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Inequality and Innovation: Barriers and Facilitators to 17P Administration to Prevent Preterm Birth among Medicaid Participants

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Abstract

Objectives Strategies to prevent preterm birth are limited. 17 Alpha-Hydroxyprogesterone Caproate (17P) injections have been shown to be effective, but the intervention is under-used. This mixed methods study investigates barriers and facilitators to 17P administration among Medicaid and CHIP participants enrolled in Strong Start for Mothers and Newborns, a federal preterm birth prevention program. *Methods* Twenty-seven awardees with more than 200 sites in 30 states, the District of Columbia, and Puerto Rico enrolled approximately 46,000 women in Strong Start from 2013 to 2016. Participant data, including data on preterm birth and 17P, was collected for each woman. Intensive interviews (n = 211) conducted with Strong Start program staff and providers (n = 314) included questions about 17P provision. *Results* Of women whose data included a valid response regarding 17P initiation, 3919 had a prior preterm birth and current singleton pregnancy; 14.95% received 17P. Barriers to 17P administration include late entry to prenatal care, administrative burden of preauthorization, cost risks to providers, limits in scope of practice for non-physician providers, and social barriers among participants. Facilitators for provision include streamlined work flows and the option of home administration. *Conclusions for Practice* A universal insurance authorization process could mitigate many barriers to 17P use. Providers need continuing education regarding the effectiveness of 17P, and expanding scope of practice for non-physician prenatal care providers would increase access. Targeted program interventions can help to overcome social barriers Medicaid participants face in accessing care. Streamlined work processes and the option of home health services are two effective program-based facilitators for providing 17P to a Medicaid population.

Keywords Preterm birth · 17 Alpha-hydroxyprogesterone caproate (17P) · Medicaid · Barriers to care · Prenatal care · Maternal health · Health disparities

Significance

What is known? Preterm birth has short and long term health consequences. 17P injections can prevent recurrent preterm birth, but rates of administration are low. Studies

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of administration rates are usually limited to a single site or state and are quantitative in nature.

What this study adds? This study offers a mixed methods evaluation of programs targeting preterm birth prevention among high-risk, Medicaid-enrolled women in 30 states, the District of Columbia and Puerto Rico. Programs include three different care venues (maternity care homes, group care, and birth centers) and both physician and non-physician prenatal care providers.

Introduction

Infants born before 37 weeks gestation are preterm. According the Centers for Disease Control and Prevention (CDC), preterm infants are at risk for health problems including respiratory difficulties, cerebral palsy, developmental delays and death, with poor outcomes more common at earlier gestations (CDC 2016). Approximately 10% of U.S. infants are born preterm every year (CDC 2016).

Some preterm births are conducted intentionally to resolve an acute medical issue or result from a multiple gestation (World Health Organization 2016), but the majority (70–80%) are spontaneous births of singleton infants and have no identifiable direct cause (Institute of Medicine 2007a, b). While women can avoid some behaviors that increase risk (e.g. smoking), the majority of risk factors are outside of women's control (e.g. health conditions, poverty) (Institute of Medicine 2007a, b). Though no widely established risk-scoring systems exist, studies indicate that women with one spontaneous preterm singleton birth are at more than 5 times the risk for a subsequent preterm birth (Laughon et al. 2014).

One of the only proven medical interventions to prevent repeat preterm births is injections of 17 Alpha-Hydroxyprogesterone Caproate, known as 17P, but most studies of rates of 17P administration have investigated a single site or state and are quantitative in nature (e.g. Orsulak et al. 2015; Yee et al. 2016). This mixed methods study investigates rates of 17P administration among women with prior preterm births enrolled in Strong Start for Mothers and Newborns (Strong Start), a Centers for Medicare and Medicaid Innovation (CMMI)-funded preterm birth prevention program for women covered by Medicaid or the Children's Health Insurance Program (CHIP) in more than 30 states. Quantitative analysis identifies rates of use and characteristics of women receiving 17P, while qualitative analysis of staff interviews identifies barriers and facilitators to appropriate use with Medicaid participants.

Background

In 2003, published results from randomized control trials indicated that the preterm birth rate for high-risk women was one-third lower in the 17P group than in the control group (Meis et al. 2003). In 2008, the American Congress of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) issued a practice bulletin stating that 17P should be offered to women with a prior spontaneous preterm birth and current singleton pregnancy (American College of Obstetricians and Gynecologists and Committe on Obstetric Practice 2008). United States Food and Drug Administration (FDA) guidelines issued in 2011 (U.S. Food and Drug Administration 2011) approved the brand-name version of 17P, Makena. Prior to Makena's availability, all 17P was compounded at a cost of $10–$20 per dose; Makena's cost is approximately 50 times higher (Patel and Rumore 2012). However, there is evidence that compounded 17P's quality can vary by pharmacy, and the FDA recommends use of Makena to meet the highest standards of efficacy and safety (U.S. Food and Drug Adminstration 2012).

Estimates indicate that universal 17P administration to eligible women would decrease national preterm birth rates by about 2% (Petrini et al. 2005). 17P has also been shown to extend gestational age even when an infant is still preterm (Bastek et al. 2012; Meis et al. 2003), helping to prevent the earliest births and shorten NICU stays (Mason et al. 2005). Despite support for administration from numerous studies, ACOG, SMFM and the FDA, the proportion of eligible women who receive 17P remains low (Association of State and Territorial Health Officials (ASTHO) 2015). Besides 17P, interventions to prevent recurrent preterm birth either have no known effectiveness (e.g. bed rest/activity restriction) (Maloni 2010; SMFM 2014), limited effectiveness (e.g. tocolytics) (Haas et al. 2012), mixed evidence of limited effectiveness (e.g. cerclage, pessaries) (Abdel-Aleem et al. 2013; Alfirevic et al. 2017), or no established effectiveness for women with high-risk pregnancies (e.g. midwifery models of care, CenteringPregnancy) (Gareau et al. 2016; Sandall et al. 2016). Prenatal care providers are not always aware of the most up-to-date research and protocols for providing optimal care, especially regarding various forms of progesterone (Batra et al. 2017; Miller et al. 2016; Renfrew et al. 2014). Some providers offer vaginal progesterone as a substitute for 17P because of its lower cost and ease of use; however, though vaginal progesterone has been associated with reduced incidence of preterm birth among pregnant women with short cervical length (Khandelwal 2012), it does not have demonstrated effectiveness for preventing recurrent spontaneous preterm birth (Norman et al. 2016; O'Brien et al. 2007).

Makena instructs that weekly injections should begin at 16–20 weeks gestation and continue to 37 weeks gestation or birth, whichever comes first (AMAG Pharmaceuticals 2018); the same protocol applies to compounded 17P. Some research indicates 17P can be effective if begun later in the second trimester (Mason et al. 2010) or if the woman misses doses (Haider et al. 2017). Although Medicaid covers prescription drugs, only some state Medicaid programs specify coverage of Makena, compounded 17P, or both (National Academy for State Health Policy and National Institute for Children's Health Quality 2016) and policies/prices are inconsistent across insurance providers and states (ASTHO 2015; Batra et al. 2017).

Medicaid participants are generally low-income, and many are from minority groups that have historically faced systemic discrimination. Many experience barriers to care such as lack of funds for transportation or a general lack of trust in medical providers and institutions (Call et al. 2014; Lewis et al. 2012). Still, though disparities exist (Yee et al. 2016), previous research indicates that when Medicaid-enrolled women are prescribed 17P, most adhere to the protocol, especially with care coordinator support (Lucas et al. 2012). Some states specifically promote use of 17P among Medicaid beneficiaries, but even in these cases administration rates remain low (ASTHO 2015; Orsulak et al. 2015).

This study aims to identify characteristics of women enrolled in the federal Strong Start for Mothers and Newborns initiative who received 17P and to explore facilitators and barriers to 17P administration among providers and participants in Strong Start.

Methods

Strong Start was designed to provide psychosocial interventions to reduce preterm births and low birthweight among Medicaid or Children's Health Insurance Program (CHIP)-enrolled women (the two programs are combined in many states; for simplicity, they are hereafter referred to as Medicaid). In 2013, CMMI awarded 27 cooperative agreements to support enhanced prenatal care for at-risk women at birth centers, maternity care homes, or group prenatal care sites in 30 states, the District of Columbia, and Puerto Rico (Centers for Medicare and Medicaid Services 2016). Relationship-based care, care coordination, referrals, and education were the foundation of most programs (Hill et al. 2016). Awardees included health systems, state-based agencies, private practice groups, and national organizations. Programs began serving women in 2013/2014, with more than 200 sites ultimately providing services, and all births occurring by March 2017. By the end of the program in 2017, awardees had served 45,999 women. Evaluation included participant-level data analysis and case studies. The Institutional Review Board at the Urban Institute approved all elements of this study.

Participant-Level Data Analysis

As part of participant-level data collection, participants and awardee staff completed four forms at designated points throughout maternity care (at participant intake; during the third trimester; and two forms postpartum: one for participants and a chart review completed by staff). Among many elements, forms collected women's demographic profiles, history of preterm birth, program enrollment date, receipt of 17P, and birth outcomes; all medical information was derived from the chart reviews (Hill et al. 2016). Forms were collected and processed quarterly. We received forms for 45,427 women, from which we exclude 607 women with a current multiple gestation, as current guidelines recommend against 17P for multiple gestations (resulting n = 44,820).

Under the section "Treatment prior to or during labor," on the final chart review form, staff marked "yes," "no," or "not known" for the item "Progesterone injections to prevent preterm birth (e.g., 17P, P17 or 17-OHP; hydroxyprogesterone caproate)." The total number of women with a prior preterm birth and definitive documentation of receipt or non-receipt of 17P was 3919 ("not known" responses were coded as missing). To calculate the proportion of potentially eligible participants who received 17P, we divided the number of women who received 17P (n = 586) by 3919. Women without 17P data were more likely to be black than women with data (48.5 vs. 42.46%, $p < .001$). Data on 17P was far more likely to be missing among women in group prenatal care (40.87%) than among women in maternity care homes (30.85%) or birth centers (7.98%) ($p < .001$).

Case Study Methods

For the case studies, a team of uniformly-trained researchers collected qualitative data annually using triangulated methods. During semi-structured interviews in program year three, researchers presented key informants with participant-level data on 17P administration rates and asked whether their Strong Start intervention addressed 17P use and whether Medicaid/CHIP reimbursement and patient adherence were mitigating factors.[1] Researchers conducted a total

[1] Specific questions asked were: "We are trying to learn more about Strong Start sites' use of 17P (17-alpha-hydroxyprogesterone caproate) to prevent preterm births. Does 17P administration play a role in your Strong Start intervention? (Please describe.) Based on participant level data you've submitted, through the first quarter of 2015 around [awardee specific percentage] of participants had received 17P treatment during their pregnancy. Does this reflect your experience? (Please explain.) Is Medicaid/CHIP reimbursement an issue? How about patient compliance?

of 211 interviews with 314 key informants (some interviews included more than one key informant). Key informants for all 27 awardees were included in the interviews. Researchers obtained informed consent from all interviewees using IRB-approved procedures. All groups were digitally recorded and attended by a note taker in addition to the facilitator. Data were cleaned, organized by theme, and then coded and analyzed using the software program NVivo and a framework designed to address the evaluation's primary research questions. The team conducted multiple rounds of qualitative database testing to obtain high inter- and intra-coder reliability. More in-depth information about the federal program evaluation's methods is available in the evaluation annual reports (Hill et al. 2016).

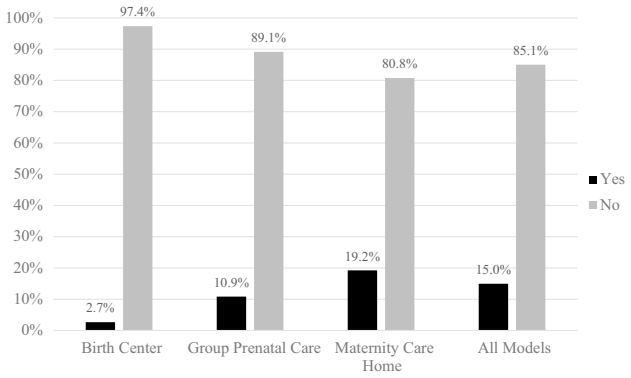

Fig. 1 Proportion of eligible women who received progesterone injections. *Note*: N = 3919 women with a prior preterm birth, singleton gestation, and non-missing data for receipt of 17P

Results

Among multiparous women in Strong Start, 5583 (21.1%) had a prior preterm birth. Valid data confirming receipt or non-receipt of 17P receipt was available for 3919, approximately 70% of them. Among these women, 42.5% were Black, 21.7% were white, and 27.6% were Hispanic. The vast majority (78%) were age 20–34. Just over half had a high school diploma or GED; another quarter had not completed high school. Most women were in a relationship of some kind (77%), but only 26% were married. Two-thirds of women received care in maternity care homes, 16.7% in group care, and 17.4% in birth centers. Although similar proportions of women were in relationships across the three models, women in birth centers were more likely to be married ($p < .001$). Women in group prenatal care were most likely to have initiated care prior to 17 weeks, while women in birth centers were most likely to have entered care after 20 weeks ($p < .001$).

Women in different models of care had some significant demographic differences. Black women were disproportionately represented in maternity care homes, white women in birth centers, and Hispanic women in group prenatal care ($p < .001$). Group care enrolled more teens (though absolute numbers were small); maternity care homes had the largest proportion of women age 20–34, and birth centers were more likely than the other models to serve women 35 and over ($p < .001$).

Given that most preterm births are spontaneous (Institute of Medicine 2007a, b), it can be inferred that well over half the final sample would be eligible for 17P, but only 14.95% received 17P. Across the three Strong Start intervention models, women in maternity care homes were most likely to receive 17P (19.23%), followed by women in group care (10.86%), and women in birth centers (2%) (See Fig. 1), but rates varied widely among maternity care homes (range 0–43.75%) and group care programs (range 0–42.92%). Among women in the final sample, Black women were more likely to receive 17P than white women or women with missing race/ethnicity data ($p < .05$), and at the marginally significant level, ($p < .10$), white women were more likely to receive 17P than Hispanic women. Significance is assessed using Chi square tests and pairwise comparison of means tests, as appropriate for the measure. Among women with a prior preterm birth who did not receive 17P, 2.01% did receive vaginal progesterone, but we do not have information on cervical length to assess accurately whether administration of vaginal progesterone was for evidence based indications or was in lieu of 17P.

Among the 77% women with documented date of entry to prenatal care (n = 3011), timing of prenatal care initiation was similar among women in the sample who did and did not receive 17P, with more than three quarters of women beginning care by the end of 16 weeks and approximately 90% by 20 weeks whether they received 17P or not. However, women were significantly less likely to receive 17P if they began care after 20 weeks' gestation ($p < .001$), which is to be expected given that guidelines recommend beginning 17P injections by 20 weeks. Among women who initiated care through 16 weeks 16.5% received 17P, among women who initiated from 17 up to 20 weeks, 18.57% received 17P, and among women who initiated at 20 weeks and beyond 10.88% received 17P.

Key informant interviews identified multiple barriers to providing 17P, including timing of entry to care, administrative burden, costs, knowledge and scope of practice, communication, and participants' challenges. Some informants identified promising practices that facilitated 17P administration, including streamlined workflow and home health visits.

Late Entry to Care

Although only 10% of women in the sample enrolled after 20 weeks' gestation, late entry to prenatal care was a commonly identified barrier to 17P initiation. Administration protocols indicate injections should begin between 16 and 20 weeks' gestation (AMAG Pharmaceuticals 2018), but many awardees reported that contracted insurers would not approve initiation after 16 weeks. Even when women began care early, authorization processes complicated 17P initiation. One maternity care home provider reported:

> The barrier is just getting the medication. I meet [a patient] and…determine the need for [17P] and we fill out the form through the nurse. Sometimes it takes 2–3 or maybe even 4 weeks to get the medicine. I am supposed to start it at 16—but then I need to plan ahead because then the lady needs to be at 12 weeks, then we place the order and by the time she is 16, the supply comes in.

Administrative Burden

Administrative burden influenced providers' motivation to initiate 17P. In group care and birth center sites, the provider prescribing 17P was usually a specialist and not the primary prenatal care provider. The specialist was often off site and didn't always have ready access to a woman's records. Insurance protocols for prior approval sometimes changed, and different insurers had different processes. One maternity care home site tried many strategies to keep up:

> We have the forms, we have to get the prior authorization form, we print out the patients' demographics and fax [them] out to the different people [they] need to be faxed to, [the sub-contractor who does the 17P] will try to call you. We also have OB meetings once a month where [a representative] comes in [to talk]. We've had ups and downs. When insurance changes, it changes our protocol for doing things.

If an office did not have a streamlined protocol for obtaining 17P, a provider's time spent on insurance authorization might take away from delivering direct patient care. Care coordinators for a maternity care home with an explicit goal of increasing access to 17P said that some physicians did not want to take the time to initiate an application and would instead write a prescription for vaginal progesterone, despite different indications for the two (e.g., Norman et al. 2016).

Cost

Cost influenced some insurers' 17P authorization processes; one key informant reported, "Providers face increased administrative burden in ordering 17P now that it is…Makena [and] costs $800 per dose compared to $10 per dose previously." Some awardees in states where Medicaid approved use of the cheaper compounded version reported fewer authorization difficulties; a key informant at a group care site in such a state explained, "Some Medicaid plans…take 2 days for prior authorization, and I had another where I called and insurance said we didn't need one."

Even when Medicaid explicitly covered 17P, some health plans imposed financial risks on providers. One interviewee at a maternity care home reported that while Medicaid reimburses for 17P, the rate is low and there are challenges in storage and administration:

> The drug comes in a five-dose vial with a shelf life of about a month. The provider's office purchases the vial for a patient, and then claims Medicaid reimbursement for the administration fee and the drug itself as each dose is administered. If a patient does not show up for the 17P injection appointment, the provider's office cannot claim reimbursement and must eat the cost of that dose.

Knowledge, Scope, and Communication

Provider-level challenges also contributed to low 17P use. Some birth center or group prenatal care sites could not offer 17P because prescription and administration privileges do not extend to certified nurse-midwives (CNMs) or other advance practice nurses (APNs) in all states, and some birth centers are operated by certified professional midwives, whose scope of practice excludes prescribing medications. Birth center informants conveyed frustration that restrictions for CNM/APNs result in less effective prenatal care. At the same time, some midwives and advance practice nurses were not comfortable managing high-risk cases or 17P prescriptions on their own, and some birth center midwives believed that their more individualized model of care already mitigated risks of preterm birth, negating the need to refer out for 17P.

Still, women at midwife-staffed sites could usually be referred to physician specialists while still receiving routine care at the Strong Start site; thus, almost all eligible Strong Start women should have had access to 17P. As one birth center midwife reported,

> "I haven't started anyone on progesterone. I don't think any of our midwives would feel comfortable doing that. [Our collaborating OB] has a separate clinic, we

just refer to him. I would have the woman [with a prior preterm birth] go see [OB], and he could start her on 17P if he wanted. But I do think she should still keep coming to us."

Although using 17P is within scope of practice for all physicians, some were not knowledgeable about 17P or, like some midwives, not comfortable prescribing it. At one high-risk academic medical center operating a maternity care home, an informant said that 17P "is not a big part of the program" and site data indicate that no Strong Start participants had received it. Another maternity care home, this one operated by a managed care organization, flagged eligible women for providers, but rates of administration remained low. An informant there said that providers may not be comfortable prescribing the drug, even with a "zero tolerance" policy for cases when a woman was eligible for, but not receiving, 17P.

Providers and patients sometimes lacked effective communication, and patients did not always trust medical systems or providers, which could influence needs assessment and uptake. Women pursuing birth center care sometimes had a generalized mistrust of the standard medical establishment or pharmaceutical interventions. Birth center and group care providers sometimes had difficulty following up on referrals because EHRs were not coordinated among institutions.

Communication issues related to provider continuity were a particular issue for maternity care homes. While women receiving care at maternity care homes almost always had a consistent care coordinator, this person was often a social worker or community health worker without extensive medical knowledge. It was common for women to see a different medical provider at every visit, and visits were usually short, sometimes lasting only a few minutes. The provider might not know the woman needed 17P or might not have time for a lengthy discussion explaining 17P's potential benefits. At one maternity care home, informants reported that records were inadequate, and by the time a provider discovered a woman's history of preterm birth, it was too late to begin 17P; a care coordinator said, "Today I saw a patient—this is her third pregnancy with us—and there's no OB history on her." A care coordinator at a community clinic said that some participants believed the injections could cause a preterm birth; at another health center, a care coordinator indicated that some patients were not concerned about preterm delivery because their previous preterm baby was healthy.

Patient-Level Challenges

Because injections are administered weekly for approximately 20 weeks, women faced many barriers to the regimen. Though common side effects of 17P are relatively benign, they can be unpleasant (e.g. nausea), and the shots are painful. Work, transportation and childcare can make attending weekly appointments extremely difficult. One maternity care home informant said,

I think as healthcare providers we are not always empathetic to the fact that it's hard for women to come in for prenatal care—especially if they don't have their own car and are relying on public transportation to get here, and then have to wait 1–2 h for an appointment that lasts 10 min.

Insurance policies also challenged participants. One company required representatives to speak with participants, even though many had inconsistent phone access, ran out of phone minutes, or did not respond to unrecognized numbers. Another routinely rejected pre-authorizations for 17P and insisted that the patient, not her provider, must call to obtain the override. Some awardees reported that insurance companies shipped 17P to participants to bring to their appointments, but many Strong Start participants did not live at the same address for the duration of their pregnancies.

Promising Practices

The most consistent facilitator for participants' 17P adherence was flexibility in administration location. As one informant implementing the group prenatal care model said,

[Strong Start participants] are given 17P if they are a good candidate. No barriers here because there are programs who take care of it.…Some programs go to [women's] homes to give injections. Some come [to the clinic].

Though some women had reservations about allowing medical professionals into their homes, informants overall reported home-based services as having the strongest impact on 17P administration. Information about home care was not always well-publicized, however, and discovering this resource required research by Strong Start awardees, as explained by a maternity care home key informant:

Some of our providers and care coordinators have been savvy and found out that managed care organizations offer home administration to their patients, so we do that as much as we can.

In other cases, home visiting was standard or awardees participated in programs that taught family members or women themselves to administer 17P.

Another facilitator was a well-designed work flow or cooperation among entities involved in providing, administering, and paying for 17P. One maternity care home at an academic medical center had particularly high rates of 17P administration; this group cross-trained staff so that people

other than the provider could initiate insurance authorization processes. Employing registered nurses as care coordinators was valuable in this instance:

> The referral process is typically 'smooth and easy' since 17P is well established and accepted as the standard of care [at our site]. The care navigators feel comfortable starting the referral process for 17P…and will set it in motion if they notice during their initial review of risk factors that a patient has had a previous preterm birth and otherwise meets the criteria.

Other awardees reported standardizing collection of obstetric histories or establishing liaisons with insurance companies to be useful processes. For example, when one maternity care home awardee encountered an insurance company that required speaking to the patient for prior authorization, staff would call the company during the woman's appointment.

Discussion

Strong Start's rates of 17P initiation exceed rates reported in the literature for Medicaid participants (ASTHO 2015; Orsulak et al. 2015), but the program's overall rate of administration to women with a prior preterm birth and current singleton gestation remains relatively low at just under 15%. The literature indicates that the vast majority of preterm births are spontaneous (Institute of Medicine 2007a, b), meaning that we would expect the majority of women to be eligible and thus the administration rate to be well over 50%. Within the Strong Start program, models of care appeared to impact women's receipt of 17P more than their demographic characteristics. For instance, Black women were most likely to receive 17P and were also most likely to be enrolled in maternity care homes, which had the highest rates of 17P administration.

Although Strong Start participants who enrolled in maternity care homes initiated 17P more often than those in group prenatal care or a birth center, even in maternity care homes, only 19.2% of women who were potentially eligible received 17P. Despite being staffed by physicians with full prescription capacity and often with specialized training in managing high-risk patients, some maternity care homes did not administer 17P to any women.

Medicaid participants often have financial and social vulnerabilities that can affect their access to care and their trust in the health care system (Call et al. 2014; Lewis et al. 2012). In addition to problems they encounter in navigating insurance systems and keeping up with current research, providers are not always aware of or able to fully address the needs of their Medicaid-enrolled patients (Batra et al. 2017). Through qualitative analysis of interviews with primary sources from across the nation, this research has systematically identified common barriers that may prevent eligible Medicaid participants from accessing 17P injections as well as factors that may facilitate administration.

Barriers to 17P do not occur in isolation, and a confluence of issues may impact an eligible woman's uptake. As noted previously, Makena, the patented version of 17P, is far more expensive than the compounded version. Even with insurance coverage, the cost of Makena produces barriers, particularly when financial risk is transferred to providers. Costs may contribute to administrative burdens associated with prior authorization, as a high price tag motivates insurers to scrutinize eligibility and may also contribute to limiting initiation to 16 weeks, rather than from 16 to 20 weeks as recommended.

Administrative burden's impacts are twofold: the time it takes to process an authorization can push a woman past the initiation window, especially if set at 16 weeks, and the time and confusion involved in completing paper work reduces provider motivation to offer 17P. Administrative burden was most frequently cited by maternity care homes, which were most likely to provide 17P "in house." In some maternity care homes, key informants indicated that these burdens led some physicians trained to care for high-risk pregnant women to disregard information about 17P, offer less-effective or ineffective treatments (e.g., vaginal progesterone), or refer women elsewhere.

Regulations and restrictions on non-physician providers can limit availability of 17P, a particular issue for group care and birth center sites in Strong Start, where women with a prior preterm birth were less likely to receive 17P. Depending on the state, midwives and other APNs providing prenatal care may not be able to prescribe or administer 17P, or if they can, may have to do so under the direct supervision of a physician. Some midwives or other APNs do not feel comfortable handling a high-risk case without physician involvement, and some physicians themselves do not feel comfortable administering 17P, instead referring eligible women to maternal-fetal medicine specialists.

Referrals contribute barriers as well. The lack of a universal health records system meant follow up on 17P referrals could be difficult for sites that couldn't offer 17P in house. According to key program informants, Medicaid participants' inconsistent phone access and unstable housing often made appointment verifications difficult. Many lower-income women rely on public transportation, which costs money, can be unreliable and is difficult to use in bad weather. Women may have difficulty taking time off of work or arranging childcare. Waiting times for appointments often far exceed the time in the appointment itself. Women who already have tenuous relationships with the medical system may be particularly unlikely to visit or

trust an unknown provider. As noted previously, many of these barriers apply to Medicaid participants in general; when weekly appointments for 17P administration are introduced, these barriers are potentially insurmountable.

Key informants also indicate that many of the patients they serve do not understand why 17P is important or may not trust providers' assessments of its necessity or safety. Time allotted for physician visits may not be adequate for relationship building and education; a typical prenatal care appointment lasts 5 to 10 min (Stevens et al. 2016). Women whose prior preterm infant was ultimately healthy may feel 17P is not worth the inconvenience and discomfort. Even when home visits are available, key informants reported that some women do not want unfamiliar health workers in their homes or may not have a stable residence to receive regular injections.

Despite some women's reported resistance to home visits, home visiting was commonly identified as facilitating 17P administration, along with flexibility about when and where injections were administered and training family members or women themselves to administer injections. Awardees that could not offer these services felt that being able to do so would increase 17P uptake. Awardees with established practices for eligibility assessment and authorization and those with working relationships with insurers felt those strategies facilitated uptake.

Though this study offers unique additions to our knowledge of 17P use among Medicaid providers and participants, it also has a number of limitations. Awardees reported 17P receipt based on participants' medical records, but "unknown" responses indicate that awardees may not have had access to records of services provided outside of the awardee entity; approximately 30% of women with a prior preterm birth and a current singleton pregnancy did not have valid data on 17P administration. We were not able to control for all reasons for a prior preterm birth and thus can only estimate the proportion of eligible Strong Start women based on the supposition that Strong Start participants are medically similar to women in the literature. Our data indicate that a woman received 17P, not that she completed the full regimen. Demographic variables may have impacted women's likelihood of receiving 17P within the models, but we did not have sufficient sample size or data quality to analyze these differences. Quantitative results should be viewed as descriptive. Qualitative data were gathered as part of a larger evaluation. Prenatal care sites were offering innovative programs under the Strong Start initiative and may not be representative of typical prenatal care sites. While interview protocols specifically addressed 17P use, the question was one topic among many, and the data do not directly address patients' perspectives on 17P.

Conclusion

In health care, moving from the findings of randomized control trials to adoption of practice takes an average of 17 years (Institute of Medicine (US) Committee on Quality of Health Care in America 2001). While our data were collected only 13 years after the 2003 randomized control trial demonstrated 17P's effectiveness, 17P has a long way to go in being adopted as a standard of care, even though supporting evidence continues to accumulate. While our results are not from a random sample and are not generalizable, they do offer insights regarding barriers and facilitators to 17P administration that may be generally useful. Alleviating administrative burdens for preauthorization through universal processes, increasing patient and provider knowledge, and mitigating social barriers among low-income women could increase access for Medicaid participants. Provider continuity can facilitate both patient trust and provider awareness of the need to initiate 17P. Expanded scope of practice, prescribing privileges, and targeted training for CNMs and APNs, who are becoming common providers of prenatal care, would also increase access. Promising practices demonstrated to facilitate 17P uptake include home administration; flexible times and locations for administration; and streamlined, collaborative processes for screening and authorization. Despite the vulnerable populations they serve, many Strong Start programs achieved rates of 17P administration above averages cited in the literature, and some programs that focused on overcoming barriers had rates that were much higher. These findings indicate that with targeted efforts, it is possible to provide 17P to most eligible pregnant women enrolled in Medicaid.

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