Implementation of a Shared Decision Making Tool for Patients Considering Trial of Labor After Cesarean Section.

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Abstract

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Introduction: The American healthcare system has seen a renewed shift of focus towards improving care quality and patient satisfaction. Part of ensuring care quality and satisfaction stems from engaging patients in their health care decisions. Shared decision-making is one mechanism used to engage patients in a conversation with their doctor about the different clinical options available to them. This study specifically looks at the implementation of a shared decision-making tool to help women who have previously had a cesarean section come to a decision about whether to have another cesarean section or try labor.

Methods: Qualitative, semi-structured phone interviews were conducted among 20 individuals (3 administrators, 7 providers, and 10 patients). All respondents were from one of three pilot sites, all residing in the Puget Sound region of Washington state.

Results: All three sites struggled in some form or another with implementation, the most consistent struggle being workflow integration. While provider attitudes towards shared decision-making were generally positive, there was continued hesitancy among providers towards implementing a shared decision-making tool. This push back may stem from a chronic shortage of OBGYNs creating a high patient load and limited time. The inability of certified nurse midwives to follow trial of labor after cesarean section (TOLAC) patients adds to the patient load of OBGYNs, and thus furthers the burden. Patient attitudes were positive towards the tool and the shared decision-making process as a whole. Women who had a traumatic previous birth experience seemed to appreciate the intervention more, stating that it helped them understand and acknowledge the uncertainty that can accompany childbirth.

Conclusion: While the implementation of a shared decision-making tool may receive provider push-back at first, there is evidence of patient satisfaction and provider willingness to continue its use.

I. Introduction

The American healthcare system is seeing a continued shift of focus towards improving care quality and patient satisfaction. 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"[1]. One of three models CMS is supporting is the shared decision-making (SDM) model, defined as a collaboration between provider and patient[1]. According to CMS, SDM is best for "preference- sensitive conditions", or conditions in which there is no clear evidence that one option or course of treatment is better than another[1]. These preference-sensitive conditions enable the provider to really engage the patient in their own medical decision-making by having conversations with them about what the patient wants, what they value, and explain the risks and benefits to the patient in a way he/she understands their own risk of a complication occurring[2]. It helps the patient come to terms with all possible outcomes before the procedure occurs and makes both the patient and provider more confident in the decision, which can lead to greater patient satisfaction after the procedure. Studies of various medical choices, mostly centered around orthopedic surgeries such as hip or knee replacements[3], show SDM improves patient knowledge and satisfaction[1,2,4]. This increase in knowledge helps the patient to understand and take responsibility and accountability for their own medical decisions, while still maintaining trust in the expertise of the provider. While SDM itself is not new, the implementation of SDM at the systems level, meaning the entire health care system (including administrative staff, providers, and patients), is novel[5].

Integration and implementation of SDM has its challenges. Integrating SDM into clinical practice is not as easy as having a patient sign an informed consent document, and it has been

shown that providers struggle integrating SDM into their workflow, often feeling overworked, crunched on time, and burned out[1], even though there is some research to suggest that SDM might help reduce physician burn out[7,8]. To help implement SDM, tools (sometimes called patient decisions aids) have been developed to support patients and providers throughout the SDM process[5]. A previous paper by LeRouge et al looked at the certification process for these SDM tools and how well the tools themselves worked[6].

While not often thought of as a condition or treatment, pregnancy and birth (either vaginally or by cesarean) fit the description of a preference-sensitive condition quite well, especially for women who have had a previous cesarean section. Research indicates that for each cesarean section, a women's risk of uterine rupture, bleeding or infection increases, yet vaginal birth after a cesarean section carries risks of uterine rupture and increased bleeding as well[9,10]. However, these differences are still small (with a previous transverse incision, the risk is only 1 out of 500)[11], and vary from woman to woman, making a general recommendation for one way or another very hard from a provider's perspective. One component that may contribute to providers supporting secondary cesarean section over trial of labor after cesarean section (TOLAC) is liability, or fear a lawsuit if a patient has a complication during a TOLAC[12]. Implementing a shared decision making tool (decision aid) can enable the patient to take on more accountability and responsibility for their medical decision. The current study was conducted to determine how shared decision making occurs among patient-provider interactions, specifically looking at how a shared decision-making tool (a decision aid) given to the patient helps the patient and provider come to a consensus decision on TOLAC or cesarean section, and how confident in/satisfied with the decision both parties are after birth.

Previous findings in SDM implementation for this pilot focused on the pre-implementation of the SDM tool[13]. Interviews were conducted with administrators, providers, vendors (those who were creating/selling the tools), Washington state tool certification experts, as well as people in charge of information technology (IT) of the electronic health records (EHR) systems at each site. Patients were not interviewed prior to implementation. Preliminary results found that healthcare system leaders (administrators) were optimistic about implementing SDM at their clinics. Providers were more mixed about implementing SDM, with many reporting that they believed they already practiced SDM without a tool. Vendors reported excitement in that their tools were being recognized, and integrated into health systems, with one even creating an online, EHR compatible version of the tool. Washington state tool certification experts were very optimistic about the potential of the tools, and prided themselves on being the first state to certify decision aids. IT professionals had some concerns about integrating non-electronic tools into the EHR, as an upgrade to the EHR was already in progress.

The purpose of this paper is to present the post-implementation findings on the success of implementing the shared decision-making tool (decision aid) with obstetric patients at the three pilot sites. Qualitative, semi-structured phone interviews were conducted with administrators, providers, and patients, and were analyzed to determine what aspects of the implementation were a success, what needed to be improved upon, and the sustainability of SDM in the realm of women's healthcare.

II. Materials and Methods:

Study Setting and Design

The health care authority of Washington State supported the current pilot study that looked at the various stages of implementation of a shared decision-making tool for TOLAC. This study used observational data of patient and provider interviews from three sites in the Puget Sound area using three different TOLAC shared decision-making tools. To measure changes in shared decision making, data collected prior to the tool implementation as well as follow up were collected to identify differences in the way the conversation between patient and provider occurs from before to after implementation. Baseline assessment results were reported previously[13]. Details about the certification process for the patient decision aids (tools) can be found in an article by Lerouge et al[6].

The observational pre-post assessment study was conducted using qualitative interviews of key administrative officials, providers, and patients from three clinical sites in the western Washington area. **Table 1** includes more details on each of the three sites.Site A is part of a health system serving the north Seattle population. At site A, paper copy of British Columbia women's clinic's "Power to Push" tool 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. A shared decision-making tool in the form of a booklet was developed with Health-Wise (the certified shared decision 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. Providers referred eligible patients to attend a one-hour class, adapted from the British Columbia women's clinic's "Power to Push" tool.

The current study focused on the follow-up interviews with administrators, providers and patients after the pilot had been in effect for over 6 months. Most of the patients, at the time of their follow up interview, had given birth and thus were able to reflect upon the entire

process of the pilot study. Six months after the implementation launch at the three pilot sites, administrators, patients, and providers were asked if they could be contacted by our evaluation team for a follow up survey and interview. At the time of the follow-up interview, I explained the consent process and asked permission to audio record the interview for transcription purposes.

Study Participants

Three types of participants were part of our study population: administrators, providers, and patients. Administrators were eligible if they worked at one of the three pilot sites in administrative roles (e.g.program coordinator, director of population health management), and had any role in planning or implementing the SDM pilot. Providers were eligible to be interviewed if they had any contact with patients that were given the tool or discussed options on method of delivery with the patient at any point in the pregnancy. There were two main provider types for this pilot: certified nurse midwives (CNMs), and medical doctors (MDs). There was also one physician assistant. Patients with a previous history of cesarean section, and who had received the decision aid between weeks 24-38 of pregnancy were eligible for the current study.

Eligible participants, at the three pilot sites were asked if they wanted to participate in a follow-up phone interview. Those that indicated they were willing, gave their email address. Those emails were used to invite potential participants to schedule an interview. Patients were interviewed only after completion of the SDM process (after a decision was made). In many instances, this meant that patients were interviewed after the birth of their child. Our sample included 20 individuals (3 administrators, 7 providers, and 10 patients). Our sample enabled analyses of a continuum of care, allowing for a more meaningful and representative evaluation of how well the provider facilitates the SDM process for their patient, and, likewise, how the patient

engages in the SDM conversation. The Washington State IRB determined this study did not qualify as research and thus is IRB exempt (IRB application number E-101916-A)

Data Collection

The interviews were between 25 and 45 minutes long, and were used to collect responses to a series of questions related to implementation effectiveness, SDM knowledge, time when decision was made, experience with the tool, and, provider and patient and satisfaction with the entire process. Administrators and providers were also asked about formal or informal training that occurred prior to the launch of the pilot in addition to the importance of certification for the tools used in the pilot.

At the end of the interview, the audio recording of the interview was sent to a transcription service. The notes taken during the interview were uploaded to SharePoint where they were accessed at a later time. Once the transcripts arrive, they were uploaded to SharePoint where a researcher (either me or other coders) can access them and 'clean' them by fixing any grammatical errors or misheard words to make sure the transcripts are coherent and not missing any information.

Data Analysis

There were a total of 20 (three administrative, seven provider, and ten patient) interviews. Transcribed, 'cleaned' (meaning grammaticaly correct) audio interviews were uploaded to Dedoose to be coded. Thematic coding was conducted independently by 2 coders using a shared codebook to increase inter-rater reliability. Administrative interviews were coded for themes that included any previous experience working on projects that focused on SDM, how SDM fits into their role, and what the value proposition was to them for incorporating SDM into their health care system administration. Provider interviews were coded for themes

that included implementation effectiveness (facilitators and barriers), organization priorities and goals (buy-in), tool evaluation, program effectiveness, potential for innovation, and future improvements. Patient interviews were coded for themes that included what helped them make a decision (tool characteristics, provider conversations), patient characteristics (initial perceptions, knowledge base, and support system), tool evaluation, and future improvements.

Results

Leadership (Administrative Perspectives)

Administrative leadership continued to perceive SDM as compliance with state requirements and contractual obligations. However, all administrators indicated that SDM is part of a changing healthcare landscape aimed at making consumers more involved in their healthcare consumption and decision. One administrator even insinuated that SDM is integral to the future of population health.

> *"I think shared decision making has become an important area for [pop] health. And 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 [pop] health without integrated shared decision making in the point of care"* (Pilot Site A).

All administrators also indicated that SDM is sustainable for their organizations and that there was both organizational buy-in and provider buy-in throughout the pilot.

Provider Perspectives

The CNMs and MDs ended up with having very different responsibilities concerning the implementation of the SDM TOLAC tool, since midwives at one site were not allowed to follow

TOLAC/VBAC patients. However, the interviews with the CNMs offered insight into the difference in practice between CNMs and MDs, with CNMs almost universally indicating that SDM has always been a key tenant 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).

More than that, the CNMs 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)

The value of SDM was quite evident among midwives, however both midwives and MDs offered insight into the barriers to providing SDM to patients. The most common barrier cited by interviewees was a lack of time.

> "*The OBs 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 CNMs have a considerably longer appointment time with patients compared with OBGYNs, and thus have the time to implement SDM measures and tools. OBGYNs consistently expressed that they valued SDM.

> " *It's kind of like when they give [the tool] to us (OBGYNs) 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 alright, how can I help engage people in the conversation more?"* (Pilot Site A)

However, the time constraints and severe workload (bordering on exhaustion) kept OBGYNs more skeptical about the sustainability of SDM long term, with one physician stating the the main barriers to the sustainability of SDM at their site were "*time and resources*" (Pilot Site B) Another provider justified the additional work as something that improves her patients' overall wellbeing as follows:

> "*It's like you get… it's like it's one more thing and it's like, you got to take yourself and take the high view and it's like 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)

Some of the most insightful information from the interviews with providers was how SDM could be incorporated into other areas of women's healthcare. 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 CNMs and OBGYNs suggesting that there is a future for SDM in women's healthcare.

Patient Perspectives

Most of the patients interviewed (all except one) indicated that their decision was to try labor (TOLAC). Some patients had specific reasons for why they ultimately chose to 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 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 pregnancies that I may have."* (Pilot Site A).

While most indicated that they knew "*immediately after my first C-section*" that they wanted to TOLAC the next time around. (Pilot Site A). It is important to note that about 5 women self-identified themselves as healthcare providers, 4 of which were actually OBGYNs themselves, which may be a reason for the high number of women in our sample that went for the TOLAC. The one woman who chose to go through with another C-Section indicated that it was because she did not want to go through what she went through with her firstborn (she had 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 informing the information these woman sought out on TOLAC/VBAC for their most recent pregnancy.

> "*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 I 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)

This may be why women consistently listed the statistics and graphs in the tool as the most beneficial component that helped 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 like it was very informative. So it did the job that it had been intended to do. But it didn't give me a… the whole way along I'd been looking for the right answer and it really depends on ultimately me so it 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)

As far as patient perspectives towards the provider conversation component of SDM, 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 have SDM conversations with their patients? Remember to keep the values of the patient in mind, as evidenced 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 patient 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 were the patients who were medical providers. These patients also indicated they would love to use this with their own patients.

Both patients and providers had suggestions for improvements, but one common suggestion among both was that the tool should be available in more languages

> "*it would have been great to have it was to have the tools available in other languages*" (Pilot Site C)

This was heard from all sites, as there are decent sized immigrant populations among all sites.

III. Discussion

It is clear that there is administrative, patient, and provider support for SDM, especially when it comes to TOLAC, however, the amount of provider hesitation to "add another thing" to their workflow was astounding. It emphasizes the issue of the shortage of OBGYNs, and their heavy patient load that makes it a challenge for them to implement practices (like SDM) that align with what they think is "the right thing to do". This conflict between wanting to provide quality care but struggling to do so is something that needs to be taken into consideration by

public health and medical officials. A possible solution, as brought up in the interviews by the midwives, is allowing midwives to practice and accept patients who want to TOLAC. The biggest barrier, according to the midwives interviewed, was a guideline from the American College of Obstetricians and Gynecologists (ACOG) that stated a physician must be "immediately available" in the event of a complication, which many hosptials and health systems interpreted as having an OBGYN in hospital 24/7[14]. Many facilities are not able to achieve this, and thus stopped offering women the option of TOLAC. An updated guideline from ACOG in 2010 stated that "women and their physicians may still make a plan for TOLAC in situations where there may not be staff 'immediately available' to handle emergencies…"[14]. This update was in response to the many hospitals that discontinued offering TOLAC after the first guideline was released. The update came out eight years ago, and still there are overly- cautious policies in place that disregard a woman's choice to TOLAC with her preferred provider, in this case, midwives. This is frustrating because allowing midwives to practice and follow TOLAC patients would alleviate some of the pressure from OBGYNs who can then focus on following women with more complicated pregnancies, balancing workflow, and allowing for the use of SDM, culminating in an overall higher quality of care and patient satisfaction.

Another key discussion point is how much this implementation helped women who had suffered a previous traumatic birth experience. It is estimated that between 25-34% of women experience a traumatic birth, defined as "When the individual believes that her or her baby's life was in danger, or that a serious threat to the mother or baby's physical or emotional integrity existed[14]. These women expressed feeling much more at ease and a lot less anxiety, not just from the tool, but from the conversations with their provider. The whole SDM process allowed these women to talk to their doctor in a way that conveyed how their previous birth

impacted them and what they want to happen for this birth and really allowed to provider to understand where they were coming from, but also prepare them for the different possibilities of what could happen during this pregnancy. This is the point of SDM, and why it is so beneficial to patients, but especially those that had an unexpected emergent situation the first time around, as it helps them gain a sense of control, or at the very least an acceptance of a lack of control over what will happen this time around.

Related to the previous point, having patients take responsibility for their decisions towards medical care and treatment is essential to care quality and satisfaction. In the updated guidelines discussed earlier, ACOG referenced the "onerous medical liability climate for OBGYNs" as a contributing factor to the decline in TOLAC[15]. With increased integration of SDM into obstetric systems, there is a real possibility of increased patient ownership of medical decisions and decreased provider liability. A few of the providers even referenced this liability issue as a reason for being supportive of SDM for TOLAC.

Limitations

One of the limitations of this study was that there were three (30%) patients who were physicians themselves or worked in the medical field and thus had more extensive knowledge of TOLAC than expected of the general population. This primarily affects the generalizability of this study, and may indicate selection bias in that those who worked in the medical field were more likely to agree to participate in the interviews.

Another limitation is the small number of sites (three), which were not population based,meaning that the population interviewed is not representative of the general population. In addition, one of the sites dropped out of the follow-up surveys, meaning we were not able to contact or collect data from patients at this site, resulting in interviews with patients from only

two sites This site really struggled with integration and expressed extreme workloads and a diverse patient population as reasons for not participating in follow-up. We were able to receive some feedback in the form of an emailed questionnaire, but were not able to get extensive verbal feedback on how the implementation went.

There is also the limitation of conducting only qualitative analyses. Reaching saturation is an important part of the qualitative process, and gives more credibility to the study when saturation is reached[16]. However, there is no strict definition of saturation other than "when you can gain no new information by completing more interviews"[16]. While we were able to conduct 20 interviews, we struggled to get to that number. The response rate (here meaning gave us an answer of yes or no to an interview) was 75% for administrators (3 out of 4 responded), 51% (17 out of 33) providers, and 38% of patients (18 out of 47). Of these respondents, those who said yes to an interview were even smaller. While we asked those who responded no for a brief reason, not every responded with one. Of those who did, the most common answers were "no time", " no longer working in obstetrics", "no patient contact", and "no knowledge of the SDM tool". In addition, one email given to us was no longer active. While we reached 20 interviews, the saturation for patients and providers may not have been met, and thus may not be representative.

IV. Conclusion

A lot of insight was gained through this implementation of shared decision making for women considering TOLAC. There is an inner conflict among OBGYNs who want to provide highest quality care but are constrained by their workload to do so. A possible solution to this is allowing midwives to practice and follow women who want a TOLAC. While implementation success varied by pilot site, overall there was a consensus that SDM is

something that should continue to be integrated into obstetric care and has potential for innovation outside of obstetrics. The biggest lesson learned is that SDM is one way to improve patient ownership of decisions while increasing quality of care and patient satisfaction.

Future research should focus on how to integrate a tool into a clinic's electronic medical record for a smoother workflow, which would allow providers to send the tool electronically to the patient and prompt the provider to ask specific questions pertaining to SDM at appointments, enhancing the implementation of SDM at the clinic.

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Table 1: Description of enrolled clinical sites

	Pilot Site A	**Pilot Site B**	**Pilot Site C**
Hospital Type	Academic, Voluntary Nonprofit	Governmental Hospital District	Voluntary Nonprofit
Location	Urban	Urban	Urban
FQHC Status	No	No	No
# of Clinics in Pilot	2	5	1
# of Clinicians in Pilot	17 (9 OBGYNs, 8 midwives)	40 (all OBGYNs)	3 (2 OBGYNs, 1 midwife)
Certification Program Component: Patient Decision Aid (PDA)			
SDM PDA Vendor	Non-Certified Vendor	Non-Certified Vendor	Certified Vendor
PDA Modality	Paper	In-Person Class	Paper
Clinicians Required to use PDA	No	No	No
Certification Program Component: EHR Customization			
EHR System	EPIC	Different systems at each clinic	EPIC
EHR Documentation	7 fields built into EHR	Physician note	SmartText for charting
Certification Program Component: SDM Concept Training			
SDM Concept Training Vendor	Certified Vendor	Certified Vendor	Certified Vendor
Clinicians Required to Take SDM Concept Training	Yes	No	Yes
Certification Program Component: Vendor Guidance/Mentoring			
Guidance/Mentoring Vendor	Certified Vendor	Certified Vendor	Certified Vendor
Site-Specific Procedural Training			
Training Modality	Informal group meeting	Informal group meeting	Informal group meeting