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Implementation of Pharmacy Access to Hormonal Contraception

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ABSTRACT

Women report significant barriers to obtaining hormonal contraception prescriptions, including difficulty scheduling clinician appointments, inconvenient clinic hours and desire to avoid pelvic examinations. To increase contraceptive access, states throughout the United States have and continue to pass legislation authorizing pharmacists to prescribe hormonal contraception, allowing women to initiate contraception directly at the pharmacy without involvement of a physician. Despite patient and pharmacist interest in direct pharmacy access to contraception, many pharmacists report challenges to prescribing contraception. Few studies have assessed the uptake of pharmacy-prescribed contraception in states with expanded pharmacist prescriptive authority, but no prior studies have evaluated the implementation process of establishing pharmacist-prescribed hormonal contraception.

This thesis evaluates the current literature on the availability of pharmacist-prescribed hormonal contraception in the United States, presents research on implementation of pharmacist-prescribed contraception, and discusses the importance of understanding implementation for future legislative policy changes.

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Section 1

Introduction

Inconsistent contraceptive use results in increased unintended pregnancy rates.[1] Almost half of pregnancies in the United States are unintended and low-income women have disproportionately high rates.[2] Unintended pregnancies result in significant human costs, including the decision to continue a pregnancy or to choose pregnancy termination, as well as associated health care costs. In 2008, U.S. births from unintended pregnancies resulted in approximately $12.5 billion in government expenditures.[2] Improving access to comprehensive contraception increases reproductive autonomy and reduces unintended pregnancy rates, health care costs and health inequities.[1]

One reason for inconsistent use of contraception is the requirement that women have a prescription to obtain hormonal contraception. Women have identified common barriers to obtaining contraception prescriptions, including lack of clinician appointments, inconvenient clinic locations and the requirement of a pelvic examination or pap test.[3] Although the ultimate goal in improving hormonal contraception availability is for over-the-counter access, the American College of Obstetricians and Gynecologists identified pharmacist-prescribed contraception as an important intermediate step to expand contraception access.[1]

Pharmacist-prescribed hormonal contraception allows women to initiate contraception directly at the pharmacy without the involvement of a separate clinician visit. In Washington state, community pharmacists safely screened and prescribed hormonal contraception; women and pharmacists alike were satisfied with this pharmacy access.[4] In a survey of pharmacists, 85% expressed interest in providing direct pharmacy access to hormonal contraception.[5] In a national survey, 63% of women agreed that hormonal contraception, including oral contraceptive pills, the patch or ring, should be available without a prescription if the patient was first screened by a pharmacist.[6] Women also described many potential personal benefits, including not needing to pay for a clinician visit and convenient pharmacy hours.[6]

To expand access through pharmacist prescribing, states pass laws authorizing pharmacists to prescribe hormonal contraception and the language of the law varies by state. Initially, Washington state authorized pharmacist prescribing of hormonal contraception through collaborative practice agreements between a pharmacist and another provider (e.g.

physician) with prescriptive authority.[7] In 2016, California and Oregon were the first states to allow pharmacists to independently prescribe hormonal contraception directly through legislative approval of statewide protocols.[7,8] By April 2020, the District of Columbia and 19 states including Arizona, Arkansas, California, Colorado, Delaware, Hawaii, Idaho, Illinois, Maryland, Minnesota, Nevada, New Hampshire, New Mexico, North Carolina, Oregon, Utah, Vermont, Virginia and West Virginia have passed statutes or regulations authorizing independent pharmacist prescribing of contraception.[9]

As legislation authorizing pharmacist prescribing of hormonal contraception spreads throughout the United States, studies show pharmacists remain interested in offering hormonal contraception prescriptions. In a national survey, 65% of pharmacists reported continued personal interest in prescribing hormonal contraception.[10] Pharmacists report more support in states where pharmacist prescribing had already been enacted.[10] When asked about motivation for prescribing hormonal contraception, 94% of pharmacists reported enjoying individual patient contact, followed closely by opportunities for professional development, benefits for patients, and contraception as an important public health issue.[10]

Despite their interest, pharmacists have discussed challenges to prescribing hormonal contraception. In prior qualitative studies and surveys, reported barriers include the lack of payment for counseling/prescription, need for pharmacy workflow changes, pharmacist time constraints, liability concerns and need for additional space and education/training.[7,10–13] Few studies have evaluated the impact of these challenges on the uptake and implementation of pharmacist-prescribed contraception. Without further guidance of interventions to implement this service, strategies to expand access to hormonal contraception are limited.

The objectives of this thesis are to evaluate the current literature on the availability of pharmacist-prescribed hormonal contraception in the United States, understand the state-level steps and strategies to implement pharmacist-prescribed contraception, and discuss the importance of understanding implementation for future legislative policy changes. To begin, the following section presents a scoping review of the existing literature on the uptake of pharmacist-prescribed hormonal contraception in the United States. A subsequent section will present a qualitative study on the implementation steps, facilitators, and barriers of state-level implementation of pharmacist-prescribed hormonal contraception. The last section is a

commentary on the lessons learned from implementation of policy changes to reduce the gap from passage of legislation to clinical practice.

Section 2

The Availability and Uptake of Pharmacist-Prescribed Hormonal Contraception in the United States: a Scoping Review

Abstract

Background: Pharmacist prescribing of hormonal contraception is rapidly disseminating throughout the United States as a strategy to increase contraceptive access.

Objectives: This review reports on the body of evidence examining uptake of pharmacist-prescribed hormonal contraception in states with expanded pharmacist prescriptive authority.

Methods: We performed systematic searches in PubMed, Web of Science and Ovid MEDLINE. Articles met inclusion criteria if they described the availability or uptake of pharmacist-prescribed hormonal contraception in states with expanded prescriptive authority in the United States. One reviewer extracted data, including methodologies, sample size and findings, of all included studies.

Results: Database searches identified 286 studies; after applying exclusion criteria, we chose 39 for full text screening; eight met inclusion criteria. The majority of studies (62.5%, n=5) used secret shopper telephone surveys to determine the number of pharmacies offering pharmacist-prescribed contraception. Two studies (25%) used Medicaid claims data to evaluate uptake. The proportion of pharmacies providing pharmacist-prescribed contraception ranged from 5.1-46.0%; chain pharmacies were more likely to provide pharmacist-prescribed contraception than independent pharmacies. Oral contraceptive pills were the most frequently available hormonal contraceptive.

Conclusion: This review supports the conclusion that some pharmacies offer pharmacist-prescribed hormonal contraception services in states with expanded authority. States vary in the proportion of pharmacies reporting pharmacist-prescribed contraception availability and method of contraception prescribed. Further studies evaluating the implementation of pharmacist prescribing will help explain state variations and provide a foundation to understand best practices to continue to expand access.

Background

Consistent contraceptive use results in reduction in unintended pregnancy rates.[1] The prescription requirement for hormonal contraception in the United States creates obstacles to consistent contraceptive use. In national surveys, thirty percent of people report barriers to obtaining a prescription for contraception, including lack of clinician appointments, inconvenient clinic hours, and inability to take time off work.[2,3] Additionally, Spanish-speaking and uninsured women have greater odds of reporting barriers to obtaining prescriptions compared to English-speaking women with private insurance.[2]

Pharmacist prescription of hormonal contraception is a strategy to expand contraceptive access and to address the barriers inherent in the model of a clinic visit to obtain a prescription. Pharmacist prescriptive authority for hormonal contraception is rapidly disseminating throughout the United States. In 2016, California and Oregon were the first states to allow pharmacists to independently prescribe hormonal contraception directly through legislative approval of statewide protocols.[4,5] As of February 2020, the District of Columbia and 19 states have passed statutes or regulations authorizing independent pharmacist prescribing of contraception.[6]

Recent studies focus on pharmacist and patient perspectives on pharmacist prescribing. Studies of pharmacists report high pharmacist interest in or intent to prescribe hormonal contraception.[7] In a national survey of pharmacists, 85% expressed interest in providing direct pharmacy access to hormonal contraception.[8] In a qualitative study of California pharmacists, when asked about motivation for prescribing hormonal contraception, 94% reported enjoying individual patient contact, followed closely by opportunities for professional development, benefits for patients, and contraception as an important public health issue.[9] Similar studies have demonstrated patients' interest and comfort in obtaining hormonal contraception prescriptions directly from pharmacists.[7,10] Women also describe many potential personal benefits of pharmacist prescribing, including avoiding the cost of a clinician visit and convenient pharmacy hours.[3] In a cohort study, women who obtained contraception from pharmacies instead of clinicians were younger and more likely to be uninsured.[11] Despite interest, patients and pharmacists report challenges to pharmacist prescribing including the need for reimbursement for pharmacist time for

counseling in the form of consultation fees, liability concerns, and need for confidential space within the pharmacy.[4,7,9,12–14]

To improve contraceptive availability through pharmacist prescribing of hormonal contraception, pharmacists, pharmacies, and other key stakeholders must move beyond interest to actual implementation of pharmacist-prescribing.

Objective(s)

The purpose of this review is to describe existing literature on the uptake of pharmacy access to hormonal contraception in states with expanded pharmacist prescriptive authority. The results of this review may help inform best practices for and next steps in implementation of pharmacist prescribing by describing the availability of and gaps in these programs following state policy changes.

Methods

Frameworks outlined by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) and Arksey and O'Malley informed the methodology of this scoping review.[15,16] We included studies describing the uptake of pharmacist-prescribed hormonal contraception following state legislation of statues or regulations permitting pharmacist-prescribed hormonal contraception. We excluded studies that were conducted outside the United States, in states that had not yet passed pharmacist prescriptive authority for hormonal contraception or were not written in English. We also excluded abstracts, gray literature, research protocols, literature reviews and reports with unpublished results.

Search Strategy

We conducted a search of the published literature to identify relevant articles. We searched three electronic databases from January 2022 to March 2022: PubMed (MEDLINE), Web of Science and Ovid MEDLINE. All databases were searched from 2016, the first year legislation for pharmacist prescriptive authority of hormonal contraception was implemented in the United States. Search terms included "pharmacist," "pharmacist prescribing," "pharmacies," "contraception" and "hormonal contraception."

Study Selection

We screened articles in two phases: first, we screened article titles and abstracts for eligibility. Researcher L.D. then reviewed the full text of articles identified as possibly relevant after the initial screening. We also reviewed the reference lists of included studies to identify any additional articles not captured in the original database searches.

Data Extraction

We developed a data extraction tool to capture key outcome information of included articles according to the study objectives. Researcher L.D. extracted data and charted using Microsoft Excel. The data gathered and recorded included primary author, article title, year of publication, study design, geographical setting, data source, sample size, time since legislation of pharmacist-prescribed contraception and study results. We grouped articles by study design, abbreviated key findings into descriptive tables of pharmacist-prescribing uptake, and compared studies.

Results

We identified 286 records by searching the published literature. After we removed 110 duplicate articles, we identified 39 records for full text review. Most studies did not meet inclusion criteria due to a focus on emergency contraception, a focus on pharmacist/patient perspectives and not uptake or study performed outside the United States. We included eight studies for detailed review (Figure 1).

Characteristics of included studies

Table 1 summarizes characteristics and methods of the studies included in this review. All included studies were published within the past 5 years.[12,13,17–22] The majority (62.5%, n=5) used secret shopper telephone surveys to determine pharmacy/pharmacist response to individuals asking about pharmacist-prescribed hormonal contraception.[12,13,17,19,20] One study sampled a cross-section of pharmacies providing pharmacist-prescribed contraception and included qualitative interviews with pharmacists.[18] Of these six articles, five were conducted in a single state or county within the state, four in California and one in Utah.[12,13,17–20] One study was performed in two states, New Mexico and Oregon.[12]

Two studies (25%) used Oregon Medicaid claims data to assess uptake of pharmacist-prescribed contraception in Oregon's Medicaid-covered population.[21,22] One of these articles

used retrospective claims analysis and the other used a difference-in-difference approach to compare receipt of contraception in the Medicaid-enrolled population before and after implementation of a statewide protocol for pharmacist-prescribed contraception.[21,22]

All included studies were conducted at varying times, from one to four years, after the state in which the study was based passed the rules and regulations for pharmacist prescribing of hormonal contraception. Most studies were performed one year after state implementation of protocols outlining pharmacist prescribing (62.5%, n=5).[13,17,19,20,22] Only one study included data collected four years after state implementation of pharmacist prescribing of hormonal contraception.[18]

Proportion of Pharmacies Reporting Pharmacist-Prescribed Contraception

Six studies (75%) evaluated the percentage of pharmacies reporting availability of pharmacist-prescribed hormonal contraception using secret shopper or telephone surveys.[12,13,17–20] The proportion of pharmacies providing pharmacist-prescribed contraception ranged from 5.1–46.0% (Table 2).[12,13,17–20]

Pharmacy Type: Chain versus Independent Pharmacies

Seven studies (87.5%) commented on the type of pharmacy, independent versus chain pharmacy, and relationship with reported availability of pharmacist-prescribed contraception.[12,13,17–21] Four of the seven studies (57.1%) found pharmacies reported pharmacist prescribing was available in more chain or retail pharmacies than in independent pharmacies.[12,18,19,21] In contrast, two of the seven studies (28.6%) found no significant difference in availability of pharmacist-prescribed contraception by pharmacy type.[13,17] One study (14.3%) reported mass merchandise/food stores were significantly more likely to offer availability than chain/independent pharmacies.[20] This is the only study to make a distinction between mass merchandise/food stores and other pharmacy types.

Location of Pharmacy: Rural versus Urban

Four studies (50.0%) explored differences in reported availability of pharmacist-prescribed contraception based on pharmacy location. The majority found no difference between proportions of urban and rural pharmacies providing pharmacist-prescribed hormonal contraception (75%, n=3).[12,13,17] In contrast, one article found that 75% of pharmacies reporting pharmacist-prescribed contraception were characterized as non-rural.[19] This study also utilized geospatial analysis to evaluate the geographic distribution of

pharmacies prescribing contraception throughout the state. The researchers determined that 40% of Utah census tracts with high proportions of residents living below the poverty line had low access to pharmacist-prescribed contraception.[19] These census tracts with limited access to pharmacist-prescribed contraception were primarily rural, although some were in suburban and highly populated areas in Utah.[19]

Contraceptive Methods Provided

Four studies (50.0%) commented on the type of contraceptive method (contraceptive pills, patch, ring or injection) available in the included pharmacies.[12,13,17,19] Oral contraception was the most common available method for pharmacist prescribing in all four studies (Table 3).[12,13,17,19]

Using insurance claims data from the Oregon Medicaid population, combined oral contraceptive pills were the most common method prescribed by pharmacists (90.5%), followed by progestin-only pills (5.6%) and transdermal patch (3.2%).[21]

Pharmacist Consultation

Three (37.5%) secret shopper telephone surveys further evaluated information provided to potential clients about the pharmacist consultation process.[12,17,19] Most pharmacies (77.3–91%) informed researchers during the telephone survey that a health history or self-screening assessment was required by the state to receive a contraception prescription by a pharmacist.[17,19] A smaller proportion of pharmacies (25%) discussed the state requirement for blood pressure screening at the time of consultation.[17,19] Only one study reported that a minority of pharmacies required an appointment for pharmacist-prescribed contraceptive services, 12% of rural and 7% of urban pharmacies.[12]

Cost to Patients: Consultation Fees and Cost of Medications

Three studies (37.5%) evaluated whether pharmacies reporting availability of pharmacist-prescribed hormonal contraception charged patient fees for consultation or pharmacist prescribing services.[12,13,19] All three found that most pharmacies charge the patient for consultation fees, as opposed to either no-fee consultation or billing patient insurance for consultation.[12,13,19] The average consultation fee ranged from $30–$45.[13,19] The highest consultation fee reported in all studies was $70.[19] Chain pharmacies were more likely to have set fees compared to independent pharmacies; fees did not differ by urban or rural pharmacy location.[13,19]

Two studies also evaluated the patient cost of prescribed contraception.[12,19] The cost of medication to patients varied across pharmacies, with an average estimated cost of $20 per month.[19] Most pharmacies reported that the monthly cost depended on the patient's insurance and that contraception would be covered by insurance when prescribed by a pharmacist.[12,19] However, when asked about Medicaid coverage for pharmacist-prescribed contraception, over 80% of pharmacists did not know whether Medicaid-covered benefits included either pharmacist consultation or medication prescribed.[12]

Utilization of Insurance Coverage

Two studies used Medicaid claims data to evaluate the utilization of pharmacist-prescribed contraception among Oregon Medicaid beneficiaries.[21,22] A retrospective analysis of Medicaid claims data two years after policy implementation in Oregon showed that pharmacists wrote 10% of all new oral and transdermal contraception prescriptions among Medicaid enrollees.[21] The total number of claims by pharmacists in the two-year study period was 1,313, but the total number of contraceptive claims by any provider in Oregon during this time was not reported.[21]

A second utilization study compared Medicaid claims data prior to and one year after policy implementation in Oregon.[22] In contrast to the prior findings, this study showed a similar probability of receiving contraceptive services before and after pharmacist-prescriptive policy implementation, indicating no significant intervention effect when using difference-in-difference models.[22] The first year after policy implementation, 0.3% of all filled oral and transdermal contraception was prescribed by a pharmacist. In the second year, this percentage increased to 0.6% and no difference was noted in prescriber type between continuing or new contraceptive users.[22]

Discussion

This review examined current research on availability of pharmacist-prescribed hormonal contraception services in states with expanded pharmacist prescriptive authority. In the states reviewed, hormonal contraception was available by pharmacist prescribing in a small proportion of pharmacies, with the highest availability reported in 46.0% of sampled Oregon pharmacies.[12] Pharmacist prescribing of contraception was also more commonly reported in chain compared to independent pharmacies, but no differences in availability

were reported in rural versus urban pharmacies. These contraception access findings align with prior published studies and reviews and indicate that pharmacist-prescribed hormonal contraception is transitioning from a policy change to clinical practice in states with expanded pharmacist prescriptive authority. [7,8,14]

Full implementation of health care policies requires time. Based on translational research, implementation of practice changes suggested by original research into the health care setting with subsequent improvement of patient care takes an average of seventeen years.[23] An average of nine years of this time is required for evidence-based recommendations from systemic reviews or guidelines to be fully implemented in clinical practice.[24] The majority of studies included in this review were conducted only one year after implementation of pharmacist-prescribing policies in the respective states. It is encouraging that even after this short time period, pharmacies, pharmacists and stakeholders have begun to implement this service. The two studies conducted three and four years after policy implementation reported higher proportions of pharmacies with pharmacist-prescribed hormonal contraception compared to studies conducted at one year.[12,18] These results align with prior understanding of the required time for implementation of health care policy. We anticipate that with ongoing time from initiation of pharmacist prescribing, a higher proportion of pharmacies will offer pharmacist-prescribed hormonal contraception.

When evaluating the range of contraceptive services offered, oral contraceptive pills are the most frequently available in sampled pharmacies. In prior studies, pharmacists reported increased levels of comfort with prescribing oral contraceptive pills compared to other methods, including after training or education sessions.[7,25] Additionally, data from the 2017-2019 National Survey of Family Growth revealed that oral contraceptive pills are the second most common contraceptive method, after permanent sterilization, utilized by women aged 15-49 years old.[26] It is beyond the scope of this review to determine whether pharmacist comfort, increased demand for oral contraceptive pills, or other factors explain the dominance of oral contraceptive prescriptions. Future studies evaluating pharmacy-level implementation of contraceptive services could determine why other hormonal contraception methods are less prescribed by pharmacists.

Beyond availability of methods prescribed, these studies also revealed that many pharmacies charge consultation fees, averaging $30-$45, along with the cost of the

prescribed medication, if not covered by insurance. In prior studies only 36% of participants reported willingness to pay more than $20 for pharmacist-prescribed contraception.[27] Current reported costs of pharmacist consultation may contribute to barriers limiting access. While pre-implementation studies focused on patient perspectives of pharmacist-prescribed contraception, implementation studies focused on pharmacist and pharmacy-level barriers to providing this service. Therefore, limited data describe other patient-related barriers to access to pharmacist-prescribed contraception.

The two insurance claims studies indicated an increase in pharmacist prescribers for oral contraceptives and transdermal patch in Medicaid populations after implementation of pharmacist-prescriptive authority, but no overall increase in number of contraceptive prescriptions.[21,22] The lack of increase in prescriptions raises the question of whether patients who already obtained contraceptive prescriptions from other healthcare providers were simply switching provider type. Ideally, pharmacist prescribing would expand access to patient populations with limited access. Prior studies have indicated that women who seek pharmacist-prescribed contraceptive services are younger, less educated and more likely to be uninsured.[28] Claims data cannot evaluate the impact of pharmacist prescribing on contraception access for uninsured patients.

While the studies in this review highlight successful pharmacy uptake of pharmacist prescribing in the states studied, many unanswered questions remain about contraceptive access on the individual patient or population level. For example, is there a proportion of pharmacies that need to provide pharmacist-prescribed contraception to ensure all individual have access to direct pharmacy contraceptive access? Should pharmacies provide all contraceptive methods or is availability of oral contraceptives indicative of expanded access or successful implementation? Further implementation studies may answer these questions and guide implementation efforts, especially as states evaluate the impact of their policy changes and additional states consider expanding pharmacist prescriptive authority.

This review has limitations. First, only a small number of studies from a select few states met inclusion criteria, limiting the significance of the findings. However, the limited data illustrates the delay in states to adopt pharmacist prescriptive authority for hormonal contraception. Additionally, there are differences across states affecting uptake or availability of pharmacist-prescribed contraception including differences in type of contraceptive

methods approved for pharmacist prescribing, or presence of legislation allowing for pharmacist reimbursement for consultative services. State differences may affect findings including the length of time since implementation of state policy or protocol, and data collection methodology. It is unclear if the variations in review findings across states are secondary to state level differences, study characteristics, or other facilitators/barriers that might affect implementation of pharmacist prescribing in individual states.

The majority of the studies included used secret-shopper telephone surveys to determine availability of services in pharmacies. This study design has inherent biases, including variability in the knowledge of pharmacist prescribing based on the survey respondent. However, this study design is robust for understanding the information provided to women seeking pharmacist-prescribed hormonal contraception, which aligns with the goal of this review to understand current real-world access to pharmacist prescribing.

Conclusion

This review provides evidence that pharmacist-prescribed hormonal contraception is available to individuals in states with expanded pharmacist-prescribed authority. Pharmacies have begun to provide prescriptions for hormonal contraception, although variations remain in the proportion of pharmacies reporting services and availability of different types of contraceptive methods. Future research focused on determinants of successful implementation programs will be helpful in continuing to expand the availability and uptake of pharmacist-prescribed hormonal contraception.

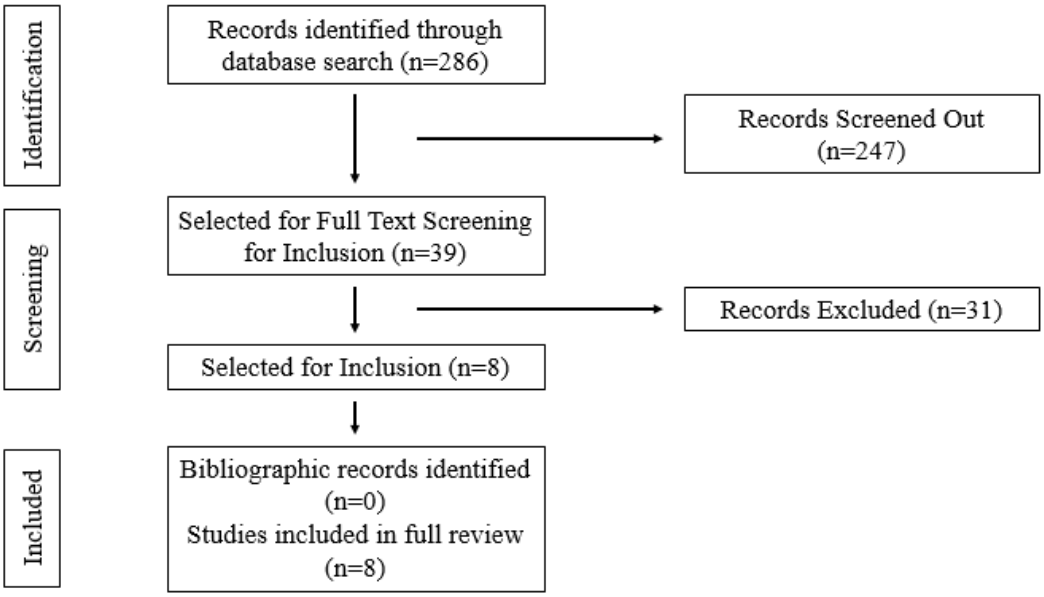

Figure 1. Flow diagram of literature review and screening results.

Table 1. Methodological characteristics of included studies.

Primary Author	Title	Year	Study Design	Setting	Time Since Implementation	Data Source	Sample Size	Primary Outcomes
Secret Shopper Studies								
Batra	An evaluation of the Implementation of Pharmacist-Prescribed Hormonal Contraceptives in California	2018	Cross-sectional "secret shopper" telephone survey	California	1 year	Random sample of pharmacies in California	480 pharmacies	• 5.1-22% of pharmacies reported providing pharmacist-prescribed hormonal contraceptives (95% CI 2.9–7.2%) • No significant difference between the proportions of nonrural pharmacies (5.1%, 95% CI 2.8–7.3%) and rural pharmacist (4.7%, 95% CI 1.6–7.7%), p=0.83 • No significant difference between the weighted proportions of independent pharmacies (6.4% 95% CI 2.3–10%) and chain pharmacies (4.3% 95% CI 1.8–6.8%, p=0.4) • 77.3% of pharmacies providing pharmacist prescribed hormonal contraceptives informed secret shoppers that assessment of medical history would be required; 36.4% mentioned BP screening
Gomez	Availability of Pharmacist-Prescribed Contraception in California, 2017	2017	Cross-sectional "secret shopper" telephone survey	California	1 year	Random sample of all pharmacies in California	1008 pharmacies	• Pharmacist prescribed contraception available in 11.1% (95% CI 9.3%–13.2%) of pharmacies • Most pharmacies were urban (85.7%) and affiliated with chains (70.3%) • Among pharmacies offering this service, 67.9% (95% CI 58.5–75.9%) indicated a specific fee requirement (median $45, (IQR, $40–45)

Magnusson	Accessibility of Pharmacist-Prescribed Contraceptives in Utah	2021	Cross-sectional "secret shopper" telephone survey and geospatial analysis	Utah	1 year	All class A pharmacies identified by Utah Health Department as enrolled in contraceptive prescribing	163 pharmacies	• Of all operating retail pharmacies in Utah (n=459), 127 (28%) reported providing pharmacist-prescribed contraception • Most pharmacies are characterized as chain (80%, n=102) and nonrural (75%, n=95) • Consultation fees varied from $0-$70; only 2% (n=3) of the pharmacies provided a no-fee consultation; fees did not change based on rural vs urban location
Qato	Pharmacist Prescribed and Over-the-Counter Hormonal Contraception in Los Angeles County Retail Pharmacies	2020	Cross-sectional "secret shopper" telephone survey	California	1 year	All retail pharmacies in Los Angeles County	1,611 pharmacies	• One in 10 pharmacies (10.1%) in LA county offered pharmacist-prescribed contraception • Chain and independent pharmacies were significantly less likely to offer pharmacist prescribed contraception (9.3% vs 8.9%) compared with mass merchandise/food stores (17.9%)
Rodriguez	Availability of Pharmacist Prescribed Prescription of Contraception in rural areas of Oregon and New Mexico	2020	Cross-sectional "secret shopper" telephone survey	Oregon and New Mexico	3 years (Oregon) 1.5 years (New Mexico)	Random sample of all Oregon and New Mexico pharmacies	300 pharmacies	• 42% of pharmacies reported availability of pharmacist prescribed contraception (46% Oregon and 19% New Mexico) • Majority of pharmacies offering this service were chain pharmacies in both rural (68% versus 32%, $p<0.0001$) and urban locations (75% versus 25%, $p<0.001$) • Similar proportion of rural pharmacies reported offering pharmacist prescription as urban locations (36% vs 46%)
Chen	Implementation of hormonal contraceptive furnishing in San Francisco community pharmacies	2020	Cross-sectional study of pharmacies; qualitative study of pharmacists	California	4 years	All retail and independent pharmacies in San Francisco	113 community pharmacies	• 21 locations (19%) indicated that they furnished hormonal contraception • 20 of the 21 pharmacies with pharmacist prescribed contraception were chain pharmacies

Medicaid Claims Data

Anderson	Pharmacist Provision of Hormonal Contraception in the Oregon Medicaid Population	2019	Retrospective analysis of Medicaid claims data	Oregon	2 years	Oregon Medicaid claims data 1/2016 - 12/2017	NA	• 10% of patients (367/3614 total patients in Oregon Medicaid program) received new prescription for oral and transdermal methods from pharmacist • 162 pharmacists prescribed contraception, resulting in 1313 fill claims • Most claims originated from retail chain pharmacies (94%) in urban areas (71%)
Gibbs	Pharmacist prescription and access to hormonal contraception for Medicaid-insured women in Oregon	2020	Difference-in-difference analysis using Oregon Medicaid Claims data	Oregon	1 year	Oregon Medicaid data 2015-2017 for women ages 15-44 yo	NA	• Monthly probability of receiving contraceptive services was similar before and after passage of pharmacy access • Monthly probabilities of receiving any contraceptive service and filling pill/patch prescription was similar over time • In 2016, the first year of implementation, 0.3% (n=520) of all filled pill/patch claims were prescribed by a pharmacist (1.1% of pill/patch claims were missing prescribing provider information) • In 2017, 0.6% filled pill/patch claims prescribed by a pharmacist

Table 2. Proportion of pharmacies reporting pharmacist-prescribed contraception.

Primary Author	Total Pharmacies Sampled (No.)	Pharmacist-Prescribed Contraception Available (No.)	Pharmacist-Prescribed Contraception Available (%) [95% CI]
California			
Batra	457	22	5.1% [2.9-7.2%]
Chen	113	21	19%
Gomez	1008	112	11.1% [9.3-13.2%]
Qato	1482	--	10.1%
Utah			
Magnusson	459	127	28%
Multiple States			
Rodriguez	300 (total)*	127 (total)*	46% Oregon; 19% New Mexico

* State level data not provided in study

Table 3. Proportion of pharmacies reporting specific contraceptive methods available by pharmacist prescription.

Type of Contraceptive Method Available	Primary Author			
	Batra	Gomez	Magnusson	Rodriguez
Pills	68%	77.7%	100%	60% rural, 69% urban
Patch	46%	38.4%	2%	32% rural, 33% urban
Ring	41%	40.2%	14%	30% rural, 28% urban
Injectable	23%	8.9%	NA*	25% rural, 24% urban
All methods	23%	--	--	--

*Injections not approved for pharmacist prescribing in Utah.

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Section 3

The prior scoping review illustrates that pharmacists are prescribing hormonal contraception in a subset of states with expanded pharmacist prescriptive authority. The studies provide initial insight into the implementation process of pharmacist-prescribed contraception by describing the uptake of this service. However, further evaluation of integration of pharmacy access to hormonal contraception, including the implementation steps, challenges and facilitators, is currently lacking. As states continue to pass legislation authorizing pharmacist prescribing of hormonal contraception, knowledge of the implementation steps may help guide state policy development. Additionally, by comparing and contrasting the process in different states, states can share successful implementation strategies and lessons learned across state lines.

Implementation science uses frameworks to evaluate the integration or implementation of evidence-based health programs into standard practice.[14] The Consolidated Framework for Implementation Research (CFIR) is one such framework by which to explore the implementation process.[14] Researchers can use this framework as a guide for implementation of evidence-based interventions or to understand and evaluate data surrounding implementation strategies. The use of an implementation framework allows for an enhanced understanding of the varying factors that influence the implementation of interventions.

To obtain a broad understanding of the implementation process of pharmacist prescribing of hormonal contraception, the next section is a qualitative research study evaluating implementation of pharmacist prescribing at the state level with use of an implementation science framework.

Section 4

Implementation of Pharmacy Access to Hormonal Contraception

Abstract

Background: States throughout the United States are passing legislation to authorize pharmacist prescribing of hormonal contraception to decrease barriers to access to contraception. However, there is limited existing research characterizing the state implementation process.

Objectives: To understand the steps states have taken to promote pharmacist prescribing of hormonal contraception, including implementation challenges and facilitators.

Methods: We conducted a qualitative study of interviews with 18 key stakeholders from 10 states with pharmacist prescriptive hormonal contraceptive authority. We used relevant constructs from the Consolidated Framework for Implementation Research (CFIR) to develop an interview guide that explored participants' experiences with implementation of pharmacist prescribing of hormonal contraception including facilitators, barriers and potential approaches to promote implementation. We analyzed data using directed qualitative analysis principles and compared experiences across states. We organized the data using the CFIR framework and explored the facilitators of and barriers to states' implementation efforts.

Results: We interviewed 10 individuals from the state Pharmacist Association or Board of Pharmacy, six community pharmacists and two individuals from Medicaid offices. Participants identified four key steps to implement pharmacist prescribing at the state level: development of reimbursement and billing mechanisms for pharmacist time, creation of state rules and regulations, development of educational programs for pharmacists and expansion strategies for pharmacists and pharmacies. Participants identified early involvement of key stakeholders and a culture of support for clinician pharmacists as facilitators to implementation. Challenges included complexity and cost of billing mechanisms, lack of funding for implementation efforts and competing priorities of stakeholders.

Conclusion: States implementing pharmacist prescribing of hormonal contraception should prioritize strategies to overcome reimbursement and billing challenges early in their efforts to expand contraceptive access.

Background

One-third of women report barriers to obtaining a prescription for hormonal contraception including lack of clinician appointments, inconvenient clinic locations or the requirement of a pelvic examination or pap test prior to prescribing.[1] Barriers increase inconsistent use of contraception and unintended pregnancy.[2] One mechanism to expand contraceptive access is to allow pharmacists to prescribe hormonal contraceptive methods without a clinician visit. As of May 2022, nineteen states and the District of Columbia have passed statutes or regulations to authorize pharmacist prescribing of contraception, allowing facilitated access and initiation of contraception at the pharmacy.[3]

Uptake of pharmacy access in states with expanded pharmacist prescriptive authority has been varied. In California, one year after receiving expanded authority, telephone surveys of a random selection of pharmacies revealed that 11% of pharmacies provided pharmacist-prescribed contraception; 68% charged a fee for the service.[4] In similar studies, 42% of Oregon pharmacies, 27% of Utah pharmacies and 19% of New Mexico pharmacies reported availability of pharmacist-prescribed hormonal contraception.[5,6] In Utah, the majority (75%) of participating pharmacies were located in non-rural areas. Two years after Oregon's expanded authority, Medicaid claims data demonstrated that pharmacists wrote 10% of all new oral and transdermal contraception prescriptions in Medicaid enrollees, avoiding an estimated 51 unintended pregnancies.[7] However, a difference-in-difference analysis of Oregon Medicaid claims did not find a significant policy effect on receipt of contraceptive services.[8]

Despite variable uptake of pharmacist prescribing, pharmacists report interest in prescribing hormonal contraception. In a national survey, 65% of pharmacists reported personal interest in prescribing hormonal contraception, with more support in states where legislation allowing pharmacist prescribing had already been enacted.[9] Despite their interest, pharmacists have reported challenges to prescribing hormonal contraception including lack of payment for counseling/prescription, need for pharmacy workflow changes, pharmacist time constraints, liability concerns and need for additional space and education/training.[4,5,9–11] There is little guidance on interventions to support pharmacies and pharmacists in establishing and implementing direct pharmacy access to contraception.

Objective(s)

We sought to understand the implementation process of pharmacist prescribing of hormonal contraception in states that have expanded pharmacist prescriptive authority. Our primary objective was to describe the steps taken by states to implement pharmacist prescription of hormonal contraception. Secondary objectives included comparing implementation challenges and solutions and identifying determinants of successful pharmacist prescribing program implementation.

Methods

Study setting and sample

We performed a qualitative evaluation of implementation of pharmacist prescribing of hormonal contraception in states that have authorized pharmacists to prescribe hormonal contraception by statewide protocol, standing order or independent prescriptive authority. We conducted semi-structured interviews with key stakeholders involved in pharmacist prescribing to understand the steps taken to enable pharmacist prescription of hormonal contraception, compare different states' perceived barriers and solutions, and determinants of successful program implementation. The University of New Mexico Health Sciences Center's Human Research Protections Office approved this project.

We used a purposive sampling approach to identify individuals in each state that were knowledgeable about or participated in implementing pharmacist prescribing of hormonal contraception.[12] The study engaged individuals from state Medicaid offices, state pharmacist associations or boards of pharmacy and community pharmacists. We recruited participants by contacting the pharmacist association, board of pharmacy or college of pharmacy for each of the 12 U.S. states and District of Columbia that had authorized pharmacists to prescribe hormonal contraception by August 2020, including California, Colorado, District of Colombia, Hawaii, Idaho, Maryland, Minnesota, New Hampshire, New Mexico, Oregon, Utah, Virginia and West Virginia.[13] We invited the Executive Director or equivalent of the state pharmacist association to participate and to identify champions or advocates for expanding pharmacist prescriptive authority, including hormonal contraception, for their state. We recruited further participants through snowball sampling.[12] We asked each study participant to list other important individuals involved in pharmacist prescribing

implementation, including representatives from the Medicaid office or community pharmacists in their state or nationally. If participants were unable to identify representatives from the state Medicaid office, we contacted the state Medicaid office directly to reach individuals knowledgeable about pharmacist prescribing.

Data Collection

We used relevant constructs from the Consolidated Framework for Implementation Research (CFIR) to develop the interview guide that explored participants' experiences with establishing pharmacist prescribing of hormonal contraception, including the steps taken, facilitators of success, perceived barriers and potential solutions.[14] We used CFIR because this framework has guided implementation of evidence-based health programs, including evaluating and defining implementation of public health initiatives at the state level.[15,16] We structured the guide to capture information from participants in states with various stages of implementation to allow collection of a wide range of experiences. Study team members in the University of New Mexico College of Pharmacy and community pharmacists in Albuquerque, NM familiar with pharmacist prescribing of hormonal contraception piloted the interview guide.

We conducted interviews from March 2021 through April 2022. One researcher (L.D.) conducted all interviews over the telephone or using an audiovisual platform based on participant preferences.

Participants provided verbal consent immediately prior to the start of their interview and all interviews were audio-recorded. Interviews lasted an average of 50 minutes. All participants received a merchandise card at conclusion of interview. A transcription company transcribed the audio recordings verbatim. Research staff verified transcripts against the audio recording for accuracy and removed all identifying information, including names, institutions, locations and dates. We imported the transcripts into the qualitative analysis software program Dedoose for coding and analysis.

Data Analysis

We conducted qualitative data analysis using directed content analysis.[17] We developed the initial data analysis codebook using anticipated implementation steps for pharmacist prescribing. We further refined the codebook throughout data collection based on the emergence of new findings and themes. Two researchers (L.D and V.M.) independently

coded and analyzed the transcribed data to assure comprehensive and consistent coding application. We used Dedoose to generate queries for interpretation of data.

We organized key themes or concepts by reviewing the small sets of interviews grouped by each state. Once we understood each state as a unit, we performed cross-state comparisons. The research team systematically explored and integrated these different themes, focusing on the steps integral to implementation and facilitators/barriers.

We used CFIR as a framework to interpret the findings by distilling the key themes and concepts based on the CFIR domains and constructs. Supplemental Table 1 presents the facilitators, barriers, implementation strategies and selected quotes identified using these CFIR domains and constructs. This allowed further exploration of the challenges and facilitators of the implementation process and their relationship to perceived success of implementation of pharmacist-prescribed contraception.

Results

We reached twenty-two individuals from ten of thirteen states with expanded pharmacist prescriptive authority. Table 1 shows the professional role of these individuals. Eighteen individuals participated in interviews; two reported no implementation whatsoever in their state and declined to participate, and two declined due to job restrictions. Table 2 shows the pharmacist prescribing characteristics of the states included in the study. We could not contact or identify any individuals in the three additional states with pharmacist-prescribed contraception. Participant-identified key implementation steps were organized as steps taken at the state level and those performed at the individual pharmacy or chain level. Figure 1 illustrates these key steps.

State Level Implementation

At the state level, participants identified development of a protocol or standing order, development of pharmacist education requirements, advertisement to pharmacists/pharmacies and the establishment of reimbursement and billing mechanisms as key steps following passage of enabling legislation.

Unless the passed legislation included rules and regulations, the state board of pharmacy is responsible for development of rules/regulations surrounding a prescribing

protocol. Some states developed the protocol completely, with input from state experts or other stakeholders, while others adapted pre-existing protocols developed by earlier states. Participants noted that when this process took longer than 3-6 months it decreased momentum for further implementation steps.

As each state board of pharmacy developed regulations for its pharmacist-prescribed contraception protocol or standing order, they also determined both the education requirements and associated programs. Content experts, particularly from colleges of pharmacy, often helped to direct these continuing education programs. Some states recognized training from other states or national programs, while others endorsed only select locally developed programs. Three states also determined that new graduates from a college of pharmacy in their state could prescribe hormonal contraception without additional training.

At the state level, champions of pharmacist-prescribed hormonal contraception, together with state pharmacist associations, led the education and guidance for pharmacists seeking this training. Most states lack a centralized program to direct these efforts, leaving individual pharmacists to advocate independently for implementing this in their pharmacies.

Lastly, development of reimbursement and billing mechanisms fell to the pharmacist association or individuals at the state Medicaid office. Seven out of ten states passed additional legislation for reimbursement of pharmacist consultation time for individuals enrolled in state Medicaid programs. Participants reported individual state Medicaid offices are typical responsible for developing the steps for pharmacist billing and reimbursement of services rendered. Participants reported varying levels of progress.

In states with defined steps for pharmacist reimbursement, the individual pharmacist applies for Medicaid provider status; state Medicaid offices must create a system to register pharmacists as providers and a process for billing. States typically established billing processes modeled after traditional medical billing performed by physicians and physician offices. The pharmacist-provider then submits medical billing codes for a contraception consultation visit. Concerns exist around pharmacist knowledge of medical billing, and pharmacist time to submit the appropriate codes. Additionally, to expand services to all individuals seeking hormonal contraception prescriptions, other insurance payers must also reimburse pharmacist consultation time. The majority of study participants identified

establishment of billing resources and infrastructure to incentivize pharmacies as the most important step to increase implementation of pharmacist-prescribed hormonal contraception through their respective states.

Pharmacy Level Implementation

Study participants identified additional steps required for implementation of pharmacist-prescribed hormonal contraception at the individual pharmacy or within a pharmacy chain. Pharmacies often performed key implementation steps in parallel. These steps, listed in Figure 1, include development of pharmacy/chain prescribing protocols, advertisement strategies to potential patients, identifying consultation space, obtaining equipment to measure blood pressure, education of pharmacists and staff, establishing a plan for appointment or walk-in services and development of reimbursement mechanisms and billing submission or consultation fees. The individual champions in independent pharmacies or corporate policies in chain pharmacies typically direct these steps.

Facilitators, Barriers and Implementation Strategies

Using the CFIR implementation framework, we identified four domains and eight constructs as the most relevant to implementation of pharmacist-prescribed hormonal contraception among the states included in this study (Supplemental Table 1). The order of the presented constructs does not reflect any specific priority or importance. The definitions of the domains and constructs in the setting of pharmacist-prescribed hormonal contraception are included.

Intervention Characteristics

The "intervention characteristics" domain pertains to the key attributes of pharmacist-prescribed contraception, which can influence implementation success. The most important CFIR constructs for pharmacist-prescribed contraception were/are intervention source, complexity and cost.

Intervention Source: factors surrounding development of the intervention at a state level. In some states, non-pharmacist health care provider legislators introduced the bill for pharmacist prescribing, creating challenges including lack of knowledge or interest from the

pharmacist community. Involvement of the state pharmacist association reduces some of these barriers. Some states also developed commissions to bring together key stakeholders across disciplines to ensure agreement between physicians, nurses and pharmacists. Additionally, inclusion of key state stakeholders in drafting the legislation ensured inclusion of appropriate contraceptive methods and reimbursement provisions.

Complexity: perceived difficulty of implementation of the intervention. Study participants identified multiple barriers related to the perceived complexity of the implementation process. Participants noted pharmacist concern surrounding complexity of counseling about hormonal contraceptive options as a common barrier. Board of pharmacies developed or identified continuing educational opportunities to train pharmacists and increase comfort with this counseling. Additionally, participants noted lack of pharmacist time to provide consultation about contraception due to increased workload of pharmacists, including administration of COVID-19 vaccinations, as a major barrier. To address this, one state is expanding the role of pharmacist technicians to increase pharmacist availability. The most common barrier identified was the perceived complexity around pharmacist reimbursement, including development of billing mechanisms and need for an electronic medical record system to document services provided. One participant reported working to develop an electronic medical record for pharmacies, but many states were unable to provide resources or strategies to address the barrier of billing for pharmacist consultation.

Cost: cost to pharmacies or pharmacists with implementation of the intervention. Participants reported concerns about the cost of establishing pharmacist-prescribed contraception. Multiple states allow recent graduates from in-state Colleges of pharmacies to prescribe contraception after graduation without additional courses or training requirements, reducing cost concerns about continuing education programs for new graduates. The majority of pharmacies already have blood pressure machines and private consultation spaces, reducing potential costs to pharmacies. However, lack of reimbursement mechanisms, limited knowledge of pharmacists about billing for consultation time, diversion of pharmacist time from other reimbursed services and reimbursement restrictions to Medicaid-insured individuals remain significant barriers. Pharmacies are charging consultation fees to reduce these cost concerns, but participants reported funding for efforts to implement services and mechanisms to incentivize pharmacy implementation at the state level remain lacking.

Outer Setting

This domain includes the national social and economic context of pharmacist-prescribed contraception in the United States. The salient construct in this domain is cosmopolitanism.

Cosmopolitanism: Degree to which a state networks with other states or external organizations. Stakeholders engaging across multiple states to share resources and lessons learned is a common facilitator for state level implementation. These connections allow states to use other state protocols or continuing education trainings, reducing the time for individual state boards of pharmacy to develop state-level programs. Participation in national organizations, including the National Alliance of State Pharmacist Associations (NASPA), can connect pharmacists associations across states.

Inner Setting

The "inner setting" domain refers to the structural, political and cultural context within a state through which pharmacist prescribing of hormonal contraception proceeds. The most salient constructs in this domain include networks and communication and culture.

Networks and Communications: Nature and quality of formal and informal communications within a state. Many participants reported limited communications between stakeholders and Medicaid offices, ultimately impeded progress within states. To ensure communication, one state developed regular meetings between Medicaid offices and state pharmacy prescribing champions. Pre-existing relationships between stakeholders, including prior employment in the same pharmacy or system, facilitated ongoing communications and development of implementation programs.

Culture: values and basic assumptions of a state regarding intervention. Multiple participants noted that states with a pre-existing culture of a clinician pharmacist model, support from college of pharmacy or baseline progressive culture facilitated forward progress towards implementing pharmacist-prescribed contraception. Other states noted that a pervasive resistance to change in the pharmacist community created barriers due to decreased motivation to integrate these changes. Additional challenges existed in states where physicians resisted expanding pharmacist prescriptive authority by physicians, resulting in

extended time to pass legislation or rules/regulations of pharmacist prescribing. Education of the state community, including pharmacists and physicians, about the benefits of expanding pharmacist scope of practice and impacts on expanding contraceptive access help address these challenges.

Process of Implementation

The salient constructs in the "process of implementation" domain are engaging champions and reflecting and evaluating.

Engaging Champions: attracting and involving stakeholders who dedicate themselves to supporting pharmacist prescribing. Study participants frequently discussed the importance of engaging stakeholders and other champions to support pharmacist-prescribed contraception. Participants identified faculty from college of pharmacies, individuals from reproductive health organizations and state pharmacist associations as common sources of these champions. The involvement of these champions typically started with passage of legislation and continued through engagement in implementation efforts with involvement in developing protocols or education programs for pharmacist prescribing. Additionally, creation of a task force by one state pharmacist association was a strategy to engage these champions to continue to move efforts further. Due to the changing nature of pharmacist roles secondary to the COVID-19 pandemic and vaccination efforts, competing priorities of these champions resulted in difficulty with engagement during the past 2 years.

Reflecting and Evaluating: quantitative and qualitative feedback and quality of implementation. Study participants reported challenges to evaluating implementation efforts including lack of access to data from Medicaid offices or absence of systems to collect number of prescriptions of hormonal contraception written by. States with stakeholders involved in research in pharmacist prescribing did note this as a facilitator to work on methods to evaluate implementation efforts. One state uses a data management system by Department of Health to record prescriptions written by pharmacists, but relied on pharmacists to enter prescriptions into the database. Additionally, when asked about the success of implementation programs in each respective states, the majority of interviewed individuals reported success in their respective state, as defined by having services available. There remained uncertainty around if there is a specific number of prescriptions or

participating pharmacists that would further reflect successful program implementation, limiting ability to further reflect on and evaluate the implementation process.

Discussion

This study on implementation of pharmacist-prescribed hormonal contraception across ten states reveals the complexity of this implementation process. Key steps of implementation conducted at the state level are identified, including development of state rules/regulations, education programs and reimbursement and billing mechanisms. For states considering expanding pharmacist prescriptive authority, the identification of these steps and their associated facilitators can help guide planning of implementation of pharmacist prescribing of hormonal contraception.

This study also identified persistent barriers to implementation, including limitations on pharmacist time, pharmacist culture or support towards the intervention and lack of reimbursement and billing mechanisms. These barriers align with previously identified barriers from interviews and surveys of pharmacists.[4,5,9,11,18] This study highlights the importance of establishing reimbursement and billing mechanisms for pharmacist consultation, as identified in multiple prior studies.[4,9,11,18] Without these mechanisms, many pharmacists and pharmacies lack incentive to implement pharmacy prescribing. However, this study further broke down implementation steps for pharmacist reimbursement and billing in states with pharmacist reimbursement statues for state Medicaid. Identification of additional challenges to these steps, particularly around perceived complexity of reimbursement mechanisms, including pharmacist capability to perform medical billing due to lack of electronic medical record systems and training in medical billing, will allow states to further address and navigate these challenges.

The evaluation and comparison across ten states with pharmacist-prescribed hormonal contraception in the United States is unique to this study. Prior studies evaluating implementation of pharmacist-prescribed hormonal contraception are limited to a single city or state.[4,18] By comparing and contrasting across multiple states, this study obtained a broad perspective of the implementation process, including the variety of strategies utilized. It also displayed the importance of communication between states, including lessons learned,

sharing of state protocols and continuing education programs, to facilitate implementation strategies and eliminate challenges already overcome in other states.

This study utilized the CFIR implementation framework to interpret the results and catalogue the findings based on this organization framework. Using an implementation framework allowed for identification of the key constructs that influence state implementation of pharmacist-prescribed hormonal contraception. By identifying these constructs and implementation strategies previously utilized, this information can assist future states when designing their implementation efforts.

We recognize utilization of CFIR to evaluate a state as opposed to organization level intervention is relatively unique. Two previous studies used CFIR to evaluate state level programs implementing immediate postpartum long acting reversible contraception and provide evidence for broader application of this implementation framework.[15,16] This study contributes to this literature and facilitates further discussion on the application of CFIR to evaluating implementation of statewide initiatives or policy changes.

Additionally, we designed this study to evaluate the key implementation steps of pharmacist-prescribed contraception at the state level. The goal was not to determine individual pharmacy success of implementation of this intervention, although we did identify key implementation steps at the individual pharmacy level. These findings generate questions for future work, including evaluation of steps necessary for successful program implementation of pharmacist-prescribed implementation at the pharmacy level.

We cannot overlook the impact of the COVID-19 pandemic on pharmacists and pharmacies. Throughout the COVID-19 pandemic, the role of pharmacists has changed, including expanded authority to administer COVID-19 testing and their integral involvement in administration of COVID-19 vaccines. Additionally, the high level of burnout among pharmacists known prior to the COVID-19 pandemic is continuing to rise in the pharmacist community secondary to stress from the pandemic.[19,20] Study participants reported concerns about pharmacists and pharmacies focus on vaccination, a profitable service for pharmacies, increased pharmacist demands and pharmacist burnout as possible causes for reduced focus on implementation of pharmacist-prescribed contraception. Although one study of surveyed pharmacists in California and Colorado showed that only 2% of pharmacists suspended pharmacist prescribing of hormonal contraception services during the pandemic, other

studies have demonstrated pharmacists discontinuing this service during the pandemic at a higher rate.[6,21] As we conducted this study after the start of the COVID-19 pandemic, it is difficult to comment on changes to implementation strategies prior to the pandemic. However, based on the interviews performed, the COVID-19 pandemic has derailed implementation efforts. The effects of the pandemic on pharmacists and pharmacies, we also believe decreased the availability of stakeholders and pharmacies to speak with researchers for this study due to competing interests. As pharmacists continue to expand into these new roles within the healthcare system, future studies may consider evaluating the associated effects on implementation strategies for pharmacist prescriptive authorities.

This study has additional limitations. We encountered significant difficulty with recruitment for study participation. Ultimately only individuals from ten of the thirteen states participated in the study. Although snowball sampling assisted with identification of possible study participants, difficulties persisted including lack of response to participation despite multiple inquiries by research staff or inability to participate due to limitations by employer. Upon review of participants at conclusion of the study, we identified that states with easily identifiable stakeholders (or > 5 years since passage of legislation) ultimately drove the sampling, with more interviews conducted in these states. This aligns with the understanding that implementation of policy changes takes years, on average greater than nine, to become integrated into clinical practice.[22]

There are additional limitations secondary to the inherent biases of this study design. To addresses these limitations, we specifically developed the interview guide to ensure appropriate collection of data regardless of stage of implementation and to minimize social desirability bias by asking specific questions about the steps, facilitators and barriers of this process.

Conclusion

This multi-state study evaluates the key steps, facilitators and barriers of state level implementation of pharmacist-prescribed hormonal contraception. Consideration of these key steps in the setting of the relevant domains and constructs, may allow states to continue to develop implementation strategies for establishing pharmacist-prescribed hormonal contraception.

Table 1. Professional Role of Study Participants

Professional Role (n=22)	**n (%)**
Pharmacist	16 (73)
Pharmacist Association/Board of Pharmacy	10 (45)
Community Pharmacist	6 (27)
Medicaid Office	6 (33)
Interviewed	2 (9)
Contacted - declined participation due to job restrictions	2 (9)
Contacted – declined participation due to nothing to report	2 (9)

Table 2. Characteristics of Study States

Characteristics	**Number of States (n=10)**	**Number of Interviews Conducted (n=18)**
Time Since Legislation Passed		
≥ 5 years	5 (50)	12 (66.7)
4 years	3 (30)	4 (22.2)
3 years	1 (10)	1 (5.6)
2 years	1 (10)	1 (5.6)
Type of Prescriptive Authority		
Statewide Protocol	7 (70)	14 (77.8)
Standing Order	2 (20)	3 (16.7)
Other	1 (10)	1 (5.6)

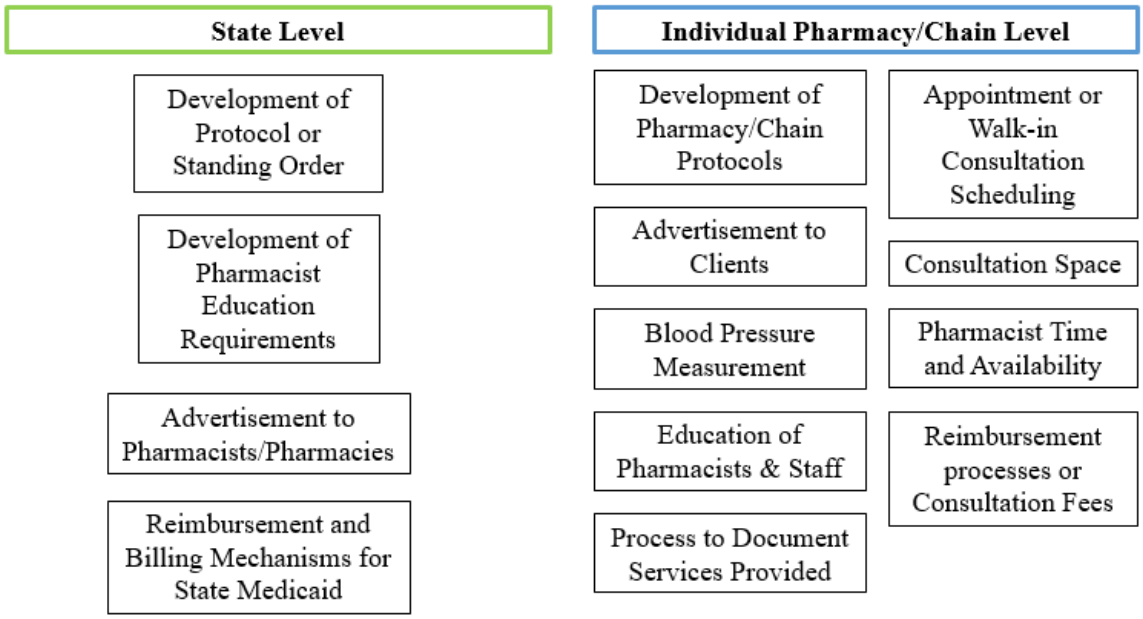

Figure 1. Key implementation steps divided by state level implementation versus individual pharmacy/chain level implementation.

Supplemental Table 1. Facilitators, barriers and strategies for implementation of pharmacist-prescribed hormonal contraception, by domain and construct of the Consolidated Framework for Implementation Research (CFIR).

CFIR Construct	Facilitators	Barriers	Implementation Strategies	Selected Quotes
Domain I: Intervention Characteristics Key attributes of pharmacist prescribed contraception				
Intervention Source: factors surrounding development of intervention at the state level	• Involvement of pharmacist association	• Development by non-pharmacist legislators • Lack of knowledge from pharmacist community • Lack of stakeholder involvement in drafting bill	• Commission to bring legislators, lobbyists, pharmacists and pharmacist association together • Engagement of stakeholders when developing protocol	• **"**establishing the Commission was brilliant because all of those conversations happen in a meeting with representatives and Senators who wanted to compromise" • "I think that helped, actually, having expertise within the state, and the Board deferring to us rather than trying to create it themselves without that clinical knowledge."
Complexity: perceived difficulty of implementation of pharmacist prescribed contraception	• N/A	• Perceived lack of pharmacist time and complexity of consultation • Technical complexity around reimbursement and billing mechanisms • Need for electronic medical record for documentation	• Expanding scope of pharmacist technician role • Development of multiple training opportunities for pharmacists • Passage of legislation ensuring pharmacist reimbursement • Development of electronic medical record systems for pharmacists	• "a lot of pharmacies are understaffed and they don't have the ability to take this up. They don't have the ability to number one, have the time or the resources to do this. But they also don't have a billing specialist. A lot of them don't have the resources or the computer technology, right. They're not enrolled or they don't have access to the portal." • "Pharmacists in general, particularly in the community pharmacy practice setting, are burned out and stressed. So the thought of adding on new services is not always, particularly within the chain environments, it's a challenge." • "Having a Licensed Advanced Pharmacy Technician there to do product verification and bagging frees up about three and a half hours of time. So there's your time."
Cost: cost to pharmacies or pharmacists with implementation of pharmacist prescribed contraception	• Blood pressure machines, consultation rooms in pharmacies • Legislation for pharmacists to be reimbursed as providers	• Lack of pharmacist billing knowledge • Reimbursement limited to Medicaid enrollees	• Charging patient consultation fees • Working with Medicaid for mechanisms for medical billing	• "if pharmacists aren't given that provider status to be able to bill insurances for the clinical service of that consultation or taking blood pressure, then pharmacists aren't going to do it"

		• Cost of continuing education courses • Lack of funding to support implementation efforts	• Graduates from college of pharmacy certified for prescribing • Variety of continuing education courses available	• "there's nothing behind it to ensure they actually get paid for those charges. So they're doing more work and no one's, really, the Medicaid, private [insurance], private providers, are not paying for the services"
Domain II: Outer Setting National Economic, political and social context of the intervention				
Cosmopolitanism: degree to which a state is networked with other states or external organizations	• Stakeholders talking across states • Active professional organizations (i.e. NASPA, ACOG)	• Legislative policies vary across states • Inability to identify stakeholders in certain states	• Use of other state protocols or continuing education trainings to discuss lessons learned including reimbursement clauses in initial legislation	• "And we looked more towards the [other state] model." • "But again, we have 15 states using our educational program. We're contracted with all these national chains. People are being trained across the nation to do this." • "So NASPA provided a lot of resources, but because [we are a] member, I was able to get best practices, things to look out for from the other states that have passed it before us."
Domain III: Inner Setting Structural, political and cultural context within a state through which implementation proceeds				
Networks and Communications: nature and quality of formal and informal communications within a state	• Pre-existing relationships between stakeholders	• Limited communication with Medicaid • Lack of formalized communications between stakeholders	• Regular meetings between Medicaid and state stakeholders • Active state forums with stakeholders and pharmacist associations	• "she was always a big champion. I had a regular meeting with her just to see what's coming down the line and what we need to be prepared for and the billing." • "We have a really good relationship with the College of Pharmacy and I've made it a habit of meeting with them once a month. So it's every first Tuesday of the month, I basically have a half hour call just to see their faces and talk to him about what challenges we're running into."
Culture: values and basic assumptions of a state regarding intervention	• Support of clinician pharmacist • Inclusion of college of pharmacy or academic pharmacy sites	• Baseline resistance to change in pharmacist community • Opposition by physicians	• Education on importance of increasing access • Discussion of increasing pharmacist scope of practice • Commissions to discuss regulations and potential impact on other providers	• "to realize that the literal financial cost savings, this will bear out have huge implications for public health and for states" • "I saw a need, but everybody else is like, 'God, no one ever asked us for this. Why would we have to do this 20 hours or however many hours of training if we never see it?'"

				• "I think it was generally embraced by our pharmacists. We tend to be a very progressive practicing state"
Domain V: Process Strategies or tactics that might influence intervention				
Engaging Champions: attracting and involving stakeholders who dedicate themselves to supporting the intervention	• Academics at College of Pharmacies • Reproductive health organizations support with legislation • State pharmacist associations	• Competing priorities	• Inclusion of stakeholders in drafting legislation and protocol development • College of Pharmacy has input in education plan • Development of task force by pharmacist association	• "Someone from our team from the [state] Pharmacy Association and the [college of pharmacy], they collaborated and worked together to draft up protocols and guidance documents for these three categories" • "having the school involved from an unbiased perspective and looked at as leaders in the profession, but also the state society involved, ended up being that perfect pairing to push things forward."
Reflecting and Evaluating: quantitative and qualitative feedback and quality of implementation	• Key stakeholders involved in research in the state, including with data	• Lack of access to Medicaid claims data • No system to collect number of pharmacist prescriptions of contraception • Unclear definition of goal for successful implementation	• Use of data management system to record prescriptions by pharmacists • Partner with researchers in state to access data	• "pharmacists to enter [prescriptions] in REDCap." • "As the foremost champion in this topic in my state, it's so hard to get information from my state [Medicaid] program. Like, "Can you tell me how many people have billed for this?" Or, like, "What zip codes or anything?" I can't get any data." • "I would say yes, it is successful because it is happening. Could it be improved? Absolutely."

Abbreviations: NASPA, National Alliance of State Pharmacist Associations; ACOG, American College of Obstetricians and Gynecologists; N/A, Not applicable.

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Section 5

As described in the qualitative study, implementation of policy changes into clinical practice is complex. On average, it takes nine years for evidence based recommendations to be integrated into clinical practice for improvement in patient care.[15] Policies expanding pharmacist prescriptive authority for hormonal contraception are still relatively new. Policies in Oregon and California, the first two states to enact a standing order, have been in place for only six years. It is not surprising to hear the continued need for the development of strategies to address the challenges of implementation throughout the states in the United States with expanded pharmacist prescriptive authority. However, the findings in the qualitative study exemplifies the gap from passage of legislative policy and clinical practice. The following section is a commentary on lessons learned from integration of pharmacist prescribing of hormonal contraception to help reduce this legislative gap and the similarities to implementation of a related state policy change-- immediate postpartum long-acting reversible contraception.

Section 6

From Legislative Intent to Clinical Practice – Reducing the Implementation Gap

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Throughout the past few years, state legislations have focused on passing a wide range of health care legislation, including policies to expand health care access and address health care affordability. Once passed, the focus shifts to implementation of policy changes, which can create a gap in time when the potential impact of the policies are severely limited. This commentary discusses examples of implementation of legislative policy changes and provides extrapolated lessons about reducing the gap from legislation to clinical practice change.

Pharmacist-Prescribed Contraception

Pharmacist prescribing of hormonal contraception is one strategy to expand contraceptive access by addressing barriers associated with the need for clinician prescription. In 2016, California and Oregon were the first states to allow pharmacists to independently prescribe hormonal contraception through legislative approval of statewide protocols, allowing individuals to initiate contraception directly at the pharmacy.[1,2] As of May 2022, the District of Columbia and 19 states have passed statutes or regulations authorizing independent pharmacist prescribing of contraception.[3]

Studies evaluating the uptake of pharmacist-prescribed contraception through secret shopper telephone surveys indicate that between 5-46% of pharmacies in California, Oregon, New Mexico and Utah offer this service.[4–9] All of these studies were conducted 1-4 years after passage of legislation expanding pharmacist prescriptive authority.[4–9] Additional studies detailing pharmacist-reported challenges to implementing this service found the most common barriers were lack of reimbursement or billing for pharmacist consultation, limited pharmacist time, and need for pharmacy work-flow adjustments.[1,6,9–11]

As further studies evaluate implementation of pharmacist-prescribed contraception, conversations with pharmacists and stakeholders across multiple states indicate that lack of insurance reimbursement for pharmacist consultation limits uptake. To address these concerns, a few years after initial legislation, select states passed follow-up legislation

establishing pharmacists as state Medicaid providers eligible for reimbursement. Other states have taken these lessons learned and included reimbursement provisions in their initial legislation for pharmacist prescribing. However, the time-consuming processes of pharmacist enrollment with Medicaid payers and of pharmacies following through with medical billing, a new and different system, have slowed the implementation of pharmacist reimbursement for consultation time in these states. Without systems to ensure pharmacist reimbursement for this service, many pharmacies lack financial incentive to implement pharmacist-prescribed contraception.

As a result of these reimbursement challenges, a majority of pharmacies charge patients for consultation fees at the point of service instead of billing insurance for the pharmacist consultation.[6,8,9] Although direct patient payment ensures the service is available to individuals willing and able to pay out of pocket for a contraception prescription, these fees create new barriers to contraception access for insured individuals that would otherwise benefit from pharmacist-prescribed contraception.[5]

Additionally, a positive implementation climate created by those with enthusiasm for change is a clear factor in the dissemination of pharmacist-prescribed contraception. Although studies have indicated that the majority of pharmacies providing this service are chain as opposed to independent pharmacies, anecdotally independent pharmacies have been early adopters of this change.[5,8,9] Based on conversations with pharmacists, early adopters support a climate of change and recognize the importance of the concept of the clinician-pharmacist. This finding is mirrored at the state level; states with self-reported increased support for clinician-pharmacists also report increased implementation success compared to states hesitant to change the pharmacist role. Although it is possible to spark interest and momentum in areas resistant to change, implementation frameworks recognize that an implementation-friendly climate has positive impacts on practice change, regardless of the specific intervention.[12]

Along with implementation climate, states with active implementation efforts clearly identify the champions and stakeholders for expanded pharmacist prescriptive authority. Champions typically develop protocols or continuing education required for pharmacist prescribing. Additionally, states engage champions from other states to discuss lessons learned and adopt previously developed continuing education programs or state protocols. To

reduce the gap from legislation to pharmacist practice, stakeholders are integral to the momentum of implementation programs.

Immediate Postpartum Long Acting Reversible Contraception

Long-acting reversible contraception (LARC), methods including intrauterine devices (IUDs) and the contraceptive implant, is among the most effective contraception available.[13] Unlike other types of prescription contraception, obtaining LARC involves a device placement visit with a trained clinician. Providing LARC during a birth hospitalization can increase access to patients' desired contraception. In 2017 the American College of Obstetricians and Gynecologists (ACOG) recognized immediate postpartum (IPP) LARC as a best practice and recommended offering it routinely.[14]

One barrier to IPP LARC is the high cost of the devices.[15] Hospitals in the United States are typically reimbursed a standard "global obstetric" payment for all care provided during the hospitalization for birth, regardless of LARC provision.[16] In 2012 and 2013, South Carolina and New Mexico became the first states to separate payment for IPP LARC from the global obstetric payment. By 2018, 38 states had published statewide policies on IPP LARC and 76% permitted device cost reimbursement separate from the global payment.[17] During this time of rapid policy adoption, IPP LARC insertion remained much less common than outpatient postpartum LARC insertion (0.06% versus 5.14% of deliveries).[18]

The case of IPP LARC implementation in New Mexico, an early-adopter state, illustrates several strategies to bridge the gap from legislative intent to clinical practice change.[19] Although New Mexico's IPP LARC policy became effective in 2013, three years later only one hospital in the state offered IPP LARC; this trend was common among early-adopter states.[20]

To assist New Mexico hospitals in IPP LARC implementation, the New Mexico Perinatal Collaborative (NMPC) adopted IPP LARC as a statewide initiative. The NMPC first developed and introduced a standard toolkit including clinical and administrative training to facilitate IPP LARC implementation; other state perinatal quality collaboratives introduced parallel initiatives around this time.[21] IPP LARC implementation resources are now available nationally through ACOG's Postpartum Contraceptive Access Initiative.

After clinical and administrative hospital-based training, the NMPC offered technical assistance focused on challenges individual hospitals encountered during the IPP LARC implementation process. Early in the initiative, the NMPC identified that state Medicaid billing guidance for IPP LARC was not compatible with current hospital billing systems. The NMPC collaborated with hospital stakeholders and the state Medicaid office to revise IPP LARC billing guidance to be usable by all hospitals within the state.[19] In 2021, New Mexico further increased equitable access to IPP LARC by issuing regulation requiring all insurers, not just Medicaid, to cover IPP LARC.

Conclusion

Pharmacist-prescribed contraception and IPP LARC both have the potential to increase contraception access in novel ways and also show how legislative policy changes do not result in immediate implementation and practice change without additional efforts. In both examples, the importance of attention to sustainable reimbursement and billing mechanisms cannot be understated. Without a financial break-even after implementing policy changes, health care institutions and individuals may be hesitant to place energy into implementation efforts. Ensuring institutions and individuals receive payment for services provided and mechanisms are in place is key. Without pathways, significant delays or disruption of implementation into clinical practice can ensure. Additionally, engaging champions and stakeholders in both processes have been integral to the forward motion of implementation processes.

As advocacy efforts continue to identify areas of legislative policy change, lessons extrapolated from this commentary's examples may help guide the development and implementation of policy changes to reduce the time from legislation to clinical practice.

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Section 7

Conclusion

Pharmacist prescribing of hormonal contraception is an impelling strategy to expand contraception access in the United States. As an increasing number of states pass or consider legislation, it is vitally important to continue to assess the process of implementing these policy changes and the uptake of pharmacist-prescribed hormonal contraception. This research provides a synthesis of the existing literature on the availability of pharmacist prescribing, along with an initial insight into the facilitators and barriers of implementing pharmacy prescribing of hormonal contraception at the state level. We expect these findings will guide future research to understand the implementation of pharmacist prescribing at the individual pharmacy level. Additionally, this research will foster continued conversations about effective means to reduce the gap between legislation and clinical practice, including the importance of reimbursement mechanisms and the engagement of champions early in the implementation process. The collection of this research and findings will support efforts in current and future states, including New Mexico, to expand pharmacist prescriptive authority for hormonal contraception, and in turn, increase access to hormonal contraception.

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