

An Evaluation of the Spread and Scale of PatientToc™ from Primary Care to Community
Pharmacy Practice for the Collection of Patient-Reported Outcomes

Final Report

Principal Investigator: Margie E. Snyder, PharmD, MPH, FCCP, FAPhA

Organization: Purdue University College of Pharmacy

Project Period: 4/1/2019-3/31/2024 (NCE)

Project Officer: Christine Dymek

Acknowledgement and Grant number: This study was funded by the Agency for Healthcare Research and Quality grant number R18HS025943. The content is solely the responsibility of the authors and does not necessarily represent the official views of the Agency for Healthcare Research and Quality.

Structured Abstract

Purpose

To evaluate the spread and scale of PatientToc™ from primary care to community pharmacies for the collection and use of medication adherence patient-reported outcomes (PROs).

Scope

This was a two-phase (pre-implementation and implementation) mixed-methods study conducted in partnership with practice-based research networks in California, Indiana, Minnesota, and Wisconsin.

Methods

In Aim 1, site visits were conducted at 2 primary care clinic offices already using PatientToc™ and 9 community pharmacies interested in future use of PatientToc™ to identify expected barriers, facilitators, and implementation recommendations for community pharmacies. Data were collected via semi-structured interviews, observations, and contextual inquiries. In Aim 2, the adapted PatientToc™ intervention (informed by Aim 1 findings) was piloted in 3 community pharmacies and implementation outcomes evaluated. In Aim 3, PatientToc™ use was scaled to 12 pharmacies and implementation outcomes and quality of care outcomes were evaluated. Across all 3 Aims, quantitative and qualitative data were synthesized via intra- and inter-site summaries and final results reviewed with a stakeholder advisory panel.

Results

Aim 1 identified 4 key barriers, 4 key facilitators, and 14 implementation recommendations. Only half of the recommendations could be implemented. Overall, in Aims 2 and 3, adoption of PatientToc™ was low, only the pharmacist champion at each store used it, and fidelity to the intervention was poor. While generally considered easy to use and appropriate for a community pharmacy, issues with PatientToc™ acceptability and feasibility were still noted. In Aim 3, 7 of 12 pharmacies dropped out before the end of the data collection period.

Key Words

Community pharmacy, pharmacists, medication adherence, digital interventions, patient-reported outcomes, implementation science

Purpose

To evaluate the spread and scale of PatientToc™ from primary care to community pharmacies for the collection and use of medication adherence patient-reported outcomes (PROs). The specific aims of the study were to:

- **Aim 1:** Conduct a pre-implementation developmental formative evaluation to determine community pharmacy workflow and current practices for identifying and resolving medication non-adherence, potential barriers and facilitators to PatientToc™ implementation, and create a draft implementation toolkit.
- **Aim 2:** Conduct two plan-do-study-act cycles to refine an implementation toolkit for spreading and scaling implementation of PatientToc™ in community pharmacies.
- **Aim 3:** Conduct a *comprehensive*, theory-driven evaluation of the quality of care, implementation, and patient health outcomes of spreading and scaling PatientToc™ to community pharmacies.

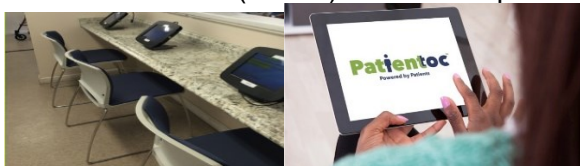
Scope

Background

Collecting and using patient-reported outcomes (PROs) can effectively improve patients' medication adherence.^{1,2} However, PROs-collection is not commonly done in the community pharmacy setting. Incorporating any new service or procedure into a community pharmacy's workflow can be challenging, due to the pharmacists' workload and understaffing.³ With mobile technology becoming an ubiquitous part of day-to-day life, some have suggested that it may serve as an opportunity to facilitate communication between pharmacists and patients about medication adherence.⁴ Previous interventions have used technology to collect PROs to spark conversations between pharmacists and patients.⁵ Collecting PROs digitally, which has also been shown to improve medication adherence,² may address some of these implementation challenges. Salaffi et al.⁶ and Coons et al.⁷ showed that collecting PROs from patients digitally reduced the time it took to complete a PROs questionnaire, which may alleviate both pharmacists' and patients' concerns about PROs collection being too time-consuming. The workflow of most community pharmacies may also be conducive to collecting PROs, because pharmacy staff can ask patients to complete the questionnaires while waiting for their prescriptions to be filled. Digital collection of PROs may also support medication adherence interventions by providing opportunities to utilize a range of functionalities via integration with the pharmacy's dispensing software.⁸ That said, the implementation supports needed by a pharmacy team to incorporate electronic PROs completion for medication adherence are unknown, as well as the adoption, acceptability, appropriateness, feasibility, fidelity, costs, penetration, sustainability, and effectiveness of such interventions.

Context- PatientToc™ in Primary Care⁹

PatientToc™ a digital tool for capturing patient-reported outcomes, was originally designed for use in primary care physician practices and was developed out of the LA Net practice-based research network (PBRN). The below pictures show PatientToc™ in use at physician practices.



Setting-Community Pharmacies⁹

Community pharmacies were recruited from practice-based research networks in Indiana, Minnesota, and Wisconsin. Our recruitment goal varied by study Aim, as described below. Eligible pharmacies included those interested in future implementation of PatientToc™ (Aim 1) or who agreed to implement and use PatientToc™ as requested (Aims 2 and 3) and agreed to study procedures including the researchers' taking photographs, and (for Aims 2 and 3) used Qs/1 or PioneerRx dispensing systems. The latter was required to promote transferability of study findings to future planned integrated models of PatientToc™ (i.e., with prescription data pre-populated) with these systems. Within each pharmacy, pharmacists, pharmacy staff, and patients were recruited to participate.

Methods

Methods—Aim 1¹⁰

Study Overview

This was a convergent parallel, qualitatively driven mixed-methods study design. This design equipped researchers to investigate expected barriers, facilitators and actionable recommendations for PatientToc™ implementation in community pharmacies. This informed adaptations to make to PatientToc™ for implementation in community pharmacies as well as the creation of a draft implementation toolkit. Qualitative methods were the primary methods used for data collection and analysis. Data were collected during visits to primary care practices already using PatientToc™ and to community pharmacies interested in using PatientToc™ in the future.

Participants

A purposive sample (n=11) of study sites was recruited from LA Net and the community pharmacy networks. To better understand how PatientToc™ has been implemented in primary care, we recruited two LA Net primary care practices in California, with varied approaches to PatientToc™ implementation. Three community pharmacies, consisting of a wide range of practice types and settings (e.g., urban vs. rural) from each of the remaining three states (nine total) were recruited to better understand potential barriers, facilitators, and recommendations for spreading PatientToc™ to community pharmacies. A purposive sample, targeting five clinicians/staff and five patients (18 years of age or older having at least one chronic condition for which they routinely take medication) from participating primary care and pharmacy practice sites, were invited to engage with researchers during one-day site visits.

Data Collection

Qualitative data collection consisted of audio-recorded semi-structured interviews, investigator observations of staff and patients at participating primary care and pharmacy sites and contextual inquiries. Observations were conducted to provide insights into how PatientToc™ is currently used (primary care) and could be used (pharmacies). Contextual inquiries consisted of informal interviews with participants demonstrating and describing elements of their work duties. Lastly, to be reflexive of the research process, summary recorded debriefs following each site visit and resulting data were included as part of our formal data collection. Quantitative data collection consisted of study site and participant demographics. Study site demographics, e.g., type of practice, number and type of staff members, prescription volume, were self-reported from the primary site contact and collected by telephone in advance of the one-day site visits. Participant demographics, e.g., age, role, race, years employed at practice site, were self-reported and collected at the end of each participant's interview. All quantitative data were collected and managed using Research Electronic Data Capture (REDCap™).

Data Analysis and Synthesis

The qualitative analysis team included two trained student research assistants and an investigator. Audio-recorded semi-structured interviews, investigator observation summary debriefs, and contextual inquiries were transcribed verbatim (InfraWare Inc, Terre Haute, IN) and checked for accuracy. The qualitative analysis team coded transcripts using NVivo 12 Pro (QSR International). Both deductive (using CFIR) and inductive (emergent from the data) approaches were used in developing the codebook. The CFIR Codebook Template was adapted to fit the context of our study and frame code definitions and coding inclusion/exclusion criteria. Rotating pairs of analysts independently coded and reconciled the same transcripts for two study sites, until all transcripts for these sites were reconciled. Subsequently, analysts independently coded an approximately equal number of different transcripts for the remaining study sites. No double coding (i.e., using more than one code to code the same pieces of text) was permitted. Three other investigators with expertise in qualitative research, reviewed approximately one third of all coded transcripts and met with the qualitative analysis team regularly to provide feedback and ensure the codebook was applied consistently.

Intra-site summary documents were created to summarize qualitative and quantitative findings for each participating primary care practice and pharmacy. Mixing and triangulation consisted of the qualitative analysis team noting convergence or salient differences in qualitative findings by qualitative method used (e.g., if investigator observation summary debrief data confirmed or differed from interview data) and select quantitative variables, site and participant type. Informed by *intra*-site summary documents, an *inter*-site summary document was created to facilitate investigator synthesis and identification of final themes during planned research team discussions. During the course of two days (13 hours total), research team members met virtually (due to COVID-19 travel restrictions) via videoconferencing software to review *intra*- and *inter*-site synthesis documents and identify themes by CFIR construct. The principal investigator compiled and summarized notes from the research team discussions to identify overarching major themes, categorized as barriers or facilitators and recommendations mapped to applicable CFIR constructs. Research team members who participated in the two-day group discussions had opportunities to review the major themes/recommendations and accuracy of mapping to CFIR constructs.

Evidence-based Quality Improvement (EBQI) Process and Draft Implementation Toolkit

Resulting major themes informed the EBQI process for this study. This process consisted of assembling a multi-stakeholder advisory panel. In addition to a subset of study team members, the target number of Advisory Panel members was nine stakeholders—a pharmacist, technician, and a patient from each state (i.e., one participant of each stakeholder type representing each pharmacy study site). In selecting stakeholders to invite, we attempted to balance demographics including gender, race, number of medications taken and frequency of pharmacy visits (patients), as well as expected contributions/willingness to share ideas (based on interview responses), and perceived engagement with the site/project (for pharmacists/staff, based on site visits). For this phase of the study, we held a total of four, 120-minute virtual EBQI sessions via videoconferencing software. To gather the unique perspectives of pharmacy staff and patients, “breakout” groups were held during the sessions to discuss priority questions relevant to each stakeholder group. Their insights were then shared with the whole group. The first three sessions consisted of member checking and prioritizing findings. Panelists’ initial recommendations from these sessions informed: 1) mock-up of the adapted PatientToc™ application and 2) draft toolkit resources for initial spread of PatientToc™ in community pharmacies. These items were reviewed during the fourth EBQI session and panelist recommendations for PatientToc™ adaptations and implementation were finalized.

Methods—Aim 2¹

Study Overview

This was a descriptive evaluation of the initial implementation of PatientToc™ in community pharmacies. We utilized a convergent, parallel, mixed-methods design for data collection and analysis. Implementation outcome measures were selected using Proctor et al.'s taxonomy. Specifically, we evaluated adoption (i.e., utilization of PatientToc™ by pharmacy teams and patients), acceptability (i.e., satisfaction with use), feasibility (i.e., ability to use within pharmacy's workflow), fidelity (i.e., extent PatientToc™ was used as planned), appropriateness (i.e., perceived "fit" in pharmacy), and implementation costs.

PatientToc™ Intervention

Our Aim 1 research¹⁰ resulted in a two-part community pharmacy-based intervention ready for further testing: 1) patient uses PatientToc™ on an Android tablet at the pharmacy to answer medication adherence questions, requiring no more than 10 minutes, and 2) pharmacist uses patient responses to intervene and resolve medication adherence and other concerns at the point of dispensing. For this initial implementation of PatientToc™ in community pharmacies, participating pharmacy teams were asked to use PatientToc™ at their discretion (e.g., with all pharmacy patients or focused subgroups) with a goal of using the application with at least 50 patients in the first month. Pharmacists would then review patient responses, select and deliver interventions of their choice as needed, and document the interventions electronically after each patient encounter. This documentation occurred by using either a separate provider tablet or through use of a free Android emulator program downloaded to a computer in the pharmacy. Each pharmacy received an implementation toolkit (collection of resources) and was assigned a dedicated "practice facilitator" to assist with implementation/troubleshooting.

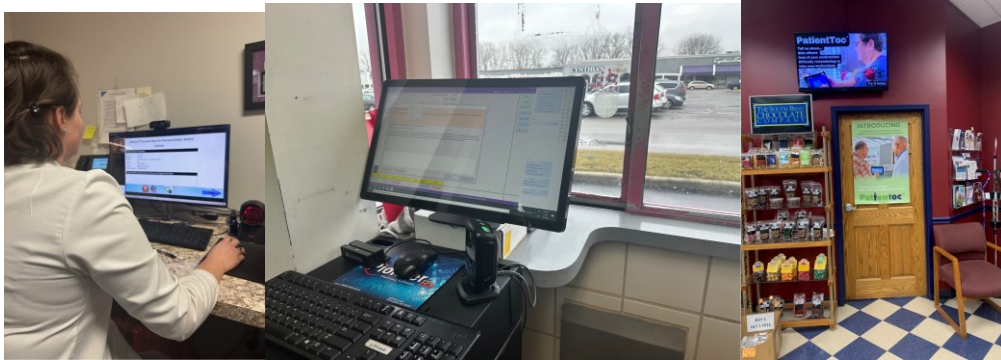
Toolkit items consisted of:

- Kickoff agenda template
- Mission statement
- Audit and feedback report
- SDOH CE modules
- PatientToc™ Training Module #1-#4
- Scripted language
- Poster (large)
- Poster (small)
- Pamphlets
- Bag stuffers
- Social media content
- Sample PatientToc™ workflows
- Referrals cheat sheet

Planned facilitation activities included, but some flexibility was permitted:

- Virtual touchpoints with pharmacist champion prior to launch
- Launch visit to the pharmacy
- Bi-weekly pharmacy visits, alternating with check-in telephone calls

The below pictures show PatientToc™ in use at community pharmacies.



Pharmacies and Participants

Our goal was to recruit two to three pharmacies per network, particularly targeting pharmacies who participated in our prior formative research. Within each participating pharmacy, we then recruited pharmacists, pharmacy staff, and patients. Pharmacists and pharmacy staff were eligible if they were aged 18 years or older and were a paid or unpaid (e.g., PharmD student) member of the pharmacy team during the PatientToc™ implementation period. Patients were recruited electronically, with information about the study and consent documents displaying on PatientToc™ for those meeting our inclusion criteria. Inclusion criteria were age 50 years and older, taking at least one oral medication for diabetes, hypertension, and/or dyslipidemia per self-report, filling one or more targeted medications at the study pharmacy as 30-day supplies, and baseline non-adherence on the Brief Medication Questionnaire as indicated during their PatientToc™ assessment for one medication of their choosing for one of the study-targeted chronic conditions. Patients electronically provided written consent and HIPAA authorization for sharing their protected health information; waivers of consent and HIPAA authorization were granted for patients having legal healthcare representative complete PatientToc™.

Data Collection

Both qualitative and quantitative data were collected, with specific data sources varying by implementation outcome measure. Adoption, Acceptability, and Fidelity were evaluated with both quantitative and qualitative data. Quantitative Adoption (e.g., number of assessments completed), Acceptability (e.g., presence of skipped questions), and Fidelity (e.g., timing of when pharmacists reported reviewing PatientToc™ assessments and delivering interventions) data were collected from PatientToc™ records. Qualitative Adoption, Acceptability, and Fidelity data (e.g., positive and negative experiences with utilization of PatientToc™ by pharmacy teams and patients) were collected through individual audio-recorded semi-structured interviews with pharmacy staff and patients and through observation visits to participating pharmacies. Observation notes were documented in REDCap, a secure electronic data capture program. Feasibility was also evaluated with both quantitative and qualitative data, however quantitative data for Feasibility was collected from researchers' records in REDCap (e.g., the number of unscheduled contacts made with participating pharmacies.) Appropriateness was evaluated with qualitative data only, also collected during interviews and observations. Costs were evaluated with quantitative data only, collected from researchers' records.

Data Analysis, Synthesis, and Identification of Adaptations for Future Scaling (EBQI)

Qualitative interview data were coded by two Doctor of Pharmacy students trained by the investigators. A deductive approach to coding was followed, with codes created in alignment with the Proctor implementation outcomes. To promote consistency in applying the codebook,

three transcripts were coded by both students and reviewed and discussed with two investigators. The remaining transcripts were divided between the students for coding and one investigator reviewed the coding for each transcript with the student responding to comments and making coding changes as needed. Any coding decisions requiring discussion were reviewed during regular meetings between the students and investigators. Coding was conducted using NVivo software. Observation notes in REDCap were not formally coded; these were reviewed by student coders to provide further context during data synthesis. Quantitative data were analyzed using descriptive statistics computed in SAS.

After both quantitative and qualitative data were analyzed independently, we synthesized the data by preparing an intra-site summary document for each participating pharmacy. These documents were created using a team approach, with quantitative and qualitative data, respectively, populated on the summary by the specific analyst. The site's practice facilitator reviewed quantitative and qualitative data for each implementation outcome when applicable (i.e., Acceptability, Adoption, Fidelity, Feasibility) to identify areas of convergence and divergence and summarize findings at the site level. After the intra-site summaries were prepared, one investigator populated an inter-site summary that allowed for the examination of all outcomes across sites to identify any differences by pharmacy type, implementation scope, and other pharmacy-level variables. This document was reviewed by the first author and then the entire team met for ninety minutes to review and summarize findings for each implementation outcome as well as proposed adaptations to the PatientToc™ application, facilitation plan, and toolkit. These findings were then discussed with our external project advisory panel comprised of patients, pharmacists, and pharmacy staff to elicit feedback.

Methods—Aim 3¹²

Study Overview

This was a convergent mixed-methods evaluation of scaled use of PatientToc™ in community pharmacies.

PatientToc™ Intervention

For this Aim, we scaled the adapted PatientToc™ intervention to community pharmacies in three states using it for the first time. Pharmacies implemented PatientToc™ and were asked to use it with at least 50 patients in the first month if targeting patients with our pre-selected conditions of interest (diabetes, hypertension, dyslipidemia) or 150 patients if not targeting. Pharmacies were asked to then use it for an additional six months with their sample of patients completing PatientToc™ at approximately monthly intervals when returning to the pharmacy for prescription fills. Pharmacies could choose their approach to using PatientToc™. For this Aim, we:

- 1) Increased from one launch visit to three in the first week with clear goals for each and added webinars for the first month to help with adoption and feasibility.
- 2) Decreased frequency of visits and telephone calls.

Pharmacies and Participants

Our recruitment goal was five pharmacies per state for a total of 15 pharmacies. Within each participating pharmacy, we then recruited pharmacists, pharmacy staff, and patients. Inclusion criteria were the same as for Aim 2, except patient eligibility was expanded to 18 years+ and filling any medication as a 30-day cycle in order to encourage use with more patients.

Data Collection

Data collection followed the procedures described for Aim 2. We also evaluated two additional implementation outcomes, penetration and sustainability. Penetration was defined as the extent to which PatientToc™ was adopted across pharmacists within a pharmacy. Sustainability was defined as the number of months (up to 7) that the pharmacy used PatientToc™. Penetration data was collected from PatientToc™ administrative data and sustainability was collected from researcher records documenting dates of site drop out when applicable. To monitor for any unintended consequences of PatientToc™ implementation, we also evaluated quality of care measures: patient satisfaction with their pharmacy, prescription volume, and prescription transfers in and out of the pharmacy. Patient satisfaction was assessed using four items answered by patients at the end of their PatientToc™ assessment on a 5-point Likert scale (1=poor to 5=excellent). Prescription volume and transfers were collected from the pharmacy management software for the months during which PatientToc™ was implemented at the pharmacy and for the same period in the year prior. To provide further context for these data, the practice facilitator collected data from the pharmacy each month on items such as personnel changes and non- PatientToc™ related impacts on pharmacy business.

Data Analysis and Synthesis (EBQI)

Data for implementation outcomes were analyzed and synthesized as described for Aim 2. Prescription volume and transfers were analyzed using SAS version 9.4.

Results

Principal Findings—Aim 1¹⁰

Table 1. Potential barriers and facilitators to PatientToc™ implementation in community pharmacies

Potential Barriers
1. Lack of <u>existing integrations among technology vendors</u> and/or concerns about the <u>feasibility/effectiveness of future integrations of existing technology with PatientToc™</u> .
2. Some <u>sub-groups of patients</u> (e.g., older adults, those with arthritis, those who don't physically come in to the pharmacy, those who prefer paper over technology) might be challenged and/or <u>uneasy/unwilling to use PatientToc™</u> .
3. PatientToc™ could be difficult to incorporate into <u>pharmacy workflow</u> due to space (e.g., small waiting areas, shared space) or staffing (e.g., time required, possible need for additional staff, staff turnover, competing demands) constraints and/or communication gaps among staff.
4. <u>Data security</u> concerns (e.g., privacy of information provided in PatientToc™ by patients, mistrust of technology, uncertainty regarding where the information is sent) could limit uptake of PatientToc™ by patients and pharmacy staff.
Potential Facilitators
1. Pharmacy teams are generally willing to try new things, like PatientToc™ if it will help advance their <u>number one goal of improving patient care</u> .
2. Pharmacy <u>leadership is respected and generally strong communication</u> across team members is present, which would support PatientToc™ implementation.
3. <u>Measures of importance to pharmacy teams</u> (e.g., STAR rating, CPESN metrics, patient satisfaction, medication adherence, ROI) <u>align with those expected to be impacted by PatientToc™</u> and measured by the research team.

4. Most stakeholders (pharmacists, pharmacy staff, patients) felt PatientToc™ was easy to use and training requirements would be minimal and offered limited suggestions for improvement.

Table 2. Summary of recommendations, implementation strategies^a, and initial PatientToc™ implementation toolkit developed through the EBQI process.^b

Recommendations made by type of participant (pharmacy staff, patient, both)	Implementation Strategy ^a	Specific Toolkit Item/Strategy
1. Ensure <u>all pharmacy team members</u> (pharmacists, technicians/other support staff, management) are <u>engaged/bought-in</u> to implementation of PatientToc™. (Staff)	<i>Develop Stakeholder Interrelationships: Conduct Local Consensus Discussions</i>	<ul style="list-style-type: none"> - PatientToc™ Mission Statement Template - Kickoff Agenda Template - Have check-in meetings - Audit and Feedback Report Template
2. Have clear PatientToc™ implementation <u>goals, measure outcomes</u> (e.g., adherence, patient satisfaction, pharmacist interventions made, ROI), and <u>provide feedback on outcomes and progress toward goals.</u> (Staff)	<i>Use Evaluative and Iterative Strategies: Audit and Provide Feedback</i>	<ul style="list-style-type: none"> - PatientToc™ Mission Statement Template - Have check-in meetings - Audit and Feedback Report Template
3. Explore the <u>use of incentives</u> for pharmacy team members (e.g., bonuses, food, praise) and/or patients (e.g., coupons, food, gift cards) to support PatientToc™ implementation. (Both)	<i>Utilize Financial Strategies: Alter Incentive/ Allowance Structures</i>	Not applicable (incentives were not included as part of the toolkit) ^d
4. Provide hands-on training and resources for pharmacy teams, possibly for continuing education credit, to support PatientToc™ implementation. (Staff) ^c	<i>Train and Educate Stakeholders:</i> <ul style="list-style-type: none"> • <i>Conduct Ongoing Training</i> • <i>Provide Ongoing Consultation</i> • <i>Develop Educational Materials</i> • <i>Make Training Dynamic</i> • <i>Distribute Educational Materials</i> • <i>Conduct Educational Outreach Visits</i> • <i>Work with Educational Institutions</i> 	<ul style="list-style-type: none"> - PatientToc™ Training Modules - Social Determinants of Health (SDOH) Continuing Education (CE) modules

Recommendations made by type of participant (pharmacy staff, patient, both)	Implementation Strategy ^a	Specific Toolkit Item/Strategy
5. Work with pharmacy teams and vendors to ensure PatientToc™ is <u>well integrated</u> with the pharmacies' dispensing systems. (Staff)	<p><i>Adapt and Tailor to Context: Promote Adaptability</i></p> <p><i>Provide Interactive Assistance: Provide Local Technical Assistance</i></p>	Not applicable (rather than being part of the toolkit, efforts were made to create an integrated version of PatientToc™.)
6. Ensure a PatientToc™ 24/7 <u>help line</u> is available to pharmacy teams. (Staff)	<p><i>Provide Interactive Assistance: Centralize Technical Assistance</i></p>	Not applicable (a help line was not part of the toolkit but pharmacies received guidance on how to reach PatientToc™ and/or the study team with any questions or needs.)
7. Consider adapting PatientToc™ for <u>more languages</u> . (Both)	<p><i>Adapt and Tailor to Context: Promote Adaptability</i></p>	Not applicable (language needs at each pharmacy were assessed through discussions with site champions and it was determined that only a small proportion of patients at each pharmacy would be unable to use an English version of the application so this was not pursued due to time and resource constraints.)
8. Provide <u>clear and simple messaging to patients that emphasize the expected benefits</u> of PatientToc™ to patients. These messages should be provided 1) verbally by pharmacy staff, 2) written as part of introductory instructions in the PatientToc™ application, and/or 3) written as part of general pharmacy marketing materials (e.g., websites, waiting room televisions). (Both) ^c	<p><i>Engage Consumers: Prepare Patients/Consumers to be Active Participants</i></p>	<ul style="list-style-type: none"> - Patient-facing print (large and small posters, pamphlets, bag stuffers) and digital media (social media posts) materials - Provide scripted language for pharmacies' use
9. Implement PatientToc™ first with <u>specific patient sub-groups</u> (e.g., complex patients). (Both)	<p><i>Engage Consumers: Prepare Patients/Consumers to be Active Participants</i></p>	Not applicable (This was not a part of the toolkit; rather, pharmacies could choose which patient subgroups to use PatientToc™ with.)

Recommendations made by type of participant (pharmacy staff, patient, both)	Implementation Strategy ^a	Specific Toolkit Item/Strategy
10. <u>Enable access to PatientToc™ in various ways</u> (e.g., tablet in adjacent primary care practice site, delivery drivers bring a tablet, patient uses application on their own device) based on pharmacy workflow/patient needs. (Both)	<i>Change Infrastructure:</i> <ul style="list-style-type: none"> • <i>Change Physical Structure and Equipment</i> • <i>Change Service Sites</i> 	<ul style="list-style-type: none"> - Sample workflows - Workflow cheat sheets
11. Ensure patients can complete PatientToc™ questionnaires in <u>2-10 minutes</u> (e.g., pre-populate information when possible, reduce need for typing). (Both) ^c	<i>Engage Consumers: Prepare Patients/Consumers to be Active Participants</i>	Not applicable (This was not a part of the toolkit but was the time target for the design of the adapted PatientToc™ application.)
12. Use PatientToc™ to <u>optimize patient prescription wait times as well as other appointment-based services</u> (e.g., MTM, medication synchronization program). (Both)	<i>Engage Consumers: Prepare Patients/Consumers to be Active Participants</i>	<ul style="list-style-type: none"> - Sample workflows - Workflow cheat sheets
13. Use PatientToc™ to <u>update patient demographics (e.g., contact information, allergies etc.)</u> and medication lists. (Both)	<i>Support Clinicians: Support Relay of Clinical Data to Providers</i>	Not applicable (This was not part of the toolkit but was considered in the design of the adapted PatientToc™ application.)
14. Consider including <u>patient education and/or information/referrals</u> to pharmacy services on PatientToc™. (Both)	<i>Adapt and Tailor to Context: Promote Adaptability</i>	- Referrals Cheat Sheet

Abbreviations: CE = Continuing Education; EBQI = Evidence-Based Quality Improvement; MTM = medication therapy management; SDOH = Social Determinants of Health;

^a Implementation strategies are per: Waltz TJ, Powell BJ, Matthieu MM, Damschroder LJ, Chinman MJ, Smith JL, et al. Use of concept mapping to characterize relationships among implementation strategies and assess their feasibility and importance: results from the Expert Recommendations for Implementing Change (ERIC) study. *Implement Sci.* 2015;10(1):109.

^b EBQI process was per: Curran GM, Mukherjee S, Allee E, Owen RR. A process for developing an implementation intervention: QUERI Series. *Implement Sci.* 2008;3(1).

^c Multi-stakeholder advisory panel (pharmacy staff and patients) designated recommendation as one of the top-3 highest priority recommendations.

^d Researchers did not provide pharmacies with funds to create staff incentives but pharmacies could design incentives if they so desired and at least one participating pharmacy did implement staff incentives.

Principal Findings—Aim 2¹¹

Pharmacy characteristics

- 2 independent pharmacies and 1 health-system outpatient pharmacy located in a grocery store
- 2 rural, 1 suburban

Pharmacy Staff

- 2.1 Pharmacist FTEs
- 4.2 staff FTEs

Services

- All pharmacies offer automated refill reminders, 90-day fills, and scheduled adherence calls.

Patient selection

- 2 pharmacies did not target specific patients (e.g., diabetes)

Table 3. Implementation resources used by pharmacies, mean (SD)

Total number of facilitator contacts with pharmacy, mean (SD)	20.3 (9.7)
Average amount of time (both direct and indirect) per contact spent on planned contacts, (minutes) mean (SD)	202.9 (85.6)
Average amount of time (both direct and indirect) per contact spent on unplanned contacts, (minutes) mean (SD)	7.8(3.1)
Method of contact (percent per category), mean (SD)	
-in-person visit	34.3 (5.1)
-Telephone call	37.3(6.4)
-Text	10.7(9.7)
-Email	18.7(1.5)
-Video call	4.2(7.2)
Type of contact, (percent per category), mean (SD)	
-planned	60.5 (17.5)
-unplanned, initiated by study team	27.0 (14.9)
-unplanned, initiated by site staff	11.5(8.7)
-unplanned, initiated by patient/ proxy	0

#Contacts to facilitate implementation

A total of **7 unplanned contacts** occurred across all pharmacies

- 2 for technology issues
- 3 for questions about the intervention
- 2 for other things

Table 4. Toolkit Resources Used by Pharmacies (n=3)	n (%)
Kickoff agenda template	2 (67%)
Mission statement	2 (67%)
Audit and feedback report	3 (100%)
SDOH CE modules	1 (33%)
PatientToc™ Training Module #1	2 (67%)
PatientToc™ Training Module #2	2 (67%)

PatientToc™ Training Module #3	2 (67%)
PatientToc™ Training Module #4	2 (67%)
Scripted language	1 (33%)
Poster (large)	1 (33%)
Poster (small)	2 (67%)
Pamphlets	2 (67%)
Bag stuffers	1 (33%)
Social media content	0
Sample PatientToc™ workflows	1 (33%)
Referrals cheat sheet	0
Other	0

Table 5. Patient assessments and pharmacist interventions, mean (SD), n=3 pharmacies

Total number of patients using PatientToc™,	27.3 (14.2)
Percent of encounters with pharmacist documentation	72.5 (39.0)
Percent of encounters with pharmacist documentation completed same day	12.1 (7.0)
MTPs found per survey completed	1 (0)
Actions taken with patient per encounter	0.13 (0.48)
Actions taken with prescriber per encounter	0.04 (0.20)

Table 6. Overarching Findings, by Implementation Outcome	
Acceptability	
<ol style="list-style-type: none"> 1. Patients overall <u>spent about 6 min on the app, which aligns with the goal</u> from the pre-implementation work (target was 2-10 min) but some staff still feel this is perceived as too long for some patients. 2. Many <u>patients start the app but are stopping before entering their name and contact information.</u> 3. There is a <u>need for improved pharmacist and staff introduction of PatientToc™ to patients to “level-set” expectations in order to enhance satisfaction and promote further use (e.g., why patient name and contact information are being collected, how information will be used to improve patient care, and that it will take about 5 minutes to complete so patients should plan on that.)</u> 	
Appropriateness	
<ol style="list-style-type: none"> 1. The app is viewed as <u>overall appropriate for a community pharmacy environment but might be less appropriate for some specific contexts (e.g., grocery setting, drive through) where patients have an easier opportunity to go do something else while waiting for prescriptions or were not expecting to take the extra time to complete the questions.</u> 	

<p>Adoption</p> <ol style="list-style-type: none"> 1. Overall, <u>adoption by staff (i.e., asking patients to use PatientToc™)</u> was lower than <u>expected</u> which was often due to a perception that it would take too long, patients were not expecting to wait, some patients might struggle with using technology, or staff were not fully knowledgeable about PatientToc™ or bought into the purpose of adopting PatientToc™. 2. <u>Adoption was better among patients waiting</u> for their medications. 3. Staff were <u>generally satisfied with toolkit items</u> but did not consistently use them, which could partly be due to how toolkit items were made available to the pharmacy (i.e., to the site contact who was then expected to share them with staff.) 4. <u>Drivers of patient adoption</u> included using the app for a newly prescribed medication, having medication concerns at baseline, and having a strong existing relationship with pharmacy staff. 5. <u>Low staff adoption likely make it hard to fully assess other outcomes</u> (e.g, acceptability is unclear if not using it, feasibility is unclear if not using it, and unknown whether staff would have made changes that impact fidelity.)
<p>Feasibility</p> <ol style="list-style-type: none"> 1. Staff exhibited some misunderstanding of where patient data goes and there was sometimes a <u>disconnect in timing the collection and review of patient data and completion of follow on surveys</u> in the pharmacy workflow. 2. Pharmacy <u>workflow was not heavily impacted</u> but this could be due to overall low adoption pharmacies or and/limited review of patient surveys and completion of the follow on survey at the time the patient is present. 3. Use in <u>some contexts (e.g., waiting patients) was more feasible</u> than in other (e.g., drive throughs). 4. <u>Unscheduled contacts with PFs decreased over time</u> but in some situations this was also associated then with less adoption over time.
<p>Fidelity</p> <ol style="list-style-type: none"> 1. Overall, <u>pharmacies used PatientToc™ as planned in their workflow but fewer follow-on surveys than encounters were logged</u> in our database. Observations and interviews point to three potential reasons: 1) pharmacists often reviewed the patient survey data but did not wish to take any clinical action which may have led to them not completing the follow on surveys, 2) technical issues impacting completion and/or data transfer, and 3) limited familiarity and buy-in to the purpose of having patients use <u>PatientToc™</u>.
<p>Costs</p> <ol style="list-style-type: none"> 1. Equipment, advertisement, supplies (\$1280) 2. Pharmacy staff time (\$290/month) 3. Research support staff time (\$630/month)
<p>Quality of Care Outcomes</p> <ol style="list-style-type: none"> 1. Limited data were available but <u>outcome measures stayed the same or improved</u>; no outcome measures worsened during the observation period.

Principal Findings—Aim 3¹²

Pharmacy characteristics

- 4 independent pharmacies and 8 chain (4 or more locations)
- 3 rural, 4 suburban, 5 urban

Pharmacy Staff

- 2.4 Pharmacist FTEs
- 4.9 staff FTEs

Services

- All pharmacies offer automated refills and 90-day fills

Patient selection

- 6 pharmacies did not target specific patients (e.g., diabetes)

Table 7. Implementation resources used by pharmacies, mean (SD)

Total number of facilitator contacts with pharmacy, mean (SD)	20.3 (9.7)
Average amount of time (both direct and indirect) per contact spent on planned contacts, (minutes) mean (SD)	202.9 (85.6)
Average amount of time (both direct and indirect) per contact spent on unplanned contacts, (minutes) mean (SD)	7.8 (3.1)
Method of contact (percent per category), mean (SD)	
-in-person visit	34.3 (5.1)
-Telephone call	37.3(6.4)
-Text	10.7(9.7)
-Email	18.7(1.5)
-Video call	4.2(7.2)
Type of contact, (percent per category), mean (SD)	
-planned	60.5 (17.5)
-unplanned, initiated by study team	27.0 (14.9)
-unplanned, initiated by site staff	11.5(8.7)
-unplanned, initiated by patient/ proxy	0

#Contacts to facilitate implementation

A total of 87 **unplanned contacts** occurred across all pharmacies

Table 8. Toolkit Resources Used by Pharmacies (n=12)	n (%)
Kickoff agenda template	6(50)
Mission statement	6(50)
Audit and feedback report	10(83)
SDOH CE modules	4(33)
PatientToc™ Training Module #1	9(75)
Scripted language	8(67)
Poster (large)	8(67)
Poster (small)	8(67)
Pamphlets	10(83)
Bag stuffers	8(67)
Social media content	4(33)
Sample PatientToc™ workflows	3(25)
Referrals cheat sheet	5(42)
Contacting other participating pharmacies	7(58)
Tips and tricks shared document	7(58)
No. sites adding additional toolkit resource(s) used after start of study, n(%)	3(25)

No. of sites developing additional toolkit resources, n(%)	3(25)
--	-------

Table 9. Patient assessments and pharmacist interventions, mean (SD), n=12 pharmacies

Total number of patients using PatientToc™	25(12.5)
Percent of encounters with pharmacist documentation	92 (9.3)
Percent of encounters with pharmacist documentation completed same day	10.7(15.0)
MTPs found per survey completed	7.3(8.0)
Actions taken with patient per encounter	0.20 (0.03)
Actions taken with prescriber per encounter	0.05 (0.02)

Table 10. Overarching Findings, by Implementation Outcome	
Acceptability	
<ol style="list-style-type: none"> 1. The PatientToc™ application was generally easy for patients to use but was perceived as overall a bit “clunky” with specific issues noted when users attempted to complete data entry for open-ended questions wherein the tablet keyboard would partly cover the screen. 2. The perceived clinical value of PatientToc™ to pharmacy teams was lower than desired. 	
Appropriateness	
<ol style="list-style-type: none"> 1. Space constraints, patient populations, and pharmacy culture need careful consideration during implementation as some pharmacy teams and patients noted infrastructure challenges (e.g., drive throughs and limited space for completing PatientToc™ in the pharmacy) and patient and pharmacy team characteristics (e.g., patients not comfortable using tablet technology) that reduced the perceived appropriateness. 	
Adoption	
<ol style="list-style-type: none"> 1. Adoption was generally poor, with no pharmacies achieving PatientToc™ use targets, and declined over time, which appeared to be driven both by staff behavior and limited patient engagement. 2. It was challenging to get patients to use PatientToc™ if they were not going to wait on a prescription. Generally, older adults seemed more receptive and willing to wait than younger adults. 3. Adoption would have been better if patients could install and use PatientToc™ on a personal device. 4. Adoption was not clearly tied to a pharmacy’s prescription volume. 5. A driver of adoption was emphasizing that the pharmacy was implementing PatientToc™ as part of a research project with a local university. 	
Feasibility	
<ol style="list-style-type: none"> 1. Pharmacy workflow generally was not heavily impacted; however, it is unknown if achieving higher adoption would have had a greater impact on workflow. 2. Using a point-of-sale alert in PioneerRx to identify patients to offer PatientToc™ to was important for pharmacy workflow. 	
Fidelity	
<ol style="list-style-type: none"> 1. Fidelity to the overall planned PatientToc™ intervention was low, with most pharmacies reviewing 50% or fewer of patient encounter data on the same day. 2. Fidelity was not clearly tied to a pharmacy’s prescription volume. 	
Costs	
<ol style="list-style-type: none"> 1. Equipment, advertisement, supplies (\$7734) 2. Pharmacy staff time (\$259 /month) 3. Research support staff time (\$15.450 /month) 	

Penetration

1. Penetration was universally poor, with no site expanding PatientToc™ use beyond the one pharmacist champion.

Sustainability

1. Sustainability was universally poor. Only 1 pharmacy sustained the full intervention (i.e., completion of both patient encounters and pharmacist documentation) for the full study period.

Quality of Care Outcomes

- There were no statistically significant changes in pharmacies' mean monthly prescription volume or prescription transfers.

Key Discussion Points

- Implementing a mobile application in community pharmacies for the purposes of identifying and resolving medication non-adherence is challenging and requires extensive pre-implementation work to mitigate barriers and promote adoption by pharmacy teams and patients.
- Conducting a pre-implementation evaluation has considerable value.¹³
 - All expected barriers identified in Aim 1 aligned with what we observed in Aim 2 (and many remained pervasive in Aim 3 in spite of efforts to enhance practice facilitation)
 - Three of the four expected facilitators aligned
 - Unable to implement half of the identified recommendations which likely contributed to the limited adoption observed in Aims 2 and 3
- Clear scope of work with vendor is essential
 - While intent was for an integrated application (with the dispensing software), PatientToc™ was unable to deliver in a timely/cost-effective manner
 - Non-integrated application requires text write-in that was not observed in Aim 1 formative phase and has challenges in the display impacting acceptability; need for formal usability testing
- Minimal staff adoption beyond pharmacist champions
 - Limited perceived value of intervention; no payment model
- Challenging context in pharmacies post-pandemic; ask to do “one more thing”

Key Limitations

- Limited adoption made it difficult to fully assess other implementation outcomes
 - 7 of the 12 Aim 3 pharmacies dropped out early
 - Additionally, the Aim 3 patient sample size was too small with limited repeat encounters so primary outcome of patient-reported adherence on the BMQ could not be evaluated.
- Team variation in adherence to planned facilitation activities
 - Multi-PBRN collaboration without prior pilot work to explore team dynamics and impacts on facilitation
 - Increased resources/pilot testing of facilitation to improve adoption should be planned for in future projects
- No national chain pharmacies participated in any study Aim; therefore, transferability of our findings to these settings is unclear

References

1. Fredericksen R, Crane PK, Tufano J, Ralston J, Schmidt S, Brown T, Layman D, Harrington RD, Dhanireddy S, Stone T, Lober W, Kitahata MM, Crane HM. 2012. Integrating a web-based, patient-administered assessment into primary care for HIV-infected adults. *J AIDS HIV Res.* 2012;4(2):47-55.
2. El Miedany Y, El Gaafary M, El Aroussy N, Bahlas S, Hegazi M, Palmer D, Youssef S. 2017. Toward electronic health recording: Evaluation of electronic patient reported outcome measures (e-PROMs) system for remote monitoring of early systemic lupus patients. *Clinical Rheumatology.* 2017;36:2461-2469.
3. Clabaugh M, Newlon JL, Illingworth Plake, KS. 2021. Perceptions of working conditions and safety concerns in community pharmacy. *Journal of the American Pharmacists Association,* 2021: 61:761-771.
4. Gatwood J, Hohmeier KC, Brooks IM. 2019. Beyond the reminder: The next steps in pharmacist-driven mHealth patient engagement. *Journal of the American Pharmacists Association.* 2019;59:S21-S24.
5. Witry MJ, Doucette WR, Zhang Y, Farris KB. 2014. Multiple Adherence Tool Evaluation Study (MATES). *Journal of Managed Care & Specialty Pharmacy.* 2014;20(7):734-740.
6. Salaffi F, Gasparini S, Ciapetti A, Gutierrez M, Grassi W. 2013. Usability of an innovative and interactive electronic system for collection of patient-reported data in axial spondyloarthritis: Comparison with the traditional paper-administered format. *Rheumatology.* 2013;52:2062-2070.
7. Coons SJ, Gwaltney CJ, Hays RD, Lundy JJ, Sloan JA, Revicki DA, Lenderking WR, Cella D, Basch E. 2009. Recommendations on evidence needed to support measurement equivalence between electronic and paper-based Patient-Reported Outcomes (PRO) measures: ISPOR ePRO good research practices task force report. *Value in Health.* 2009;12(4):419-429.
8. Franklin P, Chenok K, Lavalee D, Love R, Paxton L, Segal C, Holve E. 2017. Framework to guide the collection and use of patient-reported outcome measures in the learning healthcare system. *Generating Evidence & Methods.* 2017;5(1):1-17.
9. *Snyder ME, Chewing B, Kreling D, et al. An evaluation of the spread and scale of PatientToc™, ™ from primary care to community pharmacy practice for the collection of patient-reported outcomes: a study protocol. *Res Social Adm Pharm.* 2021;17:466-74.
10. *Adeoye-Olatunde OA, Curran GM, Jaynes HA, Hillman LA, Sangasubana N, Chewing BA, Kreling DH, Schommer JC, Murawski MM, Perkins SM, Snyder ME. Preparing for the spread and scale of patient-reported outcome (PRO) data collection from primary care to community pharmacy: a mixed-methods study. *Implement Sci Commun.* 2022;3:29. Doi: 10.1186/s43058-022-00277-3
11. Snyder ME, Hettinger KN, Qudah B, Hillman LA, Newlon J, Adeoye-Olatunde OA, Chewing B, Schommer J, Curran G. A digital intervention for medication adherence patient-reported outcomes collection in community pharmacies: pilot implementation outcomes. Presented as a poster at the 2024 American Pharmacists Association meeting in Orlando, Florida, USA. Paper in development.
12. Snyder ME, Jaynes HA, Riddell KN, Adeoye-Olatunde OA, Qudah B, Chewing B, Newlon J, Kreling D, Schommer J, Curran G, Musick B, Perkins SM. A Convergent Mixed-Methods Evaluation of Patient-Reported Outcomes Data Collection in United States Community Pharmacies to Promote Medication Adherence. Accepted for poster presentation at the 2024 International Social Pharmacy Workshop in Banff, Alberta, Canada. Paper in development.
13. Hettinger KN, Qudah B, Hillman LA, Adeoye-Olatunde OA, Newlon J, Curran G, Jaynes HA, Chewing B, Schommer J, Nichols MA, Snyder ME, Comparison of Expected and Experienced Barriers and Facilitators to Implementation of a Digital Health Intervention in

Community Pharmacies. Presented as a poster at the 2024 American Pharmacists Association meeting in Orlando, Florida, USA. Paper in development.

* Most text taken verbatim from published papers resulting from this work. Please see papers for list of specific citations.

List of Publications and Products

- (1) Snyder ME, Chewning B, Kreling D, et al. An evaluation of the spread and scale of PatientToc™, ™ from primary care to community pharmacy practice for the collection of patient-reported outcomes: a study protocol. *Res Social Adm Pharm*. 2021;17:466-74.
- (2) Adeoye-Olatunde OA, Curran GM, Jaynes HA, Hillman LA, Sangasubana N, Chewning BA, Kreling DH, Schommer JC, Murawski MM, Perkins SM, Snyder ME. Preparing for the spread and scale of patient-reported outcome (PRO) data collection from primary care to community pharmacy: a mixed-methods study. *Implement Sci Commun*. 2022;3:29. Doi: 10.1186/s43058-022-00277-3
- (3) Snyder ME, Hettinger KN, Qudah B, Hillman LA, Newlon J, Adeoye-Olatunde OA, Chewning B, Schommer J, Curran G. A digital intervention for medication adherence patient-reported outcomes collection in community pharmacies: pilot implementation outcomes. Presented as a poster at the 2024 American Pharmacists Association meeting in Orlando, Florida, USA. Paper in development.
- (4) Snyder ME, Riddell KN, Qudah B, Hillman LA, Newlon J, Adeoye-Olatunde OA, Chewning B, Schommer J, Nichols MA, Jaynes HA, Musick B, Perkins SM, Kreling D, Curran G. Lessons Learned from Piloting a Digital Patient-Reported Outcomes Intervention in Community Pharmacies. Accepted for podium presentation at the 2024 International Social Pharmacy Workshop in Banff, Alberta, Canada.
- (5) Hettinger KN, Qudah B, Hillman LA, Adeoye-Olatunde OA, Newlon J, Curran G, Jaynes HA, Chewning B, Schommer J, Nichols MA, Snyder ME, Comparison of Expected and Experienced Barriers and Facilitators to Implementation of a Digital Health Intervention in Community Pharmacies. Presented as a poster at the 2024 American Pharmacists Association meeting in Orlando, Florida, USA. Paper in development.
- (6) Snyder ME, Jaynes HA, Riddell KN, Adeoye-Olatunde OA, Qudah B, Chewning B, Newlon J, Kreling D, Schommer J, Curran G, Musick B, Perkins SM. A Convergent Mixed-Methods Evaluation of Patient-Reported Outcomes Data Collection in United States Community Pharmacies to Promote Medication Adherence. Accepted for poster presentation at the 2024 International Social Pharmacy Workshop in Banff, Alberta, Canada. Paper in development.