



Community Pharmacist Intervention to Close Statin Gaps in Diabetes Care: The GuIDE-S Study

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Disclosure

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Learning Objectives

1. Explain the utility of hybrid implementation-effectiveness study designs in pharmacy practice-based research
2. Describe the potential impact of community pharmacists on closing statin gaps in care in people with type 2 diabetes based on the findings of the GuIDE-S study
3. Recall strategies for partnering with community pharmacies on practice-based research

Background



Statin therapy is recommended for people with type 2 diabetes (T2D) to lower cardiovascular risk¹



Evidence suggests gaps in statin therapy exist

In 2019, 60-75% of eligible patients received statin therapy²

Estimates of statin nonadherence range from 18% to 83%³



Community pharmacist intervention is potential strategy to increase statin use in people with T2D

¹ElSayed NA, Aleppo G, Aroda VR, et al. 10. Cardiovascular Disease and Risk Management: Standards of Care in Diabetes-2023 [published correction appears in Diabetes Care. 2023 Jan 26;]. *Diabetes Care*. 2023;46(Suppl 1):S158-S190. doi:10.2337/dc23-S010

²NCQA. Statin therapy for patients with cardiovascular disease and diabetes (SPC/SPD). Available at: <https://www.ncqa.org/hedis/measures/statin-therapy-for-patients-with-cardiovascular-disease-and-diabetes/>. Accessed August 31, 2023.

³Deshpande S, Quek RG, Forbes CA, et al. A systematic review to assess adherence and persistence with statins. *Curr Med Res Opin*. 2017;33(4):769-778. doi:10.1080/03007995.2017.1281109

Previous Research

Renner et al.⁴

- Population:
 - Patients with T2D aged 40 – 75 years
- Intervention:
 - Pharmacists identified eligible patients via lists from EQuIPP platform and then contacted providers by phone or fax
- Results:
 - 21% (n=46) patients in intervention group vs. 8.5% (n=17) patients in control group prescribed statin (p<0.001)

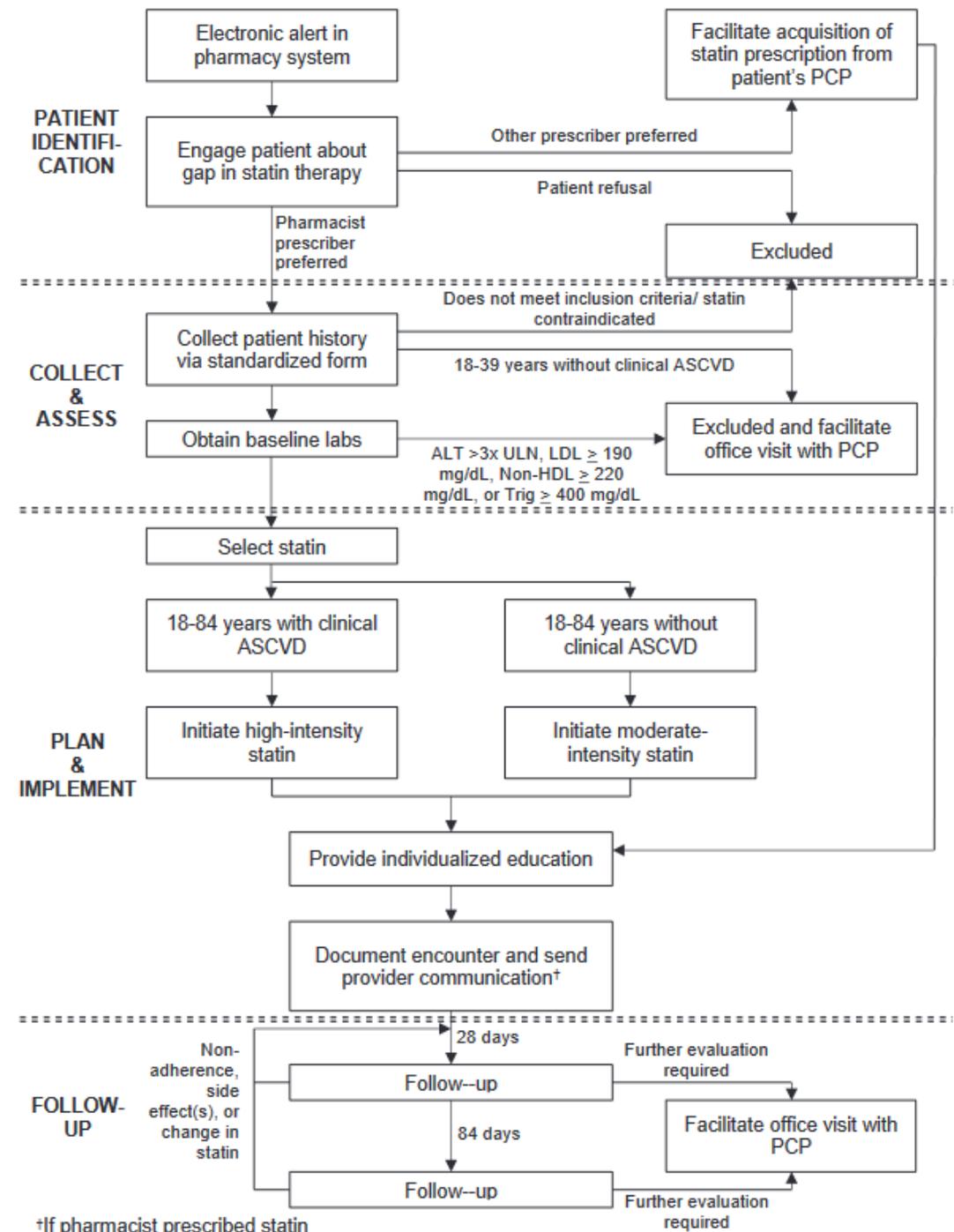
Drake et al.⁵

- Population:
 - Patients with T2D aged 40 – 75 years
- Intervention:
 - Pharmacists identified eligible patients screening algorithm in workflow and then contacted providers by fax
- Results:
 - 23% (n=7) patients identified by algorithm received statin

⁴Renner HM, Hollar A, Stolpe SF, Marciniak MW. Pharmacist-to-prescriber intervention to close therapeutic gaps for statin use in patients with diabetes: A randomized controlled trial. *J Am Pharm Assoc (2003)*. 2017;57(3S):S236-S242.e1. doi:10.1016/j.japh.2017.04.009

⁵Drake ES, Harris DK, Marciniak MW. Community pharmacist-led intervention to identify persons with diabetes not on statin therapy. *J Am Pharm Assoc (2003)*. 2018;58(4S):S125-S130. doi:10.1016/j.japh.2018.05.010

The GuIDE-S Intervention



Objectives

- Primary:
 - To evaluate the impact of a community pharmacist intervention on statin initiation in people with T2D
- Second:
 - To evaluate the impact of the ongoing intervention on statin adherence in new users with T2D
 - To evaluate pharmacists' self-reported perceptions of the intervention feasibility and fidelity to the intervention

Implementation Strategies

1. Develop educational materials

- 15-page manual with protocol, guidelines, forms, and documentation templates

2. Conduct educational meetings

- Required 90-minute computer-based, accredited continuing education program

3. Conduct educational outreach visits

- Initial visit to each pharmacy within 2 weeks of online training completion; ongoing visits as needed

4. Remind clinicians

- Electronic alert in dispensing system to identify eligible patients

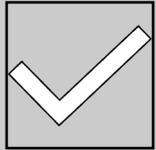
5. Alter incentive structure

- Hosted competitions to recognize and award high performers

6. Audit and provide feedback

- Intervention completion reports monitored every 2 weeks

Methods



Design

Type 1 hybrid effectiveness-implementation study



Setting

9 intervention and 18 control pharmacies within a large community pharmacy chain in Washington State

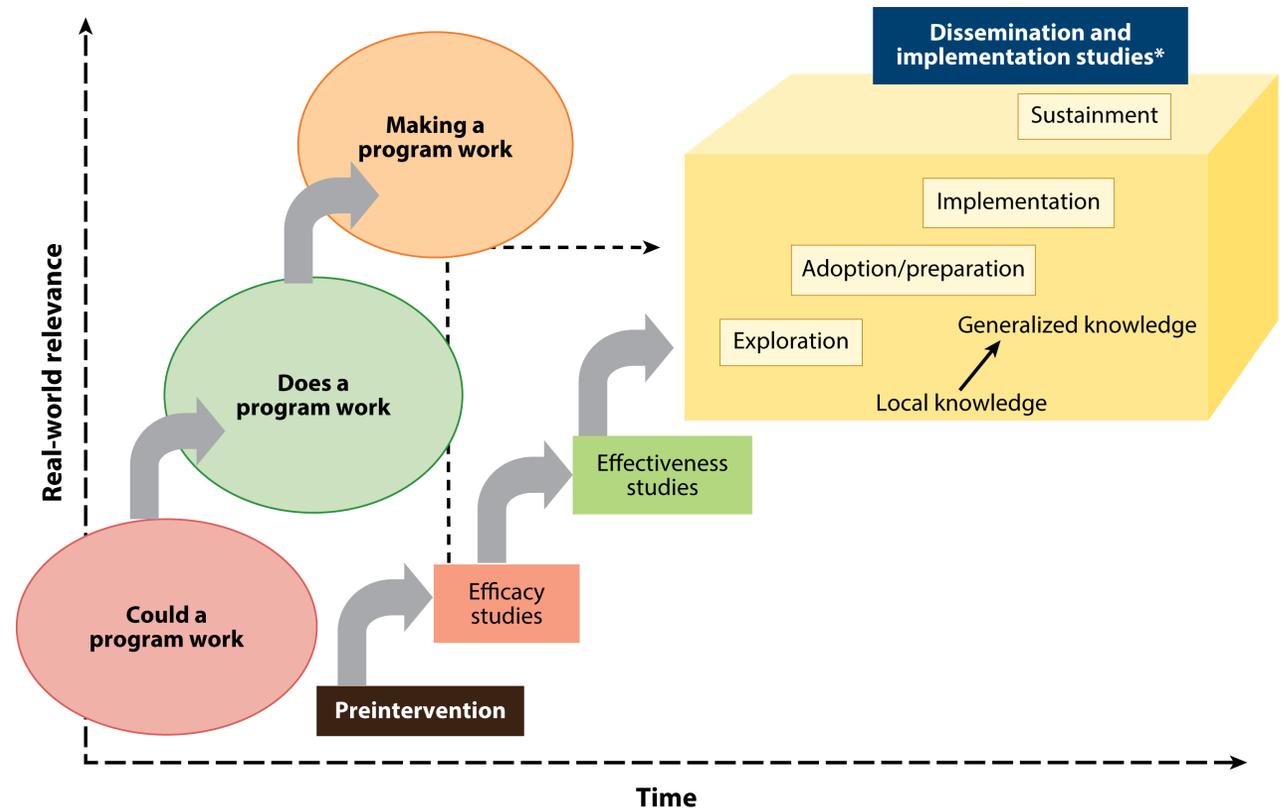


Timeframe

Patient enrollment conducted August 8, 2018 – December 31, 2019;
12-month follow-up period concluded December 31, 2020

Hybrid Effectiveness-Implementation Studies

Translational Research Pipeline⁶



*These dissemination and implementation stages include systematic monitoring, evaluation, and adaptation as required.

AR Brown CH, et al. 2017.
Annu. Rev. Public Health. 38:1–22

Hybrid Effectiveness-Implementation Studies

Types of hybrid designs⁷

Hybrid Type 1	Hybrid Type 2	Hybrid Type 3
<p>Primary Aim:</p> <p>Determine effectiveness of an intervention</p> <p>Secondary Aim:</p> <p>Better understand context for implementation</p>	<p>Primary Aim:</p> <p>Determine effectiveness of an intervention</p> <p>Co-Primary* Aim:</p> <p>Determine feasibility and/or (potential) impact of an implementation strategy</p> <p>*or Secondary Aim</p>	<p>Primary Aim:</p> <p>Determine impact of an implementation strategy</p> <p>Secondary Aim:</p> <p>Assess clinical outcomes associated with implementation</p>

⁷Landes SJ, McBain SA, Curran GM. An introduction to effectiveness-implementation hybrid designs. *Psychiatry Res.* 2019;280:112513. doi:10.1016/j.psychres.2019.112513

Implementation Outcomes⁸

Implementation Outcome	Definition
Adoption	The intention, initial decision, or action to try or employ the service (uptake, utilization, initial implementation, intent to try)
Appropriateness	Perceived fit, relevance, or compatibility of the service for a given practice setting, provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem.
Acceptability	Perceptions that service is agreeable, palatable, or satisfactory
Feasibility	Extent to which a service can be successfully used or carried out within a given agency or setting (suitability or practicability)
Fidelity	Degree to which the service is implemented as intended (includes adherence, dosage, quality of delivery, participant responsiveness, reach, etc.)
Cost	The financial impact of an implementation effort (refers to cost of implementation)
Penetration	Integration of a practice within a service setting and its subsystems (spread)
Sustainability	The extent to which a newly implemented treatment is maintained or institutionalized with a service setting's ongoing, stable operations

⁸Proctor E, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health*. 2011;38(2):65-76. doi:10.1007/s10488-010-0319-7

Methods: Statin Initiation and Adherence

Outcome	Statin Initiation	Statin Adherence
Design	Quasi-experimental	
Participants	Adult patients with T2D	
Measure(s)	Receipt of any statin within 12-month of a patient-specific index date	Continuous and categorical proportion of days covered (PDC)
Data Collection	De-identified patient, prescription, and intervention data extracted from pharmacy dispensing system	
Data Analysis	Cox proportional hazards model	Linear and logistic regression

Methods: Feasibility and Fidelity

Outcome	Feasibility	Fidelity
Design	Repeated cross-sectional	
Participants	Pharmacists practicing at intervention pharmacies	
Measure(s)	Intervention Outcomes Questionnaire – Feasibility ⁹	Adapted Comprehensive Medication Management Patient Care Process Fidelity Assessment ¹⁰
Data Collection	REDCap survey administered at 6- and 12-months post implementation	
Data Analysis	Descriptive statistics	

⁹Livet M, et al. Measuring implementation of medication optimization services: Development and validation of an implementation outcomes questionnaire. *Res Social Adm Pharm.* 2021;17(9):1623-1630. doi:10.1016/j.sapharm.2021.01.001

¹⁰Livet M, et al. Ensuring effective implementation: A fidelity assessment system for comprehensive medication management. *J Am Coll Clin Pharm.* 2020;3(1):57-67. doi:10.1002/jac5.1155

Results: Statin Initiation

Demographics

Characteristics	Control (n=3,358)	Intervention (n=1,679)
Age (years), mean (sd)	56.6 (14.8)	55.5 (14.1)
Female, n (%)	2,032 (60.5)	960 (57.2)
Insurance, n (%)		
Commercial	1,872 (55.7)	1,160 (69.1)
Government	1,332 (39.7)	452 (26.9)
Self-pay	154 (4.6)	67 (4)
No. unique medications in previous 12 months, mean (sd)	8.4 (6.1)	7.2 (6.5)
Fill of any cardiovascular medication in previous 12 months, n (%)	3,182 (94.8)	1,277 (76.1)

Results: Statin Initiation

- 26.3% (n=442) of intervention patients vs. 25.4% (n=854) of control patients initiated a statin within 12 months of their index date
- 2.7% intervention patients (n=12) initiated a statin prescribed by a pharmacist via the collaborative practice agreement (CPA)
- Likelihood of statin initiation was not significantly different between intervention and control patients (adjusted HR: 1.00; 95% CI: 0.83, 1.21)

Results: Statin Adherence

Demographics

Characteristics	Control (n=370)	Intervention (n=185)
Age (years), mean (sd)	61.7 (11.3)	57.9 (10.7)
Female, n (%)	164 (44)	91 (49)
Insurance, n (%)		
Commercial	188 (51)	144 (78)
Government	177 (48)	37 (20)
Self-pay	5 (1)	4(2)

Results: Statin Adherence

Continuous PDC

- Mean statin PDC was 66.1% in the intervention group vs. 64.5% in the control group
- PDC was 3.1% higher in the intervention group (95% CI: -0.037, 0.098)

Categorical PDC

- 45.5% of intervention patients had PDC \geq 80% vs. 44.1% of control patients
- Patients in the intervention groups were 21.2% more likely to have a PDC \geq 80% (95% CI: 0.828, 1.774)

Results: Feasibility

Item	6-months post implementation (n=15)		12-months post implementation (n=12)	
	Slightly – Strongly Disagree	Slightly – Strongly Agree	Slightly – Strongly Disagree	Slightly – Strongly Agree
The amount of time to implement this service is manageable.	8 (53.3%)	7 (46.7%)	4 (33.3%)	8 (66.7%)
The guidance documents needed to carry out this service are feasible to use.	3 (20%)	12 (80%)	1 (8.3%)	11 (91.7%)
The financial resources needed to carry out this service are reasonable.	5 (33.3%)	10 (66.7%)	2 (16.7%)	10 (83.3%)
The staff needed to carry out this service is reasonable.	8 (53.3%)	7 (46.7%)	4 (33.3%)	8 (66.7%)
The space needed to carry out this service is reasonable.	4 (26.7%)	11 (73.3%)	0 (0%)	12 (100%)
The pharmacist(s) responsible is able to dedicate the appropriate time to deliver this service.	9 (60%)	6 (40%)	4 (33.3%)	8 (66.7%)
The amount of time required for documentation of this service is reasonable.	7 (46.7%)	8 (53.3%)	1 (8.3%)	11 (91.7%)
Preparation for carrying out this service is reasonable.	5 (20%)	10 (80%)	3 (25%)	9 (75%)

Results: Feasibility

Feasibility Scores

Pharmacist Survey	Feasibility Score
6-months post implementation	4.0
12-months postimplementation	4.2

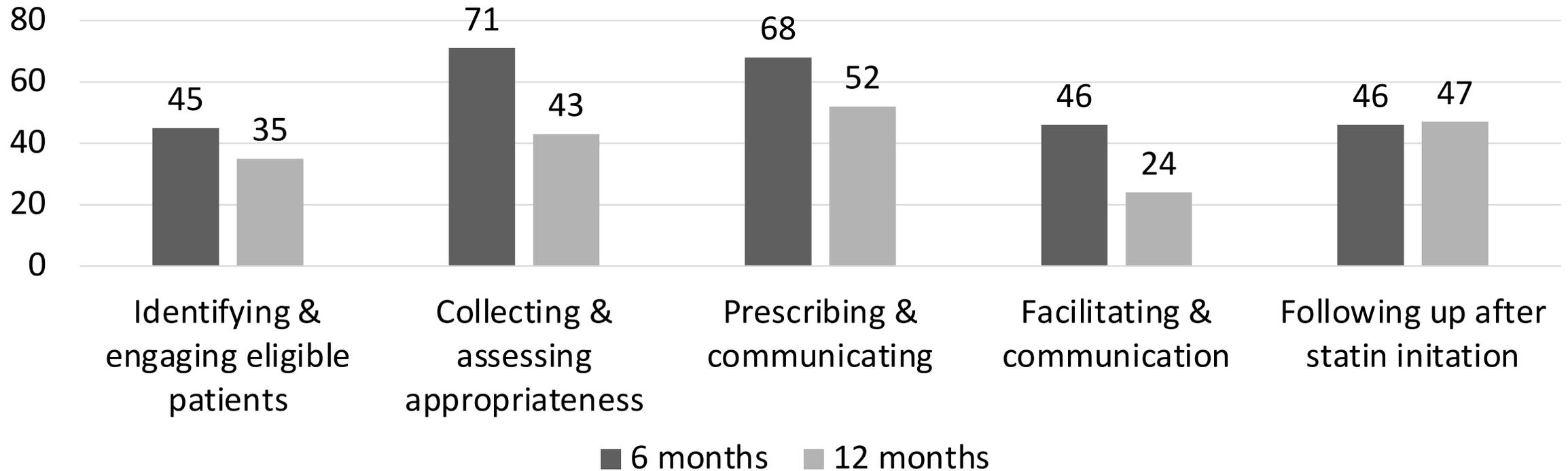
Interpretation:

≥ 3.5 : Service is highly likely to be feasible to implement at this site

< 3 : Service is less likely to be feasible to implement at this site

Results: Fidelity

Percent of respondents indicating high fidelity (>80%) to intervention protocol at 6- (n=15) and 12- (n=12) months post implementation



Discussion



Among 1st studies to evaluate model for community pharmacists initiating statins via a CPA



Pharmacists prescribed statin via CPA for small percentage of patients (2.7%) in study

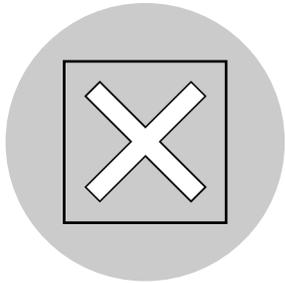


Difference in time and complexity between initiating statin via CPA and acquiring prescription from another prescriber likely influencers

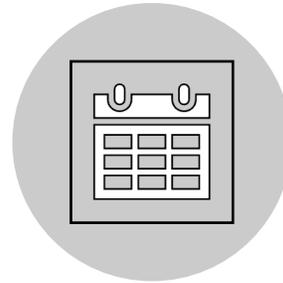


CPA alone not sufficient to improve statin use in people with T2D; Patients appear to prefer more collaborative approach

Limitations



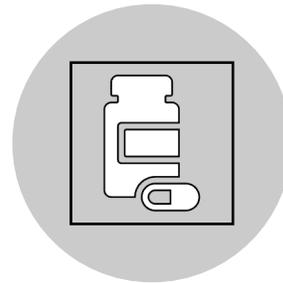
May have been systematic differences between intervention and control sites due to lack of randomization



Assumptions were required to calculate patient-specific index dates for statin initiation



Controlled for insurance type to account for overrepresentation of patients with government-funded insurance in control group



Statin fills at other pharmacies not included in PDC calculation using pharmacy-based fill data

Conclusions

- Community pharmacist-led intervention resulted in more patients initiating statin therapy and higher statin adherence as compared to usual care; however, differences were not statistically significant
- Opportunities to optimize impact of community pharmacist-led intervention to close statin gaps in care include:
 - Increasing awareness of statin therapy availability among patients
 - Integrating pharmacist-physician communication via the electronic health record
 - Implementing intervention in more structured patient care workflow (e.g., appointment-based model, medication synchronization)

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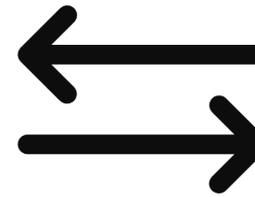
- This research was supported by a grant from the National Association of Chain Drug Stores Foundation

Publications:

- Bacci JL, et al. Community pharmacist intervention to close statin gaps in diabetes care: The GuIDE-S study. *J Am Pharm Assoc.* 2023;63(1):108-117. doi:10.1016/j.japh.2022.08.025
- Bacci JL, et al. Community pharmacist intervention to optimize statin adherence in diabetes care: The GuIDE-S study. *J Am Pharm Assoc.* 2023;63(3):946-951. doi:10.1016/j.japh.2023.03.002

Community –
Academic
Partnerships
for Research

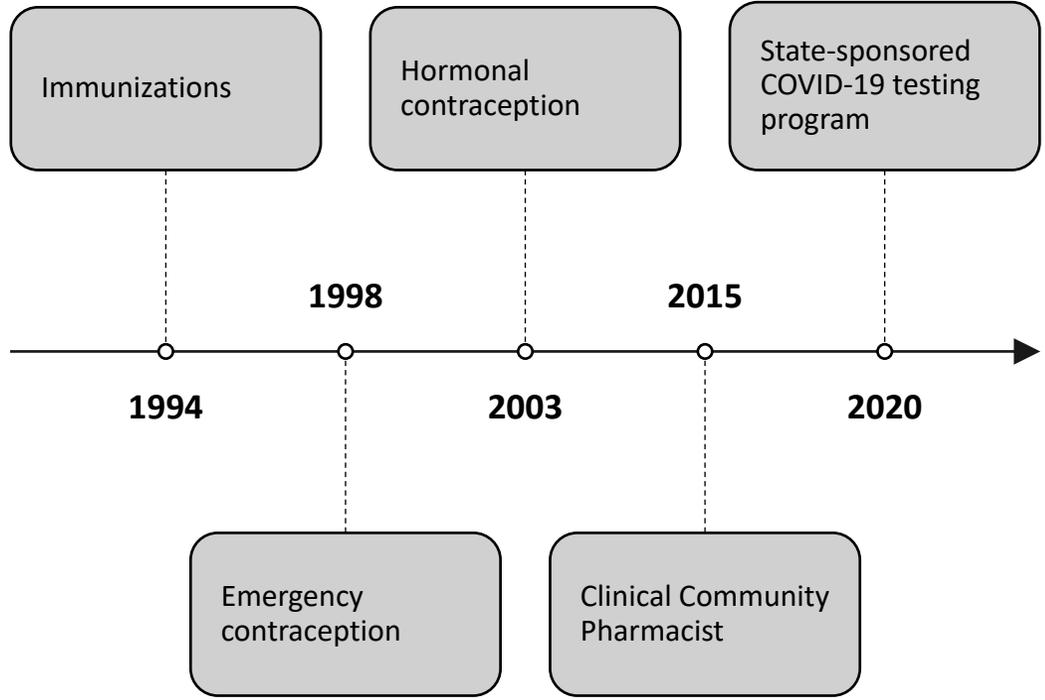
Scholarship



**Practice
Transformation**



The Washington State Experience



SPECIAL FEATURE

Pharmacist prescribing of hormonal contraceptives: Results of the Direct Access study

Jacqueline S. Gardner, Leslie Miller, Donald F. Downing, Stephanie Le, David Blough, and Solmaz Shotorban

Abstract

Objective: To describe implementation of a collaborative drug therapy protocol to screen and counsel women for safe use of hormonal contraceptives prescribed by community pharmacists.

Design: Community-based intervention study.

Setting: Metropolitan Seattle, Wash, from June 2003 to December 2005.

Participants: 26 community pharmacists and 214 women enrollees.

Intervention: Pharmacists identified women at risk of unintended pregnancy and offered to evaluate them to determine whether they could safely use oral contraceptives, contraceptive patches, or the contraceptive vaginal ring. Interested women self-administered medical and contraceptive history questionnaires. Pharmacists measured weight and blood pressure and prescribed hormonal contraceptives according to the protocol guidelines. Study interviewers followed up with women via telephone at 1, 6, and 12 months.

Main outcome measures: Effectiveness of pharmacist interventions was measured by continuation of hormonal methods by women. Feasibility was determined by measuring acceptability and sustainability. Acceptability was measured by interviewing women and pharmacists. Sustainability was measured by evidence of willingness to pay for the services.

Results: 195 women (91%) were prescribed hormonal contraceptives by participating pharmacists. A self-administered screening tool and physical measures (weight and blood pressure) enabled pharmacists to evaluate women for safe use of contraceptives. Most women (87%) were experienced users of hormonal contraceptives. More than 80% of women paid for the pharmacist's services out of pocket. At 12 months, 70% of women responding to an interview reported continuing use of hormonal contraceptives. Women reported that they would want to obtain a gynecologic exam within 3-month intervals while taking hormonal contraceptives. Both women and pharmacists were satisfied with the experience. Nearly all respondents expressed willingness to continue to see pharmacist prescribers and to receive other services from them.

Conclusions: Community pharmacists can efficiently screen women for safe use of hormonal contraceptives and select appropriate products. Women and pharmacists were satisfied with the services, and women were willing to pay for them.

Keywords: Collaborative practice, contraceptives, prescribers, research.

J Am Pharm Assoc. 2008; 48:212-24. doi:10.1331/JAHPA.2008.11

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RESEARCH

The Emergency Contraception Collaborative Prescribing Experience in Washington State

Bunshin D. Swenson, Nathorn Chaiyaprasitkul, Jacqueline S. Gardner, and Jennifer Winkler

Objective:

To describe how prescribers and pharmacists view the Emergency Contraceptive Pills (ECP) program, and to evaluate pharmacist performance through the use of a consumer survey.

Design: Self-administered provider satisfaction surveys were mailed 6 months after the program's inception. Consumer satisfaction surveys were distributed at the point of ECP service for return by mail.

Setting: The program encouraged pharmacists and prescribers in western Washington to enter into collaborative prescribing agreements, increasing consumers' access to ECP.

Patients or Other Participants: Pharmacists who had attended ECP training sessions, prescribers who had authorized pharmacists to prescribe ECP, and women who had been prescribed ECP by pharmacists.

Main Outcome Measures: Provider reasons for participating, attitudes toward the ECP program, and experiences with ECP as a result of the program; feedback from women receiving ECP from pharmacists.

Results: 309 pharmacist surveys and 56 prescriber surveys were sent, of which 199 (64%) and 27 (48%), respectively, were returned. Meeting patient needs and having a professional responsibility to participate were commonly reported reasons for ECP program involvement. Both pharmacists and prescribers (82%) reported being "satisfied" or "very satisfied" with their prescribing agreements. On the 478 consumer surveys returned out of 7,000 distributed (6.8%), pharmacists were rated highly satisfactory for their interactions with patients and the quality of information about ECP use given, but less satisfactory for information about adverse effects, recognition and follow-up of ECP failure, and regular contraceptive methods.

Conclusions: All participants expressed satisfaction with the ECP program. This example should support the initiation of similar programs in other states.

Despite advances in contraceptive technology and public education, unintended pregnancy remains a common problem in the United States. Of the 5.38 million pregnancies recorded in the United States in 1994, 49% were unintended.¹ This rate exceeds that of other developed countries.² For example, a woman in the United States has an average of 1.3 unintended pregnancies during her lifetime, whereas women in Canada average 0.79 and women in the Netherlands average 0.28 unintended pregnancies.³ Emergency contraception may be used postcoitally to prevent

unintended pregnancy. The two most widely used methods for emergency contraception are copper intrauterine devices (IUDs) and high-dose oral contraceptives administered within 72 hours after unprotected intercourse. The inclusion of either of the latter method is unknown, but research suggests it may prevent pregnancy in several ways, including inhibition or delay of ovulation and endometrial alteration prior to fertilized ova implantation.^{4,5} The convenience, low cost, and high effectiveness of the oral method have made it the most desirable form of emergency contraception for many women.^{6,7}

A program was developed to increase patients' access to emergency contraceptive pills (ECP) by encouraging collaborative prescribing agreements between community pharmacists and prescribers in Washington State. The ECP program was implemented by the Program for Appropriate Technology in Health (PATH) in collaboration with the Washington State Pharmacy Association (NSPA), the University of Washington Department of Pharmacy, the Washington State Board of Pharmacy, and Elgin DDB. These prescribing agreements transferred dependent prescribing authority to pharmacists according to patient eligibility criteria and protocols agreed to by both parties. The program's rationale was reinforced by the following facts:

REVIEWS



A Practical Guide to Establishing Vaccine Administration Services in Community Pharmacies

Jacqueline S. Gardner

Objective: This article describes requisite components of a community pharmacy-based vaccine administration program and provides resources for obtaining training and materials to facilitate implementation in the pharmacy.

Data Source: Published medical literature accessed via Medline; interviews of pharmacists who initiated vaccine administration programs; government publications; professional publications including manuals and newsletters; and the resources of the Washington State Board of Pharmacy.

Background: Pharmacists in several states have initiated vaccine administration programs for adults, adolescents, and children within their pharmacies with acceptance by patients, third party payers, and other health professionals. In some states, collaborative prescribing agreements between physicians or nurse-practitioners is available, enabling pharmacists to implement high-volume immunization clinics as well as individual patients services. Standardized training is available from several sources, and in most settings vaccine administration services can be implemented with low initial investment.

Conclusion: Vaccine administration may soon become an integral function in community pharmacist responsibilities for the health and well-being of patients.

J Am Pharm Assoc. 1997;NS37:889-93.

Immunization—A National Effort

In recent years, national attention has been focused on the reemergence (e.g., measles during 1989-1991) or continued prevalence (e.g., pneumococcal disease and influenza) of vaccine-preventable diseases in the United States despite the availability of safe and effective vaccines and federally subsidized programs for vaccination. Analysis of the reasons for this unsettling situation reveals several interrelated problems pertaining to the cost of and access to vaccines.⁸ Often, insurance carriers do not reimburse for vaccination. Many of the same barriers that prevent more widespread immunization also restrict access to other health care services, and include the need for an appointment, restricted clinic hours, inaccessible clinic locations, and language barriers.⁹

In light of the national goals for reduction of vaccine-preventable diseases, as articulated in *Healthy People 2000: National Health Promotion and Disease Prevention Objectives*¹⁰ (Table 1), multiple federal initiatives have been undertaken to increase vaccine coverage of target groups. In 1981 the Health Care Financing Administration (HCFA) authorized payment for pneumococcal vaccines and their administration to Medicare enrollees.¹¹ That coverage was extended to influenza virus vaccine in 1993. The National Vaccine Injury Compensation Program (VICP), authorized by Congress in 1988, became the arbiter of claims of injury resulting from the childhood vaccines, whether as a result of adverse reaction to the vaccine itself or a

September 4, 1997.
University of Washington, Seattle, WA.
or editorial review.
of Pharmacy, University of Washington, Seattle, WA.
Box 357330.

J Am Pharm Assoc. 2007;47:60-6.

Community – Academic Partnerships

- Community pharmacists are interested in research opportunities to:^{11,12}
 - Improve care delivery
 - Increase knowledge and innovation
 - Change patients' perspectives
 - Increase patient satisfaction and loyalty

¹¹Li JS, Blake V, George S, Carroll JC, Somma McGivney MA, Coley KC. Formation of a statewide community pharmacy practice-based research network: Pharmacist opinions on research participation and engagement. *J Am Pharm Assoc (2003)*. 2020;60(6):951-956. doi:10.1016/j.japh.2020.07.008

¹²Carroll JC, McGivney MS, Coley KC. Stakeholder-Guided Formation of a Statewide Community Pharmacy Practice-Based Research Network. *Pharmacy (Basel)*. 2019;7(3):118. Published 2019 Aug 17. doi:10.3390/pharmacy7030118

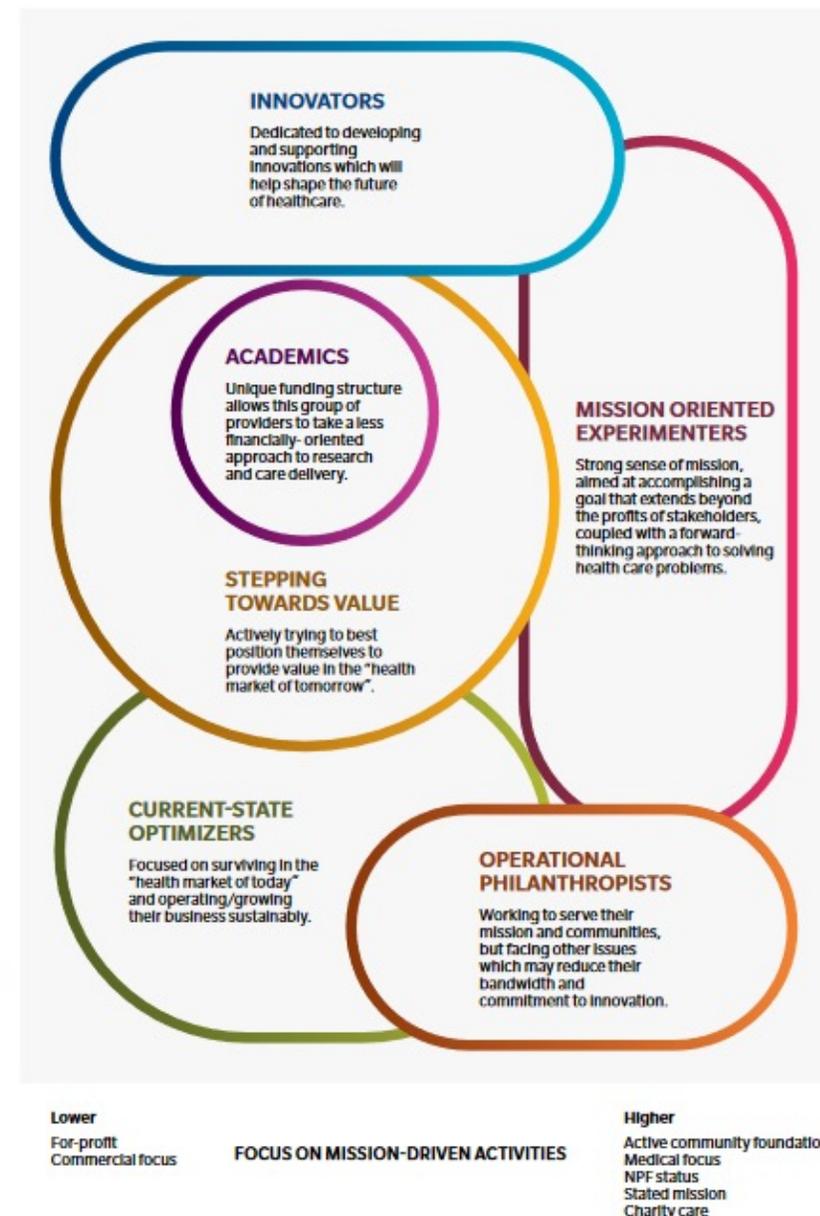
Partnership Framework¹³

- Payer and provider interest indicators:
 1. Mission focus
 2. Operational focus
 3. Innovation focus
 4. Consumer (patient) focus
 5. Move to value-based healthcare
 6. Community focus
 7. Advocacy

More innovation and diversification, disruption of today's model
Innovation arms
Diversified subsidiaries
Visible strategic investments
True value-based transformation

FOCUS ON TODAY'S MODEL

More "operate today's business"
Current financial trouble
Subscale to drive investment
Publically traded status
Recent or planned large M&A



My Lessons Learned



Invest time in community pharmacy partners and their priorities



Quality partnerships are built over time



The best research questions come from practice



Sustainability

Assessment Question #1

Which of the following is a benefit of hybrid effectiveness-implementation study designs?

- a. Decreases the time and cost of conducting practice-based research
- b. Increases the likelihood of observing an intervention effect if one exists
- c. Decreases the time between development of an evidence-based intervention and routine uptake in practice
- d. Increases internal validity

Assessment Question #2

Which of the following was a finding of the GuIDE-S study?

- a. The community pharmacists prescribed statin therapy for most enrolled patients via the collaborative practice agreement
- b. The community pharmacist intervention resulted in more patients initiating statin therapy
- c. The community pharmacists perceived the intervention was less likely to be feasible to implement
- d. The community pharmacist intervention decreased statin adherence

Assessment Question #3

Which of the following are indicators that researchers can use to determine strength of alignment when partnering with community pharmacies for research?

- a. Innovation focus
- b. Mission focus
- c. Move to value-based healthcare
- d. Patient focus
- e. All the above