visit the provider:</p> <ul style="list-style-type: none"> Clarifies patient values/main questions Reviews laminated copy of decision aid with patient or briefly discuss it and ask patient to review paper copy at home for later discussion Gives paper copy of decision aid and/or print decision aid in after-visit summary Answers questions and agrees to next steps (when to revisit, decide, etc.) If decision made: provider supports the decision and helps patient carry it out <p>B: If discussion not had and/or decision not made in A revisit and discuss between 37–42 week visit(s)</p>

<p>Test of Change (decision aid)</p>	<p>Four page decision aid included what is spontaneous labor, what is induction, when is induction recommended, who chooses, how common it is to go past my due date, three choices, data associated with each choice, whether age and parity matter, what's the same no matter what, what can help labor start on its own, what is the experience like for induction vs. waiting, checkboxes decision-making space</p>	<p>Changes made to decision aid:</p> <ul style="list-style-type: none"> • Changed when induction recommended to focus only on timing recommendations • Data presented in bar charts (rather than numbers) • Added illustrations • Added statistics for membrane sweep efficacy • Shortened information about experience of induction vs. waiting • Increased “your choice” language and added questions a person could ask • Replaced values-based check boxes with a table <p>Removed specifics about whether age and parity matter</p>	<p>Changes made to decision aid:</p> <ul style="list-style-type: none"> • Changed the overall look (more white space/better for black & white printing, some illustrations, etc.) • Simplified when labor induction is recommended • Changed icon arrays to percentages for how common to go past my due date • Specified that choice of induction before 41 weeks is 39–41 weeks • Added induction options • Revised data presented as differences to ensure, balanced, meta-analysis backed statements
<p>Predicted Results</p>	<ul style="list-style-type: none"> • Patients will be knowledgeable about choices and pros and cons of each choice (Measure: patient interviews) • Patients will feel like the decision was one they made or they made in collaboration with their provider (Measure: patient interviews) • Providers will feel like the tool and process helps them act on the BMC guidelines that call for shared decision-making on this topic (Measure: provider feedback sessions) 		

During each PDSA cycle, we aimed to interview between six and eight pregnant people who experienced the decision aid and discussed it with their provider to get feedback on the tool and process. Six to eight interviews was deemed a sufficient sample given the specific nature of targeted questions that focused on the decision aid and conformity of the process to shared decision-making. This number is also aligned with research on the number of people typically needed to reach saturation in qualitative studies.⁷⁴

Patient recruitment was passive when we started the first PDSA cycle, meaning that patients who received the tool with a recruitment postcard had to reach out for an interview. This recruitment strategy proved ineffective; therefore I sought and received approval from the BUMC IRB to do warm handoff recruitment whereby the provider could ask permission to share the pregnant person's contact information with me so that I could contact them for an interview. This approval happened within the first PDSA cycle and the pace of interviews improved.

Once I made contact with a patient who agreed to participate in an interview, I verified their eligibility and then conducted a 20–30 minute interview by phone or video call. The interview was semi-structured with simple questions adapted from LTM III and the DECISIONS Survey^{16,75} and questions informed by PRISM constructs (noted in Table 1) and previous qualitative research findings referenced in the background section. The full interview guide can be found in Appendix 3.

As PDSA cycles went on, I expanded the study's eligibility criteria (see Table 3) to include patients at different community health centers (CHCs) affiliated with Boston

Medical Center and to interview pregnant people in Spanish. This expansion in eligibility increased the number of eligible patients and accommodated some of the prenatal care providers who were involved in testing the decision aid where they practiced most of their prenatal care.

Table 3. Patient Eligibility by Plan-Do-Study-Act (PDSA) Cycle

Table 3. Patient Eligibility by Plan-Do-Study-Act (PDSA) Cycle	
PDSA Cycle (Dates)	Eligibility Criteria for Interviews (<i>italic/bold</i> denotes added eligibility)
1 (April–June 2021)	<ul style="list-style-type: none"> • Currently receiving prenatal care at Boston Medical Center • At least 37 weeks pregnant • No medical indication for labor induction • English speaking • Received decision aid and counseling
2 (July–September 2021)	<ul style="list-style-type: none"> • Currently receiving prenatal care at Boston Medical Center <i>or East Boston Neighborhood Health Center</i> • At least 37 weeks pregnant • No medical indication for labor induction • English speaking • Received decision aid and counseling
3 (October–December 2021)	<ul style="list-style-type: none"> • Currently receiving prenatal care at Boston Medical Center or East Boston Neighborhood Health Center <i>or Dorchester House Community Health Center</i> • At least 37 weeks pregnant • No medical indication for labor induction • English <i>or Spanish</i> speaking • Received decision aid and counseling

Pregnant people were incentivized to participate in interviews. After completing an interview, participants received a \$25 gift card as a thank you for their time. Each time, I followed procedures approved by the BUMC IRB to protect the privacy of those

contacted for an interview.

I took handwritten notes during interviews. At the conclusion of each PDSA cycle, I typed up all notes from all interviews, summarized themes and highlighted specific comments, de-identified them, and shared them with the QI team. This method of summarizing patient feedback in an abbreviated fashion aligned with the iterative nature of PDSA cycles rather than a full qualitative research transcription and coding process. In order to create the summary, I read all of the notes in full, then highlighted themes, and pulled out meaningful segments of notes that illustrated those themes for the QI team. Themes were grounded in the data in alignment with an inductive analysis approach.⁷⁶ Themes were defined with shared decision-making tenets (knowledge of options, understanding of pros and cons, perception of who was the primary decision maker) and PRISM concepts (patient perspective, characteristics of patients) in mind. A summary of themes was shared back with the QI team.

After patient interviews were complete in each PDSA cycle, I reached out to all participating providers to get feedback on barriers and facilitators to using the tool and achieving shared decision-making; we also discussed specific feedback on the tool. The QI team then met to review all data from patients and providers and to complete the PDSA cycle worksheet. We then made any revisions needed to the tool, provider guide, or process and set up the next PDSA cycle. The three versions of the decision aid that were tested can be found in Appendix 4 along with an example provider guide in Appendix 5.

From the outset, we had agreed as a team that the series of PDSA cycles would

stop when one of the following was true:

- 1) Members of the QI team and pregnant patients interviewed universally described the decision aid as helpful OR
- 2) Four full PDSA cycles were completed

We were ultimately interested in the decision aid and implementation strategies resulting in more shared decision-making (i.e., patients consistently naming choices, pros and cons, and saying it was their choice or a shared choice with their provider).

The QI team oversaw the adaptation and testing of the decision aid on routine labor induction at or beyond 39 weeks from September 2020 through December 2021. QI process mapping and prioritization matrixes were used alongside group and one-on-one provider feedback sessions to create the initial prototype and implementation plan. The decision aid was tested and refined by conducting PDSA cycles, during which patients from BMC, East Boston Neighborhood Health Center, and Dorchester House Community Health Center were interviewed using semi-structured interview questions. At the end of each PDSA cycle providers who had tested the decision aid provided additional feedback on the tool and process in one-on-one sessions.

CHAPTER THREE: RESULTS

Overview

Using QI methods to adapt and test a decision aid facilitated shared decision-making tool regarding if and when to induce labor in healthy pregnancies at or beyond 39 weeks. PDSA cycles that included interviews with pregnant people and providers provided helpful, concrete feedback to improve the decision aid and its implementation.

Three PDSA cycles were completed during this tool development. By the end of the second PDSA cycle we reached our initial goal: that the tool and process was described as helpful for both patients and providers. We completed a third PDSA cycle to reflect patient and provider feedback in the decision aid and ensure that the revisions enhanced shared decision-making. In the third PDSA cycle we saw a repeat from cycle 2 in all patients feeling that it was their decision or one shared with a provider. In the third cycle, we saw improvement in interviewee's ability to name their choices and specific pros and cons of each. Given those results and fewer comments from both patients and providers about how the tool could be better, we decided the third PDSA cycle would be the last.

Nearly all pregnant people interviewed across PDSA cycles indicated that they experienced shared decision-making. Many spoke about how meaningful this process was to them and named the tool and process as a source of empowerment and deep satisfaction. Providers interviewed also found the decision aid helpful, citing that it lessened the extent to which their own bias towards or against induction was affecting their counseling. Providers also noted that using a standardized tool with all patients

ensured consistency in their practice and reduced inequities in access to information and choices on this topic.

Who Was Interviewed & Involved in Testing

A total of 24 interviews with pregnant people who received the tool and associated counseling were conducted across the three PDSA cycles. Five interviewees identified as Black or African American, five identified as Latina or Hispanic, and four identified as white or Caucasian. The others identified as multiple races and/or ethnicities or a specific nationality or ethnic identity. About one third of people interviewed were born in the U.S. and about two thirds were born outside of the U.S., mostly but not exclusively in Central America and the Caribbean. Their ages ranged from 22 to 42 years old. Two thirds were Medicaid-insured and one third had private, employer-based health insurance. (See Table 4 for additional detail.)

The pregnant people interviewed had a wide variety of provider types, visit settings, and used different language versions of the tool. Fourteen interviewees were patients of midwives, seven were patients of nurse practitioners, and three were patients of an obstetrician. Twenty-two of them received prenatal care at Boston Medical Center while the other two received care at East Boston Neighborhood Health Center, a Boston-based community health center. Three interviewees noted receiving the tool and counseling during group prenatal care visits. The other twenty-one received the tool and counseling during individual prenatal care visits. Five of the interviews were conducted in Spanish.

Table 4. Demographic Characteristics of 24 Pregnant People Interviewed Across Plan-Do-Study-Act Cycles

Table 4. Demographic Characteristics of 24 Pregnant People Interviewed Across Plan-Do-Study-Act Cycles	
Demographic Characteristic	Value
Age, range	22–42
Born outside of the U.S., number	15
Born in the U.S., number	9
Have public insurance, number	16
Have employer-based insurance, number	8
Self-identified race and/or ethnicity^{vi}, number	
Black only (African-American or Black)	5
Latinx only (Hispanic or Latina or White Hispanic)	5
White only (White or Caucasian)	4
Asian only	2
Two or more races or ethnicities	8
Black and Latinx or Caribbean (Afro-Latina or Black & Hispanic or Caribbean and African-American or Black)	5
Two other races and/or ethnicities	3

All nine prenatal care providers who were actively involved in testing the decision aid and recruiting patients for interviews provided feedback during one or more testing cycles. These nine providers represented the three main departments at BMC that provide prenatal care: midwifery, obstetrics, and family medicine. They included certified nurse midwives, obstetricians, and nurse practitioners.

^{vi} Interview participants were asked how they identified racially and ethnically with an open-ended question. There was a wide variety in responses. Words inside the parentheses were those used by participants when answering the question. Words not in parentheses are for summary purposes.

Main Results from Patient Interviews & Provider Feedback Sessions

Overall, patients reported having little knowledge about labor induction before receiving the decision aid. Receiving the decision aid was a positive experience for pregnant people and all but one interviewee understood that they were the primary decision-maker regarding if and when their labor would be induced. After reviewing the tool and discussing it with their provider, most pregnant people understood that they had more than one choice and most could name specific pros and cons of the different choices. Providers who participated in feedback sessions said that using the decision aid was helpful in providing high quality, evidence-based counseling and minimizing the extent to which different biases they held impacted their care. Based on the decisions interviewees were making about if and when to have labor induction, there is no indication from the three PDSA cycles that the decision aid changed patients' decisions in a consistent temporal direction.

Pre-existing knowledge of patients about labor induction was limited

Pre-existing knowledge about labor induction was sparse and anecdotal among the 24 patients interviewed. Nine people knew nothing about labor induction prior to their current pregnancy. Seven people knew very basic information about it (e.g., what it was, that it is often for medical reasons or used when the baby does not come on its own). Six people knew at least one person who had had labor induction and knew about their experience. Three people had previously experienced labor induction. No one had extensive knowledge of induction and the information in the decision aid was largely new

to them. These findings underscored the need for education and counseling about labor induction as an essential foundation to support shared decision-making.

The process of receiving the decision aid and associated counseling largely adhered to shared decision-making and the experience was very positive

The process of presenting the decision aid and counseling adhered to shared decision-making as we had operationalized it for PDSA cycles. By the end of cycle 3 most pregnant people could name more than one choice available to them, could name one or more pros and/or cons of the different choices, and felt that they were the decision-maker or that the decision was a shared one with their provider. (See Table 5). Most people interviewed were somewhere between 38 and 41 weeks pregnant and were close to, or currently, acting on their decisions.

There was variation in how pregnant people understood and named pros and cons of the different choices when asked in interviews. The first and third PDSA cycles had a higher proportion of people interviewed who could name specific, accurate pros and cons. The strongest results were in the third PDSA cycle both in quantity and content of pros and cons named. The most common pros and cons named across cycles regarded: 1) time in the hospital, 2) risks to the baby after 41–42 weeks, 3) predictability and/or control over the timing, and 4) amount of pain and pain medication in labor. The third PDSA cycle was the only cycle in which people interviewed named a lower chance of cesarean birth associated with induction as a pro or con.

Table 5. Plan-Do-Study-Act Cycle Results

Table 5. Plan-Do-Study-Act (PDSA) Cycle Results			
PDSA Cycle (dates)	1 (April–June 2021)	2 (July–September 2021)	3 (October–December 2021)
Results	<ul style="list-style-type: none"> • Four out of six pregnant people interviewed named pros and cons of different choices. • Five out of six pregnant people interviewed felt it was their choice or a shared one • All providers interviewed felt like the tool and process helps them practice shared decision-making on this topic. 	<ul style="list-style-type: none"> • Four out of nine pregnant people named pros and cons of different choices. • All (nine out of nine) pregnant people interviewed felt it was their choice or a shared one • All providers interviewed felt like the tool and process helps them practice shared decision-making on this topic. 	<ul style="list-style-type: none"> • Seven out of nine pregnant people named pros and cons of different choices. Two pregnant people named pros and cons that were incorrect. • All (nine out of nine) pregnant people interviewed felt it was their choice or a shared one • All providers interviewed felt like the tool and process helps them practice shared decision-making on this topic.

Ultimately, 23 of the 24 pregnant people interviewed who received the decision aid and counseling felt like they made the choice regarding if and when to have labor induction (see Table 5). When they felt they had experienced shared decision-making, pregnant people used strong positive words to describe what it was like to have this conversation, receive and read the decision aid, and make a choice that was right for them. One person called going through the process “really empowering,” and said that being given the choice was very meaningful and noted it was not something friends of theirs who had recently given birth had experienced at other hospitals. Another person

said, “this gives me so much power.” Another person said that this process felt decidedly different than the rest of the prenatal care they were receiving. They said, “otherwise I felt like I was on a conveyor belt [in my prenatal care]” and called receiving the decision aid, reading it, and then discussing it with their provider, “awesome.”

The one person who did not feel that it was their decision was one of the first interviews in the first PDSA cycle, was over 41 weeks pregnant and preferred not to have labor induction. This result mirrored how providers had described previous practice patterns of routine induction at or around 41 weeks.

In one instance, a pregnant person interviewed during the first PDSA cycle shared that they disliked the decision aid and felt it was “misleading.” This interviewee said the decision aid did not center the safety of the mother and baby, that they disagreed with age being a risk factor, and that it was overwhelming to think about a pregnancy lasting 42 weeks. Despite these negative feelings about the decision aid, they felt labor induction was their choice. While it was not a theme, the word “misleading” was such a strong comment it seemed worth noting within the results given the relatively small number of patients interviewed in the project.

Providers felt like the decision aid transformed their induction counseling

All provider types reported that using the tool improved and standardized the way they counseled patients about labor induction. One provider felt that using the decision aid helped protect against their bias towards induction. Other providers felt that the decision aid helped them more uniformly talk about induction options with all of their

patients and reduced their bias against induction before 41 weeks. During the first PDSA cycle, one provider reflected that this project was pushing them to have the conversation with all of their patients rather than only discussing it if they or a patient happened to bring it up. After the third PDSA cycle was complete, the same provider noted that using the decision aid had transformed the way they counseled everyone. It standardized their counseling even when they could not use the decision aid because the patient spoke a language other than English, Spanish, or Haitian Creole. Many providers shared similar comments about how much the tool had changed their counseling.

Decisions about induction and timing varied

The goal of the project was to achieve shared decision-making, not to change people's decisions about induction in any particular temporal direction. Therefore, it was reassuring that pregnant people's decisions about induction timing varied throughout the project. In the first PDSA cycle, the variation in choices made by pregnant people was narrower and followed previous practice patterns of routine induction at or around 41 weeks. There was wider variation in choices made in later PDSA cycles in both temporal directions.

Feedback About the Decision Aid and Barriers and Facilitators to Implementation

Pregnant people and providers were asked for their specific feedback about the decision aid in order to improve its clarity and value as a tool. Table 6 summarizes the main feedback on the decision aid from both perspectives. The top three aspects most

appreciated by patients were: data on how common it is for a pregnancy to go past the due date, clarity of available choices, statistics about different outcomes associated with choices. The top two pieces of constructive feedback were: statistics about different outcomes for the different choices were difficult to interpret and patients disliked having to think about possible negative outcomes like infant death and neonatal intensive care unit (NICU) admission. Providers shared their reflections on facilitators and barriers to implementing the tool during individual feedback sessions. Providers identified the top facilitators to implementation as: having a balanced and evidence-based tool and having it in multiple languages. Providers identified three main barriers to implementation: time, logistics, and prior practice/biases.

Table 6. Decision Aid Feedback and Changes Made Across Plan-Do-Study-Act Cycles

Table 6. Decision Aid Feedback and Changes Made Across Plan-Do-Study-Act Cycles			
	PDSA Cycle #1	PDSA Cycle #2	PDSA Cycle #3
Main Positive Feedback from Patients	<ul style="list-style-type: none"> • The data • How common it is to go past due date • Clear options • What's the same no matter what 	<ul style="list-style-type: none"> • Pros and cons with all choices • Clear and easy to understand • Comprehensive • Clear options 	<ul style="list-style-type: none"> • Helpful information and comprehensive • Types of induction methods • Time frames and associated data • How common it is to go past due date • Decision-making table on last page
Main Positive Feedback from Providers	<ul style="list-style-type: none"> • Balanced and evidence-based tool • Same information getting to all patients 	<ul style="list-style-type: none"> • More succinct than version 1 • Images are warm/ approachable • Right content • Easy to use and explain 	<ul style="list-style-type: none"> • This version feels like it can stand alone, so can be sent home to read and discuss at next appointment • Visually pleasing

Main Constructive Feedback from Patients	<ul style="list-style-type: none"> • Did not like “maybe” and “probably” words • Too wordy • Add induction methods • Make patient values clarification items relate to one another more 	<ul style="list-style-type: none"> • Did not like thinking about possible risks to baby • Data hard to read • More emphasis on difference in length of time in hospital before birth • Explain why some babies come later • Add induction methods 	<ul style="list-style-type: none"> • Did not like thinking about possible risks to baby • Bar charts hard to read • Did not understand “birth experience” in decision-making chart
Main Constructive Feedback from Providers	<ul style="list-style-type: none"> • Too long/ too time consuming to cover well • “Early” related to 39–41 week induction is biased 	<ul style="list-style-type: none"> • Add induction methods with images • Add more nuance to the “no clear benefits of induction before 41 weeks” to align better with ACOG 	<ul style="list-style-type: none"> • Bar charts still take the most time

Patients identified clear choices and data as the most helpful parts of the decision aid

Across cycles, pregnant people were most likely to appreciate the data regarding how common it is for pregnancies to last more than 40 weeks, believed that the choices presented in the tool were very clear, and thought that data was presented in a balanced way across choices. In the third PDSA cycle, pregnant people noted that including the types of induction methods (which had not been included in prior versions) and the decision-making table on the last page as helpful.

Some patients struggled to interpret the data and disliked thinking about negative outcomes

Across the three PDSA cycles, the most common pieces of constructive feedback were that the data (i.e., charts and statistics) were difficult to interpret and that pregnant people did not like thinking about some of the risks included in the tool (admission to the NICU and infant death). There were many individual pieces of constructive feedback about the decision aid (see Table 6) that were helpful in improving the tool. Both thematic and individual patient and provider comments informed decision aid revisions between testing cycles.

Providers identified time, logistics, and prior practice/biases as top implementation barriers

The most common barrier to implementation of the decision aid noted by providers was time — both the limited time in each prenatal visit and the amount of time it took to use the decision aid. Time persisted as a barrier across PDSA cycles, although comments about how much time the tool took to use lessened as providers grew used to using the tool and as the tool became shorter and more user-friendly. The barrier of time was exacerbated in some cases by patients who needed additional services. For example, having greater social needs (e.g., needing help to find stable housing) increased the extent to which time was a barrier during a particular visit. In other cases, the time needed to use a translator for a language that was not English, Spanish, or Haitian Creole, exacerbated time as a barrier.

The second most common barrier that providers reflected on, particularly in the first and second PDSA cycles, was their bias towards or against induction and their previous induction counseling practice. One provider said remembering to do the counseling was difficult as their previous practice was to delay bringing up the topic of induction until after the due date passed; they had a disbelief that early induction choices were ‘real’ choices at BMC. Other providers, particularly midwives, expressed discomfort in bringing up induction earlier in pregnancy because of a worry that it contradicted their practice of promoting and supporting less medicalized birth.

Lastly, some providers named logistical barriers to implementing the tool. Some noted that printers were not reliable for including the tool in the after-visit summary. Additionally, some providers noted that the physical copies of the tool were not always easily accessible.

Providers identified having an available, balanced, evidence-based tool in multiple languages as the primary facilitators to implementation

A number of providers noted the balanced nature of the tool as a key facilitator to use. They said that the lack of bias in presenting the evidence and the fact that the tool did not seem to steer patients in any particular decisional direction was the major reason they wanted to use the tool. As the PDSA cycles went on, and the tool improved, providers also began to say that it was easier to send home with patients as a standalone tool and was more visually appealing.

Having physical printed copies in convenient places and in multiple languages

was an important facilitator. During the second PDSA cycle we moved where the tool was being stored at Boston Medical Center to a more central location, which helped providers access it more easily. Additionally, options to use it electronically and include it in an after-visit summary supported providers in using the tool consistently.

Overall, the development and testing of the decision aid was successful in achieving shared decision-making regarding whether and when to induce labor in healthy pregnancies at or beyond 39 weeks. These results suggest that a balanced, evidence-based decision aid can support patients and providers in improving communication, improving knowledge about different choices and pros and cons, and clarity regarding decision-making roles. Many interviewees experienced the tool and process as empowering and positive and many providers reflected on their positive impact on the consistency and content of their labor induction counseling.

CHAPTER FOUR: DISCUSSION

Overview

All medical professional organizations in the U.S. along with many researchers and clinicians recommend or call for shared decision-making to be applied to the decision of whether to induce labor when a person has a healthy pregnancy at or beyond 39 weeks.⁵⁻¹³ Shared decision-making can have substantial positive impacts on pregnant people who face this choice and is part of high quality, person-centered care.⁵⁴⁻⁶⁰ Despite both the recommendations for, and impacts of, shared decision-making, there are no current patient decision aids or guidelines to support the implementation of shared decision-making for routine labor induction.¹⁸⁻²⁰

This project to develop and test a decision aid on labor induction in healthy pregnancies at or beyond 39 weeks succeeded in achieving shared decision-making on this topic for a very diverse set of patients. The use of the decision aid with provider counseling appeared to empower pregnant people to exercise more autonomy and choice in a vulnerable and meaningful moment. The results of this project demonstrate the potential of using QI processes to develop tools aimed at improving shared decision-making for people of color and those who are Medicaid-insured. Developing and implementing high quality decision aids could significantly improve patient experiences within maternity care and potentially in other medical decisions. High quality, evidence-based tools can improve equity in access to shared decision-making by ensuring the same information and choices are given to all patients regardless of identity and individual access and agency. Developing and implementing high quality decision aids on key

topics may be a concrete and relatively simple way to increase equity within a health system amidst calls to do so.

QI and Qualitative Methods as a Replicable Model for Patient Decision Aid Development and Testing

Existing literature has demonstrated that high quality decision aids can support shared decision-making and that there is no current decision aid for the topic of routine labor induction in healthy pregnancies at or beyond 39 weeks.¹⁷⁻²⁰ The QI tools and qualitative methods used in this project to adapt, develop, test, and refine a decision aid and supporting implementation strategies were successful in achieving shared decision-making for a diverse set of patients. As referenced in the results section, the experience of receiving and reading the decision aid improved and became more consistent from the first to the last PDSA cycle. This adds to the literature supporting QI methods for decision aid development.⁷⁷

Patient input is critical in decision aid development and testing. The PDSA cycles and qualitative interviews in this project were an effective way to get patient feedback on content, data presentation, and other aspects of both the decision aid and implementation process. Semi-structured interviews provided space for patients to comment on all aspects of their experience reading the tool and discussing it with their provider.

The QI process supported providers' adoption and sustained implementation of the decision aid. QI is familiar to many clinicians and can build provider buy-in during the process.⁷⁸ PDSA cycles helped providers reflect on results and supported initial and

sustained practice change. This project suggests QI methods can be particularly helpful when a change in practice not only presents logistical or habit changes, but touches on more deeply held beliefs or biases a provider might hold, consciously or unconsciously. For the providers involved in implementing the decision aid, it was a significant shift in practice to move to a model of shared decision-making on a broader set of options regarding timing of induction. Feeding patient interview data back to providers, and meeting with them one-on-one to reflect on implementation barriers and facilitators supported their practice change. This is evidenced by the fact that the two negative results in the first PDSA cycle were not repeated in subsequent PDSA cycles. In the first PDSA cycle one pregnant person did not feel it was their choice to have labor induction and another described the tool as “misleading.” The fact that these comments only showed up in the first PDSA cycle may reflect the imperfect initial tool and in-process change providers were making to their practice. The wider range of patient decisions in cycles 2 and 3 is also suggestive of this practice adjustment and improvements in the clarity of the tool.

The Power of Patient and Provider Diversity

Using QI and qualitative methods centered patient and provider feedback to ensure the final product would be one that met the needs of both users. The level of diversity in the patients interviewed and the providers who tested the tool strengthened the end result. Since pregnant people of color and those who are Medicaid-insured are least likely to experience shared decision-making,^{15,16} it was important to center their voices in

particular in the tool development process to ensure a decision aid would meet their needs. Centering identities that are experiencing inequities in a QI project is one of two main strategy options to bring equity into quality improvement projects according to a 2012 report by the University of California – San Francisco Center for the Health Professions.⁷⁹

Boston Medical Center, East Boston Neighborhood Health Center, and Dorchester House Community Health Center were crucial development and testing partners. Having these institutions as partners ensured that patients with marginalized identities were centered in the design and any improvements in care would benefit them. Most interviewees were people of color and were Medicaid-insured and many were immigrants to the U.S. and non-Native English speakers. Recent immigrant and first-generation American interviewees described how their beliefs about induction timing were influenced by induction practices in their country of origin or country of heritage. Some interviewees described social reasons for induction such as limited childcare options for existing children and limited transportation options to get to the hospital when in labor. This incredibly diverse group of interviewees provided feedback on what was important to highlight in the tool (e.g., time in the hospital), what data should be included, and how the values clarification table should include ‘other’ personal and cultural reasons to validate these additional reasons. Their feedback strengthened the final version of the tool.

Translating the tool into Spanish and Haitian Creole from the initial prototype and throughout testing also strengthened the results. This choice allowed more recent

immigrants to benefit from, and help evaluate, the tool as it was developed. Comments in interviews showcased why having tools in multiple languages is important. An interviewee who only spoke Spanish described being unfamiliar with the term “induction” before receiving the tool despite having had labor induction in the past. A patient who used the Haitian Creole version talked about how positive the experience was to receive a tool like this in their native language. Interviewing patients who received all language versions of the tool also allowed us to collect feedback about specific word choices in all three languages.

While most patients at Boston Medical Center are people of color and Medicaid-insured,^{62,63} there are also patients with higher socio-economic status and private insurance. Their voices were also included in this process. For example, interviewees within this patient population disliked vague language that was included in earlier decision aid versions like “maybe” and “probably” when describing potential risks. They often had questions about hospital induction policies at BMC before receiving the tool and appreciated that the decision aid answered them. The diversity of patients interviewed with such a range of identities across a broad socio-economic spectrum provided a rich set of patient feedback. This level of diversity suggests that the tool may be applicable to different settings and patient populations.

The diversity of provider types involved in developing and testing the decision aid also strengthened the results. Different types of providers have different orientations to maternity care, different attitudes about interventions, and differing views on optimal timing for induction of labor.^{11,13} Including providers who were midwives, obstetricians,

and family medicine providers in the project supported the objective that the final tool reflect their different viewpoints and experience. Providers questioned data sources behind statistics that did not agree with their own perspective about ideal timing of routine induction. Providers who were biased towards induction questioned data sources that supported waiting for spontaneous labor, especially past 41 weeks and providers who were biased against induction questioned data sources that supported early induction. This push and pull resulted in rigorous discussions about which data should be presented. For example, when a provider questioned the lack of specific reference to the ARRIVE trial in the tool, the QI team met to discuss the pros and cons of doing so. Ultimately, we decided to add systematic review data that included the ARRIVE trial and take out an individual study whose results supported waiting for spontaneous labor. This push and pull helped us be consistent in the type of data we were sharing in the tool regardless of the outcome supported by its results. One of the QI team members aptly described this process of differing viewpoints resulting in a more balanced tool by saying, “if this tool makes the midwives and the OBs slightly uncomfortable but they’re all willing to use it, we’ve probably got a good tool.” Through the end of the project all providers remained least comfortable with the options presented in the decision aid that were farthest from their pre-existing bias and practice but they trusted the tool development process because they saw the push and pull and that their feedback was taken seriously.

A 2020 scoping review of patient decision aids on maternity care topics highlighted that few decision aids exist that are for patients with lower literacy levels. Even fewer are developed for culturally diverse groups or translated into other languages.²⁰ Three

equity-centered design principles that worked well in this project and should be included in future projects to develop shared decision-making tools are to:

1. Select pilot sites that have highly diverse patient populations where the majority of patients are people of color and Medicaid-insured to center the voices of people who are least likely to experience shared decision-making.
2. Pilot decision aids in multiple languages from the beginning to center non-Native English speakers and ensure greater diversity in cultural beliefs and experiences represented in the development and testing process.
3. Engage multiple provider types (and/or opposing perspectives) in the development and testing process to make it most likely the end result presents data in the most balanced way possible.

Calls for shared decision-making are increasing across many areas of care including common health conditions such as hypertension and asthma.^{80,81} The QI process, with explicit ways to center equity like designing with and for people of color and those who are Medicaid-insured, could be applied to answer the calls to incorporate equity in shared decision-making tools and processes.

Shared Decision-Making for Improving Patient and Provider Experience

Many pregnant people interviewed for this project used strong, positive words (e.g., “awesome” and “empowering”) to describe the experience of using the tool and discussing it with their provider. This fits with the pre-existing literature that links more

involvement in decision-making in prenatal care to increased satisfaction with care and decreased depressive and post-traumatic stress symptoms after birth.⁵⁴⁻⁶⁰ It also suggests that a relatively small change (the introduction of a decision aid into an otherwise unchanged prenatal care practice) can have positive and meaningful effects on patient experience. Words like “awesome,” “empowering,” and comments like, “this gives me so much power” indicate the strength such a change can have. Supporting shared decision-making could have a significant impact on patient experience even without larger systemic changes to prenatal care delivery. It may be less complicated than we imagine to change a person’s prenatal care experience from “being on a conveyor belt” or feeling mechanistic (as another study found)⁸² to feeling that it is “awesome,” individualistic, and affirming care.

Provider experience using this tool was also positive and has practice implications. Providers talked about how supportive the tool was in alleviating some of their burden to explain concepts and remember and correctly state statistics on different choices when patients request that data. Having a tool that they trusted, was visually pleasing, was easy for patients to read, and was easily available, made their counseling easier and more in alignment with the type of care they wanted to provide. This finding fits with prior research regarding provider satisfaction while using tools and practicing shared decision-making for other health-related decisions. For example, a 2017 study found high satisfaction ratings among maternal fetal medicine specialists who field tested a decision aid with decision coaching with parents facing decisions about extreme prematurity.⁸³ Projects like this, therefore, have the potential to increase provider

satisfaction as well.

Increasing Equity and Reducing Bias in Care with Shared Decision-Making

Equity and anti-racist work are at the forefront of many people's minds. The continued increased media attention on the murders of Black people by police, the Black Lives Matter movement, and the inequities in health care and outcomes experienced by Black people and other people of color in the COVID-19 pandemic have brought on a racial reckoning in the U.S.⁸⁴⁻⁸⁶ This broader racial reckoning adds to national calls to improve care for Black pregnant people given the stark inequities in outcomes like maternal mortality.⁸⁷⁻⁹² Black women are approximately three times as likely to die from a pregnancy-related cause as white women.⁹² Compared to any other group, Black women experience the highest rates of nearly all Centers for Disease Control and Prevention's severe maternal mortality indicators.⁹² Disparities in prenatal care seeking earlier in pregnancy and consistently throughout their pregnancy contribute to inequities in outcomes such as infant and maternal mortality.⁹³

Pregnant people, especially those who are Black or Hispanic and those who are Medicaid-insured or without health insurance, are experiencing discrimination when they access health care and feel they are not being treated as an equal and informed partner in their care.^{45,92,94} Between 2017 and 2019 the gap between Black and White people who reported their providers only sometimes or never asked them to help make decisions when there was a choice between treatments widened.⁴⁶ Within prenatal care the LTM III survey found that 40% of participants reported communication issues and 24%

experienced discrimination during a hospital-based birth with higher levels of discrimination experienced by people identifying as Black or Hispanic and those without health insurance.⁴⁵ We know that many barriers to seeking prenatal, and other care, are structural,⁹⁵ and also that the experience we each have individually and collectively interacting with the healthcare system shapes how hesitant or likely we are to seek care.⁹⁶

The existing literature on decision aids and their usefulness mostly focuses on acquired knowledge of options, value congruency, decisional conflict, patient satisfaction and patient outcomes.^{17,20} By getting regular feedback and reflections from providers, this project illustrated the effect a high quality decision aid can have on reducing multiple layers of bias that otherwise exist in individual providers' practice. A 2015 systematic review found associations between providers' implicit bias and patient-provider interactions, treatment decisions, treatment adherence, and patient health outcomes.⁹⁷ The biases this project uncovered and solved for in providers' practices (those towards and against induction and possibly implicit biases that led to only some patients receiving this type of counseling before the tool was implemented) could suggest that adoption of evidence-based, balanced educational materials and decision aids may be an effective and concrete way to moderate these associations.

Calls to action have increased for elected representatives, hospitals, and health systems to do more to improve health equity, maternal health equity, and anti-racism, both upstream in the community and within their institutions.^{89,98} This project's findings that the experience of receiving and discussing a decision aid could support effective communication and positive patient experience may mean that genuinely experiencing

shared decision-making could be a concrete antidote to the communication issues experienced by so many and reduce some of the impacts of provider bias.

Strengths and Limitations

QI and qualitative methods

The combination of a rigorous implementation science framework with QI and qualitative methods used was a key strength of this project. The QI process involved key stakeholders in the development and testing. While the clinical context at other institutions may vary, the development and implementation process and method for obtaining feedback from patients and providers is generalizable to the development of decision aids on other health topics and other healthcare settings.

The qualitative feedback collected in patient interviews and provider feedback sessions in each PDSA cycle informed the revisions to both the tool and process and resulted in improvement over time. The choice to use qualitative interviews with an inductive approach as opposed to surveys or chart notes gave depth and nuance to the patient and provider feedback. This allowed for more unexpected results to emerge and for greater depth of feedback on the usefulness of the decision aid and how to improve it. If we had instead chosen to use surveys and more quantitative methods our learning might have been more limited to the tool's effectiveness in relaying information. Without using open-ended questions, we may not have fully understood what it meant to people to be given this choice and have this type of interaction with their provider. However, we could have employed complementary quantitative methods to enhance the

results of this study. The lack of quantitative measures, especially rates of induction and timing choices across the full swath of patients who received the tool and/or compared to those who did not, is a limitation of the findings.

Collecting only qualitative data is a common methods choice for decision aid development projects.⁹⁹⁻¹⁰¹ However, the tradeoff in this choice is that the number of people providing feedback is often smaller. We relied on the comments of six to nine patients in each PDSA cycle to be representative of the broader population of BMC and the two community health centers. It is possible that the 24 patients interviewed are not representative of the broader patient population. In the results section we noted that one pregnant person disliked the initial decision aid in PDSA cycle 1 and called it “misleading.” They seemed not to trust the data presented in the tool. With only 24 interviewees it is impossible to know if this was an outlier or a sentiment that might be expressed more if more patients were interviewed.

An additional limitation of the methods is the timing of the interviews. Most (22 out of 24) interviews were conducted while interviewees were still pregnant. It is possible that interviewees felt differently about the tool and their decision after they experienced induction or spontaneous labor and birth, as was the case in Moore et al 2016.⁵⁰

Another limitation of the methods and a lesson learned from this project was the slow pace at which we moved through early PDSA cycles because of the slow pace of patient interviews. After we changed the protocol to include warm handoff recruitment, expanded to additional health centers, and started conducting interviews in Spanish, the

pace of interviews improved.

Diversity

Another key strength of this project was the diversity of patients and providers providing feedback on the decision aid and its implementation and the fact that it was tested in three languages. This diversity gives the decision aid the best chance at meeting the needs of pregnant people of color and those who are Medicaid-insured and the best chance at being transferrable to other settings whether they be midwife or obstetrician or family medicine dominated. Importantly, the choice to test this at BMC, East Boston Neighborhood Health Center, and Dorchester House Community Health Center means the decision aid is well positioned to address the needs of pregnant people who are least likely to experience shared decision-making because of the diverse set of identities represented by the 24 interviewees.

One limitation to the patient diversity reflected in the patient interviews was that interviews were only conducted in two of the three languages in which the decision aid was tested. While I did interview pregnant people who used the Haitian Creole version of the tool, the results may have been stronger if I conducted interviews in Haitian Creole – or in any other languages beyond English and Spanish.

Another limitation to the diversity of perspectives in the project and its results is the relative lack of racial and ethnic diversity of the QI team and of providers involved in testing. I, the project lead, and my four fellow core QI team members were all racially white. A greater diversity in lived experience within this core leadership team could have

strengthened the project, its process, and its results. If we had had core QI team members who identified as people of color or non-Native English speakers, perhaps we would have designed the study to include multiple languages from the beginning and perhaps our initial prototype would have been stronger than it was. Getting a wider set of feedback on the prototype and testing plan helped mitigate this limitation by surfacing calls from providers of color to change the plan to include multiple languages and emphasize language about choice on the initial prototype. However, there may be other aspects of the process, evaluation, and ultimate results that would have benefited from a deeper level of involvement and leadership by providers of more diverse backgrounds, especially those with low-income backgrounds who identify as people of color.

The setting in which the tool was developed and tested is a potential limitation of broader application. While it is typical in tool development processes to limit the setting to one or a few sites, the limited sites involved are still a limitation to the findings. In the three settings in Boston, MA where the decision aid was tested, the majority of patients with uncomplicated pregnancies are seen by midwives. This meant that while the obstetrics and family medicine departments were involved in testing, they were a much smaller segment of provider feedback and fewer obstetricians and family medicine patients were interviewed compared to midwifery patients. This is not representative of the broader landscape of perinatal care in the U.S. – the vast majority of which is provided by obstetricians.⁴ The decision aid might need to be adapted for use in different settings or healthcare systems, especially in regions with greater differences in provider practice and perspectives on labor induction or in a non-academic setting.

Transferability to Other Institutions and Topics

There are many reasons to expect the decision aid that was developed in this project would be widely transferrable to other institutions. It was developed and tested by obstetricians, midwives, and family medicine providers and patients of incredibly diverse identities participated in interviews. Their combined comments informed revisions to the decision aid. The decision aid is written at a grade 6 reading level or below in English and most of the pregnant people interviewed found the final tool easy to understand. It was tested in three languages and received similar feedback in all languages during patient interviews.

The process by which the decision aid was developed and tested can and should be applied to other topics within and beyond maternity care. QI processes provide a helpful framework for iterating and refining a decision aid and qualitative interviews were helpful in uncovering the impact of the decision aid's implementation, while obtaining helpful specific feedback on the tool itself. Testing tools in multiple languages with diverse patient populations, and a variety of provider types and/or viewpoints on a given health decision are additional aspects of the methods that are translatable to other institutions and topics. Amidst calls for more shared decision-making within and outside maternity care^{80,81} and calls for greater equity in the development of decision aids²⁰ this is a relatively quick but rigorous way to create more high quality decision aids. This project's methods, choice of pilot sites, and results could serve as a model to ensure more high quality patient decision aids exist that meet the needs of pregnant people with more marginalized identities on a reasonable timeline.

Implications for Public Health Policy and Practice

A major implication for public health practice and policy is that we should incentivize more shared decision-making and decision aid tool development to increase patient voice and empowerment, help providers, and measure the impact of these new tools. Patient participation in decision-making is part of higher quality care and is key to improving experience and decreasing inequities.⁹² Providers' implicit biases are negatively affecting patient-provider interactions, treatment decisions, treatment adherence, and patient health outcomes.⁹⁷ This small QI project and its resulting decision aid resulted in pregnant people who were mostly people of color and Medicaid-insured describing experiences receiving this prenatal care counseling as a positive and empowering experience. We should further evaluate the impact of shared decision-making and decision aid adoption on reducing bias in care, within and beyond maternity care. We should specifically measure the impact of interventions that change the culture of care and health outcomes for people who hold more marginalized identities.

Another implication for public health practice from this project is that shared decision-making tool development is possible and relatively quick. It was feasible for the team to develop a shared decision-making tool on this topic with the help of patients and providers. We were able to pilot the shared decision-making tool at a large, tertiary safety net hospital amidst a pandemic. This demonstrates how capable we are of this kind of change. We are capable of moving from more restricted choices to excellent patient experience and full choice within two or three PDSA cycles.

In order to act upon these public health implications there must be funding. The

Affordable Care Act encourages use of shared decision-making. Section 3506 established funding to develop consensus-based standards and certify patient decision aids. As Emily Oshima and Dr. Ezekial Emanuel argued in a perspective piece in the *New England Journal* in 2013, both the Department of Health and Human Services and the Center for Medicaid and Medicare and Medicaid Innovation have the power to fund the development and testing of decision aids.¹⁰² These government entities could and should provide incentives for researchers and practitioners to develop, implement, and disseminate these types of tools to improve quality of care. This type of funding and oversight could ensure additional decision aids are created and could incentivize uptake.

High quality decision aids designed for and with people of color and those who are Medicaid-insured may be powerful tools for improving care experience, increasing appropriate use of care, including more preventative care seeking, and advancing equity within our systems. This project suggests that QI and qualitative methods with explicit equity lenses can be a rigorous but relatively quick way to create decision aids that could support shared decision-making and more patient centered care in ways that also improve provider experience. The development, implementation, and evaluation of patient decision aids for maternity care and beyond deserve more attention, study, and dissemination.

NEXT STEPS

I recommend three main steps: 1) pursue decision aid certification, 2) disseminate the tool, and 3) further study the impact of using this decision aid.

Decision Aid Certification

The Washington State Health Care Authority is the only U.S.-based entity that currently certifies patient decision aids. They have certified one other patient decision aid related to maternity care. Through the certification process the decision aid and its development process will be vetted by a third party. If certification is achieved, this will improve the credibility of the decision aid and help pregnant people and providers trust it.

Dissemination

In order to disseminate the decision aid and the findings of this project, I plan to pursue decision aid certification. This distinction will increase trust in the tool for providers, institutions, and pregnant people who were not involved in its creation. It will also make it easier for other people to find because it will show up in certified decision aid databases and perhaps future scoping and literature reviews of existing decision aids. I will simultaneously pursue a copyright for the decision aid in order to protect the contents of the tool from being modified or used outside of its intended purpose.

Next, I hope to post the decision aid on the Internet so that it can be found easily for those who are searching for this type of tool and want to implement it. I will pursue academic publication and possibly mass media publication another means of

dissemination. In addition, I plan to attend relevant conferences and network with large professional organizations and like-minded smaller organizations to spread information about this tool and the development process.

Based on this experience, I believe the best way for an institution to adopt this tool is to use a QI process. Time and provider biases and concerns that using the tool will steer patients towards more or fewer inductions will likely be present in a new setting. Using a QI process, especially if an institution already does QI projects, will help adapt the use of the tool to work in their specific setting. QI projects also naturally identify and engage key stakeholders and early adopters, unearth and address barriers and facilitators to implementation, and evaluate how adoption is going. The guide to adopting this decision aid for other institutions (Appendix 6) should also support this effort.

I would also like to translate the decision aid into additional languages. Some of the providers involved in the project talked about how meaningful having the tool in multiple languages was because they did not need to worry as much about whether a medical translator was being as careful with their word choice as they would like them to be. Providers talked about their nervousness when using a translator in conversations that are sensitive and values-based like that of labor induction. Patients who received the decision aid in their language also appreciated this level of access. For both of these reasons, it is ideal for the tool to be professionally translated and reviewed by native-speaking pregnant people and providers in additional languages common in the U.S..

Areas for Further Study

Now that an effective decision aid on the topic of labor induction exists, it should be further studied to contribute to the gap in knowledge of the impact of decision aids like this in maternity care.²⁰ Barriers and facilitators to implementation named by providers at Boston Medical Center, East Boston Neighborhood Health Center, and Dorchester House Community Health Center should be measured. Specifically, it would be helpful to measure the impact of using the decision aid on visit length, patient induction choices, induction rates at different gestational ages, and their impact on the labor & delivery floor. Impact data on these outcomes would help other institutions and their providers assess whether implementing the tool with their patients will work in their setting.

Additionally, patient experience and outcomes could be further evaluated. Mixed methods should be used to study the impact of this tool on pregnant people's experience of their care and associated outcomes like depressive symptoms after birth. It would be especially helpful to mirror the temporal qualitative study design of Moore et al 2016⁵⁰ and interview pregnant people after induction counseling and then again after they have given birth to understand how they feel at both points in time. Measuring this set of outcomes in diverse settings would be powerful data to support next steps in providers adopting this tool more broadly. Comparing a set of institutions that were practicing standard of care counseling and another set of institutions using this tool for induction counseling would be ideal especially if both patient and provider experience is measured. Analysis within these studies looking for any differences in experience or understanding of the decision aid across socio-economic variables would further contribute to

understanding real and potential impact.

APPENDIX 1: International Patient Decision Aid Standards

International Patient Decision Aid Standards (IPDAS) v.4.0 (2013) Qualifying Criteria (e.g., criteria for tool to be considered a decision aid)	
Dimension	Qualifying Criteria
Information	The patient decision aid describes the health condition or problem (treatment, procedure, or investigation) for which the index decision is required
	The patient decision aid explicitly states the decision that needs to be considered
	The patient decision aid describes the options available for the index decision
	The patient decision aid describes the positive features (benefits or advantages of each option)
	The patient decision aid describes the negative features (harms, side effects, or disadvantages) of each option
Values	The patient decision aid describes what it is like to experience the consequences of the options (e.g., physical, psychological, social)

International Patient Decision Aid Standards (IPDAS) v.4.0 (2013) Certification Criteria (e.g., criteria for a tool to be a certified decision aid)	
Dimension	Certification Criteria
Information	The patient decision aid shows the negative and positive features of options with equal detail (e.g., using similar fonts, sequence, presentation of statistical information)
Evidence	The patient decision aid (or associated documentation) provides citations to the evidence selected
	The patient decision aid (or associated documentation) provides a production or publication date
	The patient decision aid (or associated documentation) provides information about the update policy
	The patient decision aid provides information about the levels of uncertainty around event or outcome probabilities (e.g., by giving a range or by using phases such as "our best estimate is")

Disclosure	The patient decision aid (or associated documentation) provides information about the funding source used for development
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International Patient Decision Aid Standards (IPDAS) v.4.0 (2013) Quality Criteria (e.g., desirable criteria to enhance a decision aid)	
Dimension	Quality Criteria
Information	The patient decision aid describes the natural course of the health condition or problem, if no action is taken (when appropriate)
	The patient decision aid makes it possible to compare the positive and negative features of the available options
Probabilities	The patient decision aid provides information about outcomes probabilities associated with the options (i.e., the likely consequences of decisions)
	The patient decision aid specifies the defined group (reference class) of patients for whom the outcome probabilities apply
	The patient decision aid specifies the event rates for the outcome probabilities
	The patient decision aid allows the user to compare outcome probabilities across options using the same time period (when feasible)
	The patient decision aid allows the user to compare outcome probabilities across options using the same denominator (when feasible)
	The patient decision aid provides more than 1 way of viewing the probabilities (e.g., words, numbers, diagrams)
Values	The patient decision aid asks patients to think about which positive and negative features of the options matter most to them (implicitly or explicitly)
Guidance	The patient decision aid provides a step-by-step way to make a decision.
	The patient decision aid includes tools like worksheets or lists of questions to use when discussing options with a practitioner
Development	The development process included a needs assessment with clients or patients
	The development process included a needs assessment with health professionals

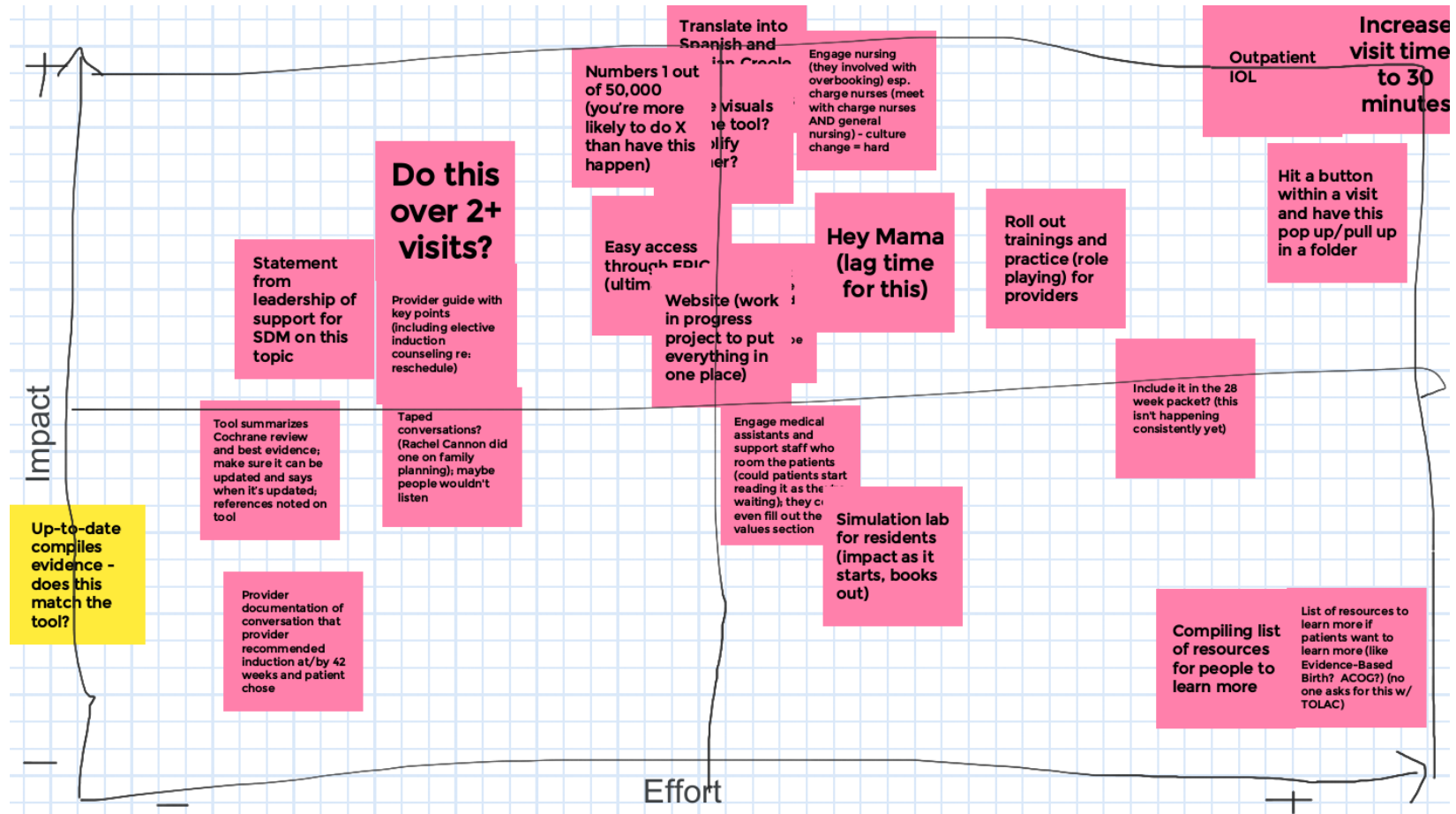
	The development process included reviews by clients/patients not involved in producing the decision support intervention
	The development process included reviews by professionals not involved in producing the decision support intervention
	The patient decision aid was field tested with patients who were facing the decision
	The patient decision aid was field tested with practitioners who face the decision
Evidence	The patient decision aid (or associated documentation) describes how research evidence was selected or synthesized
	The patient decision aid (or associated documentation) describes the quality of the research evidence used
Disclosure	The patient decision aid includes authors'/developers' credentials or qualifications
Plain language	The patient decision aid (or associated documentation) readability levels (using 1 or more of the available scales)
Evaluation	There is evidence that the patient decision aid improves the match between the preferences of the informed patient and the option that is chosen
	There is evidence that the patient decision aid helps patients improve their knowledge about options' features

APPENDIX 2: Plan-Do-Study-Act Process Documents

Ideal State Map



Prioritization Matrix



APPENDIX 3: Patient Interview Guide

FOR PREGNANT PEOPLE

- Objectives:
 - Determine the extent to which the tool is supporting shared decision-making from the patients' perspective.
 - Identify ways that the tool could be improved to better support shared decision-making from the patients' perspective.

Eligibility Criteria

- Do you feel comfortable speaking in English during this brief interview? Yes/No
- Do you receive prenatal care at Boston Medical Center? Yes/No
- How many weeks pregnant are you?/When is your baby due?
- Do you have any significant pregnancy complications?
 - Pregnancy with more than one fetus (twins, triplets, etc.)
 - Hypertension or diabetes
 - Fetal abnormality
 - Another known complication: _____
- In this pregnancy, have you and your provider discussed the possibility of induction of labor? Yes/No

Descriptive Questions

Which type of provider are you seeing for your prenatal care?

- OB/GYN
 - Midwife
 - Family Medicine Dr.
 - Nurse Practitioner
- What is your age or date of birth?
 - How would you describe your race and/or ethnicity?
 - Were you born in the United States? Yes/No; If no, where were you born?
 - Do you have health insurance? If so, what health insurance do you have?

Questions

1. **Prior to this pregnancy, what did you know about induction of labor?**
 - a. Probe: where did you learn that information?
2. **Tell me about any conversations you've had about induction of labor with your prenatal care provider during this pregnancy.**
 - a. Probes:
 - i. When was it brought up?
 - ii. What did you understand your options to be? (To be induced or not, when to be induced, different induction methods)
 - iii. What do you understand the pros and cons to be of inducing labor?
 - iv. What do you understand the pros and cons to be of waiting for labor to begin naturally?

- v. Did your provider ask you about your preferences and goals regarding induction of labor? Your birth preferences overall?

3. Tell me about any decisions that were made during those conversations.

a. Probes:

- i. Whose decision do you feel it was? What makes you say that?
- ii. Whose decision do you feel it should be? What makes you say that?
- iii. If the last two are different: What would need to change for you to feel like it was more of a joint-decision?
- iv. How are you currently feeling about the decision of whether or not and when to induce your labor? What makes you feel that way?

b. IF NOT THEIR/SHARED DECISION:

- i. What got in the way of you feeling like you could be an equal part of the decision-making?
- ii. What would help you to feel more like an equal partner in making this decision?

c. IF SHARED DECISION:

- i. What helped you like you could be an equal part of the decision-making?
- ii. What would help you to feel even more like an equal partner in making this decision?

4. [If the tool is a physical pamphlet or other source of information beyond a discussion] What did you think about the [tool]?

- a. Probe: What was helpful/clear about it? What was unhelpful/unclear? What should stay the same? How could it be improved?

5. What else would you like to tell me?

APPENDIX 4: Decision Aid Version

Version for PDSA Cycle 1

Spontaneous labor or induction of labor?

A decision aid for people with healthy pregnancies and no medical indication for induction of labor



What is spontaneous labor?

Spontaneous labor is labor that starts on its own and is powered by your body and your baby. It is most likely to happen between 37 and 42 weeks.

What is induction of labor?

Induction of labor is when a care provider tries to start your labor with medicines or other treatments instead of waiting for your body to start labor on its own.

When is an induction recommended?

- When you have a medical problem that could get worse if you stay pregnant
- When your baby has a medical problem that is becoming worse and is best treated after birth
- You are at or beyond 41 or 42 weeks pregnant (recommendations vary)¹⁻³

Who chooses?

- It is **your choice** whether to have an induction or not and you can change your mind.
- Your care provider may recommend an induction of labor for the health of you or your baby. You can ask about the reasons for their recommendation and decide to say yes or no.

Is it normal to go past my due date?

Yes! More than half of pregnant people will still be pregnant on their due date without intervention but most people will go into labor by 42 weeks on their own.

Without intervention...

At 40 weeks and 5 days
1 out of 2 people still pregnant



At 41 weeks and 3 days
1 out of 4 people still pregnant



After 42 weeks
1 out of 10 people still pregnant



Only 5% of babies are born on their due date.⁴

What are my choices?

1

Wait for labor to start on its own

2

Schedule an induction between 41 and 42 weeks

3

Request an induction before 41 weeks

1

What are benefits of waiting for labor to start?

Lower chance of having intense and very frequent contractions

- 48 in 100 people who wait for labor to start have intense contractions.
- 63 in 100 people who have an induction have intense contractions.⁵

Lower chance of using pain medication in labor (epidural/regional analgesia)

- 46 in 100 people who wait for labor to start use pain medication.
- 51 in 100 people who have an induction use pain medication.⁵

Probably less time in the hospital because you will come when you are in labor (and not before).

Probably more satisfaction with your care.⁶

2

What are benefits of induction of labor between 41 and 42 weeks?

Lower chance your baby will be admitted to the NICU (neonatal intensive care unit)

- 9 in 100 people who wait for labor to start beyond 41-42 weeks have a baby admitted to the NICU.
- 7 in 100 people who have an induction between 41-42 weeks have a baby admitted to the NICU.⁵

Lower chance that your baby will die before, during, or in the first week after birth

- 35 in 10,000 people who wait for labor to start beyond 41-42 weeks have a baby who dies.
- 4 in 10,000 people who have an induction between 41-42 weeks have a baby who dies.⁵
- The reason induction of labor is recommended between 41 and 42 weeks is because of the increase in this risk as pregnancy goes on.

Probably a lower chance of delivery by cesarean (C-section)

- 17 in 100 people who wait for labor to start beyond 41-42 weeks have a cesarean.
- 16 in 100 people who have an induction between 41-42 weeks have a cesarean.⁵

3

What are benefits of early induction of labor (after 39 weeks and before 41 weeks?)

There is no clear evidence of specific benefits of early induction of labor (after 39 weeks and before 41 weeks).⁵

- Early induction of labor does not improve outcomes for pregnant people or their babies compared to waiting for labor to begin.⁵
- This is why early induction is elective (or preference-based).

There may be specific personal reasons that early induction benefits you.

While there are no specific benefits, there are also no known additional risks of early induction compared to induction at 41 weeks or beyond.⁵

Does my age matter?

Maybe if you are over 35 and probably if you are over 40.⁷⁻⁹ People who are pregnant and over 35 (and more so over 40) have a higher risk of stillbirth (baby dying before or during birth) overall and as pregnancy continues so induction of labor can be more beneficial. The chance that your baby will die before or during birth is still less than 1%.⁵

Does it matter if it is my first birth?

Maybe.⁹ Some evidence shows a higher risk of stillbirth (baby dying before or during birth) when it is a person's first birth so induction of labor might be more beneficial in this case.

What is the same no matter what I choose?

- **Same chance of breastfeeding** when leaving the hospital⁵
- **Same chance of neonatal complications** (seizures in baby, pneumonia in the baby, harm to the baby's body, or problems getting air to baby's brain)⁵
- **Same chance of a severe tear** in the vagina⁵
- **Same chance of too much bleeding after the birth** (postpartum hemorrhage)⁵
- **Same chance of needing help to get the baby out with tools** like forceps or a vacuum⁵

What can I do to help my labor start on its own?

- **Membrane sweeps** after 39 weeks increase the chance your labor will begin. A membrane sweep involves a care provider doing a vaginal examination and making circular movements in the area of your cervix with their finger.¹⁰
- **Nipple stimulation** (manually or with a breast pump) probably helps.¹¹
- **Acupuncture** might help.¹²

What happens if I wait for labor to start on its own?

- Your care provider will offer you extra check-ups after 41 weeks
- You might find it hard to wait or you might enjoy the extra time before your baby comes

What would coming to the hospital in labor be like?

- When your contractions are 5 minutes apart or if your water breaks, you will call to see if it's time to come to the hospital
- When you arrive you will be offered a vaginal exam to check how dilated you are
- If it is early in your labor you may be asked you to come back later or take a walk
- When it's time you will go to a labor room where you can walk, use a birth ball, get in the shower, or use medicines to help you cope with labor
- It can take 8-24 hours until your baby is born (sometimes shorter, sometimes longer)

What happens if I choose to have an induction of labor?

- You and your care provider will agree on the date and time that is right for you and book your appointment
- Sometimes the date and time you want isn't available or needs to change

What would coming to the hospital for induction be like?

- When you arrive for your induction you will be offered a vaginal exam to check how dilated you are
- You care provider will recommend a cervical balloon or medicines to help start your labor
- You can walk, use a birth ball, get in the shower, or use medicines to help you cope with labor
- The process can move very quickly or slowly
- It can take 2-3 days until your baby is born (sometimes shorter, sometimes longer)

Decision Making Reflection Space

Which of these are most important to me?

- I want my labor to start on its own.
- I want to avoid using pain medication or getting an epidural during labor.
- I want as few medical interventions as possible during my labor.
- I want to avoid any increase in the chance in my baby dying or needing to be admitted to the NICU.
- I want to give birth sooner for other reasons:
- Something else that is important to me:

Questions and thoughts to share with my provider:

Right now I am leaning towards (circle one)

- 1

Wait for labor to start on its own
- 2

Schedule an induction between 41 and 42 weeks
- 3

Request an induction before 41 weeks

How was this decision aid made?

This decision aid prototype was created by a group of public health and medical professionals at the Boston University School of Public Health and Boston Medical Center (BMC) in Boston, MA. Patients at BMC are currently being asked for their input about this decision aid and the way it is being used by prenatal care providers.

Last updated: February 2021
Next update planned: May 2021

Sources

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What is the same no matter what I choose?

- **Same chance of breastfeeding** when leaving the hospital⁵
- **Same chance of neonatal complications** (seizures in baby, pneumonia in the baby, harm to the baby's body, or problems getting air to baby's brain)⁵
- **Same chance of a severe tear** in the vagina⁵
- **Same chance of too much bleeding after the birth** (postpartum hemorrhage)⁵
- **Same chance of needing help to get the baby out with tools** like forceps or a vacuum⁵

What can I do to help my labor start on its own?

- **Membrane sweeps** after 39 weeks increase the chance your labor will begin. A membrane sweep involves a care provider doing a vaginal examination and making circular movements in the area of your cervix with their finger.¹⁰
- **Nipple stimulation** (manually or with a breast pump) probably helps.¹¹
- **Acupuncture** might help.¹²

What happens if I wait for labor to start on its own?

- Your care provider will offer you extra check-ups after 41 weeks
- You might find it hard to wait or you might enjoy the extra time before your baby comes

What would coming to the hospital in labor be like?

- When your contractions are 5 minutes apart or if your water breaks, you will call to see if it's time to come to the hospital
- When you arrive you will be offered a vaginal exam to check how dilated you are
- If it is early in your labor you may be asked you to come back later or take a walk
- When it's time you will go to a labor room where you can walk, use a birth ball, get in the shower, or use medicines to help you cope with labor
- It can take 8-24 hours until your baby is born (sometimes shorter, sometimes longer)

What happens if I choose to have an induction of labor?

- You and your care provider will agree on the date and time that is right for you and book your appointment
- Sometimes the date and time you want isn't available or needs to change

What would coming to the hospital for induction be like?

- When you arrive for your induction you will be offered a vaginal exam to check how dilated you are
- You care provider will recommend a cervical balloon or medicines to help start your labor
- You can walk, use a birth ball, get in the shower, or use medicines to help you cope with labor
- The process can move very quickly or slowly
- It can take 2-3 days until your baby is born (sometimes shorter, sometimes longer)

Decision Making Reflection Space

Which of these are most important to me?

- I want my labor to start on its own.
 - I want to avoid using pain medication or getting an epidural during labor.
 - I want as few medical interventions as possible during my labor.
 - I want to avoid any increase in the chance in my baby dying or needing to be admitted to the NICU.
 - I want to give birth sooner for other reasons:
- _____
- Something else that is important to me:
- _____

Questions and thoughts to share with my provider:

Right now I am leaning towards (circle one)

- 1

Wait for labor to start on its own
- 2

Schedule an induction between 41 and 42 weeks
- 3

Request an induction before 41 weeks

How was this decision aid made?

This decision aid prototype was created by a group of public health and medical professionals at the Boston University School of Public Health and Boston Medical Center (BMC) in Boston, MA. Patients at BMC are currently being asked for their input about this decision aid and the way it is being used by prenatal care providers.

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Version for PDSA Cycle 2

Spontaneous labor or labor induction? Your choice.

A decision aid for people with healthy pregnancies and no medical indication for induction of labor



EXCEPTIONAL CARE. WITHOUT EXCEPTION.




What is spontaneous labor?
Spontaneous labor starts on its own and is powered by your body and your baby. It is most likely to happen between 37 and 42 weeks.


What is labor induction?
Labor induction is when a care provider tries to start your labor with a cervical balloon or medicines instead of waiting for labor to start on its own.


Is it normal to go past my due date?

Yes!

Without intervention...

At 40 weeks and 5 days
1 out of 2 people still pregnant 

At 41 weeks and 3 days
1 out of 4 people still pregnant 

After 42 weeks
1 out of 10 people still pregnant 

When is induction recommended for healthy pregnancies?

- The World Health Organization recommends induction at 41 weeks¹
- The American College of Obstetricians and Gynecologists recommends offering induction between 41 and 42 weeks and recommends induction of labor at 42 weeks²
- The American College of Nurse Midwives recommends offering induction by 42 weeks³


Who chooses if and when I have an induction of labor?

- It is **your choice** to have an induction or not and you can change your mind.
- Your care provider may recommend an induction of labor for the health of you or your baby. You can ask about the reasons for their recommendation and decide to say yes or no.

1 Wait for labor to start on its own

2 Schedule induction between 41 and 42 weeks

3 Request induction before 41 weeks



What are the differences between these choices for me and my baby?


1 Why might I want to wait for spontaneous labor?

Lower chance of having intense & very frequent contractions⁶ & using pain medication.⁵

Intense & very frequent contractions	48%	63%
Use pain medication in labor	49%	52%

■ People who wait for labor to start ■ People who have an induction

Probably more satisfaction with your care.⁶



2 Why might I want a labor induction between 41 and 42 weeks?

Lower chance of delivering by cesarean (C-section), your baby being admitted to the NICU, and infant death.⁵

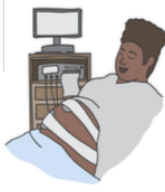
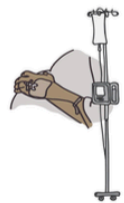
Delivery by C-section	11%	10%
Baby admitted to NICU	6%	5%
Infant death	0.40%	0.10%

■ People who wait for labor to start beyond 41-42 weeks
■ People who schedule induction between 41-42 weeks

3 Why might I want an early labor induction (between 39 and 41 weeks)?

There may be specific personal reasons that you prefer an early induction.

There are no specific benefits to early induction but there are also no known additional risks.⁵

1 Wait for labor to start on its own

2 Schedule induction between 41 and 42 weeks

3 Request induction before 41 weeks

← Wait for spontaneous labor past 42 weeks

Schedule induction at or around 42 weeks

Schedule induction sometime between 41 and 42 weeks

Schedule induction at or around 41 weeks

Request induction between 39-41 weeks →

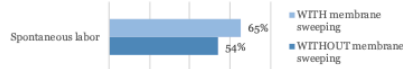
What else should I know about waiting for spontaneous labor?

- Your care provider will offer you extra check-ups after 41 weeks to make sure you and your baby are healthy.
- You will probably spend less time in the hospital because you will come when you are in labor (and not before).



What can I do to help my labor start on its own?

- **Membrane sweeps** increase the chance your labor will begin. A membrane sweep involves a care provider doing a vaginal examination and making circular movements in the area of your cervix with their finger.¹⁰



- **Nipple stimulation** (manually or with a breast pump) seems to help.¹¹
- **Acupuncture** might help.¹²

You can ask your care provider what options they offer to induce labor.



What is the same no matter what I choose?

- **Same chance of breastfeeding**⁵
- **Same chance of neonatal complications** (seizures, pneumonia, injury, or problems getting air to brain)⁵
- **Same chance of a severe tear** in the vagina⁵
- **Same chance of too much bleeding after the birth** (postpartum hemorrhage)⁵
- **Same chance of needing help to get the baby out with tools** like forceps or a vacuum⁵

Decision Making Reflection Space

What is most important to me?	Not important	Somewhat Important	Very Important	Not sure
Have labor start on its own.				
Avoid using pain medication or getting an epidural during labor.				
Avoid any increase in the chance in my baby needing to be admitted to the NICU (6% vs. 5%) or dying (0.10% vs. 0.40%)				
Have my baby sooner than later.				
Something else:				

Tell your provider what is important to you and what decision you want to make.



Reminder: It is **your choice** to have an induction or not and you can change your mind.

Right now I'm leaning towards... (circle one or put an "x" in between options depending on what feels right)

- 1

Wait for labor to start on its own
- 2

Schedule induction between 41 and 42 weeks
- 3

Request induction before 41 weeks

How was this decision aid made?

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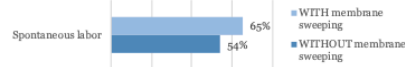
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- **Acupuncture** might help.¹²

You can ask your care provider what options they offer to induce labor.



What is the same no matter what I choose?

- **Same chance of breastfeeding**⁵
- **Same chance of neonatal complications** (seizures, pneumonia, injury, or problems getting air to brain)⁵
- **Same chance of a severe tear** in the vagina⁵
- **Same chance of too much bleeding after the birth** (postpartum hemorrhage)⁵
- **Same chance of needing help to get the baby out with tools** like forceps or a vacuum⁵

Decision Making Reflection Space

What is most important to me?	Not important	Somewhat Important	Very Important	Not sure
Have labor start on its own.				
Avoid using pain medication or getting an epidural during labor.				
Avoid any increase in the chance in my baby needing to be admitted to the NICU (6% vs. 5%) or dying (0.10% vs. 0.40%)				
Have my baby sooner than later.				
Something else:				

Tell your provider what is important to you and what decision you want to make.



Reminder: It is your choice to have an induction or not and you can change your mind.

Right now I'm leaning towards... (circle one or put an "x" in between options depending on what feels right)

1 Wait for labor to start on its own

2 Schedule induction between 41 and 42 weeks

3 Request induction before 41 weeks

How was this decision aid made?

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Version for PDSA Cycle 3

YOUR CHOICE: SPONTANEOUS LABOR OR LABOR INDUCTION?

A decision aid for people with healthy pregnancies and no medical reason for labor induction

WHAT IS SPONTANEOUS LABOR?

Spontaneous labor starts on its own and is powered by your body and your baby. It is most likely to happen between 37 and 42 weeks.

IS IT NORMAL TO GO PAST MY DUE DATE?

YES!

Without intervention...



Having a longer pregnancy is more likely if this is your first birth, you are older, or you have had other longer pregnancies.¹

WHAT IS LABOR INDUCTION?

Labor induction is when a care provider tries to start your labor with a cervical balloon or medicines instead of waiting for labor to start on its own.

WHEN IS LABOR INDUCTION RECOMMENDED IN HEALTHY PREGNANCIES?

The American College of Obstetricians and Gynecologists recommends **offering labor induction between 41 and 42 weeks and recommends labor induction at 42 weeks.**²

WHO CHOOSES IF AND WHEN I HAVE LABOR INDUCTION?

- It is **your choice** to have an induction or not and you can change your mind.
- Your care provider may recommend labor induction for the health of you or your baby. You can ask about the reasons for their recommendation and decide to say yes or no.

WHAT ARE MY CHOICES?

- 1 Wait for labor to start on its own**
- 2 Schedule an induction between 41-42 weeks**
- 3 Request an induction between 39-41 weeks**



WHAT SHOULD I KNOW ABOUT THESE CHOICES?

WHAT IS IT LIKE TO WAIT FOR SPONTANEOUS LABOR?

- You wait at home for signs of labor.
- Your care provider will offer you extra check-ups after 41 weeks.
- It can take 8-24 hours for your baby to be born (sometimes shorter, sometimes longer).

WHAT IS IT LIKE TO SCHEDULE LABOR INDUCTION?

- You and your care provider will make an appointment for your induction.
- Sometimes the date and time you want isn't available or needs to change.
- It can take 1-3 days in the hospital until your baby is born (sometimes shorter, sometimes longer).

WHAT CAN HELP MY LABOR START?

WHAT CAN HELP MY LABOR START ON ITS OWN?

- Membrane sweeps** after 39 weeks increase the chance your labor will begin. A membrane sweep involves a care provider doing a vaginal examination and making circular movements in the area of your cervix with their finger.⁴



- Nipple stimulation** (manually or with a breast pump) probably helps.⁵
- Acupuncture** might help.⁶

WHAT MEDICINES AND TREATMENTS CAN INDUCE MY LABOR?

- Misoprostol** is a pill that helps the cervix get ready for labor. The pill can be swallowed or put inside the vagina. Sometimes misoprostol can cause contractions.
- A **cervical balloon** is a tube with a balloon that is placed inside the cervix to help slowly open the cervix (dilate). It is put in for up to 12 hours to help get the cervix ready for labor.
- Oxytocin (Pitocin)** is a medicine that can be given in an IV that starts your labor and starts contractions.



Ask your care provider questions you have about these options.



WHAT IS THE SAME NO MATTER WHAT I CHOOSE?

- Same chance of breastfeeding.³
- Same chance of complications for baby (seizures in baby, pneumonia in the baby, harm to the baby's body, or problems getting air to baby's brain).³
- Same chance of a severe tear in the vagina.³
- Same chance of too much bleeding after the birth.³
- Same chance of needing help to get the baby out with tools like forceps or a vacuum.³

Think about what matters most to you.



WHAT ARE THE DIFFERENCES FOR ME AND MY BABY?

1 Wait for labor to start on its own

- Possibly lower chance of using pain medication in labor.³



- Probably more satisfaction with your care.⁸
- Probably less time in the hospital before your baby comes.
- You might want this for personal or cultural reasons.

2 Schedule an induction between 41-42 weeks

- Lower chance of your baby being admitted to the NICU and infant death.³



- Induction sometime before 41-42 weeks probably lowers the chance of cesarean birth.³



3 Request an induction between 39-41 weeks

- You might want this for personal or cultural reasons.

WHAT CAN HELP ME CHOOSE?

Think about what is important to you, ask your care provider questions you have, and tell them what you choose.

How important is this to me?	Not important	Somewhat important	Very important	Not sure
My labor starts on its own				
My baby comes sooner than later				
Birth experience				
Lower risks to me and my baby after 41-42 weeks				
Personal and/or cultural reasons				
Something else...				

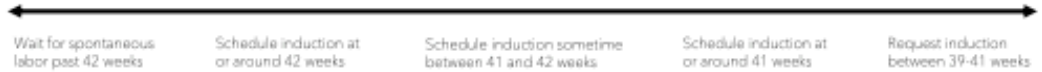
MY QUESTIONS AND NOTES:

Right now I'm leaning towards... (circle one or more options depending on what feels right)

1 Wait for labor to start on its own

2 Schedule an induction between 41-42 weeks

3 Request an induction between 39-41 weeks



How was this decision aid made?
This decision aid was made by a group of public health and medical experts at Boston University and Boston Medical Center in Boston, MA. We are asking pregnant people who are using the decision aid how we can make it better.

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Next update planned: December 2021



APPENDIX 5: Provider Guide Example (Updated for PDSA Cycle 3)

PROVIDER PROTOCOL

Materials Needed

- Laminated copy of decision aid prototype (in English, Spanish, and/or Haitian Creole)
- Printed copies of the decision aid prototype (in English, Spanish, and/or Haitian Creole)
- [Research information](#) (info card about how to give feedback on the tool)
- SmartPhrases
 - BMC
 - SmartPhrase for adding decision aid to AVS =
.bmcobiolshareddecisionENGLISH .bmcobiolshareddecisionSPANISH .bmcobiolshareddecisionHAITIAN
 - SmartPhrase for progress note =
.bmcobiolshareddecisionCOUNSELING
 - East Boston
 - SmartPhrase for adding decision aid to AVS =
.iolshareddecisionENGLISH .iolshareddecisionSPANISH .iolshareddecisionHAITIAN
 - SmartPhrase for progress note = .iolshareddecisionCOUNSELING

Eligibility

- Pregnant people receiving prenatal care at BMC, Dorchester House Community Health Center, or East Boston with healthy pregnancies (no medical indication for induction).

Pilot Protocol

1. **Conversation happens between 37–38 weeks in a prenatal appointment (summarized in BMC SmartPhrase .bmcobiolshareddecisionCOUNSELING or EAST BOSTON SmartPhrase .iolshareddecisionCOUNSELING)**
 1. Now that your pregnancy is coming to an end, I'd like to talk to you about choices you can make about how and when your labor starts.
 2. I want to give you a new tool we are trying. My goal is to support you in understanding the options and making the right choice for you.
 1. [Make sure to emphasize these **three key messages**]
 1. This is your choice and all choices are valid
 2. There are pros and cons of each choice
 3. My role is to support you in making the right choice for you
 - c. [Based on what the patient has said they care about in previous conversations or during this one, highlight any data about those (e.g., they are most concerned about avoiding a c-section)]

- d. [Consider the following notes based on which way the patient is leaning]
1. Medical indications can come up later in pregnancy (e.g., you can develop high blood pressure) so the factors and date we are considering today might change.
 2. Non-medically indicated inductions sometimes get moved around to accommodate others who need to be induced for medical reasons
- e. This tool and conversation are new. We want your feedback. Could I share your contact information (name, phone number, email address) with a BU student named Ann Peralta? If so, she would contact you and ask for feedback during a short (20–30 min) interview. You will receive a \$25 Target gift card for doing so. NOTE: If they say yes, please email this information to Ann Peralta (aperalta@bu.edu) or call her with it (617-850-5213). You should not text the information.

Depending on timing either go through the tool with the patient or ask the patient to review the tool and discuss it in the next (or subsequent visit).

2. Patient leaves with decision aid (add with SmartPhrase .bmcobiolshareddecisionENGLISH .bmcobiolshareddecisionSPANISH .bmcobiolshareddecisionHAITIAN)

- a. After the conversation, add the decision aid to the After Visit Summary (AVS) with
 - i. BMC: .bmcobiolshareddecisionENGLISH .bmcobiolshareddecisionSPANISH or .bmcobiolshareddecisionHAITIAN
 - ii. East Boston: .iolshareddecisionENGLISH .iolshareddecisionSPANISH .iolshareddecisionHAITIAN
- b. Give the patient a printed copy *with* the research information sheet so that we can gather their feedback about the tool.

What happens after the conversation?

1. If a patient agrees to give feedback on the tool Ann will interview them about their experience for 20–30 minutes and provide them with a \$25 gift card as a thank you for their time.
2. Once we have tested the tool across providers and the PI has interviewed 6–8 patients to get their feedback we will revisit the tool and process and start a new PDSA cycle IF NEEDED.

FAQ When Using the Tool

What are the latest recommendations from professional organizations on this topic?

- [WHO](#) recommends routine induction at 41 weeks

- [ACOG](#) recommends offering patients induction between 41 and 42 weeks and routine induction of labor at 42 weeks
- [ACNM](#) recommends offering patients induction by 42 weeks
- *All of them*, and [the BMC guidelines on this topic](#), recommend shared decision making given the evidence of the low absolute risk (<1%) of stillbirth and perinatal death for any individual.

Where does the evidence come from in this tool?

- Most of the evidence comes from [the most recent Cochrane Review](#) on the timing of induction of labor in healthy, low-risk pregnancies. This was published in July 2020 and includes the ARRIVE trial and the SWEPSIS trial in its results. Statistical analysis based on the latest meta-analysis methods was used to calculate the point estimates (%X) in the aid if they were not included in the Cochrane Review itself.
- The data about methods to help labor start on its own are from Cochrane Reviews on those topics: [membrane sweeps](#) (2020), [breast stimulation](#) (2005), and [acupuncture](#) (2017).
 - Membrane sweeps increase the likelihood of spontaneous onset of labor by 21% (average risk ratio (aRR) 1.21, 95% confidence interval (CI) 1.08 to 1.34, 17 studies, 3170 participants)
 - Breast stimulation increases the likelihood of spontaneous onset of labor (93.6% went into labor within 72 hours compared with 62.7% of those with no intervention) across 6 trials and 719 participants. This result was not significant in women with an unfavorable cervix.
 - “Acupuncture showed some benefit in improving cervical maturity, however, more well-designed trials are needed.”
- Patient experience data is from a qualitative research review article summarizing 20 separate qualitative studies ([Coates 2020](#)).
- The gestation information comes from a study looking at how long pregnancy lasts without intervention ([Jukic 2013](#)). U.S. birth data was not used because induction practices have shortened gestation.

What about the ARRIVE trial?

- The ARRIVE trial is included in [the most recent Cochrane review](#) and is behind the 39–41 week reduction in C-sections result. We did not include their finding on reducing hypertensive disorders because we did not include any outcome of a single study (that favors induction or waiting).
- If a patient is worried about hypertensive disorders you can share the results from a [recent meta-analysis](#) (2018) on five studies looking at 39 week inductions vs. waiting until 41 weeks (that was mainly powered by the ARRIVE trial) that found a reduction in maternal hypertension that favored induction (9% in early induction groups vs. 13% in expectant management groups).

What other evidence might help me do high quality counseling on this decision?

- We did not include data related to maternal age and parity in this tool but if relevant here is some data from articles ([Reddy 2006](#) and [Page 2013](#)) referenced in the BMC policy.

Data from Page 2013 (note these are stillbirth rates observed and not comparisons with induction. In the tool the risk from Cochrane we're using is perinatal death not stillbirth) so that is one of the causes for different numbers.

Length of pregnancy	Rate of stillbirth (the baby dies before or during birth)		
	less than 35 years old	35–39 years old	40 years or older
39 weeks	0.39 per 1,000	0.46 per 1,000	0.67 per 1,000
40 weeks	0.68 per 1,000	0.91 per 1,000	1.42 per 1,000
41 weeks	0.85 per 1,000	1.25 per 1,000	2.87 per 1,000
42 weeks	2.8 per 1,000	1.4 per 1,000	11.26 per 1,000

Does it make a difference if I've had a baby before?		Risk of stillbirth* at any point between 37 and 41 weeks of pregnancy	
Risk of stillbirth is lower if you have already had a baby before, regardless of your age. *These numbers are different than the risks of stillbirth quoted earlier for people at 39-40 weeks (i.e., 2/1000 for clients 40 and over and 1/1000 for people under 35). That's because the numbers to the right represent the risk of stillbirth at any point between 37 and 41 weeks of pregnancy.		During a first pregnancy	Age: Under 35 years About 4 in 1000
			Age: 35 to 39 years About 6.5 in 1000
			Age: 40 years and older About 9 in 1000
		During a second, third, fourth (or later) pregnancy	Age: Under 35 years About 1 in 1000
			Age: 35 to 39 years About 2 in 1000
			Age: 40 years and older About 3 in 1000

Are we really supporting all of these choices (with scheduling and L&D)?

- Yes! L&D scheduling is aware that we are doing this pilot. You can schedule patients for elective inductions any time after 39 weeks if that is what they choose.

Background FAQ

What is this project trying to accomplish?

To have pregnant people with healthy term pregnancies feel that they can make an informed and supported decision about whether and when to have an induction of labor.

Why are we doing this?

- BMC guidelines, along with the broader medical community calls for shared decision making on this topic.
- Shared decision making is high quality, patient centered care.

- Involvement in decision making increases pregnant people's satisfaction with their provider and birth overall and decreases depressive and post-traumatic stress symptoms after birth.
- Pregnant people who are people of color and have lower socio-economic status are much less likely to experience shared decision making.

How was this tool developed?

- This decision aid prototype was created by a group of public health and medical professionals at the Boston University School of Public Health and Boston Medical Center (BMC) in Boston, MA in alignment with [International Patient Decision Aid Standards](#).
- This project had no external funding and was driven by a DrPH student who was doing this as her dissertation project.
- No one involved in the design of this decision aid has anything to gain or lose by choices that patients make after using this tool.
- Patients at BMC are currently being asked for their input about this decision aid and the way it is being used by prenatal care providers.
- The tool was developed in English and is currently translated into Spanish and Haitian Creole.
- We expect the tool and process to improve as we change it based on user experience and feedback.

What is the SMOG reading level of this tool?

Grade 6

How up-to-date is this tool and process?

- Most of the data presented in the tool is from the most recent Cochrane Review on induction of labor in healthy pregnancies (published July 2020)
- The tool was last updated in October 2021.

How have previous iterations of this tool been tested?

- During each PDSA cycle patients and providers who used the tool were interviewed to get their feedback. We paid specific attention to acceptability and ease of use for providers and the following three aims for patients 1) they were clear about their role in making the decision, 2) they knew what the options were, and 3) they understood pros and cons about their options.

What are the dates of this PDSA cycle?

- Third PDSA cycle: late October – late November 2021

How will my feedback be solicited?

- Ann Peralta, the BUSPH doctoral student, will ask for it via email or Zoom. Please feel free to reach out to her at any time by email or phone at aperalta@bu.edu or 617-850-5213.

How will this tool be updated after testing ends?

- Once this tool is finalized, the data will be reviewed and updated alongside [the BMC guidelines on this topic](#).

APPENDIX 6: Guide for Application at Other Institutions

Introduction & Set Up:

- **Identify key champions and early adopters** who are most excited about using this tool and practicing shared decision-making.
- **Orient** the champions to the tool & project.
- **Key champions introduce the tool to providers to obtain feedback regarding acceptability and feasibility of use.** If relevant, discuss bias towards and/or against labor induction and the value of using a tool like this to center patient values and beliefs.
- **Consider piloting the tool to assess how to best implement it in your setting.** Map what ideal tool use looks like and get input from key stakeholders. Identify and solve for your specific barriers and facilitators and ideal workflow. Providers who tested the tool wanted a printed tool in all exam rooms and for a medical assistant to provide the tool to the patient during a certain visit (usually 36–38 weeks) for the patient to read while waiting in the exam room for their provider visit. This might or might not work for your setting.
- **Determine how you will know if using the decision aid is adding value for providers and patients in your setting.** You could look at patient and/or provider experience or use quantitative data to assess impact.
- **Identify and troubleshoot pre-existing systems that facilitate or impede patient decisions.** Examples of this might include your induction scheduling system, facility resource limitations, specific policies, or standards of care.

Implementation Considerations:

- **The provider guide can be used and modified to meet the needs of your setting.**
 - **This decision aid was effective when introduced during a 36–38 week appointment, either discussed in the visit or given to the patient and discussed in the subsequent visit.** Patients appreciate discussing it before 39 weeks because it allows them to have time to sit with the information and make a decision that is right for them.
- **Consider printing the decision aid in color if you have the funds to do so.** It is designed to print on 11x17 paper and then folded in half as a handout for patients. Providers and patients appreciate having hard copies, particularly in color. Providers are able to show it on their computer screen or use laminated copies in their office.
- **Consider adding the tool to the after visit summary.** Consider how patients receive other documents.
- **Consider where else to integrate the decision aid.** Do you want a pre-written phrase to document counseling in your electronic medical records? Should this be bundled with other patient education materials you provide at a certain visit or week?

Adaptations to the decision aid:

- **Please correspond with the decision aid’s author, Ann Peralta, about any ways you might need or want to alter the decision aid.** The decision aid has been written to be as universal as possible in terms of the categories of choices that one can make at most institutions. Because it is copyrighted you must seek permission from the author to use it in any way that is different than written.

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CURRICULUM VITAE

