

# **Implementation of Shared Decision Making in Three Obstetric Clinical Settings**

Final Report

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Final version

## **Executive Summary**

In 2016 Washington State began a state-level SDM certification and implementation program to increase the use of Shared Decision Making (SDM). The University of Washington team evaluated the SDM implementation process for the state in the area of obstetric decisions for Cesarean birth. We interviewed healthcare system leaders, providers, and patients from three healthcare system clinical sites, before and after the implementation of SDM processes, to better understand the facilitators and barriers to implementation. In general, healthcare system leaders were positive about the implementation process for SDM, both before and after the implementation. Providers were mixed in their opinions about SDM and the use of the SDM process, while patients were very positive and supportive. Overall in two of the three healthcare system settings the implementation was found to be successful. This report includes suggestions regarding use of the SDM process that could guide future implementation efforts. These include increasing the initial buy-in of providers to the need for SDM, assisting providers to engage in a process that includes self-evaluation and feedback, and consideration of clinical work flow changes that could help providers engage patients.

## **Background**

Cesarean birth (birth by C-section) is a surgical procedure that involves an abdominal incision into the uterus to extract the fetus. In the U.S., C-section rates have skyrocketed, increasing from 21% to 32% between 1990 and 2015.<sup>1</sup> C-sections, as with any surgical procedure, carry risks of complications, including increased bleeding, uterine rupture, infection to the mother, and breathing problems for the child. These risks increase with each C-section performed. Women who have given birth by C-section in the past have the option in WA state of delivering either by a repeat C-section, or by a trial of labor after cesarean (TOLAC) (i.e., attempting to give birth vaginally). The decision depends in part on the risk status of the woman and fetus.

Approximately 26% of C-sections are performed on women characterized as “low risk” for birth complications: women with a singleton, term (37+weeks) pregnancy, and vertex presentation (head first) at birth.<sup>2</sup> These populations of low risk women are prime candidates for TOLAC. However, the decision to

attempt vaginal birth or to schedule another C-section has been controversial. Many providers see TOLAC as a malpractice liability, given the risk of adverse events to the mother or fetus, while many of the patients do not fully grasp the risks and benefits of either option.

Various initiatives are underway to promote shared decision making (SDM) and the use of personal decision aids (PDA's) as standard of care, particularly for complex medical and treatment decisions, like TOLAC. The process of SDM educates both the provider and the patient while taking into consideration the values and preferences of the patient. PDA's support patients in the SDM process by providing knowledge, discussing risks and benefits, and weighing preferences for care options. Research shows that use of PDA's leads to increased knowledge, more accurate risk perception, and fewer patients remaining passive or undecided about their care. However, most clinical settings do not use PDA's and little is known of the best methods to implement SDM programs into clinical practice, particularly since they involve a culture shift towards a more centralized and defined concept of shared decision making.

In an attempt to promote SDM among providers, in 2016 Washington State began a state-level SDM certification program. The Washington State Health Care Authority (HCA) recently certified a SDM tool to help providers convey information to potential TOLAC candidates and to facilitate a conversation about the best option for the pregnant patient. Washington's TOLAC SDM pilot program consists of multiple parts, including the certification of a PDA, SDM concept training, and optional vendor guidance/mentoring for the SDM implementation.

We conducted an evaluation of the pilot implementation program using qualitative data collected from patient-provider interviews and content analysis of documentation associated with the program implementation to determine: a) if SDM tool is being used, b) how it is affecting the patient experience of delivery choices, and c) how it is affecting the provider experience.

### **Significance of the Problem**

Shared decision-making is a recent focus for implementation in the medical setting. Studies of various

medical choices indicate that SDM improves patient knowledge and satisfaction with many types of complex medical decisions.<sup>3</sup> However, evidence reveals that providers struggle with integrating SDM into their workflows and often feel overworked, crunched on time, and burned out.<sup>3</sup> Despite these barriers, the value of SDM is recognized not only by providers, but researchers and health care systems as well. The center for Medicare and Medicaid Services (CMS) announced in 2016 that it was going to support “beneficiary engagement services” defined broadly as “the actions and choices of individuals with regard to their health and healthcare.”<sup>3</sup> CMS is supporting three models, one of which is SDM, defined as a decision-making collaboration between provider and patient.<sup>3</sup> According to CMS, SDM is best for “preference-sensitive conditions,” or those for which there is no clear evidence that one option or course of treatment is generally clinically superior to another.<sup>3</sup>

While not considered a condition or treatment, pregnancy and birth (either vaginally or by cesarean) do fit the description of a preference-sensitive condition, especially for women who have had a previous C-section. Research indicates that for each cesarean, a women’s risk of uterine rupture, bleeding, or infection increases, but vaginal birth after a cesarean also carries risk of uterine rupture and increased bleeding.<sup>1,2</sup> However, these differences are small and vary from woman to woman – making a general recommendation very difficult from a provider’s perspective. One component that may contribute to provider support for secondary cesareans over TOLAC is fear of liability if a patient has a complication during a TOLAC. HCA has supported a pilot study that examines various stages of implementation of a PDA for TOLAC and provider SDM education.

This study uses interview data from stakeholders before and after the implementation period of the SDM process from three obstetric clinical sites using two different TOLAC SDM tools. To measure changes in SDM, we compared data collected pre-PDA and SDM training implementation with follow-up data to see if there is a change in the clinical care patient-provider interaction after implementation.

## **Methods**

### **Design**

This is a pre-post observational study. The primary exposure is the TOLAC SDM process used during the patient visit. The primary exposure was assessed by qualitative interviews with key stakeholders: HCA, vendors, health system leaders, providers, and patients, assessing what SDM steps were used and what steps were of most value in making the final decision.

The implementation of SDM involved multiple components, and each of these components needed attention and support by implementers and clinics. Figure 1 shows the components of the SDM process as they were seen for evaluation purposes. The SDM process has multiple components to be implemented, including training, tool selection, integration into clinical flow, and documentation. The hypothesis is that implementation of these components shown on the left hand side of Figure 1, will result in improvements in both consumer and provider perspectives on the decision and will enhance communication between the two entities. Table 1 shows the principles of SDM used for the evaluation purposes. These principles came from the extensive literature on SDM processes and tools<sup>3-7</sup> and were used to guide the implementation and the evaluation.

### **Settings and Sources**

The University of Washington team conducted the evaluation of the SDM process. Qualitative interviews took place with study participants from all three of the study sites. Table 2 contains a brief description of the sites. Additional data sources included documents on the technology itself (i.e., the PDA's, electronic training materials, and Electronic Health Record (EHR) documentation protocol); implementation plans provided by the vendor; and project management plans, training modules, and IT-related content provided by the pilot sites.

### **Study Participants**

Our evaluation provided data on the entire SDM process -- from patient uncertainty regarding choice of delivery type, to provision of the patient decision aid, to the ultimate decision of delivery method. We selected participants across multiple levels of stakeholders: government sponsor, pilot site, role-model health system, training vendor, PDA vendor, providers and patient. Healthcare system leaders were selected if they

had a role in planning or implementing the SDA process. Providers were eligible if they had any clinical contact with any patients regarding the decision on method of delivery, at any point in the pregnancy and birth process. Patients (follow up only) were eligible if they were between 24 and 38 weeks pregnant at the time of the interview and were receiving care at the enrolled clinical system. Thus, some patients were interviewed after the birth of their child. This enabled the researcher to analyze a continuum of care, allowing for a more meaningful and representative evaluation of how well the provider facilitates the SDM process for the patient and, likewise, how the patient engages in the SDM conversation.

Eighteen pre-implementation interviews were conducted with implementation stakeholders. Fourteen post-implementation interviews were conducted with providers, and 20 post-implementation interviews were conducted with patients. We attempted to complete surveys of all providers and patients, as well as interviews. Two of the three sites recruited and enrolled in the study refused to allow surveys of their providers and patients. Therefore, we only present interview data from all three sites.

### **Data Collection Content**

For pre-implementation, there were three interview guides, one for each of the following groups: provider, vendor, and government sponsor. Areas addressed in the protocols include a) implementation effectiveness, b) workforce issues, c) context, and d) program effectiveness.

For provider post-implementation interviews, there was a single interview guide. Areas addressed in the protocols include a) workforce issues, b) context, and c) program effectiveness. The patient post-implementation interview guide focused on characteristics of the patients (i.e., patient name, age, preferred language, site, stage of pregnancy [expected delivery date], number of previous pregnancies and delivery type, whether the patient has looked at the SDM tool) as well as characteristics of the patient-provider interaction.

### **Data Collection Procedures**

Stakeholders were asked if they wanted to participate in data collection activities. Interested participants then were invited by e-mail to be interviewed. The interviews were conducted by the lead UW investigator and/or an experienced research assistant using a semi-structured interview protocol. At the time

of interview, the Principal Investigator (PI) explained the informed consent process and asked permission to audio-record the interview for transcription purposes. If consent for audio recording was obtained, the PI pushed start on the recorder. Interviews lasted 45-60 minutes, were conducted by phone, and audio-recorded with permission. The interviews were completely confidential. The notes taken during the interview by the PI and scribe were uploaded to a secure server for later access if needed. Audio recordings and their transcripts were stored on a secure server accessible only by the research team. At the end of the interview, which lasted between 45 minutes to an hour, the PI stopped the recording and sent it to a transcription service. Once the transcripts arrived, they were uploaded to a secure server, where the PI or other coders could access and edit them to ensure coherence and completeness of information. Interview results were de-identified before being reported.

Follow-up interviews were collected with relevant health system leaders and providers at approximately six months post implementation. We interviewed patients from each site using the same general procedures for collecting and securing data as for the providers.

### **Data Analysis**

Transcribed and 'cleaned' audio interviews were uploaded to Dedoose, a qualitative data management software<sup>8-9</sup>. Data were analyzed using iterative deductive and inductive content analysis. Dedoose © software was used for qualitative data management and analysis. Deductive content analysis consisted of identifying quotes that fit within pre-identified categories (i.e., SDM training, culture/context, readiness, sustainability, satisfaction with PDA, challenges, facilitators) developed by the research team based upon prior research and suited to the goals of the evaluation. Further content analysis entailed open-coding and iteratively revisiting and reconciling coding labels associated within each pre-identified category as new codes emerged. The team analyzed the resulting codes to identify, reconcile, and stabilize key themes and insights; through this process we moved coded data to reconciled descriptions suited to addressing the purposes of this evaluation. Patient-related factors were included in this analysis to help reveal how patient characteristics might impact the

conversation between patient and provider and the level of shared decision making that took place. The qualitative analysis aimed to identify implementation insights and patient and provider perceptions of the tool and implications for future use of SDM.

## Results

The sites chose differing SDM tools for implementation. In Site A, part of a health system serving the north Seattle population, a paper copy of an SDM tool developed by the British Columbia (BC) women's clinic called "Power to Push" was handed to the patient during a visit between 26-32 weeks of pregnancy. Site B is part of a health system serving the southern Puget Sound population. In Site B, a SDM booklet was developed with Healthwise (the certified SDM tool vendor) and given to the patient during a visit between 28-32 weeks of pregnancy. Site C is part of a health system serving the north King and south Snohomish counties. In Site C, providers referred eligible patients to attend a one-hour class, which they adapted from the "Power to Push" tool.

### BASELINE INTERVIEWS

#### *Contextual Factors*

**Adoption, Planning, and Engaging.** HCA was strongly motivated about the SDM initiative, with an internal champion stating, *"We have such a huge opportunity here to test something that's really important."* They (HCA) were also well-positioned to launch the pilot program, having had a local role model with 3.5 years of SDM experience to serve as a consultant. At the heart of the many of the obstacles to SDM adoption, however, is a phenomenon that as one participant said, *"It's still kind of a chicken and egg thing"* As stated by a state administrator, (HCA) for health care systems to adopt SDM widely, SDM proponents need to *"actually show and demonstrate that this works."* But to accrue evidence of SDM's value, SDM needs to be more widely adopted. The hope was that the pilot program would *"plant the seeds"* of SDM (HCA).

**Information Transmission.** Although clinical champions were seen as a catalyst to SDM implementation and adoption, participants felt that there was a general lack of communication about the value of SDM. This communication gap was identified as a barrier to the clinical community's support of SDM

and the pilot program. Some participants felt that the state could do much to raise awareness and make existing SDM training and PDA's and resources available to health care providers. Some participants also felt that HCA should more clearly communicate the value of SDM and certification to providers.

**Organization Priorities and Goals.** Implementation of SDM was a means to comply with state requirements. Though the pilot sites are contracted to provide SDM only to the Public Employees Benefits (PEB) members, all pilot sites deployed SDM to all patients. The process of PDA selection was a challenging and *"critical step"* (Pilot Site A) that could have stalled the implementations; the pilot sites ultimately pushed forward because they felt it was *"the right thing to do for our patients and families"* (Pilot Site A).

**Culture / Climate / Context.** The level of enthusiasm at each site depended on how SDM was presented. According to the participants, SDM and the SDM program needed to be sold through its concept, rather than its content. Some stakeholders maintained that SDM should be sold as a quality improvement initiative; otherwise, it may be perceived as yet another task that adds to the workload. *"Getting somebody's LDL from 101 to 99 so that I counter a score on a website is not necessarily something that's easy to sell to a family practice because (they) could just feel overworked, because they don't think it matters. And it's quality improvement that matters; that when they see it and feel it, they know that they changed their practice in a way that they know made it their practice."* (Healthwise vendor)

**Absorptive Capacity / Structural Characteristics.** All pilot sites encountered competing priorities (e.g., EHR upgrade) and numerous, unexpected delays that drained their initial enthusiasm about the pilot program. Constraints on cost and time led Pilot Site B to begin with a paper-based PDA versus their ideal electronic PDA that required expensive EHR integration. Pilot site stakeholders said they felt frustration because *"factors out of our control"* (Pilot Site A) were causing the delays.

**Sustainability.** Implementing SDM is an expensive undertaking, so before making such investments, health organizations have to be convinced that these investments add value. Participants indicated that return-on-investment of SDM is difficult to demonstrate, however, making it vulnerable to cost cutting. Participants also noted that health care organizations operating with thin margins are unlikely to have extra

money to invest in PDA's on their own. As one provider expressed, *"we assessed different opportunities [...] and the cost was just very, very high and prohibitive for a pilot."* (Pilot Site A) Some reported hesitation to participate in the pilot, due to uncertainty about future HCA financial and resource support for SDM.

**Scalability.** Despite this vulnerability, the pilot sites all demonstrated initial commitment to the intent and goal of the SDM initiative and were all looking past the initial implementation to replicate efforts, either to expand to additional OB clinics or to additional service lines.

### ***Innovation Components***

**Evidence Strength and Quality.** One of the challenges that the HCA encountered with getting the pilot sites to choose the certified PDA was lack of physician buy-in. For example, despite administrative leadership endorsement of Healthwise's certified PDA, physicians initially held up SDM implementation because they were dissatisfied with the PDA and the inability for Healthwise to modify it (as it would need to go through the certification process again). Of TOLAC PDA's in general, *"I felt like they weren't complete. They were a little bit biased. Some of them [...], I think, would provoke some anxiety and alarm with patients."* (Pilot Site A)

**Adaptability.** Although the original vision was for electronic PDA's (rather than paper-based), participants debated the advantages of the different PDA modalities. Pilot Sites A and C ultimately chose the paper option as a starting point, and Pilot Site B created a one-hour class based on their chosen paper-based PDA. Participants commented that paper PDA's are easier for patients and providers to use. The paper and classroom options require less upfront time and resources and do not require modification of EHR systems. *"The IT build is one of our major time obstacles. We don't have an IT department that's going to prioritize this as number one, and so we needed something fairly simple for them to be able to get it done in less than a year, really."* (Pilot Site A) All sites recognized that electronic tools can be powerful and hoped to one day move in that direction. As one provider said, *"I think electronic is absolutely where this should go. I mean, that is where our millennials want us, going in that direction."* (Pilot Site A)

**EHR Integration.** Some participants spoke of the importance of documenting the SDM process, informed consent, and final decision. This required another component of SDM innovation – EHR customization. As shown in Table 2, the three pilot sites differed in their EHR capabilities, resulting in a range of EHR customizations. Pilot Sites A and C worked with their IT departments to create long-term EHR solutions for PDA implementation. Pilot Site B, due to limited resources, did not build a permanent EHR solution and instead documented SDM in the physician note.

**Cost.** Finally, an important consideration for all components of the SDM innovation was cost: *“It’s really costly. It is not just costly to typically license the tool, but you have to think about the engagement of an IT team, possibly doing some development work, you know, long-term tracking, making sure the data elements are filled and then set up correctly.”* (Healthwise) In a completely-electronic scenario, use of Healthwise’s electronic, EHR-integrated PDA would have cost each pilot site \$2,100 per month per 10 providers. One provider noted that she preferred Healthwise’s electronic, certified PDA to the paper-based one by BC Women’s Clinic, but it was simply *“cost prohibitive”* (Pilot Site B). All three sites ultimately chose the free paper or classroom versions of the PDA’s.

In terms of training, HCA provided free access to Healthwise’s SDM skills course and implementation services; however, the pilot sites did not use these free services because of the cost of personnel time. To decrease the time demands of training, Pilot Site C created a way for their staff to take the SDM skills course in a group setting, after clinic hours, with all members of the clinic discussing the course together.

### ***Implementation Process***

**Overall Process.** In designing the SDM process, the pilot sites also took similar steps to carry out the implementation. They furthermore had similar outlines for the distribution and documentation of SDM: 1) Distribute PDA to patient at specified time; 2) have SDM conversation with patient; 3) document SDM encounter; and 4) document patient’s outcome. There was variation, however, among the pilot sites on the details of these four steps. One example of minimal enforcement was reflected by a clinical champion: *“I just*

*have faith that the providers out there are aware of the (PDA), and so I'm hoping that they're sending their patients to the (PDA)."* (Pilot Site B) In terms of assembling an implementation team, participants noted the importance of identifying a clinical champion, as well as obtaining leadership support.

**Indicate conformance with legal requirements.** All pilot sites were frank about their participation in the SDM program being driven in part by their contractual obligations to HCA. While all pilot sites saw value in SDM for patient care, they were engaged in the pilot program also *"to fulfill what HCA is asking."* (Pilot Site B) During the interviews, we noted that the extent to which a pilot site considered this a contractual obligation moderated their level of enthusiasm and engagement in all components of the SDM program.

### ***Evaluation of Implementation Effectiveness***

None of the sites initially planned for a formal self-evaluation of the pilot program. HCA did not set standardized criteria or benchmarks but did expect sites to share their results.

**Fidelity.** The pilot was not carried out by healthcare systems in the ways it was originally intended. For example, HCA had hoped to implement electronic PDA's because of their potential to record patient interaction, assess understanding, document choice, use branching, and present information in multiple formats (e.g., video). But as mentioned, all the pilot sites used a paper or classroom format.

**Reach.** Some measurable metrics identified by our interviewees included: Were providers trained in SDM? Were providers able to distribute the PDA? Were providers able to get the PDA to the right people (i.e., eligible patients)? How frequently did the PDA get into the hands of patients?

Healthwise also provided the participating sites with a report at the end of every week that indicated: a) who completed the training, b) who did not log in, and c) who opened the training but did not complete the course. At Pilot Site C, all staff directly involved in TOLAC (including front desk staff) completed the training. For Pilot Site A, only 4 out of 30 providers participating in the SDM program did not complete the training (87% completion rate). For Pilot Site B, the SDM training was available and providers participating in the program were invited via email and at a department meeting. However, no one completed the course. Explanations as to why no one completed the course included: a) no time, b) lack of continuing medical

education (CME) credits, and c) not necessary. As one clinician participant put it, *“Most of us do this anyway”* (Pilot Site A).

Regarding patient reach of SDM PDA’s and education, one clinical champion felt that 100% patient adoption was a *“pipe dream,”* citing language and literacy barriers (Pilot Site B); this provider thought it was more realistic to aim for 80% patient adoption. To assess its patient reach goals, Pilot Site B developed a postpartum survey, containing questions about the SDM patient-provider encounter and whether the patient attended the class. Pilot Sites A and C used the paper-based PDA and developed evaluation reports using data collected through the EHR to determine the number of patients engaged in the TOLAC SDM program.

**Care Quality and Health Outcomes.** Regarding the influence of TOLAC on C-section rates, one participant said *“My gut feeling is that’s not, it’s not going to shift in either way.”* (Pilot Site B) All stakeholders were hoping for better health outcomes, but reduced C-section rates were not expected. One barrier to reducing C-section rates is that patients may have had a traumatic birth experience during their previous pregnancy that resulted in an emergency C-section. One provider talked about how they have to *“take away everybody’s fear”* when first discussing TOLAC with those patients. (Pilot Site C)

**Perceived Value of SDM.** Every pilot site reported that SDM was something providers already provided. Providers from two sites stated *“most of us do this in our own way”* (Pilot Site B & C). One indicated that it was the language that they hadn’t heard before, but that the concept was something that had always been done. *“You know, honestly, before this pilot study happened, I wasn’t familiar with the term shared decision making. I do think a lot of our providers are offering shared decision making. They are just not aware that it’s (called that) some people were presenting it like this novel idea and it’s really not.”* (Pilot Site A) In addition, there seems to be uncertainty among providers in regards to the difference between SDM and patient education, with one provider stating *“I don’t think there is real difference. I think the shared decision making tool is education.”* (Pilot Site A)

Interviewees recognized SDM’s aim to enhance the conversation between the patient and provider, aligning medical expertise with patient’s values. However, they commented that this is difficult to measure.

The following anecdote showcases a successful SDM encounter: *“One of my patients went through the class. I had initially said, ‘I really don’t want you to try labor. I don’t think you’ll be successful, but if you really want to do it and you go to this class, we’ll let you.’ (...) She had a very complicated labor, ended up with another C-section anyway, ended up needing to be in ICU and get a transfusion. But at the end of the day, she said, ‘I made that decision. You all told me what could happen, and I knew I could have a complication. But I still feel better that I tried.’”* (Pilot Site B)

## **FOLLOW-UP INTERVIEWS**

### ***Leadership (Administrative Perspectives)***

At the three pilot sites, healthcare system leadership continued to perceive SDM primarily in terms of compliance with state requirements and contractual obligations. However, administrators from all sites indicated that SDM is part of a changing healthcare landscape aimed at making consumers more involved in their healthcare consumption and decision.

One administrator mentioned that SDM will be integral to the future of population health: *“I think shared decision making has become an important area for [population] health. So, even where we came from, which was very much around ‘oh we need to meet a contractual deliverable’ it’s [baked] into our contract. The road going ahead over the next two, three, four years to me is we cannot do [population] health without integrated shared decision making in the point of care”* (Pilot Site A).

The administrators for both sites that implemented SDM across all clinical encounters indicated that SDM was sustainable for their organizations and that there was both organizational buy-in and provider buy-in throughout the pilot.

### ***Provider Perspectives***

There were two main provider types for this pilot: certified nurse midwives (CNM’s) and medical doctors (MD’s). There was also one physician assistant. The CNM’s and MD’s ended up with very different responsibilities concerning the implementation of the SDM TOLAC tool, since midwives at one site were not

allowed to follow TOLAC patients. The interviews with the CNM's offered insight into the difference in practice between CNM's and MD's, with CNM's almost universally indicating that SDM has always been a key tenet of midwifery: *"It's the standard of practice for us...we are always giving our [patients] all of their options. We always have the patient at the center of care in the midwifery practice. It's just how we run; it's how we flow."* (Pilot Site A) Furthermore, the CNM's expressed excitement that SDM was beginning to take root in other medical practices: *"[The] wonderful part was the thought that maybe all providers were... if many providers were being required to do this, that would increase patients being really actually at the center of care in the whole system."* (Pilot Site A)

Both midwives and MD's offered insight into the barriers to providing SDM to patients. The most common barrier cited by interviewees was lack of time. *"The OB's at [Pilot Site A] are working so hard that we rarely have a chance to talk about [the SDM tool]"* (Pilot Site A). This makes sense when considering that CNM's have a considerably longer appointment time with patients, compared with OBGYN's, and thus have more time to implement SDM measures and tools. OBGYN's consistently expressed that they valued SDM: *"It's kind of like when they give [the tool] to us (OBGYN's) it's like one more thing to do, and it felt onerous. Then I got some positive feedback on it and then it's like all right, how can I help engage people in the conversation more?"* (Pilot Site A) However, the time constraints and severe workload (bordering on burnout) kept OBGYN's more skeptical about the sustainability of SDM long term, with one physician stating the main barriers to the sustainability of SDM at their site were *"time and resources"* (Pilot Site B). Another provider justifies the additional work as something that improves her patients' overall well-being: *"Is it improving the overall interaction and quality? And the answer is yes, and so that's the answer. It's one more conversation to have and it's... it takes time but that's what we are here to do."* (Pilot Site A) These findings indicate that it might be time-efficient to engage midwives in discussions with patients about SDM more frequently, given the comfort with the discussion and the time spent with patients.

Some of the greatest insights from the provider interviews related to how SDM could be incorporated into other areas of women's health. Suggestions included making formal SDM tools for health issues such as

fibroids, menstrual bleeding, birth control options, and miscarriage management. These suggestions came from both CNM's and OBGYN's – suggesting that there is a future for SDM in women's health.

### ***Patient Perspectives***

Most of the patients interviewed indicated that their decision was to try labor (TOLAC). Some patients had specific reasons for why they ultimately chose TOLAC, such as the benefit of a faster recovery time: *“from a recovery standpoint and just how things are naturally supposed to work [my husband and I] wanted to try and stick with a natural birth, as close to that as possible.”* (Pilot Site A) Another reason for wanting a TOLAC was to lessen the risk for complications for future pregnancies: *“I felt like when I previously had had the C-section, I didn't realize the risk for the second pregnancy. And so I really wanted to do the VBAC to reduce even greater risks to pregnancies that I may have.”* (Pilot Site A)

While most patients indicated that they knew *“immediately after my first C-section”* that they wanted TOLAC the next time around (Pilot Site A), five women self-identified themselves as healthcare providers, four of whom were actually OBGYN's themselves, which may be a reason for the high number of women in our sample that chose TOLAC. The one woman who chose to go through with another C-Section indicated that she did not want to go through what she experienced with her firstborn (a traumatic birth experience that resulted in an emergency C-section).

Having a previous traumatic birth experience was not uncommon among our sample and was pivotal in shaping the information these woman sought regarding the choice of TOLAC/VBAC for their most recent pregnancy. *“There are so many barriers and so I felt like... well now, I have more clear and definite information about what the risks are and the benefits are. I was able to talk to my doctor about my own experience with my first birth and what kind of anxiety that produced.”* (Pilot Site A) This may be why women consistently listed the statistics and graphs in the tool as the most beneficial component in helping them make their final decision: *“I was **like** wow this has a lot of facts. I guess I was impressed by this factual data but also I felt like **well gosh** either way there's risks and benefits. So it was really info I felt [...] was very informative. So it did the job that it had been intended to do. [...] It really depends on ultimately me, so it [the tool] didn't give me the*

*right answer, but it gave me the information in order for me to make a good decision” (Pilot Site A). They also stated that it was beneficial for their partners, that it helped them understand the risks of each and put their partners at ease (because their partners were also afraid of another traumatic birth experience). “So my husband and I had several conversations around [TOLAC or C-Section], and we had an unplanned C-section with our first child, our daughter, and with the second pregnancy we really wanted a natural birth. We were pretty satisfied with how the doctors handled everything with the first one but from a recovery standpoint and just how things are naturally supposed to work, we wanted to try and stick with a natural birth as close to that as possible.” (Pilot Site A)*

All patients indicated that their provider was very supportive of their decision and helped them affirm their original thoughts: *“I think her openness in discussing my preference and really talking through everything with me. So she fully understood where I was coming from and what I wanted and then she was there to help support that path forward and provide the best guidance she could.” (Pilot Site A)* Every patient also responded that providers should continue to have conversations with their patients, and check in with them about their own beliefs: *“What advice would you give to providers having SDM conversations with their patients? Remember to keep the values of the patient in mind, as evidence-based data may not persuade a large percentage of people, but their choices may be based on anecdote or other reasoning. Try to gauge the strength of opinion and ask the patient what kind of information they need or want to help them with their choice.” (Pilot Site A)*

The overall satisfaction with the pilot and tool was overwhelmingly high, with most participants indicating they were “Highly satisfied.” (Pilot Site C) The only patients who said it was not of particular help to them as patients were the patients who also were medical providers. These provider-patients indicated, however, they would love to use this with their own patients.

Both patients and providers had suggestions for improvements. One common suggestion was that the tool should be available in more languages: “It would have been great to have the tools available in other languages” (Pilot Site C). This need for diverse languages was heard from all three sites.

## LESSONS LEARNED FROM THIS EVALUATION

- **Health systems can leverage compliance with state SDM requirements to advance their organizations' priorities and goals.** Implementation of SDM was a means to comply with state requirements, as well as to improve care. This is likely a positive finding, as it accomplishes two important goals.
- **Perceptions of SDM depend on organizational culture, climate, and context.** The model used for evaluation produced several insights that might help future healthcare systems explain and improve upon the implementation process.
- **An organizational culture of "Plan, Do, Study, and Act" (PDSA) can be a powerful facilitator of SDM implementation.** This kind of a culture is becoming usual care in health care settings where new findings must be incorporated. Only in one clinical site was the SDM evaluation embraced and welcomed, and where feedback about the baseline was used to guide later implementation efforts. Setting the expectations for such activities would be helpful for future practice changes to be more successful.
  - **SDM implementation requires more time and resources than many organizations anticipate.** Organizational change takes time, and not allowing that time meant delays in start date, evaluation, and change. Furthermore, the certification program seemed to add time to the implementation process, *"You need to start about six months sooner than you think. It's not smooth because of contracting issues."* [HCA]
- **A strong business case is necessary to convince organizations to implement SDM.** Many of the comments of healthcare system leaders and providers focused on cost, in many forms (e.g., dollars, time, discussion, etc). Better attention to cost and resources, plus better planning, might make for more efficient and timely implementation.
- **Organizations see SDM as part of a long range strategy.** Organizations take the long view, and short term issues are often not as important as ultimately implementing good care over time. This contrasts with some providers' views about the short term disruption of common procedures.
- **Customizable PDA's are more likely to get physician buy-in.** For TOLAC, the heavy workload of OBGYN's was a barrier to physician buy-in. Some physicians perceived SDM as just another administrative burden.

Many felt that SDM is something that they already practice, while others confused SDM with the informed consent process. A PDA that physicians can tailor to their specific needs is more likely to increase efficiency, trust, and buy-in. Despite administrative leadership endorsement of the certified PDA, physicians initially held up SDM implementation because they were dissatisfied with the PDA and the inability for the vendor to modify it (as the PDA would need to go through the certification process again if it were modified). Of TOLAC PDA's in general, *"I felt like they weren't complete. They were a little bit biased. Some of them [...], I think, would provoke some anxiety and alarm with patients."* [Pilot Site A].

- **Electronic PDA's are the ideal, but low-tech PDA's are faster and easier to implement.** With two of three sites choosing paper tools over electronic tools, and choosing to not take time to alter the EHR to document Shared Decision Making, the immediate and short term solution was seen as easier to implement.
- **EHR integration is important for documenting the SDM process.** Even sites that chose a paper tool wished that they had the resources to alter their EHR.
- **Cost is a major barrier to SDM implementation.** An important consideration for all components of the SDM innovation was cost and resources to implement anything new.
  - **A clinical champion is important to shepherd SDM implementation.** The general process for SDM at the pilot sites was to: 1) Distribute PDA to patient at specified time; 2) Have SDM conversation with patient; 3) Document SDM encounter; and 4) Document patient's outcome. There was variation, however, among the pilot sites on the details of these 4 steps, such as when the PDA was distributed to patients, how the SDM encounter was documented, and even whether the SDM process was required or simply recommended.. Clinical champions for TOLAC should include CNM's in addition to physicians. CNM's might be better suited to deliver SDM for TOLAC, or at the very least should be able to follow TOLAC patients to alleviate some of the burden from OBGYN's.

- **Timely certification is valued.** Overall, participants reported that they saw value in the certification process to ensure rigor in the PDA. Some pilot sites viewed the certification process as taking too long, and adding little value. The lengthy review process led some to conduct their own review and research of PDA's.
- **Contractual obligations for SDM need to be stated clearly.** Sites worked to the contract specifications, or used them to guide implementation.
- **Metrics can yield valuable insights on SDM reach.** All pilot sites were interested in provider satisfaction, patient satisfaction, whether the information was being presented in an unbiased way, the percent of eligible patients using the PDA, how many steps of the SDM process were being completed, and C-section rates.
- **Stakeholders see value in SDM implementation even if improved health outcomes are not immediately demonstrable.** One government sponsor stakeholder even noted that improving standard health outcome metrics "*would be a first*" [HCA]. The end-goal, however, was for an informed decision process that helped to determine when TOLAC is appropriate and C-sections could be avoided. Prior to the pilot, none of the pilot sites had a way to explicitly document that a SDM conversation occurred. The essence of the SDM pilot program was an opportunity for standardization and implementation of a process and philosophy of patient engagement, a process that otherwise may only sporadically be used.
- **High levels of patient health literacy are a potential facilitator of SDM implementation.** In the project, the patient population included a high proportion of patients with medical field expertise. This may have contributed to the higher number of TOLACs/VBACs in our sample, as well as a biased level of knowledge on VBAC vs C-section. Only one patient thought their provider was biased towards TOLAC, but this patient also changed providers (from out of state, to Washington) which may actually indicate that providers outside of Washington spend less time discussing TOLAC/VBAC vs. C- sections:

*And I talked to... we actually moved to Washington halfway through my pregnancy, so I started out my prenatal care in Wisconsin. And I talked to the doctors there and when I moved here Dr. Tory was phenomenal at North West but she continued to support my decision and make sure that I knew all the risks and benefits and everything with moving forward with the way that we wanted to. (Pilot Site A)*

And this quote illustrates that well-informed patients will choose providers on the basis of perceived quality of care: *"I chose my provider specifically because she is the most VBAC friendly provider in Seattle, so I already knew her position, and she knew I was there for a VBAC"* (Pilot Site A)

- **Provider satisfaction with SDM is impacted by the training experience as well as patient satisfaction and ownership of medical decisions.** Regarding provider satisfaction, the only data currently available is informal feedback on a SDM training sponsored by the certification program. On the positive side, trainees indicated that the training was interesting, composed of short modules, allowed self-pacing, facilitated interaction, allow you to *"hear what the patient says,"* were useful and presented in an attractive way. On the negative side, some trainees commented on the length of the training (*"Does it have to last 90 min? Is that the most effective way for training?"*), technical glitches, and redundant information.
- **Regarding patient satisfaction, early evidence from the pilot indicates that it can be increased through SDM.** Pilot sites evaluated satisfaction through informal conversations with providers and more formal data collection from their patients. Pilot Site B, which deployed their PDA as a class, used their organization's course evaluation survey to gather immediate feedback from patients. Thus far, providers reported hearing from patients that the SDM process helps patients take *"ownership of that decision"* [Pilot Site B]. Unbiased PDAs also help *"take away some of the fear and anxiety and possible trauma that [patients] might have had with the first delivery."* [Pilot Site C] Indeed, women who suffered a traumatic delivery experience may be the ones that benefit the most from SDM for TOLAC. It can put them at ease with their decision while also reassuring them that nothing is set in stone. As

one patient said: *“Because there are so many barriers and so I felt like well now I have more clear and definite information about what the risks are and the benefits are. But then I was able to talk to my doctor about my own experience with my first birth and what kind of anxiety that produced and I'm not willing to go through that again. And kind of looking at my own reaction to this emergency situation and gosh is that going to be helpful or not. And so it was good to be able to verbalize that out loud rather than having it kind of going around in my head.”* (Pilot Site A) Both providers and organizational leaders want to capitalize on the power of SDM as a way to incorporate more patient ownership of decisions: *“I feel this is a great way to have the patients become involved in their care and making the decisions that they are comfortable with.”* (Pilot Site C)

Figure 1. The process of shared decision making as implemented in three clinical sites.

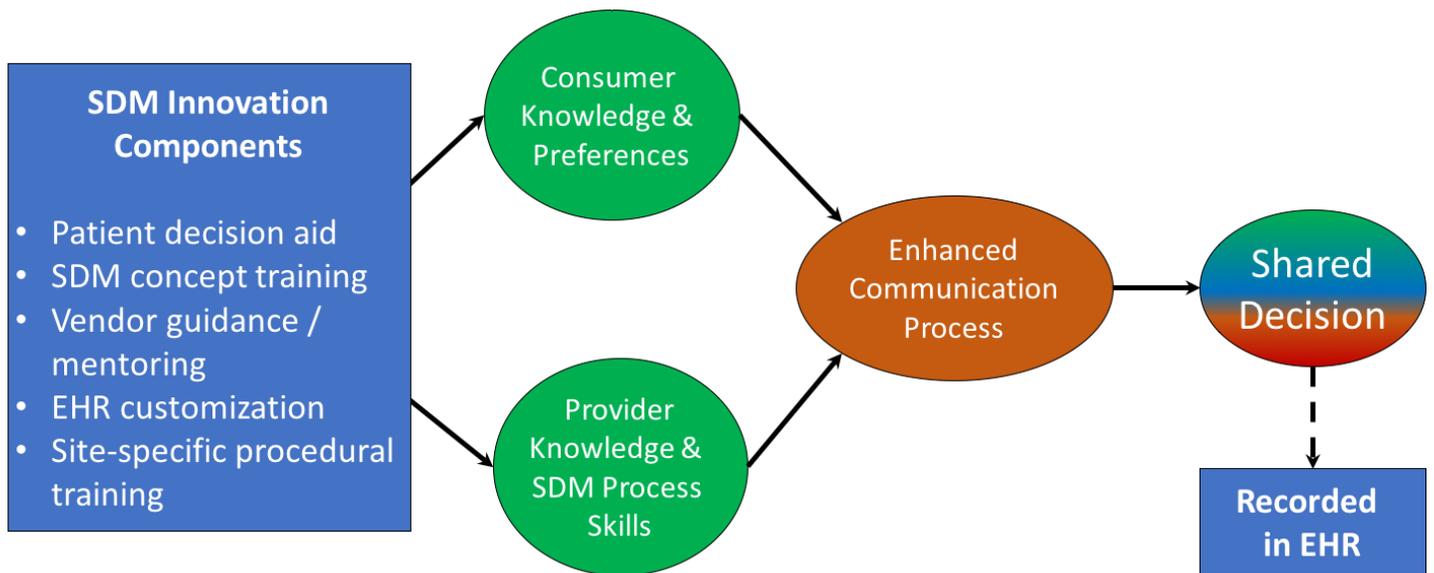


Table 1: Key definitions throughout the SDM process

<b>Steps of Shared Decision Making</b>	<b>Definition</b>
Develop relationship with patient	Identify preferred communication preferences of patient and provide relatable information
Portrayal of preferences and values	Patient and provider make mention of their preferences and values to the decision at hand
Definition of options	Provider gives a description of the process/procedures for each of the options
Rationale for options	Provider explains reasoning behind choosing one option or the other(s)
Risks	Provider explains possible risks, side-effects, or decreased quality of life associated with each option
Benefits	Provider explains benefits or increased quality of life associated with each option
Outcome expectations	Provider and patient explore ideas, fears, and expectations with each of the options
Patient/provider self-efficacy	Reference to ability to adhere to the decision (by patient and/or provider)
Checking understanding	Reference made to patient's understanding of process and reactions (i.e. fears, ideas, expectations) and it is clear the patient's understanding is sufficient based on their comments
Patient acceptance confirmed	Reference to patient's acceptance of process and decision-making role
Decision made	Make, discuss, or defer decision
Plan for follow-up	Arrange for follow-up regarding the discussed decision or further information needed to decide

Table 2. Description of three clinical sites for implementation of SDM.

	<b>Pilot Site A</b>	<b>Pilot Site B</b>	<b>Pilot Site C</b>
<b>Hospital Type</b>	Academic, Voluntary Nonprofit	Governmental Hospital District	Voluntary Nonprofit
<b>Location</b>	Urban	Urban	Urban
<b>FQHC Status</b>	No	No	No
<b># of Clinics in Pilot</b>	2	5	1
<b># of Clinicians in Pilot</b>	17 (9 OBGYNs, 8 midwives)	40 (all OBGYNs)	3 (2 OBGYNs, 1 midwife)
<b>Patient Decision Aid (PDA)</b>			
<b>SDM PDA Vendor</b>	BC Women’s Clinic “Power to Push”	BC Women’s Clinic “Power to Push”	Healthwise
<b>PDA Modality</b>	Paper	In-Person Class	Paper
<b>Providers Required to use PDA</b>	No	No	No
<b>EHR Customization</b>			
<b>EHR System</b>	EPIC	Different systems at each clinic	EPIC
<b>EHR Documentation</b>	7 fields built into EHR	Physician note	SmartText for charting
<b>SDM Concept Training</b>			
<b>SDM Concept Training Vendor</b>	Healthwise	Healthwise	Healthwise
<b>Providers Required to Take SDM Concept Training</b>	Yes	No	Yes
<b>Vendor Guidance/Mentoring</b>			
<b>Guidance/Mentoring Vendor</b>	Healthwise	Healthwise	Healthwise
<b>Site-Specific Procedural Training</b>			
<b>Training Modality</b>	Informal group meeting	Informal group meeting	Informal group meeting

**Table 3. Summary findings from interviews with HCA, vendors, and providers.**

### **Certification**

- To sustain and expand SDM certification programs, the following are needed:
  - Widespread promotion of the value of SDM certification
  - Clear understanding of the PDA vendor and clinical SDM audience
  - Early definition of operational processes
  - A plan for various expansion pathways which consider the variance in EHR capabilities and resources (e.g., more PDA options, in paper and electronic form)

### **Implementation (Organization)**

- Confusion about the cost effectiveness of SDM plays into leader and provider buy-in
- If providers feel overburdened and not involved in the process, they are less likely to support system change.
- To make SDM changes system-wide, providers need to understand both individual needs for some patients to be involved in a major decision, like TOLAC, and a population focus to bring shared decision making to as many patients as are interested and comfortable. However, these two perspectives are currently not easy to combine.
- Internal evaluation activities integral to both the healthcare systems and to providers improves the implementation process and measuring implementation outcomes.
- Electronic systems (e.g., referral systems, medical records) need to be brought up to date to make SDM easier.
- EHR integration was consistently a challenge due to competing demands on IT resources, costs, up-keep, and maintenance.
- All three sites are recording SDM efforts in their EHR in different ways – via fields built into the EHR, a physician note, and SmartText for charting. However, no pilot sites were able to implement an electronic PDA in the near term, despite all having initial interest in an electronic PDA.
- Sites felt that they could manage their own implementation process and did not extensively use available vendor consultative services.
- Organizational buy-in and administrative support were fundamental to successful implementation. While all sites had an administrative contact and at least one clinical champion, sites that had buy-in from *both* administrative and clinical staff were much more invested in the pilot, and were ultimately more successful in implementing the pilot.

### **Implementation (Providers)**

- Providers perceived SDM to be similar, if not the same, as informed consent, and viewed SDM as something they have always done in their practice.
- Provider buy-in, while present at all sites, was moderated by the general perception time was a barrier to implementation.
- Providers who took the online SDM concept skills course (training) found it useful but too long.

### **Tools**

- All sites want multiple tool options.
- Sites want both paper and electronic tool options.
- Sites wanted more understanding of the tool review process particularly, how specialists were involved.

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